

Stimulating Peripheral Activity to Relieve Conditions (SPARC)

Informational Webinar for OTA-18-019

SPARC Partnership Opportunity: Custom Arrangements for
Device-Based Clinical Studies with Flexible Data and Intellectual
Property Rights

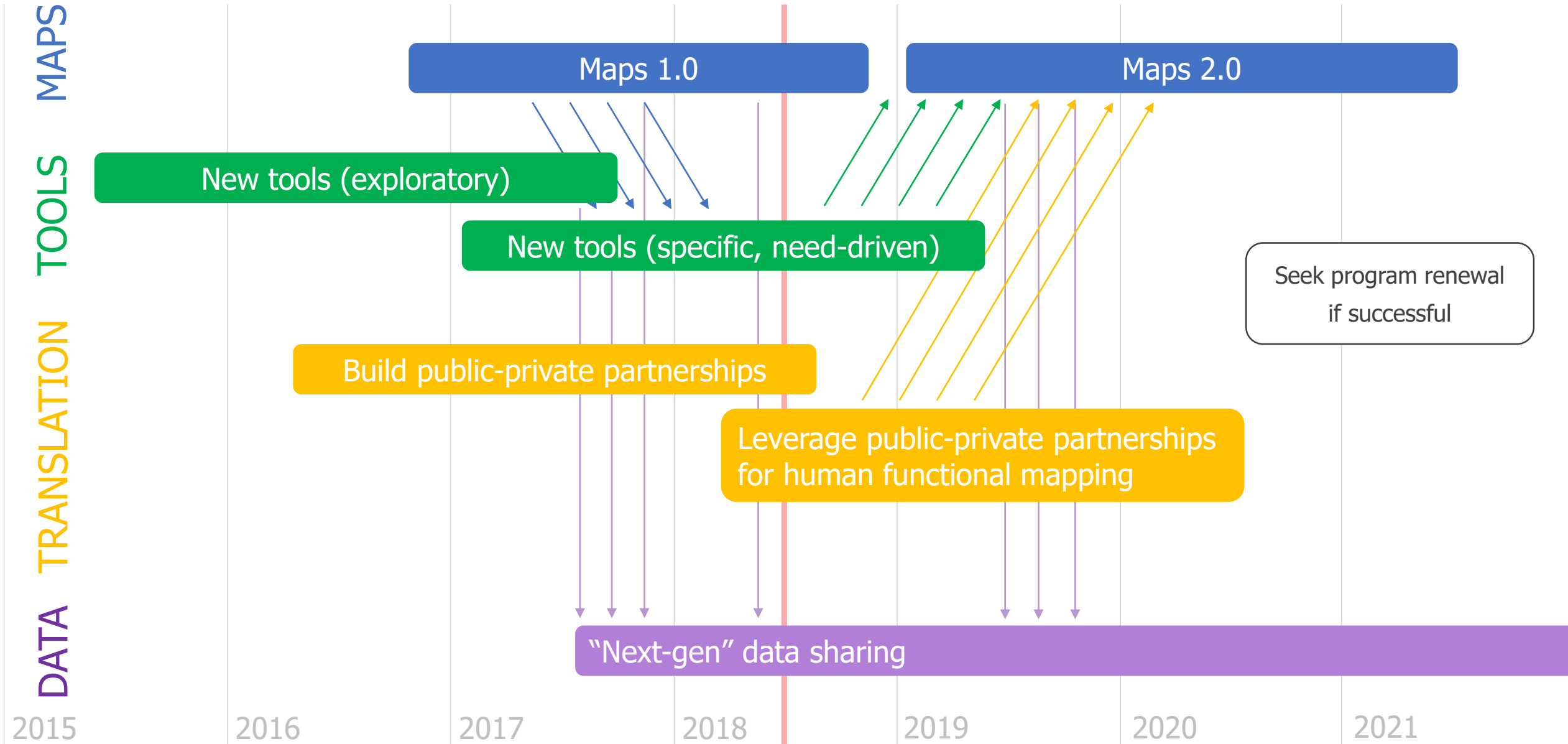
SPARC - Stimulating Peripheral Activity to Relieve Conditions

NIH Common Fund Program

Challenge: Neuromodulation of organ function holds promise in treating many diseases. However, the mechanisms of action for neuromodulation therapies remain poorly understood. Results among patients are highly variable. Sham effects are large.

Mission: Catalyze rational target development for peripheral neuromodulation indications by **building anatomical and functional maps of the autonomic nervous system in relation to major organs.**

SPARC High-Level Plan



Objectives of Partnership Announcement OTA-18-019

Create partnerships around **device-based clinical studies** to catalyze collection of **human research data** in support of the SPARC mission

- Beyond those addressing clinical health-endpoints
- Enhance anatomical and functional understanding of the neural control of end-organs
- May utilize invasive or non-invasive techniques to measure neural activity or biomarkers of organ function

- Neuromodulatory interventions targeting the peripheral nervous system or the spinal cord
- New, planned or ongoing clinical studies
- May involve acute or short-term procedures

Example device study: Neuromodulation for bladder control

- Primary health outcome: Incontinence episodes and urinary frequency -> **Insufficient data**
- Additional data: Quantitative urodynamic measures (e.g. bladder pressure)

Non-responsive activities

- Direct brain stimulation
- Neuromodulation of sensory organs of the head or voluntary muscles
- Non-clinical testing
- Pivotal device trials
- Proposals focusing exclusively on therapeutic feasibility

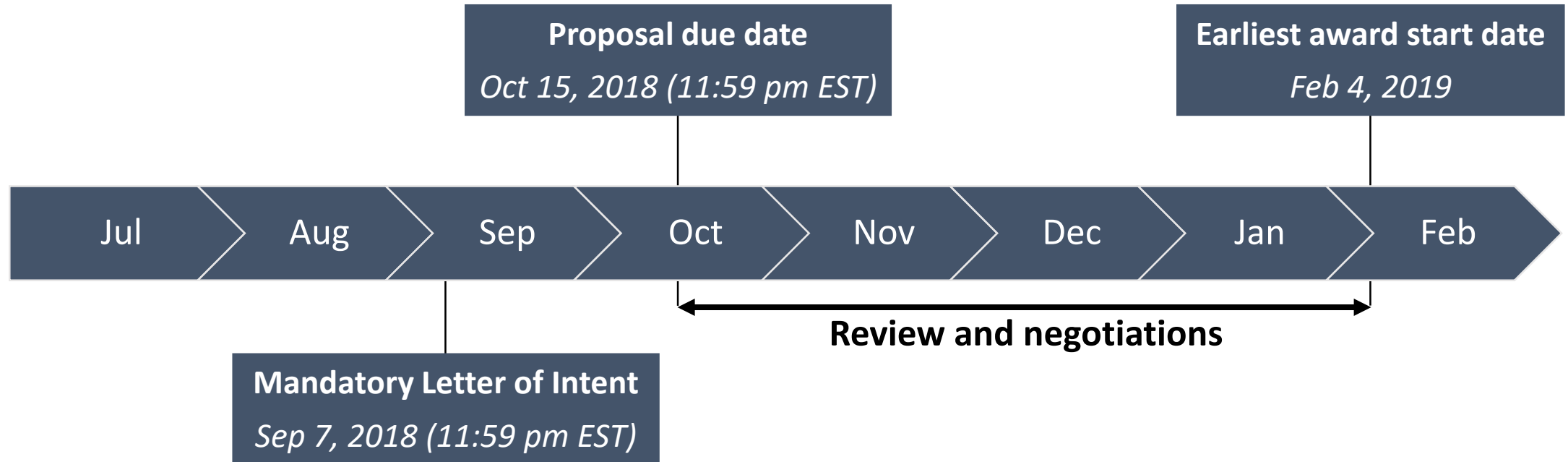
Objectives of Partnership Announcement OTA-18-019

Create **partnerships** around device-based clinical studies to catalyze collection of human research data in support of the SPARC mission

- Negotiations to establish partnerships may result in Other Transactions (OT2) awards *(Not grants, contracts or cooperative agreements)*
- Awards will have Terms & Conditions that are **customized** on a case-by-case basis *(e.g. data sharing requirements)*
- OT mechanism provides flexibility to design **unique collaborations with private sector entities**
- OT awards involve active NIH program management

See SPARC Other Transactions Award Policy Guide: <https://commonfund.nih.gov/sparc/othertransactions>

Timeline and Submission Process



Proposal Submission: 2 steps

1. Email attachment (PDF format) to SPARC_TPNI@mail.nih.gov by an authorized representative (**no late applications accepted**)
2. In addition, submit online via NIH eRA ASSIST system (instructions provided inside announcement).
No penalties for late submission due technical difficulties.

Application Content

Cover Page

Study plan

- Describe study objectives and rationale
- Task plan should include milestones with quantitative metrics (example table provided)

Human Subjects Research Plan

- Refer to guidance document - Human Subjects and Clinical Research Information

Capabilities

- Roles of key personnel and their institutions in accomplishing study objectives

Budget

- Overall expected costs and justification per year for personnel, equipment, travel, subawards (refer to budget table template)

Data Deliverable

- Plan for release of data to SPARC Data and Resource Center
- Must align with SPARC Material Sharing Policy

Additional Information

- Letters of support (Institutional, recruitment sites, industry collaborators)

Objective Review

Not traditional peer review

- Participation of NIH Program staff along with external experts
- Written summary of review instead of summary statements

Criteria

- Scientific Merit
- Personnel and Environment
- Clinical Study Practices
- Institutional Capabilities

Public-Private Partnership Resources

Industry partners: Several device companies have agreed to consider collaborations and to make their technology available to SPARC-supported investigators

➤ *See SPARC program website for list of companies and points of contact*

Template agreement documents to facilitate collaborations:

- Confidential Disclosure Agreement (CDA)
Enables transfer of technical details necessary to inform application.
- Collaborative Research Agreement (CRA)
Rules and responsibilities governing data and intellectual property.



Regulatory and IRB Approvals

- Studies may span IRB-approved non-significant risk studies or significant risk studies requiring an Investigation Device Exemption from the FDA
- Approvals (IDE and/or IRB) to initiate study must be secured within the first six months
- If necessary, a pre-submission meeting with FDA will need to be held within the first 3 months
- Awards will be restricted until all regulatory approval are obtained

FAQs

- Do we need to collaborate with an existing SPARC awardee?
- Do we have to choose an industry partner from the existing SPARC list?
- What is an appropriate budget?
- Number of patients or human subjects?
- Does the study need to involve a market-approved device?
- Does the research data have to be relevant for specific organs?
- Is new patient recruitment required?
- Does it have to be an Early Feasibility Study?