

## **NCI PAVES: *Biotechnology & Bioentrepreneurship***

*James W. Lillard, Jr. PhD MBA*

*Professor & Senior Associate Dean for Research & Innovation*

# Background



**James W. Lillard, Jr. PhD MBA**  
**Senior Assoc Dean for Research,  
Innovation, & Commercialization**  
**Professor Immunology**  
**MPI, NCI U54 Partnership**  
**Director of MSBT, MSHI, & OTT**

- 20 years in research & graduate level teaching
- Launched 12 biotech (start-up) companies
- ~\$75 million in R&D and > private equity \$100 million funding
- 94 publications and 51 patents, cited 10,000+ times
- Distinguished Fellow, American Association of Immunologists
- Fellow, National Academy of Inventors
- Fellow, American Association for the Advancement of Science
- Service on scientific & medical advisory boards

## **Education**

*Ohio State University*

Degree: BS in Electrical & Computer Science  
Engineering

*University of Kentucky College of Medicine*

Degree: PhD in Microbiology & Immunology

*Emory University Goizueta Business School*

Degree: Executive MBA with Biotechnology focus

# *Characteristics of an Entrepreneur*

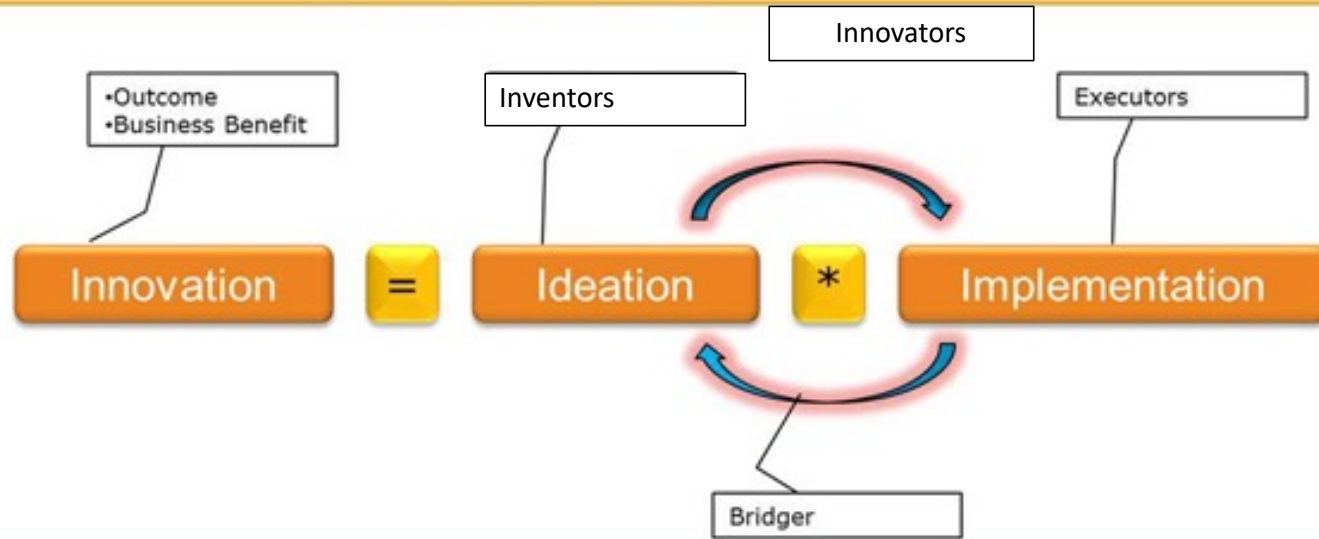
- Plays well with others
- Loves Learning
- Risk Bearing
- Innovative
- Creative (and share strategically)
- Leadership and Coordination
- High Achievement Capacity
- Professional and Organized
- Business-Oriented

# ***Definitions/Activities of Entrepreneurial Leadership***

- Four distinct types of entrepreneurial organizations; **small businesses, scalable startups, large companies** and social entrepreneurs
- The activity of **setting up a business** or businesses, taking on financial risks in the hope of profit.
- **Creating a business**, while building and scaling it to generate a profit.
- Identifying a solution to a problem, **quantifying** the solution's **value** and fit in the marketplace

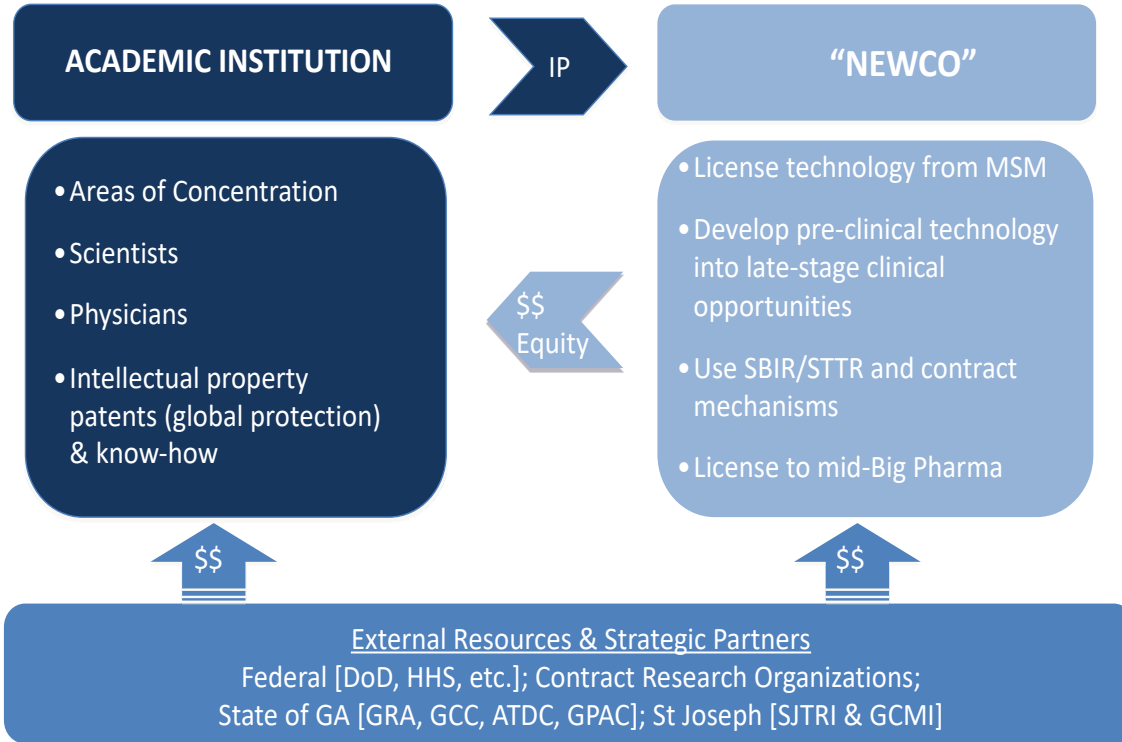
# Definitions of Innovation

Innovation is **people** creating **value** by  
**implementing new ideas**

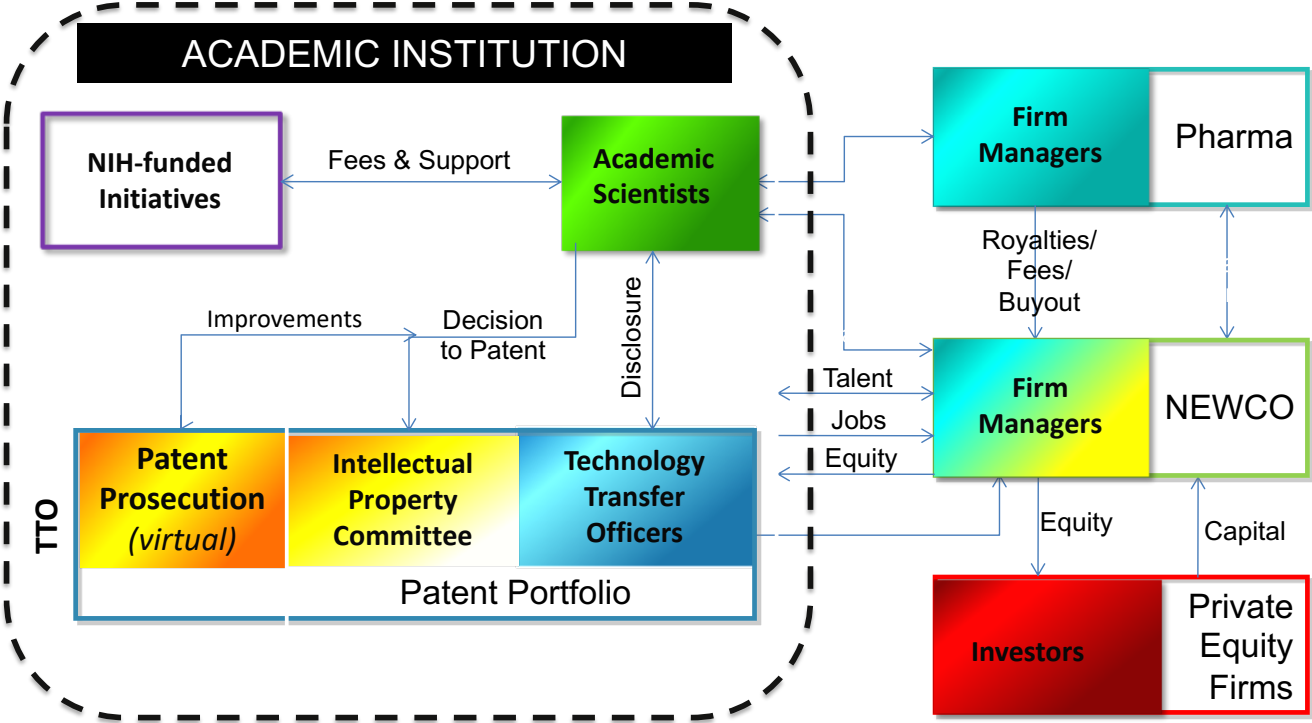


Innovation is 1% ideation, 9% evaluation & polishing and 90% implementation

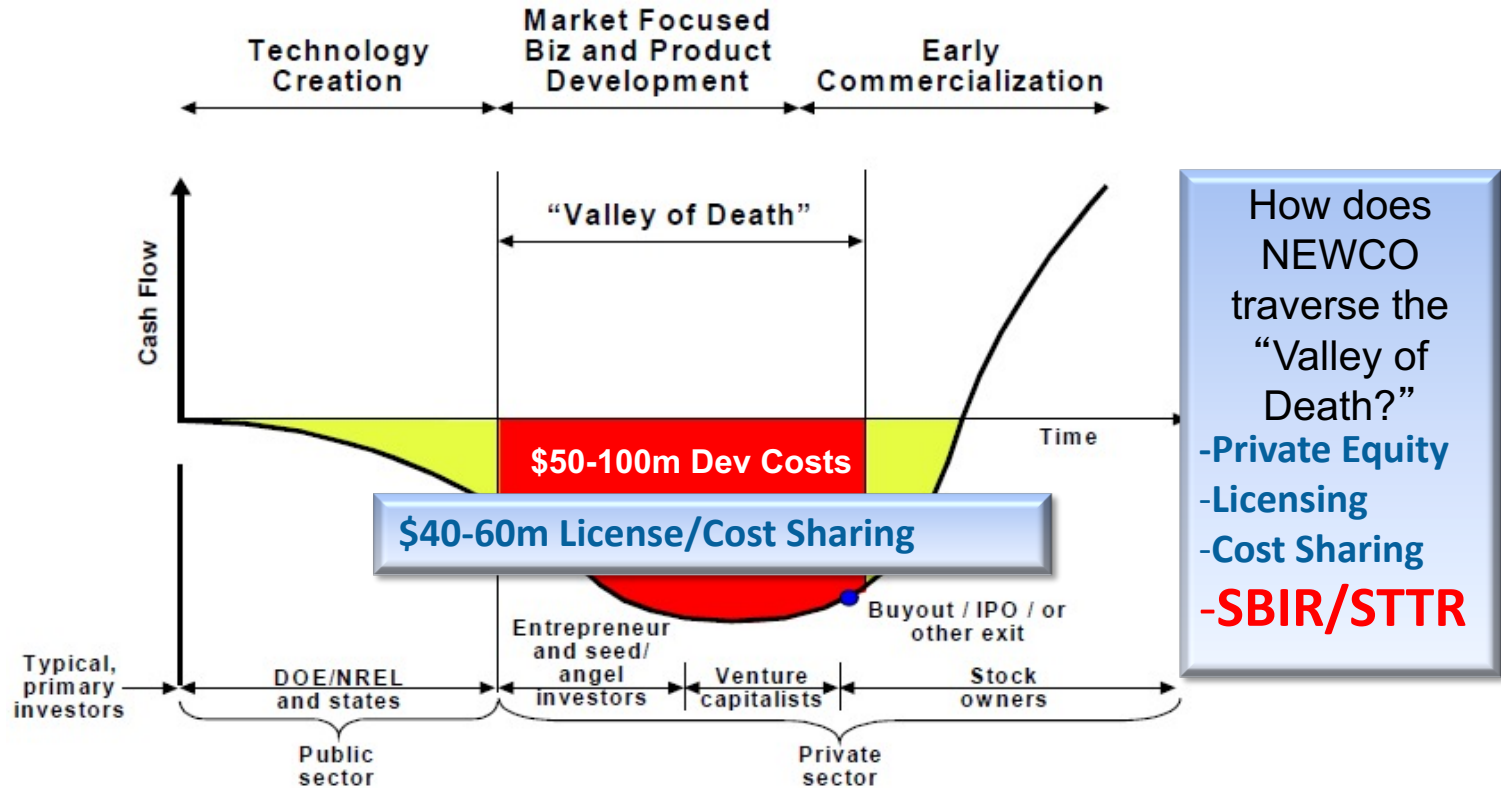
# The Dream



# The Dream

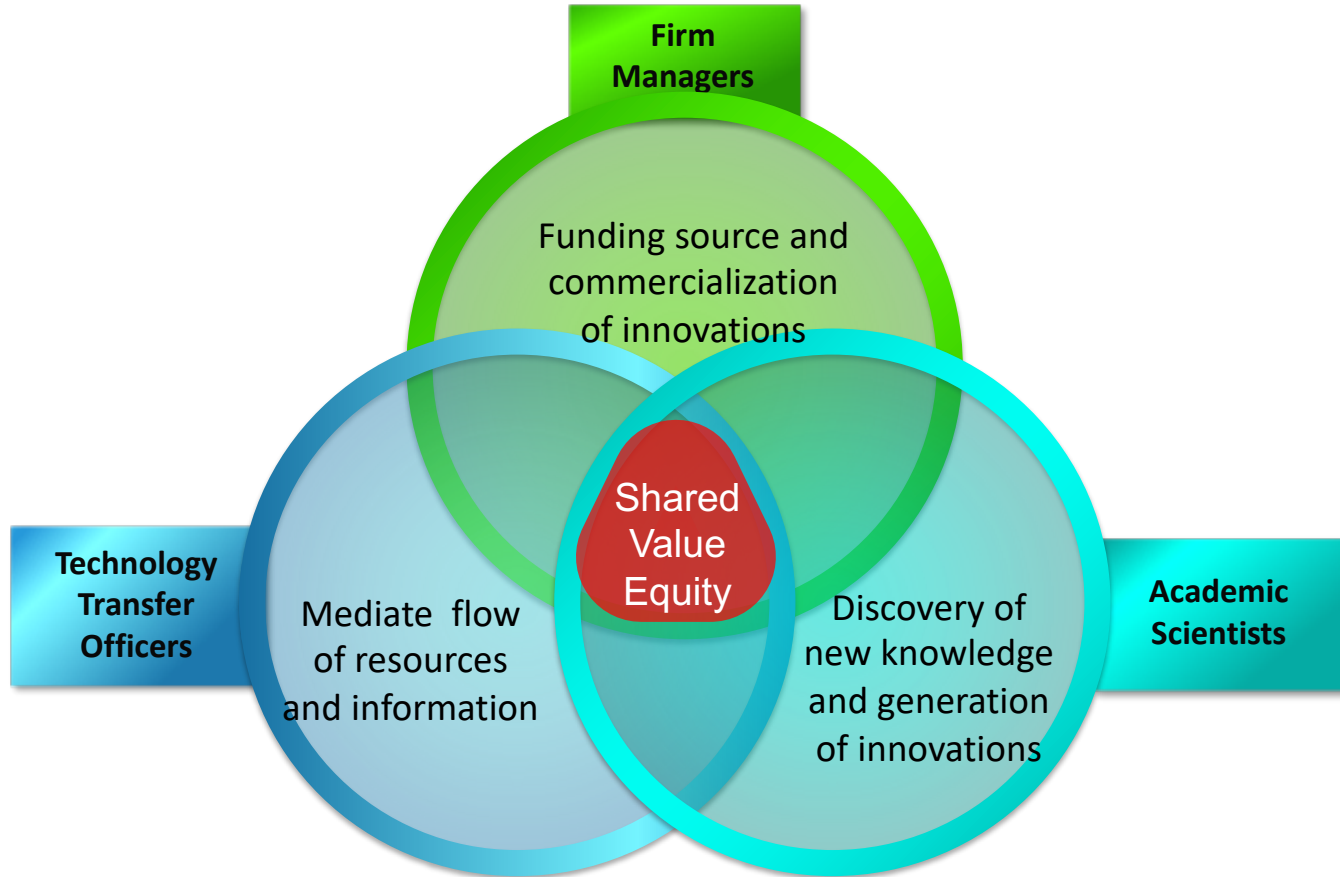


# The Reality

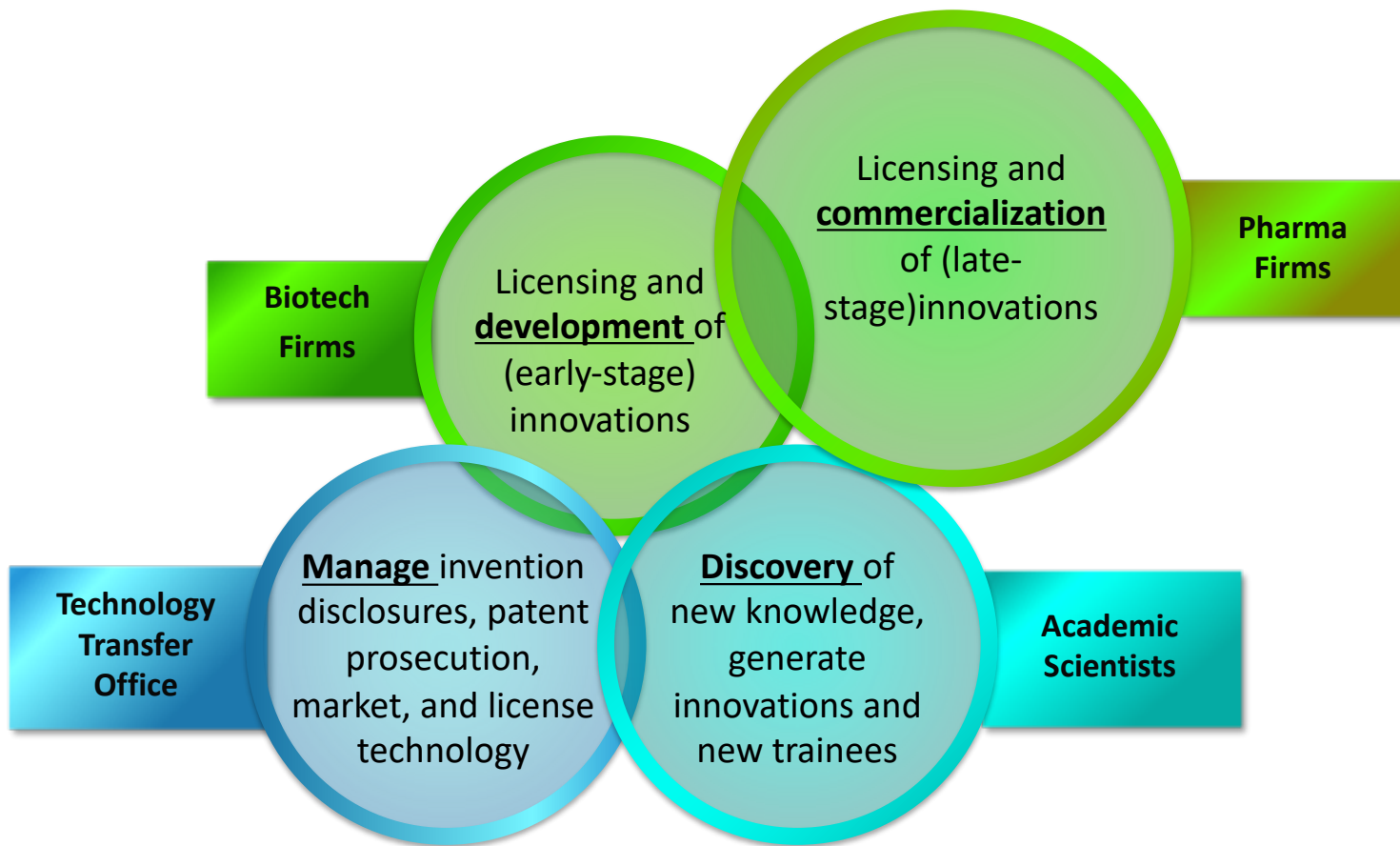


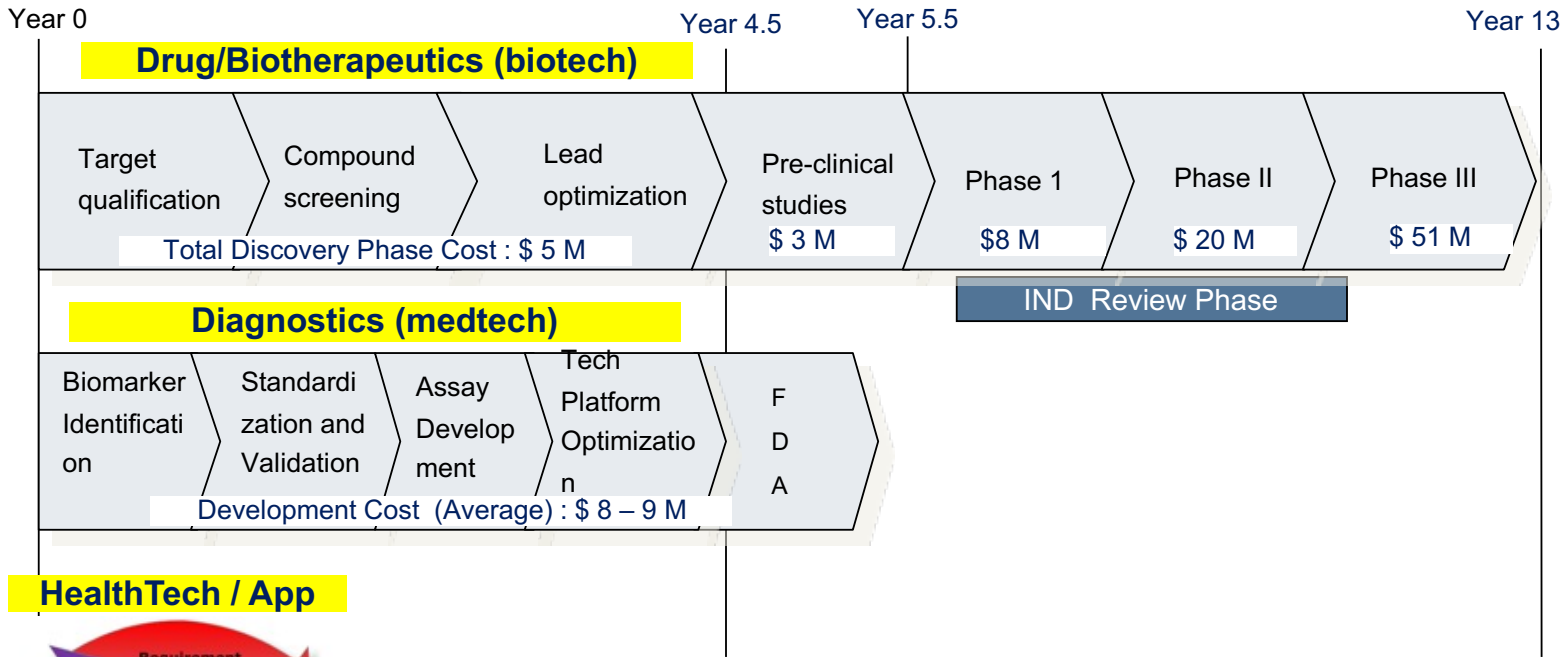


# CHALLENGES *(misconceptions)*

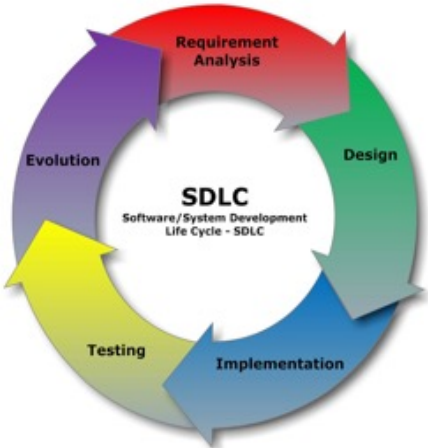


# CHALLENGES *(realities)*





### HealthTech / App



***Contextual & Time Differences in Commercialization of Health Science and Life Science Innovations***

# FORTUNE



TRANSLATIONAL TECHNOLOGIES  
MOREHOUSE SCHOOL OF MEDICINE

Fortune Magazine reported, May 19, 2019 on the number of patents produced by Historically Black Colleges and Universities. **Morehouse School of Medicine** is at the top of that list. Between 2009 and 2019, MSM was been granted 63 patents.

# *Don't be afraid to fail (risk bearing)*

4DGENOME, INC.



NutriGlobal S



# Startups & Partnerships Commercializing MSM Biotech



Haplo~~mic~~s

RZ Pharma



Complexa



NutriGlobal S, Inc.

- BrainGEN 13' (Ford): neuregulin to treat CNS injuries and stroke IVD. **Inactive**.
- Haplo~~mic~~s 11' (Lillard): FVIII therapies for hemophilia A patients (**\$575K from two STTR and one SBIR awards**).
- R & Z, Inc. 14' (Xiong/Simon): peptide and small molecule ASIC1a inhibitors for CNS injuries associated with acidosis.
- Chinook Tx 20' (Newman): method of using endothelin antagonists to treat kidney disease. Company has raised **\$106 million** in funding. Phase III clinical trials begin 2021.
- Complexa 11' (Chen): synthetic nitro fatty acid (CXA-10) to treat acute renal injury has raised **\$83 million** in funding. In two Phase 2 studies for primary focal segmental glomerulosclerosis and pulmonary arterial hypertension.
- JYANT Technologies 10' (Lillard): chemokine/chemokine receptor and nanotechnologies for cancer, inflammatory diseases, and their diagnosis (**\$1.2 million from one SBIR and three STTR awards**). Starting **capital campaign (\$30 million)** for preclinical/clinical studies for antibody drugs.
- Orunmila Pharma 15' (Bond): mortalin/HSP65 peptide inhibitor to treat cancers, inflammatory disease, and viral infection. **CRADA signed with NCI**.
- Nutriglobal 12' (Hibbert): medicinal foods for sickle cell anemia and cachexia. **Received GRA grant (\$50K) and SBIR (\$295K)** for food prototype.

# Startups and Partnerships Commercializing MSM Apps & Devices



- AccuHealth Technologies 12' (Ofili): app for chronic disease care & clinical trials. **Active, but unfunded.**

4DGENOME, INC.

- 4DGenome 13' (Song): chromosome-specific haplotyping software and single cell isolation equipment (**\$225,000 SBIR award**)



- Akuba Diagnostics 13' (Stiles): saliva-based tests for parasitic infections. **Prototypes developed** and **150 patients tested** in Ghana.



- DevMar 16' (Lillard, He & Jones): biohazard Clean Up product. **Signed partnership/distribution agreements** with CoreCivic, Marriott International, Avendra, Alabama Power, Southern Company, and 3M.

NewMark  
Dx

- NewMark 17' (Newman): urine-based test for HIV, hepatitis C, and other viruses. **200 patients tested. Received STTR grant (\$297K)** for prototype development



TRANSLATIONAL TECHNOLOGIES  
MOREHOUSE SCHOOL OF MEDICINE

# Collaborate on SBIR/STTR Awards

AWARD	PROJECT NAME	PI/FACULTY NAME	TOTAL AWARD AMOUNT	PROJECTED AWARD TO MSM
4DGenome R43HG007621-01	Cost-effective and high-throughput chromosomal haplotyping	Song	\$218,556	<b>\$65,567</b>
Exscien Corporation R41NS086267-01A1	Enhancing mtDNA Repair During Stroke Reperfusion to Reduce Brain Damage	Wilson / Simon	\$149,171	<b>\$59,668</b>
Haplomics R41MD008156-01A1	Evaluation of the Antigenicity of Restricted FVIII Haplotypes	Lillard	\$184,545	<b>\$73,818</b>
Haplomics R41MD008809-01	Novel Pharmacogenomic Approach for Identifying T Cell Epitopes in Replacement FVIII Therapy	Lillard	\$203,848	<b>\$81,539</b>
Haplomics R43MD008660-01	H3 FVIII for Hemophilia A Patients at High Risk for Anti-Drug Antibodies	Lillard	\$243,349	<b>\$97,340</b>
JYANT Technologies R43DK096857-01A1	Treatment of Colitis and Ileitis using a Novel CXCR3 Biologic Antagonist	Lillard / R Singh	\$317,247	<b>\$126,898</b>
JYANT Technologies R41CA183399-01A1	Novel adjuvant therapy for triple negative breast cancer	Lillard / Gonzalez	\$225,000	<b>\$90,000</b>
JYANT Technologies R41MD010320-01	Anti-CXCL13 mAb to mitigate prostate cancer health disparities	Lillard / S Singh	\$315,320	<b>\$126,128</b>
JYANT Technologies R41CA214080-01	Anti-CCL25 mAb to treat castration resistant prostate cancer	S Singh / Lillard	\$365,320	<b>\$126,128</b>
NewMark Diagnostics R41MH122980-01 (current)	Detection of HIV proteins in urine to diagnose infection	Newman / Lillard	\$294,076	<b>\$149,083</b>
Nutriglobal R43HL149489-01 (current)	Cost effective nutritional therapy for managing sickle cell disease complications	Stiles / Hibbert	\$293,987	<b>\$66,849</b>
		<b>TOTAL</b>	<b>\$2,810,688</b>	<b>\$1,052,445</b>



***Don't be afraid to fail  
(risk other people's money)***

# ***SBIR/STTR Program Overview***

**\$3.3B**

## **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

Set-aside program for small business concerns to engage in Federal R&D

-- with potential for commercialization.

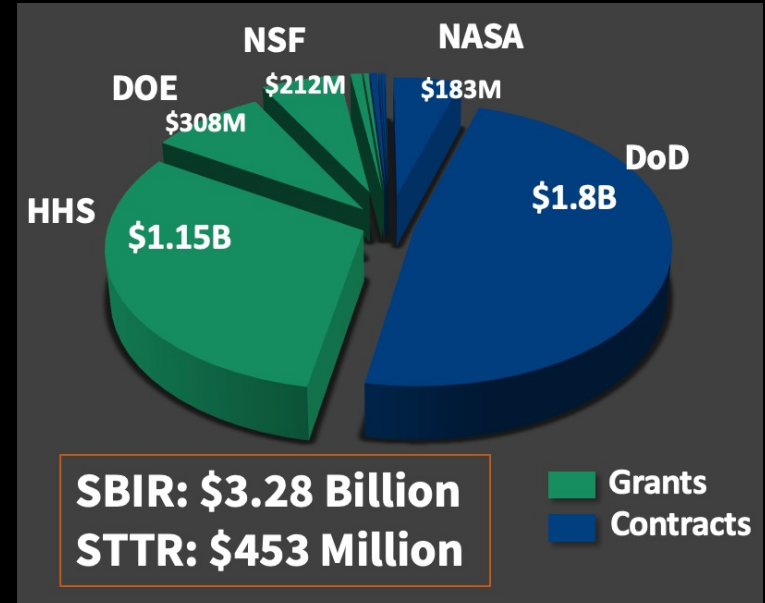
**\$0.4B**

## **SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

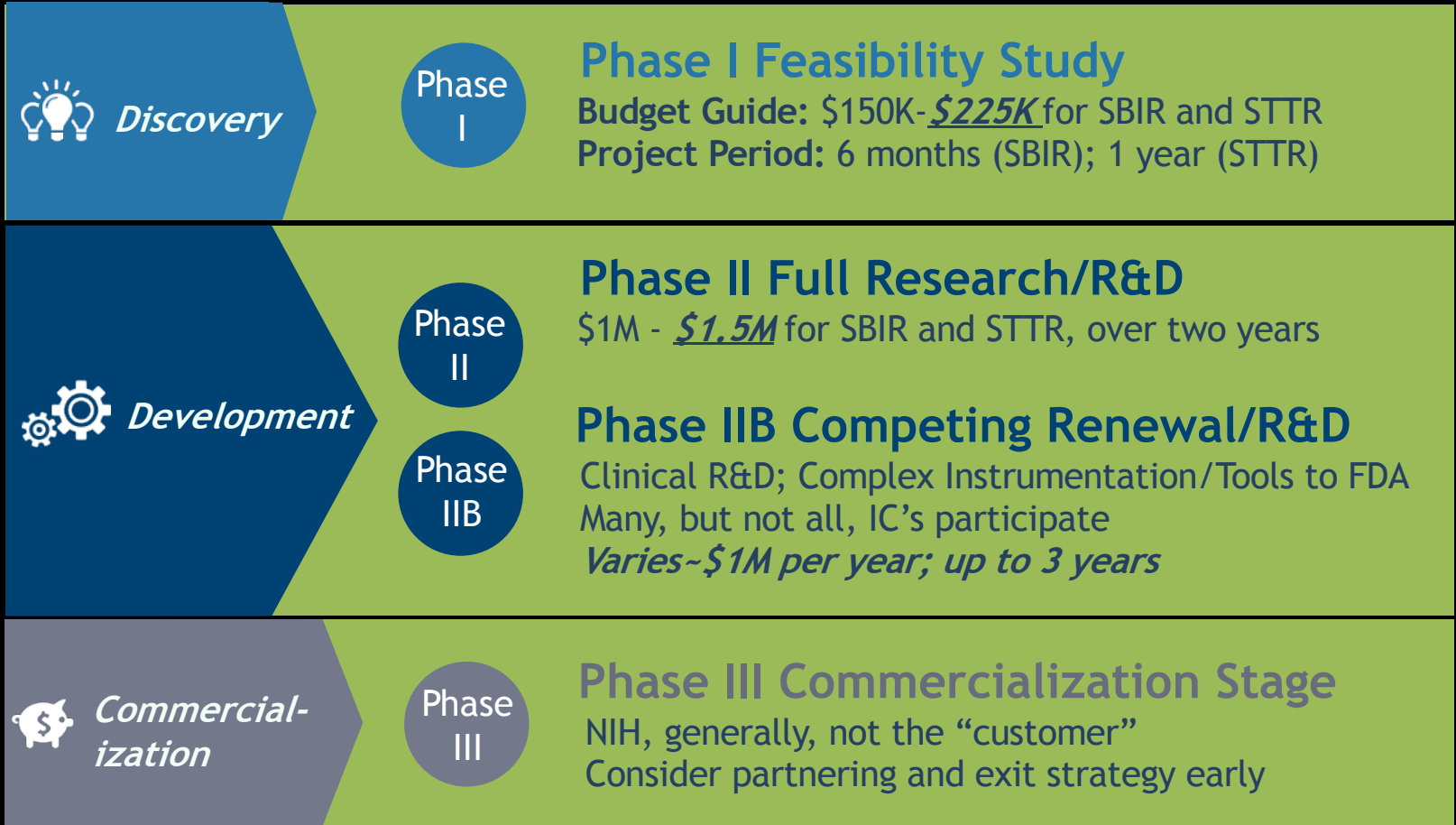
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions -- with potential for commercialization.

Agencies	Budget
Department of Defense (DoD)*	\$1.80 B
Department of Health and Human Services (HHS)**, including the National Institutes of Health (NIH)	\$1.15 B
Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)	\$308 M
National Science Foundation (NSF)	\$212 M
National Aeronautics and Space Administration (NASA)	\$183 M
U.S. Department of Agriculture (USDA)	\$30 M
Department of Homeland Security (DHS)	\$17 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA)	\$9.5 M
Department of Education (ED)	\$8.4 M
Department of Transportation (DOT)	\$5.2 M
Department of Commerce: National Institute of Standards and Technology (NIST)	\$3.9 M
Environmental Protection Agency (EPA)*	\$3.6 M

## FY2019 SBIR/STTR Budgets by Agency



## Three Phase Process



# Keep Learning (love learning)

I-Corps™ Training Program



## Program Description

- Intensive **Entrepreneurial Immersion** course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes **Reaching out to Customers** to test hypotheses about the need and market for the technology being developed.
  - Each team is expected to conduct over 100 interviews over 10 weeks.

## Gain New Insights

- Clinical Utility
- Customers / Customer Segments
- Product Value / Value Proposition
- Role of Partners

**New Insights Gain have Dramatic Affect on Phase II SBIR/STTR Aims**

# *Dream Big!*



Gale Newman, PhD  
*Loved Learning*



Chinook has 2 meds targeting this disease - the oral drug **#Atrasentan** (which previously was tested in combination therapy for lung cancer) and the new targeted biologic drug **#Zigakibart**. While the financial implications are exciting and grabbing headlines, the acquisition shows an increased focus and resource allocation towards treating this under-recognized condition! Great news for those living with IgAN!

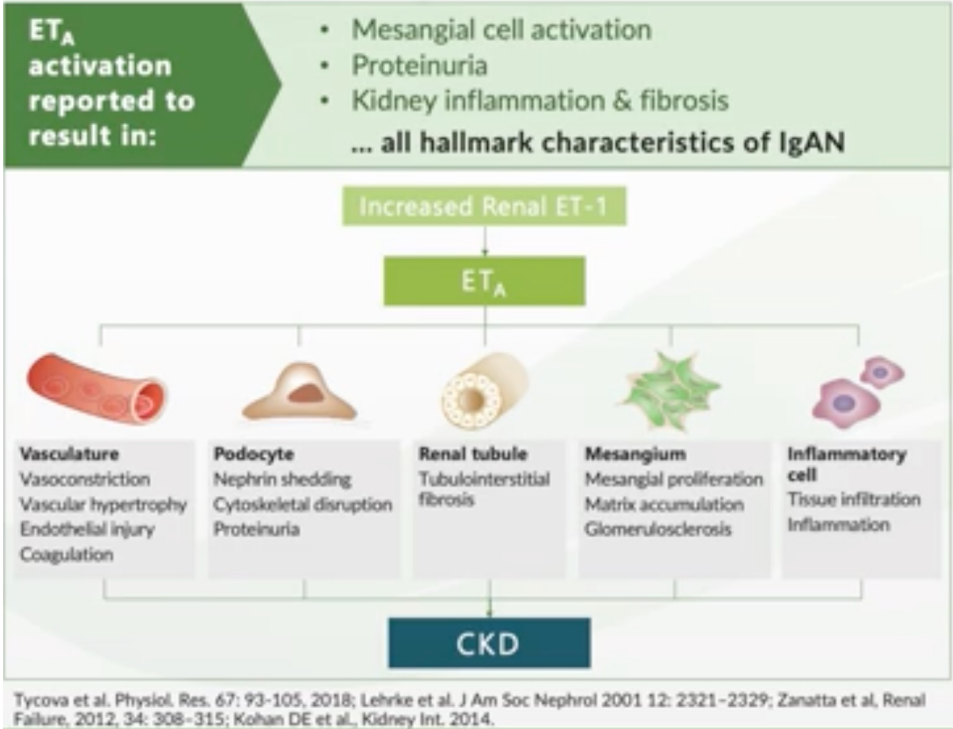
Hopefully, at least one of these meds is proven effective, and we see them come safely to market, helping those in need!

June 12, 2023



Novartis buys Chinook for \$3.5 billion in race to treat rare kidney disease

# Endothelin System Activation in IgAN Progression





***Learn from Service***

***Serve on scientific / medical advisory boards !!  
(play well with others & love learning)***

Tech

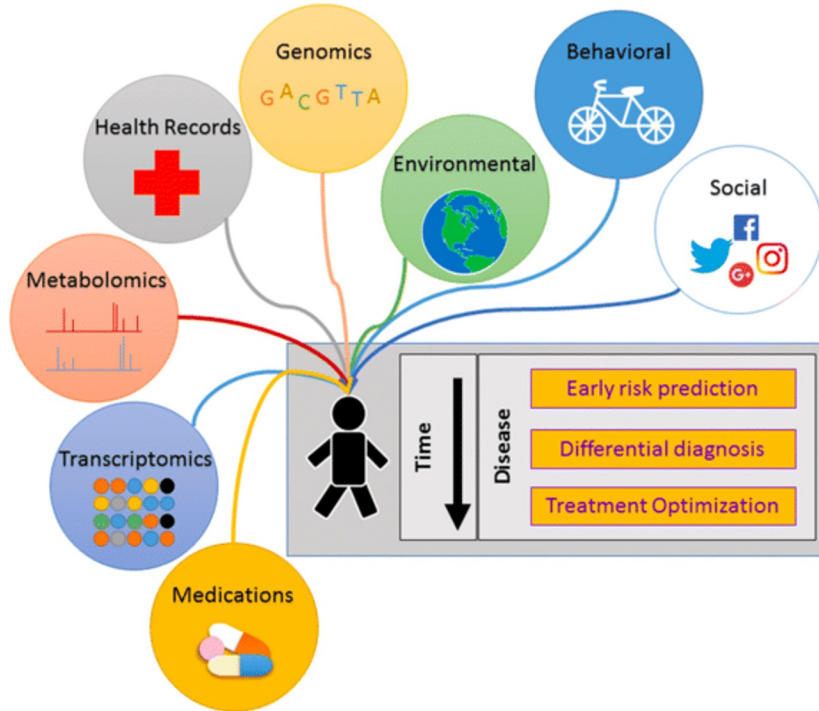
## **Invitae scoops up consumer health tech firm Ciitizen for \$325M**

by Heather Landi | Sep 8, 2021 7:45am



# Precision Medicine vs Multi-Omics vs Genetics

Convergent (Data + Health + Social) Science



Precision  
Medicine



Health Science Degrees

**Medicine & Public Health**

**Biomedical Sciences**

**Biotechnology**

**Health Informatics**

*Precision Medicine*

*Genetic Counseling*

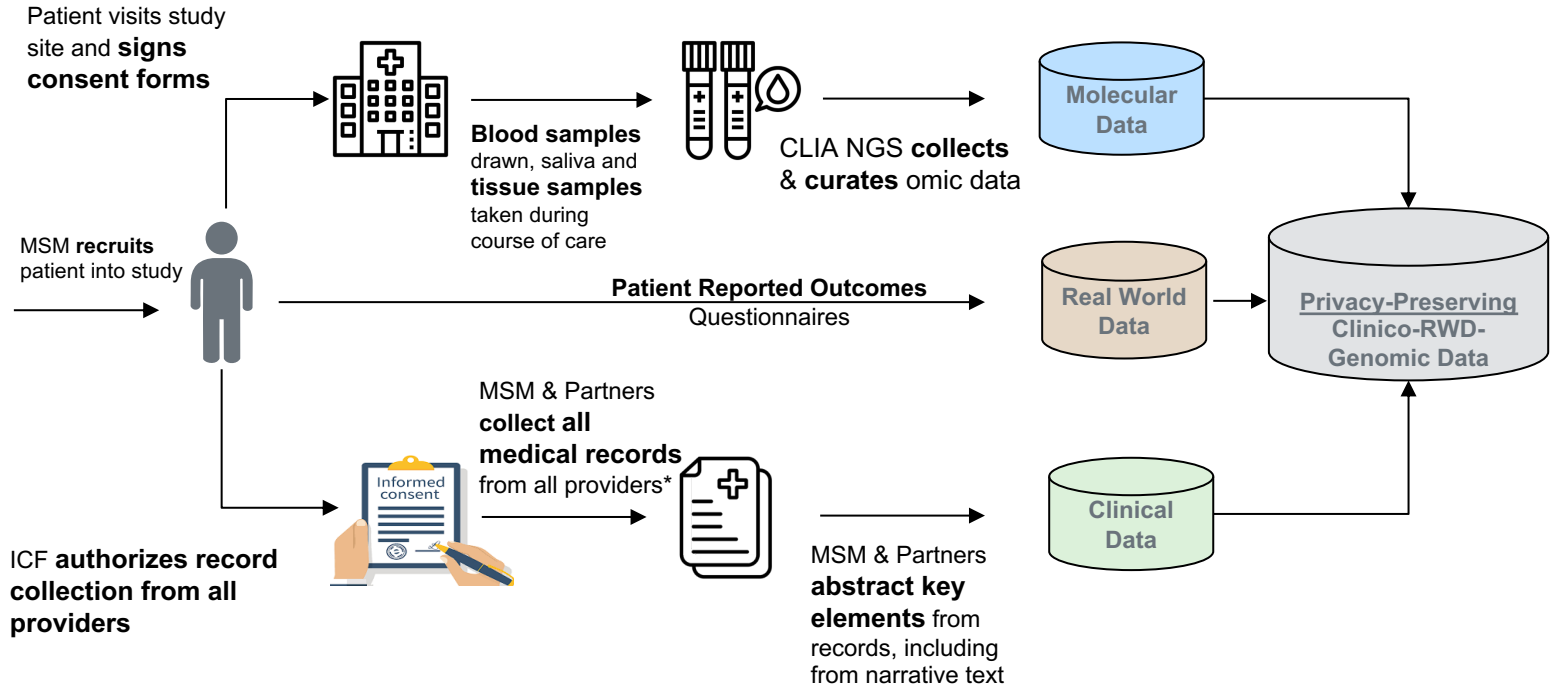
*Bioinformatics & AI/ML*

*Pharm Sci & Manu, / Pharmacy*

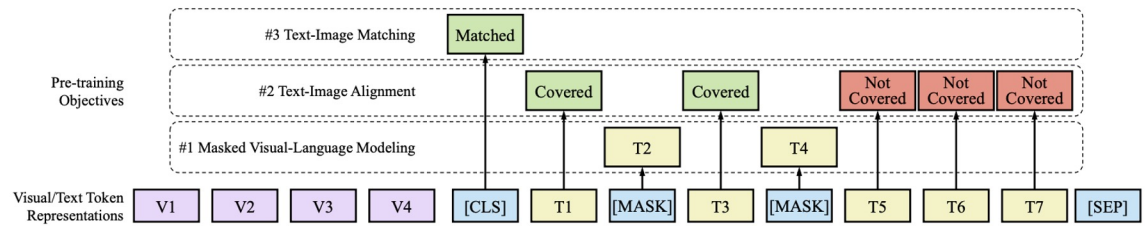
*Bioethics*

*Genetics*

# Collaborative Process for Generating Datasets / Patient Registries

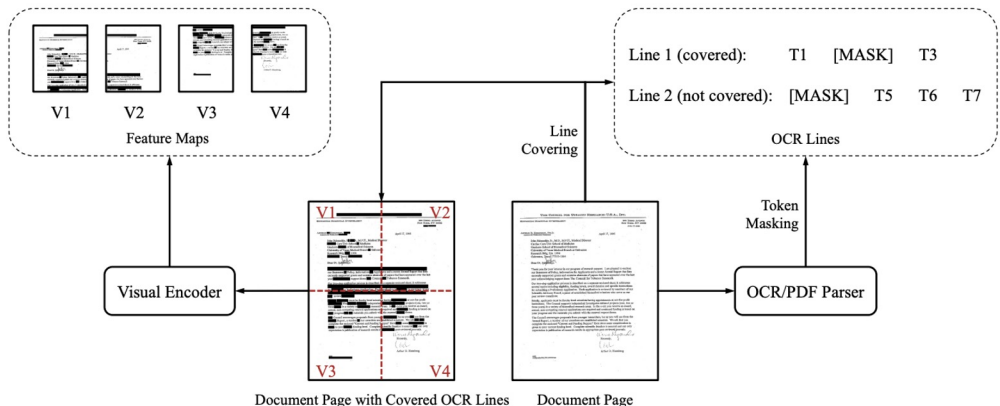


Integrated AI/ML Platform ( for the 10,000+ cases )



**Transformer Layers**  
with Spatial-Aware Self-Attention Mechanism

Segment Embeddings	C	C	C	C	A	A	A	A	A	A	A	A	
1D Position Embeddings	0	1	2	3	0	1	2	3	4	5	6	7	8
2D Position Embeddings	Box <sub>V1</sub>	Box <sub>V2</sub>	Box <sub>V3</sub>	Box <sub>V4</sub>	Box <sub>PAD</sub>	Box <sub>T1</sub>	Box <sub>T2</sub>	Box <sub>T3</sub>	Box <sub>T4</sub>	Box <sub>T5</sub>	Box <sub>T6</sub>	Box <sub>T7</sub>	Box <sub>PAD</sub>
Visual/Text Token Embeddings	V1	V2	V3	V4	[CLS]	T1	[MASK]	T3	[MASK]	T5	T6	T7	[SEP]

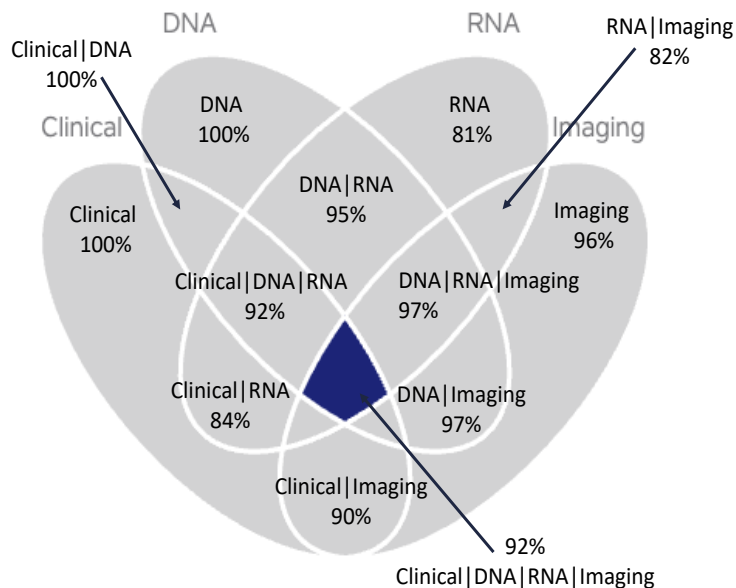


Information  
Extract  
Pipeline:

LayoutLM v2  
Multiple  
Convolutional  
Neural Network(s)  
(i.e., Transformer)



## Breast Cancer Cases



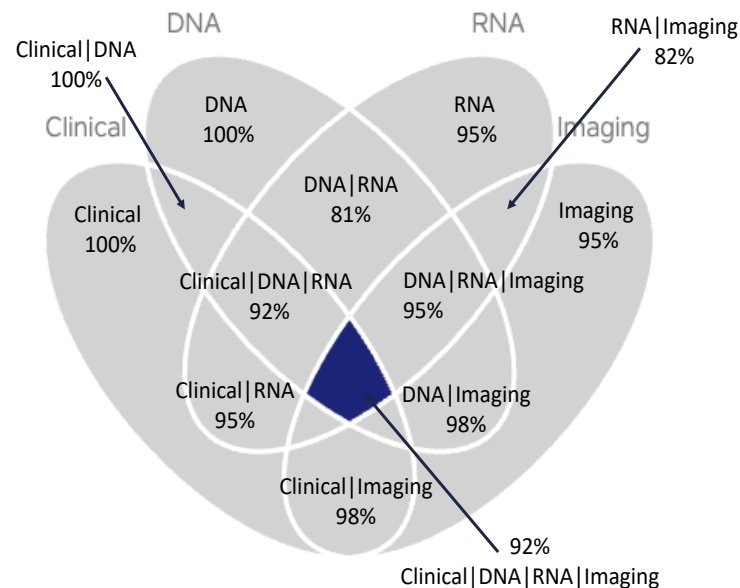
86% had VUS

76% of cases MSI stable

71% had actionable somatic mutations

10% had a germline mutation

## Endometrial Cancer Cases



100% had VUS

84% of cases MSI

63% had actionable somatic mutations

11% had a germline mutation

*Clinical trials were available for 66% and 76% of cases had unique treatment indications*

# 21<sup>st</sup> Century Community Health Learning Systems



## *Multiple Channels to Disseminate Findings*

### Data & Relationship Management

CLIA WES&WTS

RUO WGS data

Questionnaires & RWD

Clinical Trial Liaison

Community

Patient Advocacy



Training



Research



DIAGNOSIS



Drug  
Discovery



Clinical Trial  
Matching



PRECISION  
Medicine



Clinical Decision Support



Treatments



WELLNESS



# 21<sup>st</sup> Century Community Oncology Learning Systems

CommonSpirit  
Microsoft Campuses  
WellStar

Socio-Clinico-Genomic Data Licensed to  
Health Data, AI and Life Science Companies

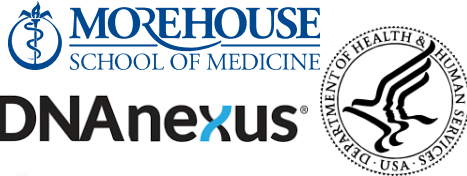
*"Morehouse CARhES"*

*Health Data*

*Artificial Intelligence*

*Life Science*

**Patients/Participants**



leidos  
Leidos Biomedical Research, Inc.

citizen

NCl at Frederick

Atomwise

NATIONAL  
CANCER  
INSTITUTE

FDA

IQVIA

Svapse

OPTUM

Google  
DeepMind

Oncora  
MEDICAL

CloudMedx

PRECISION  
HEALTH.AI

Genentech

Bristol-Myers Squibb

Pfizer SANOFI

MERCK  
Biogen

Research Revenue Generation and  
Share Value to Sustain Relationships, Trust, and Infrastructure



***Thanks!!!***

# The Top 31 Master's in Biotechnology Degree Programs

**Intelligent™**



01

INTELLIGENT PICK

**MOREHOUSE  
SCHOOL OF  
MEDICINE**

^

02

BEST PRIVATE INSTITUTION

**JOHNS HOPKINS  
UNIVERSITY**

v

03

BEST PUBLIC INSTITUTION

**UNIVERSITY OF  
MARYLAND**

v

04

BEST FOR IMMUNOHEMATOLOGY

**GEORGE  
WASHINGTON  
UNIVERSITY**

^

05

BEST FOR AGRICULTURE

**NORTHEASTERN  
UNIVERSITY**

v

06

BEST IN THE NORTHEAST

**BOSTON  
UNIVERSITY**

v

07

BEST THESIS OPTION

**COLUMBIA  
UNIVERSITY**

v

08

BEST FOR ENTREPRENEURS

**HARVARD  
UNIVERSITY**

v

10

BEST FOR MOLECULAR BIOLOGY

**UNIVERSITY OF  
PENNSYLVANIA**

v