Blueprint MedTech
Program Overview

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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.
Program Vision

Combines the Strengths of Research and Industry

**Investigator-initiated ideas**
- Groundbreaking device idea

**Industry expertise**
- Advisors with extensive device development experience
- Industry-standard contract services

Groundbreaking Technology
Blueprint MedTech Participating ICs

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
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National Institute on Aging (NIA)
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National Institute on Alcohol Abuse and Alcoholism (NIAAA)
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National Institute on Drug Abuse (NIDA)
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For specific IC requirements and interest statements: https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-medtech/blueprint-medtech-ics-and-contacts
Blueprint MedTech Provides both:

1. **Non-dilutive funds** to support medical device development activities led by investigators

2. **Free Resources** and support services through access to NIH funded consultants, CROs and NIH Staff
Blueprint MedTech Program Structure

Proof-of-Concept → Development → Translation → Feasibility / Pivotal Study
Blueprint MedTech Program Structure

**Development**

- **Early-stage (Seedlings)**
  - Solicited by Hubs

- **Late-stage development**
  - Solicited by Hubs

**Translation**

- **Feasibility / Pivotal Study**
  - Non-clinical testing for IDE/IRB
    - UG3/UH3 PAR-21-315
    - U44 (Phase I/Phase II) PAR-21-282
  - First-in-human study

**Individual projects (Non-dilutive funding $)**
Blueprint MedTech Program Structure

Development

Early-stage (Seedlings)
- Free Resources (provided by NIH)
  - Regulatory, Compliance, Quality System

Late-stage development
- Solicited by Hubs

Translation

Non-clinical testing for IDE/IRB
- UG3/UH3 PAR-21-315
- U44 (Phase I/Phase II) PAR-21-282

First-in-human study
- Solicited by Hubs

Individual projects (Non-dilutive funding $)

Free Resources (provided by NIH)
- Design, Prototype, Bench Test
- Business Development
- Consultants & Industry Experts
- Regulatory, Compliance, Quality System
- Biocompatibility & Animal Studies
- Clinical
- External Oversight Committee
Incubator Hubs

- Centers to coordinate and manage resources for the Blueprint MedTech program
- Hubs will be responsible for providing innovators with resources to support development of human-grade prototypes.
Blueprint MedTech Program Structure

**Development**
- Early-stage (Seedlings)
  - Free Resources (provided by NIH)
  - Regulatory, Compliance, Quality System
- Late-stage development
  - Solicited by Hubs
- Business Development
- Consultants & Industry Experts
- Design, Prototype, Bench Test

**Translation**
- Non-clinical testing for IDE/IRB
  - Solicited by Hubs
- First-in-human study
  - UG3/UH3 PAR-21-315
  - U44 (Phase I/Phase II) PAR-21-282
- Clinical Activities
- Biocompatibility & Animal Studies

**Free Resources (provided by NIH)**

**Individual projects (Non-dilutive funding $)**

**External Oversight Committee**
Advance Projects for Hand-Off

Entry:
• Proof-of-concept
• BP MedTech Mission

Technology Optimization
IDE submission or IRB NSR designation
Clinical Feasibility/First-in-human studies
Feasibility and Pivotal Study

Exit:
• External funding/partnership
• Other grants
• Attrition
• 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.
Funding Opportunities

Incubator Hub Funding Opportunity
• **PAR-21-314**: Blueprint MedTech: Incubator Hubs (U54)
  – to coordinate and manage program’s resources

Research Funding Opportunities
• **PAR-21-315**: Blueprint MedTech: Translator (UG3/UH3)
• **PAR-21-282**: Blueprint MedTech: Small Business Translator (U44)
  – UG3 / U44 Phase I, to support late-stage technology development/optimization
  – UH3/ U44 Phase II, to support first-in-human clinical studies

Applications Due: October 20, 2021
Early-stage projects

Mechanism Details

• Seedling funds
• Funded through subawards from BP MedTech funded incubator hubs

Mechanism Goals:

• Provide mentoring and design support
• address any business, regulatory, clinical, and technical issues surrounding the project
Late-stage development projects

Mechanism Details

– Funded through subawards from BP MedTech funded incubator hubs

Mechanism Goals:

• Develop a clinical-grade commercial prototype that is
  o as close to the 'final system' as possible, and
  o manufactured using processes very close to the intended product to be marketed
Translator projects: Two Phase Funding Mechanism


All translator projects enter in the non-clinical testing phase (UG3 or U44 Phase I)

1. Non-clinical Testing (UG3 or U44 Phase I):
   - Up to four years of funding for UG3; Up to two years for U44 Phase I
   - Identify and conduct all non-clinical testing necessary to obtain approval to conduct the clinical study (i.e. testing to support IDE submission or to obtain IRB approval for an NSR clinical study)
   - Design execution plans and go/no go milestones for all subsequent phase (UH3/U44 Phase II)


2. Clinical Feasibility Study (UH3 or U44 Phase II):
   - Up to four years of funding for UG3; Up to three years for U44 Phase II
   - 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 use of the clinical experience to inform device design decisions.

The total project period (including both phases) must not exceed five years.
• Inventorship determined per US patent law

• NIH Blueprint has no stake in the IP

• Prior to grant award, PI’s institution must have up-front IP agreements in place with all potential inventors. These agreements must address:
  – Who will hold title to IP
  – Royalty arrangements

• IP agreements should aim for unencumbered IP
Blueprint MedTech

Innovators developing groundbreaking medical device technologies face a number of challenges along the translational path from bench to bedside. The Blueprint MedTech program is an NIH incubator that aims to address such challenges and support the innovators by accelerating the development of cutting-edge medical devices to diagnose and/or treat disorders of the nervous system. The mission of the program is to catalyze the translation of novel neurotechnologies from early-stage development to first-in-human clinical studies. The program will provide:

(a) non-dilutive funds to support medical device development activities led by investigators, and (b) additional resources and support services including, but not limited to:

- Planning resources to support concept development, team building, needs assessment, and other early translational activities.
- Streamlined access to translational services and expertise (e.g., design and prototyping, bench testing, large animal testing, biocompatibility assessment, manufacturing, medical monitoring).
- Assistance from consultants (e.g., on regulatory, reimbursement, intellectual property, commercialization, and strategic partnership issues).
- Advice from industry experts (e.g., meetings with an external oversight committee).

The overarching goal of the Blueprint MedTech program is to accelerate patient access to groundbreaking, safe, and effective technologies.
Some Things To Do

- Read the Funding Opportunity Announcement carefully
- Discuss your proposal with NIH BP MedTech Program Directors (PD) & relevant Institute’s PDs for disease interest
- Contact SBIR PDs for SBIR specific issues
- Stick to page limit
- Put forth solid scientific preliminary data to support your proposal and address the rigor of that data in your research strategy section
- Address obvious criticisms
- Clearly indicate what will be done as part of the grant and what is expected by BP MedTech contractors
- Include budget sheets for all years of the grant
• If you are applying to UG3/UH3 program and **ANY** proposed budget year exceeds $500K in direct costs than you need permission to submit. Request must be made 6-8 weeks prior to submission date.

• Talk with your tech transfer/BD group.
  – Need to plan for funding patents and licensing activities
Things NOT To Do

• Please do not plan for this to be sole funding for your lab
  – Milestone driven program can end abruptly

• Please do not under-resource the budget to avoid limits
Funding Opportunities

Incubator Hub Funding Opportunity

- **PAR-21-314**: Blueprint MedTech: Incubator Hubs (U54)
  - Reviewed by a Scientific Review Group convened by NIBIB

Research Funding Opportunities

- **PAR-21-315**: Blueprint MedTech: Translator (UG3/UH3)
- **PAR-21-282**: Blueprint MedTech: Small Business Translator (U44)

- **Next Applications Due: October 20, 2021**
- Reviewed by NSD-C: [https://public.era.nih.gov/pubroster/standingCommitteeRoster.era?CID=101608](https://public.era.nih.gov/pubroster/standingCommitteeRoster.era?CID=101608)
Blueprint MedTech Core Team

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Thank You!

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