TRWG Public Comment Synthesis
These are responses to a request for public comment that was issued December 20, 2005 through January 27, 2006 at http://trwg.cancer.gov

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Summary of Response Demographics

As shown in the table below, 179 individual responses to the public comment forum were received. More than one-quarter of responses were from those who self characterized as "academic translational researchers" while nearly twenty percent were from individuals self-characterizing as patients or patient advocates.

Demographics of Responses	Total	Percentage of Responses
Academic Translational Researcher	46	25.70%
Patient Advocate/Patient	33	18.44%
Academic Clinical Researcher	19	10.61%
Academic Basic Researcher	17	9.50%
Government	17	9.50%
Other	17	9.50%
Community Oncologist/Health Professional	8	4.47%
Industry	8	4.47%
Care Provider	5	2.79%
General Public	4	2.23%
NGO/Foundation	3	1.68%
Legal/Regulatory	2	1.12%

Nearly ten percent of respondents self-categorized as "Other", including:

- Postdoctoral fellows/graduate students (2)
- Population researchers (2)
- NGO (2)
- Cancer Center director
- Cancer Center administrator
- Patient
- NCI intramural investigator
- Biostatistician at cancer center
- Bioincubator personnel

Definition of Translational Research

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographics of Respondents	Total	Answered Question 2
Academic Basic Researcher	17	15
Academic Clinical Researcher	19	16
Academic Translational Researcher	46	40
Care Provider	5	3
Community Oncologist/Health Professional	8	5
General Public	4	2
Government	17	11
Industry	8	6
Legal/Regulatory	2	1
NGO/Foundation	3	2
Other	17	12
Patient Advocate/Patient	33	25
Grand Total	179	138

Note: There was not sufficient time before the Roundtable to limit the demographics to codeable respondents. As a result, the number of those answering each question as shown in the table is larger than the number of "codeable" respondents discussed in the text of each analysis):

2. Please comment on the DRAFT definition:

R&D activities

1. Linking basic and clinical research in a dynamic cycle
- **Moving a promising laboratory or basic epidemiology discovery into initial (Phase I/II) testing in the clinic or community**
- **Applying clinical research findings to stimulate new lines of laboratory or epidemiological research**

2. Focusing on clinical objectives
- **Intervention (agent, diagnostic, screening tool, etc.)**
- **Biological endpoint**
- **Patient cohort**
- **Intervention/cohort/endpoint combination to test in a human trial**

From the 138 respondents, a total of 163 comments were received. Of these, 31 were not interpretable or raised issues beyond the scope of the question, leaving 132 responses that directly addressed the definition of translational research.

- Approximately one third of the responses were non-specific expressions of support or approval, while fewer than ten percent were non-specific criticisms or expressions of disapproval.
- Almost one-third of the responses called for inclusion of specific topics that could be considered implicit in the definition. These included:

  - The character of translational research, such as the bidirectional flow of information between lab and clinic
  - Types of research, such as computer and statistical sciences, and IND-type studies
  - Specific research goals, such as risk markers and identification of targets of therapeutic agents
  - Key research resources, such as high quality pathological evaluations
  - Measures used to assess the impact of an intervention, such as patient-reported outcomes and other clinical endpoints
  - Aspects of the cancer care continuum, such as prevention, assessment of risk, and diagnosis
  - Types of intervention, such as behavioral interventions and complementary modalities
  - The character of interventions, e.g. “evidence-based”

- About one in 10 of the responses raised issues or recommendations, including:
  - How research should be done, such as interdisciplinary team effort, collaboration and communication, and the creation of research networks and consortia
  - Timeliness of achieving clinical results
  - Importance of patient safety and risk management
  - Specific areas that warranted increased attention, such as improved grading/staging, and improved clinical laboratory methods
  - Overall focus of translational research, such as on disease models rather than biological mechanisms, or on targeted therapies
  - Need to consider potential new research models

- Another one in 10 of responses sought to expand the scope of the definition to include later stages in the process, such as late-stage clinical trials, dissemination and implementation in the community, financing, and access to the new interventions.

Barriers to/Incentives for Translational Research

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q3	Q4	Q5	Q6
Academic Basic Researcher	17	13	11	10	10
Academic Clinical Researcher	19	16	12	9	12
Academic Translational Researcher	46	42	40	33	32
Care Provider	5	2	1	0	0
Community Oncologist/Health Professional	8	5	5	4	5
General Public	4	2	2	1	1
Government	17	13	13	11	12
Industry	8	7	7	5	5
Legal/Regulatory	2	1	1	1	1
NGO/Foundation	3	3	2	1	1
Other	17	11	10	8	9
Patient Advocate/Patient	33	21	18	17	18
Total	179	136	122	100	106

3. Please comment on the most significant successes and challenges in translational research and the improvements needed in the process.

Of the 134 respondents, several gave multiple answers, for a total of 208 responses to consider.

- The majority of the respondents focused on the challenges of translational research. However, between ten and fifteen percent of the respondents mentioned successes, including:
    - Collaborations, between researchers and clinicians as well as interdisciplinary teams
    - SPORE program
    - Targeted therapies (e.g., Gleevec, Herceptin)

Challenges included:

- The need for improved resources was cited as a significant challenge by one-third of the respondents.
    - Increased financial support was mentioned by one-fifth of the respondents.
    - Other resource issues mentioned included access to biospecimens, access to infrastructure and production facilities, improved animal and toxicity models, and technology transfer resources.
- The need for a team approach to research was mentioned by one-fifth of the respondents, including:
    - Collaboration between clinicians and researchers as well as multidisciplinary teams
    - Support, incentives, and recognition for team approach
    - Collaboration between academic and community sites
- One in ten respondents cited a wide range of challenges involving the regulatory system, including issues regarding IND submissions, HIPAA, IRBs, and FDA.
- Other challenges noted by respondents included:

- Incentives for faculty to conduct translational research
- Peer review for translational research – need for specific study sections Bioinformatics resources
- Communication and understanding between clinicians and basic researchers
- Integration of academia and industry
- Training and retention of young investigators

4. Please comment on the policies, procedures, and structures within NCI programs, academic medical centers, industry, etc. that are barriers to the coordination, collaboration, and hand-off that are essential to translational research.

Of the 114 respondents, several gave multiple answers, for a total of 146 responses to consider.

- Forty percent of the respondents cited barriers concerning collaboration. Specific issues cited by multiple respondents included:
  - Barriers to collaborations between clinicians and basic researchers
  - Barriers to collaborations between industry and academia
  - Barriers to working with community physicians
  - Intellectual property concerns
  - Competition instead of cooperation
- One-third of the respondents cited barriers concerning resources, with more than half of these comments involving financial resources. Other barriers regarding resources included:
  - Deficiencies in clinical infrastructure
  - Access to agents, biospecimens, and production facilities
  - Inefficient technology transfer
- About ten percent of the respondents cited regulatory issues as barriers, such as IRB and HIPAA requirements.
- Other barriers cited included:
  - Incentives for faculty
  - NCI/NIH bureaucracy
  - Bioinformatics
  - Peer review for translational research
  - Training

5. Please comment on policies, procedures, and structures within NCI programs, academic medical centers, industry, etc. that are conducive to the coordination, collaboration, and hand-off that are essential to translational research.

Of the 84 respondents, several gave multiple answers, for a total of 106 responses to consider.

- Examples of policies, procedures, and structures already in place that are conducive to translational research primarily focused on the availability of infrastructure, which was cited by about fifteen percent of the respondents. Specific examples included:
  - SPOREs
  - Translational research centers
  - Cooperative Groups
- Other items cited by respondents included:
  - Collaborative research in general
  - Funding for translational research
  - Repositories for biospecimens

- Bioinformatics, specifically caBIG

Slightly more than half of the responses addressed policies, procedures, and structures that would be conducive for translational research if they existed rather than examples already in place. These responses were very similar to those for question four, with the needs for collaboration and resources being the most frequent.

- Approximately fifteen percent cited collaborations, including:
  - Between clinicians and basic researchers
  - Between academia and industry
- Approximately fifteen percent cited the need for additional resources, especially funding
- Other recommendations included:
  - Require a plan for clinical application of research in grant applications
  - Standardization of regulatory reporting
  - Training of basic scientists and clinicians in translational research
  - Incentives for faculty

6. Please comment on changes in policy and practices by NCI and academic medical centers that would improve the incentives for conducting translational research. Please indicate if you are aware of any academic best practices that, if more widely adopted, would provide incentives for participation in translational research.

Of the 100 respondents, several gave multiple answers, for a total of 150 responses to consider.

- The need for changes in academic medical center guidelines was cited by one-fourth of respondents, including:
  - Recognizing collaborative science in promotion and tenure guidelines
  - Mechanisms for translational research training and mentorship of academic medical researchers
  - Preserving the time of physician-scientists to do research
  - Creating translational research departments or providing translational developmental research funds
- The need for changing individual-investigator grant mechanisms to promote translational research was cited by one-fifth of respondents, including:
  - Creating separate funding pools or study sections for translational R01s
  - Incorporating translational potential or clinical need into review of basic science R01s
- Ten to fifteen percent of respondents recommended one of the following:
  - Broadening incentives for community oncologists to participate in clinical research
  - Providing additional or more stable funding for translational research
  - Standardization of the process for start-up and conduct of clinical trials, especially IRBs
  - Developing system-wide resources including bioinformatics and biospecimen repositories
- With regard to academic best practices:
  - Ten percent stated that none existed
  - Nine specific programs were identified as models

Prioritization

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q7	Q7a	Q8	Q9
Academic Basic Researcher	17	8	10	7	6
Academic Clinical Researcher	19	15	15	8	8
Academic Translational Researcher	46	35	35	24	22
Care Provider	5	3	1	0	0
Community Oncologist/Health Professional	8	5	6	2	2
General Public	4	2	1	1	1
Government	17	9	9	9	8
Industry	8	3	5	2	2
Legal/Regulatory	2	2	2	1	1
NGO/Foundation	3	2	2	1	0
Other	17	11	11	3	6
Patient Advocate/Patient	33	20	20	9	8
Grand Total	179	115	117	67	64

7. Because there are more translational research opportunities available than can be funded, please comment on criteria and mechanisms for prioritizing these opportunities. (Specifically, please indicate how the criteria and/or mechanisms differ for drugs, biologics, diagnostics, screening tools, and interventional technologies such as radiation or surgery.

Of the 105 respondents, several gave multiple answers, for a total of 120 responses to consider.

- The extent of clinical need was mentioned as a criterion by one-third of respondents, including:
  - Emphasis on prioritizing rare cancers
  - Emphasis on prioritizing highly prevalent/incurable cancers

- Scientific rationale based on biological and pharmacological understanding was mentioned as a criterion by one-sixth of respondents.

- Screening and biomarker development was mentioned as a priority by one-sixth of respondents.

- A few respondents recommended prioritizing prevention.

- Other prioritization criteria included:
  - Emphasize collaboration and team-based research
  - Fund new investigators and high-risk ideas
  - Fund projects with high likelihood of success
  - Fund investigators with strong track records
  - Prioritize areas of research for which disincentives to industry funding exist

- Mechanisms by which prioritization should occur, ranging from NCI-wide prioritization to project-level review, were mentioned by one-third of respondents, including:

  - The existing peer review system is appropriate for prioritization

7a. In addition, please comment on who (e.g., NCI, investigators, industry, or some combination) should set such priorities.

Responses from the 109 respondents are characterized as follows.

- Collaborative prioritization involving NCI, investigators and industry was cited by nearly forty percent of respondents
  - Patients and/or patient advocates were often added to the list of stakeholders
  - Other government agencies – including FDA, AHRQ, and other NIH Institutes/Centers – were sometimes added as well
- NCI primacy in priority-setting was mentioned by twenty percent of respondents
- A combination of NCI and academic investigators was mentioned by nearly twenty percent of respondents
- Academic investigators – excluding NCI – was mentioned by nearly twenty percent of respondents
  - Peer review was often identified by this group as the prioritization mechanism
- Ten to fifteen percent of respondents indicated that industry specifically should not be included in the prioritization process.

8. Please comment on effective systems that exist to assess ongoing translational projects and decide on continuation. If such a system were to be developed, please comment on the milestones that would signal appropriate times to conduct an assessment, the characteristics of the assessment process, and how to implement this system.

Of the 50 respondents, several gave multiple answers, for a total of 123 responses to consider.

- The need for changes to the study-section-based review process was cited by forty percent of respondents, including:
  - Shifting the focus and expertise of panels toward translational research
  - Including a more diverse group of reviewers in study sections
- The need to use clinical results as an assessment of translational success was cited by one-quarter of respondents, including:
  - Adopting accrual into trials as a measure of success
- The “SPORE model” of continuous assessment and review was cited by one-quarter of respondents
- Ten to fifteen percent of respondents recommended the following:
  - Developing a set of milestones for translational research assessment
  - Examining annual reports to assess progress
  - Examining publication record to assess progress
- A few respondents recommended the following:
  - NCI top-down assessment of translational research
  - Site reviews and visits for assessment
  - Dissemination of findings as an assessment criterion
- With regard to timelines for review:
  - Ten percent suggested specific times at which review of translational projects should occur
  - Five specific projects were suggested as models

9. Thinking about the current NCI review process, please indicate if this process is appropriate for the translational research enterprise as a whole (both within and across programs) and for individual translational research projects.

Of the 51 respondents, a few gave multiple answers, for a total of 56 responses to consider.

- The existing review process was considered appropriate by just over twenty percent of respondents
- The existing process was considered inappropriate by just under twenty percent of respondents
- The speed of the review process was considered inadequate for translational research by just under twenty percent of respondents, primarily academic researchers
- Ten to fifteen percent of respondents stated that the SPORE program's review processes were appropriate
- Ten to fifteen percent of respondents stated that translational issues need to be incorporated into the review process
- Three universities were suggested as models for translational research review

Funding

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q10	Q10a	Q10b	Q11
Academic Basic Researcher	17	13	9	8	6
Academic Clinical Researcher	19	13	12	5	7
Academic Translational Researcher	46	39	32	23	27
Care Provider	5	1	0	0	0
Community Oncologist/Health Professional	8	4	3	2	3
General Public	4	1	1	1	1
Government	17	10	9	9	10
Industry	8	5	3	4	1
Legal/Regulatory	2	2	2	1	2
NGO/Foundation	3	1	1	1	0
Other	17	12	6	5	6
Patient Advocate/Patient	33	27	12	10	9
Grand Total	179	128	90	69	72

10. Please indicate what you consider the highest priority area for NCI investment in translational research.

Of the 128 respondents, several gave multiple answers, for a total of 152 responses to consider.

- Twenty percent of respondents suggested that NCI's investment priorities should be based on disease stage, with mentioned priorities including (in descending order):
  - Early-stage disease/diagnosis/screening
  - Patient treatment
  - Prevention of carcinogenesis
- Twenty percent of respondents suggested that NCI's investment priorities should be pathway-based, with mentioned priorities approximately evenly split among:
  - Biomarkers/risk devices – especially common among those who suggested that early-stage disease/diagnosis/screening should be a priority
  - Therapeutic agents
- Fifteen percent of respondents suggested that NCI's priorities should focus on building the infrastructure for research, including:
  - Team-based science
  - Bioinformatics and information-sharing capabilities
  - Resources such as tissue repositories
- Ten to fifteen percent of respondents stated one of the following:
  - Particular NCI programs should be the highest priority (mostly SPORE):
  - NCI's investment priorities should be disease-based, with mentioned priorities including (in descending order):
    - Prioritize rare, under-served cancers (e.g., sarcoma) – primarily from patients and patient advocates

        - Prioritize cancers with high population impact (e.g., lung cancer) – primarily from academic researchers
    - Particular fields of research deserve higher prioritization, including:
        - Genetics/genomics/personalized medicine
        - Identification and validation of targets for therapeutics

10a. Please suggest what the relative allocation of the NCI budget between discovery and translation should be.

Responses from the 73 respondents are characterized as follows.

- Two-thirds of respondents provided a numerical split between discovery and translation
    - Median and mode of responses - 50:50 split
    - Range - 16:84 - 80:20 discovery:translation
- The remaining respondents provided qualitative answers, including (in descending order of frequency):
    - Allocations should be flexible and driven by scientific needs
    - Discovery and translation are inter-related
    - More funds for translation than currently
    - Protecting allocations for basic research is vital

10b. Please comment on the appropriateness of NCI in funding development activities (e.g., medicinal chemistry, toxicology, GMP manufacturing, etc.).

Responses from the 62 respondents are characterized as follows.

- More than half of respondents stated that NCI funding of medicinal chemistry, toxicology, and GMP manufacturing were appropriate.
- Twenty percent stated that NCI funding of these three development activities was not appropriate
- A few respondents recommended the following:
    - NCI funding of these three development activities was appropriate, but only for rare cancers
    - SBIR/STTR mechanisms were particularly appropriate for funding these activities
    - RAID/DTP was particularly appropriate for funding these activities

11. Please comment on how NCI could better integrate and coordinate its programs for funding translational research. Please indicate if a standard set of sequential programs across the translational research continuum would be more efficient. Please comment on how translational research can be more effective–– by relying on the ideas arising from individual investigators, or by facilitated mechanisms transcending individual investigators.

Of the 77 respondents, several gave multiple answers, for a total of 214 responses to consider. Not all respondents answered all parts of the question.

- Mechanisms to encourage collaboration were suggested by nearly twenty percent of respondents, including:
    - Greater collaboration among extramural scientists
    - Greater collaboration across NCI and NIH

    - Greater extramural-intramural investigator collaboration
- A few respondents recommended the following:
    - Centralized or top-down coordination by NCI
    - Using SPORE or SPORE-like mechanisms to integrate and coordinate programs
    - Creating a separate set of funding mechanisms for translational research
    - Incorporating outside stakeholders into the prioritization process
- Respondents were split as to whether a standard set of sequential programs would be more efficient, with:
    - Ten percent answering “no”
    - Just under ten percent answering “yes”, and
    - Just under ten percent answering “not sure”
- Respondents were split as to whether translational research can be made more effective by relying on ideas arising from individual investigators or by facilitated mechanisms:
    - One-third of respondents said that facilitated mechanisms would be more effective
    - One-quarter said that individual investigators’ ideas would be more effective
    - One-quarter said that it was not an either/or question and stated “both”

System Organization

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q12	Q13	Q14	Q15	Q16
Academic Basic Researcher	17	9	7	6	7	8
Academic Clinical Researcher	19	5	5	5	4	6
Academic Translational Researcher	46	20	16	13	16	21
Care Provider	5	1	0	0	0	0
Community Oncologist/Health Professional	8	2	3	2	2	3
General Public	4	1	1	1	1	1
Government	17	10	8	7	10	7
Industry	8	3	3	1	0	3
Legal/Regulatory	2	2	1	2	2	2
NGO/Foundation	3	1	1	1	1	2
Other	17	4	5	1	1	5
Patient Advocate/Patient	33	16	13	10	9	13
Grand Total	179	74	63	49	53	71

12. Please comment on the appropriate roles of NCI, academia, industry, foundations, and advocates in translational research.

Of the 70 respondents, several gave multiple answers, for a total of 111 responses to consider.

- One-third stated that translational research should be an equal collaboration among all five groups.
- Ten to fifteen percent of respondents stated one of the following:
  - All should collaborate but NCI should play the lead role.
  - All should collaborate but NCI and academia should jointly play the lead role
  - Cancer patients and patient advocates should play a stronger role
  - Foundations should play a funding role, especially in funding high risk research.
  - NCI and foundations fund, academia discovers, industry implements, and advocates champion and educate the public.
- A few respondents recommended the following:
  - Industry should not be involved at all
  - NCI sets priorities, academia and industry partner to implement, and foundations and advocates have input but no resource control
  - Foundations and advocates lobby and champion
  - NCI should focus on novel areas of research and not compete with industry

13. Please comment on how the pharmaceutical and biotech industry could be better integrated into NCI-funded translational research efforts and how NCI could facilitate the hand-off to and from industry.

Responses from the 52 respondents are characterized as follows.

- One-fourth of respondents provided a general statement that industry relationships should be encouraged, including the following general comments:
  - Input should be obtained from pharmaceutical and biotechnology companies
  - SPORE meetings and FNIH PPP projects are examples of encouragement
  - Companies should be treated as partners, not sub-contractors.
- About one-fifth of respondents stated that there should not be any relationship between industry and NCI.
- Ten to fifteen percent of respondents stated the following:
  - Addressing intellectual property concerns could facilitate translational research efforts, including use of industry-developed drugs and drug combinations in NCI clinical trials
  - Sharing information with industry would facilitate translational research efforts – examples included conferences, NCI meetings, and providing clinical trial information.
- Other comments included:
  - Clear, defined rules for interactions with industry
  - Pooling financial resources of NCI and industry
  - Standardized agreements between NCI, academia and industry
  - Companies believe working with NIH will "slow them down."

14. Please suggest specific actions, practices, tools, etc. to improve the communication of correlative science, outcomes, and other clinical research findings––so as to stimulate new lines of discovery.

Of the 38 respondents, several gave multiple answers, for a total of 42 responses to consider.

- Need for publicly available data was cited by twenty percent of the respondents, including:
  - Publication of clinical results – including failures
  - Dissemination of noteworthy discoveries through creation of a "results clearinghouse"
  - General improvement of data management and the creation of publicly-accessible repositories.
- Need for focused meetings on these topics were cited by twenty percent of the respondents, including:
  - Annual "think tanks"
  - Topic/disease focused meetings or symposia
  - Retreats for top investigators
  - Creation of working groups or specific faculties
  - Carve out a focused segment at the annual American Society of Clinical Oncology meeting
- One sixth of the respondents suggested that NCI should facilitate an environment for collaboration, including:
  - Specific training programs to bridge basic and clinical research and to stimulate dialogue between the fields
  - Bring different stakeholders together to work on specific projects

  - Ensure patient involvement in the translational research process
  - Promote "protected time" for clinicians
  - NCI-sponsored community forums to share data, present results and discuss issues
- Ten to fifteen percent of respondents identified the need for increased and more stable funding for translational research

15. Please suggest specific metrics for evaluating the success of NCI-funded translational research programs and projects and the overall success of NCI funded translational research.

Of the 45 respondents, several gave multiple answers, for a total of 66 responses to consider.

- Nearly two-thirds of respondents identified measurable clinical outcomes as appropriate metrics of translational success. These include:
  - Changes in patient care: number of patients diagnosed, number of patients treated, number of patients enrolled in trials, change in cancer incidence, change in survival rates, improved quality of life for cancer patients
  - Changes in clinical practice: improved patient management, new clinical standards or protocols, increased efficacy of treatment
- More than half of the respondents indicated that there should be a staged, incremental assessment of translational research based on intermediate endpoints:
  - Number of drugs/devices tested
  - Number of new biomarkers validated
  - Number of drugs/devices entering clinical trials (phase 1-3)
  - Number of drugs/devices reaching GMP production
  - Number of drugs/devices gaining IND approval
  - Number of drugs/devices being handed off to industry
  - Number of drugs/devices gaining FDA approval
- Ten to fifteen percent of respondents indicated that translational research should be measured by one of the following.
  - Time required to reach a milestone, including
    - Total time elapsed from bench to bedside
    - Time required for completion of trials
    - Time to application of results
    - Time to protocol standardization
  - Scientific outcomes including
    - Publication
    - Dissemination of results
    - Correlative science informing basic research
- About one in 10 respondents indicated that rigorous and measurable benchmarks must be established so that programs can be evaluated

16. Please comment on program management approaches that would be most successful for translational research, in particular please indicate if the successful approaches to discovery research are likely to be equally successful for translation. Please indicate if you think industry-type approaches to research would be more effective and if you think these could be adapted to an academic setting. Please indicate if a more active role for NCI in managing programs would be useful or counterproductive.

Of the 65 respondents, several answered only parts of the question.

- The large majority of the one-third of respondents who commented on the applicability of successful discovery research approaches believed that there were distinctions between the two types of research.
    - The need for greater collaboration in translational research was most often suggested as the reason for the distinction between the two.
- Respondents split as to whether industry-type approaches to translational research would be more effective:
    - One-third believed that industry approaches would not be more effective, citing the profit motive in industry and the potential for greater scientific creativity in academia
    - Twenty percent of respondents believed that industry approaches would be more effective
    - Ten percent of respondents believed that industry approaches would be more effective, but that they required changes in academic incentives
    - A few respondents believed that a mix of current academic and industry best practices would be useful in improving translational research.
- Respondents split as to whether a more active role for NCI in managing programs would be productive:
    - Nearly forty percent of respondents believed that a more active role for NCI would be counterproductive
    - One quarter of respondents felt that translational research would benefit from a more active NCI role
    - Between ten and fifteen percent of respondents believed that in some instances or for limited purposes a more active role might be productive

Facilities/Technologies

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q17	Q18
Academic Basic Researcher	17	7	5
Academic Clinical Researcher	19	5	2
Academic Translational Researcher	46	18	16
Care Provider	5	1	0
Community Oncologist/Health Professional	8	2	2
General Public	4	1	1
Government	17	6	6
Industry	8	3	2
Legal/Regulatory	2	2	2
NGO/Foundation	3	0	0
Other	17	4	2
Patient Advocate/Patient	33	9	9
Grand Total	179	58	47

17. Please comment on the facilities and technologies that are needed for translational research and if these facilities and technologies are available and accessible.

Of the 52 respondents, several gave multiple answers, for a total of 72 responses to consider

- Bioinformatics was identified as requiring enhancement by twenty percent of respondents.
- GMP manufacturing was identified as requiring enhancement by just fewer than twenty percent of respondents.
- Ten to fifteen percent of respondents stated one of the following:
    - The current portfolio of facilities and technologies are sufficient for translational research
    - Cancer Centers or other centers of excellence are required
    - Additional genomics and proteomics resources and technologies were required
- A few respondents recommended enhancements in the following.
    - Clinical trials infrastructure
    - Tissue banks/tissue resource facilities
    - Imaging and microscopy facilities
    - Animal research facilities
    - High-throughput screening technologies
    - Medicinal chemistry and pharmacokinetics facilities and technologies

18. Please indicate if you believe facilities and technologies are currently being used efficiently, or if you think there is duplication and overlap across the system. Please comment on the strategies and mechanisms that could be adopted to increase efficiency and effectiveness.

Of the 36 respondents, several gave multiple answers, for a total of 55 responses to consider.

- Two-thirds of the respondents indicated that there was duplication and overlap across the system, including:
    - A regional centers of excellence model might be preferable
    - Better mechanisms for sharing facilities and equipment might be needed
- Ten to fifteen percent of respondents commented that technological solutions (e.g., bioinformatics, portable medical records) could be adopted to increase efficiency and effectiveness.
- Ten to fifteen percent of respondents commented that organizational solutions (e.g., creating departments of translational research, standardizing IRB procedures) could be adopted to increase efficiency and effectiveness.
- A few respondents commented that:
    - There was duplication, but it could be useful
    - Existing infrastructure was being used efficiently.
    - NCI had all necessary facilities available intramurally

Manpower/Training

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q19	Q20
Academic Basic Researcher	17	7	12
Academic Clinical Researcher	19	9	5
Academic Translational Researcher	46	25	21
Care Provider	5	1	1
Community Oncologist/Health Professional	8	2	2
General Public	4	1	1
Government	17	8	9
Industry	8	3	4
Legal/Regulatory	2	2	1
NGO/Foundation	3	2	1
Other	17	3	3
Patient Advocate/Patient	33	13	13
Grand Total	179	76	73

19. Please comment on the scientific and technical skills needed for translational research and if individuals with these skills are available and accessible. Please indicate how these skills could best be provided (e.g., academic researchers, contractors, core services run by NCI, core services run by individual academic institutions, core services run by centers serving a network of institutions, etc.) Please suggest how these skills could best be integrated to promote efficient collaboration (e.g., formal consortia, informal networks, cooperative agreements, etc.). Please suggest the ancillary skills that are needed (e.g., legal, regulatory, manufacturing, etc.).

Responses from the 54 respondents are characterized as follows.

- Three quarters of respondents indicated that adequately trained individuals are not available. The skills needed could be divided into three general categories:
  - Nearly one-third of respondents identified scientific skills, especially interdisciplinary training
  - One-sixth of respondents identified technical skills, such as clinical protocol writing, GMP and SOP training, and regulatory training
  - One-sixth of respondents identified “general” skills, including communication, leadership, and collaboration
- One quarter of respondents indicated that individuals with these skills are already *available*, though not necessarily *accessible*.
- Of respondents identifying how skills could best be provided:
  - One-quarter indicated that “all of the above” would be effective
  - One-quarter identified individual academic institutions as effective
  - Twenty percent identified networks of institutions as effective
  - Ten percent identified NCI as the most effective option
- Of respondents identifying efficient mechanisms for collaboration:
  - Forty percent indicated that informal networks would be efficient
  - Thirty percent indicated that formal consortia would be efficient
  - One-sixth indicated that cooperative agreements would be efficient

  - Ten percent suggested that "all of the above" would be efficient
- Of respondents identifying necessary ancillary skills:
  - More than one third identified "legal" skills
  - One third identified "regulatory" skills
  - Twenty percent identified "manufacturing" skills

20. Please comment on what targeted training programs should be developed to train the next generation of translational researchers. Please indicate if you believe that cross-training of scientific researchers and clinical researchers would be more effective than a translational research degree or specialty. Please describe how team science can be modeled in a training environment.

Responses from the 53 respondents are characterized as follows.

- Nearly two-thirds of respondents identified training programs or grants, including:
  - Creation of interdisciplinary translational research training programs
  - Focused training in specific technical and scientific skills necessary for translational research.
  - Training grants at medical schools and at the NCI to help encourage MDs to pursue research instead of going into private practice.
- Ten to fifteen percent of respondents identified other mechanisms, including:
  - NCI faculty career development awards (K series awards)
  - Fellowships
- Of respondents identifying whether cross-training or translational degrees would be more effective:
  - More than half indicated that cross-training is generally more effective
  - One-quarter identified situations where each is warranted, identifying that cross-training is beneficial for existing researchers with translational degrees more useful for new investigators
  - Ten percent indicated that translational degrees are generally more effective
  - Ten percent indicated that neither approach is necessarily effective
- Of respondents identifying training models for team science:
  - More than half indicated that hands-on training is the only approach
  - Twenty percent indicated that team science training is best modeled in Centers
  - One-sixth mentioned that incentive structures must be in place to reward collaboration for effective team science training to occur
  - Ten percent identified case-study based approaches

Final Comments

21. Please provide us with any additional thoughts about translational research that have not been addressed.

Demographics of Response (the table includes all responses, including uncodeable responses):

Demographic Category	Total	Q21
Academic Basic Researcher	17	6
Academic Clinical Researcher	19	4
Academic Translational Researcher	46	12
Care Provider	5	2
Community Oncologist/Health Professional	8	1
General Public	4	3
Government	17	9
Industry	8	2
Legal/Regulatory	2	1
NGO/Foundation	3	1
Other	17	5
Patient Advocate/Patient	33	16
Grand Total	179	62

Many of the respondents to this question wrote solely to express their thanks at having the ability to provide their comments, or to identify themselves for further contact. Of the 39 respondents who provided additional information regarding translational research, several gave multiple answers for a total of 52 responses.

- One-quarter of the respondents were from families or friends of patients advocating increased research for specific cancers – especially sarcomas
- Nearly twenty percent commented that the current culture of competitive funding for research and of separate, stand-alone departments is not conducive to collaboration.
- Ten to fifteen percent of respondents commented on one of the following:
    - More stakeholders should be involved in research, funding, and review
    - Increased and more stable funding is necessary, especially for younger researchers
    - The SPORE program and organ-based approaches are effective models
- A few respondents commented on the importance of keeping research patient centered
- Academic researchers tended to focus on issues of research culture and funding for younger researchers, while patient advocates, patients, and health practitioners tended to focus on specific cancers, stakeholder involvement, and patient-centered care