Impacts and Insights from NIH's Research Evaluation and Commercialization Hubs

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Welcome

- \circ Introduction
- o Overview of the Research Evaluation and Commercialization Hubs (REACH) program
 - Challenges addressed by REACH
 - Key programmatic elements
 - REACH 2015 cohort
 - REACH 2019 cohort
- $_{\circ}$ Outcomes data, as of December 2022
 - Start-ups
 - Follow-on funding
 - SBIR/STTR activity
- Best practices employed by REACH 2015 and 2019
- REACH 2023 request for applications

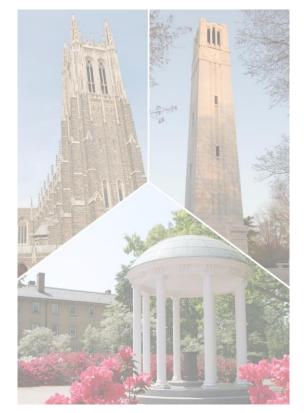
RTI International

delivering **the promise of science** for global good



RTI International is an independent, nonprofit research institute dedicated to improving the human condition. We combine scientific rigor and technical expertise in social and laboratory sciences, engineering, and international development to deliver solutions to the critical needs of clients worldwide.

About RTI



- Independent, not-for-profit research and development organization
- Founded in 1958 through a partnership between business leaders, state government, and area universities, including
 - Duke University
 - NC State University
 - UNC at Chapel Hill
- Mission: to improve the human condition by turning knowledge into practice
- Long history of evaluating science and innovation programs, including basic science, academic entrepreneurship, accelerators, and translational science programs

RTI's Summary Scope of Work for NIH

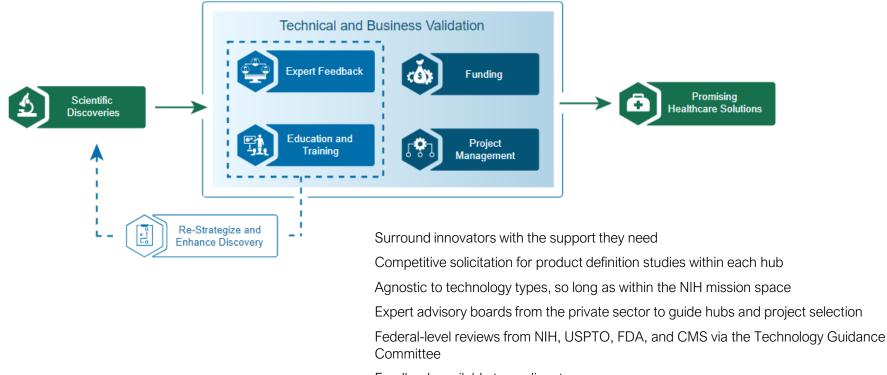
- Design and implement an evaluation program for NIH's proof-of-concept network
 - · To support administrative reviews, reporting requirements, and communications
 - To enhance program design and delivery
 - To disseminate lessons learned and insights
- \circ Key activities include
 - Analyzing processes and implementation
 - Tracking outcomes and impacts
 - Assessing costs and efficiency
 - · Providing feedback loops between sites and NIH
 - Producing reports and papers

Why does NIH invest in proof-of-concept centers?

- REACH is NIH's Phase 0 Proof-of-Concept Partnership pilot program of the 2011 SBIR/STTR Reauthorization Act, reauthorized by the SBIR and STTR Extension Act of 2022
- Challenges motivating REACH are:
 - Uneven SBIR/STTR application and awards rates, relative to the magnitude of investment in extramural basic science research
 - Limited funding for early-stage production definition studies
 - Limited knowledge among innovators about early steps of research translation and commercialization
 - Discomfort among innovators with commercialization concepts and ideas
 - · Culture than can discourage the pursuit of entrepreneurship or the conversion of
 - Limited capacity within biomedical research institutions for product development, mentorship and coaching, and relevant skills development programs

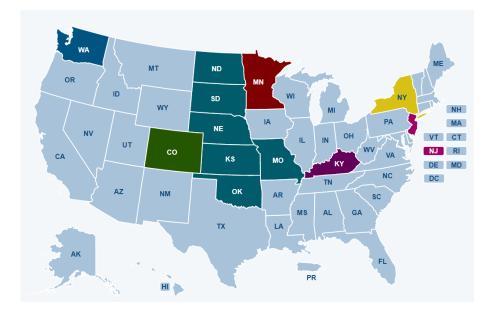
NIH Proof-of-Concept Model

Proof of Concept Hub



Feedback available to applicants

REACH 2015 and 2019



REACH 2015

- 。 Long Island Bioscience Hub, led by Stony Brook University
- o University of Minnesota REACH
- University of Louisville ExCITE

REACH 2019

- Kentucky Network for Innovation and Commercialization (KYNETIC), led by University of Kentucky and including all public universities and technical colleges in Kentucky
- o SPARK REACH at CU Anschutz Medical Campus
- Midwestern Biomedical Accelerator Consortium (MBArC), led by University of Missouri, Columbia and Kansas University Medical Center, Kansas City
- Rutgers Optimizes Innovation at Rutgers University
- Washington Entrepreneurship Research and Commercialization Hub (WE-REACH) at the University of Washington

Impact Themes/Barriers (1/2)

- Ecosystem themes voiced by institutions
 - Biomedical discoveries require significant, sustained investment to come to market
 - Limited funding/support for early-stage technology development
 - · Investors and strategic partners seek validated concepts, with supporting data
 - Inconsistent visibility and interest
 - "Proven" innovators and select therapeutic areas capture market attention
 - Promising technologies go unsupported, even in capital-rich environments
 - Locations in "fly-over territory", affecting overall awareness in addition to the probability of commercialization
 - Less dense regional clusters for biomedical innovation
- How the centers and hubs are having an impact, beyond providing funding
 - Providing coordinated commercialization support via teams
 - Serving as a "diligence engine" for promising technologies
 - Serving as an "equalizer" for institutions, departments, and innovators in each ecosystem
 - Signaling that the institution has a research portfolio worthy of review

Impact Themes/Barriers (1/2)

- Institutional challenges voiced by partner institutions
 - · Limited infrastructure for the further development of promising technologies
 - Insufficient resources, knowledge, and expertise to support innovators
 - New to adding value to discoveries in the university environment
 - Academic reward system that does not encourage commercialization
 - Competing institutional priorities
 - Few role models to emulate
- How the sites are making an impact
 - · Developing organizational and managerial awareness for translational R&D
 - Building institutional capacity and knowledge of commercialization
 - Demonstrating and disseminating good practices and required resources for accelerator and proof-of-concept programs
 - Starting from a base of institutional change regarding commercialization
 - Turning funded innovators without prior commercialization experience into role models
 - · Demonstrating what is possible

Summary of REACH 2015 Outcomes

Event	LIBH	MN-REACH	UofL ExCITE	TOTAL
SBIR/STTR Awards	7	4	4	15
SBIR/STTR Applications	16	18	13	47
Startups Launched	11	11	5	27
Licensed Technologies (not affiliated with a startup)	2	3	2	7
Optioned Technologies (not affiliated with a startup)	1	3	2	6
Follow-on Funding Secured	\$88.7 M	\$6.5 M	\$12.5 M	\$107.7 M

Data as of November 29th, 2022

Summary of REACH 2019 Commercialization Outcomes

Event	KYNETIC	ROI	WE-REACH	MBArC	SPARK	TOTAL
SBIR/STTR Awards	0	0	0	1	2	3
SBIR/STTR Applications	3	3	2	6	7	21
Startups Launched	5	3	6	4	10	28
Licensed Technologies (not affiliated with a startup)	0	1	0	1	1	2
Optioned Technologies (not affiliated with a startup)	0	0	0	0	0	0
Follow-on Funding Secured	\$1.5 M	\$10.2 M	\$40.2 M	\$36.1 M	\$7.0 M	\$95 M

Data as of November 29th, 2022

REACH Summary, as of November 2022

Strong "returns" relative to

- \$9 million NIH investment in REACH 2015
- \$20 million NIH investment in REACH 2019

REACH 2015 projects continue to progress to market

REACH 2019 has early successes and is still initiating new projects

Event	REACH 2015	REACH 2019	Total
Projects	127	100	227
Innovators trained	1,013	1,465	2,478
Start-up companies	28	29	57
Licenses	7	3	10
SBIR/STTR Applications*	47	22	69
SBIR/STTR Awards	15	3	18
Follow-on funding, Non-Federal	\$44.2M	\$57.1M	\$101.3M
Follow-on funding, All	\$107.7M	\$94.9M	\$202.6M

Site Team Composition

- $_{\circ}$ Leadership
 - Track records in academic entrepreneurship
 - High visibility and respect
 - Empathy, candor
 - Awareness of ecosystem resources
- Project managers and team members
 - Knowledge of biomedical product development
 - Experience in research operations
 - Excellent communication skills
- $_{\odot}$ Support from technology transfer offices, research VPs, and deans
- Diverse representation on site teams assists with innovator outreach

External Advisory Boards

- $_{\odot}$ $\,$ EABs should be composed of individuals from the private sector $\,$
 - Guide project selection
 - Advise on hub operations
 - · Provide ad hoc business development and market expertise
- o Often individuals represent
 - Life science companies
 - Entrepreneurs who have brought technologies to market
 - Foundations and economic development agencies
- EABs that initiated with all university faculty and administrators often transitioned to private-sector composition

Outreach to the Innovator Community

- Active outreach via story telling at faculty meetings and events
- Beating the bushes, engaging in dialogs, answering questions
- Connecting with postdocs, not just faculty members
- Consistent messaging, timelines

At the University of Louisville ExCITE

- All innovator-facing site team members were women
- 63% of innovators (PI, co-PI) were also women

Bates, P. Confessions of a faculty entrepreneur. In: AWARE:ACCESS Commercialization and Entrepreneurship Summit. Indianapolis, IN, 2018

Application Processes

- REACH Common Application
 - Value proposition
 - Market and competitive landscape assessment
 - · Commercial viability (e.g., intellectual property, regulatory, reimbursement)
- $_{\odot}~$ Sites' provided resources and feedback during application stages
 - Letters of intent steps
 - Reviews of draft applications
 - Bootcamps timed with application cycles
 - Seminars
 - Office hours
 - Reference librarians and business school resources

Project Management

- o Milestone-based project management to avoid a drift into hypothesis-driven research
- Use of industry tools
 - Target product profiles
 - Project plans
 - Risk registers
 - Gantt charts
- Project managers with industry background or relevant expertise and experience
 - Product development
 - Translational science
 - Business development and marketing
- Fail-fast models

Innovators often told us that project managers, coaches, and expertise were often more impactful than the funding itself.

Skills Development

- 1x1 coaching from site teams
 - Site leadership
 - External advisory boards
 - Project managers
 - NIH staff
 - Consultants
- Leveraging YouTube, CTSAs, I-Corps, and other training programs, rather than creating new ones
- Timing skills development courses with application cycles

REACH 2023 RFA is live!

RFA (<u>RFA-OD023-002</u>)

- NIH SEED and NIGMS hosting an informational webinar on <u>December 12 at 3:30 ET</u>
- New aspects for REACH 2023
- Collaborations with existing state and federal resources in the hubs' ecosystems
 - Partnerships with Minority-Serving Institutions, institutions that have not been recipients of past NIH support, and/or institutions in IDeA states
 - Regional and local impact, including serving innovators from diverse backgrounds and meeting pressing local or regional needs in economic development, entrepreneurial education, disease burden, and health disparities
 - Strong encouragement of \$250,000 per year of matching funds to augment the federal investment for product definition studies; funds must originate from any non-federal source

Further Reading

- <u>Anderson et al (2021)</u>. Insights from the evaluations of the NIH Centers for Accelerated Innovation and Research Evaluation and Commercialization Hubs programs. *JCTS*.
- Bates et al (2017). NIH program strives to turn more lab discoveries into real-world treatments. STAT.
- <u>Hayter et al (2018)</u>. Conceptualizing academic entrepreneurship ecosystems. *Journal of Technology Transfer*.
- <u>Antman et al (2017)</u>. NIH Centers for Accelerated Innovations Program: principles, practices, successes and challenges. *Nature Reviews Drug Discovery*.
- <u>Antman et al (2021)</u>. An overview of the process, progress, and outcomes of a National Center for Accelerated Innovation: The Boston Biomedical Innovation Center Experience. *JCTS*.
- <u>Reizes et al (2021)</u>. New programs for translating research to patient care: Lessons learned at the NIH Center for Accelerated Innovations at Cleveland Clinic. *JCTS*.
- <u>Benam et al (2021)</u>. Fostering innovation at Academic Medical Centers: The Case of University of Colorado Anschutz Medical Campus. *JCTS*.

Thank you

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