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# Technology Development at the National Institutes of Health (NIH): Summary Report

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# Executive Summary

The National Institutes of Health (NIH) supports innovative technology development as one aspect of fulfilling its mission. In July 2014, based on the recommendation of a trans-NIH group of technology-focused program directors, NIH tasked the IDA Science and Technology Policy Institute (STPI) to develop performance measures for extramural technology development projects. The task had three components. The first was development of a catalog of NIH Funding Opportunity Announcements (FOAs) that are focused solely on technology development for achieving a specific goal. The second was identification of a representative sample of FOAs from the catalog and development of case studies based on discussions with program officers knowledgeable about those FOAs. The third, also based on those discussions, was identification of candidate outcome measures for assessing technology development initiatives and development of data collection approaches that would be required to implement these measures in a consistent and ongoing manner.

## Technology Development Catalog

In developing the catalog of technology development FOAs, STPI researchers began by defining technology development. "Technology" was defined as a physical entity or a virtual entity used for a biomedical purpose (either a clinical/diagnostic purpose or a research purpose). "Development" was defined as the movement of a technology during the period of the award towards the point where it can be brought into clinical or research use. However, to be included in the catalog, not only did the objective of the FOA need to conform to this definition, but the *primary goal* of the FOA had to be technology development, and the FOA had to specify a particular technology development purpose or outcome. Additional boundary conditions were to include only: (1) FOAs issued from 2005 through 2014 and (2) Requests for Applications (RFAs) and Program Announcements (PAs), including PAs with special receipt, review, or review considerations (PARs) and PAs with set-aside funds (PASs).

Given those requirements, STPI researchers identified 284 distinct FOAs issued during those 10 years that were included in the catalog. The large majority (190) were RFAs. The FOAs in the catalog use a variety of NIH funding mechanisms, especially Small Business Innovation Research (SBIR) Phase I and Phase II grants; R21 Exploratory/Developmental Research Phase I (R21) and Phase II (R33) grants; Small Business Technology Transfer (STTR) Phase I and Phase II grants; and Research Project

(R01) grants. They encompass a range of technology areas, especially medical devices, molecular analysis technologies, and information technologies. STPI researchers identified 1,956 distinct awards associated with the 284 FOAs, representing $1.83 billion in total NIH spending and $1.36 billion in direct costs. Based on searches of the NIH RePORTER database, the public repository for the Research Portfolio Online Reporting Tools (RePORT), these awards are acknowledged by more than 7,000 publications and 41 patents.

## Case Studies

Case studies were developed for a group of representative FOAs based on discussions with program officers associated with those FOAs. The purpose of the case studies was twofold: (1) to provide greater insight on how the success of technology development programs might be measured and (2) to collect lessons learned and best practices. In selecting FOAs for the case studies, STPI researchers strove for a representative distribution. Two boundary conditions were established: (1) FOAs should have at least one iteration released in 2012 or before to maximize the likelihood that data were available regarding programmatic results; and (2) more than 10 awards should have been made under the FOA to ensure that program officers would have a sufficiently large number of awards to be able to draw conclusions about the results to date. Within those constraints, STPI researchers balanced the FOAs selected across technology areas, the intended use (research or clinical), the breadth of the technologies solicited, the funding mechanisms used, and the stage of development targeted. STPI researchers selected 26 FOAs for case studies and completed 18 case studies (4 of which included 2 FOAs each), covering 22 of the 26 selected FOAs. Case studies could not be completed for the other 4 FOAs.

### FOA Overview

As described by the program officers, there were two primary rationales for technology development FOAs. The first rationale was to meet a particular technology development need or objective identified by NIH that was not being adequately addressed by projects submitted to the general investigator-initiated pool or by FOAs from other parts of NIH. The second, which often was a companion rationale to the first, was to stimulate overall research activity in a particular technology domain that was viewed as underrepresented in the overall NIH portfolio. The majority of FOAs expected projects to begin with either fundamental discovery to establish basic principles or applied research to establish the feasibility of a technique, although some FOAs expected projects to have already established proof of principle or to have already developed prototypes as a precondition for award. PAs were often described as being used when the goal was to allow a field to grow organically, without requiring NIH to fund applications that did not score strongly in review. PARs and RFAs were most often described as being selected in order

to be able to convene special emphasis panels for review. RFAs tended to be chosen over PARs when it was deemed necessary to have designated funding in order to be able to make a reasonable number of awards or when projects were being solicited in a narrowly defined area.

Cooperative agreements were used when NIH viewed collaboration among awardees as being a critical success factor for their FOAs. R01 awards and Program Project Grant (P01) awards were used when large independent projects were viewed as the best route to achieving the technology development objective. R21 awards were used when it was deemed necessary to stimulate very early stage, potentially high-risk technology development projects in order to jump start a technology area. Both R01 and R21 awards were described as being employed when NIH specifically wanted to involve academic investigators in a technology development area. In contrast, SBIR and STTR awards were used when NIH concluded that involvement of commercial entities was the optimal route to rapid development of a particular technology.

**Lessons Learned**

The most important lesson learned from the case studies is that the program officers considered focused technology development efforts to advance NIH's mission a worthwhile use of funds. Additional lessons learned were of two types:

- Program Management Best Practices
  - *Technology development benefits from award flexibility.* Because technology development projects often require higher levels of funding or longer periods of time than comparable discovery-oriented projects, it is important to take advantage of opportunities for longer award periods and larger award sizes, if possible. The flexibility of multiple acceptance dates is also valuable.
  - *Tailored review is necessary.* Because many technology development efforts involve engineering and physical sciences disciplines and have more applied goals, tailored review processes are essential.
  - *Milestones are valuable.* Because technology development projects are intended to result in a defined physical (or virtual) entity for use in research or the clinic, milestones are valuable for charting progress. Because "milestone" refers to a quantitative, measurable indicator of technical progress, one or more of a grant's specific aims may functionally be equivalent to a "milestone."
  - *Grantee meetings with potential users and funders are valuable.* Grantee meetings open to potential investors and other commercial stakeholders as well as non-awardee researchers are valuable for sharing information among

awardees, facilitating collaborations, and exploring potential commercial relationships.

  - *Program officer expertise in technology development is critical.* Technology development program officers require three critical characteristics: (1) clear understanding of requirements for commercializing or otherwise disseminating technologies; (2) expertise in the technology field; and (3) familiarity with the relevant investigator community.

- Ongoing Challenges
  - *Commercialization is a hurdle, especially for clinical technologies.* Technologies for clinical use almost uniformly require more funding than available through standard award mechanisms. As a result, clinical technologies often languish even if early-stage clinical testing has been completed.
  - *Funding "blue-sky" technology development is 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.

## Recommended Measures of Success

### Ultimate Measures

Designing measures of success requires first a clear statement of the objective(s) of the technology development effort. Program officers described two ultimate objectives for technology development FOAs. The first was dissemination and use of the technology, which is likely to be applicable to all technology development FOAs. The second is an increase in the overall level of NIH-funded research activity in the technology development domain, which is likely to be applicable to only a subset of NIH technology development FOAs.

Measures relevant to the evaluation of dissemination and use are fundamentally different for research-focused and clinically focused technologies. For research-focused technologies, "dissemination" means that investigators in the scientific domain in question are actively using the technology in their research. Recommended measures for evaluating such dissemination and use therefore focus on the degree to which use of the technology is demonstrated in publications and grant applications as well as evidence of

commercialization of the technologies. For clinically focused technologies, measures relevant to dissemination and use include Food and Drug Administration (FDA) approval, reimbursement, sales revenues, and identification as a best practice in clinical practice guidelines. Specific recommended measures are:

- *Research-Focused Technologies*
  - Number of NIH grant applications in which use of the technology is integral to the proposed research[1]
  - Number of investigators who submit NIH grant applications in which use of the technology is integral to the proposed research
  - Number of citations and rate of citations to publication(s) describing development of the technology adjusted to include only those publications that use the technology or comment positively upon it
  - Number of publications that report use of the technology
    - Number of citations and rate of citations to those publications, as a measure of the scientific importance of the research conducted using the technology
  - Number of investigators whose publications report use of the technology
  - For research technologies that have been commercialized, sales revenue for the technology across all companies that provide it
- *Clinically Focused Technologies*
  - FDA approval or clearance of the technology
  - Reimbursement by Medicare and other insurers for use of the technology
  - Sales revenues for the technology across all companies that provide it
  - Use of the technology identified as a best practice in clinical practice guidelines

The second ultimate objective, an increase in overall research activity in the relevant technology development domain, applies primarily to FOAs for which one of the rationales was to stimulate activity in what was viewed as an underexplored technology development area. Recommended measures focus on whether there is an increase in the number of grant applications and awards in the technology domain. Specific recommended measures are:

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[1] For the NIH Common Fund (and its predecessor, the NIH Roadmap), technology development FOAs are sometimes put forward to generate technology to be used by other projects within the Common Fund initiative. Therefore, use by other projects within the Common Fund initiative would be an additional performance measure specific to these FOAs.

- Number of investigator-initiated grant applications in the technology domain
- Number of grants awarded in the technology domain
- Extent of commercial technology development in the domain

Several members of the evaluation advisory committee for this task—a committee composed of trans-NIH technology-focused program directors—suggested that two additional ultimate measures might be included, "significant contribution to new knowledge" and "improved diagnostic or treatment efficacy." The first has not been included for two reasons. First, none of the program officers with which STPI researchers had discussions mentioned this as a measure. Second, unlike discovery research, the primary goal of technology development is not the generation of knowledge per se, but rather the application of knowledge to a practical end. While some technology development projects may, in fact, generate new knowledge—and that fact should be noted when examining a given program—technology development programs that do not generate new knowledge can still be successful. Hence, contributing new knowledge would not be a valid performance measure to be applied across all NIH technology development efforts, although any scientific breakthrough that occurs as result of a project should be included as evidence of an initiative's success.

"Improved diagnostic or treatment efficacy" was also not a measure mentioned by any of the program officers and is not recommended as a measure because collecting comprehensive and valid data on clinical effectiveness across all the diverse clinical technologies developed would not be feasible. Again, when it is known that a technology emanating from a given program has shown evidence of improving diagnostic or treatment efficacy, this should be noted when examining that program, but it would not be a valid performance measure to be applied across all NIH technology development efforts.

**Intermediate Measures**

Because the ultimate measures of success for technology development FOAs cannot be assessed until several years after the awards have been completed, STPI researchers recommend that intermediate outcomes also be used to evaluate success, each of which is likely applicable to only a subset of FOAs. The intermediate outcomes are organized into five sets of measures.

- Achievement of technical milestones:
  - Percentage of projects that reach their final milestone (measured at end of award)
  - Percentage of projects that reach their intermediate milestones even though the final milestone was not reached (measured at end of award)

  - Percentage of ongoing projects that are reaching their intermediate milestones (measured regularly through annual reports)

- Conversion of exploratory awards into later stage awards:
  - Percentage of Phase I SBIR/STTR awardees that apply for a Phase II SBIR award
  - Percentage of R21 awardees that apply for follow-on R33 awards
  - Percentage of R21 awardees that apply for follow-on R01 awards
  - Percentage of Phase I SBIR/STTR awardees that receive a Phase II SBIR/STTR award
  - Percentage of R21 awards that receive follow-on R33 awards
  - Percentage of R21 awardees that receive follow-on R01 awards
- Technology licensing and pre-commercialization activity
  - Number of licenses of technology from awardees to third parties
  - Percentage of awards that have one or more technologies licensed
  - Number of new companies formed to further develop and commercialize the technology
  - Percentage of awards leading to new companies
  - Amount of venture capital/angel investment or other non-grant funding obtained for development of the technology
  - Percentage of awardees that receive such funding
  - Percentage of awardees in ongoing discussions with venture capital firms/angel investors that have not yet resulted in funding
  - Percentage of awards where the small business developer is acquired by a larger company
  - Percentage of awards where partnerships are formed between the small business developer and one or more larger companies to develop or commercialize the technology
- Progress toward clinical use (for clinical technologies only)
  - Percentage of awardees that engage in pre-Investigational Device Exemption (IDE) discussions with FDA
  - Percentage of awardees that file IDEs
  - Percentage of awardees that receive IDEs

  - Percentage of awardees that initiate early-stage clinical trials
  - Percentage of awardees that complete early-stage clinical trials
  - Percentage of awardees with successful early-stage clinical trials
  - Percentage of awardees that initiate pivotal clinical trials
  - Percentage of awardees that complete pivotal clinical trials
  - Percentage of awardees with successfully completed pivotal clinical trials
  - Percentage of awardees that file premarket notifications per Section 510(k) of the Federal Food, Drug and Cosmetic Act or premarket approval applications with FDA
  - Percentage of awardees that receive 510(k) clearance or premarket approval
- Data and software downloads
  - Number of registered users of web portals for downloading data sets/software/algorithms
  - Number of downloads of data sets/software/algorithms
  - Number of downloads by category of registered users if awardees require registration before downloading
  - Percentage of technologies that have been downloaded
  - Percentage of awards with downloads of software, algorithms, or data sets
  - Percentage of awards where all available technologies have been downloaded at least once

**Measure Implementation**

In implementing the recommended performance measures, it is important to consider the following points:

- Although the recommended performance measures were developed based on analysis of FOAs solely directed at technology development, they should also be applicable to investigator-initiated technology development projects and projects that are conducted under FOAs that have technology development as only one of several project categories.
- With the exception of the "dissemination and use" ultimate measure, which should be applicable to all technology development projects, careful attention should be paid to which of the performance measures are applicable to a given technology development initiative. In other words, the recommended measures

should be thought of as an overall framework that may be applied differently to individual programs.

- Some technology development projects may have attributes that would not be captured by the recommended performance measures. For example, some may be specifically targeted at high-risk, "blue sky" technology development objectives. For those initiatives, it will be important to also apply performance measures applicable to high-risk endeavors in addition to the measures specifically tailored to technology development.
- Technology development-related outcome measures are not readily available from existing NIH reporting frameworks. The current Research Performance Progress Report (RPPR) includes space to list technologies and products developed as free text rather than as closed-form fields suitable for analysis. Similarly, the initial iteration of the emerging NIH Portfolio Analysis and Reporting Data Infrastructure (PARDI) will focus more heavily on outcome measures related to research results, training, and clinical impact generally rather than on technology development-related outcomes specifically.

**Data Collection Approaches**

Given the breadth of the measures, STPI identified six potential methods for collecting the required data. Implementation of these data collection approaches should be based on an analysis by NIH of which might best be implemented for all technology development initiatives and which should only be implemented on a program-by-program basis.

- *Post-award reporting.* The best mechanism to collect systematic outcome data for technology development initiatives is to require post-award reporting. A reporting form that expands on the approach required at the end of Phase II SBIR awards is therefore recommended. Additional data would include publications and grants reporting use of the technology, appearance in clinical practice guidelines, conversion of exploratory awards, software downloads, and expansion of collected data on commercialization activities and progress toward clinical use.
- *Bibliometric Analysis.* Bibliometric analysis of publications that describe the technology and its development (as identified in post-award reporting) for the number and rate of citations would expand the data concerning dissemination and use. Manual analysis (which could include passive Internet-based searching such as through Google Alerts based on products' names), would further expand the data.

- *Publication/Grant Application Analysis.* Searches of MEDLINE and NIH grant databases for the name of the technology or for references to publication(s) describing the technology and its development would further expand the data on dissemination and use as well as provide data relative to increased research activity in the relevant technology development domain.
- *Commercial Activity in Technology Development Domain.* Manual searching of publicly available information and queries to NIH program officers would be necessary to evaluate commercial activity.
- *Expert Panels.* Convening expert panels to gauge whether a technology has achieved widespread dissemination and use and also, if relevant, stimulated increased research activity in the relevant technology development domain may be a useful alternative to post-award reporting and analysis of publications and grant applications.
- *Milestone Analysis.* NIH should develop a standard template for recording milestones in grant applications and a standard RPPR template for reporting progress toward achieving them.

# Contents

# 1. Introduction

## A. Statement of Task

The National Institutes of Health (NIH) supports innovative technology development as one aspect of fulfilling its mission to, "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."[2] The NIH extramural program supports technology development through a range of approaches, including: (1) unsolicited investigator-initiated grant applications; (2) broad Funding Opportunity Announcements (FOAs) for technology development proposals; (3) FOAs that solicit a mix of technology development and non-technology development proposals; and (4) FOAs requesting proposals for development of technologies aimed at a specific goal. In July 2014, NIH tasked the IDA Science and Technology Policy Institute (STPI) with developing performance measures for extramural technology development projects, using FOAs focused on specific technology development goals (category 4 above) as the basis for the analysis. As the task evolved, NIH also requested that STPI researchers identify "lessons learned" and "best practices" for technology development based on analysis of these specific FOA-directed initiatives. The task was intended to: (1) contribute towards more effective design of new program concepts, (2) provide insights for improved management of existing programs, and (3) guide a broad evaluation of NIH investments in technology development using relevant metrics.

The task had three components. The first was development of a catalog of NIH FOAs active since 2005 that are focused solely on technology development for achieving a specific goal. The second was identifying a representative sample of FOAs from the catalog and developing case studies based largely on discussions with program officers knowledgeable about those FOAs. The discussions covered the following topics: (1) overview of the initiative, (2) stage of technology development targeted, (3) measures that either were used or could be used to evaluate success of the initiative, (4) lessons learned and best practices gained from the initiative, and (5) their broader experiences and perceptions about technology development across NIH. Based on these discussions, STPI identified candidate outcome measures for assessing technology development initiatives, as well as data collection approaches that would be required to implement these measures in a consistent and ongoing manner.

[2] See NIH website, "Mission and Goals," http://www.nih.gov/about/mission.htm.

The work was guided by an evaluation advisory committee composed of the same technology-focused program directors that recommended the task be undertaken:

- Richard Conroy, National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Jennifer Couch, National Cancer Institute (NCI)
- Tony Dickherber, NCI
- Jeffery Schloss, National Human Genome Research Institute (NHGRI)
- Lawrence Solomon, NCI and National Institute for Allergy and Infectious Diseases (NIAID), replaced by Elizabeth (Betsy) Hsu, NCI
- Amy Swain, National Institute for General Medical Sciences (NIGMS)
- Kevin Wright, National Institute for Mental Health (NIMH)

## B. Organization of Report

Chapter 2 of this report provides the definition of "technology development" used to identify FOAs for inclusion in the catalog; the process used to identify FOAs meeting that definition; and a descriptive analysis of the characteristics of the FOAs in the catalog. Chapter 3 describes the approach used to identify 26 FOAs as candidates for case studies; the topics covered by the program officer discussions; and the summary results of the 18 case studies that were completed, some of which covered more than one FOA. Chapter 4 presents candidate measures for assessing NIH technology development programs and data collection approaches to support future assessment according to those measures.

The report also contains two appendices. Appendix A presents data on the catalog of NIH FOAs active since 2005 that STPI researchers identified as both meeting the definition of technology development and focusing solely on a specific technology development goal. Appendix B characterizes the 22 FOAs used as the basis for the 18 case studies according to nine parameters: (1) technology area, (2) funding mechanism(s), (3) FOA type, (4) purpose, (5) product scope, (6) intended use, (7) stage of development, (8) Institute/Center (IC) or ICs sponsoring awards, and (9) IC or ICs managing awards.

# 2. Catalog of NIH Funding Opportunity Announcements (FOAs) Focused on Specific Technology Development Goals

## A. Introduction

In developing the catalog of FOAs focused on specific technology development goals, the first step was to agree on a definition of technology development. Then, using that definition, the second step was to identify those FOAs which both met the definition and were focused solely on technology development for achieving a specific goal. These two steps are described below, followed by a descriptive analysis of the characteristics of the FOAs in the catalog and a summary of FOA outputs.

## B. Definition of "Technology Development"

The task statement of work sets out the following short definition of "technology development research programs" as a starting point: "The primary qualification criterion for inclusion of any program in this project is a focus on supporting technology development for a particular outcome(s)." While STPI researchers and members of the advisory committee accepted that general definition, they found it was not sufficiently detailed for operational purposes. For operational purposes, STPI researchers expanded on that general definition, with assistance from members of the advisory committee, to develop the following more detailed definition.

A "technology," for the purpose of this task, is a physical entity (e.g., a piece of equipment, a device, a new material, or a piece of hardware) or a virtual entity (e.g., software or methodology) used for a biomedical purpose, which could either be a clinical/diagnostic purpose or a research purpose. Examples of technologies include a new microscope, an assay in kit form, or a software platform. "Development," for the purpose of this task, is the movement of a technology during the period of the award towards the point where it can be brought into clinical or research use. The technology developed could be either wholly novel, the substantial improvement of an existing technology or the refinement or adaptation of an existing technology for a new purpose. Solicitations within the scope of technology development include those that ask investigators to develop candidate technologies/concepts to a pilot stage, to validate the performance of technologies, or to refine technologies in the expectation of their dissemination and use.

The advisory committee decided that an even more refined definition was required for information technology (IT) development. "Technology" in an IT context includes: (1) in silico methods, algorithms, and software only to the extent they are included in the functioning of a device (e.g., software that pre-processes raw data before it is analyzed by the user or software that automatically applies annotation to a sample as it passes through the device); (2) in silico methods, algorithms, and software implemented by the user to complete processing of data, perform quality control, etc. (e.g., for laboratory information management systems); or (3) in silico methods, algorithms, software, and models designed for use by others in data analysis, storage, etc. (e.g., compression algorithms, statistical packages, and computational models modularized or standardized for use by others or designed to test physical parameters of a wet technology). FOAs soliciting development of general computational, mathematical and statistical methods and algorithms that do not meet these requirements were not included in the catalog.

It was also agreed that to be included in the catalog, the *primary goal* of the solicitation must be technology development, and the solicitation must specify a particular technology development purpose or outcome. That purpose or outcome could include advancing a particular area of technology, achieving a particular research or clinical use, or addressing a particular area of unmet need.

Given this overall definition, it was agreed that the following types of solicitations were *excluded* from the catalog:

- Drug or biologic development
- Solicitations in which technology development is one of several routes to achieving a program's objectives
- Solicitations for development of new research methods and tools (e.g., mouse models) unless they were exclusively for a technology development purpose
- Solicitations for basic research that might eventually lead to the development of a technology
- Solicitations for new uses of existing technologies without any refinement or adaptation of the technology itself
- Omnibus Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) solicitations

In addition, in cases where one iteration of a FOA is predominantly for technology development, but a subsequent iteration is for using the technologies for a research or clinical purpose, only the iteration that is predominantly technology development was included in the catalog.

## C. Process for Identifying FOAs Meeting the Definition

The evaluation advisory committee recommended that the catalog have temporal boundaries and set those boundaries as FOAs issued from 2005 through 2014. While many initiatives extend further back in time, or issued new solicitations in 2015, only those iterations during 2005 through 2014 were included in the catalog. Another boundary was to include only Requests for Applications (RFAs) and Program Announcements (PAs), including PAs with special requirements. There are technology development initiatives that have been disseminated to the community via notices,[3] but because these are more difficult to trace and because the awards may not be identified separately in NIH databases, they were excluded.

STPI researchers relied upon two methods for identification of candidate FOAs within these boundaries for the catalog. First, the NIH evaluation set-aside application identified a group of FOAs as being potentially relevant. Second, STPI researchers conducted keyword searches using the NIH Office of Extramural Research (OER) Internet site[4] to identify technology development FOAs. The purpose sections of these FOAs were then reviewed by subject-matter experts to identify those FOAs that met the task definition of "technology development." The resulting list of FOAs was reviewed by the advisory committee in January and February 2015. The committee recommended certain changes, and the changes were incorporated to create the final list of FOAs for the catalog.

## D. Characterization of FOAs in Catalog

### 1. Summary Statistics

Based on the foregoing definition of "technology development," STPI researchers identified 284 distinct FOAs for inclusion in the catalog. Throughout the 2005–2014 period, in most years there were 20–30 FOAs whose first submission date occurred in that calendar year, although there were more FOAs identified in both 2006 and 2013 (Figure 1).[5]

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[3] For example, see "Prize Competition: Challenges in Single Cell Analysis," Notice Number: NOT-RM-14-014, http://grants.nih.gov/grants/guide/notice-files/NOT-RM-14-014.html.

[4] See NIH website, "Grants & Funding: Advanced Funding Opportunities and Notices Search," https://grants.nih.gov/searchGuide/search_guide.cfm.

[5] The year 2005 is an outlier because in the mid-2000s NIH changed its policies to require all FOAs to be activity code-specific whereas previously multiple activity codes could be included on a single FOA. If all activity codes associated with a single FOA are counted individually, 2005 (26 activity codes listed on 14 FOAs) would be comparable to the 2008–2012 period. It should also be noted that FOAs are active for varying lengths of time; some FOAs have only a single receipt date while others are reissued every several years. Initiatives that promulgate new FOAs rather than reissuances are therefore overrepresented when FOAs are counted.

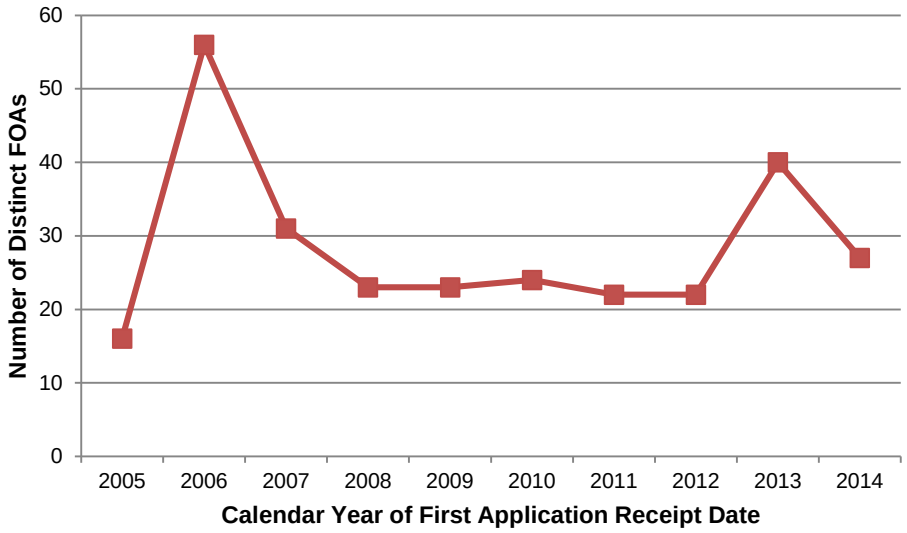


**Figure 1. Number of FOAs by Year of First Application Receipt**

The majority of the 284 FOAs are RFAs, with 190 of the 284 (67%) being solicited in this fashion. Fifty-eight of the 284 FOAs are PAs, while the remainder are PAs with special requirements: 30 PAs with special receipt, review, or review considerations (PARs) and 6 PAs with set-aside funds (PASs).[6]

Technology development FOAs solicit applications using a variety of NIH funding mechanisms (Table 1). The most common mechanisms are SBIR Phase I/Phase II awards (the R43/RR activity codes), R21 Exploratory/Developmental Phase I awards, STTR Phase I/Phase II awards (the R41/R42 activity codes), R01 Research Project Grant awards (the primary NIH mechanism of support), and R33 Exploratory/Developmental Phase II awards.[7] Cooperative Agreement awards (activity codes beginning with U), multi-project awards (activity codes beginning with P), and NIH Director's awards (activity code DP3) are used less frequently.

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[6] For more detail on individual FOA types, see NIH website, "Grants & Funding: Description of the NIH Guide for Grants and Contracts," http://grants.nih.gov/grants/guide/description.htm.

[7] For more detail on activity codes, see NIH website, "Grants & Funding: Activity Codes Search Results," https://grants.nih.gov/grants/funding/ac_search_results.htm.

**Table 1. Funding Mechanisms Used by Technology Development FOAs**

| Activity Code | Number of FOAs | Percentage of 284 FOAs |
|---|---|---|
| R43/R44 | 76 | 27% |
| R21 | 64 | 23% |
| R41/R42 | 41 | 14% |
| R01 | 37 | 13% |
| R33 | 26 | 9% |
| U01 | 16 | 6% |
| R21/R33 | 12 | 4% |
| R43 | 7 | 2% |
| R41 | 6 | 2% |
| P01 | 4 | 1% |
| U24 | 4 | 1% |
| U54 | 4 | 1% |
| DP3 | 2 | 1% |
| R03 | 2 | 1% |
| R44 | 2 | 1% |
| U44 | 2 | 1% |
| P41 | 1 | 0% |
| UH2/UH3 | 1 | 0% |

*Note*: Because some FOAs include multiple funding mechanisms, the total sums to more than 284.

## 2. FOA Grouping

These 284 FOAs fall into 83 distinct groups, where a "group" is defined as combining all reissuances of a FOA (e.g., RFA-XX-11-001 replaces RFA-XX-08-001) and all companion FOAs (e.g., PA-11-001 solicits SBIR applications, while PA-11-002 solicits STTR applications) under a common umbrella. The full list of included FOAs, organized into their respective groups, can be found in Table A-1, Appendix A. That table also shows, for each FOA group, the number of individual iterations included in the catalog. [8] Some examples of how the grouping process works follow. The first FOA group ("Adaptation of Scalable Technologies to Illuminate the Druggable Genome" was issued once, in 2013, as RFA-RM-13-010 under the U01 activity code. The second FOA group ("Advanced Development of Informatics Technology") was issued seven times. In 2012, five related

[8] An asterisk in Table A-1 identifies the eight FOA groups where one or more of the FOA iterations was issued as part of the NIH Roadmap or Common Fund.

FOAs ("companion FOAs") were issued (PAR-12-286 through PAR-12-290): one used the R01 activity code, one used the P01 activity code, two used the U01 activity code, and one used the U24 activity code. The U24 solicitation and the P01 solicitation were issued a second time ("reissuances") in 2013, as PAR-13-294 and PAR-13-330. Twenty-seven of the 83 groups represent a single FOA with neither reissuances nor companion FOAs. Twenty groups include companion FOAs issued a single time, while 16 groups include reissuances of a single FOA without any companion FOAs. Twenty groups involve both reissuances and companion FOAs. Of the 56 groups with more than one FOA, there are four groups that contain 10 or more related FOAs. Three of these four groups are associated with the Innovative Molecular Analysis Technologies (IMAT) initiative of the National Cancer Institute (NCI), while the fourth is the $1000 Genome initiative of the National Human Genome Research Institute (NHGRI).

## 3. FOA Categorization

STPI researchers first categorized the 83 FOA groups according to the technology area addressed, as shown in Table 2. Medical Devices (generically) is the most prevalent category, although there were four other categories carved out that represent more narrowly defined categories of medical devices (Low Cost Medical Devices, Point of Care Devices, Implantable Devices, and Imaging). Other common FOA categories include molecular analysis, information technologies, and genomic/proteomic analysis technologies, taken together.

**Table 2. STPI Categorization of Technology Area for 83 FOA Groups**

| 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 |
| Nonspecific | 1 |
| Manual Therapies | 1 |
| Manufacturing | 1 |
| Epigenetic Analysis | 1 |

In addition to characterizing the technology area associated with each FOA group, STPI researchers further characterized the FOA groups according to the following dimensions:

- **Purpose:** Breadth of topic area(s) within biomedical research or clinical care addressed by the FOA
  - **Broad:** FOA solicits technology development addressing a large number of potential areas within biomedical research and/or clinical care
  - **Defined Area:** FOA solicits technology development addressing a defined area within either biomedical research (e.g., proteomics) or clinical care (e.g., aging)
  - **Specific:** FOA solicits technology development addressing a specific area either in biomedical research (e.g., recording and manipulation of neural activity) or clinical care (e.g., Type 1 diabetes predictive screening)
- **Product Scope:** Range of product types addressed by the FOA
  - **Diverse:** FOA solicits technology development addressing a wide range of different product types for either biomedical research (e.g., techniques, tools, instrumentation, devices and methods) or clinical care (e.g., devices or assays for detection, diagnosis or treatment of cancer), or it defines multiple functions which products could address
  - **Defined Product Category(ies):** FOA solicits technology development addressing a single defined product category or two such categories for either biomedical research (e.g., comparative modeling methods) or clinical care (e.g., robotics)
  - **Specific:** FOA solicits technology development addressing a specific product for either biomedical research (e.g., DNA sequencing systems) or clinical care (e.g., artificial pancreas)
- **Intended Use:** Whether technologies developed under the FOA are envisioned to be used for research, for clinical purposes, or for both (There was one FOA directed at technology development for biomedical product manufacturing.)
- **Stage of Development:** Stage of technology development addressed by the FOA
  - **Early:** FOA solicits projects that are primarily discovery or early-stage development (e.g., Phase I SBIR solicitations)
  - **Early/Intermediate:** FOA solicits projects that encompass both early-stage and intermediate-stage development (e.g., R43/44 and R21/R33 solicitations) or projects that specify both discovery/early-stage

development and analytical validation, proof of concept or pilot testing, development of prototypes, etc.

  - **Intermediate:** FOA solicits projects that encompass analytical validation, proof of concept or pilot testing, development of prototypes or taking products to the point of readiness for clinical testing
  - **Intermediate/Late:** FOA solicits projects that encompass both intermediate-stage development (described above) and late-stage development (e.g., clinical testing or dissemination to the research community)
  - **Late:** FOA solicits projects that encompass late stage development (e.g., clinical testing or dissemination to the research community)
  - **Early to Late:** FOA solicits projects that encompass any stage of development from early to late or the entire continuum of stages from early to late

- **Performance Requirements:** Whether the FOA specified detailed performance requirements for developed technologies
  - **Defined:** FOA cited quantitative or semi-quantitative performance requirements
  - **Not Defined:** FOA cited only general performance requirements (e.g., sensitive, scalable, cost-effective) or no performance requirements

According to STPI's categorization of the individual FOA groups according to these dimensions, the majority of the groups have a specific purpose (39 of 83) or encompass a defined area (31 of 83) rather than a broad purpose (13 of 83). The majority also encompass a diverse set of products (53 of 83), while fewer encompass a defined set of products (13 of 83) or specific products (17 of 83). Groups are nearly evenly split between those intended for a research purpose only (40 of 83) and those intended for a clinical purpose only (36 of 83); six groups are intended for both purposes and the group coded as "manufacturing technologies" was coded as being for neither a research nor a clinical purpose.

The FOA groups solicit technologies across a variety of stages of development (see Table 3). Forty-one of the 83 groups either solicit early-stage development only or projects at an early or intermediate stage. Twenty of the groups solicit intermediate- or late-stage projects, while 22 of the groups solicit applications across the full product development life cycle. Seven of the groups had specifically defined performance requirements, while the remainder did not.

**Table 3. Stage of Development of the 83 FOA Groups**

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

## E. Summary of FOA Outputs

### 1. Awards (Number and Dollars)

For each of the FOAs included in the catalog, STPI researchers downloaded from the NIH Query/View/Report (QVR) data system the following information from the beginning of the FOA through the end of fiscal year 2015:

- Number of new awards (defined as Type 1, Type 2, and Type 4 projects)[9]
- Number of total awards, including noncompeting renewal Type 5s and supplements
- Total direct cost for all awards
- Total cost, including indirect costs for all awards

STPI researchers identified 1,956 distinct awards associated with the 83 groups, representing $1.83 billion in total NIH spending and $1.36 billion in direct costs over 10 years. There is substantial skew in the distribution of the number of applications, awards, and costs, as the largest initiatives are approximately 10 times larger than the remaining 75% of the groups, and 30 times the median group (see Table 4).

[9] It should be noted that the number of "new" awards may be inexact because some new awards are not of Types 1, 2, and 4. For example, four FOAs from the catalog are soliciting specifically for Type 3 supplements (PAR-12-046, PAR-12-286, RFA-RM-13-022, and RFA-RM-13-023). Further, the first award associated with an award number may not be a Type 1 award. For example, an award could be given to a principal investigator (PI) who is changing institutions (in which case the first award would be a Type 7) or a renewing award could switch to a different IC at the point of renewal (in which case the first award would be a Type 9). STPI researchers did conduct cross-checks between data downloaded from QVR and from NIH RePORTER and found that there was general concurrence, but it was not feasible to manually cross-check every award number.

**Table 4. Number of Awards and Costs**

| Descriptive Statistic | Number of Applications | Number of Direct Awards | Total Cost | Direct Cost |
|---|---|---|---|---|
| Minimum | 1 | 0 | $0 | $0 |
| 25th percentile | 24 | 5 | $1.8M | $1.3M |
| Median | 64 | 8 | $6.8M | $5.5M |
| 75th percentile | 163.5 | 18 | $22.4M | $16.8M |
| Maximum | 2,575 | 233 | $174.0M | $135.0M |

Seven initiatives comprise nearly half (49%) of the total funding for technology development and are predominantly for development of research technologies. All of these FOA groups are solicited via RFAs.

- Instrument Development for Biomedical Applications (165 awards, $174 million)
- Revolutionary Genome Sequencing Technologies: $1000 Genome (100 awards, $171 million)
- Clinical Proteomics Technology Assessment Consortium (CPTAC): Proteome Characterization Centers (61 awards, $161 million)
- Validation and Advanced Development of Emerging Molecular Analysis Technologies for Cancer Research (187 awards, $118 million)
- Early-Stage Innovative Molecular Analysis Technology Development for Cancer Research (233 awards, $116 million)
- National Technology Centers for Networks and Pathways Program (6 awards, $82 million)
- Exceptionally Innovative Tools and Technologies for Single Cell Analysis (42 awards, $66 million)

The eight smallest initiatives, by contrast, are more heavily weighted toward specific clinical applications. Two of these initiatives are RFAs, four are PAs, and the remaining two are PAR/PAS initiatives.

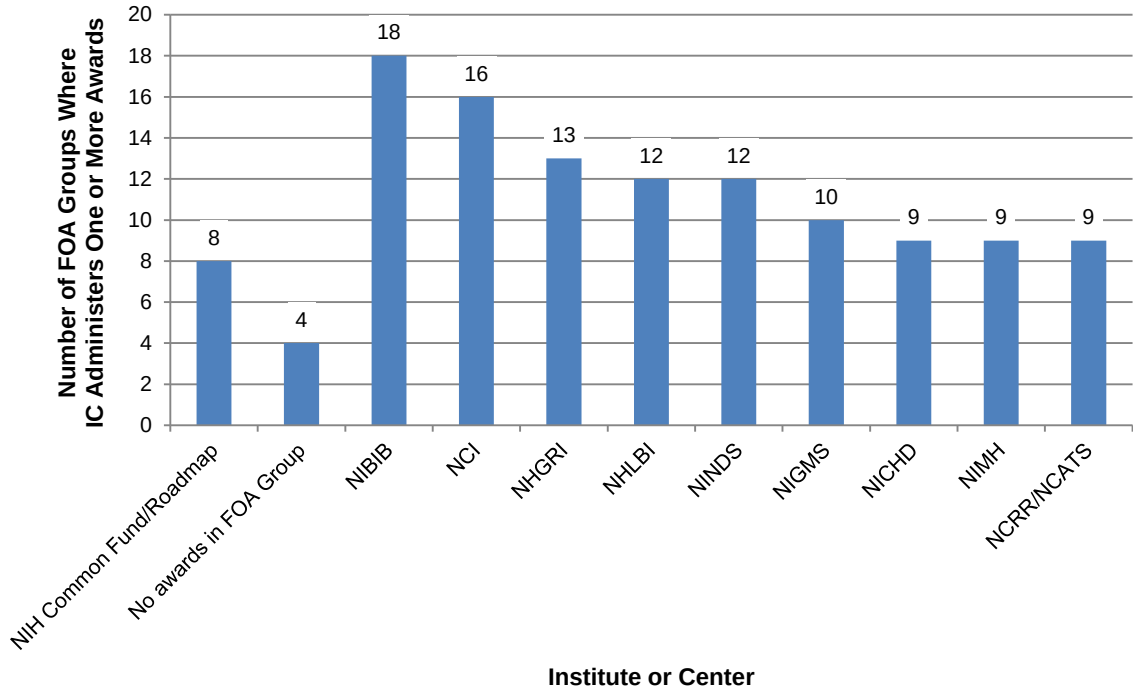
- New Technology to Screen for Mild Hearing Loss in Children (no awards)
- In-vivo Methods for Assessing Placental Development and Function (no awards)
- Development of Diagnostic Screening Test for Salt Sensitivity (no awards)
- Innovative Health Information Technology for Broad Adoption by Healthcare Systems and Consumers (no awards)

- Technologies To Assess Sleep Health Status in Populations (1 award, $0.1 million in total costs)
- Innovative Technologies and Assays in Support of HIV Cure Research (1 award, $0.3 million in total costs)
- Methods Development for Obtaining Comprehensive Genomic Information from Human Specimens that Are Easy to Collect and Store (2 awards, $0.4 million in total costs)
- Development of a Vestibular Neural Prosthesis (2 awards, $2.7 million in total costs)

A different way to characterize the technology development FOA groups is based on the ICs that administer the awards that were made (Figure 2). Eight of the FOA groups include NIH Common Fund/Roadmap initiatives, while another 4 have made no awards as of the end of FY 2015. Considering the remaining 71 FOA groups, National Institute of Biomedical Imaging and Bioengineering (NIBIB) and National Cancer Institute (NCI) administer awards from the largest number of FOA groups (18 and 16, respectively) while seven other ICs administer awards under 9 to 13 of the FOA groups.[10] Fifteen other ICs administer at least one award from at least one of the FOA groups.[11]

[10] The ICs are: National Human Genome Research Institute (NHGRI), National Institute of Neurological Disorders and Stroke (NINDS), National Institute for General Medical Sciences (NIGMS), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Child Health and Human Development (NICHD), National Institute for Mental Health (NIMH), and the combination of National Center for Cancer Resources (NCRR) and its successor, National Center for Advancing Translational Sciences (NCATS).

[11] The ICs are: National Institute on Aging (NIA) with six FOA groups; National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Deafness and Other Communication Disorders (NIDCD), and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) with five FOA groups each; National Institute of Dental and Craniofacial Research (NIDCR) and National Institute of Environmental Health Sciences (NIEHS) with four FOA groups each; National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and National Institute on Drug Abuse (NIDA) with three FOA groups each; the combination of National Center for Complementary and Alternative Medicine (NCCAM) and its successor, National Center for Complementary and Integrative Health (NCCIH), National Institute on Alcohol Abuse and Alcoholism (NIAAA), and National Eye Institute (NEI) with two FOA groups each; and National Library of Medicine (NLM), National Institute of Nursing Research (NINR), Fogarty International Center (FIC) and the combination of National Center on Minority Health and Health Disparities (NCMHD) and its successor, National Institute on Minority Health and Health Disparities (NIMHD), with one FOA group each.




*Note*: Because more than one IC can administer awards from an individual FOA, the total sums to more than 83 FOA groups.

**Figure 2. Most Common ICs Administering Awards in Technology Development FOA Groups**

## 2. Publications and Patents

STPI researchers downloaded publications and patents associated with each FOA from the NIH Research Portfolio Online Reporting Tools (RePORT) public repository (called RePORTER) in October 2015.[12] Because multiple awards may be acknowledged on a single journal article or patent application, STPI researchers chose to document publications and patents at a group level rather than by individual FOA or award. The RePORTER searches identified more than 7,000 publications and 41 patents associated with the technology development awards. The distribution of publications is even more highly skewed than the distribution of awards: 25% of the FOA groups have a single publication; the median number of publications is 9; 75% of the groups have an average of

[12] See NIH RePORTER, "Query Form," https://projectreporter.nih.gov/reporter.cfm. RePORTER draws publications from the NIH SPIRES database, which links publications to awards based upon automated identification of NIH award numbers in the MEDLINE metadata associated with the publications; patents are drawn from the iEdison data system that is maintained by NIH. The limitations of these systems, especially with respect to identifying patents, have been documented (e.g., Martin Grueber and Simon Tripp, *Patents as Proxies Revisited: NIH Innovation 2000 to 2013* Battelle, March 2015, http://www.battelle.org/docs/tpp/battelle_2015_patents_as_proxies.pdf).

64 publications; and the group with the largest number of publications has 1,184. Five FOA groups are responsible for more than half of the total publications (see Table 5).

**Table 5. Awards, Funding Level, and Publications of Selected FOA Groups**

| FOA Groups | Number of Awards | Total Dollar Value of Awards | Number of Publications (RePORTER) |
|---|---|---|---|
| Instrument Development for Biomedical Applications | 165 | $174M | 1,184 |
| National Technology Centers for Networks and Pathways Program | 6 | $82M | 607 |
| Validation and Advanced Development of Emerging Molecular Analysis Technologies for Cancer Research | 187 | $118M | 598 |
| Enabling Technologies for Tissue Engineering and Regenerative Medicine | 27 | $48M | 522 |
| Clinical Proteomics Technology Assessment Consortium (CPTAC): Proteome Characterization Centers | 61 | $161M | 520 |
| Early-Stage Innovative Molecular Analysis Technology Development for Cancer Research | 233 | $116M | 476 |
| Revolutionary Genome Sequencing Technologies: The $1000 Genome | 100 | $171M | 407 |
| Neurotechnology Research, Development, and Enhancement | 58 | $26M | 383 |

Given the small number of patents identified (68 of the 83 groups had no associated patents and the maximum number of patents identified for any group was 9), analysis of patents by FOA group was not conducted. It was not feasible to conduct manual searches for additional publications and patents (e.g., based on the authors and institutions acknowledged).

# 3. FOA Case Studies

## A. Introduction

In addition to cataloging technology development FOAs, the task included development of case studies for a group of representative FOAs based on discussions with program officers associated with those FOAs. The purpose of the case studies was to provide greater insight on how the success of technology development programs might be measured and also lessons learned and best practices. This chapter describes the process for selecting FOAs as candidates for case studies, the topics covered by the program officer discussions, and summary results from the 18 completed case studies.

## B. Methodology

### 1. FOA Selection

When developing the catalog, STPI researchers coded each FOA according to a variety of dimensions, including:

- Technology area[13]
- Funding mechanism(s)
- Solicitation approach (PA, PAR, or RFA)
- Purpose (specific, defined area, or broad)
- Product scope (specific, defined, or diverse)
- Intended use (research, clinical, or both)
- Stage of development (early, intermediate, or late)
- Performance requirements (defined or not defined)
- Year of earliest FOA iteration[14]
- Sponsor (one IC or multiple ICs)
- Awards administration (one IC or multiple ICs)

[13] Coded by STPI researchers with input from the task sponsor.

[14] If there were iterations prior to 2005, the first iteration after 2005 was indicated.

In selecting FOAs for the case studies and associated discussions, STPI researchers strove for a representative distribution across these various dimensions among FOAs that met two criteria recommended by the advisory committee. The first criterion was that the FOA should have at least one iteration released in 2012 or before. This was to increase the likelihood that program officers would have at least some information about the results of the awards and about whether it was possible to collect data regarding the measures program staff use to judge success. The second criterion was that more than 10 awards were made under the FOA.[15] This was to ensure that program officers would have a sufficiently large number of awards to be able to draw conclusions about the results to date. Based on these parameters, STPI researchers selected 26 FOAs for case studies and associated discussions (Table 6).

**Table 6. FOAs Selected for Case Study**

| Title | PA, RFA, and PAR Numbers | Research Project Activity Codes |
|---|---|---|
| Advanced Tools and Technologies for Deep Brain Stimulation | PA-10-175 | R41/R42 |
| Clinical Proteomics Technology Assessment Consortium (CPTAC): Proteome Characterization Centers | RFA-CA-07-005<br>RFA-CA-10-016 | R01, R21, R21/R33<br>U24 |
| Development and Implementation of Innovative Ultrasound Therapy Technologies | RFA-EB-07-004 | R01 |
| Early-Stage Development of Innovative Technologies for Biospecimen Science | RFA-CA-08-013<br>RFA-CA-08-014<br>RFA-CA-14-005<br>RFA-CA-14-006 | R43/R44<br>R41/R42<br>R21<br>R33 |
| Enabling Technologies for Tissue Engineering and Regenerative Medicine | PAR-06-504 | R01 |
| Exceptionally Innovative Tools and Technologies for Single Cell Analysis | RFA-RM-13-020<br>RFA-RM-13-021<br>RFA-RM-13-022<br>and RFA-RM-13-023 | R33<br>R21<br>R01<br>U01 |
| High Throughput Tools for Brain and Behavior | PA-08-001<br>PA-08-002 | R43/R44<br>R41/R42 |
| Imaging Diagnostics of Dental Diseases and Conditions Caries, Periodontal Disease, Cracked Teeth, and Pulp Vitality | PA-12-193<br>PA-12-195 | R41/R42<br>R43/R44 |

[15] It was suggested that a few FOAs that did not have many awards also be included in order to determine if there were any lessons learned from FOAs that had been unable to attract a reasonable number of fundable applications. STPI researchers contacted program officers from two such programs, (1) Novel Technologies for Rapid and Sensitive Biomonitoring in Humans and (2) Development of Diagnostic Screening Test for Salt Sensitivity, but neither chose to participate in this effort.

| Title | PA, RFA, and PAR Numbers | Research Project Activity Codes |
|---|---|---|
| Informatics Tools for High-Throughput Sequence Data Analysis | RFA-HG-10-108<br>RFA-HG-10-019 | U01<br>R43/R44 |
| Instrument Development for Biomedical Applications | RFA-RR-05-001<br>RFA-GM-14-014 | R01, R21, R21/R33<br>R21 |
| Lab to Marketplace: Tools for Brain and Behavioral Research | PA-14-250 | R43/R44 |
| Manufacturing Processes of Medical, Dental, and Biological Technologies | PA-09-113<br>PA-09-114 | R43/R44<br>R41/R42 |
| Near-Term Technology Development for Genome Sequencing | RFA-HG-07-016<br>RFA-HG-07-017<br>RFA-HG-07-018<br>and RFA-HG-07-019 | R01<br>R21<br>R43/R44<br>R41/R42 |
| Neurotechnology Research, Development, and Enhancement | PA-06-278<br>PA-06-279 | R21<br>R01 |
| New Technology for Proteomics and Glycomics | PA-11-214<br>PA-11-215 | R41/R42<br>R43/R44 |
| Revolutionary Genome Sequencing Technologies: The $1000 Genome | RFA-HG-08-011<br>RFA-HG-13-005<br>RFA-HG-13-006<br>and RFA-HG-13-007 | R41/R42<br>R01<br>R21<br>R43/R44 |
| Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings | PAR-13-090<br>PAR-13-091 | R43/R44<br>R41/R42 |
| Small Business Innovation Research to Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes (T1D): Towards an Artificial Pancreas | RFA-DK-13-028 | R43/R44 |
| Technologies and Software to Support Integrative Cancer Biology Research | PA-09-188 | R43/R44 |
| Technologies for Healthy Independent Living | PAR-14-118<br>and PAR-14-119 | R01<br>R21 |
| Technologies for Image-Guided Interventions | RFA-EB-06-003<br>RFA-EB-09-002 | R21<br>R01 |
| Technology Development for High-Throughput Functional Genomics | RFA-HG-11-013<br>RFA-HG-11-014<br>and RFA-HG-11-015 | R01<br>R21<br>R43/R44 |
| Technology Development for High-Throughput Structural Biology Research | PAR-10-074<br>PAR-13-032 | P01<br>R01 |
| Technology Development in Epigenetics | RFA-RM-07-011 | R01, R21 |
| Technology for the Detection and Characterization of Low Abundance Proteins, Peptides, or micro RNAs | PA-09-189 | R43/R44 |
| Validation and Advanced Development of Emerging Molecular Analysis Technologies for Cancer Research | RFA-CA-10-003<br>RFA-CA-14-004 | R21<br>R33 |

## 2. Program Officer Discussions

The discussions covered four core topics: overview of the FOA, stage of development, measures of success, and lessons learned. The first topic explored five areas: (1) rationale behind the FOA in order to understand why NIH decided that a specific technology development solicitation was needed; (2) whether the primary purpose of the FOA was to develop technologies for research use, clinical application, or both; (3) why a PA, PAR, or RFA approach was selected; (4) why particular funding mechanisms were used; and (5) whether a particular type of investigator was targeted. Under the second topic, the developmental stage of the technologies was discussed, including the expected stage of development at the beginning of the awards and how far along the developmental pathway the technologies were expected to advance by the end of the award. In addition, STPI researchers inquired about how investigators were expected to complete development post-award if the technology was not ready for dissemination and use by the end of the award period.

The third topic covered any measures already used to evaluate the success of the program as well as measures of success that the program officer considered potentially valuable but not currently used. For both types of measures, the discussion also covered the data source(s) required to implement the measure and challenges encountered or expected in either gathering the data or using it to measure success. Under the final topic, STPI researchers asked for any lessons learned about how best to support technology development at NIH, either from the specific FOA or from the program officer's overall experience with technology development.

During June through August 2015, STPI researchers completed discussions with 18 NIH program officers, covering 22 of the 26 FOAs.[16] Only 18 discussions were needed because in four cases, a single program officer was responsible for two FOAs. In addition, a discussion was held with the Director of the NIH office managing the Common Fund concerning general lessons learned about supporting technology development through NIH. This discussion was deemed important because the Common Fund has a substantial number of technology development initiatives within its high impact, trans-NIH programs. Following the interviews, STPI researchers provided each program officer with a draft of the case study based on the interview for his or her review. Appendix B summarizes the characteristics of the 22 FOAs included in the case studies.

[16] Case studies could not be completed for the other 4 FOAs.

## C. Results

### 1. Overview

#### a. Rationale

As described by the program officers, there were two primary types of rationale for technology development FOAs. The first, not surprisingly, was to meet a particular technology development need or objective identified by NIH program staff that was not being adequately addressed by projects submitted to the general investigator-initiated pool or by FOAs from other parts of NIH. The second, which often was a companion rationale to the first, was to stimulate overall research activity in a particular technology domain which was viewed as underrepresented in the overall NIH portfolio.

#### b. Solicitation Approach

When asked about the reasons for selecting a PA, PAR, or RFA approach for their FOAs, program officers made the following comments. PAs were often described as being used when the goal was to allow a field to grow organically, without requiring NIH to fund applications that did not score strongly in review. In addition, one program officer mentioned that a PA was used because the technology area was so broad that there would not be any value in convening special emphasis panels. PARs and RFAs were most often described as being selected in order to be able to convene special emphasis panels for review. RFAs tended to be chosen over PARs when it was deemed necessary to have designated funding in order to be able to make a reasonable number of awards or when projects were being solicited in a narrowly defined area.

#### c. Funding Mechanism(s)

Several reasons were cited by program officers for selecting particular funding mechanisms for their FOAs. Cooperative agreements were used when NIH viewed collaboration among awardees as being a critical success factor for their FOAs. R01s and P01s were used when large independent projects were viewed as the best route to achieving the technology development objective. R21s were used when it was deemed necessary to stimulate very early stage, potentially high-risk technology development projects in order to jump start a technology area. Both R01s and R21s were described as being employed when NIH specifically wanted to involve academic investigators in a technology development area. In contrast, SBIR and STTR awards were used when NIH concluded that involvement of commercial entities was the optimal route to rapid development of a particular technology. Occasionally, both SBIR/STTR and R21/R01 mechanisms were used simultaneously when it was decided that it was important to involve both academic and industry investigators.

## 2. Stage of Development

Across the 22 FOAs included in the case studies, the majority (12) expected projects to begin with either fundamental discovery to establish basic principles or applied research to establish the feasibility of a technique. Other FOAs expected a range of starting points, from a single FOA that expected all projects to start at the fundamental discovery stage to two FOAs that expected projects to have already established proof of principle and one that expected projects to have already developed prototypes as a precondition for award. The range of acceptable stages of development at the beginning of the award period for the various FOAs in shown in Table 7, along with the numbers of FOAs in each category.

**Table 7. Stage of Development at Start of Award**

| Stage of Development at Start of Award | Number of FOAs |
|---|---|
| Fundamental Discovery Only | 1 |
| Fundamental Discovery and Applied Research | 12 |
| Fundamental Discovery, Applied Research, and Proof of Principle | 2 |
| Applied Research Only | 3 |
| Applied Research and Proof of Principle | 1 |
| Proof of Principle Only | 2 |
| Full Prototype Only | 1 |

Program officers for 5 of the FOAs stated that there was no program-wide expectation for how far projects would proceed during the award period but the expected stage of development that projects would reach by the end of the award period was specified by program officers for the remaining 17 FOAs. Two of these 17 FOAs expected projects to reach proof of principle by the end of the award period, and both of those were R21-only FOAs (Early-Stage Development of Innovative Technologies for Biospecimen Science and Instrument Development for Biomedical Applications). Seven of the FOAs expected the projects to reach a full prototype, while 8 expected the projects to proceed to the point where they were ready for use by the investigators themselves or by others.

The expected stage of development at the end of the award period differed between FOAs aimed at developing technologies for clinical use and those aimed at technologies for research use.[17] All five FOAs aimed at developing technologies for clinical use expected projects to reach the full prototype stage but not to achieve FDA approval and full commercialization. However, one FOA did expect projects to collect pilot clinical data and another expected projects to begin developing a clinical grade manufacturing process. Of the 12 FOAs aimed at developing technologies for research use that had expectations

[17] One FOA is intended for both research and clinical use and is counted twice for the purpose of this analysis.

for how far projects would proceed during the award period, 2 expected projects to establish proof of principle by the end of the award period, 3 expected projects to have developed a full prototype, and 7 expected projects to have technologies ready for use by the investigators themselves or others. One of the FOAs was for development of manufacturing technologies and therefore was not categorized as either for clinical or research use. This FOA also expected projects to have developed technologies that were ready for use at the end of the award period.

## 3. Measures of Success

### a. Ultimate Measures

All of the program officers but one identified use of the developed technologies for either research or clinical purposes as the ultimate objective of their technology development programs. "Use" was broadly defined, and could include continuing use by the PI of the technology developed in the PI's own research, dissemination of that technology informally to other researchers, or licensing of the technology to a company for them to sell to the entire research community or for use in the clinic. Program officers for 10 of the FOAs stated that they use commercialization as a measure of success in achieving this ultimate objective. This included all of the FOAs focused on the development of technologies for clinical use as well as four of the FOAs aimed at the development of technologies for research use and one of the FOAs aimed at development of technologies for both clinical and research use. Program officers for 12 FOAs identified downstream use by the investigators themselves or by other researchers as an ultimate objective of their programs. These FOAs included 10 aimed at the development of technologies for research use, one aimed at technologies for both research and clinical use and the one FOA focused on manufacturing technologies. Program officers for most of the FOAs (13 of 22) stated that they were currently able to collect use-related data while program officers for 9 FOAs stated that they were unable to collect robust data regarding use of the technologies developed.

Program officers for nearly half of the FOAs (10 of 22) indicated that increased research activity in the technology development domain (which might include additional grant applications received focusing on that particular technology development domain in response to a particular FOA, or submission of grant applications in the technology domain to the general investigator-initiated pool) was another ultimate objective of their FOA. Program officers for 6 off these 10 FOAs mentioned that this objective could be measured both by an increasing number of strong applications in response to their FOAs or an increasing number of investigator-initiated applications (e.g., in response to the omnibus SBIR/STTR solicitation or to the general R01 pool) in the same technology domain. The other 4 program officers did not mention a specific measure that they used. Program

officers for 6 FOAs identified transitions (e.g., R01 applications from R21 awardees or SBIR/STTR Phase II applications from Phase I awardees) as another measure of increased research activity.

### b. Intermediate Measures

For many programs, dissemination and use are expected to occur after the awards from these technology development programs are completed. Therefore, several program officers mentioned intermediate measures of success. For the clinically focused programs, these intermediate measures tended to involve steps toward Food and Drug Administration (FDA) approval or clearance (e.g., awardees entering into pre-Investigational Drug Application [IND] or pre-Investigational Device Exemption [IDE] discussions with FDA staff, and technologies entering into or completing clinical trials, awardees receiving FDA IDEs to allow the collection of clinical data) as intermediate measures of success. Program officers for FOAs focused on developing technologies for research purposes were less likely to mention a distinct set of intermediate measures. This is not surprising given that, as noted above, research-oriented technologies are more often advanced to the point of dissemination and use by the end of the award period.

There was disagreement among program officers with respect to the utility of patents as an intermediate success measure. Some program officers considered patents a valuable indicator of programmatic success while others considered patents useful for showing that a particular award is moving technology forward but not as a meaningful program-level measure. Still other program officers considered patent data irrelevant, either because patent protection is unlikely to occur in their technology domain or because patenting is too far "upstream" of actual commercialization and use to be a meaningful measure. While technology licenses can be a necessary pre-requisite for commercialization, licenses were used by only a few of the program officers as an intermediate measure of success.

Program officers similarly were split with respect to the value of publications as an intermediate measure of success. Program officers for nearly half of the FOAs (10 of 22) considered publication-based measures not to be useful for technology development programs. Of the program officers who viewed publications as of some value, there were also divergent views. Five viewed publication and citation counts as a valuable measure; three viewed publications which either describe a technology or identify downstream use as meaningful measures; and four, while considering collecting publication data worthwhile, did not view publications as a meaningful success measure for technology development programs.

The large majority of the technology development programs analyzed include milestones in some form or expect specific aims to be milestone-like. However, to date, achievement of these milestones has not been used to measure the success of any of the programs, although one program intended to do so in the future. Rather, the milestones are

used only at the project level by reviewers in judging application quality or by program staff to determine whether projects are moving forward or not.

## 4. Lessons Learned

The lessons learned for technology development programs were either identified as such by individual program officers or considered to be lessons by STPI researchers from other aspects of the program officer discussions. The most important conclusion across all of the program officers is that focused technology development efforts advance NIH's mission and are a worthwhile use of funds. One basis for this conclusion is that in many biomedical research domains, research is held back due to a lack of adequate instrumentation (or in the case of data-intensive fields, a lack of adequate software and algorithms) to facilitate progress. Technology development therefore serves as an enabling mechanism for future discovery. The second argument is that, for clinical technologies, a focused NIH technology development effort is often needed to make advances that for various reasons are not being pursued by industry, for example, because the area is considered overly risky or too small a market to merit technology development. The final argument for focused technology development efforts was process-oriented. Because many technology development efforts are not hypothesis driven, they tend not to score well in standard review and therefore benefit from the special review panels available under PAR and RFA solicitations.

Additional lessons learned were of two types—program management best practices and ongoing challenges.

### a. Program Management Best Practices

- *Technology development benefits from award flexibility.* Program staff noted that technology development projects often require higher levels of funding or longer periods of time than comparable discovery-oriented projects. Therefore, technology development programs often take advantage of award mechanism flexibility by providing the longest possible award periods and award sizes larger than the norm. It was also pointed out that, for RFAs and PARs, it is valuable to have multiple acceptance dates rather than having a single application and review cycle. This allows investigators to amend applications based on review, facilitates transitions of successful small-scale projects (e.g., R21-to-R01 transitions), and gives investigators the flexibility to apply when a project is ready rather than to meet a single, artificial deadline.
- *Tailored review is necessary.* Because many technology development efforts involve engineering and physical sciences disciplines, and have more applied goals, program officers stressed the need to be proactive in working with the Center for Scientific Review (CSR) to design appropriate review processes.

Among the FOAs analyzed, there was a 60:40 split between RFAs and PARs, which allow for special emphasis panels, and PAs that direct applications to standing study sections. Nevertheless, program officers agreed that for emerging technology areas or areas that rely on disciplinary expertise not normally found in study sections, there is value in going the RFA or PAR route.

- *Milestones are valuable.* Because technology development projects are intended to result in a defined physical (or virtual) entity for use in research or the clinic, these projects benefit greatly from having milestones by which to chart progress toward the intended goal.[18] Milestones allow reviewers to assess the feasibility of a technology development path and focus investigators on progressing through the required steps and not becoming distracted by tangential results. When technology development projects are pursued through cooperative agreements or contracts, milestones provide NIH staff an effective tool for charting progress and managing the awards.
- *Grantee meetings with potential users and funders are valuable.* Several technology development initiatives hold grantee meetings, which are usually at least partially open to potential investors and other commercial stakeholders as well as non-awardee researchers in the relevant field. These meetings were considered highly valuable not only for sharing information among awardees, but also for facilitating collaborations and partnerships, especially for initiatives in tightly defined areas. The meetings are also an opportunity to explore potential commercial relationships. While practices vary (e.g., extent to which awardees are encouraged to protect intellectual property before the meetings), all programs that hold such meetings consider them useful mechanisms for advancing their technology development goals.
- *Program officer expertise is critical.* Successful NIH-funded technology development requires program officers with three critical characteristics: (1) clear understanding of what is required to commercialize or otherwise disseminate technologies, (2) subject-matter expertise in the specific technology field, and (3) familiarity with the relevant investigator community. Having program officers support a range of technology development efforts in a given field (e.g., both R01s and SBIR awards or both intramural and extramural

[18] For this purpose, "milestone" refers to a quantitative, measurable indicator of technical progress. Therefore, one or more of a grant's specific aims may functionally be equivalent to a "milestone." The following is an example of an embedded milestone from award R43AI110139: "The milestone for Aim 2 will be to determine whether this new mode of HCV RNA detection has a sensitive electrical response with accurate detection down to 500 IU/mL."

efforts) is beneficial in making connections and identifying potential partnerships.

**b. Ongoing Challenges**

- *Commercialization is a hurdle, especially for clinical technologies.* In many cases, funding through SBIR, R21 and R01 awards is sufficient to advance a research-focused technology to the point of dissemination and use. However, technologies for clinical use almost uniformly require more funding than is available through standard NIH award mechanisms. As a result, many promising clinically oriented technologies languish despite advancing even to the point of early stage clinical testing. Specific concerns were raised regarding SBIR awards. Standard SBIR Phase I awards were considered too short and too small to allow proof of principle for clinical technologies to be established, and Phase II awards, too small to bring these technologies to commercialization. Phase IIB awards were considered sufficient to fund pivotal testing in support of FDA approval for non-invasive Class II devices, but Phase IIB awards are so rare at NIH that this is not a generally applicable solution. Moreover, even Phase IIB awards are insufficient for funding pivotal trials of invasive devices. As a result, many NIH supported clinical technologies must obtain industry, venture capital and/or foundation funding to advance to practical use and such funding is often difficult if not impossible to achieve.
- *Funding "blue-sky" technology development is difficult.* While many technology development initiatives include fundamental research, only the R21 mechanism was viewed as being especially tailored to fund truly high-risk or "blue-sky" projects that explore a wholly new technology development approach or intend to establish fundamental principles that might be valuable in future technology development efforts. Funding such projects through either the SBIR/STTR or R01 mechanisms was viewed as more difficult because these mechanisms generally require preliminary data for applications to score well in review. To ameliorate these limitations, program officers offered two suggested solutions. One was to manage technology development programs explicitly on a portfolio basis rather than expecting each project to meet its milestones and succeed. The other was for technology development program officers to set clear, performance-driven, aspirational goals for their initiatives. Setting a difficult-to-reach goal encourages the investigator community to submit innovative applications.
- *Greater coordination of technology development efforts is needed.* Program officers were generally aware of other ongoing technology development

initiatives, but there did not appear to be any regular interactions where program officers for the various initiatives could share lessons learned and best practices. It was suggested that establishing a forum for such sharing might be valuable. The NIH Bioengineering Consortium (BECON) was mentioned specifically as an example of such a forum that had been valuable in the past. It was also mentioned that program officers may not be aware of all of the NIH technology development resources that are available for their grantees. Therefore, systematic dissemination of information about these resources across NIH would be valuable.

# 4. Recommended Measures of Success for NIH Technology Development Initiatives

Based on the discussions with the 18 technology development program officers, STPI researchers developed a set of candidate measures for assessing the success of NIH technology development initiatives. The candidate measures include both measures of success for achieving the two ultimate objectives identified by the technology development program officers (ultimate measures) and measures of success for achieving intermediate outcomes that represent steps along the way to those ultimate objectives for particular subsets of technology development initiatives (intermediate measures). STPI researchers also developed recommendations concerning data collection approaches that would be required in order to obtain consistent quantitative information for the recommended success measures.

When applying the two different categories of success measures to specific initiatives, it is essential to distinguish between early-stage development initiatives intended to explore fundamental principles and late-stage initiatives intended to develop technologies ready for dissemination and use by the end of the award period. It is also essential to distinguish between research-focused and clinically focused technologies. Research-focused technologies can often achieve dissemination and use quickly while clinically focused technologies may require a much longer period to achieve this ultimate objective. However, because use of clinically focused technologies is regulated by FDA, there are a number of distinct intermediate outcomes that are easily measurable.

In considering these candidate measures, it is also important to distinguish between measures and metrics. Measures are specifications of quantitative data points that can be collected and assessed at specific times. Metrics require some external benchmark or expectation against which a measure's collected data can be assessed. For example, a measure of dissemination and use is the number of NIH grant applications in which use of the developed technology is integral to the proposed research, but a metric is the expectation that a specific number of applications will do so. The STPI analysis yielded potential measures for assessing technology development initiatives. However, until such measures are specified, data are collected against those measures, and experience is gained concerning the various levels of technology development success being achieved, it is premature to set metrics for these measures.

Finally, in order to translate the results of this work into an overall evaluation approach for NIH technology development initiatives, it will be important to identify those

measures for which data should be collected for all NIH technology development initiatives and those measures for which data should be collected only for particular subsets of initiatives with common goals and characteristics.

## A. Ultimate Measures

Program officers described two ultimate objectives for technology development FOAs. The first was dissemination and use of the technology that is likely to be applicable for all technology development FOAs. The second is an increase in the overall level of NIH-funded research activity in the technology development domain. For the reasons described below, this objective is likely to be applicable to only a subset of NIH technology development FOAs. These ultimate measures are absolute measures (e.g., often in terms of totals or numbers), allowing analyses to be performed at the award, program, or NIH level.

Measures relevant to the evaluation of dissemination and use are fundamentally different for research-focused and clinically focused technologies. For research-focused technologies, "dissemination" means that investigators in the scientific domain in question are actively using the technology in their research. Recommended measures for evaluating such dissemination and use are therefore as follows:[19]

- Number of NIH grant applications in which use of the technology is integral to the proposed research[20]
- Number of investigators who submit NIH grant applications in which use of the technology is integral to the proposed research
- Number of citations and rate of citations to publication(s) describing development of the technology adjusted to include only those publications that use the technology or comment positively upon it
- Number of publications that report use of the technology
  - Number of citations and rate of citations to those publications, as a measure of the scientific importance of the research conducted using the technology

[19] These measures apply most directly to dissemination and use by academic investigators. While use of NIH-developed technologies by others (e.g., investigators in industry) is important, STPI researchers concluded that it would not be feasible to collect meaningful quantitative data on industry use, and therefore no measures aimed specifically at use by industry were constructed. Expert judgement (e.g., through expert panels) may be an approach for obtaining qualitative information about the use of research-focused technologies in industry.

[20] For the NIH Common Fund (and its predecessor, the NIH Roadmap), technology development FOAs are sometimes put forward to generate technology to be used by other projects within the Common Fund initiative. Therefore, use by other projects within the Common Fund initiative would be an additional performance measure specific to these FOAs.

- Number of investigators whose publications report use of the technology
- For research technologies that have been commercialized, sales revenue for the technology across all companies that provide it

For clinically focused technologies, measures relevant to the evaluation of dissemination and use are more direct:

- FDA approval or clearance of the technology
- Reimbursement by Medicare and other insurers for use of the technology
- Sales revenues for the technology across all companies that provide it
- Use of the technology identified as a best practice in clinical practice guidelines

The second ultimate objective, an increase in overall research activity in the relevant technology development domain, applies primarily to FOAs for which one of the rationales was to stimulate activity in what was viewed as an underexplored technology development area. However, except where the product goal of the initiative was very specific, stimulating research activity in the domain was often a secondary objective for the other technology development FOAs that were the subject of conversations with program officers. Recommended measures for evaluating whether research activity in a technology development domain has increased are as follows:

- Number of investigator-initiated grant applications in the technology domain
- Number of grants awarded in the technology domain
- Extent of commercial technology development in the domain

Measures such as these are, however, difficult to implement and are likely to require either considerable manual effort by NIH program staff to produce useful quantitative data or qualitative judgement of NIH program staff, advisory committees, and other stakeholders.

## B. Intermediate Measures

As noted above, the ultimate measures of success for technology development FOAs often cannot be assessed until several years after the awards granted under the FOA have been completed, especially for clinically focused technologies. In fact, these ultimate measures are what program evaluators would often consider “broader impacts” (i.e., results that are desirable from a societal perspective, but not directly under the control of the program and therefore not appropriate for use as direct measures of programmatic success). STPI researchers therefore recommend that several measures of intermediate outcomes also be used to evaluate the success of technology development FOAs. Due to the breadth of NIH-supported technology development FOAs, each of these intermediate measures is likely to be applicable to only a subset. Therefore, each initiative will need to determine which of these recommended intermediate measures are relevant. Unlike the ultimate

measures, which are expressed in absolute terms, many of these measures are expressed in relative terms (e.g., as percentages).

### 1. Intermediate Outcome 1: Achievement of Technical Milestones

NIH cooperative agreements and SBIR/STTR FOAs generally require projects to have specific, quantitative milestones, which are used for program management.[21] Some R01 and R21 FOAs also use milestones, or their applicants' specific aims are equivalent to milestones. Achievement of these milestones can represent an important intermediate outcome for technology development projects. Projects that achieve their milestones as scheduled are more likely to reach their ultimate goals than projects that are unable to achieve their milestones or must change their development path. It would also be expected that projects that achieve their milestones as scheduled are more likely to obtain follow-on support or development partners. Recommended intermediate measures of success for such an outcome include:

- Percentage of projects that reach their final milestone (measured at end of award)
- Percentage of projects that reach their intermediate milestones even though the final milestone was not reached (measured at end of award)
- Percentage of ongoing projects that are reaching their intermediate milestones (measured regularly through annual reports)

### 2. Intermediate Outcome 2: Conversion of Exploratory Awards

R21 and SBIR/STTR FOAs are designed to provide exploratory funding for the initiation of a technology development process. Therefore, for these FOAs, conversion to later stage awards is an important intermediate outcome. Many SBIR/STTR technology development FOAs explicitly expect successful projects to transition to a larger Phase II award, although in some cases a FOA is R41/R43-only and awardees are expected to apply to the omnibus SBIR solicitation for the Phase II award. Similarly, some R21 FOAs have companion R33 FOAs, while in other cases R21 awardees are expected to apply for follow-on R01 funding. Recommended measures of success for conversion of these exploratory awards are:

- Percentage of Phase I SBIR/STTR awardees that apply for a Phase II SBIR award

[21] The use of milestones is common in Advanced Projects Research Agency (ARPA)-like programs. For a 30-year-old DARPA example, see Mark Stefik, "Strategic Computing at DARPA: Overview and Assessment," *Communications of the ACM* 28 (7, July 1985): 690–704.

- Percentage of R21 awardees that apply for follow-on R33 awards
- Percentage of R21 awardees that apply for follow-on R01 awards
- Percentage of Phase I SBIR/STTR awardees that receive a Phase II SBIR award
- Percentage of R21 awards that that receive follow-on R33 awards
- Percentage of R21 awards that that receive follow-on R01 awards

### 3. Intermediate Outcome 3: Technology Licensing and Pre-Commercialization Activity

In the large majority of clinically focused programs, the academic investigators or small businesses engaged in early-stage technology development will need to transfer the technology to a new spin-off company or partner with a larger commercial firm in order to achieve commercialization and thus dissemination and use. Even some research-focused technologies developed by academic investigators will need to be licensed to commercial companies for further development in order to achieve dissemination and use. For such programs, technology licensing or other pre-commercialization activities represent an important intermediate outcome. Recommended measures of success for achieving these intermediate outcomes are:

- Number of licenses of technology from awardees to third parties
- Percentage of awards that have one or more technologies licensed
- Number of new companies formed to further develop and commercialize the technology
- Percentage of awards leading to new companies
- Amount of venture capital/angel investment or other non-grant funding obtained for development of the technology
- Percentage of awardees that receive such funding
- Percentage of awardees in ongoing discussions with venture capital firms/angel investors that have not yet resulted in funding
- Percentage of awards where the small business developer is acquired by a larger company
- Percentage of awards where partnerships are formed between the small business developer and one or more larger companies to develop or commercialize the technology

### 4. Intermediate Outcome 4: Progress toward Clinical Use

The steps required to advance clinically focused technologies toward dissemination and use are set by FDA regulations. Therefore, completion of these various FDA-mandated steps represents important intermediate outcomes for clinically focused technology development initiatives. Although the relevant measures of success will be affected by context (e.g., Class II versus Class III devices[22]), recommended measures for achieving these intermediate outcomes are:

- Percentage of awardees that engage in pre-Investigational Device Exemption (IDE) discussions with FDA
- Percentage of awardees that file IDEs
- Percentage of awardees that receive IDEs
- Percentage of awardees that initiate early-stage clinical trials
- Percentage of awardees that complete early-stage clinical trials
- Percentage of awardees with successful early-stage clinical trials
- Percentage of awardees that initiate pivotal clinical trials
- Percentage of awardees that complete pivotal clinical trials
- Percentage of awardees with successfully completed pivotal clinical trials
- Percentage of awardees that file premarket notifications per Section 510(k) of the Federal Food, Drug and Cosmetic Act or file premarket approval applications with FDA
- Percentage of awardees that receive 510(k) clearance or premarket approval

### 5. Intermediate Outcome 5: Data and Software Downloads

Downloads of software, algorithms, or data sets from technology development awards by other investigators is an important intermediate outcome. While downloads do not necessarily imply that the information technologies are used, it is a necessary step toward such use, and one that can be regularly tracked and reported by awardees. Recommended measures of success for this intermediate outcome are:

- Number of registered users of web portals for downloading data sets/software/algorithms
- Number of downloads of data sets/software/algorithms

[22] For more information on FDA device classifications, see FDA website, "What Does It Mean for FDA to "Classify" a Medical Device?" http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm.

- Number of downloads by category of registered users if awardees require registration before downloading
- Percentage of technologies that have been downloaded
- Percentage of awards with downloads of software, algorithms, or data sets
- Percentage of awards where all available technologies have been downloaded at least once

## C. Measure Implementation

In implementing the recommended performance measures, it is important to consider the following points:

- Although the recommended performance measures were developed based on analysis of FOAs solely directed at technology development, they should also be applicable to investigator-initiated technology development projects and projects that are conducted under FOAs that have technology development as only one of several project categories.
- With the exception of the "dissemination and use" ultimate measure, which should be applicable to all technology development projects, careful attention should be paid to which of the performance measures are applicable to a given technology development initiative. In other words, the recommended measures should be thought of as an overall framework that may be applied differently to individual programs.
- Some technology development projects may have attributes that would not be captured by the recommended performance measures. For example, some may be specifically targeted at high-risk, "blue sky" technology development objectives. For those initiatives, it will be important to also apply performance measures applicable to high-risk endeavors in addition to the measures specifically tailored to technology development.
- Technology development-related outcome measures are not readily available from existing NIH reporting frameworks. The current Research Performance Progress Report (RPPR) includes space to list technologies and products developed as free text rather than as closed-form fields suitable for analysis. Similarly, the initial iteration of the emerging NIH Portfolio Analysis and Reporting Data Infrastructure (PARDI) will focus more heavily on outcome measures related to research results, training, and clinical impact generally rather than on technology development-related outcomes specifically.

## D. Approaches to Data Collection

Program officers who currently collect data with respect to any of the measures described above unanimously stated that data collection for both the ultimate and the intermediate measures (with the exception of milestone achievement) requires extensive manual effort by program staff or ad hoc interactions with relevant investigators. This is because the standard annual Research Performance Progress Report (RPPR) reporting mechanism does not include the required data and, more importantly, much of the data will be available only after the end of the award period, and most awards do not require any post-award reporting to NIH. Several approaches are recommended below which should improve the feasibility and efficiency of data collection. Implementation of these data collection approaches should be based on an analysis by NIH of which might best be implemented for all technology development initiatives and which should be implemented only on a program-by-program basis.

### 1. Post-Award Reporting

Several program officers mentioned unprompted that the best mechanism to collect success-related data for technology development initiatives would be to conduct post-award investigator surveys or require post-award reporting. Some of these program officers specifically noted the final reporting required at the end of Phase II SBIR awards[23] as an approach that could, in theory, be implemented more broadly and expanded to require additional information as well as post-award reporting.

The Phase II SBIR reporting form, in addition to requesting answers to several open-ended questions, asks for the following specific information:

- If a company has changed names, the company's new name
- Lists of patents, patent applications, copyrights, trademarks, and invention disclosures
- Nature of the technology (e.g., medical device or research tool).
- Level of progress/current state of the technology
- Clinical trial progress, regulatory status, and insurance reimbursement status
- Follow-on funding by sector (e.g., venture capital, angel investor, and local government)
- Licensing status of the IP associated with the technology

[23] See U.S. Department of Health and Human Services, Public Health Service, SBIR/STTR Phase II Final Progress Report" OMB No. 0925-0002, available from http://grants.nih.gov/grants/funding/finalprogressreport_SBIR_PhaseII.doc.

- Sales associated with the commercialization of the technology

The Phase II report form thus requests information with regard to several of the ultimate and intermediate measures recommended for technology development initiatives. However, the requested information would need to be expanded substantially to cover all the recommended measures, especially for the research-focused initiatives.

STPI researchers therefore recommend that NIH consider expanding the Phase II SBIR reporting form and requiring its completion by all technology development awardees, both at the point of award completion and at designated, regular post-award intervals (e.g., 3 years and 5 years). STPI researcher recommendations for expanding the requested information are as follows:

***Dissemination and Use Measure***

- Research-Focused Technologies
  - Name(s) by which the technology is known or referenced
  - Publication(s) that describe the technology and its development (including providing PUBMED identification numbers)
  - Publications by the awardee(s) reporting use of the technology
  - Grant applications submitted by the awardee(s) to NIH and other funders where the technology is integral to the proposed research
  - Grant awards received by the awardee(s) from NIH and other funders where the technology is integral to the proposed research
  - Non-awardee investigators (names and university affiliations) using the technology, to the extent known
  - Publications by non-awardee investigators reporting use of the technology, to the extent known
- Clinically Focused Technologies
  - Name(s) by which the technology is known or referenced
  - Clinical practice guidelines specifying use of the technology

***Increased Activity in Technology Development Domain***

- Description of other research or commercial activity in the technology development domain, to the extent known

***Conversion of Exploratory Awards***

- Follow-on R33 or R01 applications (R21 awardees)
- Follow-on R33 or R01 awards (R21 awardees)

- Follow-on SBIR/STTR Phase II applications (SBIR/STTR Phase I awardees)
- Follow-on SBIR/STTR Phase II awards (SBIR/STTR Phase I awardees)

***Technology Licensing/Pre-Commercialization***

- New companies formed to further develop and commercialize the technology
- Discussions (past and ongoing) with venture capital firms/angel investors that have not yet resulted in funding
- Acquisition of the company that developed the technology
- Partnerships between the small business developer and one or more larger companies to develop or commercialize the technology

***Progress toward Clinical Use***

- Pre-IDE discussions with FDA (past and ongoing)
- IDE number
- FDA device class (e.g., Class II, Class III)
- 510(k) clearance number
- Premarket approval number

***Data/Software Downloads***

- Number of registered users of web portals for downloading data sets/software/algorithms
- Number of downloads of data sets/software/algorithms
- Number of downloads by category of registered users if awardees require registration before downloading
- Percentage of available technologies that have been downloaded

**2. Bibliometric Analysis**

If awardees identify, in post-award reporting, publications that describe the technology and its development, standard bibliometric analysis can determine the number and rate of citations to the publication(s). However, the "dissemination and use" measure requires that any citing publication that comments negatively on the technology be subtracted from the raw citation number. Therefore, the citing publications will have to be retrieved and manually examined to identify any that comment negatively on the technology.

If awardees identify, in post-award reporting, publications reporting use of the technology, standard bibliometric analysis can determine the number and rate of citations

to that publication as a measure of the scientific importance of the research conducted using the technology.

### 3. Publication/Grant Application Analysis

Although post-award reporting may identify some non-awardee investigators using the technology and some publications by non-awardee investigators reporting use of the technology, this information will not be sufficiently reliable for use in evaluating dissemination and use of a technology beyond the developing investigators. Moreover, the post-award reporting will not be useful for identifying NIH grant applications submitted and awards received by non-awardee investigators where the technology is integral to the proposed research.

Therefore, it will be important to also collect data on these measures of dissemination and use through automated searching of Medline publications and NIH grant databases for the name of the technology[24] or for references to the publication(s) describing the technology and its development. Such automated searching would also be the only approach for data collection relative to the second ultimate objective of an increase in overall research activity in the relevant technology development domain. However, in both cases, this would identify only publications, applications, and awards for further manual analysis in order to assess whether, and how, the developed technologies are actually being used or whether there is actually increased activity in the technology domain. [25] It is worth noting that NIH is funding a Data Discovery Index consortium (http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-031.html) intended to develop mechanisms for identifying data sets and other objects using formats comparable to the Uniform Resource Locator (URL). Should this consortium be successful in developing a common nomenclature for automated identification of technologies and technology development domains, this could potentially facilitate the identification of relevant publications, applications, and awards. However, manual analysis would still be required to assess their relevance to measures of success for technology development initiatives.

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[24] This would be facilitated by requesting in the post-award survey all of the names by which a technology is known or referenced.

[25] It would be possible when retrieving grant applications for manual analysis to also access the review summary statements and analyze those statements for any reviewer comments about the technology itself. However, since reviewers are not required to comment on the technology, reviewer comments would not provide valid data relative to performance across all NIH technology development efforts. Rather, such comments could be noted when examining an individual program, but could not be used for cross-program analysis.

### 4. Commercial Activity in Technology Development Domain

Although post-award reporting may provide some information on increased commercial activity in the relevant technology development domain, this will not be sufficiently reliable for use in evaluating performance of an initiative against this measure. Therefore, it will be important to collect data on this measure through manual searching of publicly available information and also by relying on the knowledge gained by NIH program officers active in the technology development domain. One approach would be to adopt a "passive" data collection approach. Internet content notification systems (e.g., such as the "Google Alert" service) use pre-set keywords to notify users when a relevant Internet document is created or changed. Program managers could develop alerts for their awardees (e.g., based on the name of the PI and the name of the technology) that would provide notification when new public information regarding "their" technologies is posted to the Internet. If a technology is successful, collating its mentions through such alerts may address some of the measures. Program officers could also use this information to identify the number of other entities working on the particular technology development problem addressed by an award or a program.

### 5. Expert Panels

Some concern was expressed that post-award reporting might not be a valid approach to evaluate success, as PIs are likely to overestimate dissemination and use. Moreover, automated searching of publications and grant applications followed by manual analysis for evidence of dissemination and use as well as an increase in overall research activity in the relevant technology development domain may prove too laborious to be implemented. Therefore, an alternative approach would be to convene expert panels to gauge whether a technology has achieved widespread dissemination and use and also, if relevant, stimulated increased research activity in the relevant technology development domain. These panels could also provide insight about dissemination and use in venues for which objective data may be difficult to obtain (e.g., use of NIH-developed technologies in industry settings).

### 6. Milestone Analysis

Collecting data with regard to achievement of milestones should be straightforward based on program officer review of awardee annual and final progress reports. However, NIH should consider facilitating identification of milestone achievement by developing a standard template for recording milestones in grant applications for technology development projects and a standard template in RPPR for reporting progress toward achieving those milestones. Program staff could then easily access the information to assess performance against this intermediate outcome measure.

## 7. Relevance of Publication and Patent Data

Program officers noted that neither the number of publications acknowledging an award nor the number of citations to those publications serve as useful measures of the success of technology development initiatives. Publications associated with awards may include fundamental research attempting to establish the basis for a technology, early efforts at technology development, full descriptions of a validated and useful technology, or follow-on uses of the technology. Citations to those publications may indicate that the technology is being used successfully or may report that the technology is ineffective or that a different technology is superior to it. Counting publications and citations, without follow-on analysis of the content, was therefore not considered meaningful. Another concern with using publications as measures of success for technology development initiatives is that small business-affiliated investigators are likely to have different incentives with respect to publication. Most companies are less likely to publish their scientific results in the peer-reviewed literature than would academics working in a similar domain that renders cross-program assessment based on publications difficult.

Similarly, patent applications and patents were not considered to be useful measures of success. One concern is that protecting intellectual property generally occurs early in the development of a technology and there is no guarantee that the protected technology will actually become fully developed or useful. Patent application and patent data are, however, viewed as useful for identifying awards whose technologies are more likely to become licensed. This information would allow any manual collection of data regarding licensing or technology hand-offs to third parties to be focused on those awards that have at least applied for patents. A second concern with relying on numbers of patent applications and patents as a measure is that there are some technology development areas (e.g., IT technologies) where patenting may be less likely to occur, so using patent activity as a standard measure may underweight the contributions of these technology development approaches.

# Appendix A.
# Funding Opportunity Announcements (FOAs) Included in Catalog

## List of FOAs by Group

**Table A-1. List of FOAs by Group**

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Adaptation of Scalable Technologies to Illuminate the Druggable Genome* | RFA-RM-13-010 [U01] | 1 | 2013 |
| Advanced Development of Informatics Technology | PAR-12-286 [R01], PAR-12-287 [U24], PAR-12-288 [U01], PAR-12-289 [U01], PAR-12-290 [P01], PAR-13-294 [U24], PAR-13-330 [P01] | 7 | 2012 |
| Advanced Neural Prosthetics Research and Development | PA-09-063 [U01], PA-09-064 [U44], PA-11-147 [U01], PAR-12-053 [U01], PAR-12-054 [U44] | 5 | 2009 |
| Advanced Technologies for Detection of Perturbation-Induced Cellular Signatures* | RFA-RM-10-004 [U01] | 1 | 2011 |
| Advanced Tools and Technologies for Cerebrospinal Fluid Shunts | PA-09-205 [R41/R42], PA-09-206 [R43/R44], PA-12-189 [R43/R44], PA-12-190 [R41/R42] | 4 | 2009 |
| Advanced Tools and Technologies for Deep Brain Stimulation | PA-07-395 [R41/R42], PA-10-175 [R41/R42] | 2 | 2007 |
| Applications of Imaging and Sensor Technologies for Clinical Aging Research | PAS-05-131 [R41/R42; R43/R44], PAS-06-130 [R43/R44], PAS-06-131 [R41/R42] | 3 | 2005 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Blood Pressure Measurement Technologies for Low-Resource Settings in the U.S. and India | RFA-EB-13-001 [U01], RFA-EB-14-002 [U01] | 2 | 2013 |
| BRAIN Initiative: New Technologies and Novel Approaches for Large-Scale Recording and Modulation in the Nervous System | RFA-NS-14-007 [U01] | 1 | 2014 |
| BRAIN Initiative: Optimization of Transformative Technologies for Large Scale Recording and Modulation in the Nervous System | RFA-NS-14-008 [U01] | 1 | 2014 |
| Cancer Detection, Diagnostic and Treatment Technologies for Global Health | RFA-CA-13-015 [UH2/UH3] | 1 | 2013 |
| Clinical Neuroscience and Entertainment Software Pilot Partnership Program to Develop Neuropsychiatric Interventions | RFA-MH-13-100 [R43/R44], RFA-MH-14-010 [R43/R44] | 2 | 2011 |
| Clinical Proteomics Technology Assessment Consortium (CPTAC): Proteome Characterization Centers | RFA-CA-07-005 [R01, R21, R21/R33], RFA-CA-07-012 [U24], RFA-CA-10-016 [U24] | 3 | 2006 |
| Computational Tool Development and Integrative Data Analysis for LINCS* | RFA-RM-10-005 [U01] | 1 | 2011 |
| Developing a Point-of-Care Device for the Diagnosis of Sickle Cell Disease in Low Resource Settings | RFA-HL-14-010 [R43/R44] | 1 | 2013 |
| Developing Improved Assessments of Tissue Oxygenation | RFA-HL-15-003 [R43/R44], RFA-HL-15-007 [R41] | 2 | 2014 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Development and Application of New Technologies to Targeted Genome-wide Resequencing in Well-Phenotyped Populations | RFA-HL-08-004 [R01] | 1 | 2008 |
| Development and Implementation of Innovative Ultrasound Therapy Technologies | RFA-EB-07-004 [R01] | 1 | 2007 |
| Development of a Microfluidic Platform for Blood Testing in Neonatal and Pediatric Patients | RFA-HL-14-025 [R41], RFA-HL-14-026 [R43/R44] | 2 | 2014 |
| Development of a Vestibular Neural Prosthesis | RFA-DC-13-001 [R01] | | 2012 |
| Development of Advanced Genomic Characterization Technologies | RFA-CA-07-021 [R21], RFA-CA-07-029 [R43/R44], RFA-CA-07-030 [R41/R42] | 3 | 2006 |
| Development of Diagnostic Screening Test for Salt Sensitivity | PA-06-033 [R43/R44], PA-06-034 [R41/R42] | 2 | 2005 |
| Development of Highly Innovative Tools and Technology for Analysis of Single Cells | PA-13-140 [R43/R44] | 1 | 2013 |
| Development of Software and Analysis Methods for Biomedical Big Data in Targeted Areas of High Need | RFA-HG-14-020 [U01] | 1 | 2014 |
| Development of Tools to Study the Synaptome | RFA-MH-12-140 [R21] | 1 | 2012 |
| Diabetes Impact Award-Closed Loop Technologies: Development and Integration of Novel Components for an Automated Artificial Pancreas System | RFA-DK-12-021 [DP3], RFA-DK-14-015 [DP3] | 2 | 2013 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Direct Phase II SBIR Grants to Support Biomedical Technology Development | PAR-14-088 [R44] | 1 | 2014 |
| Early-Stage Development of Innovative Technologies for Biospecimen Science | RFA-CA-06-004 [R21, R33, R21/R33], RFA-CA-06-007 [R41/R42, R43/R44], RFA-CA-07-003 [R21, R33, R21/R33], RFA-CA-07-010 [R43/R44], RFA-CA-07-011 [R41/R42], RFA-CA-07-022 [R21], RFA-CA-07-023 [R33], RFA-CA-07-037 [R21], RFA-CA-07-038 [R33], RFA-CA-07-043 [R43/R44], RFA-CA-07-044 [R41/R42], RFA-CA-08-009 [R21], RFA-CA-08-010 [R33], RFA-CA-08-013 [R43/R44], RFA-CA-08-014 [R41/R42], RFA-CA-09-004 [R21], RFA-CA-09-005 [R33], RFA-CA-10-001 [R21], RFA-CA-10-002 [R33], RFA-CA-12-004 [R21], RFA-CA-12-005 [R33], RFA-CA-13-003 [R21], RFA-CA-13-004 [R33], RFA-CA-14-005 [R21], RFA-CA-14-006 [R33] | 25 | 2005 |
| Early-Stage Innovative Molecular Analysis Technology Development for Cancer Research | RFA-CA-06-002 [R21, R33], RFA-CA-06-005 [R41/R42, R43/R44], RFA-CA-07-001 [R21, R33], RFA-CA-07-006 [R43/R44], RFA-CA-07-007 [R41/R42], RFA-CA-07-015 [R21], RFA-CA-07-016 [R33], RFA-CA-07-033 [R21], RFA-CA-07-034 [R33], RFA-CA-07-039 [R43/R44], RFA-CA-07-040 [R41/R42], RFA-CA-07-041 [R43/R44], RFA-CA-07-042 [R41/R42], RFA-CA-08-006 [R21], RFA-CA-08-011 [R43/R44], RFA-CA-08-012 [R41/R42], RFA-CA-09-008 [R21], RFA-CA-10-005 [R21], RFA-CA-10-013 [R43/R44], RFA-CA-12-002 [R21], RFA-CA-13-001 [R21], PAR-13-327 [R43/R44], RFA-CA-14-003 [R21] | 23 | 2005 |
| Enabling Technologies for Tissue Engineering and Regenerative Medicine | PAR-06-504 [R01] | 1 | 2006 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Exceptionally Innovative Tools and Technologies for Single Cell Analysis* | RFA-RM-11-013 [U01], RFA-RM-11-014 [R21], RFA-RM-11-015 [R01], RFA-RM-13-020 [R33], RFA-RM-13-021 [R21], RFA-RM-13-022 [R01], RFA-RM-13-023 [U01] | 7 | 2011 |
| High Throughput Tools for Brain and Behavior | PA-06-023 [R43/R44], PA-06-024 [R41/R42], PA-08-001 [R43/R44], PA-08-002 [R41/R42] | 4 | 2006 |
| Imaging Diagnostics of Dental Diseases and Conditions (Caries, Periodontal Disease, Cracked Teeth, and Pulp Vitality) | PA-12-193 [R41/R42], PA-12-195 [R43/R44] | 2 | 2012 |
| Improved Biomaterials for Urinary and Dialysis Catheters | PA-13-050 [R43/R44], PA-13-051 [R41/R42] | 2 | 2013 |
| Indo-US Collaborative Program on Affordable Medical Devices | PAR-11-044 [R03], PAR-13-390 [R03] | 2 | 2010 |
| Informatics Tools for High-Throughput Sequence Data Analysis | RFA-HG-10-018 [U01], RFA-HG-10-019 [R43/R44] | 2 | 2011 |
| Innovative Health Information Technology for Broad Adoption by Healthcare Systems and Consumers | PA-12-196 [R44] | 1 | 2012 |
| Innovative Technologies and Assays in Support of HIV Cure Research (ITAS-Cure) | PA-14-101 [R43/R44], PA-14-102 [R41/R42] | 2 | 2014 |
| Instrument Development for Biomedical Applications | RFA-RR-05-001 [R01, R21, R21/R33], RFA-RR-05-001 [R21], RFA-RR-06-004 [R21], RFA-RR-08-001 [R21], RFA-RR-09-001 [R21], RFA-RR-10-009 [R21], RFA-RR-11-005 [R21], RFA-GM-13-010 [R21], RFA-GM-14-014 [R21] | 8 | 2005 |
| Integration of Heterogeneous Data Sources | PA-06-010 [R41/R42], PA-06-011 [R43/R44] | 2 | 2006 |
| In-vivo Methods for Assessing Placental Development and Function | RFA-HD-14-004 [R41/R42], RFA-HD-14-005 [R43/R44] | 2 | 2013 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Lab to Marketplace: Tools for Brain and Behavioral Research | PA-08-071 [R43/R44], PA-11-134 [R43/R44], PA-14-250 [R43/R44] | 3 | 2008 |
| Limited Competition: Competitive Revision for Technology Development within Biomedical Technology Research Centers | PAR-12-046 [P41] | 1 | 2012 |
| Manufacturing Processes of Medical, Dental, and Biological Technologies | PA-06-012 [R41/R42], PA-06-013 [R43/R44], PA-09-113 [R43/R44], PA-09-114 [R41/R42] | 4 | 2006 |
| Methods Development for Obtaining Comprehensive Genomic Information from Human Specimens that are Easy to Collect and Store | PAR-13-203 [R43/R44] | 1 | 2013 |
| Mobile Health: Technology and Outcomes in Low and Middle Income Countries | PAR-14-028 [R21] | 1 | 2014 |
| Molecular Libraries Screening Instrumentation* | PA-06-019 [R43/R44], PA-06-020 [R41/R42], RFA-RM-04-020 [R01] | 3 | 2005 |
| Multiplex Assay Development for Arthritis and Musculoskeletal and Skin Diseases | PA-09-127 [R43/R44], PA-12-191 [R43/R44] | 2 | 2009 |
| National Technology Centers for Networks and Pathways Program* | RFA-RM-04-019 [U54], RFA-RM-08-021 [U54] | 2 | 2008 |
| Near-Term Technology Development for Genome Sequencing | RFA-HG-05-003 [R01, R21, R21/R33], RFA-HG-06-002 [R43/R44], RFA-HG-06-003 [R41/R42], RFA-HG-06-015 [R01], RFA-HG-06-016 [R21], RFA-HG-06-018 [R43/R44], RFA-HG-06-019 [R41/R42], RFA-HG-07-016 [R01], RFA-HG-07-017 [R21], RFA-HG-07-018 [R43/R44], RFA-HG-07-019 [R41/R42] | 11 | 2005 |
| Neurotechnology Research, Development, and Enhancement | PA-06-278 [R21], PA-06-279 [R01] | 2 | 2006 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| New Technologies for Transient Molecular Complex Characterization | PA-08-110 [R43/R44], PA-08-111 [R41/R42] | 2 | 2008 |
| New Technology for Proteomics and Glycomics | PA-06-128 [R43/R44], PA-06-129 [R41/R42], PA-07-451 [R43/R44], PA-07-452 [R41/R42], PA-11-214 [R41/R42], PA-11-215 [R43/R44] | 6 | 2006 |
| New Technology to Screen for Mild Hearing Loss in Children | PA-06-546 [R43/R44], PA-06-547 [R41/R42] | 2 | 2006 |
| Novel Assays for Screening the Effects of Chemical Toxicants on Cell Differentiation | RFA-ES-13-003 [R43] | 1 | 2013 |
| Novel Methods for Obtaining Molecular Information from Archived Tissue Samples | RFA-ES-13-009 [R43/R44] | 1 | 2013 |
| Novel Technologies For In Vivo Imaging | PA-06-398 [R21/R33], PA-06-399 [R33] | 2 | 2006 |
| Novel Technologies for Rapid and Sensitive Biomonitoring in Humans | RFA-ES-12-004 [R43/R44], RFA-ES-14-005 [R43/R44] | 2 | 2012 |
| Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care | RFA-HL-14-011 [R43/R44], RFA-HL-14-017 [R41/R42] | 2 | 2013 |
| Orthotics for Pediatric Populations | RFA-HD-14-028 [R41], RFA-HD-14-029 [R43] | 2 | 2013 |
| Point-of-Care Technologies Research Network | RFA-EB-06-002 [U54], RFA-EB-11-002 [U54] | 2 | 2007 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Revolutionary Genome Sequencing Technologies: The $1000 Genome | RFA-HG-05-004 [R01, R21, R21/R33], RFA-HG-06-004 [R43/R44], RFA-HG-06-005 [R41/R42], RFA-HG-06-020 [R01], RFA-HG-06-021 [R21], RFA-HG-06-022 [R21/R33], RFA-HG-06-023 [R43/R44], RFA-HG-06-024 [R41/R42], RFA-HG-07-020 [R01], RFA-HG-07-021 [R21], RFA-HG-07-022 [R43/R44], RFA-HG-07-023 [R41/R42], RFA-HG-08-008 [R01], RFA-HG-08-009 [R21], RFA-HG-08-010 [R43/R44], RFA-HG-08-011 [R41/R42], RFA-HG-09-011 [R01], RFA-HG-09-012 [R21], RFA-HG-09-013 [R43/R44], RFA-HG-10-012 [R01], RFA-HG-10-013 [R21], RFA-HG-10-014 [R43/R44], RFA-HG-13-005 [R01], RFA-HG-13-006 [R21], RFA-HG-13-007 [R43/R44] | 25 | 2005 |
| Robotics Technology Development and Deployment [RTD2] | PAR-10-279 [R43] | 1 | 2010 |
| Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings | RFA-HD-09-017 [R43], RFA-HD-09-018 [R41], RFA-HD-10-012 [R43], RFA-HD-10-013 [R41], RFA-HD-12-192 [R43], RFA-HD-12-193 [R41], PAR-13-090 [R43/R44], PAR-13-091 [R41/R42] | 8 | 2009 |
| Small Business Innovation Research to Develop New Methods and Technologies able to Identify Individuals at Risk of Developing Type 1 Diabetes (T1D) | RFA-DK-11-024 [R43] | 1 | 2011 |
| Small Business Innovation Research to Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes (T1D): Towards an Artificial Pancreas | RFA-DK-09-001 [R43/R44], RFA-DK-10-008 [R43/R44], RFA-DK-11-018 [R43/R44], RFA-DK-13-001 [R43/R44], RFA-DK-13-028 [R43/R44] | 5 | 2009 |
| Technologies and Software to Support Integrative Cancer Biology Research | PA-09-188 [R43/R44], PAS-07-242 [R43/R44] | 2 | 2007 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Technologies for Healthy Independent Living | PAR-11-020 [R01], PAR-11-021 [R21], PAR-14-118 [R01], PAR-14-119 [R21] | 4 | 2010 |
| Technologies for Image-Guided Interventions | RFA-EB-06-003 [R21], RFA-EB-09-002 [R01] | 2 | 2006 |
| Technologies To Assess Sleep Health Status in Populations | RFA-HL-14-013 [R43/R44] | 1 | 2013 |
| Technology Development for High-Throughput Functional Genomics | RFA-HG-07-028 [R21], RFA-HG-07-029 [R01], RFA-HG-11-013 [R01], RFA-HG-11-014 [R21], RFA-HG-11-015 [R43/R44] | 5 | 2006 |
| Technology Development for High-Throughput Structural Biology Research | PAR-10-073 [R01], PAR-10-074 [P01], PAR-13-032 [R01] | 3 | 2010 |
| Technology Development for Protein Modeling | PAR-10-075 [P01], PAR-10-076 [R01], PAR-13-033 [R01] | 3 | 2010 |
| Technology Development for the Detection and Evaluation of Chemical and Biological Carcinogens | PA-09-187 [R43/R44], PAS-07-240 [R43/R44] | 2 | 2007 |
| Technology Development in Epigenetics* | RFA-RM-07-011 [R01], RFA-RM-07-012 [R21], RFA-RM-09-016 [R01], RFA-RM-12-026 [R01] | 4 | 2008 |
| Technology Development to Enable Large Scale Metabolomics Analyses* | RFA-RM-11-019 [R01] | 1 | 2011 |
| Technology for the Detection and Characterization of Low Abundance Proteins, Peptides, or micro RNAs | PA-09-189 [R43/R44], PAS-07-241 [R43/R44] | 2 | 2007 |
| Tools & Technologies for Assessing Manual Therapies | RFA-AT-07-001 [R43/R44], RFA-AT-08-001 [R43/R44], RFA-AT-09-003 [R43/R44] | 3 | 2006 |
| Tools to Enhance Studies of Glial Cell Development, Aging, Disease and Repair | RFA-HD-12-211 [R21] | 1 | 2012 |

| Group Title | FOAs in Group | Number of Issuances with First Acceptance Dates in Calendar Year 2005–2014 | Year of First Issuance in the Catalog (2005 or Later) |
|---|---|---|---|
| Validation and Advanced Development of Emerging Molecular Analysis Technologies for Cancer Research | RFA-CA-06-003 [R21, R33, R21/R33], RFA-CA-07-002 [R21, R33, R21/R33], RFA-CA-07-017 [R21], RFA-CA-07-018 [R33], RFA-CA-07-019 [R21/R33], RFA-CA-07-035 [R21], RFA-CA-07-036 [R33], RFA-CA-08-007 [R21], RFA-CA-08-008 [R33], RFA-CA-09-006 [R21], RFA-CA-09-007 [R33], RFA-CA-10-003 [R21], RFA-CA-10-004 [R33], RFA-CA-12-003 [R33], RFA-CA-13-002 [R33], RFA-CA-14-004 [R33] | 16 | 2005 |
| Validation and Demonstration of Devices for Environmental Exposure Assessment | RFA-ES-13-013 [R21/R33] | 1 | 2014 |
| Validation of Molecular Diagnostics to Predict Patient Outcomes Using Specimens from Multi-Site Cancer Trials | PA-05-062 [R01, R21], PA-06-296 [R21], PA-08-133 [R21], PA-12-013 [R01], PA-12-014 [R21] | 5 | 2005 |
| Validation of New Technologies for Clinical Assessment of Tooth Surface Demineralization | RFA-DE-06-008 [R01, R21] | 1 | 2006 |

* FOA groups where one or more FOA iterations were issued as part of the NIH Common Fund/Roadmap.

## Awards and Funding

**Table A-3. Number of Awards and Funding in Groups**

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Adaptation of Scalable Technologies to Illuminate the Druggable Genome | 41 | 7 | MH | 14 | $3.4M | $5.5M |
| Advanced Development of Informatics Technology | 169 | 27 | CA | 54 | $19.9M | $27.5M |
| Advanced Neural Prosthetics Research and Development | 66 | 9 | EB, NS | 24 | $13.8M | $18.3M |
| Advanced Technologies for Detection of Perturbation-Induced Cellular Signatures | 19 | 4 | CA | 13 | $6.3M | $8.3M |
| Advanced Tools and Technologies for Cerebrospinal Fluid Shunts | 81 | 10 | NS, HD | 19 | $7.0M | $10.3M |
| Advanced Tools and Technologies for Deep Brain Stimulation | 16 | 1 | MH, NS, AG | 7 | $3.4M | $4.2M |
| Applications of Imaging and Sensor Technologies for Clinical Aging Research | 24 | 3 | AG, MD | 3 | $0.3M | $0.4M |
| Blood Pressure Measurement Technologies for Low-Resource Settings in the U.S. and India | 20 | 5 | EB | 6 | $2.4M | $2.9M |
| BRAIN Initiative: New Technologies and Novel Approaches for Large-Scale Recording and Modulation in the Nervous System | 78 | 11 | NS | 22 | $11.9M | $15.5M |
| BRAIN Initiative: Optimization of Transformative Technologies for Large Scale Recording and Modulation in the Nervous System | 46 | 8 | NS | 16 | $7.0M | $9.3M |

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Cancer Detection, Diagnostic and Treatment Technologies for Global Health | 104 | 6 | CA, EB | 14 | $5.9M | $6.8M |
| Clinical Neuroscience and Entertainment Software Pilot Partnership Program to Develop Neuropsychiatric Interventions | 32 | 3 | MH | 6 | $1.6M | $2.3M |
| Clinical Proteomics Technology Assessment Consortium (CPTAC): Proteome Characterization Centers | 423 | 61 | CA | 231 | $123.6M | $160.8M |
| Computational Tool Development and Integrative Data Analysis for LINCS | 29 | 4 | HL | 19 | $3.7M | $4.9M |
| Developing a Point-of-Care Device for the Diagnosis of Sickle Cell Disease in Low Resource Settings | 29 | 6 | HL | 12 | $2.1M | $2.7M |
| Developing Improved Assessments of Tissue Oxygenation | 14 | 4 | HL | 4 | $0.4M | $0.6M |
| Development and Application of New Technologies to Targeted Genome-wide Resequencing in Well-Phenotyped Populations | 16 | 3 | HL | 7 | $9.4M | $12.3M |
| Development and Implementation of Innovative Ultrasound Therapy Technologies | 85 | 9 | EB | 48 | $14.7M | $20.9M |
| Development of a Microfluidic Platform for Blood Testing in Neonatal and Pediatric Patients | 27 | 3 | HL | 3 | $0.5M | $0.7M |
| Development of a Vestibular Neural Prosthesis | 6 | 2 | DC | 5 | $1.8M | $2.7M |
| Development of Advanced Genomic Characterization Technologies | 46 | 8 | HG, CA | 16 | $2.2M | $3.4M |

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Development of Diagnostic Screening Test for Salt Sensitivity | 3 | 0 | N/A | 0 | $0.0M | $0.0M |
| Development of Highly Innovative Tools and Technology for Analysis of Single Cells | 57 | 8 | EB, GM, HG, HL, NS, TR | 9 | $1.2M | $1.5M |
| Development of Software and Analysis Methods for Biomedical Big Data in Targeted Areas of High Need | 106 | 18 | HG, CA, EB | 18 | $5.5M | $8.0M |
| Development of Tools to Study the Synaptome | 30 | 6 | MH | 12 | $1.6M | $2.7M |
| Diabetes Impact Award-Closed Loop Technologies: Development and Integration of Novel Components for an Automated Artificial Pancreas System | 36 | 8 | DK | 9 | $12.9M | $17.5M |
| Direct Phase II SBIR Grants to Support Biomedical Technology Development | 400 | 63 | 17 ICs | 63 | $40.2M | $53.7M |
| Early-Stage Development of Innovative Technologies for Biospecimen Science | 717 | 90 | CA | 195 | $33.1M | $46.1M |
| Early-Stage Innovative Molecular Analysis Technology Development for Cancer Research | 2,575 | 233 | CA | 514 | $78.3M | $116.5M |
| Enabling Technologies for Tissue Engineering and Regenerative Medicine | 281 | 27 | AR, DC, DE, EB, HL | 111 | $33.1M | $47.5M |
| Exceptionally Innovative Tools and Technologies for Single Cell Analysis | 340 | 42 | 14 ICs | 121 | $47.3M | $65.5M |
| High Throughput Tools for Brain and Behavior | 158 | 31 | AA, AI, DA, GM, MH, NS | 67 | $16.5M | $23.0M |
| Imaging Diagnostics of Dental Diseases and Conditions (Caries, Periodontal Disease, Cracked Teeth, and Pulp Vitality) | 22 | 8 | DE | 9 | $1.5M | $2.0M |

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Improved Biomaterials for Urinary and Dialysis Catheters | 22 | 4 | DK | 4 | $1.2M | $1.5M |
| Indo-US Collaborative Program on Affordable Medical Devices | 103 | 9 | EB | 15 | $1.0M | $1.5M |
| Informatics Tools for High-Throughput Sequence Data Analysis | 65 | 11 | HG | 40 | $18.5M | $21.8M |
| Innovative Health Information Technology for Broad Adoption by Healthcare Systems and Consumers | 39 | 0 | N/A | 0 | $0.0M | $0.0M |
| Innovative Technologies and Assays in Support of HIV Cure Research (ITAS-Cure) | 9 | 1 | AI | 2 | $0.2M | $0.3M |
| Instrument Development for Biomedical Applications | 1388 | 165 | EB, GM, RR | 488 | $134.0M | $174.2M |
| Integration of Heterogeneous Data Sources | 68 | 9 | CA, EY, HG, RR | 21 | $6.6M | $8.8M |
| In-vivo Methods for Assessing Placental Development and Function | 2 | 0 | N/A | 0 | $0.0M | $0.0M |
| Lab to Marketplace: Tools for Brain and Behavioral Research | 443 | 81 | 10 ICs | 154 | $41.2M | $54.3M |
| Limited Competition: Competitive Revision for Technology Development within Biomedical Technology Research Centers | 22 | 11 | EB, GM | 11 | $2.4M | $3.4M |
| Manufacturing Processes of Medical, Dental, and Biological Technologies | 579 | 90 | 15 ICs | 121 | $28.7M | $38.9M |
| Methods Development for Obtaining Comprehensive Genomic Information from Human Specimens that are Easy to Collect and Store | 7 | 2 | HG | 2 | $0.4M | $0.4M |

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Mobile Health: Technology and Outcomes in Low and Middle Income Countries | 228 | 16 | TW, HD, MH | 25 | $3.2M | $4.3M |
| Molecular Libraries Screening Instrumentation | 78 | 15 | HG, EB, GM, DK | 47 | $13.8M | $19.2M |
| Multiplex Assay Development for Arthritis and Musculoskeletal and Skin Diseases | 68 | 7 | AR | 7 | $1.0M | $1.5M |
| National Technology Centers for Networks and Pathways Program | 58 | 6 | GM, RR, AI, NS, HL | 37 | $62.5M | $81.7M |
| Near-Term Technology Development for Genome Sequencing | 68 | 11 | HG | 34 | $17.0M | $22.5M |
| Neurotechnology Research, Development, and Enhancement | 395 | 58 | AG, EB, DA, DC, MH, NS | 125 | $17.7M | $26.1M |
| New Technologies for Transient Molecular Complex Characterization | 28 | 3 | RR, GM | 3 | $0.3M | $0.4M |
| New Technology for Proteomics and Glycomics | 464 | 90 | GM, RR, AI, NS, HL | 163 | $34.5M | $46.7M |
| New Technology to Screen for Mild Hearing Loss in Children | 1 | 0 | N/A | 0 | $0.0M | $0.0M |
| Novel Assays for Screening the Effects of Chemical Toxicants on Cell Differentiation | 21 | 11 | ES | 11 | $1.7M | $2.5M |
| Novel Methods for Obtaining Molecular Information from Archived Tissue Samples | 13 | 5 | ES | 5 | $0.7M | $1.0M |
| Novel Technologies For In Vivo Imaging | 64 | 12 | CA | 27 | $6.7M | $8.5M |
| Novel Technologies for Rapid and Sensitive Biomonitoring in Humans | 49 | 13 | ES | 13 | $2.5M | $3.7M |
| Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care | 93 | 16 | HL | 17 | $3.2M | $4.2M |

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Orthotics for Pediatric Populations | 14 | 5 | HD | 6 | $0.8M | $1.1M |
| Point-of-Care Technologies Research Network | 68 | 7 | EB | 43 | $53.0M | $52.0M |
| Revolutionary Genome Sequencing Technologies: The $1000 Genome | 478 | 100 | HG | 302 | $134.5M | $171.3M |
| Robotics Technology Development and Deployment [RTD2] | 219 | 9 | HL, EB, HD, LM | 10 | $0.6M | $0.9M |
| Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings | 234 | 33 | HD, HL, RR | 55 | $10.9M | $13.8M |
| Small Business Innovation Research to Develop New Methods and Technologies able to Identify Individuals at Risk of Developing Type 1 Diabetes (T1D) | 24 | 7 | DK, HD | 13 | $2.5M | $3.6M |
| Small Business Innovation Research to Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes (T1D): Towards an Artificial Pancreas | 119 | 21 | DK, EB | 40 | $12.4M | $15.8M |
| Technologies and Software to Support Integrative Cancer Biology Research | 51 | 6 | CA, HG | 10 | $1.2M | $1.6M |
| Technologies for Healthy Independent Living | 292 | 22 | HL, AG, EB, HD, NS, NR | 52 | $13.7M | $19.9M |
| Technologies for Image-Guided Interventions | 191 | 15 | EB, CA | 50 | $17.6M | $26.6M |
| Technologies To Assess Sleep Health Status in Populations | 7 | 1 | HL | 1 | $0.1M | $0.1M |
| Technology Development for High-Throughput Functional Genomics | 119 | 18 | HG | 50 | $14.1M | $19.1M |
| Technology Development for High-Throughput Structural Biology Research | 120 | 16 | GM | 54 | $14.1M | $22.3M |

| Group Title | Total Applications | Distinct Awards (Type 1, Type 2, Type 4) | Institute(s)/ Center(s) Administering Awards* | Total Awards (Including Type 5s and Supplements) | Total Direct Cost of Awards | Total Cost of Awards |
|---|---|---|---|---|---|---|
| Technology Development for Protein Modeling | 46 | 4 | GM | 16 | $2.8M | $4.7M |
| Technology Development for the Detection and Evaluation of Chemical and Biological Carcinogens | 48 | 6 | CA, ES | 9 | $2.3M | $3.6M |
| Technology Development in Epigenetics | 229 | 29 | DA, ES | 113 | $28.5M | $41.8M |
| Technology Development to Enable Large Scale Metabolomics Analyses | 58 | 6 | ES | 22 | $5.5M | $8.5M |
| Technology for the Detection and Characterization of Low Abundance Proteins, Peptides, or micro RNAs | 123 | 16 | CA, RR, MH | 28 | $3.8M | $5.2M |
| Tools & Technologies for Assessing Manual Therapies | 22 | 6 | AT | 7 | $1.0M | $1.2M |
| Tools to Enhance Studies of Glial Cell Development, Aging, Disease and Repair | 80 | 8 | NH, MH, NS | 16 | $2.2M | $3.2M |
| Validation and Advanced Development of Emerging Molecular Analysis Technologies for Cancer Research | 1915 | 187 | CA | 444 | $78.9M | $118.3M |
| Validation and Demonstration of Devices for Environmental Exposure Assessment | 14 | 7 | ES | 7 | $1.2M | $1.6M |
| Validation of Molecular Diagnostics to Predict Patient Outcomes Using Specimens from Multi-Site Cancer Trials | 331 | 45 | CA | 136 | $29.2M | $40.5M |
| Validation of New Technologies for Clinical Assessment of Tooth Surface Demineralization | 56 | 8 | DE | 36 | $14.1M | $17.6M |

* The full names of the ICs these two-letter codes designate can be found at http://grants.nih.gov/grants/acronym_list.htm#ao_two.

## Publications and Patents

**Table A-3. Numbers of Publications and Patents by Group**

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Adaptation of Scalable Technologies to Illuminate the Druggable Genome | 5 | 0 |
| Advanced Development of Informatics Technology | 54 | 0 |
| Advanced Neural Prosthetics Research and Development | 13 | 0 |
| Advanced Technologies for Detection of Perturbation-Induced Cellular Signatures | 13 | 0 |
| Advanced Tools and Technologies for Cerebrospinal Fluid Shunts | 0 | 0 |
| Advanced Tools and Technologies for Deep Brain Stimulation | 1 | 0 |
| Applications of Imaging and Sensor Technologies for Clinical Aging Research | 1 | 0 |
| Blood Pressure Measurement Technologies for Low-Resource Settings in the U.S. and India | 4 | 0 |
| BRAIN Initiative: New Technologies and Novel Approaches for Large-Scale Recording and Modulation in the Nervous System | 10 | 0 |
| BRAIN Initiative: Optimization of Transformative Technologies for Large Scale Recording and Modulation in the Nervous System | 9 | 0 |
| Cancer Detection, Diagnostic and Treatment Technologies for Global Health | 2 | 0 |

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Clinical Neuroscience and Entertainment Software Pilot Partnership Program to Develop Neuropsychiatric Interventions | 0 | 0 |
| Clinical Proteomics Technology Assessment Consortium (CPTAC): Proteome Characterization Centers | 520 | 1 |
| Computational Tool Development and Integrative Data Analysis for LINCS | 30 | 0 |
| Developing a Point-of-Care Device for the Diagnosis of Sickle Cell Disease in Low Resource Settings | 1 | 0 |
| Developing Improved Assessments of Tissue Oxygenation | 0 | 0 |
| Development and Application of New Technologies to Targeted Genome-wide Resequencing in Well-Phenotyped Populations | 34 | 0 |
| Development and Implementation of Innovative Ultrasound Therapy Technologies | 140 | 1 |
| Development of a Microfluidic Platform for Blood Testing in Neonatal and Pediatric Patients | 0 | 0 |
| Development of a Vestibular Neural Prosthesis | 4 | 0 |
| Development of Advanced Genomic Characterization Technologies | 17 | 0 |
| Development of Diagnostic Screening Test for Salt Sensitivity | 0 | 0 |
| Development of Highly Innovative Tools and Technology for Analysis of Single Cells | 0 | 0 |

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Development of Software and Analysis Methods for Biomedical Big Data in Targeted Areas of High Need | 0 | 0 |
| Development of Tools to Study the Synaptome | 19 | 0 |
| Diabetes Impact Award-Closed Loop Technologies: Development and Integration of Novel Components for an Automated Artificial Pancreas System | 6 | 0 |
| Direct Phase II SBIR Grants to Support Biomedical Technology Development | 2 | 0 |
| Early-Stage Development of Innovative Technologies for Biospecimen Science | 224 | 3 |
| Early-Stage Innovative Molecular Analysis Technology Development for Cancer Research | 476 | 0 |
| Enabling Technologies for Tissue Engineering and Regenerative Medicine | 522 | 4 |
| Exceptionally Innovative Tools and Technologies for Single Cell Analysis | 270 | 1 |
| High Throughput Tools for Brain and Behavior | 56 | 0 |
| Imaging Diagnostics of Dental Diseases and Conditions (Caries, Periodontal Disease, Cracked Teeth, and Pulp Vitality) | 0 | 0 |
| Improved Biomaterials for Urinary and Dialysis Catheters | 3 | 0 |
| Indo-US Collaborative Program on Affordable Medical Devices | 6 | 0 |
| Informatics Tools for High-Throughput Sequence Data Analysis | 74 | 0 |

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Innovative Health Information Technology for Broad Adoption by Healthcare Systems and Consumers | 0 | 0 |
| Innovative Technologies and Assays in Support of HIV Cure Research (ITAS-Cure) | 0 | 0 |
| Instrument Development for Biomedical Applications | 1,184 | 5 |
| Integration of Heterogeneous Data Sources | 6 | 2 |
| In-vivo Methods for Assessing Placental Development and Function | 0 | 0 |
| Lab to Marketplace: Tools for Brain and Behavioral Research | 50 | 2 |
| Limited Competition: Competitive Revision for Technology Development within Biomedical Technology Research Centers | N/A | N/A |
| Manufacturing Processes of Medical, Dental, and Biological Technologies | 53 | 1 |
| Methods Development for Obtaining Comprehensive Genomic Information from Human Specimens that are Easy to Collect and Store | 0 | 0 |
| Mobile Health: Technology and Outcomes in Low and Middle Income Countries | 1 | 0 |
| Molecular Libraries Screening Instrumentation | 84 | 0 |
| Multiplex Assay Development for Arthritis and Musculoskeletal and Skin Diseases | 0 | 0 |
| National Technology Centers for Networks and Pathways Program | 607 | 0 |

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Near-Term Technology Development for Genome Sequencing | 40 | 3 |
| Neurotechnology Research, Development, and Enhancement | 383 | 1 |
| New Technologies for Transient Molecular Complex Characterization | 1 | 0 |
| New Technology for Proteomics and Glycomics | 106 | 0 |
| New Technology to Screen for Mild Hearing Loss in Children | 0 | 0 |
| Novel Assays for Screening the Effects of Chemical Toxicants on Cell Differentiation | 1 | 0 |
| Novel Methods for Obtaining Molecular Information from Archived Tissue Samples | 0 | 0 |
| Novel Technologies For In Vivo Imaging | 56 | 0 |
| Novel Technologies for Rapid and Sensitive Biomonitoring in Humans | 5 | 0 |
| Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care | 0 | 0 |
| Orthotics for Pediatric Populations | 0 | 0 |
| Point-of-Care Technologies Research Network | 187 | 0 |
| Revolutionary Genome Sequencing Technologies: The $1000 Genome | 407 | 9 |
| Robotics Technology Development and Deployment [RTD2] | 1 | 0 |
| Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings | 13 | 0 |

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Small Business Innovation Research to Develop New Methods and Technologies able to Identify Individuals at Risk of Developing Type 1 Diabetes (T1D) | 1 | 0 |
| Small Business Innovation Research to Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes (T1D): Towards an Artificial Pancreas | 20 | 0 |
| Technologies and Software to Support Integrative Cancer Biology Research | 8 | 0 |
| Technologies for Healthy Independent Living | 55 | 0 |
| Technologies for Image-Guided Interventions | 118 | 3 |
| Technologies To Assess Sleep Health Status in Populations | 0 | 0 |
| Technology Development for High-Throughput Functional Genomics | 153 | 0 |
| Technology Development for High-Throughput Structural Biology Research | 161 | 0 |
| Technology Development for Protein Modeling | 65 | 0 |
| Technology Development for the Detection and Evaluation of Chemical and Biological Carcinogens | 5 | 0 |
| Technology Development in Epigenetics | 179 | 2 |
| Technology Development to Enable Large Scale Metabolomics Analyses | 63 | 0 |
| Technology for the Detection and Characterization of Low Abundance Proteins, Peptides, or micro RNAs | 14 | 0 |

| Group Title | Number of Publications | Number of Patents |
|---|---|---|
| Tools & Technologies for Assessing Manual Therapies | 3 | 0 |
| Tools to Enhance Studies of Glial Cell Development, Aging, Disease and Repair | 21 | 0 |
| Validation and Advanced Development of Emerging Molecular Analysis Technologies for Cancer Research | 598 | 3 |
| Validation and Demonstration of Devices for Environmental Exposure Assessment | 2 | 0 |
| Validation of Molecular Diagnostics to Predict Patient Outcomes Using Specimens from Multi-Site Cancer Trials | 147 | 0 |
| Validation of New Technologies for Clinical Assessment of Tooth Surface Demineralization | 55 | 0 |

*Note*: It was not feasible to identify publications for Limited Competition: Competitive Revision for Technology Development within Biomedical Technology Research Centers because this FOA provided supplements to existing awards funded through other FOAs not present in the catalog; the RePORTER download cannot distinguish the publications funded through this particular FOA from the parent awards.

# Appendix B.
# Summary of Funding Opportunity Announcements (FOAs) in Case Studies

Medical device-related FOAs are most prevalent (Table B-1). Genomic and proteomic analysis technologies are more prevalent than in the full set of 83 FOA groups, while information technology and molecular analysis technologies are less prevalent than in the full set.

**Table B-1. Categorization of FOAs by Technology Area**

| Category | Number |
|---|---|
| Biospecimen Technologies | 1 |
| Cells/Tissues Analysis | 2 |
| Epigenetic Analysis | 1 |
| Genomic Analysis | 3 |
| Imaging | 1 |
| Information Technology | 2 |
| Manufacturing | 1 |
| Medical Device | 6 |
| Molecular Analysis | 2 |
| POC Devices | 1 |
| Proteomic Analysis | 2 |
| Grand Total | 22 |

The majority of the FOAs are in a defined area, though six are specific and two are broad (Table B-2).

**Table B-2. Categorization of FOAs by Purpose**

| Category | Number |
|---|---|
| Broad | 2 |
| Defined Area | 14 |
| Specific | 6 |
| Grand Total | 22 |

The large majority of the FOAs cover a diverse set of products (Table B-3). However, three solicit a specific product and one solicits products within a defined product category.

**Table B-3. Categorization of FOAs by Product Scope**

| Category | Number |
|---|---|
| Diverse | 18 |
| Specific | 3 |
| Defined Product Category | 1 |
| Grand Total | 22 |

Because the majority of NIH technology development efforts are for development of research technologies, the majority of the FOAs selected for case studies were also for development of research technologies (Table B-4).

**Table B-4. Categorization of FOAs by Intended Use**

| Category | Number |
|---|---|
| Research | 14 |
| Clinical | 5 |
| Research & Clinical | 2 |
| Biomedical Product Manufacturing | 1 |
| Grand Total | 22 |

The majority of the FOAs include early stage technology development (Table B-5).

**Table B-5. Categorization of FOAs by Stage of Development**

| Category | Number |
|---|---|
| Early Only | 6 |
| Early to Intermediate | 5 |
| Early to Late | 7 |
| Intermediate to Late | 4 |
| Grand Total | 22 |

SBIR/STTR awards were most-often used (12 of 22), followed by R01 and R21 awards. R33, U-awards, and P01 activity codes were used rarely (Table B-6).

**Table B-6. Categorization of FOAs by Funding Mechanism**

| Category | Number |
|---|---|
| SBIR/STTR | 12 |
| R21 | 10 |
| R01 | 9 |
| R33 | 5 |
| U-awards | 2 |
| P01 | 1 |

*Note*: Table does not sum to 22 as many FOA groups use multiple funding mechanisms.

Unlike the overall distribution of FOAs, there is relatively heavy use of PAs and PARs compared with RFAs (Table B-7).

**Table B-7. Categorization of FOAs by Solicitation Approach**

| Solicitation Type | Number |
|---|---|
| RFA | 9 |
| PA | 9 |
| PAR | 4 |
| Grand Total | 22 |

Nearly half of the initiatives were administered by multiple ICs. NCI, NHGRI, and NIGMS each led multiple initiatives (Table B-8).

**Table B-8. Categorization of FOAs by IC(s) Administering Awards**

| Administering IC(s) | Number |
|---|---|
| Multiple | 10 |
| NHGRI | 4 |
| NCI | 3 |
| NIGMS | 2 |
| NIDA | 1 |
| NIDCR | 1 |
| NIMH | 1 |
| Grand Total | 22 |

A plurality of initiatives involved multiple ICs managing awards, NCI, NHGRI, and NIGMS were most likely to manage all of the awards from their own FOAs (Table B-9).

**Table B-9. Categorization of FOAs by IC(s) Managing Awards**

| Institute(s)/Center(s) Managing Awards | Number |
|---|---|
| Multiple | 7 |
| NCI | 4 |
| NHGRI | 4 |
| NIGMS | 3 |
| NIMH | 1 |
| NIDCR | 1 |
| NIDA | 1 |
| NICHD | 1 |
| Grand Total | 22 |

# Abbreviations

| | |
|---|---|
| CSR | Center for Scientific Review |
| FDA | Food and Drug Administration |
| FIC | Fogarty International Center |
| FOA | Funding Opportunity Announcement |
| IDA | Institute for Defense Analyses |
| IC | Institute/Center |
| IDE | Investigational Device Exemption |
| IMAT | Innovative Molecular Analysis Technologies |
| IND | Investigational Drug Application |
| IT | information technology |
| NCCAM | National Center for Complementary and Alternative Medicine |
| NCCIH | National Center for Complementary and Integrative Health |
| NCCR | National Center for Cancer Resources |
| NCI | National Cancer Institute |
| NCATS | National Center for Advancing Translational Sciences |
| NCMHD | National Center on Minority Health and Health Disparities |
| NCRR | National Center for Research Resources (now NCATS) |
| NEI | National Eye Institute |
| NHGRI | National Human Genome Research Institute |
| NHLBI | National Heart, Lung, and Blood Institute |
| NIA | National Institute on Aging |
| NIAAA | National Institute on Alcohol Abuse and Alcoholism |
| NIAID | National Institute for Allergy and Infectious Diseases |
| NIAMS | National Institute of Arthritis and Musculoskeletal and Skin Diseases |
| NIBIB | National Institute of Biomedical Imaging and Bioengineering |
| NICHD | National Institute of Child Health and Human Development |
| NIDA | National Institute on Drug Abuse |
| NIDCD | National Institute on Deafness and Other Communication Disorders |
| NIDCR | National Institute of Dental and Craniofacial Research |
| NIDDK | National Institute of Diabetes and Digestive and Kidney Diseases |
| NIEHS | National Institute of Environmental Health Sciences |
| NIGMS | National Institute for General Medical Sciences |

| | |
|---|---|
| NIH | National Institutes of Health |
| NIMH | National Institute for Mental Health |
| NIMHD | National Institute on Minority Health and Health Disparities |
| NINDS | National Institute of Neurological Disorders and Stroke |
| NINR | National Institute of Nursing Research |
| NLM | National Library of Medicine |
| OER | Office of Extramural Research |
| PA | Program Announcement |
| PAR | Program Announcement with special receipt, review, or review considerations |
| PAS | Program Announcement with set-aside funds |
| PI | principal investigator |
| QVR | Query/View/Report |
| R01 | Research Project Grant Phase I (activity code) |
| R21 | activity code for Exploratory/Developmental Research Grant Phase I (activity code) |
| R33 | activity code for Exploratory/Developmental Research Grant Phase II (activity code) |
| RePORT | Research Portfolio Online Reporting Tools |
| RFA | Request for Applications |
| RPPR | Research Performance Progress Report |
| SBIR | Small Business Innovation Research |
| STPI | Science and Technology Policy Institute |
| STTR | Small Business Technology Transfer |
| T1D | Type 1 Diabetes |
| URL | Uniform Resource Locator |

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**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

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) to develop performance measures for technology development projects. The study had three components. The first was development of a comprehensive catalog of NIH Funding Opportunity Announcements (FOAs) that are focused on technology development for achieving a specific goal. The second was identification of a representative sample of FOAs from the catalog and developing case studies based on discussions with program officers knowledgeable about those FOAs. Finally, STPI identified candidate outcome measures for assessing technology development initiatives, as well as the data collection infrastructure that would be required to implement these measures in a consistent and ongoing manner. This document summarizes the assessment and findings.

**15. SUBJECT TERMS**

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