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NIH Centers for Accelerated Innovations Program: principles, practices, successes and challenges

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Abstract

Commercializing innovations in academic environments is notoriously challenging. Here, we describe the progress of the NIH Centers for Accelerated Innovations program — initiated in 2013 to address these challenges — which we believe could help set a new standard for the early-stage commercialization of biomedical innovations in academic environments.

There is a chasm in the path from basic biomedical research discoveries to their clinical application owing to inadequate funding for support of proof- of-concept or validation studies for early-stage development of new technologies, insufficient access to product development expertise and a lack of commercialization experience among academic investigators. In an effort to address these issues, the US National Institutes of Health (NIH) Centers for Accelerated Innovations (NCAI) program was initiated by the National Heart, Lung and Blood Institute (NHLBI) in 2013. The program identifies promising technologies that address specific diseases and provides them with funding, mentorship and resources to increase the likelihood that they will translate into products. Technologies selected address an unmet medical need, offer commercial potential following successful project completion or present other compelling reasons for continued development. Here, we describe the structure of the program, the best practices it has developed, and its successes and challenges.

Organizational structure

There are three centers in the NCAI program — the Boston Biomedical Innovation Center, the NIH Center for Accelerated Innovations at the Cleveland Clinic, and the University of

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Competing interests statement
The authors declare no competing interests.

SUPPLEMENTARY INFORMATION
See online article: S1 (table), S2 (table), S3 (table), S4 (table), S5 (table)

ALL LINKS ARE ACTIVE IN THE ONLINE PDF

California Center for Accelerated Innovation. Each center is a consortium with 5–13 participating institutions (Supplementary information S1 (table)). A lead institution provides overall management, but each center team is responsible for projects from innovators, assessing the suitability of project proposals, providing milestone-driven project management, mentoring innovators, guiding projects to exit strategies and disseminating lessons learned.

There are two other essential components. First, an external advisory board (EAB) is selected from sources outside of the participating institutions. The EAB functions as an oversight committee for each center's key operations and comprises individuals competent in science, technology, commercialization, venture funding, marketing and intellectual property; EAB members may also have relevant disease expertise.

Second, the review process collects feedback from academia, industry and government. Following an initial internal review of a proposal, a center sends it to an external selection committee comprising representatives from participating institutions and other outside experts. The most promising proposals are then sent to a technology review committee (TRC) at the NIH that comprises staff from the NIH, the US FDA, the Centers for Medicaid and Medicare, the US Patent and Trademark Office, and Kaiser Permanente, who comment on program suitability and provide feedback and recommendations to center teams. Final funding decisions rest with each center.

Best practices

Academic investigators are trained in hypothesis-driven research and are not generally experienced with product development or marketing. Thus, each center has developed programming that incorporates industry expertise, mentorship and skills development, and other resources to guide proof-of-concept development. Commercial partners are important contributors to technology selection and development. The centers also rely on feedback from the TRC, which has helped shape selection of clinical indications and business models and, when combined with industry input, provides a rich understanding of the commercial pathway for proposed projects.

Soliciting project proposals is the most important determinant of the NCAI pipeline. Multiple approaches have been used to attract proposals from investigators who have not previously engaged with the program (Supplementary information S2 (table)). The most challenging aspect is identifying and nurturing potential applications in settings where investigators have not yet sought such opportunities.

There are two types of NCAI awards. Full development awards are provided as investments in early-stage technologies that can attract independent financing and show potential for commercial translation within two years; these proposals are generally funded in the range of US$150,000 to $400,000. Projects in earlier stages of pre-commercial development are considered for pilot awards of ~$50,000, to be completed within one year, and are typically designed to address a limiting obstacle to full commercialization support, such as target validation, toxicity studies or prototype construction.

With full development awards, an innovator is assigned an industry-experienced project manager. The project manager collaborates with the innovator to develop a project plan that covers the product development strategy, a target product profile, project milestones, a detailed budget and a tranche plan. The tranche plan maps the budget to the milestones and is an important tool in implementing ‘go/no-go’ decision points described in the project plan. Institutional authorization of full proposal submission is also essential to ensuring integration with the member institutions’ compliance programs, application of conflict of interest procedures, plans for matching funds, and intellectual property attribution and protection (at the parent institution).

To date, there have been 499 initial applications. After evaluation by center leadership and/or review panels, 185 of these progressed to full proposals that were formally reviewed, and 71 of these were selected for funding (Supplementary information S3 (table)).

As federal funds provided through this program are intended to be catalytic and not intended to fully support completion of the development work necessary to exit the center, the NIH encourages awardees to secure non-federal matching funds equal to or greater than the NIH commitment. All centers use matching strategies, ranging from direct up-front matching support to post-development returns on royalties or licensing fees.

In its original funding opportunity announcement, the NIH stressed the importance of each applicant describing plans for a skills development program to address many innovators’ lack of experience with commercialization. Each center also provides learning opportunities, coaching and resources that are tailored to the specific needs of each innovator.

Successes and challenges

The development of a new biomedical technology can take more than a decade. At the time of writing, 43 of the 71 projects funded have been completed. Although only two years have elapsed since the first projects ended, there are already strong early indications of success. To date, there are 12 start-up companies targeting a mix of cardiovascular, pulmonary and haematological conditions (Supplementary information S4 (table)). One company, Platelet BioGenesis, is commercializing a bioreactor that produces platelets from human pluripotent stem cell cultures. This company has won several awards and recently closed on $10 million in series A venture funding. In addition, three technologies have been licensed and two optioned, in areas such as malaria, sickle cell disease and heart failure (Supplementary information S5 (table)). Three projects have secured five Small Business Innovation Research (SBIR) awards, and one project has moved to regulatory submission. The total follow-on funding received is $55.1 million, including $5.4 million from the SBIR program (10%), $18.9 million from private sources (34%), $23.7 million from federal translational research programs (43%) and $7.1 million from philanthropies, non-profits and other sources (13%).

The success of the NCAI program must also be considered from more qualitative perspectives. A key goal of the program is to stimulate faculty to consider not only hypothesis-driven research but also translational activities and commercialization in their

research. An independent evaluation showed that 93% of funded innovators believed that the program had accelerated the development of their technology, estimating — on average — that they were 18 months ahead of where they would have been without center guidance. Several innovators indicated that they were pushed towards an entirely new pathway or accelerated their project along trajectories that would not have been pursued without center engagement.

Other successes include establishing project management as an accepted (and highly valued) resource in an academic environment, providing mentorship and skills development, identifying exit strategies unique to each innovation, developing relationships with industry and producing early signals of a strong return on investment.

Other challenges include optimal resource utilization, securing matching funds to support projects, balancing time management and project expectations, and building bridges to industry and strategic partners to ensure a self-sustaining technology development ecosystem once the NIH-funded program ends.

Conclusion

By most objective measures, we believe the NCAI program has met its objectives so far. Although still early in its development, the program provides a scalable model that could lead to the development of adoptable best practices to facilitate commercialization of technologies in academic environments.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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