

NIH Technology Development Measures

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Context

- The National Institutes of Health (NIH) supports innovative technology development as one aspect of fulfilling its mission
- In July 2014, NIH tasked the IDA Science and Technology Policy Institute (STPI) with conducting a study aimed at developing performance measures for its technology development efforts
- The study had three components:
 - Developing a comprehensive catalog of NIH Funding Opportunity Announcements (FOAs) that are focused on technology development for achieving a specific goal
 - Developing case studies of a representative sample of FOAs based on discussions with FOA program officers to identify measures being used and lessons learned
 - Identifying candidate outcome measures for assessing technology development initiatives and a data collection infrastructure that would be required to implement these measures in a consistent and ongoing manner

Overview

- Technology Development Definition and Catalog Development
- Case Studies
- Logic Model and Recommended Outcome Measures

Definition of Technology Development

Definition developed in collaboration with advisory committee of NIH technology development experts

- “Technology” is a physical entity (e.g., piece of equipment, device, new material, piece of hardware) or a virtual entity (e.g., software or methodology) used for biomedical research or clinical/diagnostic purpose
 - Wholly novel technologies
 - Substantial improvement of existing technologies
 - Refinement or adaptation of existing technologies for a new purpose
- “Development” is the movement of a technology toward practical application for clinical or research use
 - Develop technologies/concepts to a pilot stage
 - Validate the performance of technologies
 - Refine technologies in the expectation of their dissemination and use
- More complex definition required for information technologies (IT)

Process for Compiling a Catalog of Technology Development FOAs

- Keyword searches of Office of Extramural Research (OER) Internet site to identify potential FOAs to supplement initial set provided by NIH technology development experts
- Limited search to FOAs with first acceptance dates between 2005 and 2014
- Manual review of identified FOAs to ensure technology development definition was met
- Review of candidate set of FOAs by study advisory committee to finalize the catalog

Overall Character of the Technology Development FOA Catalog

- Includes 284 distinct FOAs
- FOAs organized into 83 distinct groups that include
 - All FOAs reissued (e.g., RFA-XX-11-001 replaces RFA-XX-08-001)
 - All companion FOAs (e.g., PA-11-001 solicits SBIR applications, while PA-11-002 solicits STTR applications)
- FOAs supported 1,956 distinct awards:
 - \$1.83 billion in total NIH spending over 10 years
 - \$1.36 billion in direct costs over 10 years

STPI Characterized the 83 FOA Groups Along Six Dimensions

- Technology Area: Nature of the technology addressed by the FOA
- Purpose: Breadth of topic area(s) within biomedical research or clinical care addressed by the FOA
- Product Scope: Range of product types addressed by the FOA
- Intended Use: Envisioned to be used for research, for clinical purposes, or for both
- Stage of Development: Whether projects solicited include the following developmental stages
 - Early: Projects are primarily discovery or development of new principles
 - Intermediate: Projects encompass analytical validation, proof of concept or pilot testing, development of prototypes or taking products to the point of readiness for clinical testing
 - Late: Projects encompass clinical testing or dissemination to the research community
- Performance Requirements: Whether the FOA specified detailed performance requirements for developed technologies

Results of FOA Characterization

Technology Area

Categorization	Number of FOA Groups
Medical Devices	19
Molecular Analysis	11
Information Technology	9
Cells/Tissues Analysis	6
Point of Care Devices	6
Proteomic Analysis	6
Genomic Analysis	5
Imaging	5
Low Cost Medical Devices	5
Implantable Devices	4
Biospecimen Technologies	3
Others	4

Stage of Development

Stage of Development	Number of FOA Groups
Early Only	15
Early/Intermediate	26
Intermediate Only	4
Intermediate/Late	13
Late Only	3
Early to Late	22

- Majority address a defined area within biomedical research or clinical care
- Majority encompass a diverse set of products
- Equally divided between technologies intended for research versus clinical use
- Few have defined performance requirements

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Case Study Approach

- FOAs selected for case studies designed to provide a representative distribution across the various dimensions
- Case study FOAs also met two criteria recommended by the advisory committee
 - FOA should have at least one iteration released in 2012 or before
 - More than 10 awards were made under the FOA
- Based on these parameters, STPI researchers selected 26 FOAs for case studies based on discussions with FOA program officers
- During June through August 2015, STPI researchers conducted discussions with 19 NIH program officers, covering 23 of the 26 FOAs

Case Study General Findings

- Focused technology development efforts to advance NIH's mission considered a worthwhile use of funds
- Rationale for technology development FOAs
 - Meet a technology development need or objective not adequately addressed by projects submitted to the general investigator-initiated pool or by existing FOAs
 - Stimulate overall research activity in a particular technology domain viewed as underrepresented in the overall NIH portfolio
- Solicitation approach
 - PAs used when goal was to have a domain grow organically
 - PARs and RFAs used when special emphasis review panels deemed important
 - RFAs used when designated funding deemed necessary in order to make a reasonable number of awards or when projects were in a narrowly defined area
- Funding mechanism
 - R01/P01 when independent academic projects viewed as optimal
 - R21 when deemed necessary to stimulate early stage high risk projects
 - SBIR/STTR when involvement of commercial entities deemed critical

Lessons Learned:

Program Management Best Practices

- ***Award flexibility beneficial.*** Because technology development projects often require more time and money than typical of discovery research projects, FOAs need to take advantage of opportunities for longer award periods and larger award sizes; multiple acceptance dates are also valuable.
- ***Tailored review necessary.*** Because technology development projects often involve engineering and physical sciences disciplines and have more applied goals, tailored review is essential.
- ***Milestones valuable.*** Because technology development projects are intended to result in a defined entity for use in research or the clinic, milestones help in charting progress.
- ***Grantee meetings valuable.*** Grantee meetings open to industry, other researchers, and potential investors are valuable for sharing information among awardees, facilitating collaborations, and exploring potential commercial relationships.
- ***Program officer expertise critical.*** Technology development program officers require three critical characteristics:
 - Clear understanding of requirements for commercializing or otherwise disseminating technologies
 - Expertise in the technology field
 - Familiarity with the relevant investigator community

Lessons Learned: Ongoing Challenges

- ***Commercialization a hurdle, especially for clinical technologies.*** Technologies for clinical use almost uniformly require more funding than available through standard NIH award mechanisms. As a result, clinical technologies often languish even if early-stage clinical testing has been completed.
- ***Funding “blue-sky” technology development difficult.*** Only the R21 mechanism was viewed as being tailored to fund truly high-risk projects and additional approaches for encouraging such projects need to be developed.
- ***Greater coordination of technology development efforts is needed.*** Program officers were generally aware of other ongoing technology development initiatives, but indicated that a forum where they could share lessons learned and best practices would be beneficial.

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Outcome Measures

- Ultimate Objectives
 - Dissemination and use of the technology
 - Increase in the overall level of NIH-funded research activity in the technology development domain
- Intermediate Outcomes
 - Achievement of technical milestones
 - Conversion of exploratory awards
 - Technology licensing or other pre-commercialization activity
 - Progress toward clinical use
 - Data and software downloads

Other Classes of Measures Developed

- Measures of Dissemination and Use of Research-Focused Technologies
- Measures of Dissemination and Use of Clinically Focused Technologies
- Intermediate Outcome Measures
 - Achievement of technical milestones
 - Conversion of exploratory awards into later stage awards
 - Technology licensing and pre-commercialization activity
 - Progress toward clinical use
 - Data and software downloads

Technology Development Theory of Action Logic Model

