The LEAP Inventor Challenge
ALL ABOUT THE NEW COLLABORATION WITH SPARC
The LEAP Inventor Challenge (LEAP) awards funding to those with translational research and inventions with the goal of advancing Washington University’s intellectual property towards commercialization.

LEAP engages Washington University faculty, postdocs, graduate students, and staff teams towards commercial development of their technology or product.

There are three LEAP cycles each year. In 2016-2017, LEAP judges helped identify promising projects to whom Washington University deployed a total of $650,000 across three cycles.
The Sun Pharma Advanced Research Company Ltd. (SPARC) Collaboration allows for new funding opportunities in the LEAP Inventor Challenge:

- Up to $250,000 in awards for the first year with the potential for additional funding for up to another two (2) years
- SPARC may provide additional in-kind support for areas of expertise such as:
  - Screening
  - Medicinal Chemistry
  - Pharmacology & Toxicology studies
  - Formulation Development
  - Analytical Development
WashU’s LEAP Inventor Challenge: SPARC Collaboration

THERAPY FOCUS AREAS THAT QUALIFY FOR SPARC FUNDING

- **Oncology** – Hematological, Breast, Prostate, Pancreas, Glioma, Colo-rectal
- **Ophthalmology** – Dry Eye, Topical treatment for AMD/DME
- **Neurodegenerative** – Parkinson’s, Movement Disorders
- **Dermatology** - Immunoinflammation
- **Complex Drug Delivery & Repurposing of Existing Drugs** (in any area)
General Considerations

- Competitive projects will have a clear clinical indication in areas of unmet medical needs
- Have convincing evidence for a significant improvement over current treatment options
- Successful projects will have demonstrated promising in vivo or equivalent proof of concept
- Research programs should have demonstrable/viable IP strategy
- If patents or patent applications have not been filed, there should be a strong potential for obtaining defensible intellectual property
- Under exceptional circumstances, a novel validated target can be considered without a lead compound, provided sufficient justification (must lead to small molecule drug discovery)
Drug Discovery Projects

- Research projects in drug discovery and new chemical entities with early target validation, clear in-vitro / in-vivo strategy to screen chemical hits to identify lead candidates, availability of crystal structure of the target, availability of early in vivo proof-of-concept data would be preferred.

- Projects targeting first-in-class drug targets should be supported by well-established and elucidated disease pathway and receptor biology.

- Novel biology should be backed by in-vivo / in-vitro data generated to sufficiently characterize the drug target.

- Projects on clinically validated drug targets should be able to create and offer clear differentiation over existing treatments:
  - Example in oncology could be next generation compounds targeting treatment resistance.
Novel Drug Delivery Projects

- Research projects that aim to reformulate or repurpose existing drug molecules with the help of novel drug delivery systems shall also be considered.

- Objective of such projects could be to improve dosing & administration, enhance patient compliance, solve drug bioavailability problems, promising new clinical indication, etc.

- Oral, topical, injectable, and nanotechnology based drug delivery systems would be preferred.

- Such projects should be able to create meaningful differentiation over marketed drugs.

- Example could be topical drug delivery to the back of the eye for diseases like Wet AMD/DME.

- Novel unapproved molecules with significant PK/drug delivery challenges may be considered provided they:
  - Fit in SPARC’s therapy areas of interest.
  - Are small molecules.
  - Have sufficient In-vivo safety & efficacy in disease model(s).
WashU’s LEAP Inventor Challenge: SPARC Collaboration

PROJECT ELIGIBILITY QUICK CHECKLIST

- ✔ Small molecule
- ✔ Drug delivery
- ✔ Unmet clinical need
- ✔ IP strategy
- ✔ Preclinical proof-of-concept
WashU’s LEAP Inventor Challenge: SPARC Collaboration

GRANT AWARD STRUCTURE

• Up to USD $250,000 total cost per program for the first year with potential for renewal of funding for another 2 years based on satisfactory progress

• Additional in-kind development support at SPARC
  - Medicinal chemistry
  - Preclinical pharmacology
  - Regulatory toxicology
  - Formulation development
  - IP support – drafting/filing

• Grant support will be based on
  - Well-defined research plan with research milestones & timeline
  - Funding shall be divided in to tranches on achievement of specific research milestones

• Outcome scenarios at the end of research funding
  - SPARC gets option to license the IP on worldwide exclusive basis for further development towards commercialization in US
  - Joint Steering Committee may decide to terminate program earlier if desired milestones are not achieved
WashU’s LEAP Inventor Challenge: SPARC Collaboration

PROCESS OUTLINE

  - There, you will indicate your interest in the SPARC funding.
- **Attend the mandatory LEAP Inventor Challenge Orientation** (date and time TBD—a Skandalaris Center staff member will notify you after you register)
- **Complete Executive Summary 1st Draft (3 pages)**
  - Submit Executive Summary 1st Draft plus field-specific questionnaire (received at Orientation)
  - **Executive Summary Review**: Applicants will meet with the LEAP Inventor Challenge advisory team. This includes the heads of the Skandalaris Center, the Center for Drug Discovery, the Office of Technology Management, and each department’s supporting members, such as New Venture Analysts, the head of the high throughput screening core, and tech transfer manager and associates. This is an informal 1-hour meeting where the LEAP Inventor Challenge advisory team hears about the project and offers advice about how to best to appeal to the judges in the final presentation. SPARC representatives will also meet with relevant teams.
- **Complete Pitch Deck**
  - Submit Pitch Deck 1st Draft
  - **Pitch Deck Review**: Applicants present their PowerPoint presentation (pitch deck) to the LEAP Inventor Challenge advisory team in a more formal setting. The presentation should last about 15 minutes. Following the presentation, the LEAP Inventor Challenge advisory team will provide feedback and simulate questions that the judges might ask in the final presentation. This Q&A will last about 45 minutes.
- **Submit Final Executive Summary**
  Generally due one (1) week before the final presentation, the Final Executive Summary must match information presented in the pitch deck. This final document goes to the judges for review.
- **Present to Judges**
  Present to industry relevant judges who advise on funding, along with SPARC representatives. Similar to the Pitch Deck Review, prepare for a 15-minute presentation and 45 minutes of Q&A.
Awardees would receive cash funding from SPARC to pursue further development of the product/research program at PI’s Lab.

If some of the above further development activities require services like screening, medicinal chemistry, formulation development, preclinical pharmacology, or toxicology, then such development work may be conducted by SPARC at SPARC research facilities. In this event, research activities conducted by SPARC would be considered as in-kind funding support by SPARC.

Such in-kind funding support would be part of the grant or it could be in addition to the cash funding provided by SPARC.

If such funded projects reach predetermined critical research milestones, SPARC would have the first right and exclusive Option to license the product/technology on worldwide basis.

Licensed product/technology would be developed further by SPARC with the aim of commercialization of licensed product/technology in US.
Questions?

Contact the Skandalaris Center

LEAP@wustl.edu