# KYNETIC: Not Your Traditional Grant Program

Focusing on product development to bridge the gap between discoveries and commercialization

Linda P Dwoskin, PhD

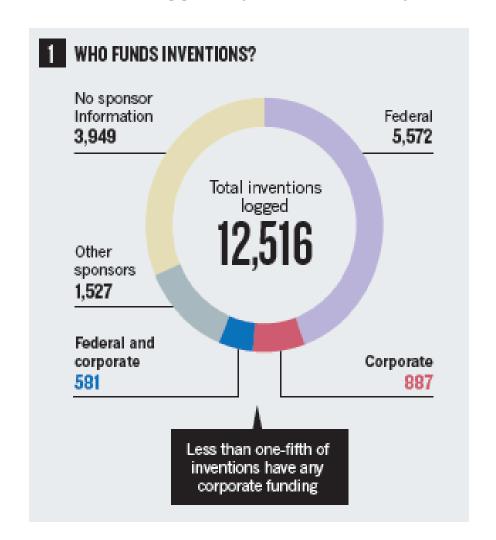
KYNETIC Contact PI

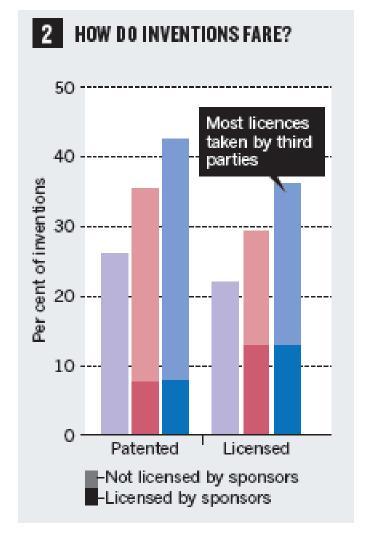
Professor and Associate Dean for Research
University of Kentucky, Lexington, KY



# NIH Supports Inventions

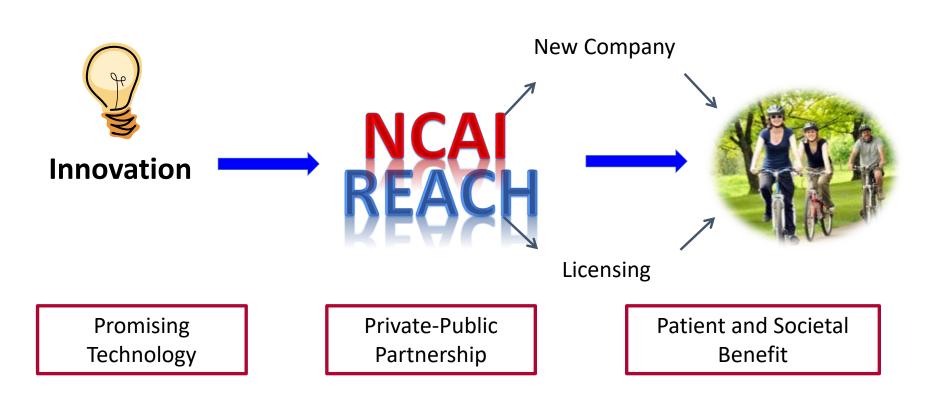
**Inventions logged by the University of California system 1990 - 2005** 





### Spin out companies - educate innovators: Phase 0 Proof of Concept Centers

NIH Centers for Accelerated Innovations (NCAI)
Research Evaluation and Commercialization Hubs (REACH)



Turning discoveries into health



NIH Small Business Program "America's Seed Fund"



\$39 Billion

Basic and applied biomedical science



>1.1 Billion

Non-dilutive funding just for small businesses









MedImmune

# NCAI and REACH Highlighted Outcomes

- 277 projects funded
- ~ 56 options or licenses
- ~ 2250 innovators received entrepreneurial training
- Over \$700M in follow on funding
- 66 start-up companies formed
  - 50 submitted SBIR/STTR applications
  - 27 have received awards so far
  - Success rate is nearly 3X higher than the NIH average for Phase 1

# Introducing the Kentucky Network for Innovation and Commercialization (KYNETIC)



Kentucky Network for Innovation and Commercialization

# KYNETIC: The Kentucky Network for Innovation and **Commercialization REACH: Research Evaluation and Commercialization Hub**

MISSION: "to nurture innovations and innovators by providing funding, mentoring, education, and a network of relevant expertise"

Access to funds, industry-type R&D expertise, business strategy, commercialization support, and assistance in the company/startup formation

#### **Members**

All KY public universities and community colleges

Research-Intensive (R1)

Regional Universities

Community & Technical Colleges (KCTCS)



Western KY

Murray State

#### **Lead Institution**

University of Kentucky



#### **Co-Lead Institution**

University of Louisville



#### **State Partner**

Kentucky Cabinet for Economic

Development (CED)



## KYNETIC Leadership and Governance Structure

Key features based on lessons learned from REACH 1.0 and other programs:

- Shared governance → stakeholders are engaged and vested in the program
- Senior academic PIs with commercialization experience → facilitates "site mining",
- Technology transfer office integral role and represented on the KYNETIC leadership team
- Shared decision-making involving external reviewers → minimizes conflicts of interest



### **KYNETIC Leadership and Governance Structure**

**NIH**: Project scientist, program officer, technology guidance committee (per RFA-OD-19-014)

← NIH and Partners

#### **External Review Board (ERB):**

Representatives from pharma, medical devices, eHealth, VC/angel investors, foundations, etc.

#### **Internal Advisory Committee (IAC):**

Representatives from EKU, NKU, WKU, Murray State, Morehead State, KSU, UK, UL, C3, CED

Advisory Boards



Co-I: April Turley (C3)



Co-I: lan McClure (UK)



PI: Linda Dwoskin (UK)



PI: Paula Bates (UL)



Co-I: Allen Morris (UL)



Co-I: Brian Mefford (CED)

\_ Leadership Team (LT)

PM 1 (UK): *TBN* 

PM 2 (UK): Kendra Hargis-Staggs PM 3 (UL): Sarah Andres PM 4 (UL): Jessica Sharon PM 5 (C3): *TBN* 



### **Program Goals**

- Not a traditional grant program
- Proof-of-concept stage innovations that need support to prepare for SBIR awards or partnership (e.g., license or private funding)
- Advance technologies to products
- De-risk technologies to position them for partnering with an established company or startup creation
- Coach innovators on the commercialization and/or entrepreneurship process

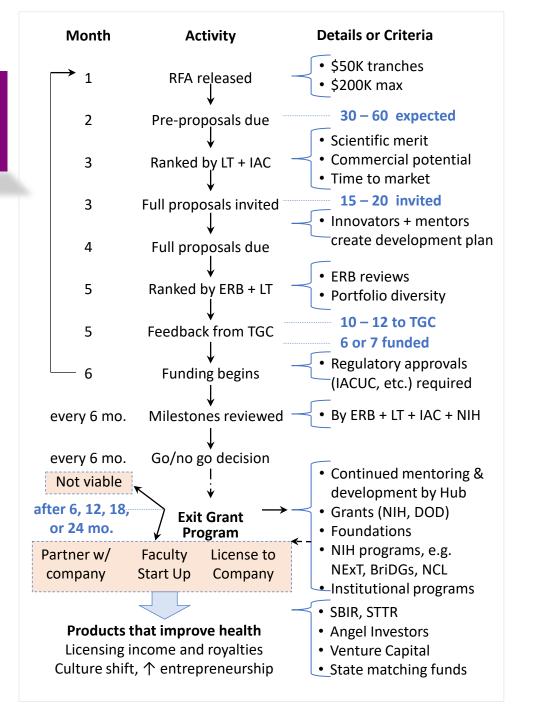


# Overview: Technology Solicitation Through Exit

#### **Approximate Timeline:**

	ACTIVITY	SPRING	FALL		
ORING	RFA released	Jan 1	Jul 1		
	Pre-proposal Due	Feb 15	Aug 15		
	Pre-proposal Review Panel	Mar 1	Sep 1	•	-
	Full application Due (invited)	Apr 15	Oct 15		Ä
MENTO	Full application Review Panel	May 14	Nov 12	•	DB/
M	Submit to TGC	May 18	Nov 16		BACK
	Receive TGC Feedback	Jun 19	Dec 18	•	
	Project Start	Jul 1	Jan 1		

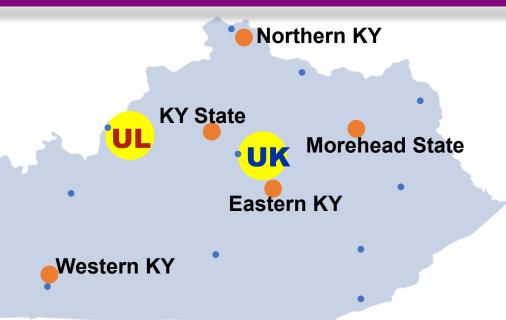




## **Project Grant Eligibility**

**Murray State** 

- Available to <u>anyone</u> at eligible institutions
- Includes faculty, staff, trainees, & students (non-faculty must have sponsor)
- GOAL = define or develop a product
- Must be (human) health-related
- Any disease or health condition
- Any technology type (drug, vaccine, device, test, app, etc.)
- Existing IP or potential for new IP (e.g. patent)
- Milestone-driven, "killer" experiments
- Grants of up to \$200k for 2 years
- Given in tranches: \$50k/6 months





### **Technology Solicitation**

Key features based on lessons learned from REACH 1.0 and other programs:

- Maximize participation! Faculty, staff, trainers, clinicians, physicians, etc.
- Seek first-time innovators—students, postdocs, staff, investigators from diverse disciplines.
- Low bar for entry into the program to maximize participation (2-page pre-proposal).
- Encourage early interactions between interested innovators and KYNETIC staff.



## **Mentoring and Coaching**

#### Key features based on lessons learned from REACH 1.0 and other programs:

- Project grants carry required participation in skills development/experiential activities.
- Teach innovators how to find the information (Help but don't do it for you!)
- Mentor early and often.
- Provide opportunities for pitching and networking— important skills need practice.

#### **Mentoring Opportunities**

- Initial idea/ pre-proposal
- Full proposal
- Pitch preparation
- Pre-award
- Monthly project meeting
- Progress report pitch
- Feedback and go/no go

# **Experiential Education** (Learning by Doing)

- Pre-proposal
- Full proposal
- Pitch competition
- Pitch to ERB
- Progress report to ERB
- External presentations



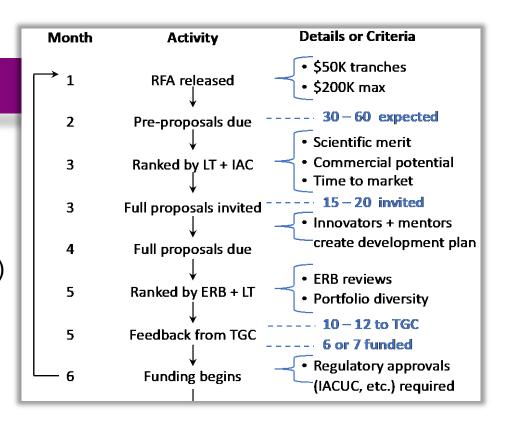
### **Review and Selection**

#### **Features**

- Low barrier to entry, but triage before full proposal stage
- Input from ERB, LT, IAC, tech transfer, project managers
- Project priority ranked by a panel of ~12 18 people (ERB + LT)
- All reviewers review all proposals

Application stage	Who reviews?	Who can comment or ask questions?	Who can vote?*
Pre-proposal (2-pages)	LT + IAC	LT + IAC + PMs + OTT/OTC	LT + IAC
Full proposal (12-pages)	LT + ERB	LT + ERB + IAC + PMs + OTT/OTC	LT + ERB
Elevator Pitch (5 min)	N/A	LT + ERB + IAC + PMs + OTT/OTC	LT + ERB
Renewal Pitch (10 min)	N/A	LT + ERB + IAC + PMs + OTT/OTC	LT + ERB

LT – leadership team, IAC – internal advisory committee, PMs – project managers, ERB – external review board, OTT/OTC – office of technology transfer/commercialization, \* - unless conflict of interest



#### **Considerations**

- Maximize # of innovators and innovations
- Fair and transparent review
- Protect proprietary information
- Encourage reviewer/participant engagement
- Maximize academia-industry interactions

## **Review Panels Through the Process**



#### KYNETIC Leadership Team (LT)

Representatives from UK, UofL, CED

# Internal Advisory Committee (IAC)

Representatives from EKU, KSU, Morehead State, Murray State, NKU, WKU, UK, UofL, CED

# External Review Board (ERB)

Industry experts, investors, entrepreneurs, and clinicians

# NIH Technology Guidance Committee (TGC)

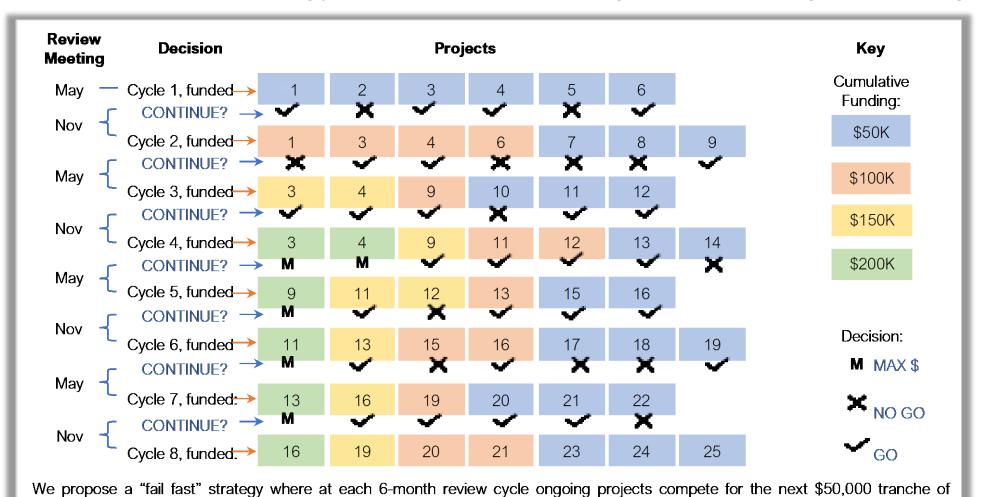
NIH & federal agencies related to intellectual property, regulatory, and reimbursement (USPTO, FDA, CMS)

# ERB & KYNETIC Leadership

Final Funding Decision

### **Go/ No Go Decisions**

• "Milestone driven" strategy to maximize funding of deserving technologies



funding. At each cycle at least 2 of the 6 or 7 selected projects will be new.



### **Skills Development**

#### **Training Course**

- 6-week training course
- Coordinate timing with application cycles
- Diverse innovators and entrepreneurs telling their stories
- "How to" tips for full application, glossary, list of resources

#### Coordination with other programs

- I-Corps/ Launchit (Lean Launchpad)
- NIGMS regional tech transfer hub (online resources)
- XOR (executive on roster)
- Kentucky Legal Launchpad
- XLerate Health bootcamp for new companies
- State programs for startups

#### **Trifecta Training Series**







#### **Topics**

- Value Proposition
- Killer Experiments
- · Business Plans
- Patents
- Regulatory
- Reimbursement
- Pitches





**Maggie Galloway** 







Eric Andreoli and Ryan Melander

Cedric Francois

#### Other components:

- Guest speaker series
- Networking events
- Pitch competitions
- Innovation awards



### **Hub Resources**



- **NIH REACH**
- NIAAA Center
- NIEHS Superfund
- NIGMS SeRTT
- NIGMS INBRE (lead)
- NIGMS COBRE (3)
- **NSF I-Corps**
- Coulter TP
- KY RISE



- **NIGMS SeRTT**
- KY RISE





- NIH CTSA
- NCI Center
- NIA Center
- NIDA Center
- NIEHS Center
- NIEHS Superfund
- NIGMS SeRTT (co-lead) .
- NIGMS INBRE
- NIGMS COBRE (3)
- EDA UC
- KY RISE



SBA FAST

#### **XLerateHealth**

 NIGMS SeRTT\* (business lead)

SBA GA

**KY RISE** 





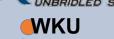
NKU













- **EDA i6 Challenge**
- **NIGMS SeRTT**
- NIGMS INBRE
- KY RISE



- **NIGMS SeRTT**
- **NIGMS INBRE**
- **KY RISE**



#### **KEY**





KCTCS College



MuSU



- **NIGMS SeRTT**





















Kentucky is home to major health insurance companies and numerous aging, long-term care, home health, and rehabilitation companies as well as various hospital systems. Several pharmaceutical and medical device companies, contract research organizations and specialist research suppliers are also located in Kentucky. Finally, the commercialization ecosystem is well supported by accelerators and service providers with health expertise









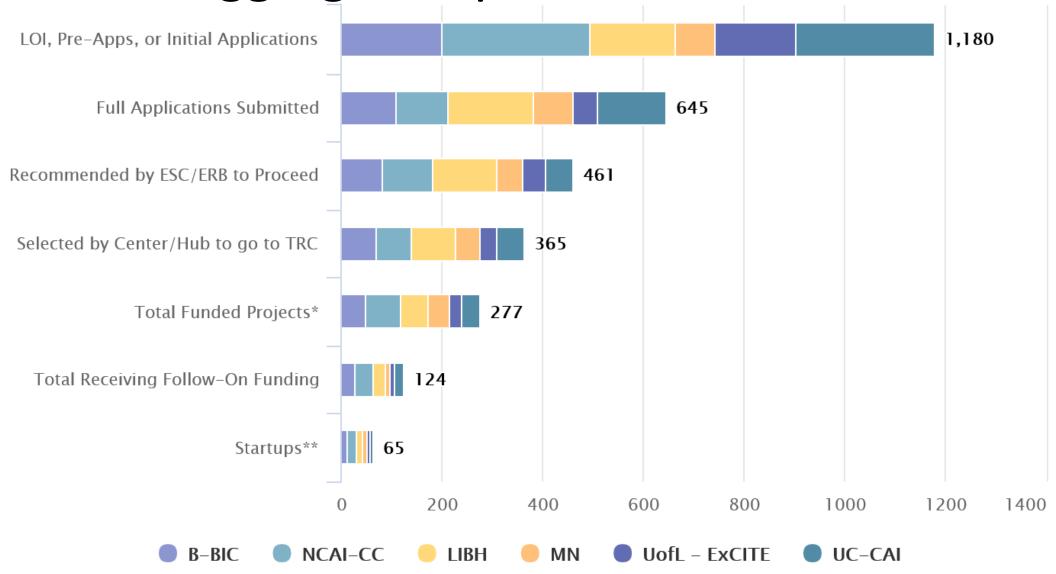


OF\_

Hospital



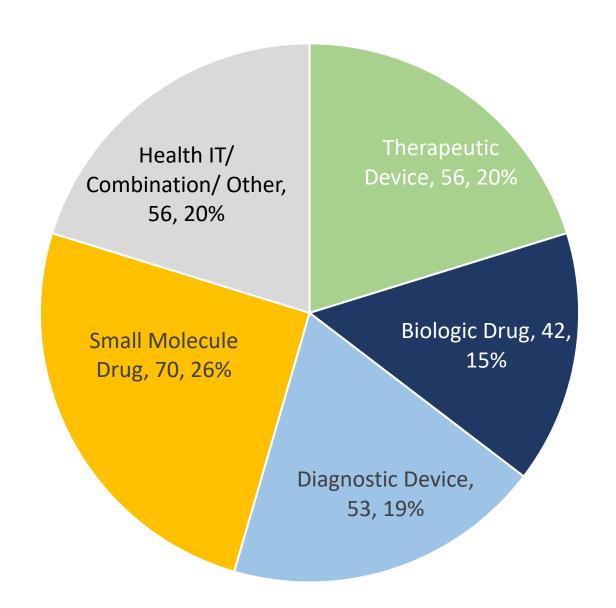
# Aggregate Pipeline Overview



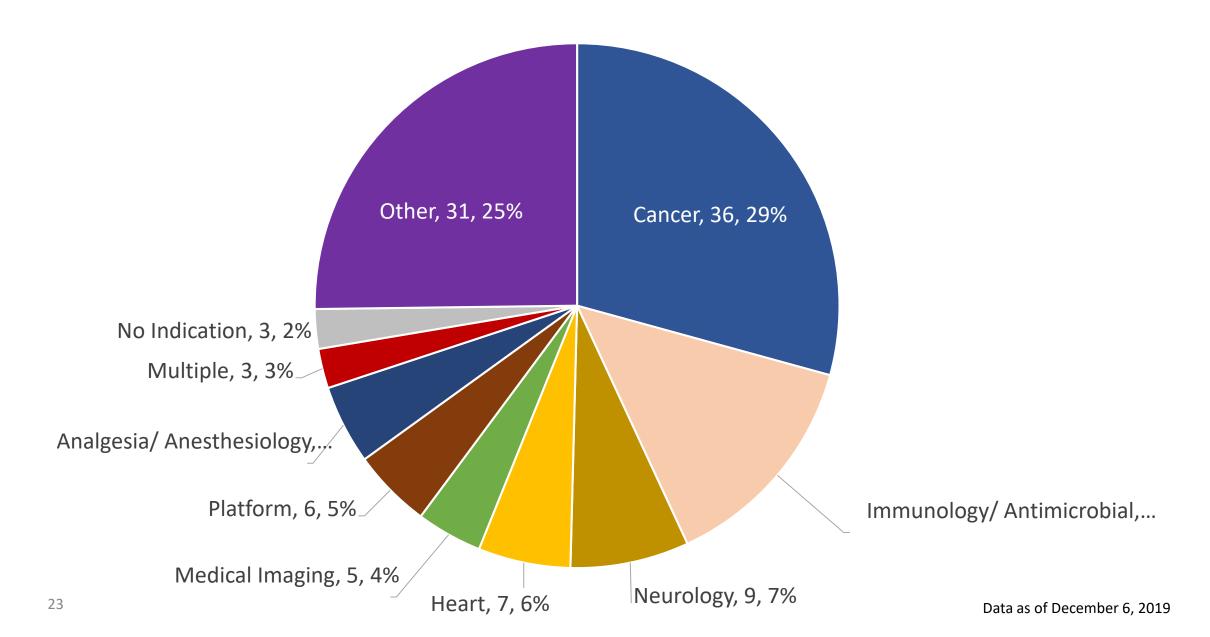
<sup>\*</sup> Number of applications that have been reported as funded.

<sup>\*\*</sup> Number of unique technologies that are affiliated with a startup.

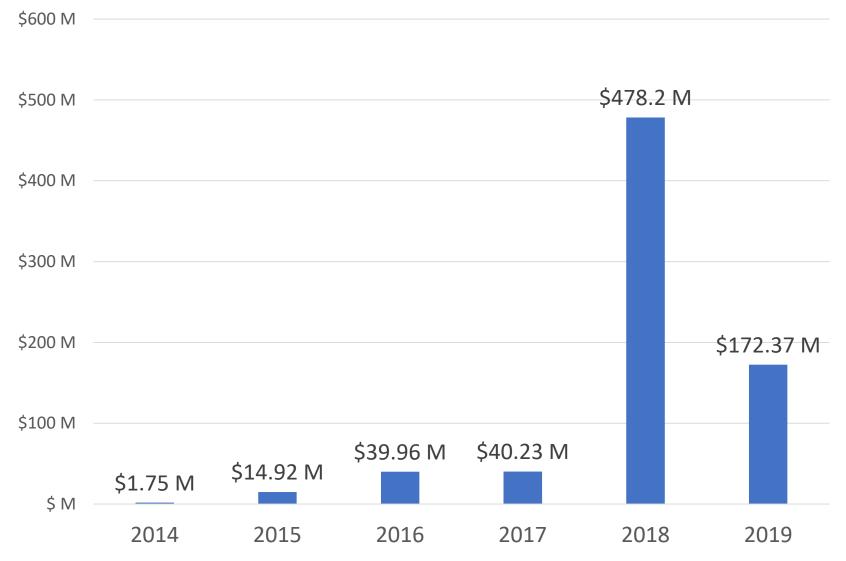
# NCAI & REACH Distribution of Projects Across Technology Types



# REACH Distribution of Projects Across Disease Areas



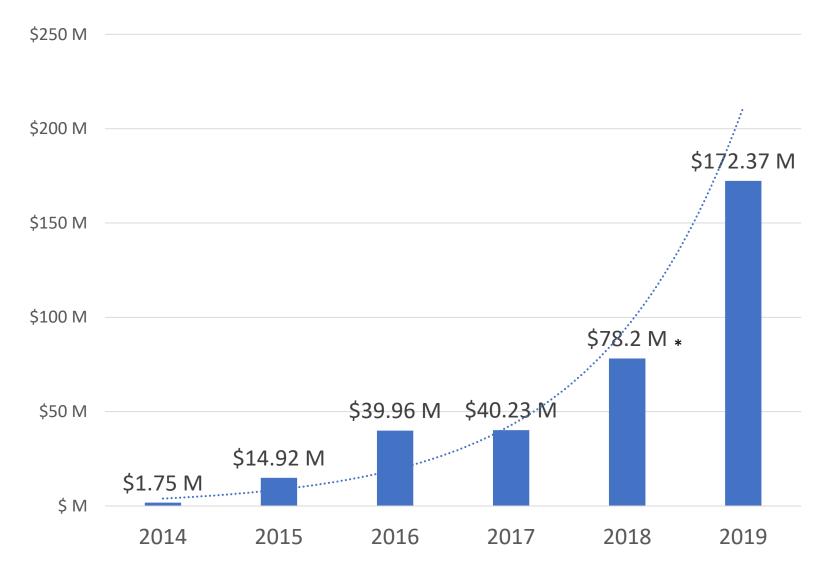
# Annual Growth in Follow-on Funding



#### Overview:

- \$747 M in total follow-on funding
- Strong increasing trend over time
- Amount of follow-on funding raised from different sources varies substantially by center/hub
- A few large investments constitute the majority of follow-on funding, while the rest is more widely distributed
- 10 new VC investments occurred since last PSC, totaling \$70.8 M

# Annual Growth in Follow-on Funding



#### 2019 Summary:

- **76** unique follow-on funding events
- 6 investments of ≥ \$10 M
- **16** follow-on investments of ≥ \$1M
- **34** investments ≥ \$250k
- **51** investments ≥ \$100k

# Follow-on Funding Recent Highlights

Platelet BioGenesis Receives \$56 Million Contract from the Biomedical Advanced Research and Development Authority (BARDA) to Develop Human Stem Cell-Derived Platelets as a Medical Countermeasure to Radiological and Nuclear Exposure

Funding will support clinical development of stem cell-derived platelet technology platform

**CAMBRIDGE**, **Mass.**, **September 30**, **2019** - Platelet BioGenesis, Inc. (PBG), the leader in stem cell-derived, on-demand human platelets (PLTs+™) and genetically engineered platelet-based therapeutics, announced today that it has signed a \$56 million contract with the <u>Biomedical Advanced Research and Development Authority</u> (BARDA), an agency of the US government's Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. PBG will use the funding to develop and establish donor-independent platelets as a medical countermeasure for treating victims of a nuclear or radiological event.

# Third Pole Therapeutics Announces Inhaled Nitric Oxide Strategic Collaboration with Actelion, a Janssen Pharmaceutical Company of Johnson & Johnson

Boston, MA, 26 March 2019 – Third Pole Therapeutics, a privately held company developing and delivering transformative cardio-pulmonary therapies, announced today that it has entered into a strategic collaboration to work with Actelion Pharmaceuticals Ltd, a Janssen pharmaceutical company of Johnson & Johnson. The collaboration will bring the global resources and know-how of the largest and most respected healthcare company to Third Pole's simple, convenient, economical, lightweight, and proprietary platform technology, capable of expanding access to potentially life-saving inhaled nitric oxide (iNO) therapy worldwide.

Third Pole's breakthrough iNO technology platform produces pure inhalable nitric oxide from air for immediate therapeutic use. Third Pole's more convenient and



portable technology promises to remove the logistical constraints and economic burden of compressed gas-cylinder-delivered iNO therapy, facilitating accessibility to more patients outside of level III units in apex institutions and regional perinatal centers.



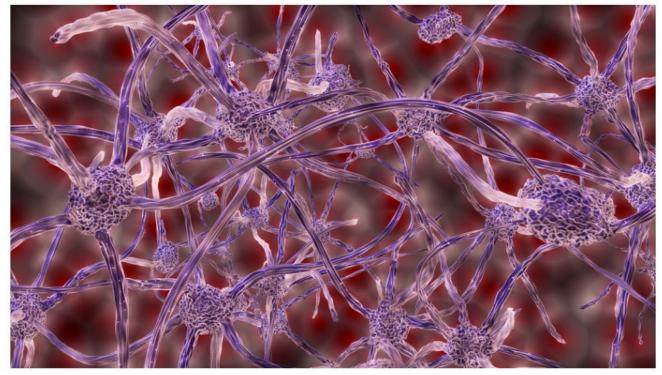
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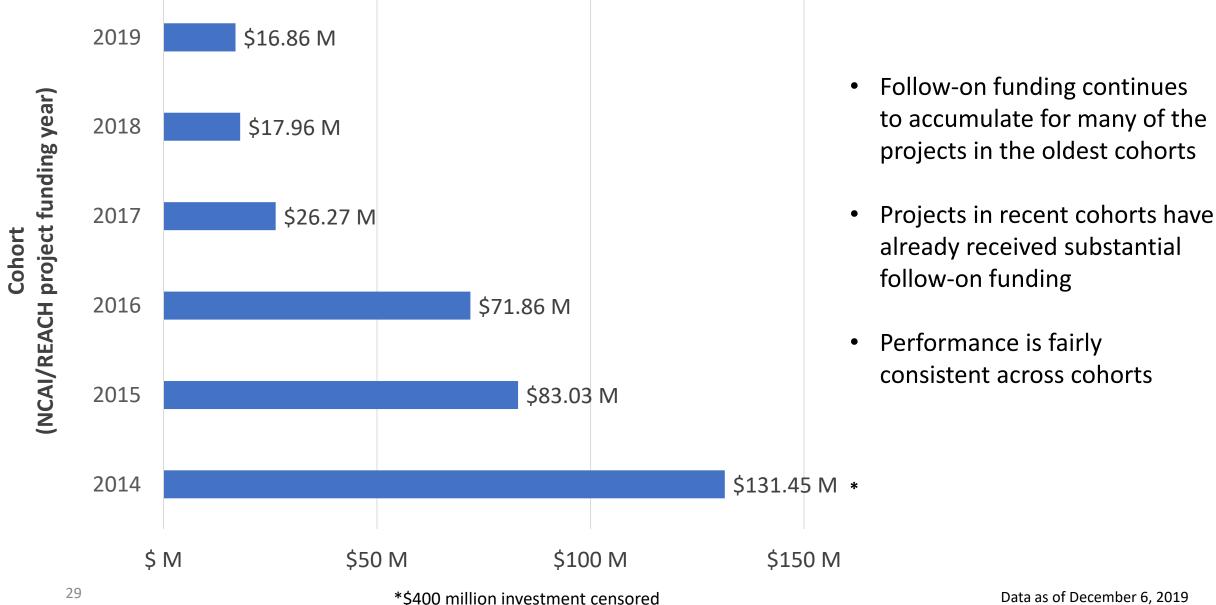
#### Nocion launches with \$27M and 'charged drugs' to selectively target pain

by Amirah Al Idrus | Apr 17, 2019 10:00am

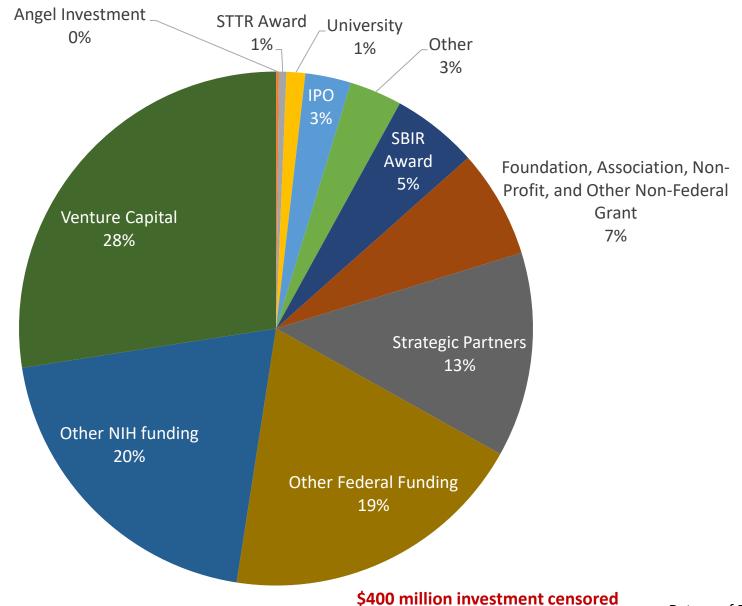


Nocion's \$27 million series A will bankroll the company from discovery through proof of concept. (Pixabay)

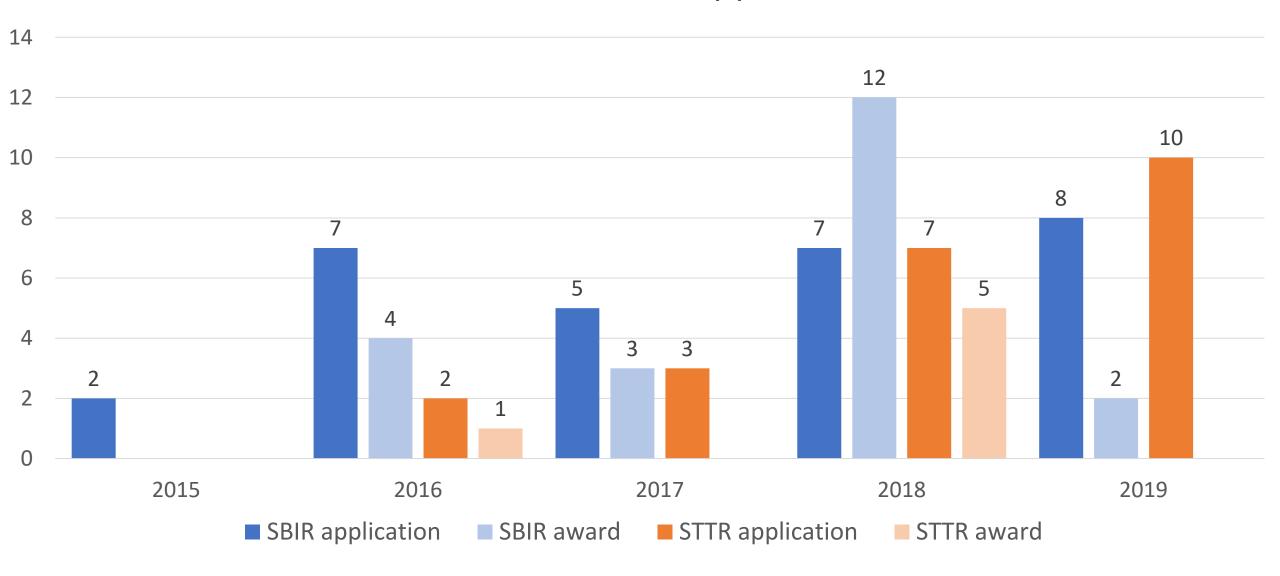
# Follow-on Funding as Projects Age – Analysis by Cohort



### Summary of Follow-on Funding by Funding Source

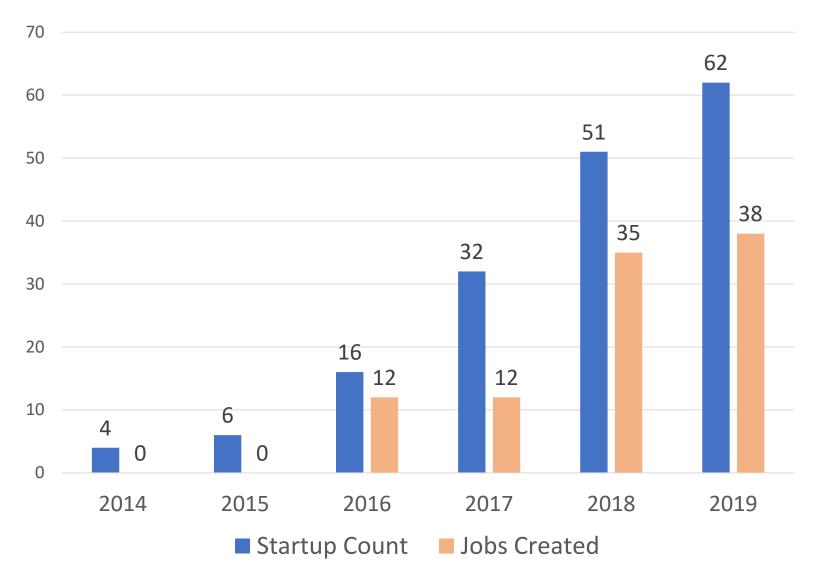


# Annual Growth in SBIR & STTR Applications and Awards



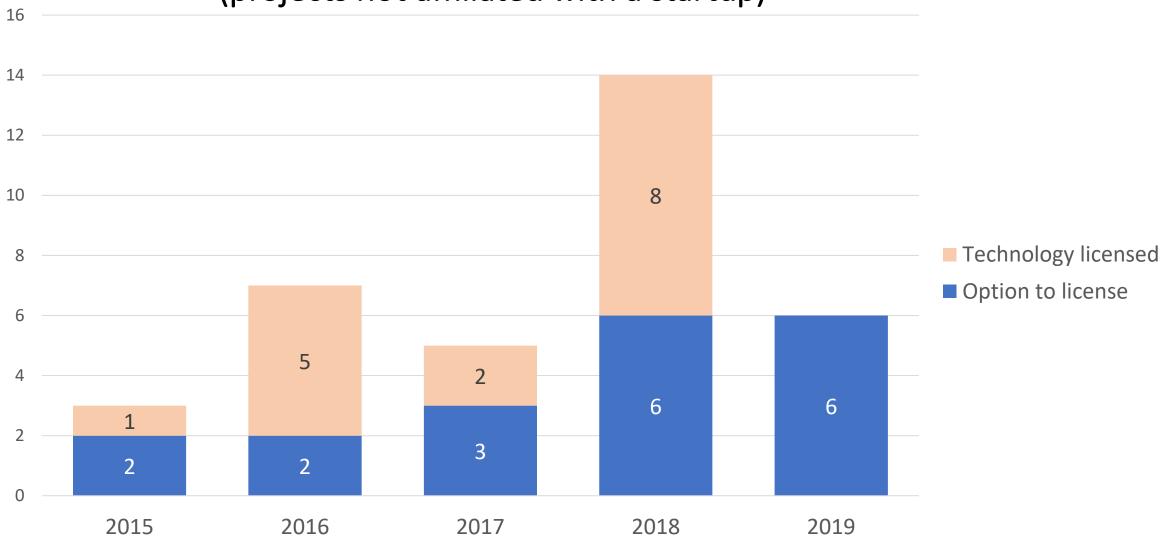
Note: the number of applications may not exceed the number of awards in any given year due to the lag times between application and award dates.

## Number of Startups over Time



- In 2014, Platelet Biogenesis and Third Pole formed, which have since raised significant follow-on funding and created a combined 25 jobs;
  - Platelet Biogenesis plans to add up to 30 new jobs in 2020
- Every site has at least one new startup in 2019
- Several recent startups have received significant follow-on funding

# Annual Growth in Licensing and Options (projects not affiliated with a startup)



Note: because multiple events can occur for a given project, the number of unique events presented here exceeds the number of projects not affiliated with a startup that are currently licensed or optioned.

### **Frequently Asked Questions:**

#### Why is KYNETIC different from other grant programs?

- not a traditional grant program
- product-focused, milestone driven and requires business-case project management
- if invited to submit a full application will work with KYNETIC staff/mentors to develop a product development plan and timeline with specified milestones

#### What benchmarks will I have to meet in the program?

- milestone-driven with monitoring of progress
- continuation evaluation (go/no-go decision) every 6 months
- non-progressing projects may be terminated and replaced with new projects

#### Who is eligible for the KYNETIC program?

- open to all faculty, staff, trainees, and students at participating Kentucky state universities and community colleges
- non-faculty applicants must identify a faculty member sponsor
- focus on developing products that have the potential to enhance human health.
- all types of products (e.g. therapeutic, preventative, device, test, software) are eligible
- multiple Principal Investigators (up to 3) is optional but permitted.

#### Does my institution participate in the KYNETIC program?

- The following institutions participate in the KYNETIC network:
- University of Kentucky, University of Louisville, Eastern Kentucky University, Kentucky State University, Morehead State University, Murray State University, Northern Kentucky University, and Western Kentucky University, and all colleges in the Kentucky Community and Technical College System.

#### Does my product have to treat one specific disease?

• There is no disease-specific requirement, but it must be related to human health.

#### What's the policy on intellectual property?

- Applications should involve ideas that originate from within a participating institution (making them potentially eligible for patent protection or some other mechanism that will return income to the program) or university-derived technologies with pending/issued patents or copyright.
- Technologies that are already licensed to a company are not eligible.

#### What's the budget?

- Requests for up to \$50,000 per project, over a period of 6 months, will be considered.
- Projects are eligible for competitive renewal every 6 months, until a maximum of \$200,000 per technology is reached.



### **Pre-application**

- 2-page project description
  - Describe product/idea and how it addresses unmet needs avoid highly technical language
  - Market and competition what's out there now and what edge do you have over the competition, size/growth of the market
  - Is it eligible for IP protection? previously licensed technologies are ineligible
  - Budget in **broad** terms for \$50,000 AND \$200,000 no indirect costs
  - Describe expertise/experience of PI/team



## **Important Questions to Ask Yourself**

- What is the unmet clinical need I'm addressing?
- Will people buy/use it?
- Who are my competitors?
  - What do edge I have over the competition?
- Is it subject to IP protection?
- Will it be profitable?
- How will the funding aid in moving the project along?



### **Pro Tips**

- Audience audience!
  - Scientists AND businesspeople
  - Be able to explain to your non-scientist friends
  - Tell a story; make it relatable
- The internet is your friend
  - Google, FDA.gov, USPTO.gov, clinicaltrials.gov
- Attend the training sessions (more info to come)
- Reach out to OTC
- Ask your KYNETIC team (<u>kynetic@uky.edu</u>)
  - We can review and give feedback leading up to the submission deadline (5 PM February 15, 2020)





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