Feasibility Study for the Innovative Molecular Analysis Technologies Program Evaluation

Final Report

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by

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EXECUTIVE SUMMARY

Outcomes of any IMAT Program evaluation should be based on the success of the technologies developed under IMAT. Many of those interviewed suggested that the IMAT Program covered the very beginning of the technology pipeline for research. According to many of our respondents during our interviews with NCI staff, technology development is critical to cancer research. Research cannot move forward if technology does not move forward. Success can be measured by whether the technology advances scientific progress over and above that which is currently available. However, as we were reminded in one interview, by definition of the IMAT Program, not all programs should or will succeed—this is the point of high risk. At the same time, in order to develop technology, you must take risks. So in evaluation terms, IMAT is the intervention while outcome measures relate to whether the technologies are allowing scientists to initiate studies or treatments they could not do before, or allowing them to do what they did before but with greater efficiency. One of the key measurements for evaluating the success is on the researchers involved in the development and utilization of the technologies and not on those involved in the initial development of the technologies because these individuals may become disassociated with the technologies over time.

Advantages to the scientific community can only be measured by whether the technology is adopted sufficiently to produce critical scientific progress in the detection and treatment of cancer. This does not necessarily mean widespread adoption since it may take one or two instances to generate a discovery. It is recognized, however, that widespread adoption of a technology would probably increase the chances of a discovery. An adequate measure of such discoveries might be papers or presentations related to the science that are facilitated by the technology.

As premised above, the appropriate evaluation approach is to follow the technology. Although the starting point would be the principal investigator (PI) who initiates the idea and receives the IMAT funding, it is critical to also identify those associated with developing the technologies, disseminating them, and using them. Obtaining this information will be facilitated by interviewing IMAT grant recipients and further identifying other potential, or actual, users of the technology and also interviewing them.

Although recognizing that the technology might be used in basic scientific laboratory research, in clinical trials, and in treating patients, we believe that the effect of the technology in the last instance would be difficult to measure at this time. Most of the technologies have not had time to develop sufficiently to be used in practice settings (a long-term outcome), and attempting to identify where the technologies are being used would be methodologically and logistically difficult. Therefore we believe that the evaluation should focus on laboratory research and perhaps in clinical trials (short- or intermediate-term outcomes)—both of which usually result in papers or other evidence of findings or discoveries.

The overall success of the program may be manifested by the overwhelming success of a single technology funded under a single grant. For instance, if the technology developed under one grant led to groundbreaking development in the treatment of cancer, then other work, even if it was unsuccessful with regard to groundbreaking developments, it would not detract as much

from the overall program success. When other technologies become successful, it would be an indicator of value added. To omit particular technologies associated with grants through sampling may miss the one groundbreaking development and may drastically underestimate the impact and importance of the program. It is important to note the concept of level of success necessary in this type of evaluation. All grants or technologies should not succeed because, y definition of a high-risk program such as IMAT, many grants should fail, otherwise it could signify that all of the proposed projects are too safe.

Theoretically, to measure the impact of IMAT, it is important to have a counterfactual or comparison. In other words, if the program shows positive outcomes, it would be important to understand whether those outcomes would occur in the absence of IMAT. The appropriate comparison would be to somehow look at activities that contain technologies that might result in an IMAT grant or in an alternatively funded venture. However, we will assume that PIs and others involved in the various grants supported by IMAT can provide information on what they would do if funding through IMAT was not available. Information on unfunded applications could also be used to verify whether researchers pursued their ideas beyond IMAT. In addition, the same approach can be asked of scientists who use the technology. It is also possible that individuals who applied unsuccessfully for IMAT funding subsequently applied for research funding elsewhere in an attempt to advance the technology proposed under IMAT.

1. INTRODUCTION AND BACKGROUND

1.1. OVERVIEW

In 1998 the National Cancer Institute (NCI) created the Innovative Molecular Analysis Technologies (IMAT) Program, which focuses on the development of technologies for clinicians and researchers to use in cancer-related basic research aimed at the diagnosis, treatment, and prevention of cancer. In 2006 NCI requested a study of the feasibility of conducting an outcome evaluation of the IMAT Program. Macro International Inc. conducted the feasibility study over a 3-month period between December 2006 and February 2007. We developed and used an approach, which included identifying grant recipients and stakeholders, performing a literature review, and conducting interviews with National Institutes of Health (NIH) program staff and principal investigators (PIs) on IMAT grants. Interviews with NCI program staff provided an understanding of the IMAT Program and how it is perceived by NCI. The interviews with PIs validated some of the information collected during the literature review and data review processes regarding publications. Although these interviews confirmed that PIs would likely be one of the most reliable sources of information on the development, use, and maturation of IMAT technologies, the role of other individuals who might shepherd the technology through later development and dissemination stages was also identified as being critical. This realization lead us to an approach in which the evaluation of the IMAT Program would be related to the technologies themselves and their development.

In this report, we present the goals of the feasibility study, describe the methods used to conduct the study, present the results of the study, and present an approach for conducting the full-scale evaluation.

2. FEASIBILITY STUDY APPROACH

The approach that we developed for conducting a feasibility study for the IMAT Program involved reviewing grant applications and analyzing data, performing a literature review, and using the resulting information to generate interview protocols to conduct interviews with PIs funded by IMAT, IMAT stakeholders, and NCI and other Federal stakeholders. IMAT and those NCI staff members familiar with IMAT were interviewed about program objectives, processes, projects, the history, structure, funding mechanisms, and overall thoughts about IMAT. Other Federal stakeholders were interviewed about programs that might have similar components or objectives to the IMAT Program.

The next phase of our approach involved interviewing eight IMAT PIs and one IMAT science panelist. These interviews provided us with an understanding of their proposed technology and how grantees operate in the field, specifically, the extent to which they collaborate, what they see as the eventual outcomes of their work, their timeframes for development and next steps, and how they use institutional and other resources in their IMAT-funded research.

2.1. FEASIBILITY QUESTIONS

The interviews that we conducted with NCI, NIH, and other Federal employees, along with those conducted with IMAT PIs, provided information that allowed us to answer the following feasibility questions. (It should be noted that the focus of this study is not the actual performance of the IMAT Program but rather the ability to collect information on this performance.)

- Is it feasible to conduct an outcome evaluation of the IMAT Program?
- What evaluation questions are answerable and will provide useful information about the program?
- What measures can be used to answer the evaluation questions?
- What data are needed to answer the evaluation questions?
- What is the most appropriate and cost-effective method for collecting and analyzing the data?
- How much time would be required to collect and analyze the data?

2.2. METHODOLOGY FOR ADDRESSING THE FEASIBILITY QUESTIONS

Our methodology was developed around an approach that included the following steps:

- Identifying and reviewing literature to inform the feasibility study
- Reviewing background information on the IMAT Program
- Identifying stakeholders associated with the IMAT Program and with similar programs within and outside of NIH
- Developing protocols and conducting interviews with various stakeholders and IMAT grant recipients
- Reviewing various data sources to determine their usefulness for the full-scale evaluation

The primary aim was to describe the IMAT Program as an intervention and understand why certain funding decisions were made.

2.3. IDENTIFYING AND REVIEWING THE LITERATURE

We reviewed several approaches for conducting the literature review for this feasibility study and a complete discussion of our efforts and findings can be found in section 3.2 of this report. These include reviewing the literature for information on the related programs and their evaluations, reviewing the literature on topics associated with the IMAT Program and/or grant number, reviewing the literature produced by individuals involved in the IMAT Program, or simply asking all PIs who received IMAT funding to provide a current list of relevant publications associated with each IMAT grant. Macro International developed a methodology to identify research articles based on a combination of several approaches, specifically, topic search and author search.

2.4. REVIEWING BACKGROUND INFORMATION ON THE IMAT PROGRAM

In order to fully understand the IMAT Program, we reviewed a series of Web sites and databases to collect relevant information on the program. The IMAT Program has the following objectives:

- To focus innovative technology development efforts on the field of cancer
- To solicit highly innovative technology development projects from the scientific and medical community
- To accelerate the maturation of meritorious technologies from feasibility through development and/or commercialization

Since the inception of the program in 1998, NCI has used several approaches and numerous grants mechanisms to administer it. The initial approach used two program announcements with special review criteria, PAR-98-066 and PAR-99-067. Table 1 shows the complete history of Program Announcements (PAs, PARs) and Requests for Applications (RFAs) for the IMAT Program.

Table 1. History of IMAT Program PAs and RFAs

	Theme 1			Theme 2			Theme 3		
	PA/RFA #	RLS DATE	EXP DATE	PA/RFA #	RLS DATE	EXP DATE	PA/RFA #	RLS DATE	EXP DATE
R21	RFA-CA-07-033	1/4/2007	9/28/2007	RFA-CA-07-035	1/4/2007	9/28/2007	RFA-CA-07-037	1/4/2007	9/28/2007
	RFA-CA-07-015	5/2/2006	9/22/2006	RFA-CA-07-017	5/2/2006	9/22/2006	RFA-CA-07-022	5/3/2006	9/22/2006
	RFA-CA-07-001	12/8/2005	5/27/2006	RFA-CA-07-002	12/8/2005	5/27/2006	RFA-CA-07-003	12/8/2005	5/27/2006
	RFA-CA-06-002	12/9/2004	10/19/2005	RFA-CA-06-003	12/9/2004	10/19/2005	RFA-CA-06-004	12/8/2004	10/19/2005
	RFA-CA-05-002	12/17/2003	10/19/2004	RFA-CA-05-003	12/17/2003	10/19/2004	RFA-CA-05-004	12/17/2003	10/19/2004
R33	RFA-CA-07-034	1/4/2007	9/28/2007	RFA-CA-07-036	1/4/2007	9/28/2007	RFA-CA-07-038	1/4/2007	9/28/2007
	RFA-CA-07-016	5/2/2006	9/22/2006	RFA-CA-07-018	5/2/2006	9/22/2006	RFA-CA-07-023	5/2/2006	9/22/2006
	RFA-CA-07-001	12/8/2005	5/27/2006	RFA-CA-07-002	12/8/2005	5/27/2006	RFA-CA-07-003	12/8/2005	5/27/2006
	PAR-01-104	5/31/2001	7/22/2003	RFA-CA-06-003	12/9/2004	10/19/2005	RFA-CA-06-004	12/8/2004	10/19/2005
	PAR-99-100	5/14/1999	5/14/2002	RFA-CA-05-003	12/17/2003	10/19/2004	RFA-CA-05-004	12/17/2003	10/19/2004
	PAR-98-067	5/8/1998	5/8/2001						
R21/R33	PAR-01-104	5/31/2001	7/22/2003	RFA-CA-07-019	5/2/2006	9/22/2006	RFA-CA-07-024	5/3/2006	9/22/2006
	PAR-99-100	5/14/1999	5/14/2002	RFA-CA-07-002	12/8/2005	5/27/2006	RFA-CA-07-003	12/8/2005	5/27/2006
	PAR-98-067	5/8/1998	5/8/2001	RFA-CA-06-003	12/9/2004	10/19/2005	RFA-CA-06-004	12/8/2004	10/19/2005
				RFA-CA-05-003	12/17/2003	10/19/2004	RFA-CA-05-004	12/17/2003	10/19/2004
				PAR-01-106	5/31/2001	7/22/2003			
				PAR-99-102	5/14/1999	5/14/2002			
R41/R42	RFA-CA-07-040	1/4/2007	9/29/2007	RFA-CA-07-042	1/4/2007	9/29/2007	RFA-CA-07-044	1/4/2007	9/29/2007
	RFA-CA-07-007	1/26/2006	9/27/2006	RFA-CA-07-009	1/26/2006	9/27/2006	RFA-CA-07-011	1/26/2006	9/27/2006
	RFA-CA-06-005	12/16/2004	10/19/2005	RFA-CA-06-006	12/16/2004	10/19/2005	RFA-CA-06-007	12/16/2004	10/19/2005
	RFA-CA-05-006	1/7/2004	10/19/2004	RFA-CA-05-007	1/7/2004	10/19/2004	RFA-CA-05-008	1/7/2004	10/19/2004
	PAR-01-105	5/31/2001	7/22/2003	PAR-99-103	5/14/1999	5/14/2002			
	PA-99-101	5/14/1999	5/14/2002						
	PA-98-066	5/8/1998	5/8/2001						
R43/R44	RFA-CA-07-039	1/4/2007	9/29/2007	RFA-CA-07-041	1/4/2007	9/29/2007	RFA-CA-07-043	1/4/2007	9/29/2007
	RFA-CA-07-006	1/26/2006	9/27/2006	RFA-CA-07-008	1/26/2006	9/27/2006	RFA-CA-07-010	1/26/2006	9/27/2006
	RFA-CA-06-005	12/16/2004	10/19/2005	RFA-CA-06-006	12/16/2004	10/19/2005	RFA-CA-06-007	12/16/2004	10/19/2005
	RFA-CA-05-006	1/7/2004	10/19/2004	RFA-CA-05-007	1/7/2004	10/19/2004	RFA-CA-05-008	1/7/2004	10/19/2004
	PAR-01-105	5/31/2001	7/22/2003	PAR-01-107	5/31/2001	7/22/2003			
	PA-99-101	5/14/1999	5/14/2002	PAR-99-103	5/14/1999	5/14/2002			
	PA-98-066	5/8/1998	5/8/2001						

The latest set of RFAs was established in 2004, emphasizing IMAT funding in the following three areas:

- **Innovative Technologies for the Molecular Analysis of Cancer (New IMAT)—**This area was the primary area for funding prior to 2004, but it has been upgraded. The program encourages funding for developing novel technologies suitable for molecular analysis of cancers and their host environment. The focus is on emerging technologies, those that are proposed or in the early development stage, suitable for in vitro or in vivo analysis of:

  - Alterations and instabilities in genomic DNA
  - Expression of genes and gene products
  - Cellular localization, post-translational modification, and protein function
  - Monitoring major signal transduction networks involved in cancer

- **Innovations in Cancer Sample Preparation—**This area is a new emphasis, focusing on novel sample preparation technologies that are suitable for molecular analysis of cancer cells and their host environments. Topics include:

  - Sample preparation methods and techniques
  - Sample isolation, storage, and purification
  - Isolation of specific classes of cells and molecules

- **Applications of Emerging Technologies for Cancer Research—**This area is a new emphasis, supporting projects that evaluate the usefulness of emerging technologies. The focus is on technologies that have passed proof-of-principal milestones, and the objective is to assess reproducibility and produce preliminary data toward a biological or clinical question.

Funding for projects under these three areas has been facilitated through the following mechanisms:

- R21 awards, for the evaluation phase
- R33 awards, for the application phase
- Phased R21/R33 awards, for both the evaluation and application phases
- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants, for small businesses attempting to develop a product

The latest fiscal year, FY 2006, had 46 awards, with 9 new awardees, which was similar to FY 2005, which had 44 awards. Just over one-third of the grantees received support from SBIR. In total, funding for FY 2006 remained steady at about $10 million.[1] Of the three areas, the New IMAT and Emerging Technologies areas accounted for a large majority of the funds and had roughly equivalent funding (approximately $4 million), compared with the Sample Preparation area (approximately $1.8 million).

Since the inception of the IMAT Program, a total of 1,377 persons have submitted 3,667 applications for new or competing IMAT grants. Of these persons, 250 (18 percent) were successful in obtaining 434 awards.

Table 2 shows the number of new or competing grants received by these 250 successful principal investigators. Of the 250 persons receiving IMAT funding, slightly over half received a single grant, slightly over a quarter received 2 grants, and the remaining quarter 3 to 8 grants each.

Table 2. Number of Different Awarded Grants by PI Count, All Years, Includes Only Appl_type_codes 1 ("New") or 2 ("Competing")

Number of Awarded Grants	Number of PIs	% of All PIs
1	137	54.8
2	71	28.4
3	23	9.2
4	13	5.2
5	4	1.6

[1] http://imat.cancer.gov/objects/pdfs/IMAT_FundTotals_FY06.pdf and http://imat.cancer.gov/objects/pdfs/IMAT_FundTotals_FY05.pdf

Number of Awarded Grants	Number of PIs	% of All PIs
6	1	0.4
8	1	0.4
	250	**100.0**

Table 3 shows a breakdown of the funding mechanisms (i.e., activity codes) for the grants received by this group of 250 successful applicants:

Table 3. Number of Distinct PIs by Activity Code(s), Awarded Grants, All Years, Includes Only Appl_type_codes 1 ("New") or 2 ("Competing")

Activity Code(s)	# of Distinct PIs	% of All PIs
R21	121	48.4
R21 R33	11	4.4
R21 R44	1	0.4
R33	43	17.2
R41	3	1.2
R41 R42	1	0.4
R41 R43 R44 U43	1	0.4
R42	4	1.6
R43	50	20.0
R43 R44	4	1.6
R44	11	4.4
	250	**100.0**

The 250 successful IMAT applicants also applied for 5,290 new or competing non-IMAT grants. Approximately 60 percent of these applications (3,153) were successful. However, only 70 of the 5,290 total applications were for IMAT-related other grants and only 9 of the related grant applications were successful. For purposes of this analysis, we have defined IMAT-related grants as grants from any of the following programs referred to on the IMAT Web site: the Cancer Genome Atlas, the Office of Biorepositories and Biospecimen Research, and the Nanotechnology Office. These opportunities are sponsored by various Institutes to include NCI, National Institute of Biomedical Imaging and Bioengineering (NIBIB), and the National Institute of Dental and Craniofacial Research (NIDCR).

Table 4 shows the number of other grants received by IMAT principal investigators, including the few categorized as IMAT-related. The number of other grants awarded IMAT principal investigators ranged from 0 (57 IMAT PIs) to 35. This table suggests that of researchers who received both IMAT and non-IMAT grants, those who received the most IMAT grants tended to receive the least number of other grants.

Table 4. Number of Awarded IMAT Grants Versus Awarded Other Grants for the 250 PIs Who Received IMAT Grants, All Years, Appl_type_codes 1 ("New") or 2 ("Competing") Only

Table of num_imat_grants by num_other_grants							
# IMAT Grants	num_other_grants(# Other Grants)						
Frequency Row Pct	0	1-5	6-10	11-15	16-25	26-35	Total
1	22 16.06	72 52.55	28 20.44	9 6.57	2 1.46	4 2.92	137
2	23 32.39	41 57.75	5 7.04	2 2.82	0 0.00	0 0.00	71
3	9 39.13	9 39.13	4 17.39	1 4.35	0 0.00	0 0.00	23
4	1 7.69	7 53.85	3 23.08	2 15.38	0 0.00	0 0.00	13
5	1 25.00	2 50.00	1 25.00	0 0.00	0 0.00	0 0.00	4
6-10	1 50.00	1 50.00	0 0.00	0 0.00	0 0.00	0 0.00	2
Total	57	132	41	14	2	4	250

Table 5 describes when IMAT PIs received other grants. Of the 250 IMAT PIs, 57 received no other grants, 156 received other awards before their IMAT grants, 14 received both IMAT and other grants during one or more of the same years, and 23 received other grants after award of their last IMAT grant. (Note: This table is based on the fiscal year of the awarded grant, so it does not reflect overlapping non-competitive IMAT and other grants. This table shows that less than 10 percent (23 of the 250 individuals receiving an IMAT award) of those individuals who receive IMAT funding remain in the NIH extramural grant system (at least not in the role of PI).

Table 5. Timing of Awarded IMAT and Other Grants For the 250 PIs Who Received IMAT Grants, All Years

Other grant(s)	First year of prior grant(s)	IMAT grant #	Other grant #	Distinct PI #
No grant awarded except IMAT		110	0	57
		110	*0*	*57*
Other and IMAT grants overlap		30	43	14
		30	*43*	*14*
Other grant(s) after last IMAT award		39	31	23
		39	*31*	*23*
Other grant(s) before first IMAT award	Before IMAT Program began (1998 or earlier)	166	752	107
	During IMAT Program (1999 or later)	89	138	49
		255	*890*	*156*
		434	*964*	*250*

Table 6 is the same as the preceding except that the "other" grants are restricted to research program grants (RPG). RPGs are mainly R01s, but also include various other funding mechanisms. The NIH standard for identifying and grouping RPG applications is defined as including: RC1, R01, R03, R15, R21, R22, R23, R29, R33, R35, R37, P01, P42, UC1, U19, National Institute of General Medical Sciences (NIGMS) P41, and U01 for FY 1982 through the present. In addition, it excludes the following:

- National Library of Medicine (NLM) for all years
- National Institute of Nursing Research (NINR) for FY 1986
- National Center for Research Resources (NCRR) for FYs 1984–89
- Fogarty International Center (FIC) for FYs 1993 and prior
- R55 was not considered an RPG from 1989 until 1992.
- From 1991–96, NCRR R21s were not considered RPGs.

Table 6. Timing of Awarded IMAT and Other RPG Grants for the 250 PIs Who Received IMAT Grants, All Years, Appl_type_codes 1 ("New") or 2 ("Competing") Only

Other RPG grant(s)	First year of prior grant(s)	IMAT grant #	Other RPG grant #	Distinct PI #
No grant awarded except IMAT		208	0	102
		208	*0*	*102*
Other and IMAT grants overlap	During IMAT Program (1999 or later)	12	35	7
		12	*35*	*7*
Other grant(s) after last IMAT award	During IMAT Program (1999 or later)	20	48	16
		20	*48*	*16*
Other grant(s) before first IMAT award	Before IMAT Program began (1998 or earlier)	146	1,567	96
	During IMAT Program (1999 or later)	48	183	29
		194	*1,750*	*125*
		434	*1,833*	*250*

With the three IMAT themes, NCI has introduced a development pathway that takes advantage of the IMAT Program's capacity to generate new knowledge and build collaborations. For example, the Sample Preparation area is seen as instrumental to the New IMAT and Emerging Technologies areas because it allows for the generation of better-quality specimens for use in the other two areas, working from the understanding that the development of new technologies is more effective if the materials being measured and identified are of higher quality. The relationship between the New IMAT and Emerging Technologies areas is also important because the former is focused on early-stage development of technologies, and the latter is focused on evaluations of more mature technologies. Therefore, successful development of technologies in the New IMAT area may lead to evaluation of these technologies under Emerging Technologies. Similar links can be established with other NCI funding programs focusing on instrumentation, collaboration, and program centers and with private sources of funding.

2.5. IDENTIFYING STAKEHOLDERS

IMAT and NCI Program staff, familiar with IMAT, provided input regarding individuals likely to be interested in an evaluation of a technology-focused program. In addition, Macro International identified stakeholders outside of NCI and NIH. Examples of non-NCI offices included in the interviews are the National Institute of General Medical Sciences (NIGMS), NIBIB, National Science Foundation (NSF) Office of Integrative Activities, and National Institute of Standards and Technology (NIST) Advanced Technology Program (ATP).

2.6. DEVELOPING PROTOCOLS AND CONDUCTING INTERVIEWS

For this study, Macro International considered it important to speak with numerous individuals associated with the IMAT Program, including program staff and grant recipients. For comparison purposes, we felt that it was also important to speak with individuals from similar programs or with an understanding of, or interest in, the IMAT Program. We also interviewed eight IMAT PIs and one IMAT science panelist. The purpose of these interviews was to understand their technology and how grant recipients operate in the field, specifically, the extent to which they collaborate, what they see as the eventual outcomes of their work, their timeframes for development and next steps, and how they use institutional and other resources in their IMAT-funded research.

The interviews were designed to provide information that would allow us to answer the following questions:

- Whether the IMAT Program can be characterized as a relatively fixed set of opportunities for researchers, that is, whether the program provides a context for conducting research that is focused and has remained relatively constant since its inception. If the main objectives of the IMAT Program changed over the years, it becomes more difficult to determine which version of IMAT is being evaluated.
- Whether the complexity of the environment would influence any results that could affect associating IMAT opportunities with outcomes. The complexity of the research environment presents two evaluation issues: the degree to which the research environment has changed since the inception of the IMAT Program and the degree to which it can be adequately identified in order to understand IMAT Program outcomes relative to outcomes associated with other NCI programs or non-NCI initiatives.
- Whether the focus should be on long-term outcomes or short- or intermediate-term outcomes. The IMAT Program may be difficult to evaluate in the long term since many of the long-term outcomes may become observable only after decades. What must be determined is whether the IMAT Program has been in existence long enough for outcomes to be observed.

It should be noted that the focus of this study is not the actual performance of the IMAT Program but rather the ability to collect information on this performance.

Macro International designed three protocols to collect information from different groups of stakeholders (see appendix A). The first interview protocol was designed to elicit information from senior IMAT staff. Our goal was to gather details about the IMAT Program that were not found in the program descriptions or mission statements or on the Web sites and to understand the changes that occurred in the mechanisms over time, including the initially coupled R21/R33 mechanism and the reasons for their subsequent uncoupling. We wanted to understand the structure of the IMAT Program and its history, including its funding history. We were also interested in how milestones were established, revised, and ultimately measured for achievability. We wanted to investigate the types of collaborative experiences that were available to IMAT PIs and gather individual perceptions of the program. In addition, we were interested in the types of information provided to the IMAT Program that could be used in the full-scale evaluation.

The second interview protocol focused on NCI staff and other Federal employees. We were aware that many NCI senior staff members had worked on the IMAT Program or were familiar with it, but we realized that their experience might not be as comprehensive as that of IMAT Program staff. During these interviews, we first asked respondents to discuss their role in their own program and any relevant evaluations in which they had participated. We asked them to describe their specific programs and any methods that they had used to conduct evaluations. Since many of these individuals were familiar with the IMAT Program, they also shared valuable information about the program during the interviews, which was useful to us in designing the evaluation plan. Finally, we asked respondents to share any thoughts they had about the IMAT Program. Most participants were affiliated with NCI or NIH, but we also conducted interviews with two individuals outside of NIH (at NSF and NIST).

The third interview protocol focused on IMAT PIs. The purpose of these interviews was to understand the IMAT Program from the grantee's perspective, including how PIs describe their technologies, explain their choice of technology, and discuss the rationale for that choice. We were interested in their perspective on issues related the structure of the IMAT Program, including completing the grant application, the different mechanisms provided by the program, and the milestones, if applicable. We also wanted to determine their level of interaction with NCI and their level of collaboration with colleagues within and outside of their institution and with the scientific community in general. We were interested in the application and dissemination of their proposed technology, including patent information and publication information, as well as funding for the technology and other types of funding that PIs had applied for or received.

3. FEASIBILITY STUDY FINDINGS

3.1. NEED FOR A FEASIBILITY STUDY

There are several critical elements that would affect whether an outcome evaluation could be conducted and the nature of such an evaluation, including the expected outcomes, supported technologies, the IMAT Program itself, other NIH research opportunities, the research environment, and the participants.

- **Expected outcomes—**Any conceptual framework developed for evaluating the IMAT Program should be clear about the outcomes. We found that it is too soon to assess long-term outcomes, such as a reduction in the incidence of cancers, or perhaps even outcomes related to the integration of findings into cancer prevention, diagnosis, and treatment activities. Short-term outcomes related to generating and disseminating knowledge, creating scientific collaborations, and advancing clinical studies would likely be measurable to some degree. The feasibility study should therefore elaborate on the possible outcomes and describe their relationship to the IMAT Program through a conceptual framework (please see appendix B for the conceptual framework).
- **Supported technologies—**Since the technologies themselves are not subject to assessment within a program evaluation framework, the evaluation should not be concerned with the technical aspects of the technologies employed. It should instead focus on describing the expected impact of the technologies in terms of how they will be used and the length of time until they can be used by practitioners or researchers. In other words, it is important to understand how the technologies will affect any possible outcomes, and in doing so some classification of the technologies should be developed. This information should be gathered from interviews with knowledgeable individuals.
- **IMAT Program—**In program evaluation terms, the IMAT Program is the intervention, that is, the program provides funding that is expected to result in greater returns than would be anticipated if the funding had been used for other initiatives. Ideally the IMAT Program would have provided the same kinds of opportunities to researchers throughout its 8-year existence. However, with the recent modifications to the original program, that continuity may have been interrupted, and the emphasis on the two new areas may result in somewhat different outcomes from those prior to their introduction. The question is whether recently funded projects can be evaluated in the same context as earlier projects. Whether the program emphasis on innovation changed is also important to consider. It would be useful to examine the ratings and/or priority scores for all responses to the RFAs during this period and compare them across funding periods.
- **Other NIH research opportunities—**NIH offers a variety of other funding opportunities to help establish centers that allow collaboration among researchers, assist in obtaining and sometimes modifying biomedical instrumentation, and conduct research. The availability of these other funding opportunities to IMAT investigators may leverage their own efforts; therefore, understanding the interplay between these opportunities is important in evaluating the IMAT Program.
- **Research environment—**Increasingly, researchers are encouraged to be more collaborative and to work across disciplines and institutions. These arrangements are expected to be more effective in bringing intellectual resources to bear on research problems of consequence.

Individuals also have access to a variety of instrumentation, including bioinformatics applications that were not available a decade ago. Describing the relationship between the availability of this environment to IMAT-funded researchers is important for the purposes of the outcome evaluation.

- **Participants—**Researchers can be funded through R21/R33 mechanisms as well as SBIR grants, which are intended to facilitate commercialization of the technologies developed under the auspices of small businesses. This differentiation, as well as other basic characteristics associated with the research teams, may be important in examining how technologies were developed, tested, and brought to market. An important factor relates to information-sharing among businesses that may be focused on maintaining proprietary information.

We believe that the entire environment should be delineated and described as part of any full-scale evaluation. Such a description helps in understanding the relationship between IMAT Program funding and outcomes as well as the facilitating factors and barriers that may affect the relationship. Our approach to the feasibility study was to understand the range and extent of these factors and put them into the context of performing an outcome evaluation or similar assessment of the IMAT Program.

Under the NIH Roadmap initiative, there has been an increased effort in recent years to accelerate scientific discovery related to the causes, diagnosis, prevention, and treatment of cancer and to disseminate the results more quickly into practice and patient care. As part of this strategy, NCI and NIH have increased the emphasis on funding innovative approaches that could potentially have a greater impact but also carry a greater risk. Such approaches may ultimately reduce the incidence and improve the outcomes of cancer. In the shorter term, the strategy will increase our knowledge about the etiology, pathophysiology, genetics, and pharmacogenetics of cancer. One critical area is basic research at the molecular level. Analysis of the structures and processes at this level requires sophisticated technologies that have only recently started to become available. Also, the development of advanced computers and software applications has increased the efficiency and effectiveness of discovery. However, it is recognized that even more sophisticated and advanced technology is needed.

3.2. LITERATURE REVIEW

Several approaches could have been used for the literature review conducted as part of this study. These include reviewing the literature for information on the related programs and their evaluations, reviewing the literature on topics associated with the IMAT Program and/or grant numbers, reviewing the literature produced by individuals involved in the IMAT Program, or asking all PIs who received IMAT funding to provide a current list of relevant publications associated with each IMAT grant. Macro International developed a methodology to identify research articles using topic search and author search. Our approaches explored the types of literature being produced as a result of the IMAT Program and are discussed in detail below.

3.2.1. Topic Searches

A topic search is one possible approach for a literature review, although it can be time consuming and expensive because it requires the identification of key terms and relevant articles, review of abstracts, and review of relevant publications identified in the articles.

To review literature on topics associated with the IMAT Program, we developed a list of key terms that described research that was conducted as part of the program. In this context, the technologies being used or developed were considered to be part of the research topic. Our approach entailed using the initial program announcement, PAR #98-067, to identify IMAT awards, compile a list of individuals associated with the awards, and construct a list of keywords/terms from a sample of these awards. We created a list of keywords/terms associated with these IMAT grants using the NIH Computer Retrieval of Information on Science Projects system[2] Thesaurus function.

We used the NIH PubMed system[3] to conduct our searches. PubMed, available via the National Center for Biotechnology Information (NCBI) Entrez retrieval system, was developed by NCBI at NLM, part of NIH. Entrez is the text-based search and retrieval system used at NCBI for services such as PubMed, Nucleotide and Protein Sequences, Protein Structures, Complete Genomes, Taxonomy, and Online Mendelian Inheritance in Man. PubMed provides access to citations from biomedical literature, and NCBI's LinkOut provides access to full-text articles at journal Web sites and other related Web resources. PubMed also provides access and links to the other Entrez molecular biology resources. Publishers participating in PubMed electronically submit their citations to NCBI prior to or at the time of publication. If the publisher's Web site offers the full text of its journals, PubMed provides a link to the site as well as links to biological resources, consumer health information, research tools, and more.

As expected, searching the literature only for the keywords yielded an extremely large number of publications, making a thorough, comprehensive review to correctly associate publications and people unrealistic within the time constraints of the feasibility study. Instead, we used a list of sample PIs and searched for each PI name, collected publications by last name (author's last name and first/second initial), and noted publication counts. We then added a search term identified for that grant to the name of the PI (e.g., Smith EE and flow cytometry), downloaded matching files, and noted publication counts for each pairing. Finally we searched each term independently and noted publication counts. Table 7 shows the results of several sample keyword searches, as well as some searches cross-referencing author and keyword.[4] Because the number of publications returned was reduced to a manageable number, this approach may be useful in the full-scale evaluation.

[2] http://crisp.cit.nih.gov/
[3] http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed
[4] We have not included the names of PIs in this table.

Table 7. Results of Sample Keyword Searches

Search Term	Count of Publications Identified Using Search Term (keyword count)	Count of Publications Using Search Terms Filtered by PI's Name
Protein folding	15,375	5
Gene expression	234,659	30
Functional genomics	4,036	5
Fluorescent in situ hybridization	16,175	9
Gel electrophoresis	47,866	10

3.2.2. Author Searches

Our objective for this approach was to generate a literature "map" based on authorship patterns (publications and citations), which would demonstrate the level of activity in publications related to the IMAT Program. To test this approach, we again used the initial program announcement for the IMAT Program to obtain a list of PIs affiliated with the grants awarded through this announcement. By using the initial program announcement, we were able to ensure that the PI had had adequate time to publish on the research or technology resulting from his or her grant. There were approximately 32 awards made from the initial program announcement; we chose a sample of about 15 PIs from these initial awards.

Our approach to author searches involved a two-pronged method using the ISI Web of Science and the Query View Reporting (QVR) system, as shown in figure 1.

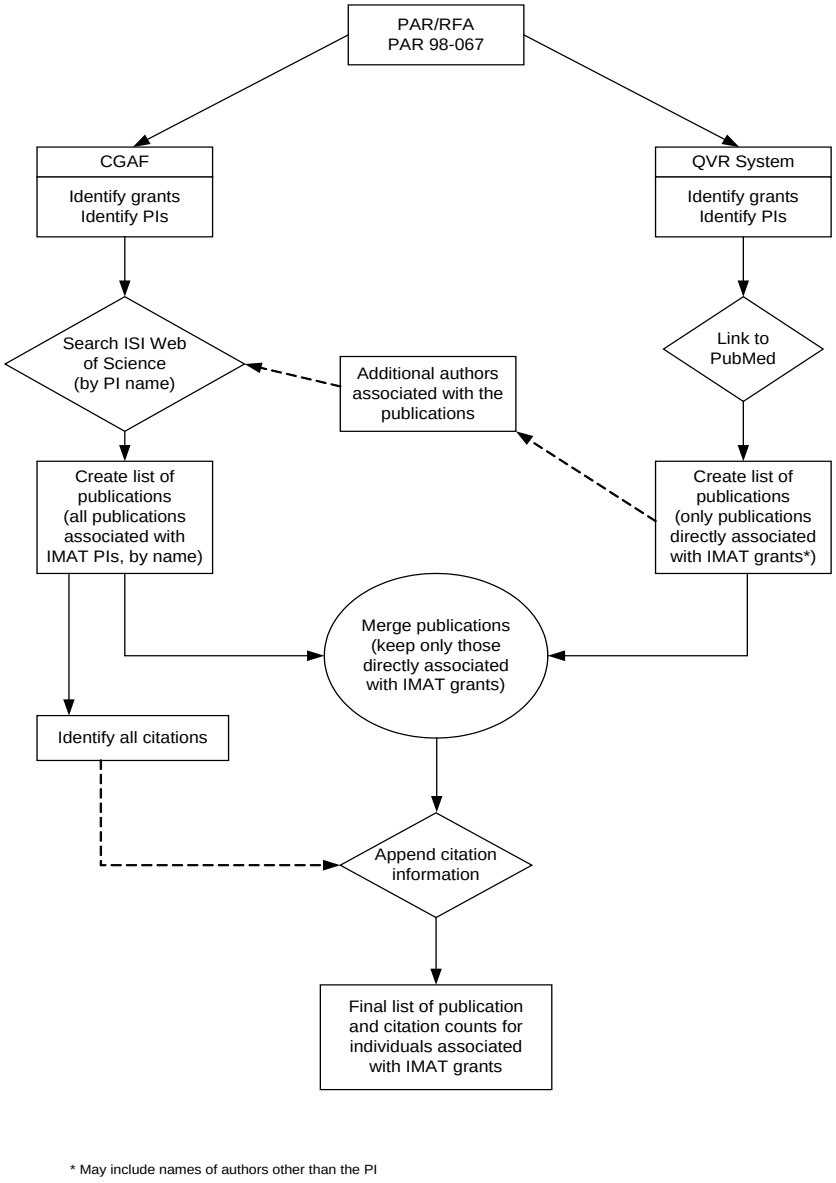


Figure 1. IMAT literature map

The first step was to identify the PIs associated with the IMAT grants. The next step used both Web of Science and the QVR system. Using Web of Science, we ran the names of our sample PIs and extracted all publications and citations associated with the name (based on last name and first initial). This step required some manual review because of issues related to the authors' names and initials, as well as substantial review to verify that the individuals identified were in fact the correct individuals. We are confident that those PIs with unusual names or more than one initial match our PIs, but are not certain that those individuals with more common last names and only one initial are perfect matches.

As expected, our search resulted in a large number of publications in some cases. However, the benefit of using Web of Science was that it provided a citation count for each publication, which may prove to be an important measure for this evaluation.

Using the QVR system, we were able to search on the initial program announcement and obtain a list of the grants awarded, with PI information provided for each grant. One of the features of the QVR system is that all the listed grants contain links to PubMed. To confirm that we were capturing all publications associated with a particular grant using QVR, we also ran queries for the same grants reviewed in QVR using PubMed. We also ran queries on publications in QVR for the PIs interviewed (where found) and asked those PIs we interviewed to review our findings. The PIs reviewed our findings and confirmed our results. Our queries included the institute code and the first six numbers of the grant, along with the identifier "[gr]" for grant. These queries produced the same counts for each grant examined in QVR.

The link to the associated publication information is a useful feature of the QVR system, but we are concerned that not every publication cites its corresponding grant. The following disclaimer is provided on the PubMed Web site:

> The Grant Publications Web Page attempts to list all publications for a given grant cycle as cited in PubMed. The page searches PubMed for all publications where the "base" grant number (or a reasonable variation of it) is referenced in the list of supporting grants. By "base" grant number we mean just the Activity Code plus the IC-serial number part of the grant number (e.g. R01 ES006882, T32 CA097761 . . .).
>
> This Web page is provided as a decision-support capability. It is not intended to be used as a rigorous analytical tool. It is not possible to ensure that the publications listed on the page are an exhaustive list of publications related to the grant in question. The following factors impact the accuracy of the list:
>
> - There is very little consistency in how grant numbers are entered by the author/journal into PubMed. This page searches PubMed using over 150 variations on grant number.
> - Not all publications related to a grant are even cited in PubMed. For example, a grant that is part of a Center may cite the publication whereas the center grant may not.
> - Not all journals in which grantees publish are cited in PubMed.
> - Not all journals even allow the author to acknowledge grant support.

We consulted with PubMed staff, who also expressed concern that not all relevant publications cite their grants.[5] NIH has established a requirement that all grant awardees cite their grants, but PubMed staff agree that there are gaps in the acknowledgment of grant support.

Once we obtained the information from PubMed, we identified individuals other than the PIs who are associated with IMAT publications and ran their names through Web of Science. This

[5] Our past experience and recent discussions with several IMAT PIs, indicate that researchers make every effort to cite the relevant grant, but because of limited space, some publications may not include the grant number. Other publications choose not to include grants if multiple authors cite different grants, due to space considerations. In addition, publications that have yet to be published or are in process are not captured by this type of review.

step ensured that we gathered publication and citation information related to the IMAT grant and not just related to the individual PI.

Our next step was to merge the information obtained from the QVR system with the information obtained from Web of Science. This step excludes those publications identified in Web of Science that were not identified in the QVR system, which should ensure that the publication and citation data are directly related to the IMAT grant. The final step was to append the citations from the Web of Science to each grant and PI (based on publications).

3.3. ADDITIONAL REVIEW FOR THE FULL-SCALE EVALUATION

For a full-scale evaluation, we suggest expanding on the literature review conducted during the feasibility study to capture publications and citations for all 267 IMAT grantees. This literature review would serve multiple purposes. One important use of the information would be to fully map out the landscape of publications and citations by IMAT researchers. Another would be to validate this map during the course of the interviews. (It would not necessarily be done during the actual interviews, but as part of the interview process.) We found in the feasibility study that the information on publications was easily verified by the PIs, which allowed us to describe the citations associated with each publication. As such, this review would provide us with a comprehensive or full map of the landscape of publications and citations associated with the IMAT grant. We believe that this kind of information would have several uses. First, it would give us valuable background about the PI prior to interview that could be confirmed during the interview. Second, if citation and patent information is available, it would provide potential candidates for interviews with users of the technology.

3.4. INTERVIEWS WITH STAKEHOLDERS

For this study, Macro International interviewed various groups of stakeholders who had been identified as important to the development of the final evaluation plan. These interviews provided the information necessary to construct a set of research questions, or evaluation criteria, for the full-scale evaluation. An important first step was to define the specific audiences and stakeholders for the evaluation. This group includes NIH officials, NCI program staff, stakeholders at various Federal agencies, and program participants

We have categorized these stakeholders into three distinct groups: internal, external, and others. Internal stakeholders include NCI senior staff, not just IMAT staff members. We believe that the unique knowledge of NCI and IMAT provided by these individuals gave us an excellent grounding to build our evaluation strategy. External stakeholders are non-NCI staff who are Federal employees and who are generally, but not exclusively, from NIH. Because the technology developed as part of the IMAT Program is used by individuals across all divisions of NCI and NIH, it is expected that individuals associated with other NIH divisions will be interested in the evaluation of the IMAT Program. For the purpose of this feasibility study, we limited the external stakeholders to NIH senior staff and staff of two other Federal entities (NSF and NIST). (For the full-scale evaluation we would expect this grouping to expand to include other Federal senior staff, as needed.) The others group is defined as researchers and the

scientific community at large. We would recommend initially focusing on PIs for the full-scale evaluation, but we will not limit our interviews to them. Stakeholders in the others group in an evaluation of the IMAT Programs could range from staff working on a specific research project to the greater community of oncologists. It was not our intent to contact every type of individual stakeholder or all groups of stakeholders for the feasibility study, but for the full-scale evaluation we anticipate expanding our contacts significantly.

Individuals interviewed for the feasibility study are listed below, by stakeholder group.

- Internal stakeholders:
    - Gregory J. Downing, Ph.D., Office of Technology and Industrial Relations, Office of the Director, NCI
    - Jennifer A. Couch, Ph.D., Program Director, Division of Cancer Prevention, NCI
    - James W. Jacobson, Ph.D., Chief, Diagnostic Biomarker and Technology Branch—Department of Cancer Treatment and Diagnosis, NCI
    - Paul D. Wagner, Ph.D., Program Director, Division of Cancer Prevention, NCI
    - Piotr Grodzinski, Ph.D., Program Director, Cancer Nanotechnology Characterization Laboratory, NCI
    - Scott McNeil, Ph.D., Director, Nanotechnology Characterization Laboratory, NCI
    - Henry Rodriquez, Ph.D., Director, Clinical Proteomics Technologies Initiative for Cancer, NCI
    - Summary of interview with Sherwood Githens, Ph.D., Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, NCI
    - Carol H. Kasten, M.D., Program Director, Cancer Genetics Network and InterLymph, Clinical and Genetic Epidemiology Research Branch, Division of Cancer Control and Population Sciences, NCI
- External stakeholders:
    - Jeremy Berg, Ph.D., Director, NIH NIGMS, Director of the National Director's Pioneer Award Program
    - William J. Heetderks, Ph.D., Director, Extramural Sciences Program, NIBIB
    - Henry Khachaturian, Ph.D., Office of the Director, NIH
    - Lorel Wisniewski, Ph.D., Deputy Director, Advanced Technology Program, NIST
    - Connie Kubo Della-Piana, Ph.D., Program Evaluation Manager, NSF, Office of Integrative Activities
- Other stakeholders:
    - IMAT grant recipients

For the purposes of the feasibility study and because of Office of Management and Budget requirements, Macro International focused on eight IMAT grant recipients[6]. For the full-scale

[6] This group included PIs funded by all IMAT mechanisms including SBIRs.

evaluation, we recommend that this population be expanded to include (but not limited to) individuals from the following areas:

- Faculty using IMAT resources but not receiving direct funding
- Senior faculty from other institutions who collaborate with IMAT grant recipients
- Researchers who have used IMAT resources but are not directly associated with the IMAT grant or the institution
- Members of the scientific community who use the technology developed with IMAT funding
- Members of the scientific community involved in clinical trials with the technology developed from the IMAT grant
- Members of the scientific or research community who have taken over the technology originally developed in the IMAT grant.
- Staff at university/institutional technology transfer offices

For the purpose of the full-scale evaluation, we recommend focusing on stakeholders that fall under the category of "others," although we will need to contact members of the two remaining groups as well. The others group is the group that designed, developed, created, and/or selected the technology for funding. These individuals are key since they are the basis for following the technology, that is, without their ideas, designs, and/or technology, there would be nothing to follow and no information to gather. To clearly understand the technology that has been developed through IMAT funding, we believe it may be necessary to interview every PI since each technology is different and since randomly excluding some PIs from the interview process may cause overlooking the one technology that makes a significant difference in cancer research and the scientific community and justifies funding for the IMAT Program. During our interviews with eight PIs for the feasibility study, we found that each PI had important information to convey, making the need to speak with every PI increasingly clear. As shown in table 2, almost half of the 250 PIs who received IMAT funding had more than one IMAT grant. This serves to reduce the overall pool of interviewees from 434 (i.e., the total number of awards) to 250 (i.e., the total number of unique PIs funded by IMAT).

3.5. DATA SOURCES

A variety of data and background information on the IMAT Program and the individual grants and proposed technology will be needed for the full-scale evaluation. We have identified several sources of existing secondary data that will be useful in conducting the evaluation. These include various NIH databases maintained by offices within the Office of the Director, NCI, and NLM, as well as several non-NIH offices. Following is a description of these sources.

3.5.1. NIH Databases

NIH collects information on all grant applications and awards, including IMAT grants. The Consolidated Grant Applicant File (CGAF) contains records for all persons applying for or receiving grants or contracts from NIH and other U.S. Department of Health and Human Services (HHS) research agencies or administrations. It compiles information about grant applications from the NIH Information for Management, Planning, Analysis, and Coordination

(IMPAC) II system, plus analytical data items that provide summary information and selected information from related files. The CGAF is linked to various other databases, including the Trainee and Fellow File (TFF), Doctorate Records File (DRF), and Association of American Medical Colleges (AAMC) Faculty Roster System.

The TFF contains data on all persons who have applied for or received fellowships or traineeship appointments from NIH and other HHS research agencies or administrations. Records for program directors of institutional training grants can be found in the CGAF, while records for trainees appointed under the training grants are found in the TFF.

The DRF, which is based on the Survey of Earned Doctorates, contains records of individuals earning academic research doctorates at accredited U.S. institutions. The DRF provides information such as Ph.D. field, Ph.D. year, conferring institution, year and academic field of all postsecondary degrees, sources of financial support, length of time in graduate school, and postgraduation plans. In addition to demographic and educational history data, the DRF contains information on career plans and sources of financial support during graduate education.

The Faculty Roster (FR) System contains records on current and former U.S. medical school faculty, providing demographic information, employment and education history, medical specialties, and U.S. board certification data.

3.5.2. PubMed

PubMed[7] is a searchable database designed to provide access to biomedical citations and abstracts. Participating publishers electronically submit their citations to NCBI prior to or at the time of publication. PubMed contains links to full text journal articles, biological resources, consumer health information, research tools, and other materials. PubMed also provides access to bibliographic information contained in MEDLINE and OLDMEDLINE, as well as the following:

- Out-of-scope records (e.g., articles on plate tectonics or astrophysics) from certain MEDLINE journals, primarily general science and chemistry journals, for which the life sciences articles are indexed for MEDLINE
- Publication records that precede the date that a journal was selected for MEDLINE indexing
- Some additional life science journals that submit full text to PubMed Central and receive a qualitative review by NLM

3.5.3. ISI Web of Science

Web of Science[8] is a database that provides seamless access to current and retrospective multidisciplinary information from approximately 8,700 research journals worldwide. This comprehensive collection is fully searchable, with complete bibliographic data, cited reference

[7] http://www.pubmed.gov
[8] http://scientific.thomson.com/products/wos

data and navigation, and direct links to the full text. The searchable databases in Web of Science include Science Citation Index Expanded and Social Sciences Citation Index, which contain data from 1975 to the present; the databases are indexed so that searches can be performed by author name. Web of Science is the only source of data on subsequent citations of publications.

3.5.4. QVR System

The QVR system is part of the IMPAC II data system. The QVR system contains a query tool to allow retrieval of select grant data, including summary statements, abstracts, basic administrative data, budget information, PI contact information, and notice of grant awards. In addition, the QVR system also contains direct links to PubMed for publications associated with specific grants. The grant information can be retrieved based on particular Program Announcements (PAs/PARs) or RFAs.

3.5.5. CRISP System

The Computer Retrieval of Information on Scientific Projects (CRISP) is a major NIH information system that contains data on all research programs supported by NIH and other research agencies of the Department of Health and Human Services (HHS) that formerly made up the Public Health Service. Most of the research falls within the broad category of extramural projects, grants, contracts, and cooperative agreements conducted primarily by universities, hospitals, and other research institutions and funded by NIH and other Government agencies. A relatively small number of research grants are funded by the Centers for Disease Control and Prevention, Food and Drug Administration (FDA), Health Resources and Services Administration, and Agency for Healthcare Research and Quality. CRISP also contains information on NIH and FDA intramural programs. While IMPAC II focuses on administrative data, CRISP focuses on scientific data. It contains brief abstracts of all research projects and subprojects and indexes these projects using subject headings from the CRISP Thesaurus. CRISP files, which go back to fiscal year 1971, are linked to IMPAC II through common data elements, notably the research project number.

3.5.6. Additional Sources of Data

We explored several additional sources of data during the feasibility study to identify viable sources of data for the full-scale evaluation. This often included speaking with individuals from the offices that maintained these sources of data. Macro spoke with a representative from the NIH Office of Technology Transfer (OTT) who stated that the information maintained by OTT was limited to Federal employees (e.g., NIH Intramural researchers).

We spoke with a representative from the Division of Extramural Inventions and Technology Resources (DEITR), which is part of the Office of Policy for Extramural Research Administration within the Office of Extramural Research in the Office of the Director at NIH. This office maintains data on patents and inventions by NIH extramural grantees. The office also maintains iEdison (which stands for Interagency Edison). The goal of iEdison is to assist

Government grantees and contractors in complying with the Bayh-Dole Act, which requires that Government-funded inventions be reported to the Federal agency that made the award.

Similar information is maintained within the NCI Office of Technology and Industrial Relations for those grantees receiving funding from NCI. This office often works with the DEITR office to validate counts, and other information, related to inventions and patents.

In addition to speaking with several Institutional Technology Transfer (ITT) Offices, we asked the PIs that we interviewed about the availability of patent and invention data within their respective ITT offices. We also reviewed the Web sites of several PI home institution technology transfer offices. Many of these institutions have full-service offices staffed with administrators capable of and responsible for undertaking the entire patent process; other offices are much smaller with more limited capabilities.

Another source of data was the actual interviews with IMAT PIs. These interviews focused on their proposed technology, understanding how grant holders operate in the field—the extent to which they collaborate, what they see as the eventual outcomes of their work, timeframes for development and next steps, and how they use institutional and other resources in their IMAT research. PIs provided detailed information about their technologies, including the reason for selecting the technology and the anticipated goals to be achieved by their technologies. In addition, PIs provided us with current information on publications, licensing, patents, and presentations.

We also conducted interviews with IMAT Program staff, NCI program staff, other senior staff at NIH, and several individuals associated with programs believed to be similar to IMAT but located outside of NIH. These interviews provided a more operational perspective on the programs.

3.6. ISSUES RELATED TO SECONDARY DATA

Many of these sources of data have potential shortcomings. For example, some of the sources rely on reporting processes that may not capture all aspects of the technology. In other cases, invention and patent data may be captured but not correctly or fully associated with the IMAT Program. In order to properly evaluate the IMAT Program, it will be important to associate outcomes such as inventions, patents, and/or use of the technology at various stages, such as in a treatment, diagnostic, or clinical setting, back to the IMAT grant.

Our proposed approach will address some of the shortcomings associated with the existing data by identifying the different aspects of the technology such as who is using or has used it, where it has been presented, and how it is being used (e.g., in other research grants or research settings). As found in the feasibility study, the PI of the IMAT grant has the best understanding of all aspects (e.g., patents, inventions, publications, collaborations, and other research) of the IMAT technology.

In addition to the recommended primary data collection, we suggest that the full-scale evaluation of the IMAT Program use some of the existing data sources to prepare background data on each

of the IMAT Program applicants (successful and unsuccessful). It has been our experience that PIs are more likely to make time to discuss their research if an interviewer already has some understanding of the PI's background. We also find it helpful to inform the interviewee early in the interview that the interviewer is not a research scientist so that PIs are more likely to frame their responses in general terms.

3.7. NEED FOR PRIMARY DATA COLLECTION

In the next section of this report we discuss our proposed evaluation approach, which includes a primary data collection. One of the reasons for recommending a primary data collection of interviewing all PIs is that the PIs seemed to have the best grasp on the current status of their technologies. For the feasibility study, we conducted interviews with PIs, IMAT Program staff, NCI program staff, other senior staff at NIH, and several individuals associated with programs outside of NIH that we initially believed to be similar to the IMAT Program. We developed general interview protocols for each type of interview. The focus of the feasibility study was not on initiating the evaluation so the results do not attempt to quantify any aspects of the technologies being developed. For the full-scale evaluation, however, some level of quantification is recommended.

4. PROPOSED EVALUATION DESIGN

In this section, we summarize our proposed evaluation design, including a presentation of our recommended research approach, a list of research questions, a conceptual framework, proposed data sources, a data collection strategy, and a costing/staffing estimate

4.1. RESEARCH EVALUATION APPROACH

We recommend an evaluation approach centered on tracking or following the technology. Under this evaluation strategy, information would be collected and associated with the technology supported under a particular IMAT grant. The history of the technology would then be tracked so that the technology can be described at each stage of its development, even prior to conceptualization for IMAT funding. At various stages in this history, we would likely need to interview individuals who have different associations with the technology in order to gather information about the current state of the technology and its potential for affecting progress in cancer research and treatment. In terms of impact, we suggest that potential users be asked to provide information on the use of the technology in improving research and treatment.

The following diagram depicts the various levels, or stages, that a technology may pass through between IMAT grant and full technological maturation.

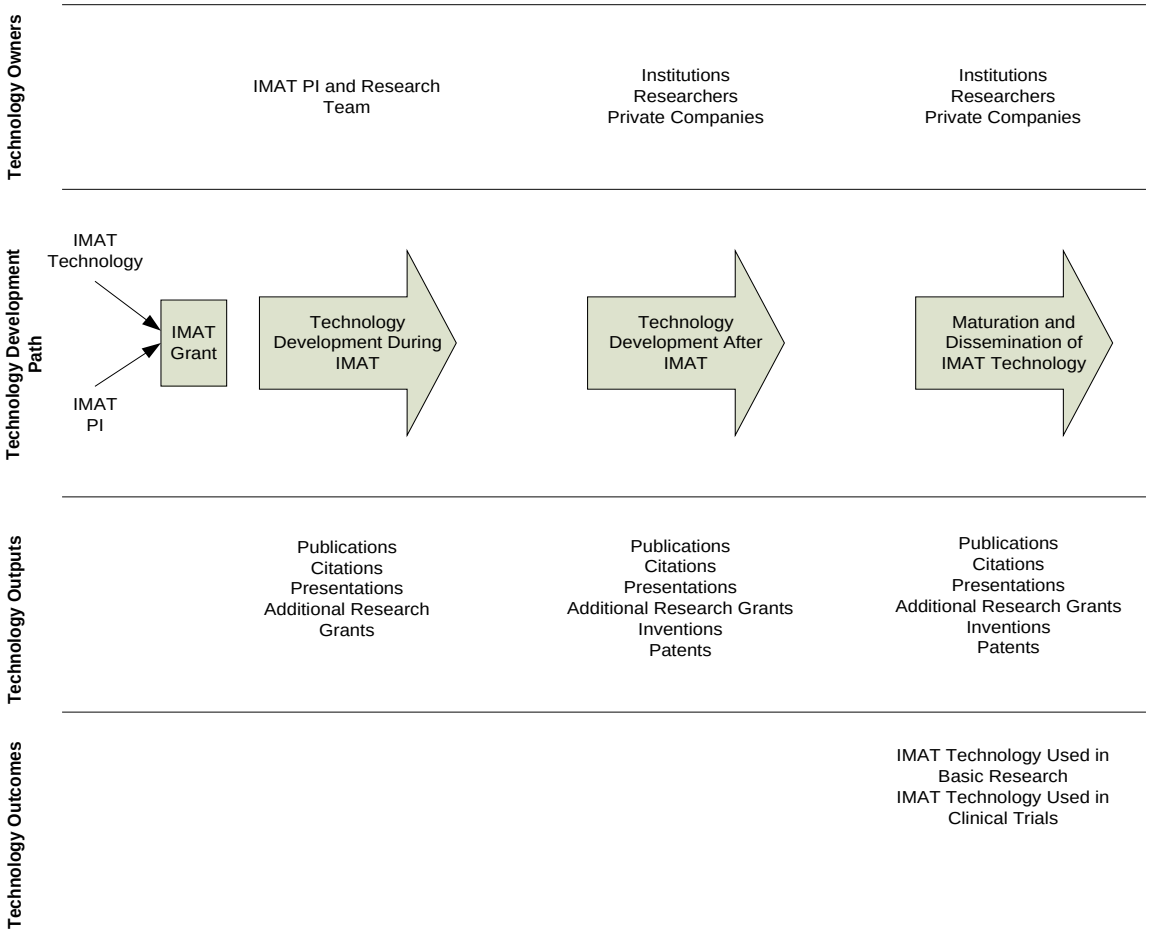


Figure 2. Follow The Technology process

We propose that a full-scale evaluation should track all IMAT grants and the technologies that they proposed. Tracking all IMAT applications is suggested because IMAT Program success may be associated with the impact of only a few funded proposals. Sampling randomly from the population or using case study methods may miss those few projects that make a real difference and thus underestimate IMAT Program success. In other words, the focus should not be on characterizing typical projects, but on overall IMAT Program success. During the feasibility study, many individuals emphasized that failures should be expected and that they would not detract from the overall success of the program, which could be measured by a relatively few number of successes.

We would also suggest tracking unsuccessful IMAT applications and using this group as a comparison. While the resulting comparison group would have selection issues, such as not being considered by NIH during the peer review process to have the same potential as funded projects, there is the potential that the technologies proposed could be funded elsewhere and possibly result in developed technologies that have an impact on cancer research or treatment. In fact, if only one of these technologies becomes successful, the evidence may be sufficient to make the counterfactual argument. However, we would expect that most of these initiatives would not be pursued due to a lack of funding. Methods for correcting the selection could include regression discontinuity using NIH peer-review scores.

The PIs for each application would be interviewed to obtain information on the appropriate elements from the following list (questions may differ for successful and unsuccessful applicants):

- Major research interests
- Description of the technologies involved
- Description of the precursor technologies and their funding mechanisms
- Objectives related to submitting applications
- Major uses of the technologies
- Assessment if funding was not provided
- Assessment of eventual impact
- Conferences relating to technology attended
- Seminars provided on technology
- Papers on technology
- Papers on research using technology
- Patent activity on technology
- Development success of technology
- Barriers in implementing technology
- Current involvement in technology
- Identification of persons responsible for next stages

In the following the technology approach, it will be important to identify individuals associated with the next stages of technology development. The second stage of our proposed approach would be to interview individuals who have taken over the ownership of the technology. This could be the technology transfer office at the university, a private business, or another researcher who would move the technology toward maturity. These individuals will be identified by the original PI or by subsequent owners of the technology. Information collected from these individuals will be similar to that collected from PIs, except that there is no interest in predecessor technologies.

Another effort will be to classify technologies in order to better describe them in more specific terms. This will assist in helping us to talk more about the technology being applied as we follow the technology. Specifically, it will provide a list of common terms that can be used with the original PI as well as others who might be involved in the technology at different stages in its development. This involves a two-step process. First, the dimensions for classification should be identified. Some dimensions may reflect the kinds of analyses the technology addresses, the specific cancers addressed, or the engineering principles on which the technology is based. The evaluation should use experts to develop this classification through content analysis of the applications. Second, the technologies themselves must be classified, which will also involve expert panel input.

Using information from these sources, we will be able to describe the original technology and its development path, including any adaptations of the technology. This step would entail collecting information on impact. Historically, programs such as IMAT have been evaluated by examining academic production as manifested by publications and associated citations, awards, patents, and

collaboration; increased research activity in the specific target areas as measured by production of new scientists; and new grants. The IMAT Program presents an issue with regard to using some of these traditional measures because focus is placed on the technologies. These outputs, although important, may not provide information on the eventual contribution to conducting research on cancer. Some of this is because many individuals avoid publishing about technologies because of concern with disclosure and proprietary ownership issues. In these cases, the technologies might remain private until a patent submission is made. Furthermore, these historical measures of success may be indicative of outputs—or indicators of production—rather than ultimate impact.

To judge impact within a short to intermediate term, we believe that some measure of utilization is necessary—based on an assumed relationship between utilization and progress in research and the treatment of cancer. Thus, in addition to characterizing outputs we propose the following approach for measuring impact for each technology:

- Identify researchers who are utilizing the technologies developed by the IMAT funding. Two potential sources for a frame of these individuals are those individuals who cite any publications produced under the IMAT, and researchers who apply for research grant funding in the areas that the technology addresses.
- Select an economical sample of these individuals maintaining an adequate sample for each technology.
- Survey these individuals and ask some or most of the following questions:

    - Have or are you using the technology to do basic research? Are you using the technology in your practice?
    - To what extent is the technology critical in your research/practice?
    - Are you using the technology to develop other derivative technologies?

        - Are you receiving funding to do this?
        - What agencies are funding this activity?

    - Have you published any results stemming from this using this technology?
    - Have you made any presentations at conferences/seminars on result stemming from the use of this technology?
    - To what extent has this technology enabled your research in terms of pursuing new ideas? In terms of producing results more quickly or more accurately?

The resulting information will provide evidence of short to intermediate term impact for each technology that is being tracked. It is a measure of acceptance of the technology and the degree to which the technology has forwarded research. The impact for each technology should then be summed up to project an overall impact for the program as a whole and compared to the potential comparison group.

4.2. RESEARCH QUESTIONS

Based on our findings and our recommended approach of tracking the technology, we propose the following research questions, which can be summarized into four general topic areas:

- Identification of IMAT and Associated Technologies
- Development Path of the IMAT Technology
- Dissemination of the IMAT Technology
- Outcomes or Impacts of the IMAT Technology

4.2.1. Identification of IMAT and Associated Technologies

- What were the pre-existing technologies that served as the basis for technology developed by IMAT?
- What kinds of technologies were proposed and what types were funded?

4.2.2. Development Path of the IMAT Technology

- How were the technologies developed during the funding period?
- What is the development path after initial funding?
- How is the technology developed after IMAT funding and/or disassociation of the original PI with the project?

4.2.3. Dissemination of the IMAT Technology

- How were the details of the technology spread to scientific audiences?
- To what extent is the technology or methodology being used?

4.2.4. Outcomes or Impacts of the IMAT Technology

- What are the short-term and intermediate-term impacts?

4.3. CONCEPTUAL FRAMEWORK

The conceptual framework and operational definitions for the IMAT Program can be found in appendix B. Although the characteristics vary slightly depending on the IMAT theme initially being pursued, the outputs and outcomes are basically the same. The proposed evaluation focuses on short-term or intermediate outcomes of technology development. For the purpose of this evaluation, we realize that many of these outcomes may not be achievable, or have reached a state of maturation in the timeframe available for this evaluation. As such, we have proposed some short-term and intermediate outcomes that may be more time-sensitive.

4.4. TARGET POPULATION

The target population includes all individuals who have been associated with any IMAT grant or any technology or methodology developed by, or initiated within, an IMAT grant. As previously described, the initial stage of data collection would involve IMAT grant recipients, but later stages would involve other researchers or individuals from research institutions or private companies that were identified during the initial stage.

4.5. PROPOSED DATA SOURCES

As part of the feasibility study, we investigated the available data, investigated an approach to using the data, and spoke to individuals regarding the use of various data. We determined that the most reliable information directly related to the technology could be collected from interviews, but that additional background and supplementary data would also be useful. In most cases, the PI interviews confirmed the background and supplementary information that we had collected and provided additional information related to the IMAT technology.

Table 8 summarizes Macro International's recommendation regarding secondary data sources for the full-scale evaluation. The table also describes the purpose or type of information to be obtained from each source.

Table 8. Recommended Secondary Data Sources for the Full-Scale Evaluation

Data Source	Purpose/Type of Data
CGAF	IMAT grant information IMAT PI grant history Other PI grant history
TFF	IMAT and other PI research training background
DRF	IMAT and other PI demographic and educational history
AAMC Faculty Roster	IMAT and other PI medical education background
PubMed	IMAT and other PI publication data
Web of Science	IMAT and other PI citation data
QVR System	IMAT grant summary statements IMAT grant publication listing
DEITR	IMAT and other PI license, patent, and invention data; patent numbers, number of patents associated with each grant, names of individuals associated with the patents, any other related information associated with the patent or technology, and information pertaining to technology/patent transfers
NIH CRISP	IMAT grant history Key search terms

These data sources could be used to describe the backgrounds of individuals applying for or receiving IMAT funding, as well as individuals in any comparison groups. This description could include creating a profile of each grant recipient, including information on his or her research training (e.g., traineeships, fellowships, career development) and doctoral experience (e.g., Ph.D. field) or medical school experience. Because the file contains a unique identifier, the SETNO, the most current grant for each individual could be retrieved, which would improve the probability of collecting current contact information. If needed, the IMPAC II system could also

be used to gather current contact information. Obtaining the most current grant information for a specific PI, including any non-IMAT grants (e.g., R01s), allows for the identification of research projects for which a PI may be using an IMAT technology.

In addition, the above data sources will also present important information pertaining to the actual IMAT grant, such as amount, length and type of funding, and publication and citation data as well as license, patent, and invention data.

Using a combination of PubMed, the QVR system, and Web of Science allows for a linkage of citation counts to the publications associated with IMAT grants. Using the literature map discussed in section 3.2 would assist in preparing a profile for each PI, which would be useful as part of the full-scale evaluation prior to contacting the interviewees. In addition to the background information on the IMAT grant and PI, this profile would contain a list of all the publications associated with the IMAT grant and their respective citations (or citation counts). Macro International tested this approach as part of our literature/publication review to identify articles for PIs and specific IMAT grants and found the list to be accurate for most PIs.

For the full-scale evaluation of the IMAT Program, Macro International recommends that data related to inventions, technologies, and patents associated with IMAT grantees be formally documented. For purposes of this invention technology/patent data documentation, grantees will be the individual institutions awarded the grants, but the invention technologies/patents would still be associated with the PI and IMAT grant.

We recommend working with DEITR to obtain this information. There are proprietary concerns associated with obtaining this information, so specific requests to DEITR for patent and/or invention data would need to originate from NCI. The information maintained by DEITR is updated regularly. For example, inventions are generally reported as they arise. There are also annual utilization reports that are produced and submitted to DEITR by each grantee institution, which typically discuss how inventions are being used. It should be noted that an invention can be pursued to practical application without receiving a patent. To obtain detailed information on patents, it is recommended that the U.S. Patent and Trademark Office be contacted.

To facilitate the linkage between IMAT PIs and patents/inventions data, DEITR requires only the IMAT grant numbers. For the evaluation study, Macro International recommends obtaining the following information from DEITR: patent numbers, number of patents associated with each grant, the names of individuals associated with the patents, any other related information associated with the patent or technology, and information pertaining to technology/patent transfers.

From our discussions with PIs and subsequent interactions with institutional technology transfer offices, we concluded that the level of service provided by these offices varies widely. Several PIs commended their institution's office of technology transfer for handling every aspect of the patent process smoothly, while others complained that these offices did little to inform or assist them with the patent process. As a followup to these comments, Macro International first reviewed the Web sites of several PI home institution technology transfer offices and then contacted office staff for further information. Many of these institutions have full-service offices staffed with administrators capable of and responsible for undertaking the entire patent process;

other offices are much smaller with more limited capabilities. During one interview, we were informed that the size of the technology transfer office "tends to be proportional to the scale of research conducted by an institution." When a technology is ready for patent submission and has been reviewed and deemed appropriate for a patent, the grantee's institution is generally the applicant for the patent, although the inventor is usually listed on the patent application and reported in iEdison and obtainable from DEITR.

4.6. DATA COLLECTION STRATEGY

For the full-scale evaluation, our recommended approach to addressing the proposed research questions includes the use of secondary data, as well as collecting additional primary data. We recommend using the existing data sources described in section 4.5 to prepare background data on each of the IMAT PIs (both successful and unsuccessful), as well as to create summaries of the IMAT grants. These background summaries will not become case studies, but be used by the evaluation team to keep track of all information related to each grant and subsequent technology.

The main aspect of the strategy is the recommended primary data collection. In section 4.1, we discussed a two-stage approach that includes conducting interviews with all IMAT grant recipients, followed by a second round of interviews with a sample of individuals identified during the first round or possibly those identified through co-authorship on IMAT-related publications.

4.6.1. Data Collection Instrument(s)

Macro International recommends using the three interview protocols similar to those that we developed and pilot tested for the feasibility study (see appendix A). These protocols are probative in nature, allowing for a free-flow discussion and interaction between the respondent and interviewer. The protocols would be modified to include further inquiries into the current status of the technology.

- **PI Interview Protocol—**This protocol focused on issues related to the PI, the proposed technology associated with the IMAT grant(s), the structure of the IMAT Program, the PI's interaction with NCI and other research organizations, application and dissemination of the proposed technology or research, and specific information related to the IMAT grant. Our goal was to obtain as much information about the PI and technology as possible to allow us to follow the technology.
- **IMAT Stakeholders Protocol—**This protocol focused on issues related to IMAT stakeholders. We focused on background information about the IMAT Program, its history, and the current status of the Program. Questions focused on respondents' background and responsibilities as they relate to the IMAT Program, the structure of the IMAT Program, IMAT funding, their interaction with IMAT-funded PIs, their interaction with NCI staff and other Federal colleagues, and their overall thoughts about the IMAT Program.
- **NCI and Other Federal Stakeholders Protocol—**This protocol focused on issues related to NCI and other Federal stakeholders. We were interested in speaking with senior NCI staff in general, whose knowledge and experience with the IMAT Program varied. We were also

interested in speaking with other NIH and other Federal stakeholders who may have worked on programs similar to IMAT or who may have knowledge of IMAT. At the same time, we were interested in speaking with individuals who had been involved in evaluations of similar programs focusing on technology.

IMAT staff provided Macro International with a list of potential PIs to interview along with recommendations of IMAT and NCI staff members to speak with for the interview phase of the feasibility study. All respondents were initially contacted either by e-mail or telephone to invite respondents to participate in the feasibility study and if respondent was willing, schedule a time for a telephone interview. Each protocol includes a short introduction (with an assurance of confidentiality) and a series of open-ended discussion questions. For the full-scale evaluation, we propose interviewing users of the technology as well. It should be noted that for the feasibility study, no interview protocol was developed and no interviews were conducted with the users of the technology. For the full-scale evaluation, Macro International recommends including this group and developing a similar interview protocol. As such, we also recommend pilot testing this particular instrument and making any necessary modifications, if needed, for the full-scale evaluation.

The majority of interviews were completed in 20–40 minutes. Discussions with a few NCI staff members ran a little longer, but all were less than 50 minutes in length. Interviewers summarized the result of each interview after completion. A contact summary form will be used to quantify and summarize each participant's responses in order to facilitate integrating this information with the rest of the data collected for the full-scale evaluation.

4.6.2. Clearance Requirements

There are several different sets of permissions that may be needed to conduct a full-scale evaluation. A contractor would need to get permission from the NIH Office of the Director to use various databases. This would include gaining access to the data sources previously discussed. In addition, permission would be needed to access information maintained by DEITR and/or Institutional Technology Transfer (ITT) offices. In order to conduct the proposed interviews with IMAT grant recipients and other individuals identified during the first stage of the evaluation, clearance would be needed from the Office of Management and Business (OMB).

4.7. TIME AND COST ESTIMATES

There are numerous details related to conducting a full-scale evaluation that could affect the costing and staffing aspects of the project. Based on Macro's proposed approach, we have created a general outline of the tasks that would be needed for such a full-scale evaluation. As discussed earlier, the recommended evaluation approach would involve the following tasks:

- Identification of all IMAT grant applications (and applicants) and grant awards (and awardees)
- Analysis of grant applications to extract descriptive characteristics of each technology
- Construction of a sample frame of unsuccessful IMAT grant applicants

- Development of a database to capture all associated output or outcome data related to the IMAT Program
- Development of Principal Investigator profiles based on data sources described in section 4 of this report
- Data analysis of applicants and awardees from the IMAT and related programs
- Development of interview protocols for successful IMAT grant recipients, successive technology owners, unsuccessful IMAT grant applicants, and other Federal program staff
- Development of data collection instruments for the various interview protocols needing clearance

To conduct all of the above activities, Macro would recommend a team comprising at least the following members:

- Project director with NIH program evaluation experience
- Sampling statistician
- Expert panel of three members
- Senior programmer/database developer
- Senior research analyst
- Junior data/research analyst
- OMB clearance expert

Assuming NIH pursues this approach, Macro would estimate that between 650 and 750 interviews would be conducted with about 3 hours per interview. The 3 hours would include some preparation time, about 40 minutes to conduct the interview and about 1.5–2 hours to summarize and classify the information obtained during the interview. An additional 15–20 minutes would likely be required by an expert to validate the classification of the technology(ies). About 10–15 minutes would be required to create a profile for each interviewee with an additional 80–120 hours to create, document, and populate the actual database. Time would be required by the senior program/database developer to conduct some data analyses on various aspects of the IMAT Program. Time would be required to create and submit the OMB clearance package, as well.

Because of the time required to obtain OMB clearance and to conduct and summarize the multiple rounds of interviews, Macro estimates a minimum of 12 months to conduct the full-scale evaluation study, with a more likely schedule of 15 months. The total estimate to NIH/NCI to conduct this study would be around 2,400 hours at a cost of between $400,000 and $450,000.

APPENDIX A:

INTERVIEW PROTOCOLS

INTERVIEW PROTOCOL FOR IMAT PRINCIPAL INVESTIGATORS

Hello, is this is Dr. _____? My name is _____, and I'm a member of the project team working with NCI to evaluate the Innovative Molecular Analysis Technologies Program. As you may know, NCI is conducting a full-scale evaluation of the IMAT Program. I work for Macro International, a research and evaluation firm in Bethesda, MD, charged with the task of conducting this evaluation. We greatly appreciate your willingness to answer a few questions about the IMAT Program and the technology funded by the IMAT award. You have been selected because you received IMAT funding for [provide grant numbers and names]. I want to assure you that your participation is voluntary and that your responses will be kept strictly confidential. We would like you to be totally candid. We will take careful precautions to ensure that your name cannot be associated with your responses. We expect our discussion to take about ____ minutes. Do you wish to proceed at this time?

If yes: Good. We realize that your time is valuable, so let's get started.
If no: Would you like to schedule another time for this discussion? (Try to schedule another time and thank the respondent for his or her willingness to participate.)

Our interview is divided into six sections, specifically:

- Your background as PI for the IMAT grant(s) and your proposed technology for your IMAT grant(s)
- The structure of the IMAT Program
- Your interactions with NCI
- Your interactions with other research organizations
- The application and dissemination of the proposed technology or research
- Specific information related to the IMAT grant

Background of PI (prepare by looking at the individual's summary statement)

1. Can you describe your grant/technology in terms of the methodologies used?
2. How was the idea for this grant/technology generated? (e.g., Was it part of any of your earlier grants?)

IMAT Structure

1. Was it difficult to frame your idea within the context/themes of the IMAT Program?
   a. Can you describe (generally) what made it difficult?
   b. What would have made it easier to frame?
2. If grant was coupled: What do you think of the coupling mechanism provided by IMAT?
3. How did you develop your milestones? Did you get input from IMAT staff regarding your milestones?
4. Did you reach your milestones? If not, what happened when the milestones were not reached by the end of the grant?

Interactions With NCI

1. Did you expect to have regular contact with NCI or NIH as part of this grant?
2. How often did you meet with individuals from NCI or NIH?
   a. Were the meetings productive and useful in developing the research/technology?
3. Were meetings attended by other grantees or experts in cancer research (or just NCI and/or IMAT staff)?
   a. Did your attendance at these meetings help foster collaborations?
4. Do you still interact with NCI and/or IMAT staff?

Interactions With Other Research Organizations (e.g., institutions, private firms)

1. Do you collaborate on this research/technology with other departments or centers at your current organization?
2. Have you collaborated with other organizations outside your current organization?
   a. Did this collaborative relationship exist before the IMAT grant?
   b. How was the collaboration initiated?
   c. Are any collaborations formed with colleagues from other disciplines?

Application and Dissemination of the Research/Technology

1. Did the technology that you developed under the IMAT Program have any relation to an earlier technology used by you or someone else?
2. Is this technology ready for widespread application or already being used in the research community?
   a. What do you see as the eventual outcome of this technology?
   b. How do you envision achieving this outcome?
3. Could you describe some ways in which you have been able to apply your research/technology?
4. Are you aware of others who are using your research/technology? Are you aware of any additional technologies that have been developed as a result/extension of the technology you developed from your IMAT grant?
   a. Are you aware of how this use began?
   b. Are you aware of an impact that your activities have had on other researchers in the field?
5. Have you filed any patents? Are you planning to file any patents? Does your institution work with you on patents? What kind of relationship do you have with your organization regarding patents and patent applications?

Our intention with the next few questions is to identify ways in which your technology is being applied or disseminated.

6. According to our research, you have published [xx] articles related to your IMAT grant. Would you agree with this list or are there more/fewer publications related to this research/technology?
7. Do you list the grant number on all publications associated with this grant?

8. Have others been involved with your grants, including any of your students/junior investigators who have taken the initial technology and moved forward with it?
    a. Have any new technologies been developed as a result?
9. If a patent was filed: Our research shows that your technology led to a patent. Could you describe the process of applying for and receiving the patent?
    a. Did you receive assistance from NIH or NCI during this process?

PI's Specific Grant

1. Would you have pursued development of this particular technology without the IMAT funding?
    a. If so, what mechanisms would you have pursued/used?
2. Regarding the funding you are currently receiving from NIH/NCI via an R01 (identify prior to call), does the technology you developed on the R21/R33 grant play a major role?
3. Are there other grants that you are currently receiving that use the technology (e.g., NSF, DOD, NIST)?
4. What other funding mechanisms support your research?
5. Were IMAT funds leveraged to increase research funding/support from other sources? (If yes, please explain.)
6. Did any postdoctorates, fellows, trainees on other grants, or other individuals work on the IMAT grant with you?

At the conclusion of the interview/discussion, we will ask the interviewees whether they have any questions regarding the interview or feasibility study. We will then thank them for their time and input to the study, as well as reiterate that they can contact Richard Aragon with any additional questions.

INTERVIEW PROTOCOL FOR IMAT STAKEHOLDERS

Hello, is this is Dr. _____? My name is _____, and I'm a member of the project team working with NCI to evaluate the Innovative Molecular Analysis Technologies Program. As you may know, NCI is conducting a full-scale evaluation of the IMAT Program. I work for Macro International, a research and evaluation firm in Bethesda, MD, charged with the task of conducting this evaluation. We greatly appreciate your willingness to answer a few questions about the IMAT Program. You have been selected because you are a senior member of the IMAT team. I want to assure you that your participation is voluntary and that your responses will be kept strictly confidential. We would like you to be totally candid. We will take careful precautions to ensure that your name cannot be associated with your responses. We expect our discussion to take about ____ minutes. Do you wish to proceed at this time?

If yes: Good. We realize that your time is valuable, so let's get started.
If no: Would you like to schedule another time for this discussion? (Try to schedule another time and thank the respondent for his or her willingness to participate.)

Our interview is divided into six sections, specifically:

- Your background and your responsibilities as they relate to the IMAT Program
- The structure of the IMAT Program
- IMAT funding
- Your interaction with IMAT-funded PIs
- Your interaction with NCI staff and other Federal colleagues
- Overall thoughts about the IMAT Program

Background of Respondent

1. How long have you worked in your capacity as _____?
2. What is your role in the IMAT Program? How long have you been associated with IMAT?
3. Have you held any other positions in the IMAT Program prior to your current position?
4. Have you worked at any other institute at NIH or another Federal agency? If yes: Where?
5. Have you ever worked on any evaluations of any NIH or Federal program? If yes: What methods were used to evaluate that program?
6. Are you involved in the evaluation of the IMAT Program? How?
7. Are you aware of any other programs that are similar to IMAT? Do you know whether they have been evaluated?

IMAT Structure

1. What do you perceive as the consequences of the IMAT Program?
2. I would like to talk about the goals of IMAT. Do you believe that the Program's current structure is appropriate to achieve the goals of the IMAT Program?
3. Do you think the current funding mechanisms (R21, R33, R41/42, and R43/44) are appropriate mechanisms for the IMAT Program? Do you think other funding mechanisms are needed?

4. Can you tell me about the coupled R21/R33 mechanism? Do you know why this coupled mechanism is no longer being offered for IMAT funding? Do you know whether any other programs offer this coupled mechanism?
5. Please tell me about the milestones that IMAT uses for the R21 mechanism. Who develops the milestones? Are the milestones that the PIs establish reasonable? What happens if the milestones are not reached at the end of the grant?
6. IMAT has changed since it was originally designed and now encompasses three programs. Why have there been changes? What was the reason for the change to the IMAT Program?
7. Do you believe these changes were helpful for the Program?
8. Do you anticipate any additional changes or modifications to the Program?
9. Do you believe that the current structure of the IMAT Program permits collaboration among scientists?
10. Do you believe that the current structure of IMAT permits collaboration with professionals in other fields (i.e., inter/multidisciplinary relationships)?
11. Do awardees have adequate interaction and collaboration with IMAT staff? If no: What types of activities would facilitate greater collaboration with IMAT staff?
12. Is the current structure of the IMAT Program the most effective means to achieve the goals of the Program?
13. What changes would you make to the IMAT Program?

IMAT Funding

1. Are you involved in the award/selection process for IMAT? (If no, proceed to next section.) If yes: What role do you play in the award/selection process?
2. Please tell me about the award process. How are grants reviewed and ultimately funded? (Probe: How are grants selected? Who sits on the panel to choose awardees? How many people make the final decision to grant an award?)
3. Is IMAT funding adequate at current levels?

Interaction With PIs

1. Do you, in your role as _____, have interaction with the PIs awarded funds? What kind of interaction? How often?
2. What do you think is the appropriate level of interaction between IMAT staff and PIs? Why? Is this level of interaction achievable?
3. Do you participate in the annual PI meetings? If yes: What is your role at these meetings?
4. Do you have regular contact with PIs as part of this grant? How often?
5. What kind of mechanisms, if any, are in place to review the progress of those programs awarded funding?
6. Do you receive progress reports or something similar from awardees? How frequently?
7. How are these [fill in type of report] reports submitted? Who reviews these reports?
8. What kind of information is collected in these [fill in type of report] reports? (Probe: Is there a Web-based submission system?)
9. How do IMAT and NCI use this information from the reports?

Interaction With NIH and Other Federal Colleagues

1. Do you meet with other NIH staff and/or other Federal agencies to discuss IMAT? During these meetings, do you discuss ongoing evaluations of other or similar programs?
2. During your interaction with other colleagues, how would you assess the perception of the IMAT Program by your colleagues?

Overall Thoughts About the Program

1. Would you consider the IMAT Program to be a successful/valuable program? Why/Why not?
2. Is there anything that would make the Program more successful or valuable?

At the conclusion of the interview/discussion, we will ask the interviewees whether they have any questions regarding the interview or feasibility study. We will then thank them for their time and input to the study, as well as reiterate that they can contact Richard Aragon with any additional questions.

INTERVIEW PROTOCOL FOR NCI AND OTHER FEDERAL STAKEHOLDERS

Hello, is this is Dr. _____? My name is _____, and I'm a member of the project team working with NCI to evaluate the Innovative Molecular Analysis Technologies Program. As you may know, NCI is conducting a full-scale evaluation of the IMAT Program. I work for Macro International, a research and evaluation firm in Bethesda, MD, charged with the task of conducting this evaluation. We greatly appreciate your willingness to answer a few questions to help us with this evaluation. You have been selected because you are a [choose correct option: senior NCI staff member, senior NIH staff member who may be/is familiar with the IMAT Program, or senior Federal employee associated with a program focusing on technology that we believe to be similar to IMAT]. I want to assure you that your participation is voluntary and that your responses will be kept strictly confidential. We would like you to be totally candid. We will take careful precautions to ensure that your name cannot be associated with your responses. We expect our discussion to take about ____ minutes. Do you wish to proceed at this time?

If yes: Good. We realize that your time is valuable, so let's get started.
If no: Would you like to schedule another time for this discussion? (Try to schedule another time and thank the respondent for his or her willingness to participate.)

Our interview is divided into three sections, specifically:

- Your background and your current program
- Program-related questions and questions about IMAT (if respondent was/is familiar with the IMAT Program)
- Overall thoughts about the IMAT Program (if respondent is familiar with the IMAT Program)

Background of Respondent and Program

1. How long have you worked in your capacity as _____?
2. What is your role in the [fill in appropriate name of program] program? How long have you been associated with [fill in appropriate name of program] program?
3. Have you held any other positions in this program prior to your current position?
4. Have you worked at any other federally funded organization? Where?
5. Have you ever worked on an evaluation of any Federal program? If yes: What methods were used to evaluate that program? Can I obtain a copy of this evaluation (ask for name and URL if possible)?

Program-Related Questions

1. Please tell me about the program you are associated with. When was this program established? Why was it established?
2. Has the [fill in name of program] program been evaluated? If yes: Who conducted the evaluation?

3. Were you involved in the evaluation of the [fill in appropriate name of program] program? How?
4. What methods did you use to conduct this evaluation? Do you have a final report that we can see? (If yes: Obtain details and name/URL.)
5. Are you familiar with the IMAT Program? Can you tell me whether you see any similarities between your program and the IMAT Program? What kind of similarities? Differences?
6. Can you tell me what you think the goals of the IMAT Program are? Do you think these goals are achievable? Why/why not?
7. Do you think that the IMAT Program's current structure is appropriate for achieving these goals?
8. Are you aware of any other programs that are similar to your program or IMAT? Do you know whether this/these program(s) have been evaluated? (Ask for any related information.)
9. Do you have any suggestions for conducting an evaluation of IMAT?

Overall Thoughts About the Program

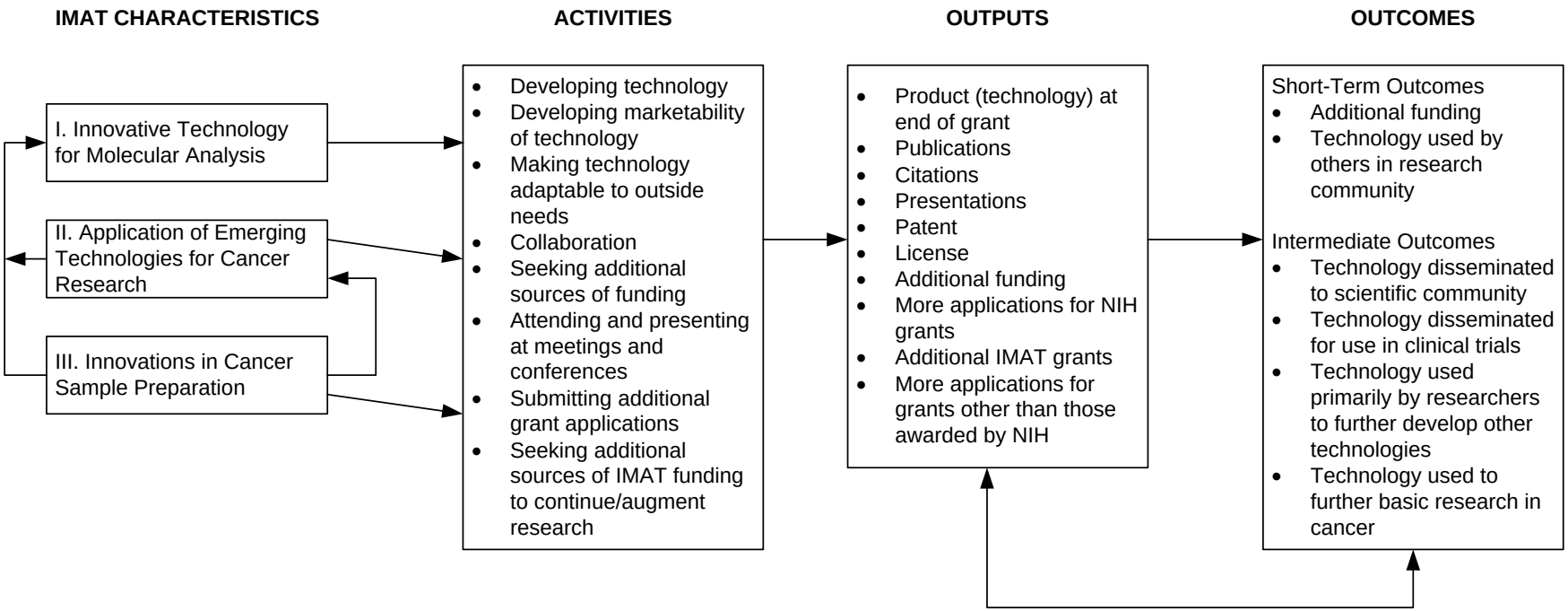
1. Would you consider the IMAT Program to be a successful/valuable program? Why/Why not?
2. Is there anything that would make the Program more successful or valuable?

At the conclusion of the interview/discussion, we will ask the interviewees whether they have any questions regarding the interview or feasibility study. We will then thank them for their time and input to the study, as well as reiterate that they can contact Richard Aragon with any additional questions.

APPENDIX B:

CONCEPTUAL FRAMEWORK AND OPERATIONAL DEFINITIONS

IMAT CONCEPTUAL FRAMEWORK



IMAT CHARACTERISTICS

I. INNOVATIVE TECHNOLOGY FOR MOLECULAR ANALYSIS

- Previous research experience of PI
- Previous experience of PI as it relates to proposed technology
- General categorical description of the technology
- Proposed objectives of the technology
- Current state of proposed technology
- Funding for the IMAT research
- Projected progress of the technology
- Environment (kind of institution) in which the technology is developed
- Sources of other funding for PI
- Resources generated from other IMAT-funded projects or from other NIH-funded projects

II. APPLICATION OF EMERGING TECHNOLOGIES FOR CANCER RESEARCH

- Continuation of earlier IMAT grant
- Previous research experience of PI
- Previous experience of PI as it relates to proposed technology
- General categorical description of the technology
- Proposed objectives of the technology
- Current state of proposed technology
- Funding for the IMAT research
- Projected progress of the technology
- Environment (kind of institution) in which the technology is developed
- Sources of other funding for PI
- Resources generated from other IMAT-funded projects or from other NIH-funded projects

III. INNOVATIONS IN CANCER SAMPLE PREPARATION

- Sample preparation methodology and technology for sample collection
- Previous research experience of PI
- Previous experience of PI as it relates to proposed technology
- General categorical description of the technology
- Proposed objectives of the technology
- Current state of proposed technology
- Funding for the IMAT research
- Projected progress of the technology
- Environment (kind of institution) in which the technology is developed
- Sources of other funding for PI
- Resources generated from other IMAT-funded projects or from other NIH-funded projects

IMAT CHARACTERISTICS

I. Innovative Technology for Molecular Analysis

- **Previous research experience of PI:** The extent to which the grant's initial PI was experienced in obtaining research grants as measured by the number of different NIH and other extramural awards obtained prior to the IMAT award and whether this experience was related to technology development or cancer research. (Data sources: NIH CGAF, IMAT grant applications, summary statements and progress reports, university/PI Web site. Note: "PI Web site" or "Web site maintained by PI" means a Web site that is maintained by the university or a PI at a given university.)
- **Previous experience of PI as it relates to proposed technology:** The extent to which the grant's initial PI knew/had knowledge of, or previous experience working with, the technology proposed for the IMAT grant. (Data sources: Prior publications, IMAT grant applications, summary statements and progress reports, university/PI Web site)
- **General categorical description of the technology:** A description of the technology for the purposes of categorization. This allows us to examine the evolution, in general terms, of the technology over time. (Data sources: IMAT grant application, summary statements and progress report, CRISP database thesaurus, interview with PI, Web site maintained by PI)
- **Proposed objectives of the technology:** A summary of the proposed objectives and goals of the technology in terms of its impact on research or treatment. (Data sources: IMAT grant application, summary statements and progress report, CRISP database thesaurus, interview with PI, Web site maintained by PI)
- **Current state of proposed technology:** The extent to which the proposed technology was currently developed/available. Status of proposed technology prior to commencement of IMAT award. A discussion of the proposed intervention/technology at its current level of development. A description of the current status of a proposed technology. Evolution of technology to the point at which it has been proposed for IMAT funding. This should include how the technology is to be used or application for use. (Data sources: Prior publications on technology, IMAT grant application, summary statements and progress reports, Notes from Study Sections, Web site maintained by PI)
- **Funding for the IMAT research:** A summary of the funding provided for the IMAT grant. (Data source: IMAT grant application, summary statements and progress report, interview with PI, PI Web site)
- **Projected progress of the technology:** A description of the projected progress that the technology will follow during the course of the IMAT grant. (Data sources: IMAT grant application, summary statements and progress reports, CRISP database, interview with PI, PI Web site)
- **Environment in which technology is developed:** A description of the type of institution or the specific facilities housing the IMAT grantee. (Data sources: IMAT grant application, summary statements and progress reports, interviews with PI, *Higher Education Directory,* AAMC directory)

- **Sources of other funding for PI:** The sources (e.g., NIH and other sources) of funding that the grant's initial PI was able to obtain prior to receiving the IMAT grant. (Data sources: NIH CGAF, IMAT grant applications, summary statements and progress reports, PI Web site)
- **Does it utilize resources generated from other IMAT funded projects from other NIH funded projects?** An analysis to see whether resources from other NIH funded projects being used to supplement the IMAT grant. (Data source: IMAT grant application, summary statements and progress reports, interviews with PIs, PI Web site)

II. Application of Emerging Technologies for Cancer Research

- **Continuation of earlier IMAT grant:** For this particular item, we are assuming that an earlier IMAT grant is being continued. The scope of technological development achieved which was funded under an earlier IMAT grant. There is an assumption here of development/growth of technology under earlier IMAT grant, perhaps meeting certain milestones. (Data sources: Publications, IMAT grant applications, summary statements and progress reports, PI Web site)
- **Previous research experience of PI:** The extent to which the grant's initial PI was experienced in obtaining research grants as measured by the number of different NIH and other extramural awards obtained prior to IMAT award. (Data Sources: NIH CGAF, IMAT grant applications, summary statements and progress reports, PI Web site)
- **Previous experience of PI as it relates to proposed technology:** The extent to which the grant's initial PI knew/had knowledge of, or previous experience working with, the technology proposed for the IMAT grant. (Data sources: Prior publications, IMAT grant applications, summary statements and progress reports, PI Web site)
- **Current state of proposed technology:** The extent to which the proposed technology was currently developed/available. Status of proposed technology prior to commencement of IMAT award. A discussion of the proposed intervention/technology at its current level of development. A description of the current status of a proposed technology. Evolution of technology to the point at which it has been proposed for IMAT funding. This should include how the technology is to be used or application for use. (Data sources: Prior publications on technology, IMAT grant application, summary statements and progress reports, Notes from Study Sections, PI Web site)
- **Sources of other funding for PI:** The sources (e.g., NIH and other sources) of funding that the grant's initial PI was able to obtain prior to receiving the IMAT grant. (Data sources: NIH CGAF, IMAT grant applications, summary statements and progress reports, PI Web site)

III. Innovations in Cancer Sample Preparation

- **Sample preparation methodology and technology for sample collection:** The extent to which a technology has been developed so that it is applicable to cancer sample preparation. Data sources: Publications, IMAT grant applications, summary statements and progress reports, PI Web site)

- **Previous research experience of PI:** The extent to which the grant's initial PI was experienced in obtaining research grants as measured by the number of different NIH and other extramural awards obtained prior to IMAT award. (Data sources: NIH CGAF, IMAT grant applications, summary statements and progress reports, PI Web site)
- **Previous experience of PI as it relates to proposed technology:** The extent to which the grant's initial PI knew/had knowledge of, or previous experience working with, the technology proposed for the IMAT grant. (Data sources: Prior publications, IMAT grant applications, summary statements and progress reports, PI Web site)
- **Current state of proposed technology:** The extent to which the proposed technology was currently developed/available. Status of proposed technology prior to commencement of IMAT award. A discussion of the proposed intervention/technology at its current level of development. A description of the current status of a proposed technology. Evolution of technology to the point at which it has been proposed for IMAT funding. This should include how the technology is to be used or application for use. (Data sources: Prior publications on technology, IMAT grant application, summary statements and progress reports, Notes from Study Sections, PI Web site)
- **Sources of other funding for PI:** The sources (e.g., NIH and other sources) of funding that the grant's initial PI was able to obtain prior to receiving the IMAT grant. (Data sources: NIH CGAF, IMAT grant applications, summary statements and progress reports, PI Web site)

ACTIVITIES

- **Developing technology:** Taking the technology proposed in the grant and developing it throughout the span of the grant. In other words, how was the technology transformed from idea to product. (Data source: Interviews with PIs, interviews with others using technology, IMAT summary statements and progress reports, any other IMAT documentation that would be appropriate, PI Web site)
- **Developing marketability of technology:** Exploring options for making technology feasible/useful for wider application to research/scientific and/or business community (Data source: Interviews with PIs, interviews with others using technology, IMAT summary statements and progress reports, PubMed, any other IMAT documentation that would be appropriate, PI Web site, Web site of others interested technology)
- **Making technology adaptable to outside needs:** Advancing the technology to make it adaptable to the needs of the scientific, research, and/or business community (Data source: Interviews with PIs, interviews with others using technology, IMAT summary statements and progress reports, any other IMAT documentation that would be appropriate)
- **Collaboration:** This activity has many possible relationships, all of which need to be examined for the feasibility study. Collaboration can mean an increase in, or the extent to which, the PI collaborates with colleagues from his or her own institution or from other institutions on matters related to the specific technology proposed for the IMAT award. Number of published (or pending) publications in referred scientific journals co-authored by IMAT participants and other researchers/scientists not associated with the IMAT award but housed at their home institution. This can also include other types of collaborations, such as

seminars, workshops, other grants, other research projects, and presentations. Collaboration can also include the interaction between the PI and staff from IMAT, NCI, and NIH. (Data sources: Interviews with PIs, interviews with others using technology or associated with technology, PubMed, licensing/patent information, iEdison data, IMAT summary statements and progress reports, PI Web site, Web site of collaborators)

- **Seeking additional sources of funding to continue/augment IMAT research:** Activities relating to applications for and receipt of additional sources of funding to continue or augment the current IMAT grant. (Data sources: NIH CGAF, interviews with PIs, and IMAT summary statements and progress reports)
- **Attending and presenting at meetings and conferences:** An increase in the number of meetings and conferences attended by PIs and individuals associated with/funded by IMAT. Overall, more interaction with scientific community, especially those in the scientific community focusing on cancer research. (Data source: Interviews with PIs, IMAT summary statements and progress reports, PI Web site).
- **Submitting additional grants:** An increase in the number of initial and amended competitive research grant applications, especially research project grant applications focusing on the continuation of the current IMAT work, cancer research, emerging cancer research technology, or cancer sample preparation technology. (Data sources: NIH CGAF, interviews with PIs, and IMAT summary statements and progress reports)

OUTPUTS

We view outputs as the technology itself at the end of the grant.

- **Technology ready for market:** The extent to which the technology is used by the scientific community. Technology is viewed as going through a development lifecycle, from conceptualization to a final usable form.
- **Publications:** Count of papers published in referred scientific journals, either published or in progress, associated with the IMAT grant. (Data source: PI interview, PubMed, QVR system, IMAT progress report and summary statements, PI Web site)
- **Citations:** Number of times a particular published paper associated with an IMAT grant has been cited. (Data source: Web of Science, PI Web site)
- **Presentations:** Number of presentations, papers, and posters associated with an IMAT grant prepared by individuals associated with a specific IMAT grant. (Data source: PI interview, IMAT summary statement and progress report, PI Web site)
- **Patents:** Number of patents, applied for and/or conferred, associated with an IMAT grant/technology. (Data source: PI interview, technology transfer office at home institution, iEdison, PI Web site)
- **Licenses:** Number of licenses applied for and/or conferred, associated with an IMAT grant/technology (Data source: PI interview, technology transfer office at home institution, iEdison, PI Web site)
- **Additional funding:** An increase in funding to support development of proposed technology. Additional funding may not always be used to support a specific IMAT technology, however. Additional funding may be acquired to pursue new research or to follow different technologies for a different IMAT grant. (Data sources: NIH CGAF, interviews with PIs, IMAT summary statements and progress reports, PI Web site)

- **More applications for NIH grants:** Increase in the number of competitive research grant applications, initial and/or amended, submitted to NIH. (Data sources: PI interviews, NIH CGAF, IMAT summary statement and progress reports)
- **Applications for grants other than those awarded by NIH:** Increase in the number of competitive research grant applications, initial and/or amended, submitted to other sources of funding from the NIH. Sources can include other Federal agencies and nonprofit organizations. (Data sources: PI interviews, NIH CGAF, IMAT summary statement and progress report)

OUTCOMES

- **Short-Term Outcomes**

    - **Additional funding:** The extent to which technology has an impact in the volume/value of funding to support development of the proposed technology. (Data sources: NIH CGAF, interviews with PIs, IMAT summary statements and progress reports, PI Web site)
    - **Technology used by others in research community**: The extent to which technology has an impact on cancer-related research, science, and the business community in general. This is a measure to evaluate the impact of a given technology. As a short-term outcome, the measure may be minimal since the impact may not have had a noticeable effect within a short period of time. (Data sources: PubMed, Web of Science, interview with PI, patent and licensing information. PI Web site, Web sites of others interested in technology)

- **Intermediate Outcomes**

    - **Technology disseminated to scientific community:** The extent to which specific sectors of the scientific community have used the technology. The impact of a technology may have a less widespread application, but may be used for specific areas of research in specific fields of cancer research. (Data sources: PI interviews, IMAT summary statements, progress reports and supplemental grant applications, PubMed, Web of Science, PI Web site, Web site of others interested in technology)
    - **Technology disseminated for use in clinical trials:** The extent to which technology has developed sufficiently/adequately to be used in clinical trials. The extent to which technology has developed sufficiently/adequately to test the viability of technology outside the laboratory. (Data sources: PI interviews, IMAT progress reports and summary statements, PubMed, PI Web site, clinical trial organization Web sites)
    - **Technology used primarily by researchers to further develop other technologies:** The extent to which technology is pursued by others in the scientific community. In some instances, originator of IMAT technology (usually the initial PI) may transfer control of the technology, and the technology then becomes the property/responsibility of another person or entity. (Data sources: PI interviews, IMAT progress reports and summary statements, PubMed, patent and licensing information, PI Web site, Web site of others interested in technology)

- **Technology used to further basic cancer research:** The extent to which the technology is used by the scientific, research, and business community to pursue their own cancer research. (Data sources: PI interviews, IMAT progress reports and summary statements, PubMed, patent and licensing information, PI Web site, Web site of others interested in technology)