DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 3, 2019

The Honorable Ben Cardin
Ranking Member, Committee on
Small Business and Entrepreneurship
United States Senate
Washington, DC 20510

Dear Senator Cardin:

The enclosed report has been prepared by the National Institutes of Health (NIH) in response to Public Law 112-81, which requires NIH to submit an evaluative report regarding the activities of the Small Business Technology Transfer (STTR) Phase 0 Proof of Concept Partnership Pilot Program.

The Research Evaluation and Commercialization Hub (REACH) program is a Phase 0 Proof-of-Concept Partnership pilot program launched in accordance with Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112-81). The program was launched to address barriers to the commercialization of biomedical basic science discoveries, including a gap in funding, a lack of knowledge and understanding by academic innovators about how new technologies are brought to market, and a lack of access to sufficient technology development and commercialization resources.

The National Institutes of Health (NIH) provided $9 million in funding for three sites for three years. The three sites selected for funding were

- Long Island Bioscience Hub, based at Stony Brook University, with partner institutions Cold Spring Harbor Laboratory, Brookhaven National Laboratory, and the Feinstein Institute for Medical Research;
- MN-REACH at the University of Minnesota; and
- University of Louisville ExCITE (Expediting Commercialization, Innovation, Translation, and Entrepreneurship).

The REACH program is an effective mechanism for transitioning basic science discoveries into the commercialization pipeline. It provided the necessary funding support, institutional incentives, and biomedical commercialization expertise to build on institutional momentum and policy changes that nurture and support academic entrepreneurship.

I am pleased to submit the report for the STTR Phase 0 Proof of Concept Partnership Pilot Program. NIH remains committed to advancing innovation through this program.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 3, 2019

The Honorable Marco Rubio
Chair, Committee on Small Business
and Entrepreneurship
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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June 3, 2019

The Honorable Steve Chabot
Ranking Member, Committee on
Small Business
U.S. House of Representatives
Washington, DC 20515

Dear Representative Chabot:

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Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 3, 2019

The Honorable Nydia Velazquez
Chair, Committee on Small Business
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chair:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 3, 2019

The Honorable Frank Lucas
Ranking Member, Committee on
Science, Space, and Technology
U.S. House of Representatives
Washington, DC 20515

Dear Representative Lucas:

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June 3, 2019

The Honorable Eddie Bernice Johnson
Chair, Committee on Science, Space,
and Technology
U.S. House of Representatives
Washington, DC 20515

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Director

Enclosure

May 2019

Review of the Research Evaluation and Commercialization Hubs (REACH) Program

Prepared for

National Institutes of Health
Bethesda, MD

Prepared by

RTI International
3040 E. Cornwallis Road
Research Triangle Park, NC 27709

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Each REACH site designed and implemented funding programs, competitive selection processes with external review boards (ERBs), milestone-driven project management with go/no-go decision points, and skills development programs. The total amount of funding available for each site was not expected to be sufficient to deliver all of the program requirements; each institution provided matching funding for technology development awards and site operations and programs.

As of November 2018, 109 technology development projects had been funded. Because it has been only 3 years since the first project teams were funded, it is too soon to observe patient (and therefore market) impacts, given the length of time required to advance biomedical technologies. However, the signals at this early stage are promising (see Table ES-1).

Twenty-two startup companies have formed to commercialize REACH-funded technologies. These companies submitted 12 SBIR/STTR applications, and 5 awards have been received so far. In addition, 8 technologies have been licensed and 2 are optioned. A total of $13.59 million in follow-on funding has been invested to move technologies closer to the market.

Interviews with funded innovators revealed that most had little to no experience with commercialization beyond basic intellectual property protections. Participation in the REACH program increased their knowledge of, comfort with, and perception of the feasibility of commercialization. At ExCITE, where women held all innovator-facing leadership positions, 63% of investigators and co-investigators were women. More than 1,000 academic innovators received at least some commercialization and entrepreneurship training through the REACH site's sponsorship or co-sponsorship of bootcamps, seminars, and lecture series.

The REACH program is an effective mechanism for transitioning basic science discoveries into the commercialization pipeline. It provided the necessary funding support, institutional

incentives, and biomedical commercialization expertise to build on institutional momentum and policy changes that nurture and support academic entrepreneurship.

Table ES-1. Summary Commercialization Data as of November 2018

	LIBH	MN-REACH	UofL ExCITE	Total
Number of funded projects	50	41	18	109
Number of startup companies	10	9	3	22
Number of SBIR/STTR applications	10	1	1	12
Number of SBIR/STTR awards	5	0	0	5
Number of licenses	2	5	1	8
Number of options to license	0	2	0	2
Follow-on funding (millions)	$10.83	$0.57	$2.19	$13.59
Number of innovators receiving training sponsored or co-sponsored by REACH	600	284	129	1,013

1. INTRODUCTION

This evaluative report presents the results and activities of the NIH REACH program. The REACH program is the Phase 0 Proof-of-Concept Partnership pilot program launched in accordance with Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112-81). A second cohort of REACH sites was announced in 2018, and the request for applications (RFA) is currently active.[1]

REACH was designed to address barriers to the translation of basic science discoveries from academia to patient benefit. Per the funding opportunity announcement,[2] these barriers include (1) a gap in funding between basic research discoveries and scientific proof-of-feasibility or validation studies required to define a product for early-stage technology development; (2) a lack of knowledge and understanding by innovators about how new technologies are brought to market; and (3) a lack of access to sufficient technology development and commercialization resources that are required for early-stage technology development.

NIH selected three REACH sites for funding:

- LIBH, based at Stony Brook University,
- MN-REACH at the University of Minnesota, and
- University of Louisville ExCITE (Expediting Commercialization, Innovation, Translation, and Entrepreneurship) chosen in part because Kentucky is an IDeA state as a specific effort to bolster underfunded states.

Launched in 2015, these three sites have supported 109 proof-of-concept projects and provided 1,013 academic innovators with training in product development and entrepreneurship. As of November 2018, approximately 3 years since the start of the early-stage technology development program, 22 startup companies had launched to commercialize technologies. These companies have submitted 12 SBIR/STTR applications and received 5 awards. As of November 2018, award decisions had not been announced for several applications. This report provides a detailed description of the pilot program, presents results achieved as of the end of calendar year 2018, and assesses the program's effectiveness.

1.1 REACH Program Objectives

Each site fosters the development of therapeutics, preventatives, diagnostics, devices, and tools that address diseases within the NIH mission. The work supported by the sites may include technical validation, market research, clarification of intellectual property position and strategy, and investigation of commercial or business opportunities.

Per the RFA, each site is expected to

- be governed by leadership experienced in translating biomedical technologies from research-performing institutions to the commercial market;

[1] See the RFA at https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-014.html.
[2] See the RFA at https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-14-005.html.

- develop the necessary collaborations and partnerships to meet NIH's goals for the pilot program;
- provide infrastructure for soliciting and selecting the most promising technologies predicated on medical need, scientific merit, and commercial potential;
- provide the funding, resources, and expertise required for early-stage technology development;
- develop and implement market-focused project management oversight and decision-making processes;
- provide innovators with skills development, hands-on entrepreneurial experience, educational experience, and networking activities with linkages to local or virtual resources; and
- implement a plan for transitioning to a self-sustaining structure.

In addition, each site is expected to implement milestone-based project management processes similar to those used in commercial environments. If decisions are made to close projects, the site is expected to have a sufficient pipeline of promising technologies such that the funding can be redeployed.

The primary outcome of interest is the transition of promising technologies to the private sector, either through a startup company or licensing opportunity. In addition, the sites are expected to establish and strengthen regional alliances and partnerships, provide educational opportunities, and create cultural and systemic changes that more rapidly move discoveries toward patient benefit.

1.2 REACH Institutional and Proposal Selection Process

The REACH RFA was published April 25, 2014, and applications were due June 26, 2014. The total amount of funding available was $9 million for three sites. Each site was permitted up to $1 million per year in total costs from NIH. The total amount of funding available for each REACH award was not expected to be sufficient to deliver all of the program requirements; awardees were expected to bring nonfederal funding to augment funding available through the pilot program.

NIH received a robust response to the RFA with applications from research-performing institutions across the United States. The application review was held on November 13, 2014. Three grants were awarded on March 20, 2015.

Applications were evaluated for scientific and technical merit through the NIH peer review system. Reviews were conducted by an appropriate Scientific Review Group convened by the National Heart, Lung, and Blood Institute (NHLBI), in accordance with NIH peer review policy and procedures,[3] using the stated criteria in the RFA, which included scored review criteria as well as additional review criteria.[4] The scored review criteria included both standard questions and questions specific to the REACH program regarding significance, investigators, innovation, approach, and environment. The additional review criteria were applicable

[3] See https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154.
[4] See https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-14-005.html.

specifically to the REACH program and included criteria for REACH hub leadership and governance; technology solicitation and selection; technology development; project management; skills development; protections for human subjects; inclusion of women, minorities, and children; vertebrate animals; and biohazards.

Reviewed applications were assigned an overall impact score by the reviewers and received a written critique. Following initial peer review, recommended applications received a second level of review by the National Heart, Lung, and Blood Advisory Council. The following were considered in making funding decisions: (1) scientific and technical merit of the proposed project as determined by scientific peer review, (2) availability of funds, and (3) relevance of the proposed project to program priorities.

1.3 REACH Sites, Award Periods, and Funding

LIBH, MN-REACH, and ExCITE were awarded REACH sites on March 20, 2015, and federally funded for 3 years through February 28, 2018. The three sites have continued operating under a no-cost extension, and all three sites will no longer be federally supported after February 28, 2020. The no-cost extensions allowed each site to continue supporting funded innovators in their technology development projects to ensure adequate completion of the originally approved project. Table 1-1 presents the funding distributed to each site.

Table 1-1. Federal Funding for Each REACH Site

Site	Award Year 1	Award Year 2	Award Year 3	Total
Long Island Bioscience Hub (LIBH)	$1,000,000	$1,000,000	$991,667	$2,991,667
MN-REACH at the University of Minnesota	$1,000,000	$1,000,000	$990,318	$2,990,318
University of Louisville ExCITE	$999,194	$999,194	$996,487	$2,994,875

Note: Original award period was March 20, 2015, through February 28, 2018; no-cost extensions were approved through February 28, 2020. Source: NIH Reporter.

The three REACH sites were modeled, in part, after three centers funded under the NIH Centers for Accelerated Innovations (NCAI) program. All six REACH and NCAI sites form a national proof-of-concept network administered by NHLBI's Office of Translational Alliances and Coordination (OTAC) to share best practices in and insights concerning early-stage product development from academic research discoveries.[5] The NCAI program is distinct from REACH in important ways: a longer original award period (7 years rather than 3); a requirement to be a consortium of multiple institutions; a larger federally funded budget; and a mission focus on heart, lung, blood, and sleep disorders.

[5] See https://ncai.nhlbi.nih.gov/ncai/.

LIBH has four partner institutions all located within close proximity to the lead institution, Stony Brook University. MN-REACH and ExCITE are single-institution awards.

Several of the processes implemented by REACH were established from lessons learned during the first 2 years of the NCAI program. Unencumbered from the administrative responsibility of managing a large consortium, the three REACH sites collaborated with one another, exchanging insights, information, best practices, and lessons learned. As reviewed in Section 2, although each site was situated in characteristically different innovation ecosystems and university environments, their operating models and practices were similar. This report therefore takes the approach of reviewing the sites' general approach and then noting significant differences.

1.3.1 Long Island Bioscience Hub

LIBH is a consortium of four institutions: Stony Brook University, Cold Spring Harbor Laboratory, Brookhaven National Laboratory, and the Feinstein Institute for Medical Research. The lead is Stony Brook University's Center for Biotechnology, a New York State Center for Advanced Technology with a statewide mandate to support bioscience, entrepreneurship, and economic development. In addition to funding from the NIH, LIBH receives support from the Research Foundation for the State University of New York, Empire State Development, and each of the four institutions. LIBH is also networked with multiple initiatives to support funded innovators, including LIBH's bioentrepreneur-in-residence program, START-UP NY, and the Long Island Biomentor Initiative.

1.3.2 MN-REACH at the University of Minnesota

Based at the University of Minnesota, MN-REACH was conceived and designed by senior faculty members to develop a proof-of-concept funding and mentorship program that would build on momentum generated by the university's policy shift in support of and toward commercialization, entrepreneurship, and research translation. Funding from NIH is matched by funding from the university's research office, colleges, schools, and departments. MN-REACH is networked with other initiatives in the Minneapolis ecosystem, including MnDRIVE (Minnesota's Discovery, Research, and InnoVation Economy), the Minnesota Device Innovation Consortium, and Medical Alley Association, among others. MN-REACH engaged the university's I-Corps program to provide skills development and training.

1.3.3 University of Louisville ExCITE

ExCITE was launched through a collaboration between senior faculty and university administration. Two of the three leads are faculty members with experience in transitioning biomedical technologies from their university labs to the private sector. The third lead was the Associate Vice President for Research and Innovation at the UofL, into whom the Office of Technology Transfer and the Office of Industry Engagement report. Funding from NIH was matched by funding from the university's research office, colleges, schools, and departments. In addition, ExCITE was networked with other initiatives at the UofL, including the Coulter Translational Partnership Award in Biomedical Engineering and I-Corps. ExCITE is partnered with Louisville-based XLerateHealth, a mentorship and startup accelerator program for early-stage companies.

1.4 Methods and Data Sources

This report was prepared by an evaluation team at RTI International under contract to NIH in close collaboration with NIH staff. The information presented herein resulted from ongoing monitoring of project performance information; site visits to LIBH, MN-REACH, and ExCITE; interviews with funded innovators, site teams, technology transfer offices, university leadership, and stakeholders in the local innovation ecosystem; and desk analysis.

1.5 Report Overview

The remainder of this report is organized as follows:

- Section 2 provides a detailed description of the pilot program, covering major programmatic elements and the processes employed to deliver them.
- Section 3 presents the funded project portfolio.
- Section 4 presents the commercialization milestones and outcomes achieved as of November 2018.
- Section 5 provides an overall assessment of the program's effectiveness.

In addition to this evaluative report, a capstone analysis and evaluation will be available during the final year of the REACH program. The analysis will produce a final report that will update the findings herein and provide additional thematic analyses from interviews with innovators, sites, universities, and stakeholders in the regional innovation ecosystems.

2. REVIEW OF REACH SITE OPERATING PROTOCOLS AND PROGRAMS

This section describes the REACH program's operating protocols and funding programs with an emphasis on key programmatic elements (e.g., funding, competitive selection of technologies, milestone-driven project management, skills development). Included in our discussion of the selection process is an accounting of the number of proposals received at each application stage.

As mentioned in the introduction, the REACH sites leveraged processes that had been established for the NCAI program and communicated insights and experiences between one another. Although the sites had some differences in approach, they operated in much the same manner. This section describes that general approach and also offers commentary on where LIBH, MN-REACH, and ExCITE notably differ.

2.1 Site Leadership and Support

Each REACH site's principal investigators (PIs) demonstrate the necessary operational, business, and scientific expertise with a documented track record of success in transitioning technologies from the discovery phase to commercialization. In addition to their technical and business accomplishments, the PIs have an excellent situational awareness with respect to their institutions' operating and cultural norms and barriers and facilitators to commercialization. The PIs are

- LIBH: Clinton Rubin (State University of New York Distinguished Professor, Biomedical Engineering and Director, Center for Biotechnology);
- MN-REACH: Charles Muscoplat[6] (McKnight Presidential Leadership Chair and Professor of Food Science and Nutrition and Medicine), Vadim Gurvich (Associate Director, Institute for Therapeutics Discovery and Development), Allison Hubel (Professor, Mechanical Engineering and Director, Biopreservation Core Resource), and Kevin Peterson (Professor, Family Medicine and appointments with the Institute for Engineering in Medicine and Institute for Health Informatics); and
- ExCITE: Paula Bates (Professor, Department of Medicine), Eugene Krentsel[7] (Associate Vice President for Research and Innovation), and Donald Miller (Director, James Graham Brown Cancer Center and Associate Vice President of Health Affairs).

PIs' responsibilities include making decisions on scientific direction, developing partner engagement, disseminating research outcomes to the community at large, and providing leadership and coordination of center activities to accomplish overall site objectives. In addition, the PIs mentor successful and unsuccessful program applicants, offering advice on product development strategy and business and scientific matters. They also share their commercialization experiences and use their leadership position as a platform to advocate for cultural and procedural changes at their institutions related to commercialization.

PIs are supported by professionals with expertise in research operations, project management, and biotechnology product development. To maximize the amount of funding available to support projects, site staff often served in multiple roles spanning operations, project management, and marketing and business development. At LIBH, the site is supported by the director of operations for Stony Brook University's Center for Biotechnology, its bioentrepreneurs in residence, and fellows from the Center's technology commercialization fellowship program. At MN-REACH, an external consultant with industry experience was contracted. ExCITE is supported by a scientific program coordinator and an operations and marketing specialist. Sites are also provided with support from their research and technology transfer offices, departmental resources, and administrative personnel. Each site leverages skills development resources at their host institutions, including I-Corps at MN-REACH and ExCITE.

2.2 Technology Development Awards

LIBH, MN-REACH, and ExCITE designed their own funding award programs. These aligned with REACH program parameters specified in the RFA and had several common elements: a common product development application, milestone-based project management with go/no-go points, mentorship by the REACH PI and staff, and hands-on entrepreneurship training and access to skills development offerings. Table 2-1 presents key award characteristics.

There are three notable differences between the site's own award programs and REACH: award type, project costs, and incorporation of educational activities into the application process. First, LIBH offers two types of awards: feasibility awards ($50,000) and proof-of-concept awards ($100,000). Feasibility awards are designed pursuant to the fast-fail approach of generating an

[6] Dr. Muscoplat retired in 2018.
[7] In 2018, Eugene Krentsel resigned from the UofL and joined XLerateHealth.

early yes or no on a concept. The larger proof-of-concept awards are designed to support research, development, testing, and analysis on existing intellectual property. MN-REACH and ExCITE each offered one type of proof-of-concept award.

Second, each site's maximum direct project cost budget differed: $100,000 at LIBH, $150,000 at MN-REACH, and $200,000 at ExCITE. The institutional match was 50%; thus, the maximum federal funding per project was $50,000, $75,000, and $100,000, respectively. In its later funding rounds, ExCITE lowered its site maximum to $100,000 and purposefully awarded more projects than would be fully supported through completion, using progress toward milestones, commercial viability, and overall technology potential to select which technologies would be approved beyond the initial 6-month funding period to spend up to their maximum award value.

Third, MN-REACH and ExCITE provide faculty and staff invited to submit full proposals training opportunities connected to their I-Corps programs during the application period. The philosophy is to deliver education and training at the moment these individuals need it most. LIBH requires applicants to submit full applications and does not have a letter of intent. Although they counsel applicants during the application process as needed, their philosophy is to assess the extent to which faculty are able to assemble on their own a compelling application with scientific, commercial, and intellectual property elements. Assessment of the application is therefore a tool that can be used to determine successful applicants' skills development needs.

Table 2-1. REACH Award Parameters

	LIBH	MN-REACH	ExCITE
Maximum direct costs	$50,000, feasibility award $100,000, proof of concept	$150,000 Cycles 1–5 $50,000 Cycle 6	$200,000 Cycles 1–4 $100,000 Cycles 5–6
Award period	6–12 months	6–12 months	6–12 months
Technology type	Therapeutic, device, diagnostic, health IT application		
Therapeutic area	All therapeutic areas within the NIH mission		
Project management	Milestone-driven project management support		
Skills development	Mentorship, post-award access to boot camps and trainings, virtual resources	Mentorship, pre-award access to trainings adapted from i-Corps to support application development, post-award trainings, virtual resources	Mentorship, pre-award access to trainings adapted from i-Corps to support application development, post-award trainings, virtual resources

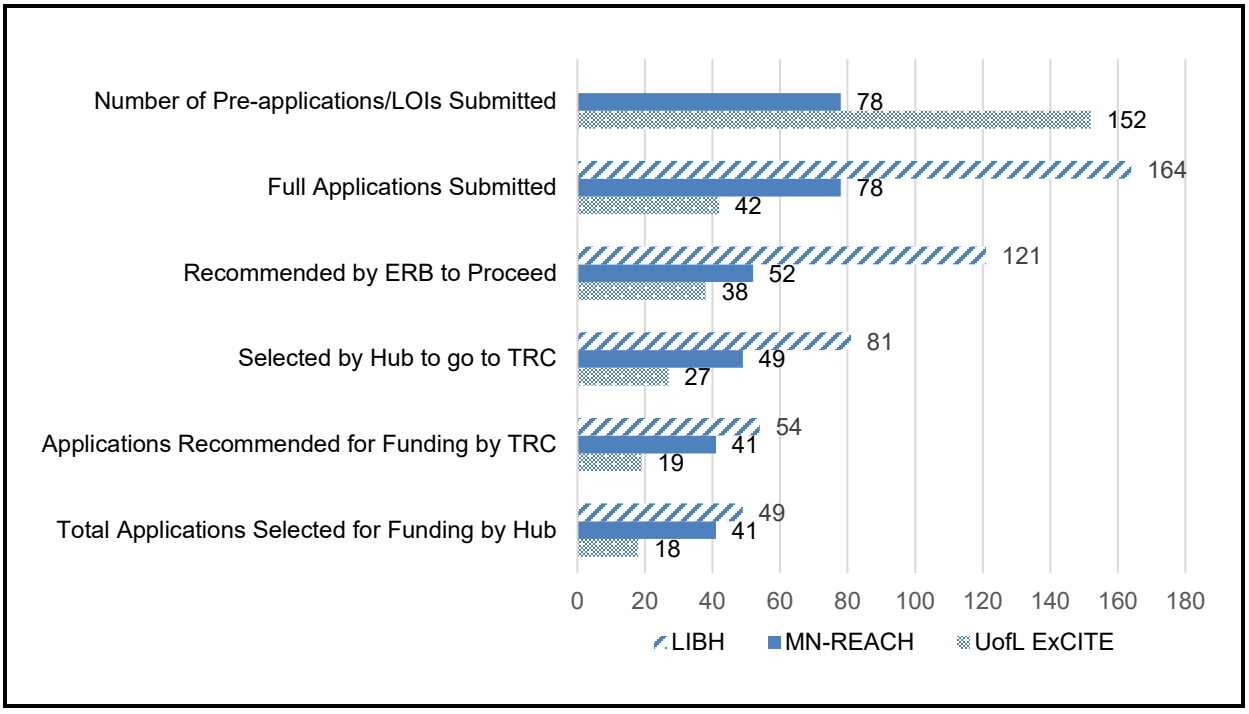
2.3 Program Promotion

REACH leadership teams promoted the program at their respective institutions through seminars and information sessions, participation in departmental meetings, integration with technology transfer offices, websites, newsletters and social media, and word of mouth. Program promotion culminated in the release of RFAs.

2.4 Application and Selection Processes

The REACH program had six funding rounds.[8] Each round consisted of multiple stages: letter of intent (ExCITE and MN-REACH only), full application review by site teams and an external selection committee (ESC) (or review board), review by the NIH technology review committee (TRC), and a final review by site teams. ExCITE was the only site to use a letter of intent stage to select which proposals should proceed to a full application stage. Although MN-REACH requested a letter of intent, it was used to counsel applicants, direct them to skills development programs, and prepare them for full application development. Figure 2-1 presents the cumulative number of proposals that reached each application stage.

Figure 2-1. Cumulative Application Pipeline



Note: ERB refers to external review board; TRC refers to the technology review committee coordinated by NHLBI, OTAC. TRC recommendations are non-binding. Data are as of November 2018.

Applications for REACH support differed significantly from traditional academic basic science proposals. In addition to scientific and technical information, the applications emphasized the

[8] Timing for funding applications and award decisions differed by REACH site; however, in general, one funding round was held in 2015, two to three rounds in 2016, and two to three rounds in 2017.

proposed project's value proposition, market potential, intellectual property position, and product development strategy. If applicable, applicants were requested to provide regulatory and reimbursement pathway expectations.

All funding decision-making authority rests with the REACH site teams. Twice during each funding round third-party reviews from outside the university are provided, first by the ERB (coordinated by the site) and later by the TRC (coordinated by NIH/NHLBI).

2.4.1 External Review Boards

Each site was required to assemble a cadre of experts to serve as reviewers on the ERB. This committee reviews candidate technology applications for acceptance into the center. Sites are expected to have processes in place that ensure fair, equitable, unbiased, and timely evaluation of candidate technologies. ERB members are selected from outside the host institution(s) and represent a balance of expertise covering both scientific and business aspects of technology development and commercialization. Each site's membership was predominantly drawn from their local community, particularly from pharmaceutical and biotechnology companies, venture funds, university leadership, and notable stakeholders and influencers in their biomedical innovation ecosystems.

2.4.2 Technology Review Committee

The TRC comprises staff with scientific and commercial expertise from across NHLBI and NIH, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the U.S. Patent and Trademark Office, and Kaiser Permanente. Program partners are experts in areas critical to product development, including consideration of the downstream business requirements, and entrepreneurial education.

The TRC reviews prospective REACH technologies for NIH mission fit and commercial potential and provides REACH hub leadership with (1) nonbinding regulatory, reimbursement, intellectual property, business development, and scientific feedback and (2) potential connections with scientific collaborators with similar technology foci within NIH and other agencies. TRC members conduct individual reviews online, and NIH sends the written feedback on the individual technology projects being considered back to the sites. Site leadership uses the TRC recommendations to inform their decision-making about which technologies to support.

2.5 Project Management

Project management was built in as a key requirement of the program. The sites are responsible for providing project managers and establishing processes for setting project milestones and timelines, maintaining and monitoring progress against established timelines, and making timely go/no-go decisions. Interviews with funded innovators indicated that close working relationships with their REACH PIs and project management team were particularly helpful in strategizing research directions for adding the most value to the technology, developing business and intellectual property plans, and providing mentorship.

Each site developed detailed processes for making decisions about continuing or discontinuing development. ExCITE discontinued projects that were either determined to not be commercially

viable or had limited resources, and the most promising technologies were awarded their later funding tranches.

2.6 Skills Development

The REACH program was designed to support entrepreneurial skills development to provide innovators with hands-on learning experience for designing and conducting product definition studies and navigating the commercialization processes required for transitioning a technology out of academic labs. Cross-disciplinary (e.g., science, business, regulatory) career development was encouraged to expose innovators to the myriad processes required to translate discoveries into marketable products.

LIBH, MN-REACH, and ExCITE leveraged existing skills development resources and programs available at their universities, including I-Corps, commercialization boot camps, and seminar series. MN-REACH developed a skills development program that provided applicants with boot camp–style trainings during the development of their full applications. The model was successful and was later replicated by ExCITE.

Table 2-2. Number of Innovators Receiving Commercialization Training

	LIBH	MN-REACH	ExCITE	Total
Number of person-events	1,372	403	246	2,021
Number of unique individuals	600	284	129	1,013

As of December 2018, more than 1,000 academic innovators across the three REACH sites had received at least some commercialization and entrepreneurship training sponsored in whole or in part by the REACH program (see Table 2-2). Attendees spanned faculty and staff, postdoctoral fellows, research associates, and graduate students.

3. FUNDED PROJECT PORTFOLIO

This section reviews the REACH-funded project portfolio as of November 2018. We present the count of funded projects by site, technology type, and therapeutic area. Section 4 presents current commercialization outcome data; however, note that many projects are still underway and have yet to reach a licensing, option, startup, or other commercialization milestone.

3.1 Count of Funded Projects by Site

REACH funded a total of 109 projects across its three sites, as of November 2018. Table 3-1 provides the number of projects funded at each hub. LIBH is the only hub that comprises multiple institutions; however, 45 of its 50 awards (90%) were made to projects at Stony Brook University. Four of the remaining five awards went to

Table 3-1. Count of REACH-Funded Projects

	LIBH	MN-REACH	ExCITE	Total
Projects	50	41	18	109

projects at Cold Spring Harbor Laboratory, and one award was made to a project at Feinstein Institute for Medical Research. Furthermore, although LIBH funded 46% of the REACH total project count, a relatively high share of projects at LIBH was funded as feasibility awards and consequently received lower funding amounts than those that received proof-of-concept awards. MN-REACH funded some projects at amounts comparable ($50,000 to $75,000) to LIBH's feasibility awards. ExCITE funded fewer projects but at higher funding levels.

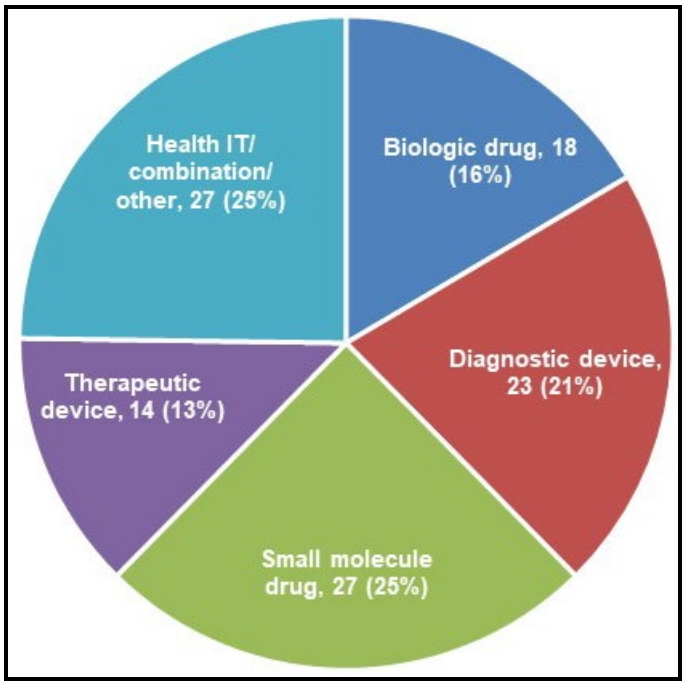
3.2 Count of Funded Projects by Technology Type

Funded projects within the REACH portfolio can be categorized by the type of technology being developed. The primary categories are biologic drugs, diagnostic devices, small molecule drugs, therapeutic devices, and a fifth category that includes health information technologies (IT), combination products, and research tools.

Each technology type faces different obstacles at each stage of technology development and must meet different technical (and later regulatory) requirements to achieve higher levels of technology maturity. Consequently, the timelines, costs, and likelihoods of success associated with developing different technology types vary. For example, biologic and small molecule drugs, on average, take longer to develop, and the ultimate success of these projects is relatively less certain than for diagnostic and therapeutic devices.[9]

Figure 3-1 shows the distribution of technology types that have been funded by the REACH program. The breakdown of the REACH portfolio by technology type reveals relatively equitable balance; no category of the five comprises more than 25% or less than 13% of the portfolio. Together, biologic and small molecule drugs comprise about 41% of projects.

Figure 3-1. Distribution of Projects by Technology Type



The mix of funded projects by technology type is similar across the three sites. Despite the relatively small number of projects at ExCITE, it has a distribution similar to that of the overall REACH program. The only variation perhaps worth noting is the slightly larger share of ExCITE projects that are biologic drugs and the slightly smaller share that are therapeutic devices. Conversely, the share of therapeutic device projects at MN-

[9] Given the variation in costs and risks associated with the different technology types, balance across the REACH portfolio is an interesting consideration, although not one that the sites explicitly make because awards are made to projects with the greatest promise, regardless of type.

REACH is relatively higher than that of REACH as a whole (see Table 3-2).

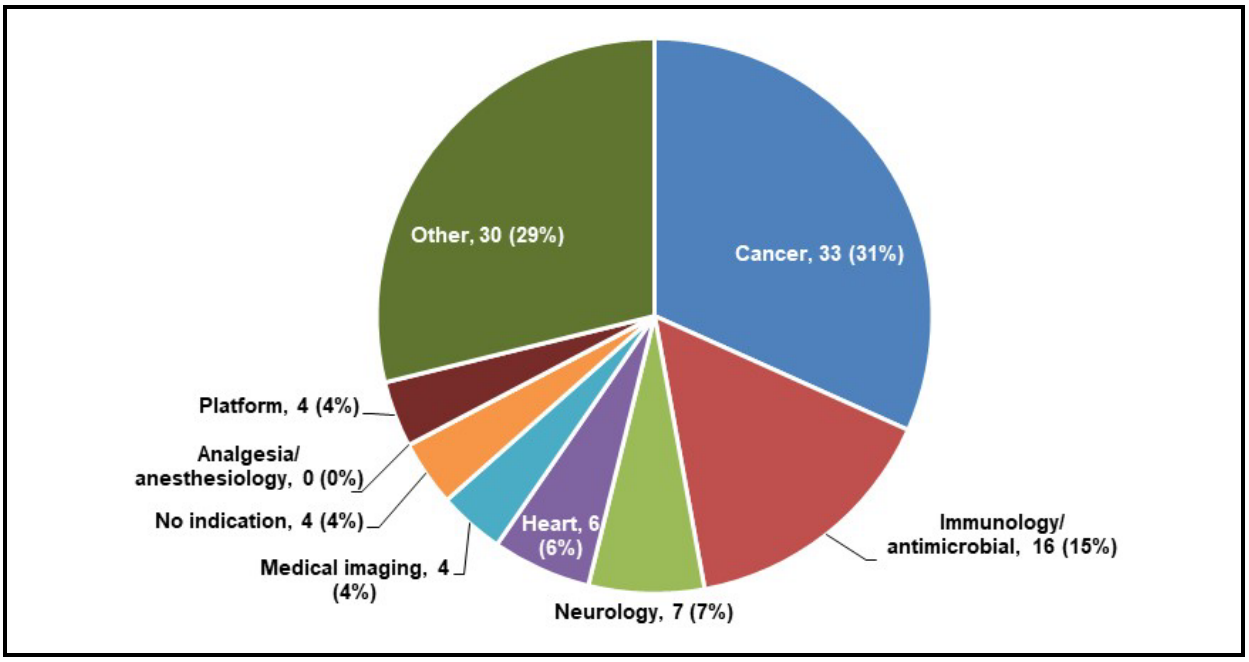
Table 3-2. Count of REACH-Funded Projects by Technology Type

	LIBH		MN-REACH		ExCITE		Total REACH	
	Count	**Share**	**Count**	**Share**	**Count**	**Share**	**Count**	**Share**
Biologic drug	7	14%	6	15%	5	28%	18	17%
Diagnostic device	12	24%	8	20%	3	17%	23	21%
Small molecule drug	13	26%	9	22%	5	28%	27	25%
Therapeutic device	5	10%	8	20%	1	6%	14	13%
Health IT, combination, or other technology	13	26%	10	24%	4	22%	27	25%
Total	50	100%	41	100%	18	100%	109	100%

3.3 Count of Funded Projects by Therapeutic Area

The project portfolio spans a wide diversity of therapeutic areas (see Figure 3-2). Cancer-focused projects represent the clear plurality. Other areas are infection control (immunology/antimicrobial), neurology, heart, medical imaging, anesthesia, and platform technologies. Additional disease areas containing only one or two projects were grouped in Figure 3-2 as other. Examples of these relatively uncommon disease areas within the portfolio are oral health, nutrition, urology, and mental health. Collectively, however, these less common disease areas comprise approximately 27% of the portfolio, which underscores the diversity of research domains from which promising technologies may be drawn.

Figure 3-2. Distribution of Projects by Therapeutic Area



4. COMMERCIALIZATION OUTCOMES

This section presents commercialization outcomes as of November 2018. The program's first awards were made in late 2015; these early-stage technology development projects had a period of performance of about 1 year, and many projects are still underway. With only 3 years of data, it is too soon to provide definitive conclusions about the impact of the REACH program. However, the commercialization results achieved within this time frame are strong and offer encouraging signals about the longer-term impact of the program.

Tracking of certain outcome measures is critical to the ongoing assessment and evaluation of the REACH program, and for these data to be most useful, the measures must be aligned with the proper context, design, and goals of the program. Outcomes should be considered in the context of the typical timelines required to facilitate and accelerate advancement of early-stage, preclinical technologies from academic settings to the market. The outcomes presented here will accumulate as more time passes.

Successful analysis of outcomes also relies on the quality of the data collected. Our evaluation team has developed systematic processes and tools to enable these quantitative analyses, including a web-based platform for efficient data collection and quality assurance systems for data coming from geographically dispersed sites. Information on commercialization events presented herein is drawn from these standardized data. We present the most salient commercialization outcomes of interest (see Table 4-1).

Table 4-1. Commercialization Outcomes

Outcome	Description
Follow-on funding	Measures the dollar amount of outside investment attracted by the technologies in the REACH portfolio after the date of the REACH award and provides a signal of interest and perceived value from outside entities
Startup companies	Measures whether a company has been formed by the innovator specifically for the purpose of progressing the REACH-funded technology and provides a signal of technological progression and commercial viability (because of the financial and time investment associated with company formation)
Licensing and option-to-license agreements not associated with a startup	Measures whether a technology not associated with a startup company has licensed its technology or has signed an option to license its technology to an outside entity and provides a signal of commercial viability as assessed by outside entities
SBIR and STTR applications and awards	Measures whether the startup company associated with the technology has applied for and been awarded an SBIR or STTR grant and provides a signal of advancement beyond early-stage research and higher probabilities of advancement beyond the "valley of death" stage

4.1 Follow-On Funding

With only about 76 of REACH's 109 projects complete as of November 2018, follow-on funding received provides an early signal of perceived value from outside entities. The amount of follow-on funding is likely to increase as new developmental milestones are achieved.

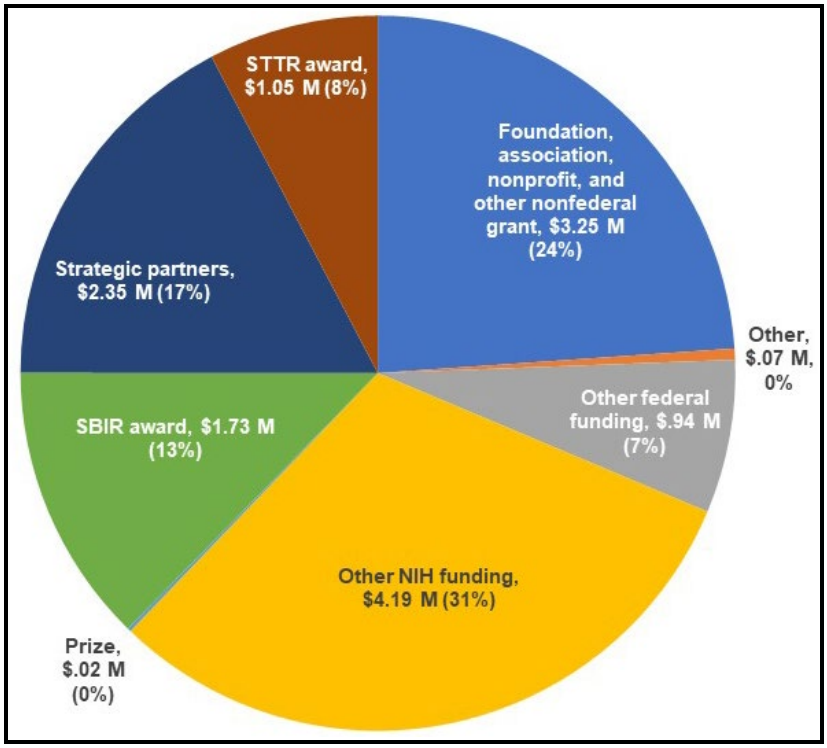
The total amount of follow-on funding, defined as funding that was received from outside sources after the notice of the REACH award, is approximately $13.6 million. Twenty-five technologies have received additional funding. Six have received multiple follow-on investments.

The average follow-on investment, across all follow-on funding instances, is $388,433. While the size distribution of follow-on funding amounts is skewed (there have been fewer relatively large investments and a greater number of smaller investments), there have been four follow-on investments equal to $1 million or greater. Those follow-on events accrued to three projects:

- Eckard Wimmer (LIBH) received a $2 million private investment from a strategic partner, Codagenix.
- Cold Spring Harbor Laboratory provided Lingbo Zhang (LIBH) with a $1.2 million investment.
- Lilianne Mujica-Parodi received multiple large awards including a $1.7 million SBIR award, a $1 million from a nonprofit foundation, and an STTR award for $225,000.

Figure 4-1 depicts the distribution of follow-on funding by source. The sources of follow-on funding can be categorized in two overarching groups: federal and nonfederal (private) sources. Federal sources include funding from SBIR awards, STTR awards, other NIH funding (besides REACH and SBIR/STTR), and other federal sources (e.g., Department of Defense). Nonfederal (private) sources include grants received from foundations, nonprofits, and other grant-making institutions; strategic partners (typically private companies with an interest in developing the technology); prizes (a special category that includes funding received from competitions or unique recognitions); and a

Figure 4-1. Distribution of Follow-On Funding by Source

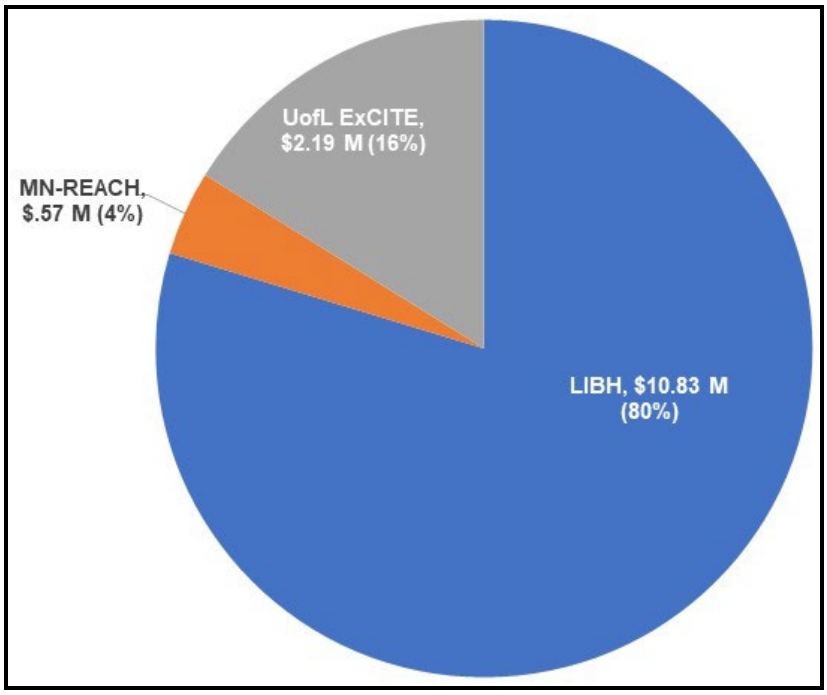


category ("other") consisting primarily of personal investments from family and friends. Angel investment, venture capital, and additional investment from universities are also considered distinct categories but are not listed here because no follow-on funding has come any of these yet.

Together, federal sources comprise about $7.9 million (58%) of total follow-on funding. Meanwhile, nonfederal (private) sources comprise the remaining approximately $5.7 million (42%). Considering that the start of the REACH projects varies from roughly 1 to 3 years ago, with an average project start date of about 2 years ago, the amount of follow-on funding is notable.

This early signal of interest and perceived value from outside is accentuated by the comparison of NIH's investment in REACH to these follow-on dollars. NIH invested approximately $9 million in REACH across the span of 3 years, and that investment has leveraged an additional $13.6 million, $5.7 million of which are from nonfederal sources. The ratio of all follow-on funding to the federal investment is 1.5 and for nonfederal follow-on funding, 0.63.

Figure 4-2. Distribution of Follow-On Funding by Source



The breakdown of follow-on funding by site is depicted in Figure 4-2. The breakdown is clearly skewed but there are many potential causes. First, it is important to recall the number of projects funded at each hub (50 at LIBH, 41 at MN-REACH, and 18 at ExCITE). Additionally, and perhaps more importantly, the strategies pursued and programmatic designs at each hub vary, as do the external factors and innovation ecosystems surrounding the hubs. The REACH sites have tailored their strategies to integrate other supports available to them, to cater to the types of technologies and innovators they are supporting, and to address the particular challenges identified to move a technology forward. For example, follow-on funding for the LIBH hub represents about 80% of the REACH total, which may not be unreasonable considering the specific requirements of its funded projects and the emphasis placed on startups by START-UP NY and the Center for Biotechnology.

4.2 Startup Companies

Table 4-2 presents the number of REACH projects that have formed a startup company for the purpose of developing the REACH-funded technology. A total of 22 startup companies have been formed across the REACH hubs. This level of activity directly suggests advancement in technology readiness and advancement toward commercialization that have taken place within the hubs. Although startups are not a direct measurement of commercial readiness, the beliefs of the innovators and project managers about their potential is demonstrated by the action to undertake the nontrivial costs and time investments associated with forming a startup company for the purpose of protecting the technology from competitors.

Table 4-2. Count of Startup Companies

	LIBH	MN-REACH	ExCITE	Total
Startup companies	10	9	3	22

Thirteen of the 22 REACH-funded technologies affiliated with a startup company have also attracted follow-on funding. These 13 technologies have attracted a combined amount of about $9.4 million, accounting for slightly less than 70% of the $13.6 million follow-on funding total.

4.3 Licenses and Options

For projects that have not formed a startup to further develop the technology, the execution of licensing and option agreements provides a signal of technology readiness and commercial viability as assessed by outside companies. Table 4-3 shows the number of projects for which licenses have been negotiated and those that have an active option agreement. As of November 2018, eight technologies have been licensed, and an additional two have active options. At least one project at each site has licensed its technology. MN-REACH has had the most licensing activity with a total of five licenses and two options.

Table 4-3. Count of Licenses and Options

	LIBH	MN-REACH	ExCITE	Total
Licenses	2	5	1	8
Options	0	2	0	2
Total	2	7	1	10

Two of the 10 technologies that have been licensed or optioned to small or large companies have also received follow-on funding. The combined follow-on funding for these two projects is $414,000.

4.4 SBIR/STTR Applications and Awards

Table 4-4 presents the number of SBIR/STTR applications and awards linked to REACH-funded projects. In total, REACH has produced 12 applications and five awards, yielding an SBIR/STTR application success rate, so far, of 42%. Five of the total 12 applications across the hubs, including applications from MN-REACH and ExCITE, are recent submissions and may ultimately be awarded.

Table 4-4. SBIR/STTR Application Submissions and Awards

	LIBH	MN-REACH	ExCITE	Total
Applications	10	1	1	12
Awards to date[a]	5	0	0	5

[a] Excludes SBIR/STTR applications submitted but for which award decisions are not yet known.

The LIBH hub has submitted 10 of the 12 applications; 3 LIBH-funded projects have combined to submit 6 applications (as each of these has submitted 2 applications). Notably, Mujica-Parodi (LIBH) was successful in both of her applications, a SBIR application and a STTR application. Of the 12 total applications, only one other SBIR application was submitted; the remaining 10 were for STTR awards.

As noted earlier, the amount of funding raised from these sources is approximately $2.8 million: $1.7 million in SBIR and $1.1 million in STTR awards. In addition to their SBIR/STTR funds, the projects with an SBIR or STTR award have a combined total of $1.4 million from other follow-on funding sources.

5. SUMMARY ASSESSMENT

The REACH program is an effective mechanism for transitioning basic science discoveries into the commercialization pipeline. It provided the necessary funding support, institutional incentives, and biomedical commercialization expertise to build on institutional momentum and policy changes that nurture and support academic entrepreneurship. Each institution expressed satisfaction with its REACH sites, which is important given that each provided an amount of funding roughly equal to funding provided by NIH.

Within less than 3 years of the program's first awards to academic innovators, 22 startup companies were formed, which ultimately submitted 12 SBIR/STTR applications. As of November 2018, 76 projects had been completed, and of these, 42% were associated with a startup company, license, or option to license.

Interviews with funded innovators revealed that most had little to no experience with commercialization beyond basic intellectual property protections. Participation increased their knowledge of, comfort with, and perception of the feasibility of commercialization. Innovators funded in later rounds noted that their peers supported in the earliest funding rounds, especially those with little to no commercialization experience, demonstrated that moving discoveries into the commercialization pipeline is possible. ExCITE's innovator-facing leadership (including the

lead PI, scientific coordinator, and business development and marketing specialist) were all women. Ultimately, 63% of funded ExCITE investigators and co-investigators were women.

More than 1,000 academic innovators (e.g., faculty and staff, research associates, postdocs, and graduate students) received at least some commercialization and entrepreneurship training through the REACH site's sponsorship or co-sponsorship of bootcamps, seminars, and lecture series. MN-REACH's model of delivering workshops and seminars related to commercialization and academic entrepreneurship aligned with the development of innovators' REACH funding applications was particularly effective.

Given the long development cycles that characterize the creation of novel biomedical products, it is too soon to predict the ultimate patient (and therefore market) impacts of REACH-funded technologies. However, over the 3 years since the program was launched, the number of startups, licenses, options, and early totals of follow-on funding ($13.6 million) signal that the technologies have market potential and that the pilot program is meeting its intended purpose.