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Peer Review for Small Business Funding: An Overview of the Process

February 24, 2022
Featured Speakers

Allen Richon, Ph.D.
Scientific Review Officer and SBIR/STTR Review Coordinator
Center for Scientific Review
National Institutes of Health

Meena U. Rajagopal, Ph.D.
Program Officer
Office of Strategic Alliances
National Center for Advancing Translational Sciences
National Institutes of Health

Monique LaRocque, M.P.H.
Senior Vice President
Ogilvy Health | FKH
MODERATOR
Agenda

Welcome, Introductions and Overview
NCATS SBIR & STTR Programs
  • Program Overview
  • Opportunities and Resources

Peer Review Process
  • Selection of Reviewers
  • SBIR/STTR Applications Review Process

Moderated Q&A
  • Please use the chat or Q&A function to submit questions at any time during the presentation
Meena U. Rajagopal, Ph.D.
Program Officer
Office of Strategic Alliances
National Center for Advancing Translational Sciences
National Institutes of Health
What Does the National Center for Advancing Translational Sciences (NCATS) Do?

Conducts and supports research on the science and operation of translation to allow more treatments to get to more patients more quickly.

Focuses on what is common across diseases and the translational process.

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.
SBIR and STTR:
One of the Largest Sources of Early-Stage Financing

41.68 Billion

2021 NIH budget for basic & applied biomedical science

1.0356 Billion

2021 NIH funds for small businesses (SBIR & STTR)

3.65% Set-aside for SBIR/STTR support

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The Benefits
NCATS SMALL BUSINESS PROGRAMS (SBIR/STTR)

Stable and predictable. Not a loan. Funds don’t have to be repaid.

Non-dilutive. IP rights are retained by the small business.

Technical assistance to advance and commercialize technologies for public good.

Projects undergo NIH’s rigorous scientific peer review process, which awardees leverage to attract other funding and collaborations.
# SBIR and STTR Critical Differences

<table>
<thead>
<tr>
<th></th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g., university)</td>
</tr>
<tr>
<td><strong>Work Requirement</strong></td>
<td>Guidelines: May outsource 33% (Phase I) 50% (Phase II)</td>
<td>Minimum Work Requirements: 40% small business 30% research institution partner</td>
</tr>
<tr>
<td><strong>Principal Investigator</strong></td>
<td>Primary employment (&gt;50%) must be with the small business</td>
<td>PI may be employed by either the research institution partner or small business</td>
</tr>
</tbody>
</table>

*Award is always made to the small business*
SBIR and STTR programs support NCATS’ mission to transform the translational science process so that new treatments and cures for disease can be delivered to patients more efficiently.

TOPICS OF INTEREST

1. Preclinical Drug Discovery & Development
2. Biomedical, Clinical & Health Research Informatics
3. Clinical, Dissemination & Implementation Research

2022-2023 DEADLINES:

- April 5
- September 5
- January 5
The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are some of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow U.S.-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

### Omnibus Solicitation
- Investigator-initiated grant funding
- Standard Deadlines: April 5, September 5, January 5

### Grant Solicitations in Targeted Areas
- Grant to advance a particular technology/research area
- Due dates may vary

### Contract Solicitation
- Contract opportunity to advance areas of high research interest
- Typically due in October or November
NIH SBIR/STTR Is a Three-Phase Program

1. **DISCOVERY**
   Phase I Feasibility Study
   - **Budget Guide:** $275,766K for SBIR and STTR ($325K Waiver)
   - **Project Period:** 6 months (SBIR); 1 year (STTR)

2. **DEVELOPMENT**
   Phase II Full Research/R&D
   - **Budget:** $1,838,436 for SBIR and STTR, over two years ($2M)
   - **Fast Track** combines Phase I and Phase 2
   - **Direct to Phase 2** – allows to skip Phase 1

3. **COMMERCIALIZATION**
   Phase III Commercialization
   - NIH, generally, not the “customer”
   - Consider partnering and exit strategy
   - Phase IIB Competing Renewal/R&D
   - Clinical R&D; Complex Instrumentation/to FDA
   - Funding Varies (~$1M per year) for up to 3 years

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# Application Process Timeline

<table>
<thead>
<tr>
<th>Due Dates</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (earliest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEPTEMBER 5</td>
<td>OCTOBER/NOVEMBER</td>
<td>JANUARY/FEbruary</td>
<td>MARCH/APRIL</td>
</tr>
<tr>
<td>JANUARY 5</td>
<td>FEBRUARY/MARCH</td>
<td>MAY/JUNE</td>
<td>JULY</td>
</tr>
<tr>
<td>APRIL 5</td>
<td>JUNE/JULY</td>
<td>AUGUST</td>
<td>SEPTEMBER OR DECEMBER</td>
</tr>
</tbody>
</table>
Targeted Funding Opportunities for 2022

- NHLBI SBIR Phase IIB Small Market Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44 Clinical Trial Optional)
  - SBIR: RFA-HL-23-008
  - Next Deadline: Feb. 28, 2022

- Notice of Special Interest (NOSI): Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health
  - NOT-EB-21-001
  - Next Deadline: April 5, 2022

- Technology for Improving Minority Health and Eliminating Health Disparities
  - SBIR: RFA-MD-22-003 (R41/R42 - Clinical Trial Optional)
  - Next Deadline: April 5, 2022

- Innovations for Healthy Living – Improving Minority Health and Eliminating Health Disparities
  - SBIR: RFA-MD-22-004 (R43/R44 - Clinical Trial Optional)
  - Posted: Jan. 5, 2022
  - Next Deadline: April 5, 2022

- Development of Highly Innovative Tools and Technology for Analysis of Single Cells
  - SBIR: PA-20-047 (R43/R44 Clinical Trial Not Allowed)
  - STTR: PA-20-025 (R41/R42 Clinical Trial Not Allowed)
Allen Richon, Ph.D.
Scientific Review Officer
SBIR/STTR Review Coordinator
Center for Scientific Review
National Institutes of Health
Peer Review and Funding of NIH Grant Applications

Mission
Our mission is to ensure that grant applications receive fair, independent, expert, and timely scientific reviews – free from inappropriate influences-so the NIH can fund the most promising research.

Focus of SBIR/STTR Review
Impact: Will the project have a sustained, powerful influence on the research field(s) or marketplace involved?
Peer Review and Funding of NIH Grant Applications

National Institutes of Health

Center for Scientific Review
Assigns to NIH Institute and Peer Review Group

Study Section
Reviews for Scientific Merit

Institute
Evaluates for Relevance to Research Priorities

Advisory Council or Board
Recommends Action

Institute Director
Takes Final Action
SBIR/STTR Peer Review

- NIH receives ~85,000 applications/year
- CSR organizes 18,000 scientists who participate in 1,300 review meetings
- ~7,500 SBIR/STTR applications are reviewed in ~40 study sections
  - Applicants can locate the one that best fits their application by using the CSR Assisted Referral Tool: [https://art.csr.nih.gov](https://art.csr.nih.gov), then use the Assignment Request Form to suggest a specific Study Section when they apply
Submission Process

• Applicant submits their application to Grants.gov or through ASSIST
• Once complete, the application is processed into eRA Commons where PIs have 2 days to check for errors
• Application is sent to the Division of Receipt and Referral (DRR) where it is assigned to an Institute(s) and an Integrated Review Group (IRG)
• DRR prescreens applications for compliance
• IRG Chief assigns applications to study sections
• Scientific Review Officers screen for fit and notify applicants
Peer Review System – The Referral Officer

• An SRO who receives significant training in the art of referral
• Works with the Institutes and Centers to make the connection between the application’s goals and NIH’s goals
• Has an in-depth knowledge of the scope of each CSR Study Section
• Prescreens applications for compliance
• Investigator has input – the Assignment Request Form (ARF)
Peer Review System – The Scientific Review Officer (SRO)

- Applications are reviewed under law defined by the Federal Advisory Committee Act (FACA) of 1972
- Designated Federal Official with overall responsibility for the review process
  - Doctoral level scientist with expertise related to the science reviewed in their Study Section
  - Legal responsibility for Study Section and the management of review
  - Reviews applications assigned to the Study Section (fit, scope, compliance, etc.)
  - Recruits the review panel based on the content of the applications
  - Ensures the review process for every application is consistent and follows applicable regulations, rules and best practices
  - Point of contact from initial assignment to release of summary statements
How Are Reviewers Selected for SBIR/STTR Study Sections?

- All SBIR/STTR reviews are conducted by Special Emphasis Panels (SEPs)
- Expertise is recruited as needed to review the science proposed in the applications, so the reviewers selected will not necessarily be the same from round to round. We seek reviewers with
  - Demonstrated scientific, technical and market expertise combined with impartiality
  - Research support – preferably small business
  - Doctoral degree or terminal degree equivalent; mature judgment; breadth of perspective
How Are Reviewers Selected for SBIR/STTR Study Sections?

• We build review panels with
  • Reviewers from academia, industry, small business, tech transfer and VC/investment firms
  • ≥25% small business or other industry members (encouraged)
  • Representation of women and minority scientists
  • Geographic distribution
  • Fresh perspectives (avoid excessive service on a panel)
Where Do We Find Reviewers?

- Successful applicants (NIH databases)
- Dimensions™ searches of patent documents
- LinkedIn keyword searches
- Google keyword searches (use the site:*.com qualifier)
- Regional incubator hubs (e.g., qb3 in Palo Alto)
- Nonprofits like the International Business Innovation Association (InBIA)
- Academic technology transfer offices
- Professional societies (e.g., the Association of University Technology Managers - AUTM)
- Volunteers from industry
Assigning Applications

• SRO makes review assignments by matching expertise on the panel to the content of the applications
• Five to six weeks before the meeting, each application is assigned to at least 3 reviewers
• Reviewers are trained on the goals of the SBIR/STTR program and on what to evaluate in applications
Conflicts of Interest (COI) – Applicant Identified

• Applicants can use the Assignment Request Form to request exclusion of companies or individuals from reviewing their application

• Rosters are published 30 days prior to the meeting – investigators can contact the SRO if they are concerned about panel members
Conflicts of Interest (COI) – SRO Identified

- Reviewers who have a major role in the application – Out of Meeting
- Letters of Support – generic versus specific
- Employed by the same organization (3-year limit)
- Co-authors on publications (3-year limit)/Past collaborations (QVR report for all key personnel in application)
- Members of any NIH Advisory Council (undue influence)
- An applicant responding to an RFA as a key personnel may not serve - even on a different Study Section
- Applications from frequent panel members (i.e., served 4 times within the last 6 rounds)
Conflicts of Interest (COI) – Reviewer Identified

• Employees of companies in direct competition with the applicant’s company
• Financial interest in the company or in competing companies (including $5K in stock holdings) or consulting agreements of $10K or more
• Financial benefits – institutional, family member, close friend
• Academic scientists that hold patents for competing technologies
• Reviewer’s company has IP overlap with application
• Patents or publications with any of the applicants
Managing Conflicts of Interest (COI)

- Personal
  - Family member/close friend
- Professional
  - Collaborator
  - Employees of companies in direct competition (or collaboration) with applicant’s company
- Financial
  - Financial interest in company or competing companies
  - Academic scientists that hold patents for competing technologies
- Institutional
- Longstanding scientific disagreement
- Personal bias
- Appearance of conflict
Confidentiality

• Reviewers are required to complete ethics training every year
• Reviewers sign a confidentiality agreement prior to reading any application
• Review materials and proceedings of review meetings represent confidential information for reviewers and NIH staff – it cannot be shared with anyone
• At the end of each meeting, reviewers must destroy or return all review-related material
• All peer review meetings are closed to the public
• Reviewers may not discuss review proceedings with anyone except the SRO and questions concerning review proceedings are referred only to the SRO
• Applicants are not allowed to communicate directly with any members of the study section about an application
Consequences for Breaching Confidentiality and COI Laws

• Reviewers serve as ad hoc advisors to the Federal government.
• Rules and regulations are codified in the Federal Advisory Committee Act.
• Reviewers legally certify lack of COI at three stages of the review process.
• Reviewers can be removed from study sections and barred from future service.
• Reviewers and applicants can be barred from receiving Federal funding.
• Cases can be (and have been) referred to the Office of the Inspector General for prosecution.
What Reviewers Look for in SBIR/STTR Applications

• Why is there a need for the envisioned product
• How will the product be first in class or a significant improvement over what is on the market
• How will successful development of the product change concepts, methods, treatments, services or interventions that drive the field
• How does the project demonstrate the commercial potential to become a marketable product
Common Problems Identified in SBIR/STTR Applications

• No Significance: describes a problem of minor interest or makes an unconvincing case for commercial potential or societal impact
• Inadequate consideration/assessment of scientific literature
• Lack of knowledge of relevant published work and/or technologies and the market
• Absence of an acceptable scientific rationale or questionable reasoning in the experimental approach
• Insufficient experimental/developmental detail or failure to consider potential pitfalls and alternatives
• Expertise in the essential methodology is not described
• Experimental plan lacks rigor and/or weak milestones
• Unrealistic amount of work detailed
Peer Review System
Template-Guided Review Process

• Microsoft Word templates are linked on IAR for every application
• 1-9 scoring scale (1 = exceptional, 9 = poor)
• Each application has five individual criterion scores: Significance, Investigator(s), Innovation, Approach, and Environment plus comments on Additional Review Criteria
• Small Business review is focused on the product, not just the science
• Each application will be given a Preliminary Overall Impact score by three assigned reviewers
• Top scoring applications (50%) will be discussed at the meeting
Managing the Review Meeting: Setting the Stage

- Preliminary Overall Impact scores and critiques are uploaded by the assigned reviewers
- SRO checks for missing information, errors and mismatched comments/scores
- Applications are divided into two clusters: Phase I (Cluster A) and Phase II/Fast Track/Direct to Phase II (Cluster B)
- SRO rank orders applications – top scoring 50% within each cluster are discussed at the meeting
- Within clusters, score order is randomized for discussion
### Managing the Review Meeting: At the Meeting

<table>
<thead>
<tr>
<th>Role</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHAIR</td>
<td>Announces title and PI. Announces conflicts and instructs them to leave the room. Reviewer names are announced, and initial scores are given.</td>
</tr>
<tr>
<td>REV 1</td>
<td>Summarizes application (2-3 sentences). Lists application's major strengths and weaknesses, focusing on score-driving points. States HS, inclusions and their acceptability.</td>
</tr>
<tr>
<td>REV 2</td>
<td>Provides NEW points and disagreements not covered by Rev 1. If rating of overall impact is better, focus on strengths. If worse, focus on weaknesses of the application.</td>
</tr>
<tr>
<td>REV 3</td>
<td>Provides NEW points and disagreements not covered by Rev 1 or Rev 2.</td>
</tr>
<tr>
<td>ALL</td>
<td>Panel discusses the application. Goal is NOT consensus but to seek additional information and point out inconsistencies in comments.</td>
</tr>
<tr>
<td>CHAIR</td>
<td>Summarizes discussion.</td>
</tr>
<tr>
<td>ALL</td>
<td>Assigned reviewers re-state their score. Chair asks for <strong>out-of-range scores</strong>. All panel members vote and mark the score sheet.</td>
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</tbody>
</table>

15-20 minutes
Peer Review and Funding of NIH Grant Applications

1. National Institutes of Health
2. Center for Scientific Review
   - Assigns to NIH Institute and Peer Review Group
3. Study Section
   - Reviews for Scientific Merit
4. Institute
   - Evaluates for Relevance to Research Priorities
5. Advisory Council or Board
   - Recommends Action
6. Institute Director
   - Takes Final Action
Peer Review Summary

- Applications are screened by several groups to ensure best fit
- Policies, procedures and Federal laws define the process
- Reviewers are carefully selected, vetted and trained
- Conflicts are checked at several points during the review process
- Review is conducted only within the study section, and the process is uniformly applied with several levels of checks and balances
Questions?

cats.nih.gov/smallbusiness | NCATS-SBIRSTTTR@mail.nih.gov
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Listserv: bit.ly/1sdOl5w
## Research Priorities

### Preclinical Drug Discovery and Development

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative platforms for identification and prioritization of targets</td>
<td>Therapeutic intervention with clear clinical impact, such as those that are: implicated for disease, have genetic variations that have been identified in functional regions of receptor targets and/or have high potential for biased signaling that would promote the beneficial effects of receptor signaling and reduce the unwanted effects.</td>
</tr>
<tr>
<td>Tools and technologies to enable high-throughput screening of compound</td>
<td>Activity on currently “non-druggable” targets.</td>
</tr>
<tr>
<td>Assays for high-throughput screening of rare diseases-related targets</td>
<td></td>
</tr>
<tr>
<td>Co-crystallization high-throughput screening techniques</td>
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<tr>
<td>Fluorescence probes to replace antibodies for determination of cellular</td>
<td>Protein translocation.</td>
</tr>
<tr>
<td>Phenotypic assay development, including stem cell technology platforms</td>
<td>“disease-in-a-dish” applications and the evaluation of toxicity.</td>
</tr>
<tr>
<td>Interventions that target molecular pathways or mechanisms common to</td>
<td>Multiple diseases.</td>
</tr>
<tr>
<td>Platforms for non-antibody biologics, cell-based therapies and gene</td>
<td>Therapy discovery.</td>
</tr>
<tr>
<td>Small molecule and biologics analytical characterization</td>
<td></td>
</tr>
<tr>
<td>Accelerated bioengineering approaches to the development and clinical</td>
<td>Application of biomedical materials, devices, therapeutics and/or diagnostics.</td>
</tr>
</tbody>
</table>
# Research Priorities

## Preclinical Drug Discovery and Development

<table>
<thead>
<tr>
<th>Development of novel technologies for enzyme replacement therapies (e.g., new cell culture/expression system) to solve a major bottleneck in rare diseases research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative methods to determine alternative uses for existing therapeutic interventions for high priority areas, such as rare diseases and pain</td>
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<tr>
<td>Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic or other intervention optimization</td>
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<tr>
<td>Technologies to deliver nucleic acid therapeutics to tissues other than the liver</td>
</tr>
<tr>
<td>Methodologies and technologies to increase efficiencies of manufacturing therapeutics</td>
</tr>
<tr>
<td>Development of novel high-throughput technologies that focus on making translational research more efficient</td>
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<tr>
<td>GMP production of exosome/extracellular vesicles</td>
</tr>
<tr>
<td>Generation of producer lines for large-scale production of exosomes/extracellular vesicles</td>
</tr>
<tr>
<td>Extracellular RNA-based biomarkers and therapeutics of human diseases</td>
</tr>
<tr>
<td>Approaches to targeting the human microbiome for therapeutic or diagnostic purposes</td>
</tr>
</tbody>
</table>
## Research Priorities

### Preclinical Drug Discovery and Development

<table>
<thead>
<tr>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scale up, manufacturing and characterization of IPS cells</td>
</tr>
<tr>
<td>3D printing technologies</td>
</tr>
<tr>
<td>Technologies to substantially improve the efficiency and reduce the cost of clinical-grade gene therapy vector manufacturing</td>
</tr>
<tr>
<td>Development of in vitro human tissue models (organs, 3D printing)</td>
</tr>
<tr>
<td>Technologies to allow therapeutic proteins other than lysosomal enzymes to be secreted and taken up by other cells via cross-correction</td>
</tr>
<tr>
<td>Novel strategies to prevent deleterious immune responses to gene therapy, genome editing and/or enzyme replacement therapy</td>
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<tr>
<td>Establishing more robust phenotypic screens that may help prioritize candidate compounds for further testing</td>
</tr>
<tr>
<td>Innovative technology for non-small molecule delivery</td>
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<tr>
<td>High-throughput epigenetics screening/characterization tools and technologies</td>
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<tr>
<td>Microphysiological systems (MPS)/Tissue Chips, including MPS/Tissue Chips that incorporate known functional variants, e.g., ACMG 59 or CPIC A alleles, for study comparison using the same derived genetic background across a set of tissue chips with the functional variant</td>
</tr>
</tbody>
</table>
# Research Priorities

## Biomedical, Clinical & Health Research Informatics

- Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays and/or technologies with evidence about their use in research studies
- Cloud-based tools and methods for meaningful sharing, re-use and integration of research data
- Novel platforms, technologies and tools for: (1) enabling clinical and translational research, particularly those with mechanisms for inclusion of patient-reported data and (2) integration of patient data collected from multiple devices and multiple/diverse clinical studies
- Development of personalized phenotypic profiling (as well as personalized intervention) based on patient-centered integration of data from multiple data sources, including social media
- Development of predictive models for translational science
- Digital applications and tools (including telemedicine platforms) that facilitate/enhance translational research and medicine in rural populations
- Generic disease registry template platforms that can be reused for multiple diseases
- Mobile device validation tools to ensure data from different brands or versions have compatible results
- Tools to assess algorithms developed with artificial intelligence and/or machine learning
- Tools that allow for persistent identifier and attribution for data contributors that give credit to the data producers while ensuring that shared data has not been altered
- Patient mobile tool platforms that facilitate tool developers to build “apps” that integrate into their medical records
- Tools and environments that enable an easy interrogation of publicly available data

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## Research Priorities

### Clinical, Dissemination and Implementation Research

<table>
<thead>
<tr>
<th>Tools and technologies that increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation and/or regulatory processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking</td>
</tr>
<tr>
<td>Tools, technologies and other strategies to evaluate and improve the process of informed consent</td>
</tr>
<tr>
<td>Educational tools for clinical and translational science</td>
</tr>
<tr>
<td>Computational or web-based health research methods, including:</td>
</tr>
<tr>
<td>• Platforms for generally applicable and scalable multi-disease registries and natural history studies</td>
</tr>
<tr>
<td>• Clinical trial designs and analyses (e.g., for pragmatic clinical trials)</td>
</tr>
<tr>
<td>Approaches, tools, platforms and environments to integrate data in novel ways for development of new biomarkers that can be tested in translational research paradigms for which there are barriers or bottlenecks</td>
</tr>
<tr>
<td>Strategies to enhance the quality of and accelerate the conduct of dissemination and implementation research</td>
</tr>
<tr>
<td>Tools and technologies that increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation and/or regulatory processes</td>
</tr>
</tbody>
</table>
## Research Priorities

### Clinical, Dissemination and Implementation Research

- Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking
- Sustainable solutions for effective tools and environments in translational research
- Development and validation of patient reported outcomes, clinician-reported outcomes and biomarkers for rare diseases that are not already supported by a disease-specific NIH Institute or Center
- Tools, technologies and other strategies that address medication adherence in clinical settings
- Tools, technologies and other strategies that address and improve community engagement
- Tools and technologies that address the rapid diagnosis and/or clinical management of rare diseases
- Patient empowerment tools/apps that allow users to compare their treatment and outcomes to normative populations existing treatment guidelines
- Telemedicine or digital health applications that focus on research in rural populations