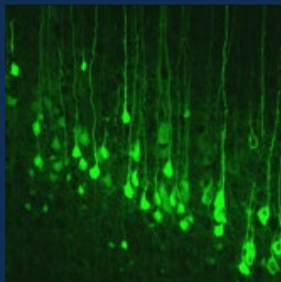


NIH **Blueprint**  
for Neuroscience Research

# Blueprint MedTech: Translator (UG3/UH3;U44)

Dr. Stacie Gutowski  
Program Officer



[Blueprint-MedTech@nih.gov](mailto:Blueprint-MedTech@nih.gov)



The Blueprint MedTech program is an NIH incubator that aims to accelerate the development of cutting-edge medical devices to diagnose and treat disorders of the nervous system.

**Mission:** To catalyze the translation of novel neurotechnologies from early-stage development to first-in-human clinical studies.

**Goal:** To accelerate patient access to groundbreaking, safe, and effective medical devices.

The program will provide support to sufficiently develop and de-risk technologies to the point where additional investments are warranted from industry partners, investors, and government.



- Novel medical device technologies that will advance upon current neurotechnology.
- Medical devices with first-of-its-kind technologies, unique and novel intended use, new safety questions, and/or new regulatory questions.
- Pivot and refine existing technologies toward new intended use and use in novel settings.
- De Novo or Premarket Approval (PMA) regulatory pathways.
- May fit within an existing 510(k) pathway may also be accepted, if
  - demonstrate a clear clinical and technological innovation beyond the state of the art;
  - provide new clinically meaningful diagnostic or therapeutic options;
  - improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations.



Proof-of-Concept

Development

Translation

Feasibility /  
Pivotal Study

## Individual projects (Non-dilutive funding \$)

Early-stage  
(Seedlings)



Solicited by Hubs

Late-stage development

Solicited by Hubs

Non-clinical testing  
for IDE/IRB

First-in-human study

UG3/UH3 PAR-21-315

U44 (Phase I/Phase II) PAR-21-282

## Free Resources (provided by NIH)



Design,  
Prototype,  
Bench Test



Business  
Development



Biocompatibility  
& Animal  
Studies



Regulatory,  
Compliance,  
Quality System



Clinical



Consultants &  
Industry  
Experts



External  
Oversight  
Committee



- **PAR-21-315**: Blueprint MedTech: Translator (UG3/UH3)
- **PAR-21-282**: Blueprint MedTech: Small Business Translator (U44 Phase I & II)
- Purpose:
  - To support innovators in pursuing translational activities and clinical studies to advance the development of therapeutic and diagnostic devices for disorders that affect the nervous or neuromuscular systems.
- Supported Activities
  - Implementation of clinical prototype devices;
  - Non-clinical safety and effectiveness testing;
  - Design verification and validation activities;
  - Obtaining an IDE for a SR study;
  - Obtaining IRB approval for an NSR study;
  - Obtaining support for a subsequent clinical feasibility study.



- Focus on a disorder that falls within the mission of participating NIH Blueprint Institutes and Centers.
- Device is very close to the 'final system' and manufactured using very close to the same manufacturing process as the device to be marketed or studied in a larger clinical trial following the completion of this project; or
- The device has received Pre-Submission feedback from the FDA.
- Require early feasibility clinical data to inform the final device design or manufacturing processes.



- First Phase (UG3 or U44 Phase I): Non-clinical testing for IDE or IRB approval
- Second Phase (UH3 or U44 Phase II): First-in-human study
- All translator projects must start in the first phase.
- Only first stage projects that have met specific criteria will transition to the second phase after NIH administrative review.
- The total project period (including both phases) must not exceed five years.
- Projects for which only a clinical phase is proposed are outside of the scope of this funding opportunity.



# Entry into Program

- Comprehensive supporting data based on bench, in vitro, and/or in vivo models of patient population and indication.
- Clinically meaningful device outcome measures.
- A compelling case for a successful IDE submission for an SR study or IRB approval for an NSR study.
- Pre-Submission meeting encouraged.





## Non-clinical testing for IDE/IRB

- UG3: up to four years of funding
- U44 Phase I: up to two years of funding
- Identify and conduct all non-clinical testing necessary to obtain approval to conduct the clinical study.
  - to obtain an IDE and IRB approval for an SR clinical study, or
  - to obtain IRB approval for an NSR clinical study
- Design execution plans and go/no go milestones for second phase.
- Relevant FDA feedback required as first milestone if not available at time of funding of application.



- Successful achievement of the defined milestones for the UG3 phase of the project;
- Likelihood of success in clinical testing;
- Competitive landscape;
- Programmatic priorities and current portfolio balance;
- For significant risk studies, documentation of final or conditional approval of the IDE from the FDA;
- IRB approval(s);
- Submission of the final clinical protocol and supporting documents to NIH for administrative review, and notification of approval by NIH;
- Feedback on activities involving human subjects obtained from the Safety and Risk Assessment Committee (SARAC) of the relevant Institute;
- Agreement on updated timeline, milestones, and budget for the clinical study; and
- Availability of funds.



## Clinical Feasibility Study

- UH3: up to four years of funding
- U44 Phase II: up to 3 years of funding
- Both phases together (UG3+UH3 OR U44 Phase1+Phase 2) cannot exceed 5 years total
- Clinical studies that provide information about the device that cannot be practically obtained through additional non-clinical assessment.
- Lead to a marketing application, a larger clinical study, or clinical use experience.



- Use of Design Control and Quality Systems processes is required.
- Intermediate steps in the Design Control and IDE submission should be represented in milestones.
- Encouraged to discuss these issues with the FDA and regulatory consultants prior to submitting an application
- Consider the Quality System requirements at the IDE stage (i.e., design controls) when preparing their device development activities.



- Strongly encouraged to consult with NIH program staff when planning an application.
  - Provide guidance on program scope, goals, and developing appropriate milestones.
- When possible, contact at least 12 weeks before a receipt date



# Application Requirements

- All required attachments (e.g., Gantt Chart, IP Strategy, Needs Assessment, Long-term care plan, Resource Checklist);
- A milestone plan;
- A neuroethics section as part of the human subjects protection attachment; and
- A clinical study protocol.



- Required attachment.
- Identifies Blueprint MedTech resource that will be utilized by the project.
  - Prototype Development
  - Electronics Manufacturing
  - Electrical safety
  - Electromagnetic compatibility testing
  - Magnetic resonance testing
  - Computational modeling
  - Software testing documentation
  - Cybersecurity testing and documentation
  - Biocompatibility, chemical characterization, extractable/leachable, and biocompatibility risk assessment
  - GLP-compliant animal testing
  - Sterilization, packing, and shelf-life testing
  - Clinical trial support including central IRB, DSMB, and trial design
  - Regulatory strategy consulting
  - IP protection
  - Good Manufacturing Practice, Quality Management System, and Compliance management
  - Business Development, Market/User Research, and Commercialization
- Indicate expectation of resources.
  - “If selected for funding, we expect that the following resources will be made available to this project by the Blueprint MedTech program. Since the program will provide these resources at no cost, this application does not request any labor or budget associated with these resources.”
- Justify any resources that will not be utilized.



- **PAR-21-315**: Blueprint MedTech: Translator (UG3/UH3)
- **PAR-21-282**: Blueprint MedTech: Small Business Translator (U44)
- **Next Applications Due: October 20, 2021**
- Review: February 2022 Reviewed by NSD-C:  
<https://public.era.nih.gov/pubroster/standingCommitteRoster.era?CID=101608>
- Council: May 2022
- Est. Notice of Award: June 2022
- Up to 5-year project period





# Questions?

[Blueprint-MedTech@nih.gov](mailto:Blueprint-MedTech@nih.gov)