

WEBVTT

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00:00:05.009 --> 00:00:11.368

Good morning everyone I'm Jason bondage the branch sheet for the biological resources branch with the National Cancer Institute.

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00:00:11.368 --> 00:00:16.768

And That'll be the MC for today's event, introducing each speaker and sharing important information throughout the day.

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00:00:16.768 --> 00:00:23.129

Thank you all for joining us today to learn about the National Cancer Institute, federally funded research and development center.

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00:00:23.129 --> 00:00:33.869

Today's agenda is designed to showcase the Frederick National laboratory for cancer research, or the innovative work currently being performed and share the vision for the requirement.

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00:00:33.869 --> 00:00:40.950

We ask that all participants remain on mute throughout the day, and all questions be entered into the chat function of Webex.

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00:00:40.950 --> 00:00:46.020

Any questions that can't be answered at the time of the Q and a portion of each block of presentations.

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00:00:46.020 --> 00:00:49.799

Will be recorded and posted with answers to beta dot Sam dot. Gov.

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00:00:49.799 --> 00:00:54.149

At the conclusion of the events and a reminder that today's event will be recorded.

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00:00:54.149 --> 00:01:01.469

At the conclusion of the presentations this afternoon, there'll be an opportunity for additional topic specific Q and a breakout rooms.

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00:01:01.469 --> 00:01:05.189

The breakout rooms includes science solicitation of procurement.

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00:01:05.189 --> 00:01:11.640

Facilities and business operations again, we ask that all questions be entered into the chat function of Webex.

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00:01:11.640 --> 00:01:20.459

For each breakout session, the 1st presentation today will provide the official welcome video and introduction by Dr. the director.

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00:01:20.459 --> 00:01:25.769

Dr, Tony denial, director and Dr Sarah hook associate director and and Frederick.

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00:01:26.155 --> 00:01:40.644

And then the fabric National lab is the

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00:01:40.704 --> 00:01:45.834

only national lab that is solely devoted to medical research.

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00:01:49.165 --> 00:02:01.015

The rebec National lab is an extraordinarily important and critical and unique resource all the critical questions that the takes on to influence cancer for the benefit of the American public.

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00:02:01.075 --> 00:02:13.764

Are supported by the Frederick National lab for cancer research, and this is in many important, and very direct way. The lab was a defense facility for the development of weapons and warfare.

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00:02:14.039 --> 00:02:25.530

But then with the National Cancer act of 1971, it transitioned into a biomedical research facility and today it's a federally funded research and development center that can ramp up quickly.

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00:02:25.530 --> 00:02:37.590

To take on new problems, as they emerge today, about 2 thirds of the research, conducted the lab concerns, cancer and about 4th is on infectious disease and other health challenges.

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00:02:37.590 --> 00:02:43.770

And if you go back to the early 19 eighties.

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00:02:43.770 --> 00:02:53.610

When was discovered in 198,390 and 84, and the 1st test to be able to screen the nation's blood supply was actually developed.

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00:02:53.610 --> 00:03:00.719

At the Frederick National Laboratory, but then well, beyond that diagnostic tests and assays related.

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00:03:00.719 --> 00:03:09.840

To Zika to Bola SARS and we're helping 1 another make great strides against the SARS covey virus.

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00:03:09.840 --> 00:03:24.835

Especially in the meeting to have responsive researchers who really looking to meet the needs of the community, wherever that may lead the lives tackle many cancer research projects of great importance.

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00:03:24.895 --> 00:03:36.055

1 of them is the cancer genome Atlas and this effort sequenced more than 20,000, primary cancer types, and they made those data publicly available in this effort. Really changed fundamentally our basic understanding of cancer.

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00:03:36.990 --> 00:03:44.639

Another major effort led to the human papilloma virus vaccine and this vaccine is being used throughout the world to try and in cervical cancer.

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00:03:44.639 --> 00:03:57.930

And then extensive research is being done on harass, which is considered by many to be the worst aka gene, and it's mutated in about 30% of all human cancers. The lab was seen as a perfect fit for an open model.

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00:03:57.930 --> 00:04:08.189

Large scale, collaborative effort, like the last initiative to take on this challenge and today we're starting to see the 1st, successful inhibitors of Raz hit the clinic for the benefit of patients.

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00:04:11.275 --> 00:04:23.845

They've been hundreds of clinical trials that have eliminated out of the Frederick National Laboratory, and they've produced, maybe close to 130 biopharmaceutical products. The lab has state of the arc computing capabilities.

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00:04:23.845 --> 00:04:32.694

That aren't found anywhere else in the world. It has a national crime, electron microscopy facility. That can image protein structures at the most atomic level.

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00:04:34.468 --> 00:04:41.249

It has a new facility and produce car T cells and these are these immunotherapy cells that are used to treat patients with advanced cancer.

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00:04:41.249 --> 00:04:45.059

Many of these resources are shared widely and freely.

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00:04:45.059 --> 00:04:55.259

Scientists other Labs, all across the United States to facilitate their own important research. I've had the experience over the years.

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00:04:55.259 --> 00:05:02.338

Of extraordinary productive collaborations with members of the laboratory at every level from fundamental basic science.

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00:05:02.338 --> 00:05:14.249

To clinical science, it's a place where passionate, highly diverse groups of scientists work on scientific disciplines that are intersecting in complex ways to really push the cutting edge.

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00:05:14.249 --> 00:05:28.709

A scientific and biomedical research innovation objective is really to function as a nucleus for large scale objects that cannot be done in other mechanisms.

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00:05:29.004 --> 00:05:39.053

I'm incredibly excited the nature of the National Lab giving researchers access to equipment. That's unique and is not found that most universities.

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00:05:40.494 --> 00:05:47.274

I think the lab is actually a gym in in a very celebrated National Institutes of health.

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00:05:47.579 --> 00:05:52.199

Enterprise spin through some of the most important.

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00:05:52.199 --> 00:06:03.504

Public health challenges that we've had a face in this made major contributions at the Frederick National Lab, we can direct very focused research on complicated problems of tremendous public health significance.

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00:06:04.014 --> 00:06:11.723

We're using size to make the whole world, a safer and a healthier place. And it's that sense of purpose that is so special.

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00:06:11.819 --> 00:06:17.519

About the Frederick national.

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00:06:19.259 --> 00:06:29.788

Us Department of health and Human Services National Institutes of health, National Cancer Institute cancer dot Gov 1800forcancer.

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00:06:30.233 --> 00:06:43.973

Produced March 2021. okay, thank you. Very much, Brendan. And just as a reminder that video and its entirety will be posted on beta that Sam for full viewing.

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00:06:46.259 --> 00:06:54.478

Let's see please now, it's time for Dr, please join me in welcoming him and see director.

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00:06:54.478 --> 00:06:58.949

For the opening remarks, the RTC industry day, do we have net on.

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00:06:58.949 --> 00:07:04.678

And thank you, Jason, it's good to be here this morning and I want to welcome everyone to Frederick.

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00:07:04.678 --> 00:07:08.699

A national I have industry day Thank you for your interest in this important topic.

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00:07:08.699 --> 00:07:13.678

This is the 1st of of course, the 1st time we've had to do something like this virtually.

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00:07:13.678 --> 00:07:17.668

And I will stipulate that is not ideal, but we hope.

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00:07:17.668 --> 00:07:22.439

That you will be able to appreciate the scope and depth of this important national resource.

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00:07:22.439 --> 00:07:30.269

Using this virtual format, we're really excited to show you the things that go on at frater, National Lab, which is Tony files. You said in the prior video is really the crown jewel.

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00:07:30.269 --> 00:07:45.113

Of the nation's biomedical research effort by the end of today's event I'm confident that we will all agree that this is a federal National lab is sort of the research center for the implementation and leading edge technologies and brilliant innovation and passion and commitment.

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00:07:45.358 --> 00:07:53.428

To ending the suffering from cancer and AIDS and other emerging infectious diseases is just a wide variety of important topics across the.

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00:07:53.843 --> 00:08:02.603

I'm also confident, you will understand what a unique and amazing resource this is it's 68 acres of facility. 330,000 square feet of research lab administrative offices spread across 100 buildings.

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00:08:02.603 --> 00:08:10.283

1 of the unique features of this lab is its founding charter as a government designated federally funded research and development center,

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00:08:10.283 --> 00:08:18.983

or I've already see this facility engages in the kinds of scientific research and projects that other government and private sector Labs really aren't able to pursue.

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00:08:18.983 --> 00:08:20.423

1 of the nations 42.

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00:08:24.269 --> 00:08:35.663

This lab and Frederick is the only 1 dedicated solely to biomedical search. It's among the largest contracts within the Department of health and Human Services, and those of us familiar with the work performed in.

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00:08:35.663 --> 00:08:48.323

Frederick take great pride and it's terrific track record, delivering real solutions and fight against cancer, infectious disease, rare disease and many other important topics. Some of what you heard about in the video if this.

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00:08:49.109 --> 00:08:54.629

It usually does this through drug discovery through vaccine development through device development.

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00:08:54.629 --> 00:09:05.754

It works in basic science areas, such as nanotechnology, and as it means capability in data science, electron microscopy and on, and on, and on, it is really cutting edge science at it's finest.

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00:09:06.024 --> 00:09:15.413

It is 1 of the engines powering present vitamins, cancer moonshot initiative as, you know. 1 of the top domestic priorities of this administration is making progress against cancer and Frederick national.

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00:09:15.899 --> 00:09:27.869

Is a key portion of that for International was responsible for key aspects of the cancer. Matt was the last initiative, the development of your Bola vaccine and it's, it's working the front of Iris pandemic response has just been.

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00:09:27.869 --> 00:09:32.548

Amazing and too Broads to really do justice in a short time.

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00:09:32.548 --> 00:09:37.739

It houses a human Petaluma virus lab, and a tumor analysis consortium.

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00:09:37.739 --> 00:09:50.573

Genomic data Commons, and really many more of these really foundational programs that are widely used across global biomedical research and are critical to making continued progress against the number of important human diseases.

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00:09:50.964 --> 00:09:59.033

And I mentioned the key response in the independent make, it was really the nimble ability of Frederick to do federally directed by medical research.

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00:09:59.278 --> 00:10:07.943

That was so key in the initial response when when the payment didn't really got going and fnl helped launch multiple clinical trials and credit virus,

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00:10:07.943 --> 00:10:09.234

including the designee trial,

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00:10:09.234 --> 00:10:17.124

that led to successful approval that agent tested devices for the it worked closely with databases.

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00:10:17.124 --> 00:10:27.114

He created national standards for credit virus testing. It was really a key player in that national response. So today you'll be exposed to this crown jewel of American scientific discovery.

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00:10:27.293 --> 00:10:40.823

It serves as a hub of for technology development, and a nucleus for large scale projects across the nation, vast scientific environment, and therein lies and future federal, national at 1 of high risk and high reward projects that only filter facility.

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00:10:40.823 --> 00:10:50.094

Like this could really pursue is future. Will hinge on boldness and creativity and ideas and their execution and this is really a high bar for those seeking to operate the lab.

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00:10:50.369 --> 00:10:57.178

This day you may feel like you're kind of getting drinking from the fire hose because there's so much to learn about in front of national and it's such an extensive facility.

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00:10:57.178 --> 00:11:05.818

But I'm sure and I hope all of you will absorb this and I hope you'll ask questions and take it in. And we're delighted you are here today and thank you for the happy to come to meet you this morning.

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00:11:07.739 --> 00:11:19.408

Right. Thank you very much. Ned. All right now please join me in welcoming from the National Cancer Institute. Office of scientific operations. The deputy director Dr.

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00:11:19.408 --> 00:11:23.849

Will be presenting an overview in history of the NCI at parties.

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00:11:23.849 --> 00:11:34.433

Listed thanks, Jason for that introduction. Yes, this is Kristen and I welcome you. All here today. I'm really excited that you'll be spending the day with us.

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00:11:34.433 --> 00:11:40.163

So you can learn about at least some of the wonderful things that we're doing up here at the National Lab.

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00:11:41.548 --> 00:11:52.859

We're looking forward to a day and we're hoping you're going to be asking us a lot of questions. Some of which, as, you know, we'll need to answer in writing following the meeting next slide. Please.

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00:11:57.683 --> 00:12:10.943

1st, I'd like to begin with an overview of the, as the operations project funded research and development center at Frederick. It's a distinctive national resource, which you heard from Dr.

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00:12:10.943 --> 00:12:16.884

sharp was it's the only that's dedicated principally to biomedical research.

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00:12:17.158 --> 00:12:31.528

It's unique and it has collaborative research and development resources to enable us to tackle difficult, urgent and intractable problems that span from basic research to clinical investigations.

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00:12:32.783 --> 00:12:47.514

This is administered by the whose mission is to help people that longer healthier life by supporting research to reduce the incidence of cancer and to improve the outlook for patients

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00:12:47.634 --> 00:12:48.803

who develop cancer.

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00:12:49.168 --> 00:12:59.759

Together along with the broader research community, we pursue highly innovative, basic applied and Translational biomedical research.

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00:12:59.759 --> 00:13:08.788

Next slide please. So now a bit about the Frederick National lab for cancer research.

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00:13:08.788 --> 00:13:16.469

The assets already see operates as the Frederick National laboratory for cancer research, or the f and.

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00:13:17.153 --> 00:13:31.254

The is positioned alongside National Cancer Institute laboratories, which provides the unique opportunities for the research community to leverage a combination of technical expertise.

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00:13:31.769 --> 00:13:35.489

Physical infrastructure and support services.

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00:13:36.443 --> 00:13:39.053

The convergence of scientific possibility,

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00:13:39.354 --> 00:13:42.203

and the need for more complex partnerships,

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00:13:42.443 --> 00:13:53.724

make this an ideal time for the National lab to underpin the nations cancer research activities along with not to exclude as another example,

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00:13:53.874 --> 00:13:58.134

the recent coded pandemic for which we have also been in.

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00:13:59.428 --> 00:14:05.489

A great deal support on and you'll be hearing more about that as the day goes on next slide.

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00:14:10.229 --> 00:14:18.984

The Frederick National lab for cancer research is really a partnership with the MTI and the N. C.

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00:14:18.984 --> 00:14:26.094

I look forward to expanding that partnership to provide for greater engagement with the biomedical research community.

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00:14:26.428 --> 00:14:34.828

And together with that greater community, and the f, now we can help people live longer healthier live.

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00:14:34.828 --> 00:14:39.208

By reducing the incidents of cancer and other diseases.

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00:14:39.208 --> 00:14:43.589

And improving the outlook of patients who develop them.

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00:14:44.759 --> 00:14:48.269

The next slide.

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00:14:48.269 --> 00:15:00.389

Now, I want to switch gears a little bit and talk to you about a specific program that we have that is available to the f. and now it's called the laboratory directed exploratory research fund.

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00:15:00.389 --> 00:15:07.649

This program includes up to 1Million dollars to fund National Lab pilot projects.

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00:15:07.649 --> 00:15:12.808

The objective of these funds is to enhance the innovation.

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00:15:12.808 --> 00:15:19.798

Creativity originality and quality of research activities at the National Lab.

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00:15:19.798 --> 00:15:27.058
It's also intended to facilitate collaborations with within the fnl.

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00:15:27.058 --> 00:15:35.219
And outside of it, including engaging universities and encouraging collaboration and strategic interactions.

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00:15:35.219 --> 00:15:42.089
Thus, enabling the demonstration of exploratory proof of concept projects.

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00:15:42.089 --> 00:15:47.548
Which will lead to durable funding to contract or grant mechanisms.

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00:15:47.548 --> 00:15:59.308
Next slide please so, a bit about our history, how did we get started? Where did we come from and where will we be going next? Slide.

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00:16:01.979 --> 00:16:05.999
fiancee's eyes the purpose is.

113
00:16:06.984 --> 00:16:16.433
For the forefront at the forefront of developing and adapting new technologies and translating basic scientific discoveries into novel agents,

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00:16:16.644 --> 00:16:23.394
approaches devices for the prevention diagnosis and treatment of cancer and other diseases.

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00:16:23.698 --> 00:16:37.678
Including, and as well as other emerging diseases. So, although it is hosted by the NCI, we also support other groups as well within the federal government.

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00:16:37.678 --> 00:16:42.658
Slide please.

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00:16:42.658 --> 00:16:44.333
So this is about our,

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00:16:44.394 --> 00:16:46.433
our most early beginning,

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00:16:47.274 --> 00:17:01.943

the present presence at Fort Dietrich was established in the early 19 seventies by then President Nixon who converted some of the fort Dietrich bio defense laboratories into a leading center for cancer

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00:17:01.943 --> 00:17:02.573

research.

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00:17:02.879 --> 00:17:16.078

And those, that facilities that were transferred over to the Department of health and Human services. So, while we're inside the fort Dietrich gate, we are separate from from the Department of defense.

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00:17:16.078 --> 00:17:22.888

In 1975, what's now known as the f was designated as an f RTC.

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00:17:22.888 --> 00:17:25.888

Which gives us special.

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00:17:25.888 --> 00:17:39.509

Abilities related to the far in 2012 the was designated as a national laboratory and at that point, got its current name, which is the Frederick National laboratory for cancer research.

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00:17:39.509 --> 00:17:51.864

Next slide the is a government owned contractor operated facility at that space operated by the,

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00:17:52.824 --> 00:17:59.723

and the contractor associated with it it can perform work for other than the sponsoring agencies under the economy and.

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00:18:00.118 --> 00:18:05.338

In addition the contractor entity is turned the.

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00:18:05.338 --> 00:18:09.659

Manages the facility up in Frederick next slide.

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00:18:13.288 --> 00:18:24.203

There's over 40 government research centers that share the designation some of them that you'll be familiar with are listed there. Many of them are the Department of energy.

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00:18:24.983 --> 00:18:38.753

Our is the, in the nation, as you've mentioned a woman and continued to say this is the only 1 dedicated flowing solely to buy a medical research, which puts us in a unique position next slide.

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00:18:43.013 --> 00:18:43.463

So,

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00:18:43.493 --> 00:18:47.814
for those of you who are reading the far alongside of your computer today,

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00:18:48.773 --> 00:18:50.663
the far adept defined to,

134
00:18:51.864 --> 00:18:52.913
by the definition,

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00:18:52.913 --> 00:18:58.223
there needs the activities that are sponsored under a broad charter by a government agency,

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00:18:58.223 --> 00:19:00.384
or agencies for the purpose of performing,

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00:19:00.594 --> 00:19:01.344
analyzing,

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00:19:01.374 --> 00:19:01.973
integrating,

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00:19:01.973 --> 00:19:05.903
supporting and our managing basic or applied research and development,

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00:19:06.534 --> 00:19:10.314
and that receives 70% or more of their financial support from the government.

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00:19:11.098 --> 00:19:16.558
It's anticipated with the contractor to be a long term relationship.

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00:19:16.558 --> 00:19:31.078
Most are all of the facilities are owned or funded by the government as I mentioned, where goco and the has access to government data employees and facilities beyond that comment in a normal contractual relationship.

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00:19:31.078 --> 00:19:34.648
So this is not a typical contract.

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00:19:34.648 --> 00:19:37.919
Next line.

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00:19:37.919 --> 00:19:42.929

The, as I mentioned is a unique national resource.

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00:19:42.929 --> 00:19:50.548

And as an, the f, unl provides the MTI with a unique resource to achieve flexibility.

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00:19:50.548 --> 00:19:58.588

By providing for a broad latitude and how the work is performed in house or subcontracts, rapid response.

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00:19:58.588 --> 00:20:08.278

New or cutting edge projects that can be accomplished more expeditiously because the broad charter and access to government personnel.

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00:20:08.278 --> 00:20:15.959

Increase efficiency, the maintains the staff of highly trained professionals.

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00:20:15.959 --> 00:20:21.239

Next slide.

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00:20:21.239 --> 00:20:27.028

We're here to meet the most urgent biomedical research needs of the nation, including the.

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00:20:27.028 --> 00:20:31.709

Other age Institutes will be hearing from some of those today.

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00:20:31.709 --> 00:20:43.318

Other government agencies, extra mural investigators, and also NCI corporate partners. So we have a broad net of partnership throughout the nation.

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00:20:43.318 --> 00:20:57.983

Next slide please, we are, the doesn't just do work on things, Frederick, although it's regional from Fred break down to that says, done between i70 corridor. In addition it supports national.

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00:20:59.038 --> 00:21:03.358

Work across the country and beyond that, it's global.

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00:21:03.358 --> 00:21:10.588

International support is provided to clinical trials, for example, in North America, South America, Africa and Asia.

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00:21:11.153 --> 00:21:21.233

Next slide this is a list of the research and research support capabilities that's an alignment with what you have seen, in

the statement of work.

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00:21:21.233 --> 00:21:28.554

If you've been looking at what we've been sending out so far, and you'll be hearing about most of these capabilities throughout the presentations today.

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00:21:28.888 --> 00:21:29.693

Next slide,

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00:21:32.604 --> 00:21:32.844

so,

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00:21:32.844 --> 00:21:35.334

in summary Paco message here today,

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00:21:35.334 --> 00:21:43.673

and the is meeting the most urgent and challenging biomedical research needs of the NCI other age Institute,

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00:21:43.943 --> 00:21:45.384

other government agencies,

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00:21:45.743 --> 00:21:47.304

and the extra community.

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00:21:48.868 --> 00:21:53.519

Next slide, thank you very much.

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00:21:53.519 --> 00:22:04.828

Great. Thank you. Kristin. All right now we're going to hear from Dr Sarah hook and she'll speak to the vision and goals and strategic program objectives. Sarah.

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00:22:04.828 --> 00:22:15.808

Thank you Jason, so, in addition I'm going to kind of sprinkle throughout a bit of an introduction to the National missions programs conducted at the.

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00:22:15.808 --> 00:22:19.019

And the next session will specifically be devoted to.

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00:22:19.019 --> 00:22:22.919

National missions, so next slide please.

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00:22:24.088 --> 00:22:31.679

So, I'll highlight 2 aspects of the S1 is the critical component of the research enterprise, and then future directions.

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00:22:31.679 --> 00:22:44.489

So next slide please. So there's 1 fnl contract that there's many constituents as we are already alluded to that have work that is conducted on the contract.

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00:22:44.489 --> 00:22:51.509

So, what comes from various stakeholders, including all of the NCI divisions, offices and centers.

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00:22:51.509 --> 00:22:57.598

And currently, we do work for 17 other institutes and centers at the age.

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00:22:57.598 --> 00:23:05.878

With a major partner, being niann, National Institute of Allergy and infectious diseases that you heard from. Dr.

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00:23:05.878 --> 00:23:14.278

So, as well, as the age institutes and centers, we also do work for 6 other federal agencies, such as the FTA.

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00:23:14.278 --> 00:23:23.969

Usa hammered et cetera so typically, we do 60 to 70% of the work on the contract is related to cancer research.

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00:23:23.969 --> 00:23:38.308

And 30 to 40% is related to infectious diseases and other biomedical problems. This past year is probably almost 50% related to infectious diseases and code related activities.

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00:23:38.308 --> 00:23:47.429

So, of course, changing demands requires changing kind of the percentages of work we do. So, next line please.

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00:23:48.509 --> 00:23:56.429

Just some highlights of what the fnl has been able to achieve over time. Some of them just in the past several years.

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00:23:56.429 --> 00:24:02.669

And the average year the fnl does over 40 H, sponsored clinical trials per year.

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00:24:02.669 --> 00:24:11.219

And since the inception, they've produced over 130 bio, pharmaceutical products, 60, these have gone through clinical trials.

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00:24:11.219 --> 00:24:15.058

For primary cancer and rare disease therapies.

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00:24:15.058 --> 00:24:23.249

In the last 5 years they produced 70, lots of clinical grade products that targets infectious diseases.

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00:24:23.249 --> 00:24:27.058

Through their 2 GMP manufacturing facilities.

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00:24:27.058 --> 00:24:36.179

1, that is overseen by Niagara and 1 that is overseen by. And Jason will give you some more insight into that later in the day.

186

00:24:36.179 --> 00:24:42.179

So importantly, they've characterized over 440 candidate, Nano formulations.

187

00:24:42.179 --> 00:24:57.023

16 of these have gone into clinical trials and to have obtained market approval. So, on the right hand side is just some of the sample projects that have been supported over the years. Ned has already alluded to many of these, both in the video.

188

00:24:57.023 --> 00:24:58.284

And in his talk.

189

00:24:58.709 --> 00:25:01.888

But I wanted to specifically pull out.

190

00:25:01.888 --> 00:25:09.509

The prevail trial betters conducted by an ion so it was for the MBO vaccines conducted in library.

191

00:25:09.509 --> 00:25:16.709

So, there are currently 3 models in which the FML staff help in conducting clinical trials.

192

00:25:16.709 --> 00:25:21.538

Those are conducting trials on site at the clinical center.

193

00:25:21.538 --> 00:25:30.209

International trials with boots on the ground and utilizing in country staff as many of the trials are.

194

00:25:30.209 --> 00:25:38.128

And they also participate in a more in a program management and coordination role in trials across the country. And throughout the world.

195

00:25:38.128 --> 00:25:52.648

So next slide please so, in the next 3 slides, I will introduce the 3 kind of top tier, national mission programs that have been coordinated by the funnel.

196

00:25:52.648 --> 00:25:56.638

So these programs were designated as national missions.

197

00:25:56.638 --> 00:26:05.338

Because they are important and ambitious projects it would be difficult to pursue without a more orchestrated effort.

198

00:26:05.338 --> 00:26:12.959

So, in this 1st slide is the last initiative which was started by Dr when he was NCI director.

199

00:26:12.959 --> 00:26:25.439

In fiscal year, 2014, and is organized in a hub and spoke model where a number of critical research projects are ongoing and lead at Frederick.

200

00:26:25.439 --> 00:26:31.259

And collaborations and contractor creatives extend into the academic groups.

201

00:26:31.259 --> 00:26:36.538

Pharma and biotech government and non profit entities.

202

00:26:36.538 --> 00:26:44.489

So 1 of the major goals of the ration initiative is to target drafts directly or to target.

203

00:26:44.489 --> 00:26:56.939

Effector interactions, so currently we're pursuing 4 novel approaches with various farm partners, and I've brought in roughly 12Million dollars of outside funds to support these studies.

204

00:26:56.939 --> 00:27:08.729

Importantly, also the graphs initiative has a robust structural biology program that is solved more than 60 crystal structures of brass within without various effective proteins.

205

00:27:08.729 --> 00:27:18.538

So next slide the 2nd effort I will describe to you today is the National facility.

206

00:27:18.538 --> 00:27:23.398

This facility is available exclusively to the extra mural community.

207

00:27:23.398 --> 00:27:27.808

Unacceptable Pre screen grids from investigators across the country.

208

00:27:27.808 --> 00:27:30.929

And delivers high quality data.

209

00:27:30.929 --> 00:27:40.288

To the users free of charge. So the group has collected in a little less than 4 years. Roughly 550 data sets.

210

00:27:40.288 --> 00:27:46.739

For 39 institutions across the country and published in top tier journals, as you see there.

211

00:27:46.739 --> 00:27:51.509

Importantly, the group has recently published on best practices.

212

00:27:51.509 --> 00:27:59.159

And has branch the into R and D to explore new platforms such as the jail cry arm.

213

00:27:59.159 --> 00:28:09.509

Methods and technology development so ultimately it would be nice to enable non structural biologists and cancer biologist to utilize.

214

00:28:09.509 --> 00:28:19.618

So next slide things. So the 3rd major effort I wanted to highlight is the work that the oh, can you go back? Sorry?

215

00:28:19.618 --> 00:28:23.578

Again, again.

216

00:28:24.023 --> 00:28:35.423

There we go, thank you. So, the 3rd, major effort I would like to highlight is the work the is conducting. Do we relate to the coven 19 pandemic? So I can't spend a lot of time on this.

217

00:28:35.423 --> 00:28:46.943

These are a few snippets of what they've done that you can take a look at. I just wanted to highlight that the set up our network across the hunter country.

218

00:28:47.189 --> 00:28:55.074

The awardees are shown on the map here in green we have some testing capacity, building sites.

219

00:28:55.374 --> 00:29:04.044

There are various, you 54 annual 1 awards across the country and they look at not only the basic biology of the source. Coby 2 virus.

220

00:29:04.888 --> 00:29:09.808

But there are also a quadri of clinical studies ongoing to follow patients and.

221

00:29:09.808 --> 00:29:18.118

And understand how they delete disease progresses clinically. So that effort was largely spearheaded by Dr. Dean. A singer.

222

00:29:18.118 --> 00:29:21.328

And John Dr Jim cherry, who will speak.

223

00:29:21.328 --> 00:29:27.568

Later in the day, so importantly, we also have a collaboration with the FDA.

224

00:29:27.568 --> 00:29:40.828

And the lab has been independently evaluating the Isis and lateral devices that have been granted emergency use authorization by the FDA.

225

00:29:40.828 --> 00:29:49.769

And we have reported back the specificity and sensitivity of these assets to the FDA so that they can further use it in decision making.

226

00:29:50.124 --> 00:30:04.614

So, as net already had highlighted, there are clinical, national standards that they've developed and I also really want to stress how important our partnership is with. And the clinical trials that we have been doing.

227

00:30:04.888 --> 00:30:09.659

So, roughly we have 12 domestic clinical trials that are ongoing.

228

00:30:09.659 --> 00:30:17.638

Some of these are listed here, the run does of our trial participation in operation work, speed, et cetera.

229

00:30:17.638 --> 00:30:25.318

And very importantly, internationally we are conducting 10 clinical trials within the countries that are listed on the slide.

230

00:30:26.759 --> 00:30:35.429

So next slide please. So now let's shift gears and look at what lies ahead in the future.

231

00:30:35.429 --> 00:30:45.209

So we envisioned the f, and will continue to support bench to bedside studies to address the most challenging needs of the global patient population.

232

00:30:45.209 --> 00:30:49.108

And researchers nationwide, next slide, please.

233

00:30:50.338 --> 00:30:56.548

You are listed so fundamental tasks that we envision as some of the major ways the.

234

00:30:56.548 --> 00:31:00.868

We'll support the research needs of the bio medical community in the future.

235

00:31:00.868 --> 00:31:05.818

So, these objectives were developed by an NCR, a working group.

236

00:31:05.818 --> 00:31:10.078

They were led by Dr Doug and Dr junior singer.

237

00:31:10.078 --> 00:31:15.269

And has been shared several times with various advisory group groups in the last year.

238

00:31:15.269 --> 00:31:21.118

So these objectives are to provide supported investigators.

239

00:31:21.118 --> 00:31:30.028

Access to services tools and resources, not readily available to individual Labs and I want to stress here. The NCA supported.

240

00:31:30.028 --> 00:31:36.028

Means extra mural researchers, intramural research servers and fnl researchers.

241

00:31:36.028 --> 00:31:40.558

So some of the types of things that we were thinking about in this category.

242

00:31:40.558 --> 00:31:45.449

Um, oh, can you go back? I'm sorry, thank you.

243

00:31:45.449 --> 00:31:49.769

Um, some of the kind of things that we're thinking about for bullet point number 1.

244

00:31:49.769 --> 00:31:55.618

Is, of course, the priorium facility, the human cell therapy facility. Ned mentioned.

245

00:31:55.618 --> 00:32:01.019

We have a facility and then there are also some cutting edge assays.

246
00:32:01.019 --> 00:32:07.648
Such as Ultra sensitive detection of, and that is performed at the national.

247
00:32:07.648 --> 00:32:13.318
These are just a few examples of what we mean by bullet point number 2 number 1.

248
00:32:13.318 --> 00:32:18.808
So, in bullet point, number 2, we see an increased need for technology development.

249
00:32:18.808 --> 00:32:22.648
And also implementation of more technologies.

250
00:32:22.648 --> 00:32:29.818
And the 3rd point we want to make here, as we've already discussed fnl functions as a nucleating agent.

251
00:32:29.818 --> 00:32:33.989
For critical projects, such as rash or the networks.

252
00:32:33.989 --> 00:32:42.148
So next slide please. So there are several strategic program objectives. We see going forward.

253
00:32:42.148 --> 00:32:51.148
1st, of course, are the are these national mission programs, and, as I've already highlighted, there are differing models for these programs, depending on the need.

254
00:32:51.148 --> 00:33:00.298
So, in the case of the rats initiative, they are really the drivers on the entire project, and they're working with various sectors of the biomedical research community.

255
00:33:00.298 --> 00:33:05.429
The answer is clearly more a user facility based on role.

256
00:33:05.429 --> 00:33:19.439
And in the role of facilitating related efforts, they're both doing validations setting standards and coordinating and a national nationwide response.

257
00:33:19.439 --> 00:33:27.568
So, the 2nd, strategic objective is really to expand the gamut of what we do here. So basic.

258
00:33:27.568 --> 00:33:30.838
Translational and clinical research support.

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00:33:30.838 --> 00:33:35.788

And this is really crucial to the entire research community as well as the patient population.

260

00:33:35.788 --> 00:33:38.878

And the 3rd objective is core research support.

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00:33:38.878 --> 00:33:46.348

It supports the FML programs here at the National Lab, but also supports intramural and intramural research programs.

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00:33:46.348 --> 00:33:55.019

So all of the scientific and business capabilities, you will hear about today, support these 3 strategic program objectives.

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00:33:55.019 --> 00:33:59.999

Next slide please.

264

00:33:59.999 --> 00:34:10.409

So, as Christine is already alluded to, in her presentation, we have organized the competition statement of work that has been released to the public.

265

00:34:10.409 --> 00:34:15.599

According to the technical capabilities that are needed at the f.

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00:34:15.599 --> 00:34:19.889

In this slide, I have highlighted just some of these.

267

00:34:19.889 --> 00:34:28.978

On the top, you see various scientific areas, and in the bottom, you see various business and technical capability business capabilities, I should say.

268

00:34:28.978 --> 00:34:32.039

Many of the programs of the.

269

00:34:32.039 --> 00:34:37.559

Utilize a wide swath of scientific capabilities.

270

00:34:37.559 --> 00:34:41.128

To fulfill the strategic objective of the programs.

271

00:34:41.128 --> 00:34:45.268

So, Additionally, execution of the business.

272

00:34:45.268 --> 00:34:53.789

Facility and logistical capabilities has a direct impact on how well, the scientific programs can execute.

273

00:34:53.789 --> 00:34:59.548

Additionally, there can be synergism between the scientific and business areas.

274

00:34:59.548 --> 00:35:02.789

To foster streamlining process improvement.

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00:35:02.789 --> 00:35:13.259

And problems, so today's presentations are aligned to some of the major technical and business capabilities needed at the f. L.

276

00:35:13.259 --> 00:35:17.849

And we have highlighted example programs throughout the day.

277

00:35:17.849 --> 00:35:24.358

That serve as illustrations of the types of work carried out at the.

278

00:35:25.438 --> 00:35:35.818

So next slide, finally, let's shift to the goals and operating principles for the operator of the f. RDC.

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00:35:35.818 --> 00:35:40.768

So, it just highlight some of the things here that we, as all of.

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00:35:40.768 --> 00:35:46.708

You know, us as the are various host and institutions really strive to achieve.

281

00:35:46.708 --> 00:36:00.028

And within the statement of work that has been released, we have a many many of these operating principles that we have outlined. But just a few of them that I'd like to highlight today are pursuing high risk, high reward projects.

282

00:36:00.028 --> 00:36:04.498

Demonstrating boldness and creativity and ideas and execution.

283

00:36:04.498 --> 00:36:07.949

Building relational bridges for shared success.

284

00:36:07.949 --> 00:36:14.159

Kristen already mentioned flexible, transparent, responsive, et cetera.

285

00:36:14.159 --> 00:36:20.128

And really, the ultimate goal here is to have a full intellectual and scientific partnership.

286

00:36:20.128 --> 00:36:27.119

With the end institutions at the age, and in other government agencies that collaborate with us.

287

00:36:27.119 --> 00:36:39.688

So this is my last slide here. I don't know Jason, if you would want Kristen and NY to answer any questions before we move on to the national mission section, but we are happy to do. So.

288

00:36:39.688 --> 00:36:51.748

If that's what we should do at this time. Thanks, Sarah, that that's a, that was a great, uh, overview and introduction to the format and of today's presentation.

289

00:36:51.748 --> 00:37:05.813

On the agenda, we have a block of time set aside for questions on this, these, these presentations as well as the next 3, which will go into more detail on the on the on the 3 national mission projects.

290

00:37:05.994 --> 00:37:16.523

So, when we go ahead and segue into that, and then we'll open it up for questions. And as a reminder, please enter all your questions into the chat box and we'll address them at the time of the Q. a session.

291

00:37:16.829 --> 00:37:29.548

All right, let's go ahead and transition over to the national mission projects and the 1st, 1 up will be from Dr Christopher came from the office of scientific operations and he'll speak to us about the rest initiative.

292

00:37:29.548 --> 00:37:34.168

Great Thank you, Jason. I'm good morning. Everyone.

293

00:37:35.184 --> 00:37:36.293

My name is Chris Kane,

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00:37:36.293 --> 00:37:43.614

and I am a program officer in the office of scientific operations with the at Frederick and it is my pleasure to present this,

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00:37:43.614 --> 00:37:46.074

talk on behalf of the rest program team,

296

00:37:46.164 --> 00:37:48.474

simply titled the rest initiative,

297

00:37:49.043 --> 00:37:50.304

which I'll be expanding on.

298

00:37:50.304 --> 00:37:52.704

Some of the comments that Sarah just spoke about.

299

00:37:53.248 --> 00:38:00.088

Next slide next slide.

300

00:38:01.043 --> 00:38:15.684

Great, thank you. So, national mission programs are designed to undertake important and ambitious projects and cancer research. That would be difficult if not impossible without a deep orchestrated a multidisciplinary effort.

301

00:38:16.079 --> 00:38:20.039

1st national mission program was the rest initiative.

302

00:38:20.039 --> 00:38:24.329

And it was launched in 2013 to target grass.

303

00:38:24.329 --> 00:38:31.440

Brass consisting of, and is the most frequently mutated gene family in cancer.

304

00:38:31.440 --> 00:38:34.739

On a nearly 30% of all tumor types.

305

00:38:34.739 --> 00:38:39.480

Is especially prevalent in long colorectal and pancreatic tumors.

306

00:38:39.480 --> 00:38:42.869

Therefore represents a high value, encourage you target.

307

00:38:42.869 --> 00:38:49.019

However, the conventional wisdom considered graphs is an therapeutic target.

308

00:38:49.019 --> 00:38:55.050

For over 30 years, fortunately for cancer patients, that notion appears to be changing.

309

00:38:55.050 --> 00:38:59.130

The rest initiative as 2 primary goals.

310

00:38:59.130 --> 00:39:04.260

1st is to seek a greater understanding of in cancer biology.

311

00:39:04.260 --> 00:39:14.969

The 2nd is to build an open collaboration model across government, academia and industry researchers to re, energize efforts to discover rest Therapeutics.

312

00:39:14.969 --> 00:39:20.190

Slide.

313

00:39:20.190 --> 00:39:31.650

The rest initiative utilizes a hub and spoke model depicted schematically here, implement the multi disciplinary science needed to realize it's ambitious national mission goals.

314

00:39:31.650 --> 00:39:34.949

Frederick National laboratory for cancer research.

315

00:39:34.949 --> 00:39:42.179

Shown is the center circle access the hub it connects the larger community of rest researchers around the world.

316

00:39:42.179 --> 00:39:47.099

Collaborating partners represent the spokes shown as the peripheral circles.

317

00:39:47.099 --> 00:39:50.730

That include intramural and extra mural Labs.

318

00:39:50.730 --> 00:39:54.539

As well, as contract research pharma and biotech.

319

00:39:54.539 --> 00:40:00.780

Together we are combining efforts and creating new ways to approach the complex issue of brass.

320

00:40:00.780 --> 00:40:09.090

We're very fortunate to have renowned rest researcher. Dr Frank McCormick service. The initiative scientific advisor.

321

00:40:09.090 --> 00:40:14.699

In order to better illustrate the broad scope of resources being applied to this biological problem.

322

00:40:14.699 --> 00:40:20.340

I'll briefly touch upon some of the major core research capabilities that include.

323

00:40:20.340 --> 00:40:26.280

Biochemistry and structural biology, your dynamics and structure based drug design.

324

00:40:26.280 --> 00:40:32.010

As well, as rest resources and interactions and our rest outreach program.

325

00:40:32.010 --> 00:40:38.460

Any other capabilities such as imaging protein expression, or an acid development not listed here.

326

00:40:38.460 --> 00:40:43.650

I used to support the initiative and are described in greater detail within the W.

327

00:40:43.650 --> 00:40:58.079

Next slide, biochemistry and structural biology disciplines are foundational aspects of our approach to better understand and define fundamental aspects of biology.

328

00:40:58.079 --> 00:41:03.090

The state of the, our proteomics facility supports analysis of full length proteins.

329

00:41:03.090 --> 00:41:12.869

And their modified Podio forms, this also includes mutation mapping and characterization of post Translational modifications, enter stoic geometries.

330

00:41:12.869 --> 00:41:18.480

Further insights regarding new target identification and structure based drug design.

331

00:41:18.480 --> 00:41:22.469

Obtained by our robust structural biology capabilities.

332

00:41:22.469 --> 00:41:25.889

A variety of methods, including extra crystal biography.

333

00:41:25.889 --> 00:41:33.809

And Omar, and are being applied to address fundamental questions regarding the wraps structure function relationship.

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00:41:33.809 --> 00:41:39.119

Number of structures have been solved and disclosed in leading scientific journals.

335

00:41:39.119 --> 00:41:42.480

Examples include full link.

336

00:41:42.480 --> 00:41:52.349

Mutants chaos and complex with the factors shown in the ribbon diagrams to the right the depicted in purple.

337

00:41:52.349 --> 00:41:57.030

And raft depicted in and yellow and green.

338

00:41:57.030 --> 00:42:02.010

As well, as a number of complex with small molecule inhibitors.

339

00:42:03.539 --> 00:42:16.079

Collectively, the structure of chaos and complex with effectors, such as wrath show, how the structure of tandem domains of the factor form 1, structural entity, and how this entity interacts with grass.

340

00:42:16.079 --> 00:42:27.869

Next slide please, Vance, computational approaches are being applied to explore rash structure and dynamics in cellular membranes.

341

00:42:27.869 --> 00:42:35.610

The goal here is to create a multi scale computational framework that users experimental input data from live cells.

342

00:42:35.610 --> 00:42:38.909

To inform next generation, molecular dynamics models.

343

00:42:38.909 --> 00:42:41.969

Is depicted in the schematic at top, right?

344

00:42:41.969 --> 00:42:47.099

The team can evaluate confirmations and dynamics of brass proteins either alone.

345

00:42:47.099 --> 00:42:50.309

As dimers or in complex with effectors.

346

00:42:50.309 --> 00:42:54.599

Additional macro scale simulations of brass behavior and membranes.

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00:42:54.599 --> 00:42:58.769

Based upon local lipid composition have also been conducted.

348

00:42:58.769 --> 00:43:07.619

With a view towards identifying novel and appreciated aspects of brass biology, such as cryptic or dynamic binding pockets.

349

00:43:07.619 --> 00:43:15.150

Major focus of the initiative is to re, energize small molecule, therapeutic development, targeting rash.

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00:43:15.150 --> 00:43:20.460

The team has taken a multi prong approach by pursuing both fragment based drug screening.

351

00:43:20.460 --> 00:43:26.760

As well, as structure based drug design, both with collaborative efforts with our external partners.

352

00:43:26.760 --> 00:43:41.639

1, competitive advantage of the rest initiative is it's advanced capabilities and structural biology. This is represented by the ribbon diagram of chaos, bound to non analog and a magnesium Ion.

353

00:43:41.639 --> 00:43:48.780

The analog and uses into a active form in both biochemical and structural studies.

354

00:43:48.780 --> 00:44:02.250

The ability to solve multiple wild type and meet and structures either alone or in complex with small to inhibitors has been instrumental in discovering development of novel chemical matter targeting.

355

00:44:02.250 --> 00:44:06.329

This is generated a robust portfolio of structurally distinct.

356

00:44:06.329 --> 00:44:10.380

Small molecule inhibitors, the feature, a wide range of mechanisms.

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00:44:10.380 --> 00:44:16.440

Including both Covalent and non inhibitors as well as other allosteric inhibitors.

358

00:44:16.440 --> 00:44:23.969

Clearly rest initiative studies in those of others have demonstrated that rash is indeed a drug target.

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00:44:23.969 --> 00:44:34.019

Next slide please, another unique aspect of the national mission program is to enable the exploration of brass biology.

360

00:44:34.019 --> 00:44:41.550

Throughout the greater scientific community by the creation manufacture and distribution of valuable rescue the agents.

361

00:44:41.550 --> 00:44:47.039

Rest raging cord generates materials to support all rest initiative hub projects.

362

00:44:47.039 --> 00:44:50.699

And assist external scientists on a global basis.

363

00:44:50.699 --> 00:44:55.170

A quick survey demonstrates the breath of agents that have been made available.

364

00:44:55.170 --> 00:44:59.519

Which includes thousands of plasmids pathway kits.

365

00:44:59.519 --> 00:45:02.610

Rest mutants in over 800 cell lines.

366

00:45:02.610 --> 00:45:15.329

Other interactions, numerous collaborations with 27 academic institutions, 12 strategic partners, and 10 industrial partners as well as community outreach efforts.

367

00:45:15.329 --> 00:45:20.670

Many outreach occurs in a variety of events, which includes the rest symposium.

368

00:45:20.670 --> 00:45:24.539

The 3rd is just around the corner on 3 may 2021.

369

00:45:24.539 --> 00:45:38.219

Online registration is currently open the rest initiative is also held multiple community workshops and special Ross sessions at national meetings and they have participated in synthetic legality network.

370

00:45:38.219 --> 00:45:42.179

Sharing our breakthrough science is also a distinguishing feature.

371

00:45:42.179 --> 00:45:47.610

Is demonstrated by over 40 publications and peer reviewed high impact journals.

372

00:45:47.610 --> 00:45:59.340

Slide please an additional critical component of the rest initiative is to foster the dissemination of information in support of brass researchers.

373

00:45:59.340 --> 00:46:11.489

It takes the form of a web based portal hosted by the, at the cancer dot Gov forward slash Gras, which is the information repository and clearing house for the program.

374

00:46:11.489 --> 00:46:19.920

It sends email updates over 4,000, international researchers and provides the forum to engage the greater a** community.

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00:46:19.920 --> 00:46:23.969

It has been used to discuss content for workshops of topical interest.

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00:46:23.969 --> 00:46:29.219

Or communicate upcoming events, such as the 3rd dress symposium are taking place. This may.

377

00:46:29.219 --> 00:46:34.469

Now, so host sub pages to facilitate exchange of ideas and discussion.

378

00:46:34.469 --> 00:46:37.619

An example is the rest dialog page shown here.

379

00:46:37.619 --> 00:46:41.489

Which allows researches the post comments best questions.

380

00:46:41.489 --> 00:46:45.239

Stay up to date with articles, contributed experts.

381

00:46:45.239 --> 00:46:54.989

Next slide please and family I would like to highlight rest lab, which is also hosted on the rash initiative website.

382

00:46:54.989 --> 00:47:04.139

Rest lab is an invitation only discussion forum to promote technical scientific exchange among researchers and cancers related to harass.

383

00:47:04.139 --> 00:47:08.190

Much like the rest dialogue site rest lab numbers allow.

384

00:47:08.190 --> 00:47:14.969

Members to post and respond to messages, upload data and contact 1 another 4 collaborations.

385

00:47:14.969 --> 00:47:18.690

Currently more than a 1000 members are involved in the discussion.

386

00:47:18.690 --> 00:47:22.920

Joining is simple. Please consult the Web site for more information.

387

00:47:22.920 --> 00:47:29.130

And with that, I would like to thank you for your attention now return to floor to Jason.

388

00:47:29.130 --> 00:47:32.820

Thank you. Thanks, Chris.

389

00:47:32.820 --> 00:47:43.380

All right now we'll pivot over to Dr Gary Robertson from the office of scientific operations with the National Cancer Institute, and he'll be presenting the program.

390

00:47:43.380 --> 00:47:46.530

Eric, thanks and Jason.

391

00:47:46.530 --> 00:47:55.110

Talked to you this morning about 1 of our premiere research programs that prior lecture microscopy program at the Frederick National Laboratory.

392

00:47:55.110 --> 00:48:09.510

Next slide please, the mission of the national program is to improve the accessibility of Cryo techniques to the broader cancer biology community within the nation.

393

00:48:09.510 --> 00:48:14.159

And also to optimize prior and techniques and workflows.

394

00:48:14.159 --> 00:48:20.309

For the overall user population, there are 2 aspects to the program.

395

00:48:20.309 --> 00:48:28.110

Uh, that Sarah alluded to earlier, the 1st, is the National private yam facility, or.

396

00:48:28.110 --> 00:48:32.010

Which began in 2017, it's focused on providing.

397

00:48:32.010 --> 00:48:37.260

Cutting edge services, data, collection services to extra mural users.

398

00:48:37.260 --> 00:48:45.059

They, they have identified 3 key user groups experts that.

399

00:48:45.059 --> 00:48:51.090

Don't have access to instrumentation, or in some cases, may actually have instrumentation, but need.

400

00:48:51.090 --> 00:48:55.769

Additional support because of workflow limitations.

401

00:48:55.769 --> 00:49:06.809

Structural biologists who don't have particular expertise in and then, thirdly, the broader cancer biology community that don't have any particular expertise in structural biology.

402

00:49:06.809 --> 00:49:13.650

The other the other group within the program is the research and development group.

403

00:49:13.650 --> 00:49:18.719

That are exploring new experimental methods and platforms in.

404

00:49:18.719 --> 00:49:26.820

Sample preparation, data, collection and data analysis in particular. So the, the program has.

405

00:49:26.820 --> 00:49:37.679

Primarily focused on group 1 above, and is now expanding into 2 and our intention is to expand and further into group 3 in the future. Next slide. Please.

406

00:49:39.329 --> 00:49:42.539

So, the national.

407

00:49:42.539 --> 00:49:54.059

Facility and CF has an aim of providing access to cutting edge criteria, microscopes and data collection capabilities to the extra marrow cancer research community.

408

00:49:54.059 --> 00:49:59.969

And stuff is intended for the use to advance the mission.

409

00:49:59.969 --> 00:50:10.800

And requires all prospective users to provide a statement that their project is relevant to cancer research. Although over the past year, a considerable amount of work has been devoted towards structures of.

410

00:50:10.800 --> 00:50:16.739

The, the SARS colonel Iris structure, and it.

411

00:50:16.739 --> 00:50:20.579

Association with the cell.

412

00:50:20.579 --> 00:50:27.000

Clients or academic or nonprofit, they don't need to be NCI grantees.

413

00:50:27.000 --> 00:50:37.619

Specimens need to be of sufficient quality that to allow for imaging and high resolution. The client will prepare the grid submit prescreening images.

414

00:50:37.619 --> 00:50:41.760

That demonstrate for freezing quality and sample concentration.

415

00:50:41.760 --> 00:50:49.139

To the, and then imaging is done on 2 krayton to tighten microscopes.

416

00:50:49.139 --> 00:50:56.309

Outfitted with and K3 bio, quantum, electronic textures. 1 of them is shown in photo to the right.

417

00:50:56.309 --> 00:51:08.190

Currently there about the 240 data collections per year, there's about a queue of 4 to 6 weeks currently to begin work.

418

00:51:08.190 --> 00:51:20.849

The goal of the group is to decrease the amount of time it takes to acquire high quality data images from 48 hours down to 24 hours, which will essentially double the throughput of the.

419

00:51:20.849 --> 00:51:30.630

Of the of the effort next slide please. So, over the course of the past 4 years the.

420

00:51:30.630 --> 00:51:40.800

Has collected more than 550 cancer related data sets from greater than 100 more than 50 institutions.

421

00:51:40.800 --> 00:51:49.289

It's a very client focus group feedback is very important to them and it has been uniformly positive from the community.

422

00:51:49.289 --> 00:51:55.050

They have been I mentioned doing a fair amount of work on 19.

423

00:51:55.050 --> 00:51:59.909

Related data collections over the past year, and I'll show an example of that shortly.

424

00:51:59.909 --> 00:52:05.610

There have been more than 40 publications in high impact journals that have acknowledged.

425

00:52:05.610 --> 00:52:14.639

And data data and incorporated and collected data, and there's been a paper describing best practices at the facility that.

426

00:52:14.639 --> 00:52:19.619

Came out in microscopy today. Next slide please.

427

00:52:22.440 --> 00:52:26.849

There are a couple just a couple of example of user successes.

428

00:52:26.849 --> 00:52:38.039

Shown on the top is a structures of serotonin receptors, add 3.3 action resolution that was published in nature in 2018.

429

00:52:38.039 --> 00:52:42.929

And below is the structure of the SARS cookie to spike protein.

430

00:52:42.929 --> 00:52:47.610

That at a resolution at 3.2 extremes.

431

00:52:47.610 --> 00:52:53.250

That was published just last year. This was a very rapid turnaround between data collection and publication.

432

00:52:54.449 --> 00:53:03.239

Next slide please the electron electron and my cross to be R and D group.

433

00:53:03.239 --> 00:53:09.239

Is focusing on evaluating under explored emerging technologies.

434

00:53:09.239 --> 00:53:14.010

As well, as establishing an internationally competitive in house research program.

435

00:53:14.010 --> 00:53:18.690

To address, challenging problems of central interest to the.

436

00:53:18.690 --> 00:53:23.550

They conduct both single particle, extra microscopy and electronic demography studies.

437

00:53:23.550 --> 00:53:31.440

Utilizing Thermo Fisher at Thermo Fisher and Joel prior on 200 instruments.

438

00:53:31.440 --> 00:53:44.670

1 of their focuses has been to explore the use of low energy, electron beams and lower cost instruments. For example, the combined cost of the ratios and Jill instruments is equivalent to that at 1.

439
00:53:44.670 --> 00:53:47.909

Tighten on instrument.

440
00:53:47.909 --> 00:53:54.030

They also utilize serial and open source software to do data analysis.

441
00:53:54.030 --> 00:54:00.030

The resolutions of these 2 instruments are around 2 or below.

442
00:54:00.030 --> 00:54:05.789

And as I mentioned for their, they're involved with both separate sample preparation efforts.

443
00:54:05.789 --> 00:54:14.880

Improving sample preparation methodologies as well as structural analysis of data. So they kind of cover the whole gamut of the.

444
00:54:14.880 --> 00:54:18.599

Uh, experimental effort next slide please.

445
00:54:21.659 --> 00:54:25.619

There's an example of data collected.

446
00:54:25.619 --> 00:54:30.599

On a benchmark protein with a Joel.

447
00:54:30.599 --> 00:54:35.340

Uh, 200 instrument at 200 electron goals.

448
00:54:35.340 --> 00:54:44.219

1.8 extra resolution, you can see the map quality for the amino acid side chains and peptides.

449
00:54:44.219 --> 00:54:49.619

These are representative examples of peptide sequences.

450
00:54:49.619 --> 00:55:00.420

The density contributions from water molecules are visible on the side chains, and you can also see density holes in the arrows works, which is a sign of the.

451
00:55:00.420 --> 00:55:04.500

A superior resolution of this experimental technique.

452

00:55:04.500 --> 00:55:09.599

More recently, I, the structure of the human ribosome.

453

00:55:09.599 --> 00:55:14.760

Was solved at 2.1 insurance and has been submitted for publication.

454

00:55:14.760 --> 00:55:18.150

And future work on.

455

00:55:18.150 --> 00:55:23.099

In this group will focus on improving resolution.

456

00:55:23.099 --> 00:55:29.099

Improving methods of preparing grids through plunge, freezing.

457

00:55:29.099 --> 00:55:33.690

And expanding into the structures of cells and tissues.

458

00:55:33.690 --> 00:55:37.170

Using Cryo, electronic demography techniques in particular.

459

00:55:37.170 --> 00:55:41.190

Focused technologies.

460

00:55:41.190 --> 00:55:47.670

Next slide please, thank you very much for your time. Appreciate it.

461

00:55:48.719 --> 00:55:49.465

Thanks Gary.

462

00:55:50.875 --> 00:55:54.505

All right before we move on to Jim's presentation,

463

00:55:54.505 --> 00:56:06.264

I want to remind everybody feel free to start entering questions into the chat box and any question pertaining to the earlier presentations as well as these 3 presentations on the national.

464

00:56:08.099 --> 00:56:15.510

So, let's go ahead and conclude with our 3rd national mission project. Uh, That'll be presented by Dr Jim cherry.

465

00:56:15.510 --> 00:56:23.190

Also in the office scientific operations, with the National Cancer Institute, and he's going to be presenting information on 0 net Jim.

466

00:56:24.175 --> 00:56:34.045

Thank you Jason hope everybody can hear me. Well, so I'm can cherry scientific program director out of the office scientific operations, which is part of the office, the director and morning.

467

00:56:34.045 --> 00:56:41.335

I will be talking a little bit about the neurological sciences program, which is part of the national mission effort at the credit national next slide. Please.

468

00:56:42.144 --> 00:56:52.195

So, this morning knowledge is not only the sciences network and clinical translations, technology task force and this morning discussion next slide. Please.

469

00:56:54.085 --> 00:56:54.565

So,

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00:56:54.925 --> 00:57:09.835

what you're seeing here is an example of the role that the credit National Lab played in collaboration with the National Cancer Institute as well as an ID to respond to rapidly to the code of 19 pandemic you've

471

00:57:09.835 --> 00:57:11.965

got several research projects here,

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00:57:11.965 --> 00:57:18.204

which is the foundational strategy work the clinical Translational sociology task force,

473

00:57:18.684 --> 00:57:24.864

the support for immunocompromised and cancer research and care and the pandemic,

474

00:57:25.255 --> 00:57:30.835

and then additional curved 19 research that was able to fund it with the neurological sciences program efforts.

475

00:57:31.110 --> 00:57:44.034

Next slide please so what you're seeing here is basically a trans governmental effort that was established back in the beginning of the pandemic with the award of the paycheck care act.

476

00:57:44.635 --> 00:57:56.605

The NCI was able to partner very closely with niann and Frederick National Lab, and the overall mission was to establish a network of researchers.

477

00:57:56.605 --> 00:58:05.994

That would be able to collaborate and create new assays to measure the immune response to infection and gain further understanding of the response.

478

00:58:06.445 --> 00:58:17.005

And variations, and the durations, we also wanted to work closely and at risk populations as well as clear communications across the scientific community.

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00:58:17.340 --> 00:58:30.954

Next slide please. So the overall goal, the theological sciences network was to conduct a basic and apply foundational research into both SARS immune response.

480

00:58:31.284 --> 00:58:37.494

We wanted to get a better understanding of the mechanisms driving innate tomorrow and sailor immune response.

481

00:58:37.739 --> 00:58:43.079

Wants to determine the host genetic and environmental modifiers of the immune response.

482

00:58:43.079 --> 00:58:57.510

Determine the neurological correlates of disease, pathogens and protection against future infections and defined access, communication and implement implementation barriers, relate it to the SARS could be to Sarah logical testing.

483

00:58:57.510 --> 00:59:04.110

Worked very closely develop assays, national reference standards and antigens and multiplex assets.

484

00:59:04.525 --> 00:59:17.934

Develop high throughput testing capacity and guidelines available to the scientific community, and they create a collaborative network of investigators that can make rapid progress and make data widely available. What you're seeing here on the right.

485

00:59:17.934 --> 00:59:21.925

Is basically a hub and spoke model, which consisted of several components.

486

00:59:21.925 --> 00:59:33.925

We have the centers centers for excellent research, which was the 50 41 grantees we had the front of national life, which we were able to pivot and rapid response to the code and 19 pandemic.

487

00:59:33.925 --> 00:59:44.275

We're also able to stand up the new app and our network coordinating center should be able to not only coordinate data that was coming in, but to be able to provide samples going.

488

00:59:45.300 --> 00:59:46.135

Next slide please.

489

00:59:50.184 --> 01:00:03.684

So the NCI, the cancer research, and the unique participants for 3 components of the theological science network, the capacity building centers, which you're seeing orange, which were subcontracts, we had the network coordinating center.

490

01:00:04.110 --> 01:00:08.489

And we had the Frederick National lab for cancer for National Laboratory.

491

01:00:08.489 --> 01:00:16.795

Next slide please. So, let me take a minute and share the goals of each of these components.

492

01:00:16.855 --> 01:00:24.775

So, for the theology lab, the main goal was to implement and qualify stars could be to align assays for both and.

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01:00:26.275 --> 01:00:39.264

Wanted to build validation proficiency panels for acid development validation. We worked very closely in collaboration with the FDA to be able to allow for approvals of for commercial assets to go on the market.

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01:00:39.744 --> 01:00:49.465

We rapidly identified procured and characterize cerumen plasma assessments for patients and necessary controls to identify negative medium and higher response.

495

01:00:50.335 --> 01:01:02.695

We produce assay standards and reference regions antigens and quantification validations of SARS Katy to Sarah logical and other related immune assays and distributed those to the network those went out to argue I want,

496

01:01:02.724 --> 01:01:10.885

you can see fours as well as the capacity bombing centers where the other exciting goals was the implementation of the US national standard,

497

01:01:10.914 --> 01:01:19.554

which was basically the ability to support cancer research and BioTrack vaccine trials were able to provide that and be at the end of 2020.

498

01:01:21.114 --> 01:01:36.085

We also work to evaluate determinants and neutralizing responses, and we partnership with regulatory bodies and ask developers for validation of eligible testing platforms to be able to overcome that barrier of getting testing capacity across the country.

499

01:01:36.985 --> 01:01:37.434

Next slide,

500

01:01:40.855 --> 01:01:52.284

the overall goal of the network recording center was to provide programmatic management coordination and communicate communication across the neurological science and network for SARS could be to.

501

01:01:52.679 --> 01:01:57.690

Coordinated sharing of the data re, agents and sample and assets.

502

01:01:57.690 --> 01:02:07.920

We coordinate comparison of results among different centers and assays inter, center collaborative studies, leading to international and theological standardization.

503

01:02:07.920 --> 01:02:20.760

They work to coordinate partnerships with national and international associations, such as CDC niann nicks and other agencies within the federal government.

504

01:02:20.760 --> 01:02:34.704

Next slide please the last component, which is a different component that hadn't been seen before, which is the ability to establish the capacity building centers as you guys all recall at the beginning of the pandemic when il of the biggest difficulties with testing.

505

01:02:34.704 --> 01:02:44.605

So 1 of the things that I wanted to do, was to be able to increase the testing capacity across the country, and we utilize the credit passive lab to establish what it costs by the capacity building centers.

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01:02:44.605 --> 01:02:54.625

Their overarching goal was to acquire and conduct quality control, assessment of critical reference samples. That was the establishment of the National reference, which was done by laboratory.

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01:02:56.579 --> 01:03:11.369

Laboratory developed and validated in partnership with the capacity building centers testing capacity for SARS can be 2 infections. We set quality serology assays at high specificity and sensitivity greater than 94%.

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01:03:11.934 --> 01:03:26.034

We also work to increase the scale high quality serology testing to meet the emerging needs of the nation and in collaboration and serious balance and Sarah protection studies for post vaccinated individuals but immunocompromised and cancer patients,

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01:03:26.724 --> 01:03:34.284

and conducted focus studies and surgical science acknowledge development to be able to increase the efficiency of the technology for testing across the country.

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01:03:34.974 --> 01:03:35.605

Next slide please.

511

01:03:38.603 --> 01:03:53.304

So, as you can see here, and this is something that was alluded to, by Dr hawk and Dr chocolates earlier in their slides was the geographical distribution of the Internet sites, as you can see here 1 of the overarching goals to make sure that we weren't all across the eastern seaboard, but we were across the entire country.

512

01:03:53.425 --> 01:03:58.405

We have 4 capacity building centers. You 50 fours, 13 new ones.

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01:03:58.795 --> 01:04:12.684

We also have the National serology laboratory and from the lab and network coordinating center and the overarching goal here is to increase communication implementation better. Understand the adaptive and innate immune response work on serious to balance.

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01:04:12.684 --> 01:04:17.635

And then also to assess public health policy makers to help with decision making.

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01:04:17.940 --> 01:04:32.905

Excellent place so, the next component of the theological science program with the establishment of the clinical translation restaurants task force and the overall mission here was to catalyze translation of research findings into public health changes.

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01:04:33.175 --> 01:04:37.105

I bringing together and engaging various governmental organizations,

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01:04:37.135 --> 01:04:48.775

academic groups as well as industry partners to provide relevant tools and information related to serology testing and help decision makers to manage the current and future status to pandemic.

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01:04:50.094 --> 01:04:53.215

The overall goal was to work with academics,

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01:04:53.244 --> 01:04:53.875

industry,

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01:04:53.905 --> 01:04:55.855

regulatory bodies policymakers,

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01:04:55.855 --> 01:04:59.965

but to also be able to identify the gaps in serology testing,

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01:05:00.235 --> 01:05:07.525

and then implement the use of standards to harmonize testing and to identify the most appropriate assays for clinical testing.

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01:05:07.829 --> 01:05:14.335

We want to foster that national international collaboration with clinical and public health organizations,

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01:05:14.514 --> 01:05:23.275

and we did that with working with mist and and promote public policy education for sciences for public health value.

525

01:05:24.295 --> 01:05:28.135

The impact of this was enabling develop development of reliable,

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01:05:28.164 --> 01:05:29.875

accurate and reproducible methods,

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01:05:30.445 --> 01:05:31.375

comparison of data,

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01:05:31.375 --> 01:05:38.215

utilizing the standards from different platforms in different laboratories to accelerate implementation of harmonized assays,

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01:05:38.244 --> 01:05:41.125

new vaccines and new vaccine recommendations.

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01:05:41.460 --> 01:05:56.394

Next slide please as you can see here 1 of the examples of the clinical translations rods task force was a big role that the credit national and played and partnership with the which is the word for work

531

01:05:56.425 --> 01:06:02.545

flow and performance evaluation of a live kits and lateral flow devices at the front of National Lab.

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01:06:04.014 --> 01:06:12.985

Agency collaborate efforts with Naya embargo as well as several academic groups to be able to collect positive samples.

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01:06:13.315 --> 01:06:22.675

We had 30 positive patients, 70 Pre pandemic controls as well as 10 positives. This was made up of the validation panel.

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01:06:23.125 --> 01:06:34.884

We were able to work closely with the FDA as acids were coming in, from commercial vendors and those assets would

come over to the Frederick National lab to be assessed versus the validation panels. And then we were able to report on.

535

01:06:34.884 --> 01:06:42.655

We have now as to date about 350 commercial assays and house at the national labs that are being processed is being sent back over to the.

536

01:06:44.099 --> 01:06:54.960

With about 10,000 or so data points to make decisions on both lateral flows and allies assays that will have either approval or disapproval of the way.

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01:06:54.960 --> 01:07:03.775

Next slide please. So, the last component that we put in a place with the SARS, could it be to post vaccination, serious surveillance studies?

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01:07:03.775 --> 01:07:12.505

And this is both for cancer immunocompromised individuals and the overall goal was developed a common study template, designed for all vaccinations studies.

539

01:07:12.985 --> 01:07:27.594

And cancer and compromised patients, establish baseline, predictive factors for coded 19 course and or vaccination response response to antibodies inside of your immunity vaccines, or infections in general cancer populations.

540

01:07:28.224 --> 01:07:43.224

Response in relation to specific therapies, immunotherapies, chemotherapies, target therapies, radiation therapy surgery as well as commentary therapy, and then priorities for recommendations, specimens, collection, time points and patient data implementation.

541

01:07:43.255 --> 01:07:50.545

We want to be able to develop an overarching umbrella of protocols that could be utilized. So, that can help to increase the.

542

01:07:50.849 --> 01:07:57.210

Process of doing post vaccination studies. Excellent.

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01:07:59.184 --> 01:08:01.795

The other component that's very important is to be able to share that data.

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01:08:01.795 --> 01:08:02.034

So,

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01:08:02.034 --> 01:08:04.074

we were able to work very closely with the product,

546
01:08:04.074 --> 01:08:04.704
National Lab,

547
01:08:04.735 --> 01:08:10.945
and the coordinating center to set up the data coordination and this allows for the research initiatives,

548
01:08:10.945 --> 01:08:11.875
grantees,

549
01:08:11.994 --> 01:08:12.625
strategy,

550
01:08:12.625 --> 01:08:13.525
lab and Frederick,

551
01:08:13.735 --> 01:08:15.355
the capacity building center as well,

552
01:08:15.355 --> 01:08:19.074
as other academic institutions that we would classify as ancillary partners,

553
01:08:19.375 --> 01:08:22.375
Sprint data into the and that date,

554
01:08:22.375 --> 01:08:25.614
according Sam will be able to not only see the data.

555
01:08:26.010 --> 01:08:35.760
But actually distributed data and make it public available. So others could see what was going on. We're able to utilize this in partnership with others like genomics, imaging and important.

556
01:08:36.265 --> 01:08:47.904
Next slide please the other exciting component of the science network was the establishment of the U. S. national reference. At the end of 2020.

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01:08:47.904 --> 01:09:01.704
we were asked, we asked the product National lab to work closely with us to develop the US national standard, which is now being utilized. It's been sent out to proximal about 40 different institutes, but academic commercial as well as government agencies.

558
01:09:01.704 --> 01:09:13.765

And this is used to be able to standardize the antibody testing it's being done across the country. We're able to use calibration Labs, conducting testing. We harmonize the assays.

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01:09:13.765 --> 01:09:28.524

We pull plasmin antibodies, Peggy to assigned binding and neutralizing units and we were able to collaborate with Debby, late show as well as standard as soon as it becomes available. So we will have not only a national, but an international standard.

560

01:09:28.524 --> 01:09:30.835

That wouldn't be unavailable to find to the community.

561

01:09:32.364 --> 01:09:42.295

Next slide please the next component we also very well established was the utilization of the protein expression laboratory at the project National Lab.

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01:09:42.625 --> 01:09:43.045

The 1st,

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01:09:43.045 --> 01:09:57.774

we were able to do at the beginning of the pandemic is we're closely with them and establish the development of the strategy development for upper proteins for the starts Katie to also be in the process of making the spike Mt Sinai animal proteins.

564

01:09:58.045 --> 01:10:11.125

The antibody proteins as well as the different variant proteins that are coming online as we see in the country today. So the source proteins and clean variants and broad insurance available to the Internet institution.

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01:10:11.154 --> 01:10:19.255

Only it's not made publicly available, elimination and large quantities and new contracts. Will be also be able to develop in the protein expression laboratory.

566

01:10:19.560 --> 01:10:24.270

Can you go back once? I think you Nope. Go forward 1.

567

01:10:26.250 --> 01:10:34.045

1 more okay so overall the impact of the science activities has been a number,

568

01:10:34.074 --> 01:10:40.765

but investigate immune response to infection vaccines develop and validate new methods for laboratory markers for protection,

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01:10:41.095 --> 01:10:41.604

monitor,

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01:10:41.604 --> 01:10:43.435

immunity and clinical trials and Pre,

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01:10:43.435 --> 01:10:49.585

clinical studies provide evidence to inform new trials and create tools to enable public health changes.

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01:10:50.064 --> 01:10:56.335

The overarching goal is to understand how hosts response the virus how vaccines work and correlates protection,

573

01:10:56.904 --> 01:11:08.604

provide evidence to move forward with new trials for novel vaccine recommendations and leading international standard initiative to enable reliable measurements of laboratory markers of immunity.

574

01:11:08.604 --> 01:11:09.895

And vaccine effectiveness.

575

01:11:10.170 --> 01:11:21.810

The overarching goal here is the Federal National lab was able to pivot rapidly in response to the code of 19 pandemic and partnership with a number of our ancillary partners across the government.

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01:11:21.810 --> 01:11:31.289

Next slide so that ends my section of the talk. If there's any questions, I think Jason, if not, I'll turn it back over to you.

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01:11:32.395 --> 01:11:34.104

Great, thank you Jim. Yes, we are.

578

01:11:34.104 --> 01:11:34.404

Now,

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01:11:34.404 --> 01:11:40.375

at the Q and a section and please enter any questions that you might have over these,

580

01:11:40.645 --> 01:11:42.744

these 3 national mission programs,

581

01:11:42.744 --> 01:11:43.854

the rest program,

582

01:11:44.125 --> 01:11:45.654

the crowd program,

583

01:11:46.015 --> 01:11:56.005

and the net program that Jim just talked about as well as any general questions you might have for Sarah with regards to the RTC vision and goals and strategic program objectives,

584

01:11:56.335 --> 01:11:59.185

or any kind of historical questions you might have for Kristen.

585

01:11:59.635 --> 01:12:02.755

So please enter those into the chat box and we'll start.

586

01:12:04.079 --> 01:12:08.520

Divvying those up and responding and we'll just wait for your questions.

587

01:12:08.520 --> 01:12:14.909

So, Jason, this is, this is Jim. Just so I know how long is this question and answer section.

588

01:12:14.909 --> 01:12:28.920

Well, we had allocated about 15 minutes for it, but we're way ahead of schedule right now. So, let's see if we can get some questions and in any up some of that time. And then we've got a break scheduled for, after that.

589

01:12:28.920 --> 01:12:32.729

Okay.

590

01:12:48.119 --> 01:12:55.409

Must be a lot of folks from the West Coast, have an ERP. Haven't woken up yet.

591

01:12:55.409 --> 01:12:55.800

Data

592

01:12:55.795 --> 01:13:50.244

science.

593

01:13:53.039 --> 01:13:56.100

Okay, I've not seen any questions come in.

594

01:13:56.100 --> 01:14:04.859

Do we know that printed? Do we know that the chat function is working making sure that nobody's cut off.

595

01:14:04.859 --> 01:14:08.340

So, Jason, there is a question that just come in. So.

596

01:14:08.340 --> 01:14:13.859

Ah, yes, I see it.

597

01:14:16.380 --> 01:14:23.784

Okay, yeah, given the ongoing nature of the work at the, and the necessity to maintain the current research staff.

598

01:14:24.145 --> 01:14:33.204

Is there a specific set of criteria That'll be deployed to evaluate any offers as opposed to the objectives provided here.

599

01:14:33.510 --> 01:14:37.079

Which are more research based.

600

01:14:37.079 --> 01:14:41.130

Who wants to field that 1.

601

01:14:43.979 --> 01:14:47.789

So, Jason, this is Sarah. I can take that 1.

602

01:14:47.789 --> 01:15:02.274

So all of the objectives in the review criteria will be published and will go out on the street. So, I think that it may be premature to speculate on this, the answer to this question.

603

01:15:02.635 --> 01:15:06.324

But I think it is an important question that we will answer in writing.

604

01:15:09.779 --> 01:15:14.010

So, Jason, there is another question.

605

01:15:19.619 --> 01:15:26.850

It is so of these major initiatives. What to what extent?

606

01:15:26.850 --> 01:15:34.409

Are these led by the contract staff at the or led by federal investigators and supported by the RTC contract staff?

607

01:15:34.409 --> 01:15:41.010

So, Jason, I can speak to this, at least from the perspective of the operation. If you're okay with that.

608

01:15:42.090 --> 01:15:45.630

Yeah, and then maybe a follow up from Sarah 2.

609

01:15:46.375 --> 01:15:58.284

Sure, just from the perspective of the Syrian operation, this is a very collaborative effort is led by the which was from doctor chocolates Dr singer and Dr.

610

01:15:58.284 --> 01:16:07.435

allele but it was a collaborative effort assigned to the discussions back and forth between, from ethanol staff as well as government staff.

611

01:16:08.335 --> 01:16:23.005

Sarah, yes, so the national program, and the ROS initiative are led by researchers. So we have an advisory growth for of extra mural community for each of those programs.

612

01:16:23.250 --> 01:16:26.699

But it's largely led by the researchers.

613

01:16:30.659 --> 01:16:41.130

All right, Here's a good general question. How does the differ from other national labs as a contract?

614

01:16:46.140 --> 01:16:49.170

Either Kristen or Sarah. Do you guys want to take that? 1?

615

01:16:54.029 --> 01:17:01.350

Yeah, so this is probably a question that I'm not an expert on, because I'm not at the other national labs.

616

01:17:01.350 --> 01:17:09.359

I think, for instance, in situations where there's a of national Labs, such as the Department of energy.

617

01:17:09.359 --> 01:17:18.029

They operate a little differently, because kind of projects are turned out and they accept proposals for the various.

618

01:17:18.029 --> 01:17:24.449

National Labs to do certain amounts of work, et cetera. So it's quite a different model.

619

01:17:24.449 --> 01:17:38.395

And there's strengths of each of the different national labs. So, in our case, we have just 1 National Lab, and we do a lot of work primarily with the community pharma, biotech, et cetera.

620

01:17:38.425 --> 01:17:40.975

And although I should mention that we do have a.

621

01:17:41.279 --> 01:17:46.859

Collaboration with 4 of the Department of energy, national labs.

622

01:17:46.859 --> 01:17:54.329

And it's all surrounding high performance computing and applied to cancer related problems. So if.

623

01:17:54.329 --> 01:18:01.979

Any of the offers are interested in more details about those programs. You can find that in the NCI.

624

01:18:01.979 --> 01:18:09.930

Division of extra mural activities website and There'll be links to the Frederick National Lab advisory.

625

01:18:09.930 --> 01:18:15.300

Um, committee where there are detailed presentations about these D. O. E. collaborations.

626

01:18:17.340 --> 01:18:26.189

Sarah, I am noticing, I'm getting the questions actually sent directly to me privately.

627

01:18:26.189 --> 01:18:33.810

So the folks, when you have a question, go ahead and do it as a public question, because the transcript's going to be.

628

01:18:33.810 --> 01:18:38.670

Um, captured, uh, for for publication later on the.

629

01:18:38.670 --> 01:18:46.020

On the website, so please don't send them to me privately. I'm going to go ahead and read them out. There's a couple still listed here.

630

01:18:46.020 --> 01:18:58.770

But go ahead and post them publicly so that that transcript can be captured. All right how many national programs? I don't know if anybody knows this how many national programs can be established at 1 time.

631

01:18:58.770 --> 01:19:08.640

Do they have to do we have to swap them out or can additional ones be added simultaneously? Is there is there a limit to the number of national programs that can be added to the DC?

632

01:19:11.640 --> 01:19:21.840

So, Jason, can you just send just because you kind of cut out and then you can answer.

633

01:19:23.154 --> 01:19:37.494

Sorry, yeah, so the question is, is there is there a limit on the number of national programs that can be onboarded or or worked on at the do they need to be swapped out? Is the is there is there an unlimited amount?

634

01:19:38.005 --> 01:19:39.774

Or is there a ceiling set.

635

01:19:43.944 --> 01:19:58.854

So this is Kristen there is no particular ceiling that set per se. Obviously we'll have the final word on what the National missions will be composed of. They don't necessarily need to be swapped out.

636

01:19:59.994 --> 01:20:05.994

But and also, from the contract perspective, there's no commitment from the contractually.

637

01:20:16.859 --> 01:20:30.539

So, Jason, there seems to be because I'm getting private Wednesday, there seems to be issues. They can't, they're not able to get their questions to go public. At least a couple of people are putting us in the aisle. So, I don't know if this is an issue or.

638

01:20:30.539 --> 01:20:34.109

Steven kind of dress it, but people are saying they can't get their stuff to go public.

639

01:20:34.109 --> 01:20:39.390

Just above where you enter your question, there should be a box labeled 2.

640

01:20:39.390 --> 01:20:48.390

Just to make sure that everyone is selected in that box, you can find them at the top of the list when you click inside of that box.

641

01:20:49.739 --> 01:20:59.250

All right, given the current environment of remote work, due to the pandemic.

642

01:20:59.250 --> 01:21:02.939

Well, the considered remote contract work in the future.

643

01:21:02.939 --> 01:21:08.010

Silence.

644

01:21:10.560 --> 01:21:20.725

So, I can see I can answer that from that perspective and I can tell you what we're doing. Now. I don't know about the future. I'll defer to Christina or Sarah for that.

645

01:21:20.725 --> 01:21:28.194

But at least from an operation, the lab individuals are in the laboratories. They are actually socially distance.

646

01:21:28.734 --> 01:21:39.265

I know that's something that Dr chocolates is very adamant about, make sure everyone's safe and protected the ones that are not in a lab or more ancillary support program management.

647

01:21:41.215 --> 01:21:52.885

I know that my guys within the fnl that support my programs are remote during this period of time. So I can't answer what can happen in the future, but I can tell what we're doing now, at least necessarily at operation.

648

01:21:53.460 --> 01:21:59.369

Question do you want to add anything to that?

649

01:22:00.414 --> 01:22:11.694

I think that's a wise wise comments. I think also, you know, since we have many different locations, we have international studies people at the clinical center.

650

01:22:11.694 --> 01:22:20.545

We're already kind of spread out at various locations. So, a model is, we're not all on site at the same place.

651

01:22:26.609 --> 01:22:33.600

The 2nd, mind Mr. question here. How do you see participating in? This works?

652

01:22:33.600 --> 01:22:39.359

And I do not know what are university.

653

01:22:39.359 --> 01:22:50.130

Gotcha, yeah, I think as long as people are capable of meeting the technical and business requirements, it's open to everyone. We encourage that.

654

01:23:01.079 --> 01:23:04.170

Okay, we get all the questions we got so far.

655

01:23:07.199 --> 01:23:18.029

Um, I, I have been getting a lot of questions as direct messages. I can try and copy and paste those to everybody.

656

01:23:19.109 --> 01:23:20.125

That'd be great. Thank you.

657

01:23:39.840 --> 01:23:43.199

How did new programs at the National lab?

658

01:23:43.199 --> 01:23:48.449

Get started socialized and prioritized for the National Lab, provide.

659

01:23:48.449 --> 01:23:53.850

Initial, the initial funding for, for building out new programs or initiatives.

660

01:23:58.194 --> 01:24:12.595

So, I can talk to the Internet perspective, so, and please, Sarah Kristen just jump in if I mistake. I know. From this perspective, we are rapidly responsive, right to do the pandemic. So it was something that we brought together.

661

01:24:13.524 --> 01:24:26.845

Chocolates brought together members within the federal government. Brought in the scientific experts from the Frederick National lab that we felt would play a big role that we could potentially pivot. And we worked very closely with them to be able to stand that effort up.

662

01:24:26.845 --> 01:24:36.744

And then we were very fortunate to get the award of the paycheck care act and April 2020, to be able to have the funds to be able to really make a big impact on standing up these new efforts.

663

01:24:36.744 --> 01:24:41.994

And that's just from the perspective of the other projects, I will defer to Sarah and Christian.

664

01:24:44.699 --> 01:24:52.380

I think usually programs are started based on need and NIS that the fnl can fulfill.

665

01:24:52.380 --> 01:25:00.114

So, if, for instance, it's it's purely research problem that we can do by a grant. We probably won't do it enough at all.

666

01:25:01.225 --> 01:25:07.854

Or if it's something that's really more pertains to a small business, we will let the small business office handle.

667

01:25:08.425 --> 01:25:10.284

The particular program,

668

01:25:10.645 --> 01:25:13.734

so it's really initial based thing but again,

669

01:25:13.765 --> 01:25:14.425

you know,

670

01:25:15.354 --> 01:25:24.444

the extra rural community plays an important part in as our advisors we often have strategic workshops.

671

01:25:24.835 --> 01:25:31.225

So, in general, you know, we engage extra neural experts to determine what sort of programs are started.

672

01:25:31.704 --> 01:25:46.614

And there are many extra programs, for instance, that pieces go to the fnl, but other pieces go to the extramarital community. So it's really a very coordinated effort. And you won't hear about some of those this afternoon.

673

01:25:52.710 --> 01:25:56.909

Here's the question with regards to the pandemic.

674

01:25:56.909 --> 01:26:03.239

Do do we need to have continuous bio surveillance or spot checks post vaccination.

675

01:26:05.395 --> 01:26:11.784

So that's a great question. So, that's a question that we've been discussing across the Syrian operation.

676

01:26:11.784 --> 01:26:23.064

So we are, in the process of doing several Sierra surveillance studies, post vaccination of immunocompromised cancer patients as well as late population.

677

01:26:23.545 --> 01:26:36.175

We're still trying to figure that piece out as well as the viruses as involved in the new variants coming online and how the vaccines are responding and combining those new variants. We're still researching that. So it's possibility.

678

01:26:41.369 --> 01:26:48.239

Hey, so Jason, I wanted to go back to the funding piece. There was part of the question. We really didn't answer.

679

01:26:48.239 --> 01:26:53.399

Um, because it says something about, how does fnl provide the initial funding.

680

01:26:53.875 --> 01:26:59.274

For building out new programs or initiatives and so the answer to that is actually no,

681

01:26:59.395 --> 01:27:09.925

so the or or whatever government program or partner will fund the effort at fnl and then it'll go on to the contract and away.

682

01:27:09.925 --> 01:27:10.314

We go.

683

01:27:18.630 --> 01:27:25.890

What's what's the opportunity to open? New big science projects? Like net.

684

01:27:25.890 --> 01:27:34.800

How does the contractor gain input to pushing such to activating new new, big science projects? Like this?

685

01:27:37.619 --> 01:27:52.409

Yeah, I'd say it's always a 2 way street for instance, if we need something and the technical capabilities are not at the FML, we could hire or we could do some sort of partnership and.

686

01:27:52.409 --> 01:28:00.869

You know, it, it's a dialogue and they're involved in the process and once we settle on a new sort of national mission program.

687

01:28:00.869 --> 01:28:14.159

We say this is kind of the general concept of what we need, and it goes to fnl and and they make a proposal and say, hey, this is how we think we can best meet this need. So they are really critical.

688

01:28:14.159 --> 01:28:28.859

In determining the strategic objectives, the nuts and bolts of what can and can be done and where where it happens, et cetera. So it's very important for us to collaborate government and staff.

689

01:28:32.489 --> 01:28:36.329

And then here's a question, it goes into a little bit more detail.

690

01:28:36.329 --> 01:28:38.125

I think with regards to the funding,

691

01:28:38.125 --> 01:28:38.364

it's,

692

01:28:38.395 --> 01:28:38.574

uh,

693

01:28:38.574 --> 01:28:39.954

it's Ken can see,

694

01:28:39.954 --> 01:28:50.994

I speak to the various funding streams coming into the RTC and I know you already touched on this a little bit Sarah and how the funds are dispersed within the contract in terms of internal divisions extra mural,

695

01:28:50.994 --> 01:28:52.465

academic partners and others.

696

01:28:53.970 --> 01:29:03.359

Okay, this is a very complex issue actually, so I wonder if we should actually address.

697

01:29:03.359 --> 01:29:18.300

This in writing perhaps so what, what generally happens is governmental entities can fund the contract. And if, for instance, it's an outside agency, such as the army.

698

01:29:18.300 --> 01:29:23.609

We actually transfer money usually by an inter agency agreement.

699

01:29:23.904 --> 01:29:37.585

But, for instance, if we are partnering with a pharma company, and they're going to fund, you know, I don't know, 3Million dollars of work for drug development. We actually do that through a contractor creator.

700

01:29:37.585 --> 01:29:51.534

So, it's an agreement that it's brokered between f and scientists and the outside partner, the government approves this and make sure that we're all on board with what the approach is.

701

01:29:51.534 --> 01:29:59.845

And then that is funded outside of the contract or through, or outside of the contract through this contract, or create a process.

702

01:30:00.840 --> 01:30:14.159

So, hopefully, that's that's not great to those on the phone. And I do believe a lot of this will be addressed later on in the afternoon when we talk about the business operations on the RTC. Yes.

703

01:30:15.630 --> 01:30:20.550

All right, let's see. Um.

704

01:30:20.550 --> 01:30:26.699

Can we discuss our view for transition and continuity?

705

01:30:26.699 --> 01:30:32.130

Of these science programs and existing science talent from the incumbent.

706

01:30:32.130 --> 01:30:35.819

To a new, how how does that work?

707

01:30:35.819 --> 01:30:48.539

Yeah, so actually that will be part of the proposals that the off hours will have to suggest how they think that transition will best happen.

708

01:30:48.539 --> 01:30:53.159

So, I think, you know, we don't have preconceived notions of that.

709

01:30:53.159 --> 01:31:00.569

There'll be some business and technical instructions that go out and if that particular.

710

01:31:00.569 --> 01:31:06.930

Question isn't clear, we'll, you'll be able to give us feedback that you need more information.

711

01:31:10.140 --> 01:31:18.420

All right, to what extent are the contracted activities handled directly by the RTC contractor and to what extent are they subcontracted.

712

01:31:18.420 --> 01:31:23.010

By the RTC contract to other organizations, institutions and businesses.

713

01:31:25.225 --> 01:31:37.314

Yeah, it's a, it's a conflict matrix of of different models and so I think we should probably address that 1 in writing as well.

714

01:31:40.289 --> 01:31:45.000

Yeah, I think it's probably best to, to address it in writing just because.

715

01:31:45.000 --> 01:31:48.300

That we can give you percentages or clear numbers.

716

01:31:48.300 --> 01:31:52.829

And again, this also be addressed, I think, in the afternoon session to.

717

01:31:52.829 --> 01:32:00.328

Yeah, yeah, and I think the other thing I would like to just say is, you know, whatever the current model is now.

718

01:32:00.328 --> 01:32:05.609

It may shift, depending on what the offers bring to the table.

719

01:32:05.609 --> 01:32:09.809

What things that they feel that they have the right expertise to do.

720

01:32:09.809 --> 01:32:12.958

Who they are subcontracts from partners are.

721

01:32:12.958 --> 01:32:16.288

So, it's it's a difficult question to answer, frankly.

722

01:32:16.734 --> 01:32:30.083

Right, but this is Chris and I think the important point here is that the, whoever has the prime contract has the flexibility to determine how they plan to.

723

01:32:32.038 --> 01:32:35.609

Address their government requirements.

724

01:32:35.609 --> 01:32:42.779

Yes, thank you. Kristin. This question question.

725

01:32:42.894 --> 01:32:46.734

Oh, go ahead, Jim. I was going to say Christian. That's an excellent point.

726

01:32:46.734 --> 01:32:52.734

And that's exactly the case for this stand up of the capacity building centers when we,

727

01:32:53.184 --> 01:32:55.104

when we put together that statement of work,

728

01:32:55.104 --> 01:33:03.413

we sat down with the caretaker of the upfront contract to discuss what's the best options available to be able to rapidly respond?

729

01:33:03.413 --> 01:33:09.533

So that was 1 of the things we did as well as the were doing as well.

730

01:33:09.779 --> 01:33:19.469

Um, Kristen for you for the 1Million dollar, new tech research programs that you mentioned in your presentation.

731

01:33:19.469 --> 01:33:24.958

Can these be submitted by anyone or only f, RTC partners for example, universities were mentioned.

732

01:33:24.958 --> 01:33:30.118

But what about other businesses, like nonprofits or or other private and public partnerships?

733

01:33:30.923 --> 01:33:42.474

So this is a good question. It's actually the contractor that operates the fnl that comes up with the proposal and submit them to the government for approval.

734

01:33:43.974 --> 01:33:52.194

Prime contractor can partner with others to put those things together. But the initiative does come from the prime contractor.

735

01:33:52.559 --> 01:34:06.149

I'm gonna post a question 3rd question that.

736

01:34:06.149 --> 01:34:10.019

We couldn't post to everybody.

737

01:34:11.213 --> 01:34:24.533

The question is, if deciding to use a new contractor for this, what are the top 3 to 4 criteria that you would want from a new vendor versus staying with the incumbent? It's quite a broad question.

738

01:34:25.679 --> 01:34:31.828

Does anybody want to tackle that? 1?

739

01:34:33.208 --> 01:34:46.498

So, Jason, I think that that is really part of the review criteria. So, again, I think we'll defer until we have that solid and I can turn it out to the community at the same time.

740

01:34:48.384 --> 01:34:54.173

Hey, Jason, this is Lisa. I also got a question that appeared to come in.

741

01:34:54.563 --> 01:35:03.384

That was private asking about can for profit companies serve as the prime for the f RTC.

742

01:35:03.748 --> 01:35:09.984

Yes, you want to take that 1? Yes, sir. I will everyone. I just want to introduce myself. My name is Lisa Coleman.

743

01:35:09.984 --> 01:35:11.934

I am the current branch,

744

01:35:11.934 --> 01:35:25.644

chief and contracting officer for the contract at the for the f RTC that operates the the answer to the question is quite honestly for profits are not excluded

745

01:35:26.543 --> 01:35:27.384

far 35.

746

01:35:27.384 --> 01:35:27.684

Oh,

747

01:35:27.713 --> 01:35:36.444

17 clarifies the types of organizations that can operate and specifically states that can be a university,

748

01:35:36.594 --> 01:35:38.304

a consortium of universities,

749

01:35:38.304 --> 01:35:48.564

other not for profit or nonprofit or industrial from as an autonomous organization or identified separate operating unit of a parent company.

750

01:35:48.564 --> 01:35:53.634

Very technical answer. But that is available in the far necessary.

751

01:35:55.439 --> 01:35:59.668

Silence.

752

01:35:59.668 --> 01:36:04.259

Thanks Lisa. All right. I think.

753

01:36:04.259 --> 01:36:09.118

I'm trying to scroll through here. I think I've covered all the questions if not.

754

01:36:09.118 --> 01:36:13.259

My my little helpers, let me know.

755

01:36:13.259 --> 01:36:19.798

And that was that was a good set of questions again. A lot of this is going to be addressed.

756

01:36:19.798 --> 01:36:25.229

In the business business operations section later on this afternoon.

757

01:36:25.229 --> 01:36:31.319

And there should be an additional opportunity for follow up questions with regards to that subject matter.

758

01:36:38.158 --> 01:36:50.333

Okay, I think Jason Jason can I just add 1 additional thing? I wasn't entirely portrayed in my my presentation.

759

01:36:50.904 --> 01:36:54.863

We do have a Frederick National Lab advisory committee.

760

01:36:55.288 --> 01:37:05.458

Made of neural f experts in, in some cases, former Department of energy lab sheets, et cetera.

761

01:37:05.458 --> 01:37:09.509

So we have an advisory group, so that helps us.

762

01:37:09.509 --> 01:37:18.779

You know, kind of assess what projects are come to the national labs. Sometimes they help review the progress of various projects, et cetera. So.

763

01:37:18.779 --> 01:37:30.118

Information about that advisory group is at the NCI division of extra general activities website so you can read more about it.

764

01:37:34.224 --> 01:37:49.134

All right, thank you, Sarah. I think we're gonna go ahead and move to the break. We're a little bit early, so it's gonna be about a 20 minute break we're going to return at 11 am and because it's a little bit of an extended break. What we're going to do is go ahead and play the.

765

01:37:50.399 --> 01:38:03.029

At the facility slide presentation that is also scheduled for later on this afternoon, but for those folks who don't want to leave their computer and have the extra time to start looking through.

766

01:38:03.029 --> 01:38:08.128

Some of our, our facilities equipment, the various.

767

01:38:08.128 --> 01:38:16.798

Components of the partisi physical physical components please enjoy the slide presentation. We'll also repeat it according to the.

768

01:38:16.798 --> 01:38:31.048

Agenda the schedule on the agenda as well this afternoon. So thanks to everybody this morning for the presentations and set some questions. We'll go ahead and break now and return at 11. 0, am Eastern time. Thanks.

769

01:38:32.729 --> 01:38:43.168

Brendan, do you see jenelle on the participant list?

770

01:38:44.248 --> 01:38:47.698

I actually do not unless she is 1 of the call in numbers.

771

01:38:53.578 --> 01:39:00.809

I can try to find her number. I might.

772

01:39:00.809 --> 01:39:09.479

Have it on the list right? I do see, we have Lou on. We might need to just.

773

01:39:09.479 --> 01:39:14.458

Jumped to his presentation until we can get her on.

774

01:39:14.458 --> 01:39:27.868

Silence.

775

01:39:32.338 --> 01:39:35.819

Yeah, let's go ahead and do that Brendan if you can.

776

01:39:35.819 --> 01:39:40.349

Double time it and fast forward to the next section.

777

01:39:40.349 --> 01:39:44.069

Lou, are you are you are ready to present? Oh, yeah, sure.

778

01:39:44.069 --> 01:39:52.078

Great. So we're just gonna jump ahead a presentation and talk about mix research.

779

01:39:52.078 --> 01:39:55.889

Dr. loosed out from center of cancer genomics.

780

01:39:55.889 --> 01:40:05.729

Answer clinical proteomics research branch will be presenting all mixed capabilities and focusing on his specialty there.

781

01:40:05.729 --> 01:40:11.668

So, take it away. Wonderful. You're going to show the slides.

782

01:40:11.668 --> 01:40:15.658

Yes, yes, they will be advanced, uh, by Brendan.

783

01:40:15.658 --> 01:40:26.128

There we go. Okay. Yeah, so we, I'm director of the center for cancer genomics at the National Cancer Institute, and we make.

784

01:40:26.128 --> 01:40:37.198

Extremely heavy use of wonderful Frederic, national labs and and I'll be able to highlight just a little bit of it during my presentation today next. Please.

785
01:40:39.569 --> 01:40:40.168
So,

786
01:40:40.194 --> 01:40:41.094
this is just a,

787
01:40:41.423 --> 01:40:52.434
just make sure we hit all the bases of what can be done at the Frederick national labs in general as you all know all mixed research is exploratory and its nature,

788
01:40:52.823 --> 01:40:58.913
and directed at understanding the relationship between molecular properties of tumors.

789
01:40:58.913 --> 01:40:59.573
Typically.

790
01:41:00.293 --> 01:41:15.113
And clinical attributes, such as response to treatment location disease, et cetera and, and the header Janae 2 between individuals with cancer and.

791
01:41:16.823 --> 01:41:22.404
There's many flavors of omits and many are supported at the Frederick National Lab.

792
01:41:23.573 --> 01:41:37.673
A lot of outstanding work in genomics, transcript comics now, spatial transcript where you can localize, which cells and a biopsy are expressing a particular.

793
01:41:38.038 --> 01:41:52.769
Gene and these include, of course, excellent next generation sequencing and now single molecule sequencing Nana string for gene expression.

794
01:41:52.769 --> 01:42:02.158
Bar coding of of for for the spatial transcript comics and and are they seek and many more.

795
01:42:02.158 --> 01:42:09.509
There are capabilities in glide comics that that use.

796
01:42:10.673 --> 01:42:17.783
Machines and then can read out the nature of glycoproteins sugars and,

797
01:42:17.783 --> 01:42:19.043
and like,

798
01:42:20.094 --> 01:42:31.974
the comics also bypass spectrometry pharmacogenomics for various markers of genomic drugs response and that kind of.

799
01:42:32.279 --> 01:42:46.948
Use and by, by a variety of molecular techniques chromatography, hplc and mass back genomics.

800
01:42:47.274 --> 01:42:49.224
Looking at the genome,

801
01:42:49.253 --> 01:42:55.944
the Chrome attend by immuno precipitation for particular proteins or or more broadly by attack seek,

802
01:42:55.944 --> 01:42:56.753
for example,

803
01:42:57.113 --> 01:43:11.844
and proteomics using the newest technologies and quantitative masses spectrometry and including the ability to look at multiple samples at the same time with

804
01:43:11.844 --> 01:43:12.173
the.

805
01:43:12.203 --> 01:43:15.533
So called multiple reaction monitoring techniques.

806
01:43:15.719 --> 01:43:25.259
So that is a very quick and a bit superficial overview, but shows you the breadth of what can be done.

807
01:43:25.259 --> 01:43:26.873
At the National Lab,

808
01:43:26.963 --> 01:43:29.904
and what the NCI needs to have done there,

809
01:43:30.144 --> 01:43:38.184
but what I would like to focus on is give you an illustration of what can be achieved in in,

810
01:43:39.474 --> 01:43:43.944
with the national labs that is rather grand in scope and next line.

811
01:43:44.484 --> 01:43:48.413
And that is started next slide please.

812
01:43:48.748 --> 01:43:56.069
That that started about 8 years or so when I took over this job.

813
01:43:56.069 --> 01:43:58.554
As director of the center for cancer genomics,

814
01:43:58.554 --> 01:44:06.503
and we had generated a large number of data sets from tumors in the cancer genome Atlas program,

815
01:44:06.503 --> 01:44:14.663
and these were all on computer systems that were really only a mother could love.

816
01:44:14.663 --> 01:44:29.154
That is the, the people in the project knew how to get the data, but no, 1 else in the world could get them. And so I thought that that was job 1 is to make all of our data that we were generating from this TC, JJ program.

817
01:44:29.154 --> 01:44:31.314
And pediatric target program,

818
01:44:31.314 --> 01:44:35.394
and other large initiatives by the NCAA available,

819
01:44:35.394 --> 01:44:44.963
broadly shared with researchers so that it can accelerate and a lot of discovery.

820
01:44:45.809 --> 01:44:49.649
So next slide please.

821
01:44:49.649 --> 01:44:57.359
So you would have seen in the previous talk, and maybe you'll see a deeper dive into what's shown on this.

822
01:44:57.359 --> 01:45:07.798
This is even a grander vision of where the wants to go with the Frederick National Lab collaborations. There.

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01:45:08.304 --> 01:45:11.094

To generate a cancer research data comments,

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01:45:11.094 --> 01:45:25.764

and we imagine now that there's multiple types of data that are collected from both tumors from patients as well as clinical data from the patients and imaging data and

825

01:45:26.333 --> 01:45:28.134

genomics and proteomics.

826

01:45:28.463 --> 01:45:41.873

And what the model is, is that each of these types of data will be stood up as a data Commons. And I'll focus today on the genomic data Commons, shown there. So, all of these.

827

01:45:42.238 --> 01:45:56.243

Circles and yellow are the various repositories for different types of data that is generating and then in green are the glue resources that allow you to

828

01:45:56.963 --> 01:45:59.783

use the data to compute on the data.

829

01:45:59.783 --> 01:46:00.024

So,

830

01:46:00.024 --> 01:46:13.163

there's operations in the cloud that that allow access to this data that all does exist in the cloud and then various

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01:46:14.003 --> 01:46:19.404

attributes that link all the data together in these various repository.

832

01:46:19.404 --> 01:46:26.543

So they're actually, although independent inter operative and people could do queries across these.

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01:46:28.168 --> 01:46:31.828

So that much.

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01:46:31.828 --> 01:46:41.759

Virtually all of this heavily involves the Frederic National Lab, but again, I will focus on just the genomic data comments. Next line.

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01:46:41.759 --> 01:46:51.509

So just give you some, a feeling for the infrastructure. So our primary.

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01:46:52.283 --> 01:46:58.554

Work is done at the University of Chicago where they stand up a actual U.

837

01:46:58.554 --> 01:47:08.184

S, government system, the genomic data Commons that is that is operated out of a data center at the University of Chicago.

838

01:47:08.873 --> 01:47:23.394

And this is coordinated through the Federal National Labs is the major major manager of that that facility and directing the work in

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01:47:23.394 --> 01:47:26.543

collaboration with people at the University of Chicago and,

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01:47:26.543 --> 01:47:28.703

especially Bob Grossman.

841

01:47:29.394 --> 01:47:40.014

Now, this shows you on this slide that there are basically now, 20,000 available, compute cores virtual that we have.

842

01:47:40.014 --> 01:47:40.373

So,

843

01:47:40.434 --> 01:47:50.543

a fairly good sized local network of compute at the University of Chicago that is used as you can see in the green,

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01:47:50.543 --> 01:47:52.404

fairly continuously,

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01:47:52.404 --> 01:47:55.283

and a very high level.

846

01:47:55.283 --> 01:48:02.873

So we're constantly churning through our data because there's a lot of it next line.

847

01:48:05.573 --> 01:48:16.944

This shows you our storage capacity on premise at University of Chicago. So we're, we're currently utilizing about 9 petabytes of data.

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01:48:16.944 --> 01:48:22.703

So, according to the people who do this, this is really big data.

849

01:48:23.484 --> 01:48:35.963

It qualifies as as a enough to get the attention of computer scientists to have to figure out how to deal with a sufficiently. We have 21.

850

01:48:36.658 --> 01:48:49.134

Petabytes of disks available how storage available however, the, the best use of that would be about 13 petabytes that we have available.

851

01:48:49.134 --> 01:48:55.764

So we'll have to continually expand that over time. Our goal of having this on premise storage.

852

01:48:56.099 --> 01:49:10.373

Is that downloaded this data should be free for everyone all researchers in the world and that is opposed to having the copy that is in the Amazon cloud of the

853

01:49:10.373 --> 01:49:11.243

GDC,

854

01:49:11.484 --> 01:49:17.064

which if you were to download this amount of data would would cost an arm and legs.

855

01:49:17.064 --> 01:49:23.904

So this is a big service and is supporting through the Frederick National Lab next line.

856

01:49:27.179 --> 01:49:30.538

So, it's very popular data Commons.

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01:49:30.538 --> 01:49:43.944

Um, here the downloads that we're getting throughout the world, obviously the majority coming from the United States that we have a lot of usage in Europe, Asia, China, Australia.

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01:49:45.413 --> 01:49:52.613

So so this is 1 way of looking at the popularity of the site next line.

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01:49:56.573 --> 01:50:09.113

Here are the number of shown this is just a screenshot of the landing page for the data portal. You see again in another slide, but highlighting on the right side.

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01:50:09.113 --> 01:50:14.484

The now we're averaging a little over 70,000 unique users.

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01:50:15.509 --> 01:50:24.719

On the GDC per month so that is that represents a good uptake by the community next line.

862

01:50:26.458 --> 01:50:36.088

So, under the hood, the GDC is extremely complicated and we are managing.

863

01:50:36.088 --> 01:50:50.844

To what we say, harmonize the data. So, the model is that we will get in a genomic data from NCI programs, but also we will get in genomic data from high quality data sets from, around the world.

864

01:50:50.844 --> 01:50:51.923

Anyone who wishes.

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01:50:52.613 --> 01:51:04.974

To submit the data to this to this service, and the data are deemed by the to be worthy of sharing and and harmonizing.

866

01:51:05.394 --> 01:51:13.014

Then those data go into this data harmonization process in which 51 different workflows.

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01:51:14.338 --> 01:51:25.974

That have all been hardened and are applied to the data and since the same workflows are applied, then you can do a study.

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01:51:26.213 --> 01:51:38.543

You can understand the genomics across projects and and this allows for a type of analysis that is not available from each individual study.

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01:51:39.083 --> 01:51:53.783

And an example on the right side is just the kind of detail that is involved in just 1 of these workflows involving alignment of next generation DNA sequencing to the genome.

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01:51:54.179 --> 01:52:03.623

Next place, so why we do this is that's mere mortal cancer researchers.

871

01:52:03.623 --> 01:52:16.014

Most of them do not have the ability to download even the TC Ga, data the TC. Ga, data at whole sequencing as you see is 353 terabytes.

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01:52:16.014 --> 01:52:23.123

Which would require you to have your own large compute centered locally. So, most people don't do that.

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01:52:23.123 --> 01:52:33.774

This is then filter down into identifying all the variance synthetic mutations and in the, and that is 68 gigabytes.

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01:52:33.774 --> 01:52:45.984

And finally, if you filter that down into a discreet set of annotated maps that are in coating regions genome now, you're down to 2 and a half gigabytes.

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01:52:45.984 --> 01:52:56.304

That is a massive reduction in the size of the data, but that data at the end is what most cancer researchers want next slide.

876

01:53:01.649 --> 01:53:13.229

So this is the again, the, the data portal landing page, and it emphasizes the current content of the, the GDC we have.

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01:53:13.493 --> 01:53:26.604

Taken in 68 projects, most from the NCI, but, uh, but probably about 1015% of external data projects that are of high value.

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01:53:26.604 --> 01:53:30.083

We're looking at 67 primary cancer sites, anatomically.

879

01:53:35.279 --> 01:53:42.868

And currently we have data on 84,000 plus, uh.

880

01:53:42.868 --> 01:53:46.139

Cases of cancer next slide.

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01:53:48.748 --> 01:54:00.509

Now, another important idea for the advocated comments is we don't want it to be just a repository, or people come to download data, but rather could.

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01:54:00.509 --> 01:54:04.798

Do some computation on the site itself?

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01:54:04.798 --> 01:54:15.809

And then perhaps learn enough that they could either make a figure for a paper or a preliminary figure for a grant.

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01:54:16.163 --> 01:54:17.724

But here's a couple of examples.

885

01:54:17.724 --> 01:54:18.083

So,

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01:54:18.113 --> 01:54:33.054

here is the protein paint viewer that we brought into the GDC from St Jude and this is the way of visualizing the position in proteins that

887

01:54:33.054 --> 01:54:37.644

are affected by certain mutations found in cancer samples.

888

01:54:37.944 --> 01:54:42.713

And of course, this is the most commonly studied tumor Suppressor in.

889

01:54:43.048 --> 01:54:51.418

Cancer TB, 53, and these recurrent mutations that are loss of function next line. Please.

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01:54:53.189 --> 01:54:57.899

So then the other concept I alluded to is that you can build.

891

01:54:57.899 --> 01:55:11.038

Cohorts of cases that exist on the GC. So this so called synthetic cohort builder allows you to grab the cases from maybe several different studies.

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01:55:11.038 --> 01:55:17.128

That all have the same, either the same histology or the same molecular characteristics.

893

01:55:17.128 --> 01:55:22.738

And create these cohorts and then compare.

894

01:55:22.738 --> 01:55:33.149

Other attributes, such as here, the clinical attributes of those cases. This is a bit of a trivial case that we all know that if you take compare the prostate.

895

01:55:33.149 --> 01:55:48.054

Cancers to the Glioblastoma, there is a major difference in survival but this also highlights that despite the name of the genomic data Commons that this is also necessarily.

896

01:55:48.359 --> 01:55:55.319

Um, containing a vast amount of clinical data that is, uh, gathered on these patients.

897

01:55:55.319 --> 01:56:09.569

Um, that was necessary and the reason for many of these studies, such as TC. J to make sense of it and that's shown on

the right. We have, of course, the demographics, the diagnosis.

898

01:56:09.569 --> 01:56:18.448

Exposures smoking and otherwise family histories followup, data, survival, treatment data.

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01:56:18.448 --> 01:56:22.019

Various molecular test pathology reports.

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01:56:22.019 --> 01:56:35.038

And, and then and lab tests and histological images, tens of thousands of histological images available on the GC next slide.

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01:56:38.668 --> 01:56:42.958

And I think this is the final slide so the.

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01:56:42.958 --> 01:56:46.194

The general idea is that also,

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01:56:46.194 --> 01:56:47.123

this is a,

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01:56:47.154 --> 01:56:58.104

the GDC is a back end data system upon which you can build a number of other technologies for analysis the data.

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01:56:58.104 --> 01:57:02.814

Some of which we're building, as I mentioned on the GDC itself.

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01:57:03.113 --> 01:57:17.453

But then other people around the world might be able to use this backend system that sort of in real time obtain data from the GDC through application programming interface API.

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01:57:17.819 --> 01:57:21.868

And then stand up their own.

908

01:57:22.793 --> 01:57:36.743

Service or what they would like to do with the data. So we have abilities to visualize gene expression, protein, mutations, protein, coating mutations.

909

01:57:37.404 --> 01:57:46.734

We've now got a new capability to look at single cell are in a seat data, and we can also on the aka grid on the right side.

910

01:57:46.734 --> 01:57:52.854

Look at the CO, occurrence of mutations and genomic abnormalities.

911

01:57:54.234 --> 01:58:03.533

We have a clinical data explore down at the bottom and then the, this tca bio lengths is just 1 example of a 3rd party.

912

01:58:03.863 --> 01:58:13.463

Our package that investigator made that is is, is then utilizing data in real time from the GDC.

913

01:58:14.634 --> 01:58:28.673

Next so that's just an overview of what we what we are doing. And I would say we still feel like we're in the infancy of the GDC.

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01:58:28.673 --> 01:58:30.713

In fact, currently.

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01:58:31.109 --> 01:58:31.559

Um,

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01:58:31.583 --> 01:58:46.224

we are undergoing a complete redesign of the interface and the user experience to create more of a app feel around each of the tasks that a user might want

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01:58:46.224 --> 01:58:46.644

to.

918

01:58:48.899 --> 01:59:03.024

Accomplish at the GDC so so we, we're constantly reinventing and, of course genomics is is a fast moving train and we're always trying to keep up with the latest at the GDC.

919

01:59:03.024 --> 01:59:09.684

And the example of that is the single cell. So, I'm happy to take questions whenever we're going to do that.

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01:59:10.019 --> 01:59:17.099

Great Thank you so much Lou. I know that you might you might have to leave early from the.

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01:59:17.099 --> 01:59:29.069

Uh, the block, but if there's any questions that come up that you're not able to answer before them to you so that they can be answered. And so that's probably be on until noon. But then I've got something.

922

01:59:29.069 --> 01:59:37.918

Great. Thanks again. All right. I think we've got connection problems, resolved and so we can flip back and.

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01:59:37.918 --> 01:59:42.149

Go to the presentation from Dr Chanel courtyard.

924

01:59:42.149 --> 01:59:47.639

Uh, presenting the advanced, the scientific computing and bio Informatics capabilities.

925

01:59:47.639 --> 01:59:52.738

Are you on you now? Thanks. Thank you. Jason. Can you hear me? Yes.

926

01:59:52.738 --> 01:59:58.828

Ah, excellent, my apologies for the technical difficulties.

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01:59:58.828 --> 02:00:04.649

So, the computationally intensive research conducted at the requires.

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02:00:04.649 --> 02:00:13.859

3 basic components, a cutting edge high performance computing environment, scientific, analytic expertise, aligned with the research. Program's needs.

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02:00:13.859 --> 02:00:17.724

And technical expertise to support the development of computational workflows,

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02:00:17.753 --> 02:00:20.663

both on premises and in the cloud taken together,

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02:00:20.663 --> 02:00:25.163

these assets provide a comprehensive flexible set of advanced computational resources,

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02:00:25.613 --> 02:00:31.344

ended accelerating both the national mission programs in the numerous IC initiatives supported through the RTC.

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02:00:31.463 --> 02:00:37.194

Many of which you'll hear about today. I will briefly highlight just 1 of those to cancer research data comments.

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02:00:38.123 --> 02:00:46.944

Next slide please, let's take a quick look at the infrastructure. Patrick is home to a Linux based high performance computing cluster. That's about 5%.

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02:00:46.944 --> 02:01:00.083

The capacity of the cluster operates similarly to bio, and is built to be fully interoperable with it. So that users can move

seamlessly between the 2 environments hosts the scientific software.

936

02:01:00.083 --> 02:01:05.184

Frederick users need to support their workflows and shares this library software with firewall.

937

02:01:05.908 --> 02:01:15.538

Notably has an abundance, persistent, high speed storage as well as access to a full range of storage modalities, necessary to support the programs.

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02:01:15.538 --> 02:01:25.828

The cluster currently consists of 100 servers, providing 3400, CPU cores and a mix of P100 v1, hundreds totaling, 185 available.

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02:01:25.828 --> 02:01:39.418

Next slide please, because, and on premises, resource subject to long procurement cycles. The challenge is to stay out in front of demand. So that expansion is matched with future needs. And long user. Wait times are prevented.

940

02:01:39.418 --> 02:01:46.559

Interestingly, the CPU utilization is dipped a bit in recent months due in part to code and in part to a shift toward space workflows.

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02:01:46.559 --> 02:01:53.189

Overall, the trend is for is absolutely increasing next slide. Please.

942

02:01:53.189 --> 02:02:04.168

Their number of innovations either in progress, or tentatively on the road map for the HPC infrastructure, which are driven by the needs of the research community. A few are listed here.

943

02:02:04.168 --> 02:02:11.069

Trial users will soon be able to manage their data, rather than their storage, using a new global file system. That's being piloted.

944

02:02:11.069 --> 02:02:20.729

Biologist will soon be able to run genomic analysis, pipelines, using a graphical user interface, rather than Linux commands, which will bring these workflows.

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02:02:22.163 --> 02:02:35.783

Into the ability for a lot more people to be able to access them and the large data generators will soon have the option to seamlessly use cloud for colder tiers of storage, which will have a big impact on our ability to control control the storage budget.

946

02:02:36.863 --> 02:02:50.453

Next sciences, computationally intensive research at the f RTC can be roughly characterized as aimed, determining the

cause and effect relationship, underlying human disease, and then leveraging those discoveries to develop precision diagnostics and Therapeutics.

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02:02:51.144 --> 02:03:01.404

This requires a highly interdisciplinary team science approach, which will recognizes data science for this reason. Scientific and technical expertise are essential capabilities provided by the contract.

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02:03:02.243 --> 02:03:10.404

In depth knowledge of the biological systems understood is, of course, required and is provided in large made sure by the investigators.

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02:03:11.213 --> 02:03:16.913

But we also require expertise and main specific analytic approaches by Informatics multimodal,

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02:03:16.913 --> 02:03:17.184

data,

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02:03:17.184 --> 02:03:17.904

aggregation,

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02:03:17.934 --> 02:03:19.073

artificial intelligence,

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02:03:19.134 --> 02:03:26.993

and numerous technical domains that for almost any of the computational intensive projects next slide.

954

02:03:26.993 --> 02:03:27.293

Please.

955

02:03:28.738 --> 02:03:43.198

The scientific domains commonly requiring computational support at the are quite broad, and I'm not going to read this entire slide to you, but rather just highlight some of the major areas. Genomics. Interest. Transcript is huge. Now.

956

02:03:43.198 --> 02:03:52.259

Retrospective data aggregation. Some times called data mining is also in wide use. There's a lot of visual pathology, including a ai based digital pathology.

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02:03:52.259 --> 02:03:59.698

Several groups require support from molecular simulations and molecular modeling and there's a lot of structural biology of Frederick.

958

02:04:00.894 --> 02:04:12.354

Next slide please, once a highly useful data, science application, or workflow has been established investigators frequently seek to make it externally facing and scale it for use by the broader research community.

959

02:04:13.043 --> 02:04:21.684

I think there's an animation on the slide that might require you advancing in those instances. Cloud, engineering and scientific web development expertise is needed.

960

02:04:23.069 --> 02:04:35.304

Next slide 1 such example is the cancer research data comments. The is a virtual cancer data science, ecosystem of interconnected data sets and analytic tools. The C, or D. C.

961

02:04:35.304 --> 02:04:41.423

is hosted by and center for biomedical Informatics and information technology, but serves the entire cancer research community.

962

02:04:42.413 --> 02:04:57.293

The, this is the next slide has 3 main sets of components, all of which are managed by the and which taken together highlight how capabilities can be harnessed to power massive data science initiative at the heart of the C or D. C.

963

02:04:57.293 --> 02:05:10.734

or the 6 domain specific or project specific repositories in addition to the GDC, which you just had a deep dive on with Dr stout, the repositories for genomics imaging, clinical trials and canine comparative oncology.

964

02:05:11.094 --> 02:05:19.764

And there's also a repository for the less well, structured cancer cancer data. That doesn't fit neatly into 1 of the other repositories, but nonetheless needs to be shared with the community.

965

02:05:20.069 --> 02:05:30.868

Taken together, there's about 3 petabytes of publicly available and controlled access data available to users on both Google and Amazon clouds from the C or D. C.

966

02:05:30.868 --> 02:05:37.378

3 additional data notes are planned centered around amino oncology, epidemiology and cancer model system.

967

02:05:37.378 --> 02:05:50.458

In addition to the data nodes here, inner operates with the 3 cloud analytic resources, and includes the infrastructure components necessary to support deployment of new data, repositories data, harmonization and interconnectivity.

968

02:05:51.173 --> 02:06:01.703

Next slide please, there's 3 main CFTC infrastructure components, which are essential for making the data fair, which is, of course, fine, double, interoperable, accessible and reasonable.

969

02:06:03.444 --> 02:06:15.203

The cancer data aggregator is a consortium that's led by the Broad Institute. It maintains the central mediated repository and provides the required retrieving and integrating data from across the C or D. C. notes.

970

02:06:16.344 --> 02:06:26.873

This sort of inner operability is required a pretty big lift. And this work is actually replicated and modeled in other other groups across the United.

971

02:06:28.109 --> 02:06:40.793

The center for cancer data harmonization is a consortium led by Oregon State University. It is focused on semantic harmonization of the DC data and on enhancing interoperability of the diverse data types.

972

02:06:41.543 --> 02:06:47.904

Currently it is supporting development of a consensus data model by the human tumor Atlas network.

973

02:06:48.208 --> 02:06:58.649

Finally, the data Commons framework service provides the open source software and expertise needed to support rapid deployment of new data, repositories, authentication services.

974

02:06:58.649 --> 02:07:11.819

In the advanced data management tools, required for ingesting, harmonizing, curating, de-identifying, querying and analyzing the data. So again, a pretty heavy lift next slide. Please.

975

02:07:11.819 --> 02:07:25.469

He has funded the development of 3 cloud based analytic resources as it means to jumpstart the cancer data ecosystem but it should be noted that this is not a closed system and interoperability with other cancer data platforms is also on the CFTC roadmap.

976

02:07:25.469 --> 02:07:39.448

While there are differences among the 3 cloud resources capabilities, all of them offer the same big advantages, which we described earlier, including the ability to access large cancer data sets and analytic tools without the need for massive downloads.

977

02:07:39.448 --> 02:07:50.128

Workspaces for users to workflows or run, hosted analytic pipelines, powered by, on demand, elastic compute and finally the ability to bring their own data and code to the environment.

978

02:07:50.128 --> 02:07:54.689

Next slide please as noticed as noted earlier.

979

02:07:54.689 --> 02:08:06.479

It supports all aspects of the C or D. C and uses the same capabilities to scale other data science initiatives. It is worth noting that the advanced data management capabilities developed for the.

980

02:08:06.479 --> 02:08:10.529

Catalyze similar efforts across the night. The final point.

981

02:08:10.529 --> 02:08:19.404

And this is the last slide I'd like to make about the contractor provided advanced computational capabilities, is that it's not a behind all behind the scenes work.

982

02:08:19.793 --> 02:08:26.064

We rely heavily on contractor expertise to engage in our behalf with other data, scientists, fence, focused entities.

983

02:08:26.634 --> 02:08:39.203

Sometimes this entails simply talking about the work being done at the are serving on working groups to assess trends project needs and make resource recommendations other times this involves representing the institute and discussions with other agencies,

984

02:08:39.234 --> 02:08:44.783

or other national labs and government agencies identifying develop potential new collaboration opportunities,

985

02:08:45.083 --> 02:08:46.703

including those aimed at leveraging unique,

986

02:08:46.703 --> 02:08:47.963

computational resources.

987

02:08:48.113 --> 02:08:49.224

Those available through the.

988

02:08:50.009 --> 02:09:04.559

I know this is a bit of a fire hose. It's hard to do an overview. That's this broad but hopefully this gives you a better sense of what the contractor role is in the advanced scientific computing the party Thank you.

989

02:09:04.559 --> 02:09:19.378

Great. Thank you. Chanel. That was a great presentation. Okay, so now we're going to move forward. I'm going to switch hats here and talk about the GMP capabilities at the so next slide. Please.

990

02:09:23.543 --> 02:09:33.594

All right, so the partisi facilities, the subcontractors produce investigational agents according to the code of federal federal regulations part 2021 that pertain to gmp's.

991

02:09:33.594 --> 02:09:39.083

That'd be 210 to 11 6068201271aswellastheinternationalconference for harmonization Q7 section on good manufacturing practice for active pharmaceutical ingredients.

992

02:09:39.083 --> 02:09:49.404

Also, the f, RTC adheres to our relevant and current guidance for industry with respect to early phase investigational agents. Next slide.

993

02:09:58.708 --> 02:10:10.198

So, the, there are 2 GMP facilities at the RTC. They provide multi product, multi platform, Biologics and vaccine manufacturer.

994

02:10:10.198 --> 02:10:16.139

As well, as quality systems, including quality control, quality assurance and quality engineering.

995

02:10:16.139 --> 02:10:25.798

Robust scale up capabilities and fermentation and bio reactor technology, regulatory, fair support, operational maintenance, engineering and support for each of the 2 facilities.

996

02:10:25.798 --> 02:10:31.259

Technology Transfer expertise and quality agreements established with the U. S. government.

997

02:10:31.259 --> 02:10:35.338

Some contractors next slide.

998

02:10:36.658 --> 02:10:41.969

So the 1st facility focuses on Biologics and cellular therapy manufacturing next slide.

999

02:10:41.969 --> 02:10:56.458

This capability was established in 1993 to provide specialized and unique technical expertise and services not available in the commercial market, perform feasibility studies of candidate agents and develop manufacturing processes and essays for these agents.

1000

02:10:56.458 --> 02:11:01.708

Connect to GMP, manufacturing, filling testing and release for early phase clinical studies.

1001

02:11:01.708 --> 02:11:05.519

Generate and submit FTA and international regulatory filings.

1002

02:11:05.519 --> 02:11:11.458

Index technology transfer to commercial entities and provide GMP training to staff and partners.

1003

02:11:11.458 --> 02:11:20.998

And the paragraph chart here shows that, since 1995, the pilot facilities produced the following number and type of bio pharmaceutical products for clinical trials.

1004

02:11:20.998 --> 02:11:27.479

22 monoclonal antibodies 20 recombinant proteins, 15 viruses, 9, nucleic, acid products.

1005

02:11:27.479 --> 02:11:31.198

For peptide products and 6 cellular products next.

1006

02:11:32.609 --> 02:11:38.338

The overall size of the facilities about 66,000 square feet.

1007

02:11:38.338 --> 02:11:53.158

It's main GP manufacturing areas about 22,000 square feet, and consists of separate trains for eukaryotic and Pro, periodic production of purification. They're also suites fulfill, finish vial, labeling and inspection for up to 10,000 files per manufacturing run.

1008

02:11:53.158 --> 02:11:58.559

There's also a self contained virus, manufacturing suite about 2500 square feet in size.

1009

02:11:58.559 --> 02:12:03.269

And a separate self therapy suite for that's about 750 square feet.

1010

02:12:03.269 --> 02:12:09.328

There are also multiple Labs for analytics process, development and product and raw material warehouse next.

1011

02:12:09.328 --> 02:12:16.229

So Here's a sampling of the equipment in the pilot facility from left to right?

1012

02:12:16.229 --> 02:12:24.359

You'll see a disposable bio reactors. Um, these, uh, these 2 bioreactors have working volumes at 50 and 200 leaders for the periodic celebrate.

1013

02:12:24.359 --> 02:12:33.748

Then, next there are 150 and 500 leader for mentors for Pro, periodic cells and these can produce up to 500 grams of raw product.

1014

02:12:33.748 --> 02:12:37.109

The next 2 slides show an act of chromatography.

1015

02:12:37.109 --> 02:12:41.878

Control their skin with 3 examples of chromatography columns for purification.

1016

02:12:42.144 --> 02:12:44.033

The next few photos show,

1017

02:12:44.033 --> 02:12:45.743

state of the art analytical equipment,

1018

02:12:45.743 --> 02:12:46.913

including a multi Max,

1019

02:12:46.913 --> 02:12:53.753

quantum multi channel cell sorter used to analyze and quantify self service proteins in the sample as well as an Agilent 1290,

1020

02:12:53.753 --> 02:12:54.173

high resolution,

1021

02:12:54.173 --> 02:12:58.734

analytical system for determining the purity of biologic products.

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02:12:59.578 --> 02:13:06.748

And finally, there's a photo of a semi automatic filling machine that accommodates between 1, male and 10 male, pharmaceutical vials for liquid fills.

1023

02:13:06.748 --> 02:13:20.639

Next slide 1 of the more recent capabilities established here at the is the primary antigen receptor T cell or car T bio engineering and manufacturing and support of multi center clinical trials.

1024

02:13:20.639 --> 02:13:23.849

It's based on a prodigy closed system platform.

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02:13:23.849 --> 02:13:27.958

We utilize some renovated space for GMP self therapy.

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02:13:27.958 --> 02:13:35.609

Establish the expertise and bioengineering capability to support the multi center autologous self therapy trial within 12 months.

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02:13:35.609 --> 02:13:45.179

Currently there, the program is producing 2 supporting to multi center, clinical trials and 4 party products that are produced today.

1028

02:13:45.179 --> 02:13:56.609

Next slide and now I'll pivot to the the 2nd facility, which focuses on a vaccine production and Therapeutics for

infectious disease. Next slide.

1029

02:13:56.609 --> 02:14:02.368

This is what we term the vaccine pilot plant. It was commissioned in 2005.

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02:14:02.368 --> 02:14:07.559

It produces direct substances as well as drug products, including fill and storage.

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02:14:07.559 --> 02:14:13.529

Index analytical release and stability testing of those products.

1032

02:14:13.529 --> 02:14:23.069

Uh, it protects an adjuvant manufacturer, including terminal sterilization, and it also utilize a subcontract mechanisms for viral vector base vaccines. Next slide.

1033

02:14:24.088 --> 02:14:32.368

The overall sizes about 130,000 square feet with its clean room area, comprising about 50,000 square feet.

1034

02:14:32.368 --> 02:14:46.854

They have 4 parallel independent trains for eukaryotic and Pro, periodic production and purification. They utilize wave technology as well as stainless steel by reactors up to 2000 leaders from a 1Million product, uh, platforms as well as a mentor is up to 100 leaders for bacterial platforms.

1035

02:14:48.238 --> 02:14:52.408

Utilize technology for formulation, fill and finish.

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02:14:52.408 --> 02:15:06.779

Including automated systems for violin labeling and 100% bio visual inspection. The capacity is over 10,000 miles per manufacturing run and the range is 3 to to 20 mil, pharmaceutical bile's fulfill.

1037

02:15:06.779 --> 02:15:15.929

Excellent now, here is the sampling of some of their equipment at, with regards to analytical capabilities.

1038

02:15:15.929 --> 02:15:23.429

Uh, from left to right for raw material identification and determination of active ingredient, content, atomic absorption analyzer is employed.

1039

02:15:23.429 --> 02:15:32.128

For releasing stability testing and micro fluid space gel, electrophoresis, measure purity while optic technology characterizes potency.

1040

02:15:32.128 --> 02:15:37.679

And for environmental monitoring engine, that analyser is utilized to determine microbial IDs and samples.

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02:15:37.679 --> 02:15:48.328

Next slide now between 2015 and 2020, the is produced the following number and type of product for clinical trials is depicted in the paragraph here.

1042

02:15:48.328 --> 02:15:54.719

8 nano particles adjuvants 3 with combinate glycoproteins, 10 DNA products.

1043

02:15:54.719 --> 02:15:59.248

1 virus like particle a PBS buffer and 40 monoclonal antibodies.

1044

02:15:59.248 --> 02:16:09.958

The bar graph on the right shows. The number of annual product fills between 2015 and 2020 with a low of 3 and 2020, and a high of 21 and 2017.

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02:16:09.958 --> 02:16:18.418

Next slide now, this table shows, the types and platforms used for producing products, that target specific infectious diseases.

1046

02:16:20.003 --> 02:16:21.774

Infectious disease agents,

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02:16:23.123 --> 02:16:25.073

the 9 infectious disease targets,

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02:16:25.073 --> 02:16:28.764

listed here highlight the specialized portfolio that's assigned to the,

1049

02:16:29.453 --> 02:16:37.254

for the development of vaccines and treatments for infectious diseases that have no cure are difficult to treat or pose a threat to global health.

1050

02:16:37.648 --> 02:16:40.648

Next slide.

1051

02:16:40.648 --> 02:16:45.959

Now, with regards to small molecule manufacture for GNP purposes, next slide.

1052

02:16:45.959 --> 02:16:55.558

The does not actually have an onsite facility for protection of small molecule pharmaceuticals, but they are tasked with procurement of these materials from time to time.

1053

02:16:55.558 --> 02:17:03.898

The expertise is going to be required for GMP synthesis, processes and purification as well as a solubility and formulation development.

1054

02:17:03.898 --> 02:17:14.129

And I believe that concludes my section and next, we're going to turn to Dr Beverly teisher.

1055

02:17:14.129 --> 02:17:19.259

Chief of the molecular pharmacology branch and the division of cancer treatment a diagnosis.

1056

02:17:19.259 --> 02:17:26.849

She'll be presenting drug developments, screening and development, chemistry, related activities.

1057

02:17:26.849 --> 02:17:41.158

Thank you Jason next slide. Please. So, I'm going to speak about the molecular pharmacology laboratories, which focus on high throughput screening and 2 D and 3 D cell culture next slide. Please.

1058

02:17:42.689 --> 02:17:52.679

So, we have automated high throughput screening laboratories, the most venerable and well, known of, which is the production screen.

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02:17:52.679 --> 02:17:57.808

The NCI, 60 screen provides.

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02:17:57.808 --> 02:18:08.304

A data to the provides data to the outside community in real time. This is a service to the global cancer research community.

1061

02:18:08.814 --> 02:18:21.443

We test small molecules proteins semester, other investigational agents as submitted by investigators from the global community, and provide them back their data in real time.

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02:18:21.953 --> 02:18:35.304

Confidentially confidentially. We also provide external investigators with the cell lines, live DNA and frozen cell pellets upon request.

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02:18:35.939 --> 02:18:42.119

Uh, we have a public facing web site where the data for more than 20 years.

1064

02:18:42.119 --> 02:18:56.933

Of screening is available to the cancer research community and includes genetic character characteristics of the cell

lines, mutations, DNA methylation and other characteristics of these cell lines. Next slide. Please.

1065

02:18:58.379 --> 02:19:06.234

We also have automated high throughput screening laboratories, which focus on specific disease panels.

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02:19:06.564 --> 02:19:07.343

For example,

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02:19:07.343 --> 02:19:11.363

we have a screen which in which we screen small cell,

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02:19:11.363 --> 02:19:12.263

lung cancer,

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02:19:12.593 --> 02:19:18.234

and other rare and recalcitrant tumor types pediatric and adults are common lines,

1070

02:19:18.593 --> 02:19:22.283

20 pancreatic cancer cell lines.

1071

02:19:22.314 --> 02:19:34.404

And again, these panels of specific disease cell lines are screened in real time and the data is provided to the external cancer community.

1072

02:19:34.884 --> 02:19:44.933

And 2 websites are listed there where these data are available along with gene expression methylation data.

1073

02:19:45.808 --> 02:19:59.783

Next slide please, we are, we are currently screening now focusing on developing screens and live screening in 3 D, culture systems.

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02:20:00.174 --> 02:20:14.843

We're screening complex, which are based on tumor cells, mixed with endothelial cells and stromal cells. We have not yet added the immune system, but that would be our next step.

1075

02:20:15.174 --> 02:20:21.113

We are also screening organoids and these are all focused on new.

1076

02:20:21.418 --> 02:20:24.863

Lines new cultures developed from patient,

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02:20:24.894 --> 02:20:28.943

clinical specimens in real time from Dr,

1078

02:20:29.273 --> 02:20:31.613

Melinda Hollings head's program,

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02:20:31.613 --> 02:20:38.334

which you will be hearing about later and the website here is provided.

1080

02:20:38.609 --> 02:20:43.019

That allows access to all of these cultures of.

1081

02:20:43.019 --> 02:20:54.713

For the cancer, global cancer research community. So again, these are data provided in real time and resources provided in real time to the global cancer research community.

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02:20:55.613 --> 02:21:07.283

We are also using these resources to screen combinations of drugs drugs, which are going into the clinical evaluation program.

1083

02:21:08.183 --> 02:21:10.793

And being used to do early.

1084

02:21:12.029 --> 02:21:13.343

Clinical trials,

1085

02:21:15.683 --> 02:21:21.263

and we are now developing an automated org annoyed screening system,

1086

02:21:21.863 --> 02:21:28.674

which we'll use as a production screen in within the next 4 or 5 years next slide.

1087

02:21:28.674 --> 02:21:29.154

Please.

1088

02:21:30.623 --> 02:21:37.674

Shown here is the automated screening system based on equipment from Thermo Fisher,

1089

02:21:37.674 --> 02:21:41.363

which we use currently on a daily basis,

1090

02:21:41.724 --> 02:21:49.373

and these are located in 7,500 square feet of lab space in building 432 and next slide.

1091

02:21:49.373 --> 02:21:49.674

Please.

1092

02:21:54.263 --> 02:21:58.494

Shown here is the automated screening system number 2,

1093

02:21:58.494 --> 02:22:00.443

which is under construction now,

1094

02:22:01.224 --> 02:22:12.773

which will be also located in building 432 and will be used primarily we're screening the production organize for running the production organized screen and the new modernized when,

1095

02:22:13.103 --> 02:22:17.273

as soon as possible the NCI 60 screen.

1096

02:22:18.869 --> 02:22:24.148

Thank you I think that makes it bad for you said.

1097

02:22:24.148 --> 02:22:30.959

Yep, yeah, thank you very much. All right, let's move on to Dr Tonya. Perfect.

1098

02:22:30.959 --> 02:22:34.289

From the national product branch in the developmental Therapeutics.

1099

02:22:34.289 --> 02:22:47.574

Program within a division of cancer treatment and diagnosis, she's going to be presenting natural products and capabilities related to that. Tanya Thank you Jason. So I'm here to present natural press.

1100

02:22:47.574 --> 02:22:50.302

This is the next slide. Please.

1101

02:22:50.968 --> 02:23:03.898

Natural product support group mechanics to provide voluntary support the natural products branch, which includes extraction of plant marine microbio, biotech Pre, fractionation of initial product extract.

1102

02:23:03.898 --> 02:23:16.828

Isolation and structure identification of biological, active, natural products and acromial, digital product, culture and extraction and I'm going to go through each 1 of these or some examples in the next slide. Please.

1103

02:23:16.828 --> 02:23:26.248

So, natural products research at based on this incredible resource called the natural product repository.

1104

02:23:26.248 --> 02:23:34.228

Which is a collection of plant, marine invertebrates and microbes collected from tropical and subtropical regions around performance.

1105

02:23:34.228 --> 02:23:43.379

The extraction capability was established in the 19 eighties for specialized laboratories from Hyperloop restriction and plant marine and.

1106

02:23:43.379 --> 02:23:55.349

And today, this program has generated a library of 230,000, natural strips at peak capacity, more than 20,000 students who will produce the year.

1107

02:23:56.574 --> 02:24:10.703

However, this resource is crude natural product extract, which is notoriously hard to screen in so, to that. And a new initiative was started to natural products and concepts over the next slide. Please.

1108

02:24:13.318 --> 02:24:22.978

This capability was established in 2016 with custom build automation laboratory, capable of generating library 1Million, natural product fractions.

1109

02:24:22.978 --> 02:24:33.838

Replicating this library into more than 55 copies of 304 wealth plates suitable. I took screening as well as automated sample storage in recovery. Can we start the video? Please.

1110

02:24:37.049 --> 02:24:48.748

Okay, if we can't, that's okay so on the left is an example of a liquid capital that which is usually used to dispense liquid.

1111

02:24:48.748 --> 02:25:01.019

To plate here, it's completely customized to perform positive pressure from the job where extract are Pre. Fractionated and the 3 hours to generate 660.

1112

02:25:01.019 --> 02:25:08.099

16 infections next slide please.

1113

02:25:08.099 --> 02:25:11.338

Okay, friction library production.

1114

02:25:11.338 --> 02:25:14.429

Since 2016.

1115

02:25:14.429 --> 02:25:18.808

A little on the half a 1Million corrections have been generated to date.

1116

02:25:18.808 --> 02:25:32.459

And we 326,000 those and release for distribution. They had to incorporate this is available to any screening center around the world straight against cancer as well as any advocacy.

1117

02:25:32.459 --> 02:25:41.849

Next slide so going forward screening the fractional library to chemistry. The chemistry is focused on.

1118

02:25:41.849 --> 02:25:56.064

Isolation and biologically active natural products, despite the progression, even screening efforts with particular emphasis on ability to capture store, generate libraries of high quality and chemistry that reflections the library and the actual.

1119

02:25:57.449 --> 02:26:00.929

And as a follow up on, that makes please.

1120

02:26:02.009 --> 02:26:14.068

It also has the ability to prefer medium and large scale for installations from natural credit excerpts, which includes anywhere from a couple of milligrams to grams of initial product.

1121

02:26:14.068 --> 02:26:21.869

And as a quick read, specialized chemistry equipment, smoked to stop inspection, magically characterization. Some, some of the examples.

1122

02:26:21.869 --> 02:26:29.039

Shown here and in machine as well as some.

1123

02:26:29.039 --> 02:26:38.279

They could handle this restriction for that and it's photo fire, right? It's a flesh. All it's capable of processing kilos of.

1124

02:26:38.279 --> 02:26:42.808

That's okay next slide please. And.

1125

02:26:42.808 --> 02:26:51.388

Okay, so the collection stopped about 5 years ago and now the emphasis on expanding the microbial strain collection.

1126

02:26:51.388 --> 02:27:01.408

Since 201,520,000 us source, new found, those strains were received this is part of the citizen science collection

program so there's.

1127

02:27:01.408 --> 02:27:05.099

There are samples from every state here.

1128

02:27:05.099 --> 02:27:16.978

Fangled metabolize involuntary process these samples, which includes plating, assessing viability contamination autographic as well January 7 miles to go back to the repository.

1129

02:27:16.978 --> 02:27:23.093

Next slide please in addition to that,

1130

02:27:23.123 --> 02:27:26.543

there's specialized laboratories able to perform small and medium scale,

1131

02:27:26.543 --> 02:27:27.533

fermentation service,

1132

02:27:28.013 --> 02:27:29.154

microbial couches,

1133

02:27:29.154 --> 02:27:33.023

which is anywhere between couple of 100 milliliters liters.

1134

02:27:33.539 --> 02:27:45.509

We have to shape the capacity to perform 101, late to counters for week and going back to the extraction with also high through the extraction and business intelligence makes lightens.

1135

02:27:47.488 --> 02:28:00.058

Most of the equipment and process is shown here required extensive customization wouldn't be done with just off the shelf equipment. So the garter prides itself. The ability to design.

1136

02:28:00.058 --> 02:28:07.769

Implement new experimented procedures, which most? 3 D printed lab, where customization of lab instrumentation and when is lunch.

1137

02:28:07.769 --> 02:28:11.638

Infrastructure the next slide please.

1138

02:28:12.718 --> 02:28:23.699

And finally, because our numbers are so huge, there's so many different integrated processes buying for meditates. Infrastructure is really important. So, development of.

1139

02:28:23.699 --> 02:28:33.478

Favorite faces into Britain, taxonomy, analytical chemistry of biological things that relational databases of friction production, lighting and chemical limitation.

1140

02:28:33.478 --> 02:28:41.279

Of the prefix natives I agree which has been shown and finally integration of legacy, that different structures into the new stable.

1141

02:28:41.279 --> 02:28:48.088

And use a friendly to face, and there is a summary of the contractor role in natural products research.

1142

02:28:48.088 --> 02:28:51.988

Thank you. Thank you, Tanya.

1143

02:28:51.988 --> 02:29:01.019

All right, let's pivot it a little bit and go to Dr cliff lane from the National Institute of allergy, infectious disease.

1144

02:29:01.019 --> 02:29:07.918

Division of clinical research Dr going to be presenting clinical studies support at the parties.

1145

02:29:09.119 --> 02:29:13.619

No, thank you, Jason. I can I get the next slide.

1146

02:29:15.388 --> 02:29:18.478

So, and the 1st.

1147

02:29:19.554 --> 02:29:20.484

4 slides,

1148

02:29:20.484 --> 02:29:24.683

I've captured the relevant areas of the statement of work,

1149

02:29:25.103 --> 02:29:26.244

I would say,

1150

02:29:26.244 --> 02:29:41.064

as a general comment that virtually any aspect of clinical management of patients and of clinical research is covered with this area of the statement of

1151

02:29:41.154 --> 02:29:41.843

work.

1152

02:29:42.984 --> 02:29:52.193

It spans providing nursing support to a clinic in the clinical center of the, and besides.

1153

02:29:53.099 --> 02:30:02.369

To helping to set up a randomized control trial of Therapeutics for Ebola, uh, in the.

1154

02:30:02.369 --> 02:30:08.939

Middle of a civil war in the Democratic Republic of Congo. So it's a really an amazing.

1155

02:30:08.939 --> 02:30:21.629

Uh, the diverse set of requirements and opportunities, so specifically providing a management infrastructure that includes oversight and monitoring of good clinical practices.

1156

02:30:21.629 --> 02:30:33.599

Providing the broad range of technical support, administrative management services program, support programs, both in the U. S. and internationally.

1157

02:30:33.599 --> 02:30:42.174

Um, much of the work supported for internationally, um, is part of a government to government engagement and indeed.

1158

02:30:42.174 --> 02:30:48.953

Parts of these are then inherently governmental and parts of them are carried out by the contract.

1159

02:30:49.974 --> 02:30:59.904

There is a need to mount a very rapid clinical research response to new public health concerns.

1160

02:31:00.203 --> 02:31:00.773

Obviously,

1161

02:31:00.773 --> 02:31:04.164

as you heard a little bit earlier from from Jim cherry,

1162

02:31:04.164 --> 02:31:07.283

there has been an enormous amount of effort recently in Colvin,

1163

02:31:07.283 --> 02:31:14.873

19 providing general programmatic support to these efforts with subcontracting logistics,

1164

02:31:14.873 --> 02:31:15.324
supply,

1165
02:31:15.324 --> 02:31:15.924
chain,

1166
02:31:15.984 --> 02:31:16.763
procurement,

1167
02:31:17.123 --> 02:31:17.814
next slot.

1168
02:31:20.513 --> 02:31:23.574
In addition that I mentioned earlier,

1169
02:31:23.693 --> 02:31:32.904
there are a variety of staff that are provided under the contract and envisioned in the statement of work these include
physicians,

1170
02:31:33.863 --> 02:31:34.763
medical affairs,

1171
02:31:34.763 --> 02:31:35.783
scientists,

1172
02:31:35.904 --> 02:31:37.043
nurses,

1173
02:31:37.074 --> 02:31:38.154
pharmacist,

1174
02:31:38.183 --> 02:31:38.634
lab,

1175
02:31:38.634 --> 02:31:39.654
technicians,

1176
02:31:39.683 --> 02:31:40.943
project managers,

1177
02:31:40.974 --> 02:31:42.564

regulatory experts,

1178

02:31:42.953 --> 02:31:48.234

bio statisticians consultants and a variety of subject matter areas.

1179

02:31:49.943 --> 02:32:00.984

Including, but not limited physicists, particularly in the area of studies of that involve imaging, artificial intelligence and medical technologists and chemists that.

1180

02:32:02.398 --> 02:32:13.289

Group diverse group of professionals, uh, will be asked to serve as a liaison with clinical regulatory and laboratory personnel on specific protocols.

1181

02:32:13.289 --> 02:32:17.308

To serve as associate investigators and protocols.

1182

02:32:17.308 --> 02:32:23.459

Those in the clinical arena to document patient care to participate in rounds.

1183

02:32:23.459 --> 02:32:38.459

Next slide order, diagnostic and related procedures as part of a license independent practitioners, assistant skilled procedures.

1184

02:32:38.459 --> 02:32:48.539

Coordinate patients, schedules, collect clinical samples, provide study coordination, coordinate courier services.

1185

02:32:48.539 --> 02:33:00.718

Next slide provide lifetime support to protocols, manage clinical trial portfolios, select.

1186

02:33:00.718 --> 02:33:13.199

Trial sites for clinical studies, provide data, warehousing, management and analysis, including bio, statistical support, provide monitoring and quality assurance.

1187

02:33:13.199 --> 02:33:18.629

Provide medical and technical writing for clinical trials.

1188

02:33:18.629 --> 02:33:23.248

Next slide.

1189

02:33:24.388 --> 02:33:32.699

Again, the support is typically requested under the contract when.

1190

02:33:32.699 --> 02:33:42.748

An age NCI, other institutes don't have a way to get this support through other means, including their own professional staff.

1191

02:33:42.748 --> 02:33:53.279

Regarding the work with, and this is often international and often very high priority and urgent.

1192

02:33:53.279 --> 02:34:03.780

And Id my Institute allergy and infectious diseases has this dual mandate of carrying out a program of basic and applied research.

1193

02:34:04.075 --> 02:34:13.225

And being able to respond rapidly to emerging infectious diseases, and we rely heavily on this contract to help us really?

1194

02:34:13.225 --> 02:34:22.764

With both parts of that mission, the support may include not just staff, but also helping with renovations of physical infrastructure.

1195

02:34:23.334 --> 02:34:36.954

The laboratory activities include routine monitoring of chemistry's as well as bringing in new technologies and some of that will be done at the campus and Frederick,

1196

02:34:36.954 --> 02:34:42.805

and often we are looking to extend some of those activities to our sites overseas.

1197

02:34:43.139 --> 02:34:46.350

Regulatory support is a key part.

1198

02:34:46.350 --> 02:34:51.090

Of what ID currently um.

1199

02:34:51.090 --> 02:34:54.569

Receives from the contract and next slide.

1200

02:34:56.940 --> 02:35:11.694

This slide provides a map of 1 where some of the key international clinical research programs funded by an ID that are heavily supported

1201

02:35:12.024 --> 02:35:13.014

by the federal,

1202

02:35:13.193 --> 02:35:14.965

the Frederick national Labs,

1203

02:35:14.995 --> 02:35:17.754

the federally funded research and development center,

1204

02:35:19.284 --> 02:35:20.364

Mexico,

1205

02:35:22.014 --> 02:35:26.875

a project that began in the setting of the 2009 H1 and 1,

1206

02:35:27.055 --> 02:35:27.805

influenza outbreak,

1207

02:35:27.864 --> 02:35:29.905

the program in Mali,

1208

02:35:30.805 --> 02:35:35.545

which has been long standing has been initially focused on malaria,

1209

02:35:35.604 --> 02:35:38.604

but evolve to also include a,

1210

02:35:38.604 --> 02:35:43.405

the programs and Guinea Liberia and.

1211

02:35:47.190 --> 02:35:56.850

All grew out of an Ebola response, but have evolved into sustained clinical research programs to look at any 1 of a number.

1212

02:35:56.850 --> 02:36:04.860

Of infectious diseases and establishing clinical research protocols in those diseases.

1213

02:36:04.860 --> 02:36:16.075

Particularly the hemorrhagic fever, viruses, Ebola, Lassa and in the we're currently looking to start a protocol on monkey pox.

1214

02:36:16.825 --> 02:36:20.844

Indonesia grew out of the 2005 5 and 1.

1215

02:36:22.889 --> 02:36:27.299

Concerns and that program.

1216

02:36:27.299 --> 02:36:35.940

Now, looks at an array of emerging infectious diseases and H, I, V. and all of these programs have been involved in 19.

1217

02:36:36.625 --> 02:36:47.754

Next slide this last slide just gives you then some of the most recent examples of clinical research supported by the Frederick national Labs,

1218

02:36:48.235 --> 02:36:50.545

the Ebola outbreak from 2015 to 2017,

1219

02:36:50.545 --> 02:36:51.295

in West Africa,

1220

02:36:51.295 --> 02:36:53.004

the outbreak in the Congo.

1221

02:36:57.090 --> 02:37:08.309

From 2018 to 2019, and again, as I mentioned in response to Kobe 19, with efforts in the US, the UK Europe.

1222

02:37:08.309 --> 02:37:14.459

West Africa, the Democratic Republic of Congo, Indonesia and Mexico.

1223

02:37:14.459 --> 02:37:18.930

Thank you thank you cliff.

1224

02:37:21.690 --> 02:37:30.120

Okay, next step let's Welcome back to Paula Jacobs from the cancer imaging program within the division of cancer treatment and diagnosis, and in.

1225

02:37:30.120 --> 02:37:33.959

She's going to be talking about structural biology and imaging technologies.

1226

02:37:33.959 --> 02:37:37.889

I believe with a little bit more a heavy focus on the imaging part.

1227

02:37:39.239 --> 02:37:48.840

Thank you Jason, just comment that illustrated here are some of the instrumentation that we use for small animal imaging next slide.

1228

02:37:50.520 --> 02:37:54.659

An overview I will discuss in vivo an, in vitro imaging facilities.

1229

02:37:54.659 --> 02:37:58.649

Supply of noncommercial imaging agents and imaging Informatics.

1230

02:37:58.649 --> 02:38:02.459

I won't be addressing structural biology imaging, particularly.

1231

02:38:02.459 --> 02:38:07.290

Kylie was addressed earlier in the National missions initiative. Presentation.

1232

02:38:07.290 --> 02:38:10.799

Techniques required include, but are not limited to.

1233

02:38:10.799 --> 02:38:14.729

M, X Ray, crystal argosy and.

1234

02:38:14.729 --> 02:38:20.489

Next slide please in detail in the next slide.

1235

02:38:26.790 --> 02:38:33.389

We in these facilities, we provide investigators with the ability to develop and characterize new animal models.

1236

02:38:33.389 --> 02:38:40.739

No, molecular markers and turn monitor tumors and be about to assist in nanotechnology characterization.

1237

02:38:40.739 --> 02:38:45.270

To support initiatives in developing standards for small animal imaging.

1238

02:38:45.270 --> 02:38:50.639

Integrating imaging and drug development characterizing patient, divide models.

1239

02:38:50.639 --> 02:38:55.440

And evaluating new imaging agents, and probes for investigators next slide.

1240

02:38:58.260 --> 02:39:02.520

Well, listed here are some of the minimum equipment and capabilities required.

1241

02:39:02.520 --> 02:39:08.819

Both the broad range needed essentially every established and experimental imaging methods that we have.

1242

02:39:08.819 --> 02:39:15.809

Particularly sophisticated on the, and the hyper polarized carbon 13.

1243

02:39:15.809 --> 02:39:20.639

Which will be expanded to cover other.

1244

02:39:20.639 --> 02:39:25.620

Hyper polarized nucleati highly sophisticated next slide.

1245

02:39:27.510 --> 02:39:31.829

Minimum support capabilities include qualified staff.

1246

02:39:31.829 --> 02:39:40.770

With handling qualified in handling radioactive materials for instrument, operation and maintenance, and for animal hamlet handling and Drug Administration.

1247

02:39:40.770 --> 02:39:44.190

We need to provide imaging agents as needed.

1248

02:39:44.190 --> 02:39:50.010

Qualify vendors for commercial agents, for example, and Carolinian agents.

1249

02:39:50.010 --> 02:39:56.879

Synthesize non commercial agents, for example, or tagged antibodies.

1250

02:39:56.879 --> 02:40:00.840

To ensure quality and performance of all ages.

1251

02:40:00.840 --> 02:40:04.260

Provide regulatory support for imaging and days.

1252

02:40:04.260 --> 02:40:10.290

Not mentioned here is to operate a small GMP facility or.

1253

02:40:10.290 --> 02:40:13.950

To use subcontracts to make radioactive drugs.

1254

02:40:13.950 --> 02:40:21.750

Available for early clinical trials and finally we need to develop analytical methods image processing.

1255
02:40:21.750 --> 02:40:30.420
Great efficiency next slide some example projects. We'll split the range supported by.

1256
02:40:30.420 --> 02:40:41.639
Projects come from investigators, the nano technology characterization, laboratory and programs such as next the NCI experimental Therapeutics program. Next slide.

1257
02:40:42.959 --> 02:40:46.829
These are some of the typical projects which have been performed.

1258
02:40:46.829 --> 02:40:51.270
Virtual call Alaska, be ultrasound, guided injections.

1259
02:40:51.270 --> 02:40:57.209
High resolution quantitative ultrasound and segmentation.

1260
02:40:57.209 --> 02:41:00.690
Small animals icon standards.

1261
02:41:00.690 --> 02:41:06.690
We can characterize animal models and is a listing here of some of the ones which had been.

1262
02:41:06.690 --> 02:41:10.530
I looked at in the past, we're not limited to those. Of course.

1263
02:41:10.530 --> 02:41:14.879
And to characterize imaging agents of Therapeutics, we've done several.

1264
02:41:14.879 --> 02:41:18.120
Labeled anybody's label drugs.

1265
02:41:18.120 --> 02:41:24.149
Metabolic reporters and 15 traders and authorized carbon, 13 and nano particles.

1266
02:41:24.149 --> 02:41:33.899
Next slide, this is more detailed example of 1 project that proceeded from in vitro to small animal to whom?

1267
02:41:33.899 --> 02:41:37.319
Headed to the mappings and approved drugs that targets.

1268

02:41:37.319 --> 02:41:45.120

The significant toxicity issues, this project developing imaging probe to quantify expression by energy.

1269

02:41:45.120 --> 02:41:51.030

And investigate it more patient selection and monitoring response are directly.

1270

02:41:51.030 --> 02:41:56.280

And the tool map was moved with a positron emitting isotope 689.

1271

02:41:56.280 --> 02:42:02.100

And tested in pretty much documentation was prepared Fi and D filing and drugs.

1272

02:42:02.100 --> 02:42:10.049

Was supply to the clinical center for small clinical trial from facility available at Frederick next slide. Please.

1273

02:42:12.450 --> 02:42:16.770

This slide shows more details from the project and includes the publish literature citation.

1274

02:42:16.770 --> 02:42:22.440

You can see the images of the animal models, which have low medium and high easier.

1275

02:42:22.440 --> 02:42:25.950

Expression which is quantified in the adjacent graph.

1276

02:42:25.950 --> 02:42:30.270

Also seen, as an example scanned from 1 of the 1st patients in the world.

1277

02:42:30.270 --> 02:42:35.520

You can see the this has been colored so that you can detect where the.

1278

02:42:35.520 --> 02:42:41.940

Uptake primarily is next slide. This is another project.

1279

02:42:41.940 --> 02:42:51.780

As part of the major program, a patient drives theophylline models mentioned briefly by Dr Tasha earlier some PDX would characterize with extensive energy.

1280

02:42:51.780 --> 02:42:55.409

Showing here is a bladder cancer model that is reliably metastatic.

1281

02:42:55.409 --> 02:43:00.690

And that's important for development to therapy see human their tumors that are also metastatic.

1282

02:43:00.690 --> 02:43:07.709

Variety of imaging methods where the therapeutic was evaluated to see if the imaging could follow the therapy.

1283

02:43:07.709 --> 02:43:11.729

Using images reduces the need for larger numbers of animals.

1284

02:43:11.729 --> 02:43:16.200

And it's much more efficient to develop in Therapeutics.

1285

02:43:16.200 --> 02:43:22.530

Next slide area of focus with.

1286

02:43:22.530 --> 02:43:28.440

Is imaging from that I currently supports a variety of data archives.

1287

02:43:28.440 --> 02:43:32.250

1 of which is for medical imaging and histology next time.

1288

02:43:34.739 --> 02:43:39.870

The current archives is called the cancer imaging archive, and most of the collections are completely open to access.

1289

02:43:39.870 --> 02:43:44.399

Currently, it contains 121 collections with almost 50,000 subjects.

1290

02:43:44.399 --> 02:43:47.430

100Million images including radiology.

1291

02:43:47.430 --> 02:43:50.909

Radiation therapy planning and historic mythology and witches.

1292

02:43:50.909 --> 02:43:59.579

Reflecting wide variety of cancers. Most of these collections have supporting data, such as clinical data image, analyses, legitimate data.

1293

02:43:59.579 --> 02:44:11.399

Notably this archive published, posting the 1st, publicly available collection of images for coded 19 Asians, as part of pivot during the code of 19 pandemic.

1294

02:44:11.399 --> 02:44:17.159

To support the community, the collection contains integrated.

1295

02:44:17.159 --> 02:44:21.360

Project data was radiology histology next slide. Please.

1296

02:44:23.610 --> 02:44:30.270

Note that a typical scan can contain several 100 separate images.

1297

02:44:30.270 --> 02:44:34.170

A significant effort is required to de identify dotcom images.

1298

02:44:34.170 --> 02:44:38.399

To remove patients.

1299

02:44:38.399 --> 02:44:43.290

Without removing technical information that is useful for further.

1300

02:44:43.290 --> 02:44:46.469

Work, particularly in.

1301

02:44:46.469 --> 02:44:52.559

Machine learning various sanitation method then are applied to prepare images for machine learning.

1302

02:44:52.559 --> 02:45:02.040

Next slide, Here's a little alphabet soup of many of the multiple projects that have images included in this archive.

1303

02:45:02.040 --> 02:45:06.870

Examples include the J which Dr stop discussed.

1304

02:45:06.870 --> 02:45:09.930

Um, the proteomics.

1305

02:45:09.930 --> 02:45:14.610

And they should just simply tap the National clinical trials network.

1306

02:45:14.610 --> 02:45:21.000

With clinical trial data, and we have the images that are associated with some of these clinical trials.

1307

02:45:21.000 --> 02:45:28.110

The imaging data comments, which I'll talk about another moment and the.

1308
02:45:28.110 --> 02:45:33.450
Integrated 9 data comments next slide please.

1309
02:45:36.270 --> 02:45:41.159
Some of these data come from supported activities, such as you mentioned.

1310
02:45:41.159 --> 02:45:44.850
Cga CP tack Apollo.

1311
02:45:44.850 --> 02:45:49.350
The National clinical trials network, and the moon bank and initiatives.

1312
02:45:49.350 --> 02:45:53.159
And the, for the PDX models that we discussed.

1313
02:45:54.659 --> 02:46:02.639
Next slide other proposals are from the community, they're reviewed monthly people send in.

1314
02:46:02.639 --> 02:46:06.989
Collections of data, which they think other people would be interested in seeing.

1315
02:46:06.989 --> 02:46:11.459
They are data generated by grants. They are challenged competition data.

1316
02:46:11.459 --> 02:46:16.379
They are publication sharing request. Many publications are now requiring.

1317
02:46:16.379 --> 02:46:20.309
That original data that used analysis.

1318
02:46:20.309 --> 02:46:24.360
Do they provide it publicly?

1319
02:46:25.739 --> 02:46:36.360
The next slide, please, the data in the PCA is being adjusted by the imaging data columns a new part of the new NCI cancer research data governance.

1320
02:46:36.360 --> 02:46:43.680
Which was discussed previously, this is a virtual expandable instruction, the standardized data secure data access.

1321

02:46:43.680 --> 02:46:48.000

Federated data access and in cloud data, analytical.

1322

02:46:48.000 --> 02:46:54.000

Characteristics next slide Thank you for your attention.

1323

02:46:54.000 --> 02:46:57.120

Back to Jason. Great. Thank you. Paula.

1324

02:46:58.829 --> 02:47:01.854

Okay, we're going to move to Dr pewter.

1325

02:47:01.854 --> 02:47:14.395

Good since he's from the NCI Nano delivery systems and devices branch, and the division of cancer treatment and diagnosis, and he's going to be presenting and our technology and bioengineering capabilities related to that at the.

1326

02:47:15.569 --> 02:47:20.700

Got it Thank you, James. Jason. Good afternoon. Everybody in next slide. Please.

1327

02:47:22.440 --> 02:47:28.290

Technology offers a significant opportunity for a concert both from the.

1328

02:47:28.290 --> 02:47:38.100

Perspective of research, and also whether it's another party delivery or building new nano technology based devices.

1329

02:47:38.100 --> 02:47:44.309

Uh, and, uh, this opportunity to entail range of different interventions from.

1330

02:47:44.309 --> 02:47:54.209

Detection and in health monitoring, or monitoring of effectiveness of the therapy, whether it's through new contrast agents.

1331

02:47:54.209 --> 02:47:59.010

For imaging, our new multiple sensors, which can be used in vitro.

1332

02:47:59.010 --> 02:48:03.149

Or, uh, for new segments.

1333

02:48:03.149 --> 02:48:14.700

Uh, where none of partners can offer more localized, deliver it to tomorrow and to be involved also in number of different combination therapies next slide. Please.

1334
02:48:14.700 --> 02:48:22.920
Now, she is relatively, or at least the use of technology concern is relatively new.

1335
02:48:23.424 --> 02:48:30.594
Field we are then recognize it to early on and started our programs almost 15 years,

1336
02:48:30.594 --> 02:48:35.934
but because complexity of development of none of technology drugs,

1337
02:48:35.965 --> 02:48:39.415
it may be higher than in case of traditional,

1338
02:48:40.465 --> 02:48:44.604
which do not need to be combined with Nano party carriers.

1339
02:48:44.879 --> 02:48:50.520
Uh, there is a need for in depth, understanding of normal materials.

1340
02:48:50.520 --> 02:48:56.520
Properties and their interaction with biological systems, both in try and space.

1341
02:48:56.520 --> 02:49:11.190
Eventually, uh, we need to standardize the essays to characterize these carriers and to make that more uniform. We need to have good mechanism to share.

1342
02:49:11.190 --> 02:49:14.700
Uh, the information and the data next slide please.

1343
02:49:16.260 --> 02:49:21.930
Because of these reasons, we started nanotechnology characterization laboratory our.

1344
02:49:21.930 --> 02:49:26.370
In 2004, uh, part to.

1345
02:49:26.370 --> 02:49:32.190
Um, of the further can National lab and the primary mission is to.

1346
02:49:32.190 --> 02:49:40.469
Uh, basically built to the overall knowledge on none of materials, which are used in both interrupt. You think like diagnostic applications for cancer.

1347
02:49:40.469 --> 02:49:48.479
And also as a disease is true uniform and well, informed characterization cascade.

1348
02:49:48.479 --> 02:49:56.579
Next slide please this essay cascade involves 3 major steps.

1349
02:49:56.579 --> 02:50:00.870
From physical chemical characterizations through in vitro characterization.

1350
02:50:00.870 --> 02:50:04.079
And in Eva characterization.

1351
02:50:04.079 --> 02:50:14.034
They are currently 72 protocols supporting the, let's say cascade and they are posted on, uh, on the web and on 1 hand they are being used within.

1352
02:50:14.364 --> 02:50:19.405
And SL, on the other hand, we encourage the researchers from.

1353
02:50:20.610 --> 02:50:25.829
The external community to adopt this essays and to.

1354
02:50:25.829 --> 02:50:29.700
Uh, and use them in their own, uh, laboratories next slide please.

1355
02:50:32.100 --> 02:50:44.520
Um, the lack has been in existence from 2004, so there is fairly long history to eat. And here there are fuel statistical data on their performance.

1356
02:50:44.520 --> 02:50:52.530
Uh, over the period of time, they looked at over 400 different material, uh, uh, formulations.

1357
02:50:52.530 --> 02:50:57.805
Uh, and, uh, the formulations involve number of different, none of materials.

1358
02:50:57.805 --> 02:51:03.444
Some of them are depicted in the graphic here and their combination with number of,

1359
02:51:03.504 --> 02:51:03.985
uh,

1360
02:51:03.985 --> 02:51:11.934
different api's for different treatment modalities that these materials are coming from,

1361
02:51:12.174 --> 02:51:15.924
are being submitted to and scale from academia industry or government blocks.

1362
02:51:16.200 --> 02:51:20.489
I already mentioned that more than 70 protocols. Um.

1363
02:51:20.489 --> 02:51:24.084
I have been developed and and being,

1364
02:51:24.235 --> 02:51:31.975
and are being shared with the community and 17 of different from the past,

1365
02:51:32.665 --> 02:51:35.485
based on partially based on the data,

1366
02:51:35.485 --> 02:51:39.864
which have been developed by NCO or at the enter to clinical trials.

1367
02:51:40.584 --> 02:51:41.364
Next slide case.

1368
02:51:44.040 --> 02:51:54.329
Um, uh, as I said, uh, is accepting a submission of a different materials, uh, with the potential in oncology.

1369
02:51:54.329 --> 02:52:01.170
From a academic and and to commercial as well as government labs.

1370
02:52:01.170 --> 02:52:05.219
Uh, there is a standardized application process we collect.

1371
02:52:05.219 --> 02:52:14.309
The applications, 4 times a year, uh, initially they involved short white paper and if the white paper is accepted.

1372
02:52:14.309 --> 02:52:20.370
Uh, then, um, it moves on to face to application process, which is more.

1373

02:52:20.370 --> 02:52:28.020

Uh, more involved next slide please again, following on some statistical information.

1374

02:52:28.020 --> 02:52:32.670

Uh, as you see, there is several.

1375

02:52:32.670 --> 02:52:46.770

Um, number of which are being submitted every year and characterize we differentiate care by a unique number particle formulations and tone on the project, submitted the difference.

1376

02:52:46.770 --> 02:52:52.799

Uh, the numbers are different because, uh, 1, unique submission may, um.

1377

02:52:52.799 --> 02:53:05.125

Consist of more than 1 type or or 1 design of non. Perfect. That's why they thought on our part. Number is higher as you also see that.

1378

02:53:05.334 --> 02:53:09.594

The submissions cover a wide range of materials.

1379

02:53:09.870 --> 02:53:14.670

From and preliminary nanoparticles to.

1380

02:53:14.670 --> 02:53:23.159

A different formulation and involving carbon nano tubes myself and and even metallic nanoparticles.

1381

02:53:23.159 --> 02:53:32.340

Mix like this standardization of of the same characterization message is, uh.

1382

02:53:32.340 --> 02:53:37.014

An important part of of the job here and,

1383

02:53:37.014 --> 02:53:37.434

uh,

1384

02:53:38.364 --> 02:53:48.565

has been interacting with both and which are standardization organizations operating domestically and internationally.

1385

02:53:48.899 --> 02:53:52.530

Uh, and a few of these protocols have been the.

1386

02:53:52.530 --> 02:54:00.659

Uh, entered as a standard team both and I saw we also worked with sneezed.

1387

02:54:00.659 --> 02:54:04.409

Uh, in addition to.

1388

02:54:04.409 --> 02:54:14.309

Or, um, initial supporters of the lab and then work with nice on.

1389

02:54:14.309 --> 02:54:18.600

Development of that will go the reference material next slide case.

1390

02:54:18.600 --> 02:54:28.200

Um, as a cascade, when submission involves oncology Cal, application of the material.

1391

02:54:28.200 --> 02:54:34.319

Uh, is this characterization? Cascade is performed at no cost to the.

1392

02:54:34.319 --> 02:54:46.829

Organization and the investigate, they're submitting it, but we also have a number of different interested parties who, uh, on the 1 hand can be interested in.

1393

02:54:46.829 --> 02:54:51.750

Um, application of technology, a non oncology call.

1394

02:54:51.750 --> 02:54:58.770

Space, um, or in other services, not involving only characterization, but.

1395

02:54:58.770 --> 02:55:01.614

Also a non aquatic formulation,

1396

02:55:01.645 --> 02:55:03.264

or reformulation of,

1397

02:55:03.295 --> 02:55:03.594

uh,

1398

02:55:03.625 --> 02:55:17.215

existing therapies and those services can be also conducted under cooperative research projects or and they involve.

1399

02:55:18.000 --> 02:55:22.020

Building a project and the budget to supporting it.

1400

02:55:22.020 --> 02:55:34.350

Next slide please another avenue of interaction with external community are so called technical service agreements, or.

1401

02:55:34.350 --> 02:55:45.149

Which are very specific element, technical elements to perform particular service and we have 2 of those and 1 and 2.

1402

02:55:45.149 --> 02:55:57.569

They are both, uh, related to evaluation of different components of the direct formulation. Inhuman plasma are.

1403

02:55:57.569 --> 02:56:06.000

I'm in right and they, uh, use the essay developed Adams here next 5.

1404

02:56:08.370 --> 02:56:13.049

Um, big part of the mission is to share.

1405

02:56:13.049 --> 02:56:17.190

Uh, their experience with the research, uh, community.

1406

02:56:17.190 --> 02:56:27.899

Um, as you see that the protocols which are on the website of are being frequently downloaded by researchers from the community over 2000 of them.

1407

02:56:27.899 --> 02:56:30.930

Downloads took place last year.

1408

02:56:30.930 --> 02:56:36.450

And 6, new protocols were added, uh, uh, in, uh, in last year.

1409

02:56:36.450 --> 02:56:45.629

Next like this, I talked to the beginning about the data sharing.

1410

02:56:45.629 --> 02:56:50.190

We also developed a database called called.

1411

02:56:50.190 --> 02:56:55.860

Which is also being operated through for the National Lab.

1412

02:56:55.860 --> 02:57:05.190

Uh, and, uh, uh, that database is fairly comprehensive from the perspective of the biological, um.

1413
02:57:05.190 --> 02:57:08.639
Aspects of the part of the behavior.

1414
02:57:08.639 --> 02:57:18.540
Uh, and to the submissions coming to the scene on the lab are from number of different sources.

1415
02:57:18.540 --> 02:57:26.190
Uh, some of that is from NCO characterization men of that is from the counties who have been funded by to.

1416
02:57:26.190 --> 02:57:35.819
Do another medicine and none of technology and we also have curator score the data from existing publications of particular relevance.

1417
02:57:35.819 --> 02:57:45.389
Next slide please so to summarize and recognize the importance of none of technology in cancer.

1418
02:57:45.389 --> 02:57:57.389
Uh, sometime ago, and, uh, that interest is being pursued on 1 hand through a number of, uh, funding opportunities. But, on the other hand, uh, by, uh, establishment of none of the characterization lab.

1419
02:57:57.389 --> 02:58:08.100
Which I described in more detail and became a very unique resource with number of different, uh, characterization and formulation formulation capabilities.

1420
02:58:08.100 --> 02:58:15.479
And serve the community for over 16 years right now I looked at over 400 different uh.

1421
02:58:15.479 --> 02:58:24.209
And then the material formulations also, uh, develop the large body of, uh, literature based on their experience.

1422
02:58:24.209 --> 02:58:29.280
Uh, and interaction with a can be conducted stroll.

1423
02:58:29.280 --> 02:58:39.600
A submission, uh, via white papers to, um, say, as well through a number of different mechanism inter agency.

1424
02:58:39.600 --> 02:58:43.110
Agreements with their government labs are sick trade.

1425
02:58:43.110 --> 02:58:48.959

Agreements with industry as well as technical service agreements and seen analog.

1426

02:58:48.959 --> 02:58:55.350

A database, uh, provide an important tool in the sharing of data.

1427

02:58:55.350 --> 02:59:05.850

Next slide please, thank you for your attention and I'll be happy to answer questions when we come to the discussion session Thank you.

1428

02:59:05.850 --> 02:59:14.790

Great. Thank you Peter. All right. Rounding out this block of presentations. We have Dr Stephen Hughes.

1429

02:59:14.790 --> 02:59:25.739

From the retrovirus replication laboratory and the center for cancer research Dr Hughes will be presenting the biology research and capabilities at the f. RDC.

1430

02:59:25.739 --> 02:59:29.250

Steve, thank you. Slide please.

1431

02:59:30.659 --> 02:59:35.760

So the f, I've already supports both Pi investigated.

1432

02:59:35.760 --> 02:59:40.799

I'm sorry Pi, investigator initiated research and core laboratories.

1433

02:59:40.799 --> 02:59:44.399

He's contributed to both intramural and extra research.

1434

02:59:44.399 --> 02:59:53.850

These involve immunological, pathological and cellular, molecular, biochemical aspects of AIDS associated viral diseases.

1435

02:59:53.850 --> 02:59:58.049

Because there's a focus on vaccine development and translational research.

1436

02:59:58.049 --> 03:00:06.659

In the technology reagent assay development there was proactive sharing of technology with the broader research community.

1437

03:00:06.659 --> 03:00:11.190

Standardized and validated neurological essays and agents.

1438

03:00:11.190 --> 03:00:15.209

Virus viral vector and virus particle generation and production.

1439

03:00:15.209 --> 03:00:19.290

And viral, typing and sequencing, please.

1440

03:00:21.504 --> 03:00:25.014

And the investigator initiated biology research,

1441

03:00:25.075 --> 03:00:27.145

there's research and viral evolution,

1442

03:00:27.235 --> 03:00:30.565

which uses molecular biology approaches the generate,

1443

03:00:30.594 --> 03:00:41.094

manipulate and employ novel viral systems to take full advantages of the benefits of non human models to test specific hypotheses in Viva.

1444

03:00:41.459 --> 03:00:49.290

Next the aim is to study the role of viruses and cancer.

1445

03:00:49.290 --> 03:00:56.340

This in this research, those studies are focused primarily on kaposi's sarcoma associated herpes virus.

1446

03:00:56.340 --> 03:01:05.969

And related malignancies, the approach encompasses epidemiology, molecular biology, Immunology, and trace Translational studies next.

1447

03:01:05.969 --> 03:01:09.780

Retrovirus cell interactions.

1448

03:01:09.780 --> 03:01:21.750

Seeks to study the interactions between AIDS viruses and their host cells, using both the human T cell and savvy T cell systems.

1449

03:01:21.750 --> 03:01:26.399

Metro viral pathogenesis carries out research.

1450

03:01:26.399 --> 03:01:31.079

In vitro and Indiegogo that are and at improving.

1451

03:01:31.079 --> 03:01:35.430

Our understanding of the basis of LUNDY viral pathogenesis.

1452

03:01:35.430 --> 03:01:45.569

Particularly those aspects that are relevant to the development and evaluation of interventions that are intended to prevent and treat the infections and dates next to them.

1453

03:01:45.569 --> 03:01:52.530

My hope resistance research uses in vivo, non human primate models of the infection.

1454

03:01:52.530 --> 03:02:03.629

In vitro and cell culture, biology and molecular biology to study of the establishment spread and maintenance of resistant AIDS virus infections.

1455

03:02:03.629 --> 03:02:09.780

And importantly, to evaluate novel treatment approaches that are intended to reduce these.

1456

03:02:09.780 --> 03:02:18.959

Next, so we're going to now move from the Pi initiated research to the core support next.

1457

03:02:20.010 --> 03:02:28.110

There's which carries out measurements of the immune responses and bridging.

1458

03:02:28.110 --> 03:02:33.840

For both academic and commercial HPV vaccine trials next.

1459

03:02:33.840 --> 03:02:39.629

Viral evolution provides specialized sequencing techniques, molecular cloning.

1460

03:02:39.629 --> 03:02:50.399

And studies, viral evolution to support intramural and extra mural investigators conducting a broad range of AIDS research studies, and putting research.

1461

03:02:50.399 --> 03:02:58.200

By reservoir identification and elimination Bernal transmission and dissemination and viral adaptation next.

1462

03:02:58.200 --> 03:03:07.950

Tissue analysis carries out state of the art tissue analysis. That is essence history. Chemistry in CCO. Hybridization.

1463

03:03:07.950 --> 03:03:12.299

Quantitative image analysis, laser capture micro section.

1464

03:03:12.299 --> 03:03:19.649

And these studies are emphasize the analysis of specimens from nonhuman primate models.

1465

03:03:19.649 --> 03:03:34.020

Next place, the core additional core support is provided by the retro protein chemistry, which provides state of the art preoperative and analytic protein chemistry for the characterization of retrovirus variants.

1466

03:03:34.020 --> 03:03:42.600

And related samples, it's important to point out this core pioneered the use of, for the purification of viral proteins.

1467

03:03:42.600 --> 03:03:57.120

Next biological products next, it provides research the research community with large quantities of high quality, purified preparations of various human immunodeficiency virus.

1468

03:03:57.120 --> 03:04:01.440

And sent me an immunodeficiency virus strands. Ex, please.

1469

03:04:01.440 --> 03:04:06.299

Quantitative molecular diagnosis diagnostics and next please.

1470

03:04:06.299 --> 03:04:18.840

Provide state of the art quantitative molecular analysis of specific nucleic acid sequences and specimens provided by the intramural and intramural research community next. Please.

1471

03:04:18.840 --> 03:04:23.760

Non human primary research support.

1472

03:04:23.905 --> 03:04:31.824

Is there to support viral article studies that are conducted by scientists and their collaborators and on human primates?

1473

03:04:32.215 --> 03:04:46.045

The support includes the ongoing scheduling of all study events and preparation specimen collection and light processing and transportation support for AIDS vaccine, pathogenesis and treatment studies.

1474

03:04:46.680 --> 03:04:47.245

Next place,

1475

03:04:49.524 --> 03:04:49.975

Chevy,

1476

03:04:50.004 --> 03:04:59.844

molecular monitoring provides say to the quantitative and sequence analysis of from clinical specimens obtained from intermural and extra mural scientists,

1477

03:05:00.264 --> 03:05:08.635

these include ultra sensitive plasma load measurements and cell associated next place.

1478

03:05:08.940 --> 03:05:22.649

Cellular immunity provides comprehensive flow cytometry, self, sorting and site our immune analysis to support and their collaborators in studies of non human primates.

1479

03:05:22.649 --> 03:05:26.700

Using advanced flow cytometry, methods, instrumentation and software.

1480

03:05:26.700 --> 03:05:33.360

Next please, so, in the last few minutes, I want to just show you a couple of quick highlights.

1481

03:05:33.360 --> 03:05:36.930

Of recent biology research next place.

1482

03:05:38.004 --> 03:05:46.495

So, integration inside analysis has become an important tool that she is to monitor the clonal expansion and persistence and H, I. V.

1483

03:05:46.495 --> 03:05:53.334

infected T cells in humans and the clonal expansion of infected T cells plays an important role.

1484

03:05:53.670 --> 03:06:00.149

In the persistence of infected cells during effective retrovirus, antiretroviral therapy.

1485

03:06:00.149 --> 03:06:03.360

Which is why there's a need to understand this process.

1486

03:06:03.895 --> 03:06:04.344

So,

1487

03:06:04.375 --> 03:06:05.725

if an infected T,

1488

03:06:05.725 --> 03:06:07.165

cell climate expands,

1489
03:06:07.704 --> 03:06:09.235
all the progeny cells,

1490
03:06:09.295 --> 03:06:10.524
have an AV,

1491
03:06:10.524 --> 03:06:13.735
progress integrated in the same exact position in a genome,

1492
03:06:14.274 --> 03:06:14.905
which is why,

1493
03:06:14.905 --> 03:06:15.415
in fact,

1494
03:06:15.415 --> 03:06:19.495
integration side analysis is both useful and powerful next place.

1495
03:06:19.770 --> 03:06:32.760
So, the question becomes, is it possible to take advantage of the system? Do experiments, monitoring reclining expansion, persistence of infected T cells that can't be done.

1496
03:06:32.760 --> 03:06:35.850
Using examples obtain from human donors.

1497
03:06:35.850 --> 03:06:49.469
Next place, and it should be clear. I think that the model would have great advantages for this kind of analysis relative to the material that can be obtained from humans.

1498
03:06:49.469 --> 03:06:55.110
Because it's possible in the mechanic analysis to control the timing of the infection.

1499
03:06:55.110 --> 03:06:59.940
And the precise therapies that are used.

1500
03:07:00.295 --> 03:07:09.834
As I'll come back to, in a minute there is, there are barcode viruses, which can be used, which also provide real advantages in the mechanic system.

1501
03:07:10.555 --> 03:07:17.125

Obviously, in the mechanics, you can manipulate the immune system, and you can do tissue sampling in the CACs.

1502

03:07:17.184 --> 03:07:30.534

Although in a way that just as impossible with human donors, however, before going forward with the model model needs to be validated to show that it is a useful useful tool.

1503

03:07:30.989 --> 03:07:36.510

Relative to what actually goes on in the human system.

1504

03:07:36.510 --> 03:07:41.670

Next please, so to validate the model.

1505

03:07:41.670 --> 03:07:48.270

The Bible to show that it's a good it's a good model for what happens in the infected humans.

1506

03:07:48.270 --> 03:07:52.350

We 1st need to know how similar the integration site distribution.

1507

03:07:52.350 --> 03:08:03.840

He is for the Pro viruses and nature, the infected cells, and he has the Pro viruses and infected mechanic cells and additionally and importantly next please.

1508

03:08:03.840 --> 03:08:07.590

We also need to show our need to know.

1509

03:08:07.590 --> 03:08:12.389

Uh, whether the clonal expansion of infected T, cells and mechanics.

1510

03:08:12.389 --> 03:08:18.840

Whether or not, that is similar to the clonal expansion of infected cells in humans.

1511

03:08:18.840 --> 03:08:26.489

Next please, so this is a little tiny excerpt from the, from the published study.

1512

03:08:26.489 --> 03:08:32.069

Which shows that, in fact, savvy and integration sites are very similar.

1513

03:08:32.069 --> 03:08:35.190

In human peripheral blood mountain, nuclear cells.

1514

03:08:35.514 --> 03:08:40.614

And s, and s, I'd be infected MCAT peripheral, but blood might've nuclear cells.

1515

03:08:41.155 --> 03:08:53.665

So, at the very top of the image, you see the distribution of integration sites and human, and what's shown on the slide is the distribution and chromosome 11.

1516

03:08:54.055 --> 03:09:03.834

but I'll tell you without showing you that this data is representative of the whole genome and what you see in the diagram along the length of the chromosome.

1517

03:09:03.864 --> 03:09:12.354

You'll see a series, a little red and blue dots, and the little red ones represent that are integrated in the same orientation.

1518

03:09:12.809 --> 03:09:21.180

As the chromosome, so they point to the right and then below, you see the ones that are integrated in the episode orientation, they point to the left.

1519

03:09:21.180 --> 03:09:27.090

And in the middle, you see the distribution of progresses when they're used.

1520

03:09:27.090 --> 03:09:38.309

To, in fact, human tbmc and it's obvious from just a glance at how remarkably similar the distributions are when is IV infects human cells. And in fact, human cells.

1521

03:09:38.309 --> 03:09:46.530

But that's not really the question that was initially posed. The question is whether or not savvy is in the same sort of places.

1522

03:09:46.530 --> 03:09:56.370

But, in fact, infects MCAT, because this is supposed to be an individual model. And what was done at the bottom, was that that is data.

1523

03:09:56.370 --> 03:09:59.184

Describing the distribution of ESA integration sites in,

1524

03:10:00.774 --> 03:10:05.155

but to facilitate the comparison in this particular case,

1525

03:10:05.155 --> 03:10:16.165

those data were mapped the savvy integration sites in the CAC were mapped to the human chromosome and you can do that because there's enough similarity in human and the CAC.

1526

03:10:16.469 --> 03:10:28.290

Genome that about 75% of the integration sites in mechanics and be directly mapped to humans. And this demonstrates quite clearly that the overall distribution is extremely similar.

1527

03:10:28.290 --> 03:10:31.649

Next slide please. So.

1528

03:10:31.649 --> 03:10:36.000

The other question of course, is whether once the infection is done in the tax.

1529

03:10:36.000 --> 03:10:44.069

Is the clonal expansion of the infected cells in MCAT solar to the infected cells humans and it is.

1530

03:10:44.069 --> 03:10:51.659

More than a 100 individual clones of infected cells were are detected and samples taken from mechanics.

1531

03:10:51.659 --> 03:11:00.780

Approximately 20% of the Pro viruses in the on therapy samples were in ponds and 6 of the 7 largest clouds were found, and at least 2 different tissues.

1532

03:11:01.104 --> 03:11:13.944

And that's important, because it says that once the cells clinically expand, they don't necessarily stay in 1 spot or 1 tissue. But the members of the clone can be distributed at least in several different tissues and the CAC model.

1533

03:11:14.514 --> 03:11:16.614

And that's actually similar to what goes on in humans.

1534

03:11:16.950 --> 03:11:28.979

Next please, there was the clones arise early in mechanics. There was 1 clone that was found in the sample taken only 2 weeks after an initial infection.

1535

03:11:28.979 --> 03:11:40.079

And that clone was found in the tissue sample, taken a year later, which says that the clones are relatively stable. 5 additional claws were seen 4 weeks after the initial infection.

1536

03:11:40.079 --> 03:11:47.010

Next please, and what this tells you, and I haven't showing you the human data, but the data are published.

1537

03:11:47.010 --> 03:12:00.690

What this shows you is that the clonal expansion of s I. V, infected cells in the CACs is really very similar to the clonal expansion of the infected cells in humans. And this serves to validate the use of the MCAT system.

1538

03:12:00.690 --> 03:12:08.819

As a tool to study clonal expansion and to do experiments in that system that you just can't do with infected humans.

1539

03:12:08.819 --> 03:12:11.819

And last, but not least next slide please.

1540

03:12:11.819 --> 03:12:24.270

I wanted to mention barcoded so 1 of the 1 of the problems that 1 faces, particularly in experiments in which infections are done in mechanics.

1541

03:12:24.270 --> 03:12:35.004

Is that you have very large numbers of viruses and in many cases, there's no way with the conventional infection with a virus no way to tell those viruses apart.

1542

03:12:35.844 --> 03:12:40.434

And there are a number of experiments many of which I think are obvious in, which it would be very helpful.

1543

03:12:40.860 --> 03:12:45.450

To be able to independently track thousands of different viruses in Viva.

1544

03:12:45.450 --> 03:12:48.989

Under circumstances in which the viruses would not.

1545

03:12:48.989 --> 03:12:52.229

Uh, be marked with mutations, which might affect.

1546

03:12:52.229 --> 03:12:59.940

Their individual behavior, and what was done was to find a way to put a sequence barcode.

1547

03:12:59.940 --> 03:13:08.430

Into the viral genome, it does not interfere with the replication of virus, nor does it do a different sequences at this position.

1548

03:13:08.430 --> 03:13:23.340

Affect the behavior of the individual viral strains, but they present or permit the use of this very nice molecular marker. And so this, the little red segment that's labeled and here.

1549

03:13:23.340 --> 03:13:35.760

Is a series of random sequences, and because each viruses separately tagged with its own sequence, that virus, and its progeny can be carefully tracked in vibo and this.

1550

03:13:35.760 --> 03:13:41.459

Taking together with the use of integration site analysis.

1551

03:13:41.459 --> 03:13:52.950

Allows a kind of monitoring of the behavior of both infected cells and infected viruses. It was not previously possible in the system and I'll stop there last slide. Please.

1552

03:13:52.950 --> 03:13:56.250

Thank you. Great. Thank you. Steve.

1553

03:13:57.084 --> 03:14:11.725

Okay, so now we're going to open it up for questions related to the basic translation and clinical research capability presentations that we just add again. Please enter all questions in the chat box. It looks like we may have been able to fix the function.

1554

03:14:11.905 --> 03:14:20.215

So, that questions can be posted to everyone that we can see, right now, we've got the 1st few questions that were posted were posted for.

1555

03:14:21.000 --> 03:14:32.575

Dr. scout's presentation and he mentioned he wasn't going to be around until he was only going to be able to be available until noon, but he did answer those questions in the chat box. So we're not going to go go through those.

1556

03:14:32.875 --> 03:14:40.254

But you're welcome to take a look plus all the questions and answers will be posted in the Q and a format after the event.

1557

03:14:40.559 --> 03:14:43.889

So, we do have 1 question for to now.

1558

03:14:43.889 --> 03:14:50.639

Uh, uh, it regards, uh, the cloud computing, cloud, cloud, application delivery.

1559

03:14:50.639 --> 03:14:54.030

An ecosystem beyond the awarded contractor.

1560

03:14:54.030 --> 03:14:55.975

At the RTC organization,

1561

03:14:56.215 --> 03:15:02.004

what internal or external organizations would be involved in activities,

1562

03:15:02.004 --> 03:15:03.715

such as interface development O,

1563

03:15:03.805 --> 03:15:04.194

M,

1564

03:15:04.434 --> 03:15:12.385

change management with respect to new features and functionality performance optimization and other required areas.

1565

03:15:15.209 --> 03:15:18.239

Hi, Jason can you can you hear me? Okay? Yes.

1566

03:15:18.239 --> 03:15:30.030

Good this is 1 where I prefer to fake that I was muted. No, I think that the, the questioner raises a really good point and a.

1567

03:15:30.030 --> 03:15:36.299

The, the, we can dig in and get some examples, but it is true that there are.

1568

03:15:36.954 --> 03:15:45.415

A critically important feature of the RTC contractors, the ability to work with a lot of different providers, and a lot of different institutions.

1569

03:15:45.864 --> 03:15:59.754

So there will be a whole host of players, depending on the specific project, you mentioned, to interface development, and you saw the just a list of that are involved.

1570

03:16:00.024 --> 03:16:02.754

So there is a need to really coordinate.

1571

03:16:02.754 --> 03:16:15.024

There's a lot of coordination that goes on at the higher level when they bring together these technical infrastructure pieces in it cuts across all from the science all the way down to the very technical pieces.

1572

03:16:15.024 --> 03:16:21.834

So it's not a trivial undertaking. And it's not a single vendor process.

1573

03:16:21.834 --> 03:16:33.655

It includes some collaborations with a consortium grand holders, and almost every manner of a mechanism support and interaction. You can imagine.

1574

03:16:34.020 --> 03:16:37.229

Thank you.

1575

03:16:38.819 --> 03:16:43.739

Okay, so that's the only question we have so far there was another question with regards to.

1576

03:16:43.739 --> 03:16:55.020

A contractor and subcontractor support and staff numbers and what not and that's going to be addressed this afternoon. The business operations section.

1577

03:16:55.020 --> 03:17:02.940

So, we want to address that at the moment and again, if there's any questions, please enter in the chat box.

1578

03:17:02.940 --> 03:17:06.270

We've got about 5 minutes before the lunch break.

1579

03:17:07.590 --> 03:17:13.709

And if we don't get any questions in the next 30 seconds or so, I think we'll break a little early.

1580

03:17:25.315 --> 03:17:31.495

Again, our thanks to the presenters in this section of talks very, very.

1581

03:17:31.709 --> 03:17:38.430

Thorough albeit compressed as we needed to be today, but.

1582

03:17:38.430 --> 03:17:46.379

As Dr sharpness mentioned earlier it is like a fire hose and all the slides will be posted as well as the.

1583

03:17:46.379 --> 03:17:50.639

Uh, reporting for today to go back to.

1584

03:17:50.639 --> 03:17:55.709

And try to digest more of this of all this information.

1585

03:17:57.569 --> 03:18:06.629

Silence.

1586

03:18:09.450 --> 03:18:14.969

So, I'm not seeing any more questions come in. I think we're going to go ahead and.

1587

03:18:14.969 --> 03:18:22.379

Call it lunch a few minutes early we're going to adjourn for now.

1588

03:18:22.379 --> 03:18:26.639

Uh, resume the meeting at 115 the Eastern time.

1589

03:18:26.639 --> 03:18:33.149

Uh, at that time, we'll start the core research services block of of presentations.

1590

03:18:33.149 --> 03:18:41.579

So everybody have a nice lunch, or maybe a breakfast if you're on the West Coast and we'll see you at 115 Eastern. Thanks.

1591

03:19:18.090 --> 03:19:25.020

A, next set of speakers are going to be presenting on the core research services and capabilities at the.

1592

03:19:25.020 --> 03:19:33.389

A reminder that we ask all questions, be entered into the chat function of Webex and if possible to list the topic of each.

1593

03:19:33.389 --> 03:19:39.120

Uh, from each section, which that your question pertains to and That'll help us sort out.

1594

03:19:39.120 --> 03:19:42.389

And divvy up the questions to the presenters.

1595

03:19:42.389 --> 03:19:51.479

All right, so 1st, up please welcome from the biological testing branch in the division of cancer treatment and diagnosis at.

1596

03:19:51.479 --> 03:19:58.889

Dr. valenta howling said she's going to be presenting the animal sciences modeling and pathology services. Linda.

1597

03:19:58.889 --> 03:20:02.069

Next lot, thank you next slide.

1598

03:20:02.995 --> 03:20:17.065

And again, next slide for the animal programs, and MTI Frederick provide animal research support, including animal husbandry as well as build technical support director, campus, houses, rodents, frogs and fish.

1599

03:20:17.424 --> 03:20:24.385

But the animal program actually manages a non human variable on the campus along with providing veterinarian,

1600

03:20:24.385 --> 03:20:39.084

administer administrative support for other species that are housed on animal Phil facilities both in Frederick and

Bethesda are fully accredited in Frederick the Vive area house over 350,000 animals largely rodents.

1601

03:20:39.114 --> 03:20:46.584

They support the center for cancer research where there's investigator driven research,

1602

03:20:46.645 --> 03:20:49.704

the division of cancer treatment and diagnosis,

1603

03:20:49.704 --> 03:20:58.915

which is developed the patient derived models as well as does preclinical drug testing and pharmacode dynamic analyses.

1604

03:20:59.575 --> 03:21:02.965

The division of cancer biology.

1605

03:21:05.364 --> 03:21:07.555

And other Institute,

1606

03:21:08.094 --> 03:21:08.784

Additionally,

1607

03:21:08.844 --> 03:21:13.135

other federal agencies can be supported through inter agency agreements,

1608

03:21:13.555 --> 03:21:14.965

and with national Labs,

1609

03:21:14.995 --> 03:21:17.274

a cancer virus program,

1610

03:21:17.604 --> 03:21:18.475

these facilities,

1611

03:21:18.475 --> 03:21:26.545

our operated as barrier facilities with full clothing changes and regular health monitoring of all facilities occurs.

1612

03:21:26.545 --> 03:21:31.315

So that we can maintain the animals at the highest health status possible next slide.

1613

03:21:33.930 --> 03:21:42.565

The animal program provides research support for diverse research portfolio from developmental biology to anti cancer,

drug evaluations.

1614

03:21:42.954 --> 03:21:55.915

These services provide individual Pi as well as entire programs with support the services include daily animal husbandry as well as professional animal program staff as shown on the slide.

1615

03:21:56.125 --> 03:21:59.514

Whose expertise can be called upon by principal investigators,

1616

03:21:59.514 --> 03:22:04.614

individual researchers as needed this systems provides a support framework,

1617

03:22:04.614 --> 03:22:06.805

or by highly skilled scientific staff,

1618

03:22:06.805 --> 03:22:11.965

within the animal program can provide the expertise for complex animal research techniques.

1619

03:22:12.504 --> 03:22:18.295

So that the individual researchers laboratories don't need to develop the specialized skills.

1620

03:22:18.690 --> 03:22:32.485

And yet they benefit from those skills existing, this allows the individual labs to focus on optimizing their science. And their particular skills the services include operating, wrote an imaging facility.

1621

03:22:32.485 --> 03:22:36.444

As you heard a little earlier this morning operating a germ free animal,

1622

03:22:36.444 --> 03:22:38.125

breeding and research facility,

1623

03:22:38.125 --> 03:22:44.665

which supports multiple institutes providing veterinary molecular pathology support,

1624

03:22:46.045 --> 03:22:49.495

providing support to the patient arrives in the graph models repository,

1625

03:22:49.825 --> 03:22:53.034

which develops patient drive models,

1626

03:22:53.514 --> 03:22:58.704

characterize them and provide them to the research community through the repository services,

1627

03:22:59.125 --> 03:23:04.375

and they conduct complex animal procedures as requested by the investigators next slide.

1628

03:23:06.145 --> 03:23:08.094

So you heard earlier about the small Adam,

1629

03:23:08.184 --> 03:23:08.485

Adam,

1630

03:23:08.545 --> 03:23:10.795

Adam animal imaging program,

1631

03:23:11.334 --> 03:23:20.844

it does support individual researchers and individual investigators research with all the variety of imaging modalities and techniques you heard about,

1632

03:23:21.145 --> 03:23:21.295

and,

1633

03:23:21.295 --> 03:23:21.715

as you heard,

1634

03:23:21.715 --> 03:23:28.254

from Dr Jacobs this morning it also supports the cancer imaging program within the division of cancer treatment and diagnosis,

1635

03:23:28.915 --> 03:23:32.485

whose mission includes characterizing anesthetic lesions advice,

1636

03:23:32.485 --> 03:23:38.334

implanted with the patient derived models will come to that here in a minute.

1637

03:23:39.024 --> 03:23:42.444

These sensitive imaging techniques identify various features of.

1638

03:23:43.014 --> 03:23:56.184

Associated with the tumor and its growth, including detecting metastatic lesions, characterizing tumor vascularization and assessing tumor metabolism as you can see from the various images as well.

1639

03:23:56.184 --> 03:24:01.975

With the images earlier today there's a variety of techniques and methodologies that are available.

1640

03:24:02.274 --> 03:24:16.194

And they all require highly trained skilled staff, which is difficult for an individual lab to provide, but with these shared resources, it becomes possible for many investigators to benefit next slide.

1641

03:24:18.954 --> 03:24:25.915

So we have a technically skilled, scientifically knowledgeable, molecular histology laboratory. It's operated within the animal program.

1642

03:24:26.245 --> 03:24:39.264

It supports routine animal health evaluations by providing rodent hematology clamp taf services with histology by qualified Mary pathologist.

1643

03:24:39.565 --> 03:24:52.344

But it also provides advanced support for a variety of scientific studies from doing micro rake construct through laser Micro to section then enriching for targets within samples.

1644

03:24:52.674 --> 03:25:05.545

So that can be run on, on a subset of cells bound within applied etc as seen here. The actually provides has provided histological confirmation.

1645

03:25:06.354 --> 03:25:15.924

That there are human tumor metastases present in the mouth liver. You see there in the middle of the slide, and you had earlier Dr jacob's presentation.

1646

03:25:15.924 --> 03:25:23.995

You actually saw the images that identified the presence of these metastases within the liver of the mouth alone with that.

1647

03:25:24.625 --> 03:25:36.625

They, they establish a variety of histological and histological techniques as needed by investigators and the other example shown here was in a separate study.

1648

03:25:37.135 --> 03:25:43.944

They were able to confirm that there are clots distributed throughout the organs of mice that had been implanted with.

1649

03:25:44.459 --> 03:25:58.920

Patient derived tumor that actually replicates the feature scene in humans with malignancy associated, which is actually a common cause of death and cancer patient next slide.

1650

03:26:01.284 --> 03:26:01.434

So,

1651

03:26:01.434 --> 03:26:04.075

we have an in house animal diagnostic service,

1652

03:26:04.075 --> 03:26:16.825

which really enhances our early discovery and control of adventitial road pathogens this in how laboratory provides rapid assay turnaround times without the time lost with samples have to be shipped outside vendors.

1653

03:26:17.094 --> 03:26:26.424

That typically loses 2 to 3 days at the profit on what the health monitoring this lab provides mouse, Gina typing and DNA fingerprinting services to investigators.

1654

03:26:26.784 --> 03:26:41.575

So that the individually investigators aren't required to develop and maintain these methods in their laboratories there's another feature that allows individual research labs to focus on their unique skills qualities while the services provided take

1655

03:26:41.575 --> 03:26:45.295

care of these need next slide.

1656

03:26:48.235 --> 03:26:51.864

So we have the availability of a skilled technical staff,

1657

03:26:51.864 --> 03:27:06.715

within the note about accessibility they provide with this provides opportunities for multiple laboratory groups to work with germ free as well as defined floor rodents as you are probably aware these rodents contribute to our knowledge of the impact of the hosts gut

1658

03:27:06.715 --> 03:27:12.625

floor on the immune system and the impact of that on cancer in its development as well as other.

1659

03:27:13.825 --> 03:27:18.774

Pathological biological phenomenon along with breeding and maintaining the germ free.

1660

03:27:19.104 --> 03:27:33.534

The facility actually provides the scientific and technical support to multiple research groups, providing experimental procedures of germ, free mice while maintaining while maintaining their germ free status as you can see from the images.

1661

03:27:33.534 --> 03:27:45.953

Their particular skills get that is required to work in these facilities and behind these Sydney flexible, flexible, fill isolated.

1662

03:27:46.559 --> 03:27:54.389

It requires a high level of skill and modification of a lot of procedures. And so by having this.

1663

03:27:54.415 --> 03:28:09.204

Shared service available again individual research groups don't have to refine the techniques. They can depend on highly skilled staff that are already available. 1 of the more recent additions to this operation is about containment racks.

1664

03:28:09.204 --> 03:28:22.254

You can see picture there the upper right. This provides an opportunity to reconstitute germ free and 5 flora mice with patient, equal cultures as well as other potential pathogens.

1665

03:28:23.004 --> 03:28:23.545

Next slide,

1666

03:28:25.825 --> 03:28:29.934

so we do have a genome modification core here within the animal program,

1667

03:28:30.295 --> 03:28:41.245

and it offers assistance to folks who are interested in modifying the genome through crisper or other methodologies.

1668

03:28:41.545 --> 03:28:55.225

They offer technical advice and expertise on gene editing. Both sell, sell, sell lines, primary, sell lines as well as working with the mouth modeling core to facilitate crisper mediated mouth model generation.

1669

03:28:56.065 --> 03:29:01.284

So it's very helpful to individual research groups. Next slide.

1670

03:29:01.799 --> 03:29:09.989

There are over 500 unique strains of my set. The Frederick.

1671

03:29:09.989 --> 03:29:24.954

Campus at any given time and so 1 of the valuable services that the animal program provides is crowd preservation and then regeneration of mice so that we don't have to have thousands of strains breeding at any given time.

1672

03:29:25.375 --> 03:29:36.684

Additionally, this group also generates new strengths by carrying various alterations as needed for individual research groups. Typically, they make between 50 and 100 new models per year.

1673

03:29:36.684 --> 03:29:51.145

These are typically support primarily, although other, and I are also supported this service provides live mice, designed to provide the new models needed for ongoing studies.

1674

03:29:51.145 --> 03:29:54.805

This group also manages the mouse repository,

1675

03:29:54.805 --> 03:30:00.415

which is a program from the division of cancer biology it contributes,

1676

03:30:00.415 --> 03:30:03.834

or distributes preserved from,

1677

03:30:03.864 --> 03:30:11.334

and embryos for reconstituting many of the well characterized mouse models that have been collected over the last 18 years or so.

1678

03:30:11.334 --> 03:30:20.965

And they also have more than 1500 with conditional expression that are also available for distribution.

1679

03:30:25.590 --> 03:30:31.979

That's the last slide I do believe and I appreciate your attention. Thank you.

1680

03:30:31.979 --> 03:30:46.649

Great thanks a lot Melinda. All right let's move on to se, development. Execution. This is going to be presented by Dr Michael develop Antonio from the division of cancer treatment and diagnosis and Michael.

1681

03:30:46.649 --> 03:30:55.860

Great thanks, Jason. So, as Jason said, I'm going to talk to you today about the essay development and execution activities that are conducted up at Frederick National Lab.

1682

03:30:55.860 --> 03:30:59.819

In support of various initiatives at the next slide, please.

1683

03:30:59.819 --> 03:31:04.350

But 1st, I'm just like to give you a little bit of background information.

1684

03:31:04.350 --> 03:31:08.520

And then I'll come to you some specific examples of assets that have been.

1685

03:31:08.520 --> 03:31:11.520

Developed up in progress next slide please.

1686

03:31:11.520 --> 03:31:17.729

So these essays support basic science.

1687

03:31:17.729 --> 03:31:23.100

Preclinical research, including as you just heard from Melinda, various animal models.

1688

03:31:23.100 --> 03:31:28.920

And I, in the animal toxicology studies case studies, PD studies, et cetera.

1689

03:31:28.920 --> 03:31:34.979

As well, as clinical trials in the form of both non clear essays for relative studies.

1690

03:31:34.979 --> 03:31:39.149

And as his performed under clear guidance and guidelines.

1691

03:31:39.149 --> 03:31:42.540

That direct patient management next slide please.

1692

03:31:44.879 --> 03:31:49.620

There are numerous purposes that's listed here for which these essays serve and I'm not going to.

1693

03:31:49.620 --> 03:31:56.159

Go through them, but suffice it to say that these are only a smattering of the different.

1694

03:31:56.159 --> 03:31:59.579

That are developed up in the next 5 please.

1695

03:32:01.290 --> 03:32:10.770

What I've listed here are some of the different laboratories of Frederick national labs that perform essays and asset development.

1696

03:32:10.770 --> 03:32:17.370

Several of these, you've heard about already this morning, such as nanotechnology from Peter.

1697

03:32:17.370 --> 03:32:25.170

The omit capabilities from Dr stout had throughput screening from production facilities from Jason.

1698

03:32:25.170 --> 03:32:28.200

And the national mission programs.

1699

03:32:28.200 --> 03:32:31.379

That you heard from.

1700
03:32:31.379 --> 03:32:35.159
Uh, Chris Kane, Gary Robinson and Jim Carrey. So I'm not gonna go through those.

1701
03:32:35.159 --> 03:32:38.370
But there are also laboratories up and Frederick.

1702
03:32:38.370 --> 03:32:44.639
That develop assays for mechanism of action studies pharmacode dynamics. pharmacokinetics.

1703
03:32:44.639 --> 03:32:51.389
And toxicology to name a few and again, I'll go through some of those assays later in the presentation.

1704
03:32:51.389 --> 03:32:57.479
Next slide please the types of bio specimens.

1705
03:32:57.479 --> 03:33:01.020
Which are evaluated are also quite diverse.

1706
03:33:01.020 --> 03:33:04.739
Ranging from tissues to.

1707
03:33:04.739 --> 03:33:10.829
So live a urine in stool, buckle, mucosa or nasal swabs. That's in the case for.

1708
03:33:10.829 --> 03:33:16.590
Uh, current coca testing, blood circulating tumor cells nucleic acids.

1709
03:33:16.590 --> 03:33:20.430
Looking at the X's homes and antibodies.

1710
03:33:21.659 --> 03:33:31.350
Next slide please and these essays utilize a broad spectrum of methodologies and technologies. Some of which are listed here.

1711
03:33:31.350 --> 03:33:36.719
That are commonly used for pharmacode dynamic essays and omits.

1712
03:33:36.719 --> 03:33:40.319
I'm not going to go through those.

1713

03:33:40.319 --> 03:33:43.860

And as new technologies are developed.

1714

03:33:43.860 --> 03:33:51.420

Those need to be brought online and in some instances, perhaps that may even involve Co development of those technologies.

1715

03:33:51.420 --> 03:33:56.670

With outside companies through the secret as that you've heard about earlier today.

1716

03:33:58.170 --> 03:34:03.870

Next slide please. So now I'm going to turn to a couple of examples.

1717

03:34:03.870 --> 03:34:08.579

Or several examples actually have assays that have been developed at the Frederick national ad.

1718

03:34:08.579 --> 03:34:13.770

Specifically for a National Cancer Institute next 5 things.

1719

03:34:13.770 --> 03:34:22.530

So, through the s, and L is established, what is known as national clinical laboratory network.

1720

03:34:22.530 --> 03:34:28.500

Or support events, sponsored precision medicine trials, conducted through the experimental Therapeutics.

1721

03:34:28.500 --> 03:34:32.399

Clinical trials network otherwise known as.

1722

03:34:32.399 --> 03:34:37.350

These are phase 1 and phase 2 trials of investigational agents.

1723

03:34:37.350 --> 03:34:42.209

Or novel, combination therapies, and under these studies BIOS specimens are collected.

1724

03:34:42.209 --> 03:34:46.739

And ship to a central viral repository where they may be processed and stored.

1725

03:34:46.739 --> 03:34:52.319

Prior to distribution to the appropriate laboratory, that's going to be conducting the trial associated assets.

1726

03:34:52.319 --> 03:34:56.670

Some of these laboratories are indicated as indicated.

1727

03:34:56.670 --> 03:34:59.879

In the orangish red boxes are.

1728

03:34:59.879 --> 03:35:02.909

Housed at Frederick National Laboratory itself.

1729

03:35:02.909 --> 03:35:07.799

While other networks are subcontractors of fnl.

1730

03:35:07.799 --> 03:35:11.430

And these subcontractors and very importantly have been qualified.

1731

03:35:11.430 --> 03:35:15.000

To perform the assays that they're being contracted to perform.

1732

03:35:15.000 --> 03:35:20.370

So, the use of this network implements, standardization of the assay is being conducted.

1733

03:35:20.370 --> 03:35:23.459

Under the various clinical trials.

1734

03:35:23.459 --> 03:35:28.799

Thereby imparting confidence in enabling a cross trial comparison of the generated data.

1735

03:35:29.850 --> 03:35:35.610

Next life this and this slide just shows some of the.

1736

03:35:35.610 --> 03:35:38.819

Core genomic assets that are being supported.

1737

03:35:38.819 --> 03:35:42.540

By the these include the online cancer.

1738

03:35:42.540 --> 03:35:45.629

Targeted gene panel known as afraid.

1739

03:35:45.629 --> 03:35:49.350

All that some sequencing are sequencing.

1740

03:35:49.350 --> 03:35:52.799

And the 500 targeted gene panel.

1741

03:35:52.799 --> 03:35:55.829

Or circulating tumor DNA.

1742

03:35:56.725 --> 03:36:09.264

Next slide so awesome. What I is trying to measure is the activation of the pathway the correlation of a specific protein.

1743

03:36:10.165 --> 03:36:13.645

We found up in Frederick labs that many years ago.

1744

03:36:13.950 --> 03:36:19.829

That rapid freezing of the tissue often within 5 minutes is necessary to preserve the possible related state.

1745

03:36:19.829 --> 03:36:23.459

The left graph shows, a level of total net protein.

1746

03:36:24.780 --> 03:36:29.309

While the graph on the right shows, the level of net phosphorylated protein.

1747

03:36:29.309 --> 03:36:32.940

Specifically, specifically at high rasheen recipes.

1748

03:36:32.940 --> 03:36:37.170

1234 and 1235 and so what you can see.

1749

03:36:37.170 --> 03:36:43.139

Is on the left graph the total net protein is quite stable after 8 minutes.

1750

03:36:43.139 --> 03:36:46.260

Whereas the phosphorylated form of the protein.

1751

03:36:46.260 --> 03:36:51.629

Degrades quite rapidly and is down to about 50%.

1752

03:36:51.629 --> 03:37:03.360

Out at 4 minutes already so often our biopsy protocols require rapid preservation and documentation of the scheme of time.

1753

03:37:03.360 --> 03:37:08.549

In order to ensure the validity of the results next slide please.

1754

03:37:11.129 --> 03:37:16.260

Within NCI, at least we've also been developing.

1755

03:37:16.260 --> 03:37:21.540

A wealth of pharmacode dynamic essays and several of those that are listed here.

1756

03:37:21.540 --> 03:37:27.510

On the right hand side in terms of cell death we're looking at not only a apoptosis.

1757

03:37:27.510 --> 03:37:32.549

But fair and other forms of cell that.

1758

03:37:32.549 --> 03:37:36.299

We have essays for looking at the damage repair and cell cycle.

1759

03:37:36.299 --> 03:37:39.959

The transition from epithelia to cells.

1760

03:37:39.959 --> 03:37:44.069

And others that are listed here on the right.

1761

03:37:44.069 --> 03:37:56.459

Next slide please. So this slide demonstrates the increased accuracy that can be obtained when you're using a tumor segmentation. Biomarker.

1762

03:37:56.459 --> 03:38:00.149

So that you're only including tumor cells in the analysis.

1763

03:38:00.149 --> 03:38:05.579

What's shown on the left is a standard agent, each staining pathologist and they've indicated.

1764

03:38:05.579 --> 03:38:08.969

In the green outlines those areas of the tissue.

1765

03:38:08.969 --> 03:38:12.780

That corresponds to material.

1766

03:38:12.780 --> 03:38:22.950

On the far, right is that same section stained with an antibody against the cross correlated form of NBS 1 protein.

1767

03:38:22.950 --> 03:38:26.340

Which is a DNA damage response signal.

1768

03:38:26.340 --> 03:38:31.139

In red, and the nuclear deputy staining is indicated in blue.

1769

03:38:32.940 --> 03:38:37.709

In order to determine how many of the tumor cells actually contain a damaged signal.

1770

03:38:37.709 --> 03:38:42.299

It's far easier when the tumor cells are visualized as indicated in the center panel.

1771

03:38:42.299 --> 03:38:45.600

With a tumor marker here, we're using data.

1772

03:38:47.129 --> 03:38:50.610

And the increased accuracy can be seen in the graphs at the bottom.

1773

03:38:50.610 --> 03:38:55.500

We're showing the percent of tumor cells with DNA damage.

1774

03:38:55.500 --> 03:38:59.159

Pre on the left and post.

1775

03:38:59.159 --> 03:39:04.950

Cycle 1 day, 8 treatment with the DNA damage inducing agent.

1776

03:39:04.950 --> 03:39:11.459

The leftmost graph is with the use of the segmentation marker and the 2nd graph.

1777

03:39:11.459 --> 03:39:15.600

Is the same analysis without using the tumor segmentation marker?

1778

03:39:15.600 --> 03:39:23.850

Where 1 is more likely, obviously to include non tumor cells and so the percentage of cells that are positive decreases.

1779

03:39:24.989 --> 03:39:29.370

And also on the graphs on the right what you're seeing.

1780

03:39:29.370 --> 03:39:33.329

Is the total number of nuclei which needed to be analyzed?

1781

03:39:33.329 --> 03:39:43.709

And so we're analyzing, so, not surprisingly without the tumor segmentation marker the graph on the right shows that many more quickly. I were included in that analysis.

1782

03:39:45.540 --> 03:39:48.569

Next slide please.

1783

03:39:48.569 --> 03:39:52.739

So this slide just shows and other panel of DNA damage biomarkers.

1784

03:39:52.739 --> 03:39:56.700

Specifically proteins involved in mismatch, repair pathways.

1785

03:39:56.700 --> 03:40:01.110

And I just want to point out that as many of you may be well aware.

1786

03:40:01.110 --> 03:40:06.569

Trying to identify antibodies that are really specific for the proteins that you're trying to measure.

1787

03:40:06.569 --> 03:40:09.690

Can be rather frustrating and disheartening.

1788

03:40:09.690 --> 03:40:13.139

And so for all the antibodies that we use in our essays.

1789

03:40:13.139 --> 03:40:17.850

We go through a painstaking process of identifying and qualifying antibodies.

1790

03:40:17.850 --> 03:40:21.899

To determine and demonstrate that they're highly specific.

1791

03:40:21.899 --> 03:40:27.299

For the proteins that we're looking at detecting, and that they show a lot a lot reproducibility.

1792

03:40:27.299 --> 03:40:35.639

So, it needs this metric repair deficient cell lines, top 1, being colon that no carcinoma and the bottom of pancreatic no carcinoma.

1793

03:40:35.639 --> 03:40:41.670

What you can see in the top, is it contaminant loss of 1 and 2.

1794

03:40:41.670 --> 03:40:48.120

Whereas in the bottom, you see loss of age, 6 and a message to protein and this is.

1795

03:40:48.120 --> 03:40:52.770

Well, known, but again, this is sort of a proof of concept that our antibodies.

1796

03:40:52.770 --> 03:40:58.170

Were actually specific for what we were looking at next slide please.

1797

03:41:00.090 --> 03:41:11.700

So this is the last example, I'm going to give you and so what's being shown here is 1 of our apoptosis essays in, in this case, this is looking at the fall out there and dogs.

1798

03:41:11.700 --> 03:41:17.370

That were treated with 2 different tilt by summaries, 2 inhibitors that are known to induce DNA double strand breaks.

1799

03:41:17.370 --> 03:41:21.000

Those double strand breaks can be visualized with an antibody.

1800

03:41:21.000 --> 03:41:25.770

Specific for the phosphorylated form of the histone H2 a.

1801

03:41:25.770 --> 03:41:29.250

Protein which is known as an H2 X.

1802

03:41:29.250 --> 03:41:35.700

And upon DNA damage, and signaling by game age, 20 X.

1803

03:41:35.700 --> 03:41:39.270

You then downstream get cleavage of tasks for these 3.

1804

03:41:39.270 --> 03:41:48.780

And the induction of that, so the microscopy images clearly show there's a difference between the 2 different agents that are being evaluated.

1805

03:41:48.780 --> 03:41:54.000

The tumor and the patient treated on the top with the 7 7 6.

1806

03:41:54.000 --> 03:41:59.610

Shows that DNA damage 1st appears around 2 hours post treatment.

1807

03:41:59.610 --> 03:42:06.299

And that's followed at 4 hours by a apoptosis as indicated by the.

1808

03:42:06.299 --> 03:42:09.750

The red staining for the cleave test phase 3 proteins.

1809

03:42:11.190 --> 03:42:15.690

The tumor patient from the patient on the bottom tree with a different agent.

1810

03:42:15.690 --> 03:42:19.500

Again, directed against the same protein 2.

1811

03:42:19.500 --> 03:42:23.850

Shows quite a different.

1812

03:42:23.850 --> 03:42:31.530

A different picture so what you're seeing there is these simultaneous induction of DNA damage, and a apoptosis.

1813

03:42:31.530 --> 03:42:36.149

At 2 hours, and this disappears by 6 hours after treatment.

1814

03:42:36.149 --> 03:42:41.520

And this is just quantitative over in the graphs on the right hand side.

1815

03:42:41.520 --> 03:42:48.600

But the point I want to make here is that, you know, this slide really demonstrates the importance of looking at multiple points.

1816

03:42:48.600 --> 03:42:54.180

To determine what is the best time to obtain your bio specimen?

1817

03:42:54.180 --> 03:43:01.290

Or measuring your marker of interest if you were only looking at the 2 hour post treatment on the top.

1818

03:43:01.290 --> 03:43:06.149

You might come to the conclusion that DNA damages induced, but not sell that.

1819

03:43:07.620 --> 03:43:11.760

And so you can go to the next slide. I think this is my last 1.

1820

03:43:13.139 --> 03:43:17.969

So, I hope I've given you an idea of the different types of assays and formats.

1821

03:43:17.969 --> 03:43:22.680

That are developed for Frederick National laboratory for supporting various activities.

1822

03:43:22.680 --> 03:43:27.090

And I, thank you for your attention and I'll take questions when we get to the Q, a session.

1823

03:43:27.090 --> 03:43:38.905

Thanks Jason. Great. Thank you. Michael. All right now I'd like to welcome is Mary. Ann Henderson. She's a senior advisor for the division resources, and bio banking, and NCI.

1824

03:43:39.415 --> 03:43:47.965

She's going to be presenting details and information on the repositories and bio specimen processing at the RTC. So, Marianne take it away.

1825

03:43:48.270 --> 03:43:52.559

Thank you Jason. Could you advance the slides?

1826

03:43:52.559 --> 03:44:07.170

So all of our activity at the f, RTC, um, for repositories and by processing, um, is subject to, um.

1827

03:44:07.170 --> 03:44:11.700

Regulations guidelines and best practices that.

1828

03:44:12.084 --> 03:44:27.055

We require the f RBC contractor to adhere to, um, I won't read through all of these, but, um, they're your your likely subjects for and, um, and repository standards.

1829

03:44:27.299 --> 03:44:32.969

The next line, the.

1830

03:44:33.235 --> 03:44:35.364

The activities within the BI,

1831

03:44:35.364 --> 03:44:36.295

molecular,

1832
03:44:36.325 --> 03:44:36.774
um,

1833
03:44:36.805 --> 03:44:48.534
work at the also are required to maintain strict quality control and quality assurance programs to maintain the integrity of the biological materials,

1834
03:44:48.684 --> 03:44:49.555
being collected,

1835
03:44:49.735 --> 03:44:54.625
processed acid stored and shared across the entire contract.

1836
03:44:54.899 --> 03:45:04.709
Next slide, I'll start with describing the Frederick that f RTC repositories.

1837
03:45:05.395 --> 03:45:14.754
Next slide the f, RTC repositories are currently housed in 4 buildings.

1838
03:45:15.114 --> 03:45:28.254
3 of these buildings are on the NCI app, Frederick campus, and they are, and 1 large building is located off site in a least space in the Frederick area.

1839
03:45:28.559 --> 03:45:41.159
The repository support and CIA intramural, and some extra mural projects as well as an ID intramural and specific small collections from other Institutes of H.

1840
03:45:41.159 --> 03:45:50.040
Approximately 95% of all the buying material in the repositories are related to clinical and epidemiologic studies.

1841
03:45:50.040 --> 03:46:01.920
Approximately 5% of the support for ongoing basic research at NCI at Frederick and storage of materials is is housed in these repositories.

1842
03:46:03.059 --> 03:46:08.790
Right.

1843
03:46:09.924 --> 03:46:24.534
As noted the cross storage space for, by specimens at f, RDC are in both on campus and off campus on campus there are 25,000 square foot measurement of.

1844
03:46:26.340 --> 03:46:30.090
Area of repository space and.

1845
03:46:30.090 --> 03:46:33.090
Nearly 90.

1846
03:46:33.090 --> 03:46:39.059
90,000 square foot off campus site and for the total.

1847
03:46:39.059 --> 03:46:45.030
The existing infrastructure, um, includes power redundancy at these sites.

1848
03:46:45.030 --> 03:46:51.479
Including backup generators and additional connections for temporary generators as necessary.

1849
03:46:51.479 --> 03:46:58.979
The off campus warehouse space is conditioned and secured with state of the art monitoring for safety and security.

1850
03:46:58.979 --> 03:47:08.850
The on campus is inside the gates of the, um, 40 trick, which means that they have that security as well.

1851
03:47:08.850 --> 03:47:15.899
Ellen, to capacity is, um, is delivered through large.

1852
03:47:15.899 --> 03:47:29.579
Uh, does that are at the facilities, and there's regular delivery of those, and there's elementary to alert the and the vendor when that that, uh, capacity is needed to be refill.

1853
03:47:29.579 --> 03:47:37.350
And the repository management is done through a software package 2.

1854
03:47:37.350 --> 03:47:42.870
And there are 2 instances that cover the majority of the collections at their repository.

1855
03:47:42.870 --> 03:47:57.209
Next slide the current collections include over 19Million specimens. Most are stored at minus 80 degrees Celsius.

1856
03:47:57.209 --> 03:48:08.125
Also listed here are the current fleet of freezers at various temperatures, needed to support quality by assessments for the Government's research. You can see that.

1857

03:48:08.125 --> 03:48:15.565

The majority of the storage units are minus minus 80 and minus 150, mechanical and liquid nitrogen field.

1858

03:48:17.459 --> 03:48:21.510

Types next.

1859

03:48:25.290 --> 03:48:33.090

The capabilities that the government seeks in support of the Frederick repository program include.

1860

03:48:33.090 --> 03:48:40.739

State of the art technical expertise in the operations of repositories at the Frederick campus and offsite.

1861

03:48:40.739 --> 03:48:49.620

Expertise in handling and maintaining stored, clinical and nonclinical, biological specimens and agents.

1862

03:48:49.620 --> 03:48:54.209

Including, but not limited to human and animal specimens.

1863

03:48:54.209 --> 03:49:01.649

Frozen tissue, blood, whole blood serum, plasma, peripheral, blood cells, urine stool.

1864

03:49:01.649 --> 03:49:10.735

Formula formula and fix paraffin embedded blocks f. F. P slides other bodily fluids and environmental samples.

1865

03:49:11.125 --> 03:49:18.444

All of these are capped at out to or lower and there are no select agents within the repositories.

1866

03:49:19.495 --> 03:49:30.504

Expertise in repository management of ambient, that's room temperature and under gas and vacuum as well as low in ultra low temperatures.

1867

03:49:30.805 --> 03:49:36.444

And the various temperatures that are necessary for expertise are listed here.

1868

03:49:37.795 --> 03:49:48.625

Next slide in addition the contract support includes curating specimens,

1869

03:49:48.895 --> 03:49:50.875

technical personnel,

1870

03:49:50.875 --> 03:49:54.145
providing technical personnel for managing the repository,

1871
03:49:54.415 --> 03:49:55.045
including,

1872
03:49:55.045 --> 03:50:00.655
but not limited to the receipt inventory storage retrieval.

1873
03:50:00.930 --> 03:50:08.190
Distribution of specimens and samples and but monitoring of storage and transport units.

1874
03:50:08.754 --> 03:50:13.344
Manual and automated processing for the receipt inventory,

1875
03:50:13.344 --> 03:50:14.125
storage,

1876
03:50:14.364 --> 03:50:28.254
retrieval and distribution of standard 1 the and 2 deep are coded vials as well as automated formatted files where the barcode is usually found at the bottom of the 2.

1877
03:50:28.590 --> 03:50:37.469
Select packaging and training of IoT transportation processes domestically and internationally.

1878
03:50:37.469 --> 03:50:40.500
Preparation of inventory.

1879
03:50:40.500 --> 03:50:46.049
Monthly storage cost reports and other reports as required and requested.

1880
03:50:46.049 --> 03:51:00.149
Maintenance of required storage units and facilities as well as a documented and comprehensive disaster plan and emergency preparedness recipes to include pandemic.

1881
03:51:01.290 --> 03:51:05.250
Maintenance of Q2 C and Q. a programs.

1882
03:51:05.250 --> 03:51:12.540
And so piece for routine and emergency operations and Q a quality assurance reporting.

1883

03:51:13.194 --> 03:51:13.795

Next line,

1884

03:51:18.084 --> 03:51:18.985

and lastly,

1885

03:51:19.014 --> 03:51:24.084

the FF RDC contract support needed for repository operations,

1886

03:51:24.084 --> 03:51:32.694

include the provision of adequate safeguards and emergency capabilities for physical repositories and it systems.

1887

03:51:32.909 --> 03:51:44.040

Maintenance and update of specimen input, tracking storage and retrieval it systems. This is currently the, as I mentioned.

1888

03:51:44.040 --> 03:51:56.729

Which feed into the contractor financial systems to support monthly vial and study level charging for activities and storage to the government sample custodians.

1889

03:51:56.729 --> 03:52:02.729

So piece for daily, weekly, monthly, yearly, preventive maintenance.

1890

03:52:02.729 --> 03:52:13.260

This includes temperature monitoring gasket cleaning professional maintenance and calibration of the storage units per the manufacturers recommendations.

1891

03:52:13.260 --> 03:52:18.299

Complete record keeping for all maintenance procedures.

1892

03:52:18.299 --> 03:52:29.579

Procedures for repairing storage equipment and validating all new or repaired equipment, including appropriate record keeping that should be put in place.

1893

03:52:29.579 --> 03:52:39.360

Providing highly skilled staffed, current on state of the art technologies for manual and automated sample management.

1894

03:52:39.360 --> 03:52:42.780

To service, or a resource to the government scientists.

1895

03:52:42.780 --> 03:52:52.530

The adoption of new technologies in sample management, in support of bias specimen initiatives is at the direction of

the government.

1896

03:52:54.239 --> 03:53:02.069

Next slide now will move into the bio processing activities of the contract.

1897

03:53:02.069 --> 03:53:16.975

Next slide bio processing at the is a generalized key activity across the basic clinical and translational research program supported by the

1898

03:53:16.975 --> 03:53:17.665

contract.

1899

03:53:17.965 --> 03:53:21.684

You've heard about several of these activities earlier today.

1900

03:53:21.959 --> 03:53:28.920

It underpins all of the molecular research supported at the f RTC using human.

1901

03:53:28.920 --> 03:53:34.260

Non human animal, microbial, viral and environmental specimens.

1902

03:53:34.260 --> 03:53:43.079

The contract supports several centralized laboratories and additional dispersed capacity for specimen processing.

1903

03:53:43.079 --> 03:53:47.520

Next slide.

1904

03:53:47.520 --> 03:53:57.870

The facilities provide fresh and previously stored specimen processing and including.

1905

03:53:57.870 --> 03:54:01.260

Those for blood fractionation.

1906

03:54:01.260 --> 03:54:06.030

Buckle cell processing, ornate and DNA extraction.

1907

03:54:06.030 --> 03:54:13.500

Tbm is and see prior preservation and post storage processing, including aliquot.

1908

03:54:14.700 --> 03:54:19.500

Breathing of samples.

1909
03:54:19.500 --> 03:54:22.799
Lash freezing of tissue in liquid nitrogen.

1910
03:54:22.799 --> 03:54:30.719
And the administrative administration, and sample management of a normal donor program and.

1911
03:54:30.719 --> 03:54:43.260
The specimen processing of blood products, buckle cells and urine are for quality control, materials and specimens for Pre analytic factor research.

1912
03:54:43.260 --> 03:54:46.290
On the contract next slide.

1913
03:54:49.200 --> 03:55:03.329
The f, facilities also provide capacity for the separation and viable, uh, prior preservation of cell lines, including routine assessment of viability.

1914
03:55:03.329 --> 03:55:09.059
Prior preservation of red blood cells to maintain enzymatic activity.

1915
03:55:09.059 --> 03:55:14.280
Generation of primary cultures and established cell lines.

1916
03:55:14.280 --> 03:55:17.790
Large scale propagation of cell lines.

1917
03:55:17.790 --> 03:55:23.340
Nucleic acid extraction, including and.

1918
03:55:23.340 --> 03:55:30.479
Distribution of specimens these are shipping and receiving domestically and internationally.

1919
03:55:30.479 --> 03:55:34.079
Supporting field centers.

1920
03:55:34.079 --> 03:55:43.020
In collection procedures, equipment, material and Kit development and sample transportation to and from the sites.

1921
03:55:43.020 --> 03:55:55.020
Support for comprehensive approach to project planning and providing input on project design, laboratory activities,

logistical plans.

1922

03:55:55.020 --> 03:56:01.379

Budgeting activity, timelines, including generation as needed.

1923

03:56:01.379 --> 03:56:05.280

Next 1.

1924

03:56:05.280 --> 03:56:19.049

Some recent examples of bio processing activities at the RTC include rapid response for Colvin, 19 collection, support and bio specimen processing.

1925

03:56:19.049 --> 03:56:27.209

Support for the Connect cohort pilot, study, activities and Pre launch site collection activities.

1926

03:56:27.209 --> 03:56:36.329

Preparation and receipt of specimen collection kits to an trial participants.

1927

03:56:36.329 --> 03:56:40.409

Processed and extracted clinical specimens.

1928

03:56:40.409 --> 03:56:54.629

Participation in network activities for supported cancer, prevention, clinical trials, network, data, management, auditing, and coordinating center and the early detection Research network.

1929

03:56:54.629 --> 03:57:03.059

Processing and extracting and storage of thousands of research samples across the f.

1930

03:57:03.059 --> 03:57:10.500

And facilitation of sample and data management prior to and post asset apply specimens.

1931

03:57:11.520 --> 03:57:15.809

Next slide, thank you.

1932

03:57:16.764 --> 03:57:27.264

Great Thank you. Marianne. Okay. We're going to move on to Dr Dave gold steam. He's in the office to the director in the center for cancer research.

1933

03:57:27.594 --> 03:57:34.254

There'll be presenting molecular in cellular biology capabilities as well as some specific examples for us.

1934

03:57:34.500 --> 03:57:37.530

Dave, thanks, Jason. You hear me. Okay.

1935

03:57:37.530 --> 03:57:42.719

Yes, all right. Thanks. You can go to the next slide. Please.

1936

03:57:43.739 --> 03:57:52.379

Okay, so NCI, investigators have access to several centralized facilities through the pharmacy that offer.

1937

03:57:52.379 --> 03:58:02.100

A wide range of advanced technology scenarios of molecular and secular biology and I'll provide you a few examples during this presentation of the focus areas.

1938

03:58:02.100 --> 03:58:07.170

Which are defined by the overall the research goals of NCI.

1939

03:58:07.170 --> 03:58:20.370

And there's a mix of facilities that involve a significant consumable reagent costs, such as, like, single cell sequencing and next thing sequencing protein production, for example.

1940

03:58:20.370 --> 03:58:24.540

And these of facilities impose.

1941

03:58:24.540 --> 03:58:32.700

Of fee for service, whereas others offer collaborative interactions and services that are essentially funded by the divisions.

1942

03:58:32.700 --> 03:58:37.649

And these often lead to interactions often, lead to Co, op ship and top tier journals.

1943

03:58:37.649 --> 03:58:48.899

Well, provide experimental, experimental design, consultation, sample, quality, quality, control and primary data analysis to ensure receive the highest quality data.

1944

03:58:48.899 --> 03:58:56.250

They also are available for testing emerging technologies and delivering new capabilities to the scientific community.

1945

03:58:56.250 --> 03:59:09.479

There's synergy across the lives that insurers complementary technologies and pulling of expertise, deliver to deliver complete biotechnology solutions to major and Sierra research initiatives and programs.

1946

03:59:09.479 --> 03:59:24.000

The next slide please. So, perhaps the largest grouping of facilities offering offers a host and genome X technologies from standard next gen, sequencing approaches, such as.

1947

03:59:24.000 --> 03:59:36.959

Little X, Omar, whole genome sequencing transcript or chip seek, attacked, seek and so forth and they also offer long rate sequencing methods, such as Pat bio and Oxford national for.

1948

03:59:36.959 --> 03:59:43.649

As well, as specialized sequencing methods, such as immune repertoire sequencing for T, cell receptor profiling.

1949

03:59:43.649 --> 03:59:54.930

And any other types of specialized methods are available to our researchers, such as mapping a viral integration and CRISPR screening and carty.

1950

03:59:54.930 --> 04:00:03.629

We have a separate need within the in general program, and it's an area of.

1951

04:00:03.629 --> 04:00:07.319

Microbial analysis.

1952

04:00:07.319 --> 04:00:14.850

Transcript dynamic sequencing is available to provide direct access to transcript information.

1953

04:00:14.850 --> 04:00:21.629

You saying, by through put sequencing of transcripts from all microbial communities and specific environmental samples.

1954

04:00:21.629 --> 04:00:34.950

The next slide other specialized technologies are available, including optimal optical genomic.

1955

04:00:34.950 --> 04:00:41.489

Mapping using viral genome mix for analyzing chromosome structural variation.

1956

04:00:41.489 --> 04:00:50.579

Both global and targeted ventilation assays are offered, including the array based aluminum, ethical writing and a targeted pirate mark.

1957

04:00:50.579 --> 04:00:53.790

Sequencing GPC islands.

1958

04:00:53.790 --> 04:01:01.799

A variety of other targeted gene panel methods are offered such as managed NATO string and counter.

1959

04:01:01.799 --> 04:01:08.489

Keep and dropped, like, digital for profiling of and Snips.

1960

04:01:08.489 --> 04:01:21.420

Next slide more recently, our investigators have a need for access to the latest single technologies on both the Frederick and the campuses.

1961

04:01:21.420 --> 04:01:34.200

And if RTC offers these technologies, including single cell in the nucleus capture library crap, and sequencing from droplet plate or micro microwave based by forms.

1962

04:01:34.200 --> 04:01:40.920

The offerings include targeting panels, whole transcript don't or in profiling methods.

1963

04:01:40.920 --> 04:01:45.059

And our researchers can also obtain cell surface marker measurements.

1964

04:01:45.059 --> 04:01:49.500

Or do sell hashing for multiplexing samples he's barcoded antibodies.

1965

04:01:49.500 --> 04:01:55.829

Content accessibility, assays or account seek and Christopher base screening is also available.

1966

04:01:55.829 --> 04:02:08.069

And a little figured inserted here shows how single cell was used to help them group events researchers, characterize differential T, cells subclusters from melanoma patients.

1967

04:02:08.069 --> 04:02:13.229

Where they looked at both responders and non responders, treated with adaptive to self therapy.

1968

04:02:13.229 --> 04:02:16.590

All these technologies that are being offered are supported.

1969

04:02:16.590 --> 04:02:21.719

And high level, quality control for the samples as well as primary data analysis.

1970

04:02:23.159 --> 04:02:32.159

Lastly, this these single cell facilities are now looking at and offering the latest spatial transcript technologies offered.

1971

04:02:32.159 --> 04:02:35.459

Um, primarily by tenants genome.

1972

04:02:35.459 --> 04:02:39.629

Next slide please the next.

1973

04:02:40.709 --> 04:02:50.700

Group of laboratories offers us full suite of protein production services from going from DNA to sales to protein.

1974

04:02:50.700 --> 04:03:00.000

This includes expert consultation on clone design. However, the cloning services are limited to when tied down downstream usage for approaching production.

1975

04:03:00.000 --> 04:03:05.489

For example, when they are needed for structural biology studies, such as X, Ray crystal atrophy.

1976

04:03:05.489 --> 04:03:09.299

Or Cryo collection on my cross to be in many of these projects.

1977

04:03:09.299 --> 04:03:16.950

I would say about 75% require significant R amp D and troubleshooting and so they're not necessarily off the shelf.

1978

04:03:16.950 --> 04:03:28.770

Processes inserted figure represents an example of how the protein production team explores new expression systems to optimize full length protein expression and this 1 example.

1979

04:03:28.770 --> 04:03:33.299

The protein expressed it both be and.

1980

04:03:33.299 --> 04:03:37.079

Where you can see protein degradation and Nikolai.

1981

04:03:37.079 --> 04:03:40.079

But it's not not evident in the afternoons.

1982

04:03:41.100 --> 04:03:54.989

Next slide, please narrative, molecular, and macromolecule characterization. There's a full spectrum of analytical technologies.

1983

04:03:54.989 --> 04:03:59.010

Made available mostly based on spectrometry.

1984

04:03:59.010 --> 04:04:09.389

In addition to the basic identification of proteins from GLB and other biological samples, the group offers global protein profiling approaches, such as or sitelink.

1985

04:04:09.389 --> 04:04:13.139

Or identification of finding partners.

1986

04:04:13.139 --> 04:04:19.200

By precipitations and characterization of post Translational modifications. They also.

1987

04:04:19.200 --> 04:04:26.639

Provide method development involving targeted metabolite, small molecule analysis as well as peptide identifications.

1988

04:04:26.639 --> 04:04:33.450

And lastly, the group offers surface plasma residence for, for measuring Kinetics.

1989

04:04:33.450 --> 04:04:38.879

Of macro, macro molecules and the figures I showed here at the bottom.

1990

04:04:38.879 --> 04:04:43.620

Or 2, analytical results from aspect, trauma, treaty and surface class and residence.

1991

04:04:43.620 --> 04:04:48.930

That order means to identify proteins and characterize the kinetics of molecular interactions.

1992

04:04:50.639 --> 04:04:59.729

The next slide and moving on to a series of of laboratories that provide microscopy and imaging technologies.

1993

04:04:59.729 --> 04:05:04.200

The 1st is optical microscopy and imaging analysis in this group.

1994

04:05:04.200 --> 04:05:09.540

Author's cutting edge rescues my cross to be both confocal and Super resolution.

1995

04:05:09.540 --> 04:05:12.959

There are 2 levels and interactions that are being are offered.

1996

04:05:12.959 --> 04:05:23.969

Basic training on this on the scopes, mostly the, for instance, microscopes for kind of do it yourself assays and folk library relationships leading to Co, author, ship on papers.

1997

04:05:23.969 --> 04:05:31.110

This group cooperates with the CCR, the advanced sample preparation and bench acquisition and analysis technologies.

1998

04:05:31.110 --> 04:05:37.350

Is there a figure here shows a multiplex residence imaging using a quite a codex technology.

1999

04:05:37.350 --> 04:05:41.430

We're up to 33 proteins can be detected simultaneously.

2000

04:05:41.430 --> 04:05:45.360

On a single tissue section, and this is 1 of the newer technologies that.

2001

04:05:45.360 --> 04:05:48.690

Are being offered to the community.

2002

04:05:49.045 --> 04:05:50.784

Moving on to the next slide,

2003

04:05:50.815 --> 04:06:00.864

please this group offers investigators access to expertise and electron microscopy technologies,

2004

04:06:00.864 --> 04:06:03.055

including specimen in preparation service,

2005

04:06:03.145 --> 04:06:03.864

processing,

2006

04:06:03.864 --> 04:06:06.325

embedding section and imaging of the samples.

2007

04:06:07.829 --> 04:06:12.120

The group offers transmission, electron microscopy scanning.

2008

04:06:12.120 --> 04:06:20.760

As well, as expertise, and, you know, electron microscopy, negative stain analysis, ultra structure analysis and virus particle characterization.

2009

04:06:20.760 --> 04:06:30.000

Example inserted here shows an electron might cross the image of damage, mitochondria and a patient with a type of kidney cancer.

2010

04:06:31.260 --> 04:06:42.600

Moving on to the next slide advancements and electron cryo-microscopy now offer researchers resolutions that allow conclusions to be drawn about structural mechanisms.

2011

04:06:42.600 --> 04:06:47.430

Analogous to what has been done with techniques like X-ray, crystallography and cryo-EM.

2012

04:06:47.430 --> 04:06:54.540

However, like these methods, single particle analysis, using electrons by cryo-EM does not require crystallization.

2013

04:06:54.540 --> 04:07:00.090

The single particle method is focused on determining structures of proteins.

2014

04:07:00.090 --> 04:07:09.149

And macromolecular complexes at the 2 to 4 nm level and this group has characterized up to 15 structures during the past this year.

2015

04:07:09.149 --> 04:07:17.850

The 2nd emphasis is involved in developing and applying volume techniques to image cells and tissues on a 3D level.

2016

04:07:17.850 --> 04:07:23.190

And this includes focused ion beam and scanning electron microscopy across the 87.

2017

04:07:23.190 --> 04:07:36.239

And more recently arranged longer free examples here, show a single particle cryo-EM and volume cryo-EM or fix them. And these are meant to show the types of results using these advanced technologies.

2018

04:07:36.239 --> 04:07:49.920

And moving on to the last slide, the Frederick base flow spectrometry group provides an array of instruments and technical support for analysis and sorting needs.

2019

04:07:49.920 --> 04:07:57.090

The facility there is supporting about 75 users and a training access to the sample process for.

2020

04:07:57.090 --> 04:08:04.139

Where the analyzers and most of the projects come into this facility are from investigator space on a private campus.

2021

04:08:05.459 --> 04:08:08.549

And that ends my presentation Thank you.

2022

04:08:10.530 --> 04:08:13.680

Great. Thanks so much. You're welcome.

2023

04:08:14.844 --> 04:08:29.305

Okay now rounding out this block of presentations we have Dr fig from the genital urinary malignancies branch at the center for cancer research and he's going to be presenting the certified lab services with a touch on

2024

04:08:29.305 --> 04:08:29.995

pathology.

2025

04:08:29.995 --> 04:08:30.174

There.

2026

04:08:30.864 --> 04:08:32.905

That excellent next slide please.

2027

04:08:34.704 --> 04:08:34.975

So,

2028

04:08:34.975 --> 04:08:35.905

the clear Labs,

2029

04:08:35.905 --> 04:08:43.014

if Frederick are really designed to perform clinical essays on human specimens for support of clinical,

2030

04:08:43.555 --> 04:08:46.315

clinical support as well as clinical trial support,

2031

04:08:47.364 --> 04:08:52.584

the labs must obtain and maintain a clear certification.

2032

04:08:52.764 --> 04:08:58.764

They provide molecular diagnostics, clinical diagnostics. And biomarker reference standards next slide.

2033

04:09:00.270 --> 04:09:08.159

And this is just more details on the, the support for the clinical trials as well as the biomarker of reference. Next slide.

2034

04:09:09.924 --> 04:09:17.635

The other component of this is pathology support, and this can be on both human tissue as well as animal tissue.

2035

04:09:18.055 --> 04:09:28.225

There must be a trained certified clinical anatomical pathologist on staff to read the tissue. And then do the essays necessary on that.

2036

04:09:28.590 --> 04:09:38.129

Next slide now, I'm going to drill down and talk about 1 area here, which is the clear molecular diagnostic lab next slide.

2037

04:09:40.704 --> 04:09:45.024

Here there are really 3 big projects for big projects,

2038

04:09:45.264 --> 04:09:45.534

uh,

2039

04:09:46.495 --> 04:09:51.864

sequencing is 1 for the lymphoma leukemia,

2040

04:09:51.864 --> 04:09:54.354

molecular profiling Nana string,

2041

04:09:55.225 --> 04:09:56.395

the Sanger sequencing,

2042

04:09:56.395 --> 04:10:05.875

which supports the as well as rascal investigators as well as a collaboration with with college and then the pharmacode genetic testing in here.

2043

04:10:05.875 --> 04:10:11.665

Again, I'm going to drill down on that last part, which is the pharmacode genetic testing next slide.

2044

04:10:13.854 --> 04:10:26.725

When we talk about drug metabolism, there are a lot of different and enzymes that can handle that both phase 1 and phase 2. this is a slide from Bill Evans and Mary railing at St. Jude.

2045

04:10:26.725 --> 04:10:41.184

They took all drugs that were FDA approved and then just make pie chart for what enzymes were handling them. And what is the most frequent that handle drugs? cytochrome p453 457 cytochrome people, 152 D6 to see not in. The are very predominant.

2046

04:10:41.184 --> 04:10:50.424

However, there can be polymorphisms in each of these enzymes. They can alter the ability of an individual to handle drugs. Next slide.

2047

04:10:55.680 --> 04:11:09.389

The gold pharmacode genetics is really to take a population of individuals and predict who is not going to respond, or have toxicity versus those that will respond and not have toxicity next slide.

2048

04:11:11.424 --> 04:11:17.754

Depending on who you talk to, you can get different opinions on pharmacode genetics. Really? What?

2049

04:11:17.965 --> 04:11:27.715

If you're a clinical Pharmacologist you're often thinking about polymorphisms that alter drug absorption, distribution, metabolism, elimination and activation.

2050

04:11:27.895 --> 04:11:37.854

And that's what we're talking about today, molecular biologist often talk about polymorphisms at the receptor level, the target protein resistance and toxicity next slide.

2051

04:11:40.405 --> 04:11:49.795

pharmacode genetic strategies are most relevant when you talk about drugs that have a narrow therapeutic window, if it's very safe. They really you don't have to worry about it so much.

2052

04:11:49.795 --> 04:11:51.385

You can take a lot more,

2053

04:11:51.385 --> 04:11:57.385

but if if we're pushing the upper limit of normal as we are for most anti cancer drugs,

2054

04:11:57.985 --> 04:12:02.485

this is when it becomes most relevant highly a degree of inter,

2055

04:12:02.485 --> 04:12:08.514

individual variability little to no other available methods and few alternative treatments next slide.

2056

04:12:08.850 --> 04:12:15.090

And again, anti cancer agents, fit all of those categories next.

2057

04:12:17.094 --> 04:12:26.905

Here are 6 anti cancer drugs listed there on the left hand, side the enzyme that's responsible for the metabolism and a T. G. S. T.

2058

04:12:27.055 --> 04:12:40.165

cytochrome people 153 a 451 snap in those enzymes can result in changes in clearance of threefold tenfold 4 to 9 full tenfold.

2059

04:12:40.405 --> 04:12:51.805

50 full, 30 full, you can quickly see that. It could increase the plasma concentration and result in severe toxicity and even death from some of these drugs next slide.

2060

04:12:55.254 --> 04:13:05.485

And in fact, this is a case report that appeared in New England Journal Madison a few years ago that got a lot of people's attention. It was a 2 year old boy that had a tonsillectomies.

2061

04:13:06.024 --> 04:13:15.504

He was put on Tylenol with codeine, a very standard agent. That is often use 2 days later the child died and an autopsy.

2062

04:13:15.684 --> 04:13:21.325

They found morphing concentrations even though he had not been given morphine that were toxic.

2063

04:13:21.354 --> 04:13:32.815

And the reason why is he was an ultra rapid metabolism of 26 causing the coding to be converted to morphine that resulted in this unfortunate depth.

2064

04:13:33.540 --> 04:13:37.530

Next slide.

2065

04:13:37.530 --> 04:13:45.683

Previously, the lab at Frederick up until last year 2020 had been using a platform f. F matrix D met platform.

2066

04:13:46.075 --> 04:14:00.174

They, they were in the middle of switching over last year towards the end of the year to a pharmacal scan a platform and the reason why is it doubled the number of markers or Snips that were being looked at here.

2067

04:14:00.174 --> 04:14:07.075

We went up to 4,627 markers in 1191 genes that cover all phase 1 phase 2 enzymes as well as transporters.

2068

04:14:14.760 --> 04:14:18.120

Next slide.

2069

04:14:18.120 --> 04:14:28.524

As a clinician, I have to give you at least some clinical, uh, case from my own patients and this is 1 that we published earlier this year.

2070

04:14:28.674 --> 04:14:36.504

Uh, this is the individual that was getting a, um, a combination chemotherapy regiment for colon cancer. Uh, next slide.

2071

04:14:37.704 --> 04:14:50.395

The standard regiment box, Allie flat and look of worn and 5, if you, you can see the dose, it was given there a very standard dose. Uh, and the individual develop an agency of 0 for over 1 month.

2072

04:14:50.694 --> 04:14:55.284

Uh, fortunately did not get an infection from that. Next slot.

2073

04:14:55.649 --> 04:15:03.899

So, we dropped the dose down, uh, considerably cut it in half and didn't give a bolus dose tolerated. Well, next time.

2074

04:15:03.899 --> 04:15:09.059

Tried to go up a little bit tolerated it. Fine next slide.

2075

04:15:09.059 --> 04:15:15.299

Went up a little more and once again dropped the agency to 0. okay. Next slide.

2076

04:15:15.299 --> 04:15:20.639

And ultimately landed on this dose that was tolerating next slide.

2077

04:15:21.834 --> 04:15:35.395

So, why, why did we not predict this since we could have measured the, the Gina typing ahead that handles 5 if you metabolism?

2078

04:15:35.424 --> 04:15:39.805

Well, the demat array was saying, this individual was wall type.

2079

04:15:40.524 --> 04:15:41.334

However,

2080

04:15:41.694 --> 04:15:44.065

once we switched over to pharmacy scam,

2081

04:15:44.215 --> 04:15:47.155

it turned out this individual had 2 very,

2082

04:15:47.155 --> 04:15:50.815

very rare polymorphisms that were,

2083

04:15:50.815 --> 04:15:52.465

or are noted,

2084

04:15:52.793 --> 04:15:56.934

but again point 6% of the population in African Americans,

2085

04:15:56.934 --> 04:15:58.194
this was an African American.

2086
04:15:58.194 --> 04:16:12.325

And if we had run the pharmacal scan before given the dose, we could have said, look, we need to be very careful and drop that dose and avoided that hospitalization in those drops. Like, we saw next slide.

2087
04:16:14.549 --> 04:16:28.559

So, the ultimate goal of farmer genetics is to provide the patient with individualized therapy, get the dose, right? Using candidate gene approach. However, just looking at 1 gene may not cover everything.

2088
04:16:28.559 --> 04:16:34.620

Because often, drugs are handled by multiple pathways, multiple transporters next slide.

2089
04:16:35.879 --> 04:16:43.350

And that's the advantage of the pharmacal scan pharmacode genetic platform. It covers all of these snips and jeans.

2090
04:16:43.674 --> 04:16:53.694

In Jane's next slide now I'm going to give some data from our own experience with a drug called handled by 1 a 1.

2091
04:16:54.534 --> 04:17:00.715

there we solve differences based upon the genotype as to the that was.

2092
04:17:00.959 --> 04:17:11.190

Uh, being seen from this clinical trial extensive was well defined, but the intermediate metabolizes, we model.

2093
04:17:11.190 --> 04:17:24.600

From 1 individual, a multiple of what it would look like and based on that, we predicted you need to drop the dose from 600 to 400 to main maintain that say same next slide.

2094
04:17:24.600 --> 04:17:33.209

The FDA looked at our data and said, yes, we agree. And in fact, put it in the package insert next slide.

2095
04:17:34.469 --> 04:17:43.440

This is from the package insert that says, basically you need to reduce the dose for those with a 1 a 1 star 2008. a lil next slide.

2096
04:17:45.715 --> 04:17:59.934

However, they also asked us to do a prospective study where we actually show this so to Gina type individuals before putting them on the clinical trial and adjust the dose to pay, depending upon what kind of result we get.

2097
04:18:00.569 --> 04:18:15.120

The molecular lab at Frederick is doing this work and has to transmit this data back has to be done very quickly, because we need to put them on the trial transmitted back to us. So we can make clinical decisions. So.

2098

04:18:15.120 --> 04:18:21.120

600 wall type, if for those individuals, 400 for those with the very next slide.

2099

04:18:22.229 --> 04:18:35.159

And, in fact, since 2015, we have done for other studies than the where we have Gina type before given the chemotherapy to make sure we get the dose right?

2100

04:18:35.159 --> 04:18:35.815

Next slide,

2101

04:18:38.454 --> 04:18:40.405

so the molecular diagnostic lab,

2102

04:18:40.434 --> 04:18:40.614

uh,

2103

04:18:40.645 --> 04:18:43.224

requirements handle all the clinical samples,

2104

04:18:43.405 --> 04:18:46.135

both for just good clinical care,

2105

04:18:46.225 --> 04:18:48.475

but also to support clinical trials,

2106

04:18:48.895 --> 04:18:52.584

handle the prospective pharmacode genetic testing for those clinical trials,

2107

04:18:52.795 --> 04:18:54.024

transmit the data.

2108

04:18:54.024 --> 04:19:00.385

This is very important back to the electronic medical record system at the clinical center,

2109

04:19:00.655 --> 04:19:02.725

generate reports for the physicians,

2110

04:19:03.354 --> 04:19:17.215

handle a retrospective Gina typing for clinical trials where it does not need to be clear certified since we're going to be doing it retrospectively and develop and optimize other assays with advanced technology tools.

2111

04:19:17.549 --> 04:19:22.770

Next slide, I'm happy to take questions at the end. Thank you.

2112

04:19:24.450 --> 04:19:37.555

Great thanks a lot Doug. All right so we're at the end of this block of question block of presentations. We are running a little bit behind. I don't see any questions popping up in the chat box.

2113

04:19:37.584 --> 04:19:51.954

Um, but I'll, I'll give a 2nd or 2 if anybody has a question again, please go ahead and submit your questions. And if we don't get to it during the day today, they will be posted with answers.

2114

04:19:52.645 --> 04:19:54.745

So that everybody can see those.

2115

04:19:54.989 --> 04:19:59.909

So, yeah, I'm not seeing any questions pop up so let's go ahead and stay on track.

2116

04:19:59.909 --> 04:20:10.799

Again, thanks to Melinda Doug, Michael and Dave and Maryann for these great presentations.

2117

04:20:10.799 --> 04:20:21.000

And now we're going to switch gears a little bit and talk about facilities and support functions at the f. RDC. 1st up. We have Fred.

2118

04:20:21.000 --> 04:20:25.530

He's from the office space and facility management.

2119

04:20:25.530 --> 04:20:31.620

And he's going to be presenting facilities maintenance of engineering at the. So Fred, go ahead.

2120

04:20:31.620 --> 04:20:41.700

Yes, next slide please good afternoon. Everyone. So I'm here to present and give you a facility overview of our facilities.

2121

04:20:41.700 --> 04:20:46.799

Within the DC and the, uh, uh, uh, for the campus.

2122

04:20:46.799 --> 04:20:56.790

So, the next slide base on this is the vicinity map to give you an idea of where this, uh, the, uh, Frederick campus is.

2123

04:20:56.790 --> 04:21:05.610

And, uh, uh, basically all the related, please facilities the vicinity and proximity to the campus itself.

2124

04:21:05.610 --> 04:21:09.930

Next slide please.

2125

04:21:09.930 --> 04:21:16.680

Here, I'm giving you an overview of of basically where the campus the campus is located.

2126

04:21:16.680 --> 04:21:19.860

In the parameter fence of Fort Dietrich.

2127

04:21:19.860 --> 04:21:28.229

It's the property of and and H, and H address, it's maintained and operated by the contract.

2128

04:21:28.229 --> 04:21:32.010

And this is an aerial view of the campus itself.

2129

04:21:32.010 --> 04:21:45.299

Next slide is this scope of work for the contractor here would be basically to facility operation in management.

2130

04:21:45.299 --> 04:21:53.579

Uh, utility operations, uh, and designer construction services, as it relates to, uh, to facilities.

2131

04:21:53.579 --> 04:22:00.389

Again, I have a small area view of the campus at the lower part of the slide next slide. Please.

2132

04:22:00.389 --> 04:22:10.829

So just a little bit about our campus it was transfer from the in 1970 to the.

2133

04:22:10.829 --> 04:22:16.170

And it's got about 97 buildings, and it's about 68 acres.

2134

04:22:16.170 --> 04:22:22.950

It totals about 1.3Million dollars gross square foot of facilities.

2135

04:22:22.950 --> 04:22:29.280

Of which 64% of the 97 buildings.

2136

04:22:29.280 --> 04:22:32.760
About 64% are 50 years of older.

2137
04:22:32.760 --> 04:22:36.149
Um, we have, uh, since.

2138
04:22:36.149 --> 04:22:40.469
I mean, 13, refurbished about 20% of those buildings.

2139
04:22:40.469 --> 04:22:46.620
Uh, 16% of the buildings that are on campus are trailers or lease.

2140
04:22:46.620 --> 04:22:54.659
And about 77% are single story so that gives you an overview of the campus itself.

2141
04:22:54.659 --> 04:23:03.389
Next slide please. So I mentioned 1.3Million square foot.

2142
04:23:03.389 --> 04:23:16.049
Uh, and, uh, for that to give you a breakdown of how it works, it's basically, but 850,000 square feet of laboratory space about 210,000.

2143
04:23:16.049 --> 04:23:20.280
Administrative 125.

2144
04:23:20.280 --> 04:23:26.549
And about 110,000 of square foot of infrastructure, to support all this.

2145
04:23:26.549 --> 04:23:30.569
We also have about 25,000 square feet of repository.

2146
04:23:30.569 --> 04:23:35.969
Again, you can see the campus in the right side. Next slide is.

2147
04:23:37.229 --> 04:23:48.870
So when I mentioned laboratories, we add out the 10,000 feet level, we can categorize our laboratories into 3 categories, biology, chemistry and.

2148
04:23:48.870 --> 04:23:56.489
Bio engineering on the right side. You'll see an old lab that was basically refurbished after 2013.

2149

04:23:56.489 --> 04:24:09.809

Next slide please. So, as far as infrastructure goes, obviously the task of the contractor will be to maintain the building and the building infrastructures.

2150

04:24:09.809 --> 04:24:15.360

Uh, the borders and children pants, energy management processes uh.

2151

04:24:15.360 --> 04:24:18.809

The industrial shops.

2152

04:24:18.809 --> 04:24:29.399

Information technology, which is part of the part of the group and the maintenance of roads, parking and maintenance, including snow removal.

2153

04:24:29.399 --> 04:24:36.299

Also storage in warehouse, we have a lot of the building infrastructures in especially the.

2154

04:24:36.299 --> 04:24:50.280

Refurbished building that are located in the ethic of the building so you could see the pictures up on the right corner and also a snapshot of a 1 of our facility shop spaces.

2155

04:24:50.844 --> 04:24:52.375

Next slide please.

2156

04:24:53.665 --> 04:24:54.385

So,

2157

04:24:54.625 --> 04:24:55.674

our utility,

2158

04:24:55.674 --> 04:24:59.274

some of our utilities are provided by US Army garrison,

2159

04:24:59.575 --> 04:25:03.415

those utilities are basically our city infrastructure,

2160

04:25:03.415 --> 04:25:04.405

electricity,

2161

04:25:04.915 --> 04:25:07.194

or water infrastructure in water,

2162
04:25:07.495 --> 04:25:11.784
sort infrastructure and waters and wastewater.

2163
04:25:12.120 --> 04:25:20.430
Any, we depend on the U. S army garrison for these utilities for the repair of this utilities.

2164
04:25:20.430 --> 04:25:33.629
Next slide please the major technology on campus just to give you a overview is we have why of pharmaceutical.

2165
04:25:33.629 --> 04:25:38.819
We have self processing, including 9.

2166
04:25:38.819 --> 04:25:46.500
We have ccmp facilities. Uh, we have imaging. Course we have facilities, including anarcho.

2167
04:25:46.500 --> 04:25:52.200
Some of the pictures that you see on their white sites are basically from 1 of our.

2168
04:25:52.200 --> 04:25:55.440
Animal facility you mentioned.

2169
04:25:55.440 --> 04:26:06.329
Facilities also the pharmaceutical pharmaceutical processing and our facilities next slide. Please.

2170
04:26:09.059 --> 04:26:14.340
So, as far as my variable goes, we thought it would be, uh.

2171
04:26:14.340 --> 04:26:21.510
Important to give you a breakdown of of what type of we have. We basically have a.

2172
04:26:21.510 --> 04:26:25.799
30 mice, conventional and clean.

2173
04:26:25.799 --> 04:26:29.790
A barrier specific pathogen free.

2174
04:26:29.790 --> 04:26:37.350
And the reason we broke it down is because obviously, as, you know, they.

2175
04:26:37.350 --> 04:26:43.829

Maintenance and every operation is facilities are a little different. Each are a little different.

2176

04:26:43.829 --> 04:26:58.709

All right, next time this, as I mentioned, we have a repository and fostering conventional, mechanical and 2 tanks and robotics.

2177

04:26:58.709 --> 04:27:05.100

The picture below are from our, our, our 10 farm repositories.

2178

04:27:05.100 --> 04:27:08.850

Including a robotic sample to.

2179

04:27:08.850 --> 04:27:19.620

Next slide please as far as security goes for the campus for perimeter is managed by the, the army.

2180

04:27:19.620 --> 04:27:27.780

The NC campus is managed by the contractor in conjunction with the police and the army.

2181

04:27:27.780 --> 04:27:32.489

So, what they do is it's 24, 7 dispatch.

2182

04:27:32.489 --> 04:27:39.270

Um, for for campus alarms, there is the key entry and access card management.

2183

04:27:39.270 --> 04:27:45.510

This management of visitors and the 24, 7 security patrols.

2184

04:27:45.510 --> 04:27:53.969

Next items, as far as a minute he goes, the campus has an auditorium.

2185

04:27:53.969 --> 04:28:03.120

Cafeteria conference center Jim, scientific libraries, occupational health facilities.

2186

04:28:03.120 --> 04:28:06.510

Picture of the right is a picture of 1 of our dining months.

2187

04:28:06.510 --> 04:28:16.889

Next slide please, we have a basically a combination of on campus and off campus lease facilities.

2188

04:28:16.889 --> 04:28:21.450

On campus, we had about 3 module buildings.

2189

04:28:21.450 --> 04:28:24.870

That equates to about 12,000 square feet. Um.

2190

04:28:24.870 --> 04:28:30.659

6,800 of it is laboratory. A 50,100 of it is administrative.

2191

04:28:30.659 --> 04:28:33.719

And then off campus, we have about 6 building.

2192

04:28:33.719 --> 04:28:39.719

Equating to about, uh, 615,000 give or take a growth square feet.

2193

04:28:39.719 --> 04:28:51.930

Of which 422 is laboratory and 137 is administrative in 89 is by specimen repositories.

2194

04:28:51.930 --> 04:28:57.840

The picture down the lows are pictures of our repository, which we repository.

2195

04:28:57.840 --> 04:29:07.110

A vaccine, clinical production building and also you have advanced technology research facilities, which I will go into a little bit more detail.

2196

04:29:07.110 --> 04:29:17.879

Uh, next slide please so to give you a breakdown of basically the square footage of this facility, which is a, a.

2197

04:29:17.879 --> 04:29:21.959

Center the arts laboratory and cgmp facility.

2198

04:29:21.959 --> 04:29:28.620

We have in that building, we have about 103,000 square feet of laboratories.

2199

04:29:28.620 --> 04:29:35.370

80,000 square feet of cgmp lab and about 60,000 administrative and, uh.

2200

04:29:35.370 --> 04:29:40.920

90,000 square feet of the infrastructure to manage all these facilities.

2201

04:29:40.920 --> 04:29:51.239

With that that's my presentation, an overview and I want to thank you if there's any questions, please send them to us and we'll get back to your writing.

2202

04:29:51.239 --> 04:29:54.809

Thank you very much. Hey, thanks, Fred.

2203

04:29:54.809 --> 04:30:09.540

Okay, now we're going to move over into it enterprise systems and cyber security. It's going to be presented by Mr. Jeff Shilling from the center of biomedical Informatics and information technology.

2204

04:30:09.540 --> 04:30:22.530

Jeff, go ahead and take it away. Thank you. Jason. Jason introduced me I'm the chief information officer for the National Cancer Institute, and today I'm going to cover it and cyber security details.

2205

04:30:22.530 --> 04:30:25.979

And some nuance of how the capabilities currently exist.

2206

04:30:25.979 --> 04:30:33.629

Next slide please, the RTC is part of the, and an age network.

2207

04:30:33.629 --> 04:30:37.709

And its system security utilizes an inheritance model.

2208

04:30:37.709 --> 04:30:42.000

And this lowers the risk and increases the speed.

2209

04:30:42.000 --> 04:30:46.110

To authorization, and today we're going to cover.

2210

04:30:46.110 --> 04:30:49.799

Networking the compute infrastructure storage.

2211

04:30:49.799 --> 04:30:57.059

Software development and its collaborations.

2212

04:30:57.059 --> 04:31:03.510

Next slide please. So, the network is.

2213

04:31:03.510 --> 04:31:07.680

If if I've already see runs a network on an extreme switch driven model.

2214

04:31:07.680 --> 04:31:11.190

This is basically utilizes software defined networking.

2215

04:31:11.190 --> 04:31:14.280

And network access control is heavily utilized.

2216

04:31:14.280 --> 04:31:19.020

1 gigabit connections our standard throughout the.

2217

04:31:19.020 --> 04:31:23.909

And all the laboratories and all the administrative facilities, 10 Gigabit.

2218

04:31:23.909 --> 04:31:31.889

A networking is provided upon request and generally building to building fiber connections are redundant. Whenever possible.

2219

04:31:32.844 --> 04:31:46.854

Next slide please. So, the for the compute, it's a fairly standard compute environment. We use Windows Mackintosh and a little less than 5% Linux desktops.

2220

04:31:47.850 --> 04:31:51.450

For that the centralized computing, there's.

2221

04:31:51.450 --> 04:32:01.559

High performance computing cluster provided by the f as well as the center for information technology provides.

2222

04:32:01.559 --> 04:32:11.219

A large compute capability and bio, and it's very important the way the scientific computing capabilities of the f. C.

2223

04:32:11.219 --> 04:32:18.719

Coordinate workloads between those 2 capabilities to ensure things are done as speeds and as low cost as possible.

2224

04:32:18.719 --> 04:32:23.159

Also, uh, cloud computing it it.

2225

04:32:23.159 --> 04:32:29.909

Is it happens a lot and it also happens on existing authorized.

2226

04:32:29.909 --> 04:32:33.840

Systems and so that's currently.

2227

04:32:33.840 --> 04:32:36.989

Is and Google Cloud platform.

2228

04:32:38.819 --> 04:32:39.774

Next slide please.

2229

04:32:48.235 --> 04:32:55.915

So is a data driven organization and our storage capability is is very high and it's somewhat complex.

2230

04:32:56.159 --> 04:33:02.159

We have storage at different layers for speed and cost efficiency and redundancy.

2231

04:33:02.159 --> 04:33:06.119

Our, and our.

2232

04:33:06.119 --> 04:33:09.540

Our cloud storage is significant.

2233

04:33:09.540 --> 04:33:14.340

In the data Commons area, both in both in Amazon and Google.

2234

04:33:15.599 --> 04:33:20.520

And it's also the last, you'll see the last line here. It's very important to note that.

2235

04:33:20.520 --> 04:33:26.340

For data management planning, we must be able to work with large data generators.

2236

04:33:26.340 --> 04:33:30.959

To ensure that they have a a proper data lifecycle management in place.

2237

04:33:30.959 --> 04:33:34.950

Uh, for their data next slide, please.

2238

04:33:39.240 --> 04:33:45.900

On the software side, if an army runs on his stomach, then the NCI runs on software.

2239

04:33:45.900 --> 04:33:55.889

And so, for many common packages, like Microsoft, 365, Oracle, these are provided either by the age, or by the or a combination of both.

2240

04:33:55.889 --> 04:34:01.020

And but it is important to know that all unique and new software.

2241

04:34:01.020 --> 04:34:05.700

Needs to be provided secured and maintained by the RTC.

2242

04:34:05.700 --> 04:34:10.049

And all the, the security needs to happen according to federal standards.

2243

04:34:10.049 --> 04:34:24.240

Next slide please for development, there's significant amount of software development that happens with the RTC and.

2244

04:34:24.240 --> 04:34:32.759

Hardware development while it is rare, it does happen, especially when we're working with equipment vendors to refine their experimental designs.

2245

04:34:32.759 --> 04:34:44.250

And it's important to note that all code must be treated according to federal records schedules and that the provides.

2246

04:34:44.250 --> 04:34:50.520

Repositories to do so also I wanted to note that.

2247

04:34:50.520 --> 04:34:57.330

Standardization of tooling is important and this is to ensure that re, useability of solutions.

2248

04:34:57.330 --> 04:35:05.279

Often, if you're doing something special, you're going to have to use very special tooling. But in general, the expectation is that.

2249

04:35:05.279 --> 04:35:09.330

The software development capabilities are.

2250

04:35:09.330 --> 04:35:12.360

Used our basically industry standard.

2251

04:35:12.834 --> 04:35:27.174

Next slide please for cyber security. It's, it's very important. Probably. The most important thing in this presentation is that all federal government work must be performed on authorized federal.

2252

04:35:27.205 --> 04:35:28.525

It systems.

2253

04:35:28.770 --> 04:35:36.509

And myself, as the chief information officer, and the also has a chief information security officer, Craig Payne.

2254
04:35:36.509 --> 04:35:42.180
We're here to support all that work and all those systems becoming authorized.

2255
04:35:42.180 --> 04:35:46.740
But it is the responsibility of the, it system owner.

2256
04:35:46.740 --> 04:35:50.549
To start and maintain their system in a secure state.

2257
04:35:50.549 --> 04:35:56.759
And they need to be able to have the funding and capabilities to patch and fix vulnerabilities.

2258
04:35:56.759 --> 04:36:02.009
And those vulnerabilities can come at any day and often come every day.

2259
04:36:02.009 --> 04:36:09.389
As we are the RTC and all NCI night systems are scanned by department of Homeland security.

2260
04:36:10.560 --> 04:36:16.590
Next slide please. So.

2261
04:36:16.590 --> 04:36:30.810
I wanted to make a special note here beyond security just on, because in order to make our complex, it environment manageable. We treat physical low systems and is a system that has no sensitive information in it.

2262
04:36:30.810 --> 04:36:35.520
We treat those differently than we do our treat our modern systems and so.

2263
04:36:35.694 --> 04:36:43.794
This allows us to move quickly, whatever we need to with a visible system, and not create excessive risk to our sensitive data.

2264
04:36:43.794 --> 04:36:52.915
So that for our sensitive data systems, where we're as physical dictates, we're doing more of the appropriate analysis to make sure those are secure.

2265
04:36:53.250 --> 04:36:58.919
And since all work at the federal level must be, must happen on authorized systems.

2266
04:36:58.919 --> 04:37:06.330

That must happen before they go into production and we have ways to facilitate and make that happen in, in the research environment that we live in.

2267

04:37:06.330 --> 04:37:09.450

And again, this is the system owner's responsibility.

2268

04:37:09.450 --> 04:37:17.310

I want to state that we use an inheritance model so just as the previous presenter. Fred.

2269

04:37:17.310 --> 04:37:26.064

Stated that, like, for example, the army runs the physical security at the gate. We inherit that physical security, physical security and our, it systems.

2270

04:37:26.064 --> 04:37:35.034

And so it's important to know and utilize those that inheritance as much as possible to make the, the system authorization.

2271

04:37:35.430 --> 04:37:41.580

As quick as possible, but also that it's it's as simple to manage and maintain.

2272

04:37:41.580 --> 04:37:55.259

Next slide, please for cloud cyber security all office moderate work must be performed on fedrap, authorized cloud services.

2273

04:37:55.259 --> 04:37:59.369

And that requires an authorization to operate.

2274

04:37:59.369 --> 04:38:07.590

And but there is a way to utilize software as a service systems that are not fed ramp, authorized.

2275

04:38:07.590 --> 04:38:14.759

We facilitate that for the end for the, but it's important to know these are only for non sensitive information.

2276

04:38:14.759 --> 04:38:20.729

There's many many cloud tools out there that we're going to need to utilize and we need to make sure that we, we don't.

2277

04:38:20.729 --> 04:38:25.650

What sensitive information in those services, unless they're fully authorized for that.

2278

04:38:25.650 --> 04:38:30.270

All right next slide, please.

2279

04:38:32.970 --> 04:38:42.389

So, in relation to the it inheritance, so the security inheritance, and also all the tooling that's available and all the.

2280

04:38:42.389 --> 04:38:45.720

Other things that are going on at the age, and the clinical center.

2281

04:38:45.720 --> 04:38:54.869

And at the idea collaborations across the, and age are critical to the success of the f already. C.

2282

04:38:54.869 --> 04:39:06.060

It and cyber security services, software, updates, training consultation. They all must be coordinated with all the other service providers.

2283

04:39:06.060 --> 04:39:09.750

At the next slide, please.

2284

04:39:12.090 --> 04:39:16.139

So, these next 2 slides are a.

2285

04:39:16.139 --> 04:39:26.310

Basically provided for you as a reference to to how the, some of the, it works in a more consolidated view. If you go to this, this slide, this is a next slide. Please, it's.

2286

04:39:26.310 --> 04:39:29.490

It's a table view of how the.

2287

04:39:29.490 --> 04:39:32.819

Type of it and the capabilities that are going to be required.

2288

04:39:32.819 --> 04:39:36.720

And then the next slide is also next slide please.

2289

04:39:36.720 --> 04:39:44.310

The next slide is for it, basically just shows how it is provided in this continuum.

2290

04:39:44.310 --> 04:39:50.669

And so that we have some very central standard things like cyber security.

2291

04:39:50.669 --> 04:39:53.790

And network are provided in a very centralized fashion.

2292

04:39:53.790 --> 04:40:00.840

But that all the very specific things are provided in a very specific capability.

2293

04:40:01.919 --> 04:40:06.569

That was the last slide, but I want you to go to the next slide. So, in closing I wanted to.

2294

04:40:06.569 --> 04:40:10.500

Conclude by stating that collaboration and integration.

2295

04:40:10.500 --> 04:40:18.450

Innovation and keeping everything secure are the keys for it to meet the mission.

2296

04:40:18.450 --> 04:40:22.830

Thank you. Great. Thanks a lot.

2297

04:40:24.209 --> 04:40:37.020

All right now we're going to hear from Mr. Sam Denny he is in in the office space and facilities management and he'll be speaking to the environment, health and safety services at the f. RDC. Sam.

2298

04:40:37.020 --> 04:40:42.540

Thanks, Jason. Sam, Danny, I'm the corps and I'll give a brief overview.

2299

04:40:42.540 --> 04:40:46.319

Uh, the, uh, program, um, next slide.

2300

04:40:48.384 --> 04:41:02.724

The mission of is to provide comprehensive environment, health and safety program and services to the NCI, Frederick staff and facilities these programs cover government and contractor employees at both government owned and lease facilities.

2301

04:41:03.264 --> 04:41:13.555

The contractors responsible for establishing and maintaining effective management systems to identify deficiencies and ensure the corrective actions are implemented in a timely manner.

2302

04:41:14.310 --> 04:41:20.759

The elements of the program may include, but are not limited to accident reports and trend analysis.

2303

04:41:20.759 --> 04:41:27.209

Emergency Management and preparedness OSHA, compliant exposure, monitoring and control.

2304

04:41:27.209 --> 04:41:30.900

An institutional animal care and news committee liaison.

2305

04:41:30.900 --> 04:41:38.310

An inspection programmed for facilities, respiratory protection and air quality evaluation program.

2306

04:41:38.310 --> 04:41:46.529

A risk assessment program for industrial, chemical and biological hazards, monitoring of select agents.

2307

04:41:46.529 --> 04:41:55.889

A biological control program and radiation safety program with site specific radioactive material used licenses.

2308

04:41:55.889 --> 04:42:05.939

Also, an OSHA training program, a program to facilitate a lack of accreditation program to perform environmental services.

2309

04:42:05.939 --> 04:42:11.009

And to provide institutional bio safety and safety officers.

2310

04:42:11.009 --> 04:42:20.610

The functional areas of the program are protective services, occupational health services, environmental protection, and waste management.

2311

04:42:20.610 --> 04:42:25.979

Safety programs and emergency management and continuity of operations.

2312

04:42:25.979 --> 04:42:29.459

Next slide please.

2313

04:42:29.459 --> 04:42:33.869

Protective services are provided on a 24, 7 bases.

2314

04:42:33.869 --> 04:42:44.880

The services include the management of access control for Frederick buildings. This includes the issuance of keys as well as the management of the electronic access control system.

2315

04:42:44.880 --> 04:42:57.840

Also, the monitoring of the scientific alarm system, which includes approximately a 1000 alarm points, the panel is located at the security dispatch desk with, which is staffed and a 24, 7 bases.

2316

04:42:58.674 --> 04:43:03.654

Security patrols are also provided for the NCI project facilities on a 24, 7 bases.

2317

04:43:03.654 --> 04:43:15.294

Also the coordination and the communication information for events, such as power outages and inclement weather, which is also distributed to the Frederick community.

2318

04:43:16.290 --> 04:43:28.709

Finally, a protective services include shuttle service that's provided from NCI Frederick to the but that's the campus on a daily basis and also out to the facility and Frederick.

2319

04:43:28.709 --> 04:43:40.979

On a daily basis, the shuttle service has been suspended since April 4, 2019, but the service is expected to resume when most staff have returned to the workplace.

2320

04:43:40.979 --> 04:43:48.720

We also noticed Fred mentioned earlier that the fort Dietrich provides a perimeter security to the fort Dietrich site.

2321

04:43:48.720 --> 04:43:54.150

And the law enforcement activities for for under campus are provided by the police.

2322

04:43:54.150 --> 04:43:58.049

Next slide please.

2323

04:43:58.049 --> 04:44:09.659

The focus of the occupational health services to protect and promote health for all employees. These services are available both to both government and contractor staff.

2324

04:44:10.165 --> 04:44:21.174

The primary function of is the operation of the occupational health clinic this unit provides assessment stabilization and investigation of workplace injuries and illnesses.

2325

04:44:21.595 --> 04:44:25.735

The clinic provides Pre, employment, physical examinations for staff.

2326

04:44:26.009 --> 04:44:38.400

And examinations for employees, returning to work following injuries and illnesses. The clinic also provides immunizations and vaccinations, including immunizations in advance of international travel.

2327

04:44:38.400 --> 04:44:43.590

Wellness programs provided by include general wellness exams.

2328

04:44:43.590 --> 04:44:47.700

Smoking cessation and the employee assistance program.

2329

04:44:47.700 --> 04:44:58.680

The research donor program serves as a central repository for whole blood samples, collect from healthy volunteers produced by contractor and government investigators.

2330

04:44:58.680 --> 04:45:09.689

There are also a number of health surveillance programs provided for employees regarding occupational exposures to various hazards. These include Bloodborne pathogens, asbestos.

2331

04:45:09.689 --> 04:45:20.970

Hearing conservation, respiratory protection, radiation and animal allergens finally asked provides related training, including.

2332

04:45:20.970 --> 04:45:24.900

And 1st aid and.

2333

04:45:24.900 --> 04:45:30.180

Next slide.

2334

04:45:30.180 --> 04:45:36.000

The focus of the Environmental Protection services includes environmental compliance and waste management.

2335

04:45:36.000 --> 04:45:46.229

This includes compliance with the state of Maryland regulations, pertaining the discharges to air and water and compliance with the National Environmental Protection Act. nepo.

2336

04:45:47.279 --> 04:45:51.659

Waste Management services include the pickup and staging of hazardous waste.

2337

04:45:51.659 --> 04:45:55.349

Chemical biological and radioactive waste.

2338

04:45:55.349 --> 04:46:00.150

And then these wastes are then picked up from staging areas and disposed of by vendors.

2339

04:46:00.150 --> 04:46:06.840

Non hazardous waste, such as municipal waste is placed in dumpsters and disposed off by a vendor.

2340

04:46:06.840 --> 04:46:18.630

And waste management service also includes a recycling program. This is a single stream recycling for paper plastics model cardboard, recycled materials are picked up.

2341

04:46:18.630 --> 04:46:21.840
By a vendor next slide, please.

2342
04:46:23.369 --> 04:46:34.740

Safety programs include industrial hygiene bios, safety ergonomics, industrial safety, life, safety, radiation, safety and contraction safety.

2343
04:46:34.740 --> 04:46:42.474

The industrial hygiene program made aims to minimize workplace risk due to exposure to chemicals and other physical hazards.

2344
04:46:42.955 --> 04:46:50.544

The bio safety program assesses the risks of biological hazards within laboratories and the risk of exposures to researchers.

2345
04:46:51.240 --> 04:46:55.200

This program also supports the institutional bias safety committee.

2346
04:46:55.200 --> 04:47:05.340

Ergonomic programs strive to eliminate or control hazards in the working environment by applying our economic principles and offices and non office environments.

2347
04:47:05.340 --> 04:47:11.430

The industrial safety program strives to minimize industrial risks to employers through engineering controls.

2348
04:47:11.430 --> 04:47:15.930

Administrative procedures and requiring the use of personal protective equipment.

2349
04:47:15.930 --> 04:47:26.849

The life safety program ensures the building construction and fire protection features are in place to protect lives property and missing a central research from the risk of the fire.

2350
04:47:27.264 --> 04:47:35.935

The radiation safety program ensures a safe working environment for persons, working with radioactive materials or radiation producing equipment.

2351
04:47:36.534 --> 04:47:49.555

This program also manages all site specific licenses for the use of radioactive materials and finally the construction safety program stops to reduce the possibility of injury and property damage.

2352
04:47:49.555 --> 04:47:52.915

And liability losses during subcontracted activities.

2353

04:47:53.580 --> 04:47:57.509

And to comply with all federal and state health regulations.

2354

04:47:57.509 --> 04:48:07.229

Next slide please and finally the emergency preparedness program develops plans for emergencies, such as fires.

2355

04:48:07.229 --> 04:48:18.654

Natural disasters, active shooter and utility outages, fire and evacuation drills are conducted once per year in accordance with and policy requirements.

2356

04:48:19.104 --> 04:48:24.625

The continuity of operations plan is an internal effort to ensure functions are maintained during.

2357

04:48:24.930 --> 04:48:30.270

But during potential emergencies through plans and procedures.

2358

04:48:30.270 --> 04:48:37.229

The coupe activities for the NCI Frederick facilities are also coordinated with NCI and and I age.

2359

04:48:37.974 --> 04:48:39.025

Next slide please,

2360

04:48:41.424 --> 04:48:50.154

so a recent example of how the program comes together to support the at Frederick as the asymptomatic Kovic,

2361

04:48:50.185 --> 04:48:51.805

19 testing program,

2362

04:48:52.555 --> 04:48:54.444

this program began in September of 2020,

2363

04:48:54.444 --> 04:49:01.825

and was established to allow asymptomatic government contractor and subcontractor staff to be tested on a weekly basis.

2364

04:49:03.569 --> 04:49:11.909

The original sites of the program where the Frederick campus, the in the vaccine pilot plant and Frederick.

2365

04:49:11.909 --> 04:49:18.180

This testing was expanded to include the NCI shady graph campus in December of 2020.

2366

04:49:18.180 --> 04:49:28.319

The program is available to all all staff, government, contractor and subcontractor, and all are encouraged to voluntarily voluntarily participate in the testing.

2367

04:49:28.319 --> 04:49:33.869

Appointments are scheduled through the a symptomatic testing reservation system.

2368

04:49:33.869 --> 04:49:37.619

Performance of the testing is a group effort by staff.

2369

04:49:37.619 --> 04:49:42.299

At the test locations, the emergency management and protective services staff.

2370

04:49:42.299 --> 04:49:53.159

Assist with the management and the lines and to ensure social distancing and efficient movement on the lines and nursing staff, manage the collection and storage of the samples.

2371

04:49:53.159 --> 04:49:59.220

The samples are then sent to the, with as the campus for analysis through the courier system.

2372

04:49:59.220 --> 04:50:03.060

The HS nursing staff manage the testing results.

2373

04:50:03.060 --> 04:50:07.919

Including contact, tracing and case management for any positive cases.

2374

04:50:07.919 --> 04:50:21.450

Next slide, please, this chart represents some data relative to the asymptomatic testing program from September of 2020 until mid March of this past year.

2375

04:50:23.095 --> 04:50:36.775

The program began in September of 2020 at the 3 Frederick sites, and is currently ongoing. The NCI shady graph test site was added in December of 2020 the bar chart shows, the monthly testing volumes for Frederick shaded in blue and shady grove shaded in orange.

2376

04:50:37.075 --> 04:50:43.555

The line graph represents security number of test samples that are collected on a month by month basis.

2377

04:50:45.505 --> 04:50:58.104

In September 2020, which was the 1st, month of testing, a total of 229 samples were collected the monthly number of test samples, collected increased steadily between September 2020, and then peaked in January of 2021.

2378

04:50:58.104 --> 04:51:00.744

a total of 1759 test samples were collected in January of 2021.

2379

04:51:08.790 --> 04:51:18.750

From the inception of the program in September 2020 until mid March 2021, a total of 7,447 test samples were collected.

2380

04:51:19.525 --> 04:51:29.965

Now, the challenge to DHS was to scale up the testing capacity to meet the peak demand while maintaining efficient throughput and a safe environment with social distancing.

2381

04:51:30.415 --> 04:51:39.564

Logistics were also a concern to ensure an adequate number of test kits as well as for the workers involved in the effort, going forward the demand for.

2382

04:51:39.930 --> 04:51:50.310

Going forward is the demand for testing decreases the effort will scale back in order to control costs. The duration of the testing program is at the discretion of Nancy.

2383

04:51:50.310 --> 04:52:00.000

Next slide please. So, this concludes the overview of the program I will.

2384

04:52:00.000 --> 04:52:05.009

Remain available for questions after the next presentation.

2385

04:52:06.090 --> 04:52:14.965

Great. Thank you Sam. All right. Wrapping out this set of presentations. We have Dr Walter Hubert from the office of scientific operations at in.

2386

04:52:15.715 --> 04:52:25.014

He will be speaking to the amenities and other support services at the RTC. Walter, thank you Jason. Good afternoon. And thank you too.

2387

04:52:25.349 --> 04:52:35.250

So, if our industry day, I'm Walter Hubert, and is a scientific program director in Frederick. I oversee some of the functions. I'm going to describe here.

2388

04:52:35.250 --> 04:52:41.430

The amenities that you will learn off are critical catalyst for our research and our Dean Frederick.

2389

04:52:41.904 --> 04:52:50.544

Next slide here are some general assumptions to show the extent of our research community.

2390

04:52:51.115 --> 04:53:05.845

It is facility wide support that has research as well as administrative aspect of the government and the prime and resident subcontractors and Frederick that includes the main campus as well as several of the offsite facilities in Frederick.

2391

04:53:07.165 --> 04:53:18.955

An estimate of our workforce about 750 government and about 15 more than 1500 contracted, uh, scientists and administrators about 60% of our entire workforce conduct, scientific research.

2392

04:53:22.110 --> 04:53:29.189

Next slide.

2393

04:53:29.189 --> 04:53:32.939

It is humans who science.

2394

04:53:32.939 --> 04:53:36.360

Many, a project comes from a lunch conversation with a colleague.

2395

04:53:36.360 --> 04:53:39.869

And perhaps a scratched in the back of an app.

2396

04:53:39.869 --> 04:53:50.400

So, our cafeteria again, their 2 locations, 1 is the main campus in Frederick, and there is also a grab and go station at the advanced technology research facility.

2397

04:53:50.400 --> 04:54:02.759

They serve breakfast, lunch, menus, have snacks and soft drinks. The contractors also responsible for the maintenance and the cleaning services to insure safe operation of the cafe.

2398

04:54:04.590 --> 04:54:18.060

The 42 conference centers again, 1 on the main campus of Frederick, and then at the com conference services help to set set up scientific conferences for Frederick.

2399

04:54:18.060 --> 04:54:21.180

That includes a planning and implementation.

2400

04:54:21.180 --> 04:54:27.810

As well as speak of travel and coordination with the conference support team, like a audio and visual support.

2401

04:54:30.990 --> 04:54:34.104

Would you see in the pictures here on the top on top right?

2402

04:54:34.435 --> 04:54:36.595

Is a dining facility of the cafe,

2403

04:54:36.595 --> 04:54:39.924

and if the food service areas in the background on the left,

2404

04:54:40.674 --> 04:54:53.485

and at the bottom right picture you see a have a view of the auditorium on the main campus and turn and a projection screen in the front here.

2405

04:54:54.834 --> 04:55:03.174

Next slide we use a lab where it's cleaned in the larger research buildings, which have to necessary facilities.

2406

04:55:03.744 --> 04:55:11.064

And that includes both the cleaning and sterilization of lab, where either glass or plastics that can be used.

2407

04:55:12.659 --> 04:55:16.169

About the logistics.

2408

04:55:16.169 --> 04:55:19.560

You see.

2409

04:55:20.005 --> 04:55:21.534

At the NSA and Frederick,

2410

04:55:22.314 --> 04:55:28.194

and a contract basically also has in supply warehouse,

2411

04:55:28.194 --> 04:55:28.974

common research,

2412

04:55:28.974 --> 04:55:31.705

consumables and keeping supplies,

2413

04:55:32.305 --> 04:55:36.564

and these materials are provided on a cost recovery basis to the researchers.

2414

04:55:36.564 --> 04:55:44.305

And administrators again, here is a satellite facility at the, and also on the main campus.

2415

04:55:45.959 --> 04:55:52.740

Next slide our government own equipment is handled by.

2416

04:55:52.740 --> 04:56:04.169

Pretty management group, the activities there include tang and inventory management of our government, their own equipment, and also the surplus management for equipment.

2417

04:56:05.220 --> 04:56:08.400

The vehicle fleet in Frederick is managed centrally.

2418

04:56:08.755 --> 04:56:15.025

The aspect of management include about a fleet of 80 government owned and least vehicles,

2419

04:56:15.294 --> 04:56:21.354

which are assigned to the operational groups to distribute materials on the campus in Frederick,

2420

04:56:21.384 --> 04:56:25.645

or within the location various located in Frederick.

2421

04:56:26.040 --> 04:56:31.319

And for official travel, for example, to other campus and the shady.

2422

04:56:33.209 --> 04:56:42.330

Management group also takes care of record, keeping maintenance of the fleet as well as repairs and replacements that are necessary.

2423

04:56:43.590 --> 04:56:52.830

Next slide, the researchers must have access to published information and resources and that must be reliable.

2424

04:56:52.830 --> 04:56:59.549

As the saying goes here, an online search can get you a 1000 answers, but a librarian can bring you the right 1.

2425

04:56:59.549 --> 04:57:07.860

Our scientific library therefore is located close to the research facilities 1 on the main campus 1 at the.

2426

04:57:07.860 --> 04:57:21.779

The library staff manages digital subscriptions. There is a physical collection and of course, we have access to inter, library loan services, the library. So performs user training, facilitation of scientific.

2427

04:57:21.779 --> 04:57:25.740

And basically helps in the community building.

2428

04:57:27.029 --> 04:57:30.180

It is said that it's not science until it's published.

2429

04:57:30.180 --> 04:57:40.049

So, our scientific publications group helps research, preparing those high impact publications that we're all seek out to do.

2430

04:57:40.049 --> 04:57:46.200

That group provides publication support for posters and scientific manuscripts.

2431

04:57:46.200 --> 04:57:59.610

They help with text editing, build graphics for you and deal also with media usage. They also help in the newsletter preparation for our entire community and in user training. So they are adapt to work things from a desktop.

2432

04:58:01.889 --> 04:58:16.169

The picture that you see here on the right is our scientific library and that is a work area of the library in the background to the Windows kind of hard to see. But there are the stacks of the physical collection.

2433

04:58:17.580 --> 04:58:21.240

That concludes my presentation to you today. Thank you again for attending.

2434

04:58:22.259 --> 04:58:27.630

Great thanks a lot, Walter and thanks to Fred. Sam and Jeff.

2435

04:58:27.630 --> 04:58:35.729

For their presentations, it looks like we have at least 1 question to address. It looks like it would be.

2436

04:58:35.729 --> 04:58:41.009

Directed to Fred, Fred, um, since 20% of the buildings have been renovated.

2437

04:58:41.009 --> 04:58:53.669

Uh, is there a master plan to renovate the remaining buildings? And if there is a master plan, can that be shared for each building renovation status and its configuration, including room count size and type.

2438

04:58:53.669 --> 04:58:56.759

Uh, like lab, administrative storage and et cetera.

2439

04:58:57.840 --> 04:59:05.700

Uh, so very good question. So the 20% of the building that we have renovated were.

2440

04:59:05.700 --> 04:59:11.009

Basically, the labs and the multi story, most of the multi story buildings.

2441

04:59:11.009 --> 04:59:15.060

That were on campus, and as far as following.

2442

04:59:15.060 --> 04:59:18.869

How we renovated the massive vendors 2 things there's 1.

2443

04:59:18.869 --> 04:59:28.979

Following the guidelines of, uh, both, uh, the H, design policy guidelines and also they from a.

2444

04:59:28.979 --> 04:59:36.630

And, and basically, uh, we looked at those, and we tried to fit them into the.

2445

04:59:36.630 --> 04:59:39.779

Uh, basically the footprint that we had, so.

2446

04:59:39.779 --> 04:59:40.319

Um,

2447

04:59:40.584 --> 04:59:42.775

that was trends that way,

2448

04:59:42.775 --> 04:59:45.235

because they were the most that were the building,

2449

04:59:45.715 --> 04:59:56.005

the largest building with most laboratories and barbarian that existed the rest of the building as far as quite your question about whether there's a master plan for innovation.

2450

04:59:56.369 --> 05:00:03.540

We basically look at the needs that's identified as, you know, scientific needs changes.

2451

05:00:03.540 --> 05:00:07.229

You know, as as more protocols and will research.

2452

05:00:07.229 --> 05:00:17.700

Uh, comes on line and we basically evaluate our needs. Uh, we, we basically look at whether we have room on campus.

2453

05:00:17.700 --> 05:00:26.909

Or do we need to actually look at these facilities? So that's basically the way it works. Um, so hopefully that answer

your questions.

2454

05:00:30.090 --> 05:00:39.900

All right looks like an additional question to you, Fred, what is the M. S. or C. A. F. M. system used to manage the facility maintenance work?

2455

05:00:41.490 --> 05:00:48.599

Uh, right now I have to get back to you, we're looking at your systems, so I will get back to you and and and give you an answer on that.

2456

05:00:54.270 --> 05:00:57.689

Okay, other questions.

2457

05:01:06.419 --> 05:01:11.310

All right, let's go ahead and move forward with the facility slide show.

2458

05:01:11.310 --> 05:01:15.959

Thanks again for centers for your time and.

2459

05:01:15.959 --> 05:01:23.909

And information, now we're going to display the facility slide show, which is in lieu of what would usually be an in person tour.

2460

05:01:23.909 --> 05:01:34.799

These photos highlight and illustrate the variety and type of building laboratories and facilities at the, including the 68 acre campus at Frederick.

2461

05:01:34.799 --> 05:01:38.639

As well, as the least buildings, like the advanced technology research facility.

2462

05:01:38.639 --> 05:01:46.080

So this takes about 20 minutes, and then we will resume with f, RTC business operations after that.

2463

05:01:46.080 --> 05:01:46.560

Thanks,

2464

05:01:46.735 --> 05:03:46.075

Eva.

2465

05:19:46.080 --> 05:19:52.139

Hey, so that concludes facilities slide show special thanks to.

2466

05:19:52.139 --> 05:20:04.560

Facilities team for providing those images and an extra special thanks to Kristen for collecting them organizing them and getting them in the format that you see here.

2467

05:20:04.560 --> 05:20:12.810

Okay, so now let's change gears a little bit and focus on the RTC business operations overview.

2468

05:20:12.810 --> 05:20:18.900

And with that, we will start off with Dr Jeff Thomas.

2469

05:20:18.900 --> 05:20:29.669

From the technology transfer center, he will be speaking on technology development and transfer at the at the f RTC. Jeff.

2470

05:20:31.229 --> 05:20:36.150

I thank you. I can have the 1st slide please.

2471

05:20:37.290 --> 05:20:45.330

All right, the 1st, topic I want to talk about is the determination for exceptional circumstances to the Bible act.

2472

05:20:45.330 --> 05:20:48.689

Under, which the current.

2473

05:20:48.689 --> 05:20:51.810

Contract operates.

2474

05:20:51.810 --> 05:20:55.259

It's anticipated that a similar deck.

2475

05:20:55.259 --> 05:21:00.180

Will be in place for the contract.

2476

05:21:01.349 --> 05:21:10.619

So, under the under the current deck, the prime contractor assigns and inventions made by its employees to the government.

2477

05:21:10.619 --> 05:21:18.689

Except for when they are produced under contract to crater, so for contract to create a subject inventions.

2478

05:21:18.689 --> 05:21:28.470

And the contractor cradle or secret subject interventions are conditionally owned and managed by the contract or.

2479

05:21:28.470 --> 05:21:31.529

And this conditional ownership includes.

2480

05:21:31.529 --> 05:21:44.189

Uh, patenting and licensing and collecting royalties, related to these secret subject inventions. This conditional ownership remains with the contractor for as long as they are.

2481

05:21:44.189 --> 05:21:50.490

Uh, the contractor should at some point, they are no longer the contractor.

2482

05:21:50.490 --> 05:21:55.950

These assets would then be managed by a successor contractor, or the government.

2483

05:21:55.950 --> 05:22:00.060

With respect to subcontractors.

2484

05:22:00.060 --> 05:22:03.900

Under a typical Bible act.

2485

05:22:03.900 --> 05:22:13.229

They would retain ownership of their inventions, except in the following circumstances, where they would assign that ownership to the government or to a designated 3rd party.

2486

05:22:13.229 --> 05:22:20.580

And those exceptions are when they're using 3rd party proprietary materials or information, provided to the.

2487

05:22:20.580 --> 05:22:25.380

Or when using compounds developed at an age.

2488

05:22:25.380 --> 05:22:30.509

Or repurpose drugs that are in development towards potential clinical Therapeutics.

2489

05:22:30.509 --> 05:22:40.529

So, then those circumstances the subcontractors would assign ownership of those inventions to the government, or to that designated 3rd party.

2490

05:22:40.529 --> 05:22:45.900

I have the next slide please.

2491

05:22:45.900 --> 05:22:56.580

Uh, with respect to energy reporting, all inventions, including those conditionally owned by the, by the contractor are reported to NCI through the designated channels.

2492

05:22:56.580 --> 05:22:56.880

Uh,

2493

05:22:56.875 --> 05:22:58.854

on the current reporting forms,

2494

05:22:59.575 --> 05:23:12.325

the contractor will cooperate with the government to provide necessary information and to allow for appropriate review and patent filing of inventions that are assigned to the government under the deck.

2495

05:23:13.889 --> 05:23:23.849

The contract will also deposit invention information into I. Edison as appropriate and Edison is the.

2496

05:23:23.849 --> 05:23:30.450

Reporting invention reporting for the funded recipients.

2497

05:23:30.450 --> 05:23:33.689

Where they report all of their inventions.

2498

05:23:33.689 --> 05:23:39.599

I find out the next slide. Please. So.

2499

05:23:39.599 --> 05:23:48.959

The contractor also provides support to the government under the Government's research agreements.

2500

05:23:48.959 --> 05:23:52.139

This support can come under.

2501

05:23:52.139 --> 05:23:57.840

Cooperative research and development agreements are craters. These are government creators not.

2502

05:23:57.840 --> 05:24:03.389

The contractor creditors that I mentioned previously collaboration agreements.

2503

05:24:03.389 --> 05:24:08.009

And the support that's provided could include personnel.

2504

05:24:08.009 --> 05:24:14.759

Research services and expertise and Pro the deck under a CO op.

2505

05:24:14.759 --> 05:24:19.830

A collaboration agreement, the contractor inventions are assigned to the government.

2506

05:24:19.830 --> 05:24:25.709

If I can have the next slide, please. So.

2507

05:24:25.709 --> 05:24:30.779

For these collaboration agreements that are that are.

2508

05:24:30.779 --> 05:24:37.319

Let me back, let me step back so the contractor can also participate in it.

2509

05:24:37.319 --> 05:24:47.880

Independent partnering mechanisms under which the government is not involved in the, our, in the research endeavor.

2510

05:24:49.439 --> 05:25:02.400

Excuse me, so, in support of the agency mission, the contractor can establish collaboration agreements. These are your typical.

2511

05:25:02.400 --> 05:25:06.060

Research relationships there was no exchange of funds.

2512

05:25:06.060 --> 05:25:11.189

There is no advance option to inventions developed by the contractor.

2513

05:25:11.189 --> 05:25:14.759

And these inventions would be assigned to the government.

2514

05:25:14.759 --> 05:25:23.430

An example of this type of collaboration agreement could include, let's say, a testing agreement.

2515

05:25:23.430 --> 05:25:28.409

Uh, for to obtain and collaborate with.

2516

05:25:28.409 --> 05:25:33.689

An outside party for a Pre market technologies.

2517

05:25:33.689 --> 05:25:41.279

Other partnering mechanisms include the contractor crater, or C created that. I mentioned previously.

2518

05:25:41.279 --> 05:25:50.220

So, under the contract to cradle, the contractor can offer an advance option to inventions to the secret. A partner.

2519

05:25:50.220 --> 05:25:54.779

2 inventions produced under the under the C creator.

2520

05:25:54.779 --> 05:26:01.529

And the contractor laboratory can accept, create a funds.

2521

05:26:01.529 --> 05:26:05.040

Uh, to, uh, defray the cost of the research.

2522

05:26:05.040 --> 05:26:13.619

Described in the crater, there's no indirect involvement in the research by government personnel. These are this is a.

2523

05:26:13.619 --> 05:26:18.000

A contractor initiated and driven activity.

2524

05:26:18.000 --> 05:26:26.009

And as I mentioned previously, the contractor has conditional ownership of contractor, creative subject inventions.

2525

05:26:26.009 --> 05:26:32.549

And the contractor command, as I mentioned, can can manage these contract to create a subject conditions.

2526

05:26:32.549 --> 05:26:46.590

An associate associated patenting and licensing royalties to benefit the, and just some examples of the contract to credit. I think it was mentioned earlier the technical service agreements or.

2527

05:26:46.590 --> 05:26:51.509

These provide unique services to the, to the research community.

2528

05:26:51.509 --> 05:26:55.560

These are a flavor of.

2529

05:26:55.560 --> 05:26:59.220

Contractor craters. There's also.

2530

05:26:59.220 --> 05:27:03.240

Examples for creators that can be.

2531

05:27:04.860 --> 05:27:14.549

In support of bigger research projects, for example, maybe involving the brass initiative that you heard about earlier today.

2532

05:27:17.305 --> 05:27:27.715

And I should mention that the collected royalties are used to benefit the, and are not to the direct bit for the direct benefit of the contractor.

2533

05:27:27.744 --> 05:27:39.415

So, as I mentioned, they, if the contractor were to move on, and I, no longer be the contractor, there would those assets and royalties would remain.

2534

05:27:39.750 --> 05:27:46.349

At the, for future management, by a successor contractor, or by the government.

2535

05:27:46.349 --> 05:27:56.549

I can have the next slide please and finally I'd like to talk about the invention development program.

2536

05:27:56.549 --> 05:28:08.939

And this is a program that funds preclinical validation projects with the goal of de, risking code development and licensing of research inventions by private sector organizations.

2537

05:28:08.939 --> 05:28:20.069

Basically to make them more marketable, the project managers coordinate with the point of contact for each project.

2538

05:28:20.069 --> 05:28:25.950

Including partnering project management, financial management and project specific reporting.

2539

05:28:25.950 --> 05:28:38.369

Pre clinical support provided by is provided by the prime contractor or TV, or by subcontractors as appropriate.

2540

05:28:38.369 --> 05:28:44.250

And this support can include animal studies, or perhaps.

2541

05:28:44.250 --> 05:28:49.169

Material production scale up and it's.

2542

05:28:49.169 --> 05:28:54.810

There are approximately 6 projects ongoing per year.

2543

05:28:54.810 --> 05:28:57.930

I believe that is my last slide.

2544

05:29:00.060 --> 05:29:03.509

And I, thank you, and we'll be around to answer any questions.

2545

05:29:03.509 --> 05:29:14.759

All right. Thanks a lot, Jeff, thank you. Okay, next step we have miss Carolyn she's from the office of scientific operations, and she will be presenting.

2546

05:29:14.759 --> 05:29:19.290

Uh, information on subcontracting purchasing and finance at the parties.

2547

05:29:19.290 --> 05:29:23.880

Airline good afternoon. Everyone can you hear me clear.

2548

05:29:23.880 --> 05:29:30.150

Yes, we can. Yes. Perfect. Thank you next. Please.

2549

05:29:31.619 --> 05:29:39.654

Go Co, government owned director, operated term, an acronym that you heard repeated earlier. Today.

2550

05:29:39.985 --> 05:29:49.075

I want to start with that because that is the structure of our, and the responsibilities within related to the government are that.

2551

05:29:49.075 --> 05:30:03.115

The government will provide oversight within this environment infrastructure systems, equipment and property. The contractor responsibilities are to operate facility, utilize those in place systems.

2552

05:30:03.389 --> 05:30:12.060

Reform and manage the work and ensure that the required licenses certain certifications and accreditations are maintained.

2553

05:30:12.060 --> 05:30:26.755

Next lovely place, managing and administering a system of internal controls for business and administrative operations is imperative to support and achieve the scientific mission.

2554

05:30:27.450 --> 05:30:34.409

Integration of systems and internal controls across the ensures seamless success.

2555

05:30:34.409 --> 05:30:38.279

Business processes implemented are risk based.

2556

05:30:38.279 --> 05:30:45.330

Cross functional cost effective, strive to increase efficiency and enhance productivity.

2557

05:30:45.330 --> 05:30:56.250

A focus to incorporate enterprise wide processes is expected to optimize and streamline business practices and administrative functions.

2558

05:30:56.250 --> 05:31:03.180

Next slide please some contracting and purchasing management.

2559

05:31:03.180 --> 05:31:07.889

During that complexity and diversity of support to the to the.

2560

05:31:07.889 --> 05:31:16.139

From contractor may enter into subcontracts and agreements to execute work is outlined in the statement of work.

2561

05:31:16.139 --> 05:31:22.709

Generally terms and conditions of the prime contract award will float out contracts.

2562

05:31:23.305 --> 05:31:34.525

The expectation is that the prime contractor will utilize streamline acquisition strategy, which is such a strategy sourcing activities and centralizing for the fnl.

2563

05:31:34.854 --> 05:31:43.944

And there are a few examples of those agreements the few, which are consultant agreements, purchase, orders, research and research development contracts.

2564

05:31:44.159 --> 05:31:49.319

Next slide please financial management.

2565

05:31:49.319 --> 05:31:55.259

All aspects of the f. R. D. C. and must interact and be interoperable.

2566

05:31:55.259 --> 05:32:00.569

This 1 tail integration of all operational aspects.

2567

05:32:00.569 --> 05:32:07.590

Tracking of fiscal cycles, which will would entail October 1st through September 30 and each year.

2568

05:32:07.590 --> 05:32:16.680

In addition on tractor accounting processes will meet the needs of the government accounting and government financial services systems.

2569

05:32:16.680 --> 05:32:24.090

And are strain line flexible, and provide transparent financial management and cost recording.

2570

05:32:24.090 --> 05:32:31.169

Are capable of tracking evaluating and projecting financial activities for projects.

2571

05:32:31.169 --> 05:32:34.439

Integrate data from scientific.

2572

05:32:34.439 --> 05:32:39.659

Facilities operations and management and other government support functions.

2573

05:32:39.659 --> 05:32:47.849

Reduce detailed, accurate and timely reports for cost and scope and accurate schedule estimates.

2574

05:32:47.849 --> 05:32:51.509

This will provide the government with status overview.

2575

05:32:51.509 --> 05:32:56.669

Next place reporting.

2576

05:32:56.669 --> 05:33:06.630

Financial reporting, inclusive of direct and indirect cost breakouts for cost benefit analysis to determine appropriate level of support function and risk.

2577

05:33:07.014 --> 05:33:21.834

Full transparency of all financial costs reporting system and reports to allow visibility into program and cost management. This will provide the government with data for making sound business decisions.

2578

05:33:22.139 --> 05:33:33.479

Contractor and government collaboration is a, must to identify and collect common productivity and labor cost data to seek fnl wide solutions.

2579

05:33:33.479 --> 05:33:38.880

As requested develop additional custom ad hoc reports.

2580

05:33:38.880 --> 05:33:52.290

In summary, contract of financial systems look integrate with government, financial management systems to verify and document financial Stewart ships. There are a few examples of that listed below.

2581

05:33:52.290 --> 05:34:02.849

Next slide, please related to financial management support. The contractor contractor will support the government for planning.

2582

05:34:02.849 --> 05:34:12.540

Programming budgeting, evaluate financial status through a budgeting system with real time reporting capabilities.

2583

05:34:12.540 --> 05:34:16.770

With a formulation and execution of resource requirements.

2584

05:34:16.770 --> 05:34:24.389

Next slide, please financial management through electronic support.

2585

05:34:24.389 --> 05:34:31.529

Tales maintaining electronic business and data systems for organizational operations.

2586

05:34:31.529 --> 05:34:36.299

Data collection data, processing, report generation.

2587

05:34:36.299 --> 05:34:41.669

Maintain and administer and approved electronic financial management system.

2588

05:34:41.669 --> 05:34:48.090

Budgeting system capable of identifying all resource requirements for projected work.

2589

05:34:48.090 --> 05:34:53.639

Internal financial control system for tracking and expenditure of funds obligated.

2590

05:34:53.639 --> 05:34:57.299

An invoice preparation is clear concise.

2591

05:34:57.299 --> 05:35:01.080

And meets the needs of the government for providing approval.

2592

05:35:01.555 --> 05:35:12.654

Next slide, please other business aspects include property management and internal audits, property management and accountability.

2593

05:35:13.134 --> 05:35:21.174

The contractor will manage track and report accountable government owned property while ensuring safe guarding and

disposition.

2594

05:35:21.540 --> 05:35:28.290

Internal audits to establish maintain and routinely execute audits reviews.

2595

05:35:28.290 --> 05:35:35.130

And appraisals, thank you to everyone for joining us today. I will be available for questions at the end of this.

2596

05:35:35.130 --> 05:35:40.380

Session all. Right. Thank you so much. Caroline.

2597

05:35:42.509 --> 05:35:43.110

Okay,

2598

05:35:43.104 --> 05:35:53.784

and now we have an encore appearance by Dr Michael default Antonio this time he's going to be talking about scientific recruitment and project management at the,

2599

05:35:55.014 --> 05:35:55.674

as you recall,

2600

05:35:55.674 --> 05:35:58.134

he's from the division of cancer treatment and diagnosis.

2601

05:35:58.319 --> 05:36:06.630

Michael.

2602

05:36:10.529 --> 05:36:15.930

You might go on mute.

2603

05:36:15.930 --> 05:36:20.369

Thank you. Thank you. All right. Thank you. Thanks, Jason.

2604

05:36:20.369 --> 05:36:28.049

At the end of the day, so I'll try and be brief, but I think this is very important aspect of the contract.

2605

05:36:28.049 --> 05:36:33.869

I mean, we've heard all day about the scientific activities and the infrastructure activities, et cetera.

2606

05:36:33.869 --> 05:36:40.080

But I think recruiting scientific and non scientific staff.

2607

05:36:40.080 --> 05:36:43.380

As well as managing projects is a critical activity.

2608

05:36:43.380 --> 05:36:46.830

Of the contract can I have the 1st slide? Please.

2609

05:36:49.500 --> 05:36:56.040

So, as I just touched upon, you know, it's important to have a very robust recruitment program.

2610

05:36:56.040 --> 05:37:03.000

That promotes and attracts a diverse workforce to have effective and innovative approaches to.

2611

05:37:03.000 --> 05:37:16.979

Fill hard to fill positions and it's also important to hire and retain highly qualified employees. Important important doesn't to consider all of these requirements, but then the context.

2612

05:37:16.979 --> 05:37:21.270

Of flexibility of the mission and the speed of the government.

2613

05:37:21.270 --> 05:37:25.650

To stand up new programs and response to emerging needs as we heard.

2614

05:37:25.650 --> 05:37:28.889

Several times this morning, I won't go into those again.

2615

05:37:28.889 --> 05:37:36.509

But I could actually think of the, as being a fast flexible research and development contract.

2616

05:37:36.509 --> 05:37:47.310

By the next slide please. So this would entail a constant evaluation of current and future workforce.

2617

05:37:47.310 --> 05:37:51.270

Expertise, excuse me performance and staffing levels.

2618

05:37:51.270 --> 05:37:55.500

Developing appropriate workforce management and transition strategies.

2619

05:37:55.500 --> 05:38:02.220

Obtaining additional workforce in real time, as needed as new initiatives are stood up.

2620
05:38:02.220 --> 05:38:08.700
And having a very good and robust onboarding and off boarding process in place.

2621
05:38:08.700 --> 05:38:12.990
Next slide please.

2622
05:38:16.200 --> 05:38:23.250
So, in terms of positions are a number of activities.

2623
05:38:23.250 --> 05:38:27.779
That are required to sustain a large government funded biomedical enterprise.

2624
05:38:27.779 --> 05:38:31.560
And those include project and program managers.

2625
05:38:31.560 --> 05:38:36.450
Scientific or sometimes they're called technical project and program managers.

2626
05:38:36.450 --> 05:38:41.340
As you heard earlier, we have conference facilities and so.

2627
05:38:41.340 --> 05:38:46.799
There needs to be staff that are capable of providing meeting support.

2628
05:38:46.799 --> 05:38:49.830
And and writers as well.

2629
05:38:51.509 --> 05:39:02.639
Next slide please and in terms of activities, I've listed a number of different activities here. This is not.

2630
05:39:02.639 --> 05:39:06.000
Of course comprehensive, but.

2631
05:39:06.000 --> 05:39:12.029
Certainly planning and oversight of the activities, logistical, administrative, and technical support.

2632
05:39:12.029 --> 05:39:17.580
Development management and reporting, as we just heard from Carolyn of budgets cost.

2633
05:39:17.580 --> 05:39:22.830

Timelines and performance regular and transparent communication with the government.

2634

05:39:22.830 --> 05:39:31.889

Responsiveness and a quick response to needs and the ability to adjust to changes are all critical activities.

2635

05:39:31.889 --> 05:39:42.450

As the next slide, please, finally, the goals are to streamline project support.

2636

05:39:42.450 --> 05:39:51.959

Both in the planning and the execution, in terms of affecting maximum performance, without imposing burdensome processes and impediments to timelines.

2637

05:39:51.959 --> 05:40:00.299

Integrating and streamlining the business administrative processes to rapidly and effectively achieve scientific goals as we just heard.

2638

05:40:00.299 --> 05:40:04.680

From Carolyn, on the business side, this would include the financial planning and budget.

2639

05:40:04.680 --> 05:40:09.118

Counting and billing research subcontracts, et cetera.

2640

05:40:09.118 --> 05:40:14.489

And to provide a nimble, transparent and responsive support system.

2641

05:40:14.489 --> 05:40:21.838

Next slide. Please. So now I'm just going to give you a couple of examples of.

2642

05:40:21.838 --> 05:40:26.338

Programs and hopefully demonstrate the importance of program and project management.

2643

05:40:26.338 --> 05:40:40.408

I can have the next slide please. So, the experimental Therapeutics program or the next program encompasses both drug discovery and development as indicated in the pipeline at the bottom of the diagram.

2644

05:40:40.408 --> 05:40:44.969

As such expertise is needed in the various stages.

2645

05:40:44.969 --> 05:40:50.219

Of that process, starting with target validation and screening ASCII development.

2646

05:40:50.219 --> 05:40:55.379

Medicinal chemistry to convert hits the highly potent compounds with target specificity.

2647

05:40:55.379 --> 05:40:58.829

The need for Toxicology and scale up manufacturing.

2648

05:40:58.829 --> 05:41:02.789

I N. D filing and finally conducting clinical trials.

2649

05:41:02.789 --> 05:41:06.179

The discovery portion of the next program is indicated.

2650

05:41:06.179 --> 05:41:12.118

On the left there, if I could have the next slide is conducted through a consortium.

2651

05:41:12.118 --> 05:41:19.109

Subcontractors with several of the skills and expertise that I just described.

2652

05:41:19.109 --> 05:41:22.829

And this is just a map showing the current.

2653

05:41:22.829 --> 05:41:26.458

Chemical biology consortium subcontractors through.

2654

05:41:26.458 --> 05:41:32.008

And where they're located across the country and.

2655

05:41:32.008 --> 05:41:37.978

fnl however, has to have program managers with the matching set of knowledge and expertise.

2656

05:41:37.978 --> 05:41:42.899

In order to be conversant with the subcontractors to effectively write the statements of work.

2657

05:41:42.899 --> 05:41:48.929

And evaluate the proposals that are returned to manage their performance review, the invoices that are submitted.

2658

05:41:48.929 --> 05:41:53.039

And communicate progress, difficulties and remedies to the government.

2659

05:41:53.039 --> 05:41:56.248

So that we can make informed programmatic decisions.

2660
05:41:56.248 --> 05:42:01.169
Next slide please.

2661
05:42:01.169 --> 05:42:06.658
As projects move through the pipeline and not surprising that different expertise is required.

2662
05:42:06.658 --> 05:42:10.528
Project teams continue to grow and evolve to meet those new needs.

2663
05:42:10.528 --> 05:42:17.638
And those changes of course, also need to be managed. So what I've shown you here on the right side of the slide.

2664
05:42:17.638 --> 05:42:20.789
Is a node map illustrating various projects.

2665
05:42:20.789 --> 05:42:27.629
Numbers in pink circles, the various CBC contractors or subcontractors, I should say.

2666
05:42:27.629 --> 05:42:34.438
Yeah, in the purple circles as well as the applicant institutions and cmo's and green circles.

2667
05:42:34.438 --> 05:42:40.919
The size of the circles corresponds with the number of projects that each of those groups are involved in.

2668
05:42:40.919 --> 05:42:46.199
Also indicating the orange circles are labs at Frederick national labs.

2669
05:42:46.199 --> 05:42:49.318
And it's the intramural program.

2670
05:42:49.318 --> 05:42:53.879
So, this complexity clearly needs to be managed and managed to effectively.

2671
05:42:55.348 --> 05:43:06.929
Next slide please. So, this last example is of a specific government directive project. So the human cancer drug, if assuming that.

2672
05:43:06.929 --> 05:43:14.609
Is a monoclonal antibody directed against a checkpoint inhibitor protein for.

2673
05:43:14.609 --> 05:43:17.699
Which to.

2674
05:43:17.699 --> 05:43:22.289
And, uh, delivery of this drug allows the immune system to target cancer cells.

2675
05:43:22.289 --> 05:43:30.809
So, in order to Pre, clinically evaluate the use of it, we'll do a map in combination with other approved or investigational cancer therapies.

2676
05:43:30.809 --> 05:43:35.368
We wanted to do that in dogs with naturally occurring tumors.

2677
05:43:35.368 --> 05:43:39.838
Rather than in more artificial systems.

2678
05:43:39.838 --> 05:43:45.359
Such as human tumors that are typically implanted into immune deficient mass models.

2679
05:43:45.359 --> 05:43:49.228
And so we needed to develop a corresponding antibody that would recognize.

2680
05:43:49.228 --> 05:43:55.949
The canine for protein, so this requires the skills and expertise several different components.

2681
05:43:55.949 --> 05:44:03.568
Of the is indicated on the left in terms of bio. 1st excuse me biopharmaceutical development.

2682
05:44:03.568 --> 05:44:06.598
That involves immunization.

2683
05:44:06.598 --> 05:44:11.489
The of the animals hyperdome, isolation conversation.

2684
05:44:11.489 --> 05:44:17.489
cantonization, and then ultimately GMP, manufacturing and antibodies.

2685
05:44:17.489 --> 05:44:25.978
Produce and clinical trials, in terms of developing assays or pharmacokinetics or dynamics.

2686

05:44:25.978 --> 05:44:29.848

Those were required.

2687

05:44:29.848 --> 05:44:35.278

To measure the affinity and specificity of the candidate monoclonal antibodies that were identified.

2688

05:44:35.278 --> 05:44:40.949

As well, as for measuring and assessing the response of the canine patients to exposure.

2689

05:44:40.949 --> 05:44:45.989

To the antibody both to determine if the antibody was actually hitting the target that it was intended.

2690

05:44:45.989 --> 05:44:49.888

To it and Alyssa to desired immune activation.

2691

05:44:49.888 --> 05:44:56.519

But also to determine if the dogs were developing immune reaction to the drug itself.

2692

05:44:56.519 --> 05:45:01.348

Both of these activities required the expression and.

2693

05:45:01.348 --> 05:45:04.528

Production of pure purified proteins.

2694

05:45:04.528 --> 05:45:07.739

For immunization as well as for.

2695

05:45:07.739 --> 05:45:11.789

To use in the screening assets. Like, I have the next slide please.

2696

05:45:15.359 --> 05:45:20.938

So this particular project was conducted as a 5 year non several task order.

2697

05:45:20.938 --> 05:45:25.258

Which means that all of the funding was committed up front.

2698

05:45:25.258 --> 05:45:29.309

And that those funds could only be used for duration of 5 years.

2699

05:45:29.309 --> 05:45:34.469

So, within the project plan, we committed funding for multiple technical approaches.

2700

05:45:34.469 --> 05:45:40.919

To increase the likelihood of having a shot on goal and identifying and developing a for.

2701

05:45:40.919 --> 05:45:46.258

Therapeutic antibody for use in dogs that could have the next 5 please.

2702

05:45:46.258 --> 05:45:50.879

So, we were fortunate in the sense that the 1st approach that we tried.

2703

05:45:50.879 --> 05:45:57.868

Worked and so this enables the team to develop and compete a series of additional subcontracts.

2704

05:45:57.868 --> 05:46:03.449

For the development of other canine immune checkpoint inhibitors of interest to the government.

2705

05:46:03.449 --> 05:46:08.399

Utilizing those those additional funds, which were.

2706

05:46:08.399 --> 05:46:11.998

Placed on the contract and earmarked for these back up.

2707

05:46:11.998 --> 05:46:16.048

Approaches like at the next slide.

2708

05:46:18.568 --> 05:46:22.528

So, hopefully these 2 examples provide.

2709

05:46:22.528 --> 05:46:25.679

Conveyed a.

2710

05:46:25.679 --> 05:46:31.289

The fact that this is indeed an R and D contract. We're not making widgets.

2711

05:46:31.289 --> 05:46:37.379

At the Frederick National Lab, and as such 1 needs to plan for the known unknowns.

2712

05:46:37.379 --> 05:46:41.039

Such as I just described for the last project.

2713

05:46:41.039 --> 05:46:48.149

Implemented multiple approaches based on the known uncertainty of success with any individual 1 approach.

2714

05:46:49.258 --> 05:46:54.118

There's also an important need to be able to pivot and reallocate resources.

2715

05:46:54.118 --> 05:46:57.929

Adjust staffing in response to these unknown.

2716

05:46:57.929 --> 05:47:00.929

Unknowns and examples of that.

2717

05:47:00.929 --> 05:47:09.868

That you may be familiar with, or the congressional appropriations, such as the American Recovery and Reinvestment act of 2009 otherwise known as error.

2718

05:47:09.868 --> 05:47:15.899

Cancel moonshot and the National rash project that you've heard about earlier today.

2719

05:47:15.899 --> 05:47:20.879

Also need to be able to pivot and reallocate resources and staffing.

2720

05:47:20.879 --> 05:47:27.118

For disease outbreak again, which we heard about this morning or Ebola or the 2.

2721

05:47:27.118 --> 05:47:33.208

And also to stand up facilities, such as the cry orient facility.

2722

05:47:33.208 --> 05:47:37.559

You also heard about to renovate space.

2723

05:47:37.559 --> 05:47:41.008

And bring on and hire the.

2724

05:47:41.008 --> 05:47:45.658

The technical staff that are capable of running, such a facility.

2725

05:47:45.658 --> 05:47:48.989

And so with that, I'll stop and thank you for your attention.

2726

05:47:51.719 --> 05:47:56.758

Great. Thanks a lot. Michael. Yep. Okay.

2727

05:47:56.758 --> 05:48:00.059

Now, we'll go ahead and open it up to questions and.

2728

05:48:00.059 --> 05:48:08.609

As promised earlier, there was a question from this morning that was more appropriate for this section. So we're going to bring that up up front and go over that.

2729

05:48:08.609 --> 05:48:11.789

The questionnaire, so actually, as a set of questions.

2730

05:48:11.789 --> 05:48:17.758

Obviously performing the work under this contract requires a wide range of labor categories and expertise.

2731

05:48:17.758 --> 05:48:23.579

What is the total number of contract staff under the after pharmacy contract? Not including subcontractor.

2732

05:48:23.579 --> 05:48:26.818

That's question number 1. what would.

2733

05:48:26.818 --> 05:48:31.559

The provide, or would the provide a breakdown of task?

2734

05:48:31.559 --> 05:48:37.169

By task, or for these scientific programs with a number of staff and labor categories.

2735

05:48:37.169 --> 05:48:41.579

And then taking this a bit further with the, and I also be able to provide a list.

2736

05:48:41.579 --> 05:48:45.629

The subcontracts that are currently performed under this contract.

2737

05:48:45.629 --> 05:48:53.219

Including the number of staff and expertise, like labor categories required for the work under each subcontract.

2738

05:48:53.219 --> 05:48:57.658

And I think I'm going to field that 1 to Lisa Coleman. Lisa. Do you want to take that?

2739

05:49:00.533 --> 05:49:01.283

Of course,

2740

05:49:02.243 --> 05:49:06.743

so the general information about the labor categories,

2741

05:49:06.774 --> 05:49:17.783

and labor currently utilized under the contract is information that will be included in the solicitation when that is released additional information about subcontracts.

2742

05:49:17.813 --> 05:49:23.574

And current projects is also information that will likely be provided within the solicitation.

2743

05:49:25.888 --> 05:49:38.669

Thank you Lisa. All right next question and I think this, maybe Jeff can take an initial stab at it with a follow up from Carolyn and then maybe somebody from the contract in the office.

2744

05:49:38.669 --> 05:49:46.199

Under a secreting agreement is there an accounting of any cost of labor and cost of materials or other direct cost?

2745

05:49:46.199 --> 05:49:51.298

That require the contractor to pay the government for their use of labor and materials.

2746

05:49:51.298 --> 05:49:59.848

Present in the facility, I'm going to pass that question on. That's more of a contracting question, rather than a creative question.

2747

05:50:01.769 --> 05:50:06.239

All right, Carolyn or somebody for most. Do you want to tackle that?

2748

05:50:08.458 --> 05:50:11.579

I'm in agreement, I'm going to defer that to contracting.

2749

05:50:16.164 --> 05:50:29.213

All right, so I guess, I don't have anybody that I can deferred on to so I'm going to go ahead. And again, this is another 1 of those. The secret is, are actually something that function outside of the contract.

2750

05:50:29.754 --> 05:50:41.484

So, the existing or the accounting of any cost and labor, there is accounting of it, but not something that is presented back to the government.

2751

05:50:42.173 --> 05:50:49.103

And again, we can provide further information in the Q and A's. That will release.

2752

05:50:49.408 --> 05:50:57.383

With the written answers thanks. And I believe this is going to be the same answer for the next question, which is yeah.

2753

05:50:57.594 --> 05:51:11.513

Is the contractor obligated to you to the use of existing, financial and budgeting software, or are the offers free to propose their own systems provided that the government can be granted access to those systems? Yeah.

2754

05:51:11.513 --> 05:51:18.623

Again, there's, there's a lot to unpeel here in terms of being granted or actual ownership of systems.

2755

05:51:18.833 --> 05:51:27.353

So, again, the written response to that will break that out more much more clearly than I can do through the short period of time that we have here.

2756

05:51:27.629 --> 05:51:31.318

I would be okay.

2757

05:51:31.318 --> 05:51:34.888

All right any other questions from.

2758

05:51:34.888 --> 05:51:38.548

We had a group here. I don't see anything popped up yet.

2759

05:51:38.548 --> 05:51:43.618

Oh.

2760

05:51:51.958 --> 05:51:58.618

Silence.

2761

05:51:58.618 --> 05:52:07.169

Okay, here's a couple questions will make a copy of the current master ID contract available.

2762

05:52:07.169 --> 05:52:13.019

And will NCI make a copy of the current task board contracts available?

2763

05:52:13.019 --> 05:52:13.679

Yes,

2764

05:52:13.704 --> 05:52:16.973

we do plan to release those in another public notice those,

2765
05:52:17.633 --> 05:52:24.653
as I get into my portion of the presentation beta Sam is our primary point of entry,

2766
05:52:24.653 --> 05:52:33.563
but we also have the acquisition portal and those 2 documents will be made available through both of those sites.

2767
05:52:33.838 --> 05:52:57.118
Silence.

2768
05:52:58.138 --> 05:53:09.269
Jason, I see there's a question in there about ID IQ, multiple award or single award, and I'll just defer that until I get into my slides because I do address that there. Okay.

2769
05:53:09.269 --> 05:53:31.708
Silence

2770
05:53:31.734 --> 05:53:32.243
okay,

2771
05:53:32.274 --> 05:53:34.583
I think we are a little bit ahead,

2772
05:53:34.583 --> 05:53:35.844
but it sounds like,

2773
05:53:35.844 --> 05:53:36.054
uh,

2774
05:53:36.114 --> 05:53:40.103
maybe a lot more questions coming in for the next section,

2775
05:53:40.133 --> 05:53:42.173
which is gonna be Lisa.

2776
05:53:42.419 --> 05:53:55.109
Lisa Coleman, as she introduced herself earlier is from the management operations to support branch, and she will be talking about the procurement process and the.

2777
05:53:55.109 --> 05:54:00.629
An overview of the ins and outs of this. So basically go ahead and take it on.

2778
05:54:01.829 --> 05:54:05.728
Hello.

2779
05:54:08.908 --> 05:54:23.004

And Lisa, you might be on mute again. I sure was that little box popped up and said guess what you're muted. I was just paying everybody a compliment what a great job everybody has done with the presentations today. Hopefully, I can follow suit.

2780
05:54:23.033 --> 05:54:37.223

I think all the presenters, I also think the committee that put a whole lot of time and effort into making sure that we can pull this off virtually for those who may remember the last time we did this type of thing. We didn't do it virtually.

2781
05:54:37.223 --> 05:54:50.004

We did it in person and it is amazing the challenges that we've encountered trying to pull this off virtually. So kudos to the team. I really appreciate everybody's efforts also. Thank you. All the participants.

2782
05:54:50.004 --> 05:55:01.824

These have been very thoughtful questions as we mentioned before we will provide a Cuban a document. That will be publicized. So that clarifications can can be provided for whatever information.

2783
05:55:01.824 --> 05:55:16.734

We were not able to elaborate on given the time constraints today. So, as Jason indicated, I'm going to go over some of the procurement process very high level, but we will have breakout sessions afterwards.

2784
05:55:16.734 --> 05:55:27.443

Happy to answer any additional questions and again, encourage you to type your questions into the chat box. Because any questions we don't get to today, we will include in the Q a.

2785
05:55:27.778 --> 05:55:30.958
Next slide please.

2786
05:55:31.463 --> 05:55:31.763
Okay,

2787
05:55:32.033 --> 05:55:33.114
just a reminder,

2788
05:55:33.114 --> 05:55:39.414

the contracting officer with the appropriate delegated authority is the only person who can bind to the government,

2789
05:55:39.684 --> 05:55:41.754
there's been lots of people on the phone today,

2790
05:55:42.234 --> 05:55:43.074
or on this call,

2791
05:55:43.074 --> 05:55:50.844
rather that have done phenomenal presentations but questions must be directed to the contracting officer please,

2792
05:55:50.844 --> 05:55:55.074
don't reach out to individual presenters today.

2793
05:55:55.074 --> 05:56:06.623
We will make sure that we get in touch with the right person to get you the right information discussions for today's purposes or informational. Only. We're sharing with you. Some of the current activities.

2794
05:56:06.623 --> 05:56:15.804
Some of the past activities to give you insight into the operation of the, and this is not to procurement sensitive information.

2795
05:56:15.864 --> 05:56:27.473
We also remind everybody procurement sensitive information must not be discussed future activities. Again, the presenters that you've spoken to are not going to be able to provide you.

2796
05:56:28.223 --> 05:56:32.333
I think what most would hope would be a lot more insight into hey, Where's this going?

2797
05:56:32.633 --> 05:56:37.644
That's just something that we cannot do to protect the procurement any questions you have,

2798
05:56:37.644 --> 05:56:38.304
as I said,

2799
05:56:38.333 --> 05:56:39.653
chat box in here today,

2800
05:56:39.653 --> 05:56:43.074
or you can use this email address that you see in front of you the,

2801
05:56:44.243 --> 05:56:48.774
and there is an underscore and then act info at an age dot Gov.

2802
05:56:48.774 --> 05:56:54.533

We do monitor that that is monitored by contracting officers. And, as I said, we reach out to our.

2803

05:56:55.498 --> 05:57:05.153

Programmatic partners to get the right information based on the questions that we receive. Again, a reminder with procurement sensitive information.

2804

05:57:05.184 --> 05:57:15.954

There's of course always the chance you can put your organization at risk from being excluded from the competition. If you obtain information in a manner that is not in accordance with procurement integrity.

2805

05:57:16.739 --> 05:57:29.609

Official government requirements will all be clarified in the solicitation. And again, I think this is probably the 14th time. I've said this alone a formal Q and a session will be provided later.

2806

05:57:29.609 --> 05:57:32.789

Next slide please.

2807

05:57:32.789 --> 05:57:47.094

Search general background, in terms of the contract approach, and where we plan to go with the solicitation we are contemplating that it's going to be, of course, a new contract with an ordering period of up to 10 years.

2808

05:57:47.484 --> 05:58:00.594

We do anticipate that this will be an indefinite delivery indefinite quantity as we most know that as the contract mechanism and we do have requirements for both and non several task orders.

2809

05:58:00.623 --> 05:58:11.094

Options are always something that can be included both in the ordering period as well as, in any of the task orders that we award underneath that parent contract.

2810

05:58:11.454 --> 05:58:18.984

We anticipate that most, but not all work won't be supported through costs reimbursement task orders with negotiated fee.

2811

05:58:18.984 --> 05:58:28.493

If applicable we also anticipate that the new award will have a ceiling that will exceed the 15Billion dollar price threshold again,

2812

05:58:28.794 --> 05:58:38.484

aligning that with our ordering period that is just where we are with the initial estimates the ceiling again is a maximum contract value.

2813

05:58:38.484 --> 05:58:50.274

That can't be exceeded with all of the task orders that are awarded underneath it. The ceiling is not a direct funding level

that will be done on the task order specific basis. Next slide. Please.

2814

05:58:54.204 --> 05:59:09.114

Again, we plan to use far part 15, which is a negotiated award, and the source selection process will reflect the best value continuum and a potential for award to someone, other than the lowest price offer.

2815

05:59:09.173 --> 05:59:09.712

And again,

2816

05:59:09.712 --> 05:59:24.414

that's very important to make sure everybody understands all evaluation factors as is the norm will be included in the solicitation along with their sub factors and relative importance based off of

2817

05:59:24.414 --> 05:59:28.313

their potential scoring technical capability will,

2818

05:59:28.313 --> 05:59:28.763

of course,

2819

05:59:28.763 --> 05:59:39.114

be paramount in this acquisition and subcontracting plans will be critical evaluation factor as you can imagine with the large value of the.

2820

05:59:40.283 --> 05:59:49.794

This is critical importance to and as a whole additional information concerning the competitive process will be announced on the government wide point of entry.

2821

05:59:49.973 --> 06:00:02.394

I mentioned beta Sam earlier as well as the acquisition portal, but I do want to highlight that beta Sam information will always take precedence because that is our government point of entry slide. Please.

2822

06:00:05.903 --> 06:00:12.263

The statement of work, I believe just about everybody. If you haven't, it is available on our acquisition portal.

2823

06:00:12.263 --> 06:00:27.204

We released a request for information, providing a copy of the draft statement of work the objectives and activities of the f already C are dynamic and subject to change. And continuing evolution, so that's why, what you saw is just a draft.

2824

06:00:27.473 --> 06:00:39.653

The statement of work must not be all inclusive or restrictive. We're an, we need to incorporate a wide range of scientific disciplines to allow for the fast acting and dynamic response that Dr.

2825

06:00:40.704 --> 06:00:55.614

referred to earlier this model that we're using has been incorporated and used by other and allows for that broad scope of work and the definition of the requirements comes down at the task order level it's intended to provide

2826

06:00:55.614 --> 06:00:55.943

again,

2827

06:00:55.943 --> 06:00:58.463

the broad framework for the work to be performed at,

2828

06:00:59.513 --> 06:01:01.493

during the term of,

2829

06:01:01.524 --> 06:01:03.743

or the ordering period of the contract,

2830

06:01:03.804 --> 06:01:09.353

and the term of the specific task orders that are awarded underneath the again,

2831

06:01:09.353 --> 06:01:18.353

I mentioned which contains the draft statement of work is available on our acquisition portal or you can also find it under the beta Sam links for this requirement.

2832

06:01:18.719 --> 06:01:22.469

Next.

2833

06:01:22.469 --> 06:01:27.324

So just a couple of high level dates for everybody that we do contemplate,

2834

06:01:27.353 --> 06:01:31.044

issuing a draft in the 3rd quarter this year,

2835

06:01:31.133 --> 06:01:34.344

this fiscal year followed by 1st,

2836

06:01:34.344 --> 06:01:35.723

quarter of fiscal year 2022,

2837

06:01:35.723 --> 06:01:37.013

where we will release the,

2838

06:01:37.013 --> 06:01:37.794
the full solicitation.

2839

06:01:37.794 --> 06:01:46.164

We anticipate receipt of proposals to be in the 3rd quarter we are allowing for 150 days for proposal response again.

2840

06:01:46.164 --> 06:01:51.923

Our goal is to ensure that there is significant time to engage with industry,

2841

06:01:51.923 --> 06:02:05.484

and any potential offers to answer any questions and ensure that there is enough information about the solicitation and respond to any of those concerns the contract award is planned for fall of 2023.

2842

06:02:05.484 --> 06:02:19.883

of course, subject to change, I think, as a favorite word or favorite statement and so that's why we kind of gave a broad date, depending on the responses that we receive, and the number of responses but right now our projections are fall of 2023.

2843

06:02:24.353 --> 06:02:38.243

Next slide please Q and A's again, just to cover we will do a session immediately following these presentations questions must be submitted in the chat box.

2844

06:02:38.274 --> 06:02:51.563

That's the only way we are able to address them. We need to ensure that we can capture the questions and the responses and ensure that that information will also be released and included in the Q. A, that we release under beta Sam.

2845

06:02:53.033 --> 06:03:05.274

If you have questions that come about after industry day, there's been a lot of information presented today again. I encourage you to use the acquisition. Please don't email me directly.

2846

06:03:05.454 --> 06:03:12.743

You're going to have much greater success, getting a faster response by using that acquisition portal that's monitored on a daily basis.

2847

06:03:12.743 --> 06:03:21.234

As I mentioned by contracting officers, make sure you use the big bold word question in the subject line.

2848

06:03:21.234 --> 06:03:30.653

Because that will help us ensure that we provide our response as quickly as possible and the responses will be provided through a Q and a mechanism,

2849

06:03:30.653 --> 06:03:36.894

rather than a individual response to anyone 1 question received.

2850

06:03:36.894 --> 06:03:48.024

And that is just manner of helping ensure that we address all questions and get all the information relevant information out to all potential offers responses again,

2851

06:03:48.324 --> 06:03:52.013

just restating this will be on the beta Sam and the acquisition portal.

2852

06:03:52.673 --> 06:04:06.263

The portal will remain a comprehensive list of the questions that will remain easy to find and the government expects to publish questions and answers Q. and A's weekly, depending on the number of questions right now. That's our goal.

2853

06:04:06.263 --> 06:04:15.024

If the number of questions slow down, we might go to BI weekly, but that's our expectation. 1st, is to do so weekly next slide please.

2854

06:04:16.888 --> 06:04:31.559

For any additional information on the there are 3 links listed below all 3 links are active, you can go to all 3 of those links and get additional information again.

2855

06:04:31.559 --> 06:04:38.309

After you've had an opportunity to review each of those feel free to email any questions you have, and we'll ensure that they get addressed.

2856

06:04:39.054 --> 06:04:48.923

Next slide please. And that is it for my portion. I know I ran through those pretty quickly. I've been known to speak more than a mile a minute.

2857

06:04:48.923 --> 06:04:58.853

So, if anybody has additional questions, please feel free to ask, or you can hold off and wait until we go into the Q and a section and shortly following.

2858

06:04:59.188 --> 06:05:03.298

Yeah, I think since we're running really far ahead.

2859

06:05:03.298 --> 06:05:14.699

Um, we'll just go ahead and open it for any questions right now directly to you, Lisa and but before we get to the closing remarks and going into the topic breakout room so if there's any questions for Lisa.

2860

06:05:15.504 --> 06:05:26.844

Please go ahead and submit looks like they are coming in. Yes, I see. They're coming in. And do I want all the questions to be attached on this chat? They can either be included in this chat in the Q.

2861

06:05:26.844 --> 06:05:37.973

a session in the next portion that Jason just referring to capturing here. We will absolutely ensure that they're addressed. If I don't get to address all the questions.

2862

06:05:39.083 --> 06:05:45.984

I see the next question will contractors be able to access key persons at the and the contracting shop.

2863

06:05:45.984 --> 06:05:57.984

So, we can discuss solutions prior to the being released, depending on what you mean by access again, I would encourage that you can submit their questions.

2864

06:05:58.223 --> 06:06:09.563

We will certainly ensure that we are engaging with the appropriate people to provide the responses, particularly as they pertain to the many different technical aspects that were discussed today.

2865

06:06:10.493 --> 06:06:19.493

And if you have questions about solutions, we can offer feedback on proposals that has to go through the formal evaluation processes.

2866

06:06:19.493 --> 06:06:26.934

Most of you are well aware, but we can certainly help ensure that you have sufficient information to generate your proposals.

2867

06:06:28.344 --> 06:06:40.763

I see, the next question is to clarify contract is a word is estimated to be approximately a year after proposals are due in is that issuance of a formal contract to the mobilization date.

2868

06:06:41.033 --> 06:06:43.403

So, at this point, that is.

2869

06:06:44.399 --> 06:06:55.344

Why we gave just a really broad top level date. There's a lot of different factors that go into. Exactly. When the award date will go into place.

2870

06:06:56.184 --> 06:07:00.504

And it also depends on of course, whether.

2871

06:07:02.664 --> 06:07:12.653

How many proposals we receive and to the successful offer is, so I really can't answer that question at this time right now based off of our milestones.

2872

06:07:12.653 --> 06:07:21.653

We're anticipating that we'll need through fall of 2023 in order to evaluate proposals, make selections so on and so forth to get to and award date.

2873

06:07:32.579 --> 06:07:39.359

I don't see any other questions popping up yet. Nope.

2874

06:07:39.359 --> 06:07:43.649

I can't believe I was that clear in everything that I just said.

2875

06:07:45.899 --> 06:07:55.109

I still go back to the analogy of drinking from the firehouse. I think everybody like quite drowned right now. Good analogy.

2876

06:07:55.109 --> 06:08:04.079

Maybe, at least a couple more.

2877

06:08:04.079 --> 06:08:07.379

All right, well, with a list of.

2878

06:08:07.379 --> 06:08:11.789

Participants be distributed.

2879

06:08:11.789 --> 06:08:21.449

We hadn't thought about that, but we can certainly publish the list of participants on the acquisition portal.

2880

06:08:23.879 --> 06:08:38.723

And then I see please confirm that the date's presented for the drafter of we're fiscal year not calendar year. Yes, they are fiscal year, fiscal year. And if we can go back to that slide, just to ensure, I think it's back 2 or 3 slides.

2881

06:08:41.848 --> 06:08:45.179

1, more there you go.

2882

06:08:45.179 --> 06:08:54.778

Yes, those are fiscal year so the draft issuance of the or the issuance of the drafter R. F. P. we are anticipating 3rd quarter of this fiscal year.

2883

06:08:54.778 --> 06:09:05.998

Not calendar year, this fiscal year all the same with the issuance of the we're anticipating 1st, quarter of fiscal year, 2022 and receipt of proposals. 3rd.

2884

06:09:05.998 --> 06:09:10.739

Quarter of 2022 2 yes. Fiscal year is accurate.

2885

06:09:11.934 --> 06:09:18.533

This award will be for the management of the and yes so the,

2886

06:09:19.373 --> 06:09:19.524

the,

2887

06:09:21.144 --> 06:09:26.992

the sponsor is actually and or through,

2888

06:09:26.992 --> 06:09:41.723

and the current contract title is in and this award will be for the R and D requirements as well as the operation of the goco and again those requirements are outlined in the

2889

06:09:41.723 --> 06:09:45.563

draft statement of work at a very top level that was released under the,

2890

06:09:46.133 --> 06:09:49.074

that can be found in beta Sam are on our acquisition portal.

2891

06:10:12.713 --> 06:10:27.563

Okay, well the required sub contracting and focus on small business, subcontracting commitments or an approach to delivering tasks under the using a mix of contractor staff and partner subcontractors or both.

2892

06:10:28.348 --> 06:10:42.623

Wow, the small business subcontracting plan is specific to an organization's plan to utilize small businesses in the total value of the contract in which they are awarded.

2893

06:10:43.074 --> 06:10:57.804

So the plan will be specific to subcontracting with organizations outside small businesses outside of your existing labor group. If that answers your question, I believe that's what you're asking.

2894

06:11:08.938 --> 06:11:09.563

You're welcome

2895

06:11:28.463 --> 06:11:29.304

percentage is,

2896

06:11:29.304 --> 06:11:38.304

can you provide a top level expert expectation for inclusion we can include the percentages of the current year obviously,

2897

06:11:38.304 --> 06:11:40.254

those percentages change year to year,

2898

06:11:41.033 --> 06:11:42.263

in terms of goals,

2899

06:11:42.263 --> 06:11:47.094

and we can provide that information in the Q and a.

2900

06:11:47.094 --> 06:11:48.923

so that you can see the percentages.

2901

06:11:49.199 --> 06:11:58.109

For each of the different small business categories.

2902

06:12:05.848 --> 06:12:11.399

Oh, I wish I knew how to say you're welcome in French. Where's fried?

2903

06:12:13.048 --> 06:12:16.048

Thank you.

2904

06:12:34.138 --> 06:12:40.048

Wow, whoa, after this meeting. Okay, so this is.

2905

06:12:41.278 --> 06:12:44.603

Contract might be structured how it view a consortium.

2906

06:12:45.684 --> 06:12:56.934

I I mean, I see that the response says after this meeting general questions, I can, because, and Jason tell me if you're okay with this, because we are a little bit ahead of schedule.

2907

06:12:56.934 --> 06:13:04.583

I think I can go through a top level response to some of these questions again more detail will be provided in writing.

2908

06:13:04.583 --> 06:13:13.044

So, the response that I provide is meant to be the top level until we do provide clarifications through those written responses.

2909

06:13:14.638 --> 06:13:19.199

Simply said you want to go over what the question is I think you were probably sent that directly.

2910

06:13:19.199 --> 06:13:32.938

Oh, I didn't see it pop up in the chat. Yes, you're correct. I was sent that directly so I will read the questions as I go through again. Please remember that we should.

2911

06:13:32.938 --> 06:13:36.563

We should keep these questions to everyone.

2912

06:13:36.864 --> 06:13:48.144

The 1st, part of the question is, what is the view of about how the operation of the contract might be structured how it view a consortium company cancer centers academic.

2913

06:13:48.838 --> 06:13:55.193

Institutions who operate as 1 entity and provide the comprehensive expertise for this work. Again.

2914

06:13:55.193 --> 06:14:05.274

I'm going to refer Dr hook provided a a very succinct answer to this this morning, which was it really is open to whatever.

2915

06:14:05.579 --> 06:14:19.283

Structure somebody wants to propose the evaluation criteria, will list what the areas are, that are of key importance to the government. And I also referenced a little bit earlier far part.

2916

06:14:19.283 --> 06:14:22.644

35 does provide clarity on exactly.

2917

06:14:23.304 --> 06:14:37.973

What type of an organization can respond to a solicitation or can operate and those examples that you provided in, in your 1st bullet all of them fall within those guidelines provided in the far.

2918

06:14:37.973 --> 06:14:48.804

So, I don't know that views. I think that is on the offers to provide and propose what they think is going to be the most effective way to operate.

2919

06:14:48.804 --> 06:15:02.213

The part of that was, how would view a single company bitter, who simply subcontracts work again it depends on the information presented in the proposal. I don't have an answer that says, yes or no, we're in favor.

2920

06:15:02.213 --> 06:15:05.723

We're not depends on the information that's provided in the proposal.

2921

06:15:08.274 --> 06:15:09.054

Part C,

2922

06:15:09.054 --> 06:15:15.623

is NCI seeking a single company better or multiple companies who each are signed specific lanes and again,

2923

06:15:15.623 --> 06:15:19.283

I think this aligns with exactly the response that I just provided,

2924

06:15:19.283 --> 06:15:30.324

which is it depends on what information is presented in the proposal and how it aligns to the evaluation criteria that are identified in the R.

2925

06:15:30.324 --> 06:15:44.723

F. P. what does view of the role of an academic partner again? Same response what? Mti likes to increase the visibility and brand identification recognition to increase and enhance the work of the Frederick.

2926

06:15:45.083 --> 06:15:51.954

I would defer that question to either a doctor poker, or Dr who are on the call. I don't think that's.

2927

06:15:53.399 --> 06:15:59.098

Questions yeah, this is Sarah. I would in general say yes.

2928

06:15:59.098 --> 06:16:05.848

Well said, okay.

2929

06:16:05.848 --> 06:16:18.419

I have other options, other than an idea huge contract mechanism, been approach and explored. I really am going to keep that very succinct and just say, trust me. Yes.

2930

06:16:18.419 --> 06:16:19.289

Um,

2931

06:16:21.024 --> 06:16:23.304

and send another question,

2932

06:16:23.304 --> 06:16:30.684

do we national labs are required to operate under a separate financial structure special funding arrangement,

2933

06:16:30.713 --> 06:16:41.484

financing arrangement where the entire cost for the operating if every loan under portion of reimbursed under the contract does NC envision a segregated financial structure that covers the delivery of the,

2934

06:16:42.173 --> 06:16:54.083

so the solicitation will outline what our financial reporting requirements are in terms of operate under a separate financial structure.

2935

06:16:54.473 --> 06:16:55.313

There's.

2936

06:16:55.588 --> 06:17:06.114

Some yeses in some nose to that, in terms of the financial structure that we use for some of our reporting within on our standard and business systems.

2937

06:17:06.894 --> 06:17:19.554

However, the systems that are used under the contract are specific to the contract. So that's really a combination answer. And again, we can elaborate a little bit more when we provide the written answer.

2938

06:17:19.829 --> 06:17:29.219

Can I confirm that this will be a single award that is the Government's intention to make a, at the time at this time. That is the Government's intention to do this as a single award.

2939

06:17:38.008 --> 06:17:45.778

I think you guys just save all of them and then you pop them all in the text box all at once.

2940

06:17:48.504 --> 06:17:59.873

Whoa, okay. More questions about operations will you provide the number of how many contract staff or subcontracts that are currently funded it facility again?

2941

06:17:59.873 --> 06:18:13.193

I believe I addressed this earlier that the subsequent that is released will contain information about labor categories and some information about those different structures.

2942

06:18:14.033 --> 06:18:18.774

Our positions funded as indirect costs again. There's.

2943

06:18:18.989 --> 06:18:33.204

Yes, and no to that that is a little broad so I'm not sure all of the support roles. It really depends on how your organization depends on proposing it. How is project management currently handled?

2944

06:18:33.204 --> 06:18:41.544

Is there a project tracking system? How is it used? If Mike is still on the phone, or I don't know if that is a Sarah or Kristen question.

2945

06:18:47.638 --> 06:18:52.949

Yeah, this is Michael. I think I'll defer that to Chris or Sarah.

2946

06:18:54.778 --> 06:19:01.228

And Kristen, or Sarah, that can be 1 of the ones that we can provide a response in writing.

2947

06:19:03.958 --> 06:19:10.138

So this is Chris, and I think a response in writing would probably be most appropriate because it's not a straightforward answer.

2948

06:19:10.138 --> 06:19:14.278

Correct. Okay. What is the total.

2949

06:19:14.278 --> 06:19:23.754

What is the total number of staff who are staff who are directly funded again? Don't I don't have that information in front of me.

2950

06:19:23.754 --> 06:19:37.914

We can provide more information regarding the, the current structure as we go through and do a little bit more research into these questions. And that's the same for part 5 of that. And part 6.

2951

06:19:39.929 --> 06:19:51.598

There have been from the current manager of the f, for possible opportunities with small businesses. Is it anticipated that the subcontract work.

2952

06:19:52.074 --> 06:20:04.673

Or prior to the next contract, being awarded, if it is something that has been released from the current contractor, I can't speak directly to it. Of course, that is part of their business operations.

2953

06:20:04.673 --> 06:20:15.774

I would encourage you to reach out to the current contractor. And again, we will provide an additional information regarding the small business requirements for an age when we do the Q and a.

2954

06:20:53.638 --> 06:21:05.813

So, Jason, I think I'm handing it back over to you at this point, I think. Oh, nope. 1, more than just every time I start to say that toys with me. Okay.

2955

06:21:05.813 --> 06:21:18.024

What are the challenges with the current financial management tracking again? I think that that is 1 that is going to need a lot of clarification. So I don't know that I could fully answer that.

2956

06:21:19.469 --> 06:21:32.188

But we, we will certainly provide some additional information about the expectations of our financial management tracking was the last question referring to the continuity of subcontracts.

2957

06:21:32.963 --> 06:21:47.754

And that looks like that went to you. Oh, good question or a good point. And we did provide information just as a reminder, because it's actually an excellent question. That just came to me.

2958

06:21:48.353 --> 06:21:57.864

We did provide information on 1 of our request for information about the current continuity of services language in the current contract.

2959

06:21:57.894 --> 06:22:07.794

So, if any if you haven't had an opportunity to look at that highly recommended, it does provide a lot of information about some of our expectations.

2960

06:22:07.794 --> 06:22:18.144

And if additional questions from reviewing that language again, please utilize the acquisition portal and the acquisition email address and we'll be happy to respond to any questions.

2961

06:22:21.478 --> 06:22:25.618

Okay, I think I will jump in now and.

2962

06:22:25.618 --> 06:22:36.239

Turn it back over to Christian as well as you Lisa for your closing remarks, and then we'll have some additional instructions on getting them to the breakout rooms after that. So.

2963

06:22:36.239 --> 06:22:37.193

Who wants to go?

2964

06:22:37.223 --> 06:22:37.794

1st,

2965

06:22:39.324 --> 06:22:39.923

I,

2966

06:22:39.954 --> 06:22:42.414

I think I kind of actually did a little bit backwards,

2967

06:22:42.414 --> 06:22:46.223

because I started my presentation with what really should have been my closing remarks,

2968

06:22:46.223 --> 06:22:57.774

which again was a huge thank you to everyone on the committee for pulling this event off and all of the presenters a lot of information again,

2969

06:22:57.774 --> 06:22:58.133

Jason,

2970

06:22:58.133 --> 06:23:03.623

your analogy of drinking from the hose the fire hose is a great analogy for English ads.

2971

06:23:03.623 --> 06:23:08.813

I can't take credit for that. So we do encourage again.

2972

06:23:09.083 --> 06:23:19.644

We want to be as open and as transparent and provide any clarity that we can for any of the information that was presented today.

2973

06:23:19.794 --> 06:23:32.603

So please do not hesitate to utilize the resources that we've read. We've referred to today and particularly the email address for the to help provide and get you some additional information.

2974

06:23:32.903 --> 06:23:35.153

And with that, Kristen, I will turn it over to, you.

2975

06:23:36.833 --> 06:23:49.794

Thanks Lisa. So I'd like to echo Lisa sentiment. I, thank all of the presenters and the people that participated in the industry day to day, we have 1 more thing to go, which is the breakout rooms and hope everyone follows us there.

2976

06:23:50.063 --> 06:23:51.144

I would also,

2977

06:23:51.742 --> 06:23:51.984

like,

2978

06:23:51.984 --> 06:23:59.243

to thank everyone who are potential offers that have joined us today to hear about all the exciting activities that we have here at the,

2979

06:24:00.623 --> 06:24:15.054

and so I'm hoping today really help to inspire you to think about this contract and to ask us more exciting questions and being part of the lead for a national effort

2980

06:24:15.563 --> 06:24:17.603

regarding cancer and other diseases.

2981

06:24:17.603 --> 06:24:23.783

So thank you everyone. And I think we'll also be giving you instructions on how to get to the breakout sessions.

2982

06:24:24.269 --> 06:24:28.798

Yep, and they, that just popped up right there and.

2983

06:24:28.798 --> 06:24:38.579

I think I'll turned over to the AV text to go over this for everybody and, and I also want to give my thanks, especially to the presenters.

2984

06:24:38.579 --> 06:24:48.778

For your all your time and effort and coordination and follow instructions and the frustrations and what not. So I'll turn it over to AB.

2985

06:24:48.778 --> 06:24:55.618

So, Jason, this is Sarah. I would just like to pause and thank you. You've been a wonderful MC.

2986

06:24:55.618 --> 06:25:01.199

Thank you and it was my pleasure. Actually. It was actually very enjoyable. Great.

2987

06:25:01.199 --> 06:25:08.008

Okay, so the breakout rooms are open in order to join.

2988

06:25:08.008 --> 06:25:21.149

You should see at the top of your Webex window a tab that says breakout sessions or show breakout sessions. If you click on this tab, you should get a drop down menu that list the breakout rooms. And then you can join just by clicking on them.

2989

06:25:21.149 --> 06:25:31.463

Alternatively, on the participant's panel on the right side of your screen, you should see a new section that lists the breakout rooms and you can just click on the join button there to leave the breakout room.

2990

06:25:31.463 --> 06:25:38.993

You should click on the red button at the, uh, on the toolbar at the bottom of your screen. Just be careful not to leave the meeting.

2991

06:25:40.614 --> 06:25:54.864

And then to move to another breakout room, just also use the tap at the top of the screen to select new breakout room. And our users who are joining by phone, unfortunately cannot join the breakout rooms.

2992

06:25:54.923 --> 06:26:04.283

However, if you are joined today, using your computer or laptop, and you're just using your phone for audio, you should still be able to use the breakout rooms. Thank you.

2993
06:26:13.679 --> 06:26:17.248
Silence.

2994
06:26:19.079 --> 06:26:24.598
Silence.

2995
06:26:35.548 --> 06:26:48.118
And, of course, if anybody's having any issues getting into the breakout rooms, just feel free to speak up or message me using the chat box.

2996
06:27:00.359 --> 06:27:06.028
This is right so we're, we are not in a breakout from. Is that correct?

2997
06:27:06.028 --> 06:27:09.778
Ah, yes. Okay. Good. So I don't need to go somewhere.

2998
06:27:09.778 --> 06:27:09.868
I

2999
06:27:14.603 --> 06:29:09.684
am.

3000
06:53:49.408 --> 06:53:52.649
Hold on, um.

3001
06:53:54.239 --> 06:53:59.519
No problem. Yeah. Somebody just texted me. Can you join us?

3002
06:53:59.519 --> 06:54:03.478
Chris know.

3003
06:54:05.219 --> 06:54:09.298
Is this the facility break? Breakout session? The last session.

3004
06:54:09.298 --> 06:54:13.919
You are actually oh, you're in the, the main room, but that is a breakout room.

3005
06:54:13.919 --> 06:54:22.588
Okay, the facilities so at the top of your Webex window, you should see a tab that says show breakout sessions. Do you see it?

3006

06:54:22.588 --> 06:54:32.309

She'll make that decision. Yes. Okay. Okay. So if you click on that, it should list the breakout rooms for you. I believe it's a room 3 that you're looking for. So, you.

3007

06:54:32.309 --> 06:54:46.048

Yeah.

3008

07:26:14.728 --> 07:26:24.269

This is Kristen, we just close the science session meeting breakout. I don't know if there's anybody else that wants to provide information here.

3009

07:26:24.269 --> 07:26:35.489

Kristen, thank you, I just message Brandon to see if we could close all of these specific breakout rooms, because everyone is saying their goodbyes within each.

3010

07:26:35.489 --> 07:26:39.899

Yeah, I can close all of them.

3011

07:26:39.899 --> 07:26:48.239

Okay, wonderful. I think I heard from everyone that we are about ready to do that. So thank you.

3012

07:26:48.239 --> 07:26:54.508

Thanks everybody and Jason are you still on the call so you did an awesome job and seeing.

3013

07:26:54.508 --> 07:27:00.809

This is now on your resume, you're doing it for the rest of your life.

3014

07:27:00.809 --> 07:27:06.149

Silence.

3015

07:27:06.743 --> 07:27:15.923

Thanks everybody out Thank you because the support, Brandon and team you guys maintenance go so smoothly. Thank you. Thank you. Thank you.

3016

07:27:15.923 --> 07:27:22.763

Thanks for all the Pre checking and the rerunning and downloading and uploading a file. Thank you so much.

3017

07:27:23.458 --> 07:27:32.638

You're welcome. Yes, I, I very much echo that to kristen's point. Thank you again for all of the support and responsiveness throughout this.

3018

07:27:32.638 --> 07:27:38.068

Yeah, Ashley Kristen Brandon. Awesome job.

3019

07:27:38.068 --> 07:27:46.649

Really amazing. I can't see everybody else still here, but who does everybody.

3020

07:27:46.649 --> 07:27:53.399

It's been great and I'm glad at 6. 0, 1.

3021

07:28:03.088 --> 07:28:09.719

Hi, go ahead and stop the recording now. Yes, thank you.