PROGRAM DESCRIPTION AND APPLICATION GUIDELINES

SPARK NS Parkinson's Disease Translational Research Program

2025 COHORT

Table of Contents

Overview

Program Duration: Two years
Milestone-based Project Support: Up to $2,000,000 per project during the two-year program, including discretionary funding for the principal Investigator (PI) of $50,000 per year.[1]

Application Information

This **Program Description and Application Guidelines** document includes detailed descriptions of the SPARK NS Parkinson's Disease Translational Research Program, 2025 Cohort, and expectations for principal investigators (PIs) that should be considered during the application process. In addition, this document provides detailed guidance on applying to the program. A separate **Call for Proposals** document includes detailed information about the process and timeline for applying to the program.

The Need

In the current development process for new therapeutics, 86% of academic discoveries do not reach the clinic[2]. An obvious reason for the low success rate is that academia lacks the infrastructure to support commercialization. Equally important, academic researchers often have gaps in knowledge and know-how about translational research. In addition, a cultural divide between academic researchers and industry experts discourages collaboration. All components of SPARK NS Translational Research Programs are designed to close these in knowledge and know-how gaps and eliminate barriers to collaboration while supporting translational objectives.

Team members of projects selected for SPARK NS programs are grouped into cohorts. Over the two-year duration of the program, investigators participate and collaborate as a cohort in translational research education and training courses. This is in addition to individual attention from SPARK NS project managers and industry expert advisors.

While some sessions are held virtually, SPARK NS periodically brings project researchers and industry experts together in person so they can learn from each other's successes, failures,

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[1] Total funding during the two-year program will not exceed $100,000. This discretionary funding will be paid to PIs' institutions. In addition to the discretionary funding, SPARK NS will reimburse PIs' institutions for their indirect costs (IDC) and discretionary amount not to exceed $5,000 per year (that is, an IDC rate of 10%) during the two-year program.

[2] Wong, C.H., Siah, K.W, and Lo, A.W. Estimation of clinical trial success rates and related parameters. Biostatistics 20, 273-286, (2019). https://academic.oup.com/biostatistics/article/20/2/273/4817524

challenges, and opportunities. These in-person sessions build trust and encourage participants to put aside differences and competing interests to work together for the benefit of patients. Because of their importance, in-person sessions are mandatory for the PIs of selected projects.

The Program

For the SPARK NS 2025 Parkinson's Disease Program, SPARK NS will provide selected PIs with funding, education, mentorship, and networking opportunities to advance their discoveries to first-in-class therapeutics. Based on the individual needs of participating PIs, SPARK NS will vary certain aspects of the program and tailor provided resources. However, all will have access to the following four program components:

Funding

- SPARK NS will provide milestone-based funding of up to $2,000,000 per project during the two-year program based on development plans that will be created after a project is selected. This includes discretionary funding for the PIs of each project of $50,000 per year.

- Post selection, SPARK NS will work with the PIs of each project to create a development plan that meets their translational goals, sets milestones, and includes a corresponding budget.

- As the aim is to translate discoveries into industry products, we expect that most of the financial support will include research conducted at contracted research organizations or academic research facilities in addition to academic laboratories.

- SPARK NS will not own any IP rights or take any financial stake in commercial products developed during the Program.

- When appropriate, SPARK NS will recommend filing patents on new IP to ensure the potential commercialization of the work.

Please note: SPARK NS programs are funded primarily by a separate nonprofit organization with a similar mission to support neuroscience research and development. The organization has expressed interest and willingness to continue its support of projects selected for SPARK NS Parkinson's disease programs that have successfully demonstrated a robust and novel mechanism or therapeutic approach to treat Parkinson's disease. For PIs of selected projects interested in this unique funding opportunity, SPARK NS will make introductions to the organization at the appropriate time.

Education

- SPARK NS will provide PIs and additional team members with an in-person, comprehensive training course on translational research, product development, and commercialization of therapeutic discoveries at the beginning of the two-year program. Attendance by PIs is mandatory. For the 2025 program, the in-person course will be held **January 26-30, 2025**, in Southern California, USA.

- PIs and other team members will receive additional education and training both in-person and virtually via video conference from SPARK NS and industry expert advisors on advanced therapeutic development topics not covered in the initial training course.

- Team members will have access to online self-taught, self-paced education that will assist them in the development and commercialization of their products.

Mentorship

- During monthly and ad hoc meetings with their SPARK NS project managers, PIs will receive ongoing guidance to ensure milestone completion and project success.

- PIs will have access to SPARK NS expert advisors for advice and counsel. SPARK NS advisors are experts in a variety of disciplines, including (but not limited to) medicinal chemistry, preclinical development, clinical trial design, patent strategy, regulatory affairs, and commercialization strategies.

- SPARK NS industry advisors will participate three times a year in progress report meetings, periodically in monthly meetings, and will be available to PIs on an as-needed basis.

- SPARK NS project managers and relevant industry advisors may meet with PIs at their home institutions from time to time during the two-year program.

Networking

- To achieve the shared goal of advancing promising academic discoveries in neuroscience from the lab to the clinic, SPARK NS will connect PIs to a rich network of individuals and organizations in academia and industry.

- The network will include peer cohort investigators, scientists, business and regulatory experts, entrepreneurs, and commercial research organizations.

- SPARK NS also will offer PIs guidance and assistance with specific business development opportunities. Depending on the individual goals of PIs and the potential of products in development, assistance may involve making introductions to potential partners and/or investors and helping investigators craft their pitches.

- PIs will work with their project managers to identify needs for networking opportunities and determine the type and level of assistance from SPARK NS.

Expectations

- All SPARK NS program participants and advisors will sign and abide by a confidentiality agreement and all communications are confidential.

- PIs will meet with their SPARK NS project manager monthly (with additional meetings on an as-needed basis) either in person or virtually via video conference to review progress.

- PIs will present their progress at mandatory triannual (three times a year) meetings to the entire cohort. These meetings will alternate between in-person and virtual. At these meetings, PIs will also receive feedback from SPARK NS and industry expert advisors.

- Attendance at an in-person training course from **January 26-30, 2025** in Southern California, USA is mandatory for the PIs of each selected project. SPARK NS will cover the travel and accommodation costs for additional attendees from each selected project on a case by case basis.

- By submitting an application, PIs are confirming their availability and commitment to attend all required training sessions and meetings.

- The schedule of required update meetings for the 2025 cohort is as follows:
    - April 2025 (virtual)
    - August 2025 (in-person, location TBD)
    - November 2025 (virtual)
    - April 2026 (in-person, location TBD)
    - August 2026 (virtual)
    - November 2026 (in-person, location TBD)
    - March 2027 (final presentations, in-person, location TBD)

- When meetings are held in person, PIs are required to attend. SPARK NS will cover the associated travel and accommodation costs.

Consolidated Schedule of 2025-2026 Mandatory Meetings

- **Monthly and ad hoc**: Progress reports with project managers (in person or virtual)

- **January 26-30, 2025**: Initial comprehensive training course on translational research, product development, and commercialization of therapeutic discoveries, Southern California, USA (in person)[3]

- **April 2025**: Progress reports and additional training, exact date and location TBD (virtual)

- **August 2025**: Progress reports and additional training, exact date and location TBD (in person)

- **November 2025**: Progress reports and additional training, exact date and location TBD (virtual)

- **April 2026**: Progress reports and additional training, exact date and location TBD (in person)

- **August 2026**: Progress reports and additional training, exact date and location TBD (virtual)

- **November 2026**: Progress reports and additional training, exact date and location TBD (in person)

- **March 2027**: Final project presentations, exact date and location TBD (in person)

Important Application Dates and Deadlines

- **May 31, 2024, 9:00 am PDT**: Application Portal opens for submissions

- **July 26, 2024, 5:00 pm PDT**: Application submission deadline

- **August 23, 2024:** Finalists notified by SPARK NS

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[3] Attendance by PIs at the in-person training course is mandatory. PIs may nominate additional team members to attend. Travel and accommodations expenses for additional team members will be paid by SPARK NS on a case by case basis.

- **September 13-15, 2024**: Finalist presentations[4] (*The virtual finalist presentations will now take place on September 13-15, 2024, instead of September 20-22, 2024, as previously published*.)

- **October 4, 2024**: Selected projects notified

Eligibility

SPARK NS will accept applications from biomedical researchers at academic or nonprofit research institutions in the United States, Canada, the United Kingdom, and Europe. We value diversity and are committed to creating an inclusive research environment. Applicants from all backgrounds and experiences are encouraged to apply.

Project Team Composition

Each application for the Program should be completed by a single PI. The PI listed on the application is the applicant responsible for submitting all required materials through the SPARK NS application portal. The PI has overall authority and responsibility for participating in the program and reporting on the progress of the project.

The PI may name up to three co-investigators from their own or collaborating institutions. The PI and any co-investigators should hold laboratory head positions at research institutions. The PI may also list on the application an unlimited number of researchers, including post-doctoral fellows, senior scientists, and students, as project team members. Once in the program, all team members will be considered part of the 2025 cohort. However, SPARK NS will direct all communications about the status of the application and participation in the program only to the PI on the project. Projects that involve collaborations between institutions are encouraged, but not required.

Please note: SPARK NS does not expect that PIs applying to the program and their teams will have all the necessary experience and skills required to successfully advance their proposed products to commercialization. As part of the program, SPARK NS will provide guidance, assistance, and funding needed to fill gaps that might exist. The need for such assistance will not negatively impact a project's chances of being selected.

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[4] By submitting an application, PIs are confirming their availability for the finalist presentations.

Application Process

The program application is a two-step process. Applicants will initially submit an application describing their proposed product, which will be reviewed by a selection committee. The selection committee will include scientists who are generally familiar with relevant experimental methods and the subject matter, industry leaders with expertise in the various stages of the development and commercialization of therapeutics, and SPARK NS staff.

To protect the IP rights of applicants and institutions affiliated with projects, SPARK NS staff, members of the selection committee, and advisors will sign and abide by a SPARK NS confidentiality agreement containing customary non-use and non-disclosure obligations.

All parties will exercise reasonable care to use confidential information (as customarily defined) contained in the proposals, applications, communications, and descriptions of the proposed research projects only for the purposes of the Program and protect it from use by or disclosure to third parties not connected to the Program.

The initial review will filter applications based on administrative compliance, scientific validity, fit for the SPARK NS program, and the probability of success in accomplishing the proposed translational[5] objectives during the two-year SPARK NS program.

Finalists will be selected from the initial applicant pool and invited to present the details of their proposed product virtually via video conference to the selection committee. Finalist presentations will occur at assigned time slots on **September 13-15, 2024 (***the virtual finalist presentations will now take place on September 13-15, 2024, instead of September 20-22, 2024, as previously written)***. Presentations will be limited to 10 minutes, followed by 20 minutes of questions from the selection committee. Project and presentation feedback will be provided to finalists during the question-and-answer period. Finalist presentations should follow the format outlined in a Microsoft PowerPoint template that will be provided to finalists.

After the finalist presentations, SPARK NS will select projects for the 2025 program. Applicants not selected for a final presentation will be notified by email but will not receive reviewer comments.

Application Review Criteria

Applications will be evaluated based on the following criteria:

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[5] Success is defined as licensing to a large pharmaceutical company, establishing a funded biotechnology startup, and/or entering into clinical trials.

Clinical need. Applications must clearly define an unmet clinical need in the Parkinson's disease space. Applicants should describe how their proposed product will address the unmet clinical need in comparison to the current standard of care. If the product serves a subpopulation of Parkinson's disease patients, the applicant should clearly define the subpopulation and how the project plans to identify the indicated patients. SPARK NS has a strong preference for proposed therapeutics that will be disease-modifying rather than those that solely address symptoms.

Underlying biology/technology. Applicants must have a robust and novel mechanism or therapeutic approach in the Parkinson's disease space. Applicants should clearly delineate the biology and/or technology behind their proposed product. The rationale behind the proposed translational objectives should be evident from this description. Applicants are highly encouraged to include as much preliminary data as they can to support their scientific rationale.

Feasibility of translational objectives. SPARK NS will accept projects into the Program at any stage of development between target identification and entry into clinical trials. However, selected projects will have translational objectives with a high probability of being accomplished.

Program scope. For this current program, we will not select projects that focus on medical devices, diagnostics (with the exception of companion and complementary diagnostics that would facilitate the development of a proposed novel therapeutic that is the central focus of the proposal), and platform technologies aimed at screening for and identifying novel targets. We value the tremendous impact these types of efforts have had on Parkinson's disease, but our current program scope cannot currently accommodate them. Interested applicants should follow SPARK NS as our future programs may have a broader scope. Applicants with questions about whether their project fits the scope of the current program should participate in our non-confidential Optional Pre-Submission Review (see below).

After Projects Have Been Selected

Once a project has been accepted into the 2025 program, a SPARK NS program manager will be assigned to the project and will work with the PI and other team members to develop a two-year development plan that meets the translational objectives outlined in the proposal. The development plans will be finalized following the introductory education and training course on **January 26-30, 2025**. As part of the plan, specific experiments, objectives, and milestones will be included along with a corresponding budget. As needed, commercial research organizations and academic research facilities required to complete certain aspects of the project will be identified by PIs and/or SPARK NS and the cost of their service will be included in the budget.

Milestones

Funding awarded to a project through SPARK NS will be dispersed based on milestones identified in the development plan created after a project has been selected. Not all funds awarded will go to PIs' laboratories. For example, work to be done by contracted research organizations or academic research facilities will be paid for by SPARK NS directly to the organizations from awarded funds.

Amendments to the development plan

Amendments to the development plan may arise based on accumulating data throughout the Program. Any changes to the development plan must be approved by both project PIs and SPARK NS prior to reallocation of funds.

Special Requirements and Terms

Liability

The role of SPARK NS in providing funding and other support awarded through SPARK NS is solely that of a funder and SPARK NS cannot be considered a sponsor of funded projects. As such, SPARK NS will not assume any liability associated with funded projects. Applicants who are ultimately awarded funding under the program and who choose to accept such funding will be required to sign an award agreement containing provisions that releases SPARK NS from any and all liability arising from the funded projects.

Intellectual property

SPARK NS will not claim ownership of any IP rights or take any financial stake in commercial products developed during the program. In addition, SPARK NS will not disturb any present or future allocations of such IP ownership among the PIs, co-investigators, other team members, the applicant's institution(s), and/or other third parties, as applicable. The applicant must provide a draft of any manuscript, abstract to conferences, or any other public disclosure related to the supported work to SPARK NS 30 days prior to disclosure or submission for publication to determine the need to file a patent application before information is made public. To avoid loss of patentability, the applicant and their institution(s) shall reasonably consider recommendations by SPARK NS to delay such publication until a patent application is filed.

Clinical trial registration

SPARK NS requires that any clinical trial that enrolls Parkinson's disease patients conducted with its funds, including Phase 1 studies, be registered with www.clinicaltrials.gov. As part of the SPARK NS commitment to patients, the results of any patient studies (positive or negative) must be published in a timely manner.

Publication

All communications, including publications, presentations, newsletters, and abstracts, about research supported by SPARK NS must use the following in the acknowledgement:

"Mentored and financially supported by the SPARK NS Translational Research Program"

Optional Pre-Submission Review

Potential applicants are encouraged but not required to submit a non-confidential draft topline description (short project summary not to exceed 250 words) and/or graphical abstract for review by **June 28, 2024**. Within two weeks of submission, applicants will receive feedback on whether their proposal is within the scope of the 2025 SPARK NS Translational Research Program. The optional pre-submission review is now open and does not impact the overall outcome of the application. **Submit here.**

Technical Inquiries

Potential applicants may contact SPARK NS with technical questions about application submission to the SPARK NS Parkinson's Disease Translational Research Program, 2025 Cohort. Applicants are asked to contact SPARK NS well in advance of the **July 26, 2024** submission deadline so we can better assist in the preparation of application materials.

SPARK NS PROGRAM APPLICATION CONTACT

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