Call for Proposals

4D Technology Development Pilot Project Program 2016



4D Technology Development Aim: to promote technology-based solutions for unmet needs across the healthcare system (funded by CTSA)

- ISMMS researchers and clinicians are invited to submit the application by filling in the slides as application for the fourth cycle of the 4D Technology Development Pilot Program (by July 15th)
- This call is open to translational *technologies addressing unmet needs in therapeutics, diagnostics, devices and digital health*
- Multi-disciplinary teams are encouraged to apply
- Selected teams will follow a mentored curriculum during which they will execute their technology projects plans. They will also be expect to interact with relevant networks and users.
- As part of this program, the teams will interact with experts in drug discovery, intellectual property, finance and biotechnology start-ups and fine tune the plans for the next phase.
- The cycle will run from September 2016-March 31st 2017.

Instructions

You will need to fill in the slides that follow (starting from slide 5).

Please make sure you include a description of:

<u>PROJECTS</u>: What technological development do you believe is feasible within the context of the 4D program? In particular, what concrete milestones do you realistically expect to achieve during a half to one year timeframe? Project submissions and questions can be sent to <u>Louise.Lammers@mssm.edu</u>.

<u>BUDGET</u>: Estimated budget (in the range of \$10k-\$40k), but the request should be justified and tied to specific milestones and timelines (September 2016-April 1st 2017). In addition to this Conduits CTSA funding rules apply and there are restrictions as to what expenses are allowable:

http://icahn.mssm.edu/static_files/Test2/06081716/www.mssm.edu/finance/grant_restricted_funds/pdf/173.pdf

Please contact <u>Sonia.kleiner-arje@mssm.edu</u>, Director of ConduITS if you have questions regarding budget and expenses.

Prior Approvals – from NCATS & ISMMS IRB are required only for Human Subjects Research

<u>NCATS</u>: Special submission guidelines, instructions and checklists will be provided to you for NCATS prior approval. You will need to leave adequate time to prepare all the required information. You must submit your completed application documents through the ISMMS Grants & Contracts Office (GCO). The completed package must be submitted to NCATS 30 days prior to the beginning of your funding. Final award is contingent on NCATS & IRB approval.

<u>IRB</u>: For assistance with navigation of the ISMMS IRB submission process for approvals and/or waiver please contact the Office of Research Services (ORS) and indicate that this is for help with your 4D Pilot Project submission. There are many steps required for IRB submission and final award is contingent upon NCATS & IRB approval. ORS Contact Information: <u>research.services@mssm.edu</u> or 212-824-7294.

Please contact <u>Sonia.kleiner-arje@mssm.edu</u>, Director of ConduITS if you are having any issues obtaining help.

Pilot Project Timeline 2016

June 15	July 15	August 1	August 15	September 15	March 31 2017	
RFP	Application submission deadline	Review of submissions and notification of awards	Project Execution plan submitted. <i>If human subjects</i> <i>research, concurrent</i> <i>submission to ISMMS</i> <i>IRB & NCATS for prior</i> <i>approval</i>	Approved projects start date	4D funding has been expended. Pitch session	



Name of Technology

Names of PI or Project leader & team

Problem: What is the unmet medical/therapeutic need?

*Limit to one slide.

Addressable Market

*Include specifics (if known) about patient #s, tests performed and/or \$\$s.

Limit to one slide.

High-level Summary of Technology

*Focus on conclusions here.

Comment on (potential) Intellectual Property of the technology.

These slides must address:

What makes you, the investigator, so excited about this project?

Data status

*Present only the most significant validating data that is the center of the technology

here. Be sure to include conclusions.

Status, milestones & budget requested

What are tangible milestones could you achieve during the next 6 months (and

longer term milestones)

Proposed budget for the first 6 months (link to milestones)

Competition

*Focus on communicating the differentiating factor(s) of the technology compared

to the current standard of care and other approaches.

Note: <u>www.clinicaltrials.gov</u> may be helpful in providing up-to-date information on competing studies.

Regulatory

How will you make a plan to achieve clearance to market?

Do you already have internal IRB approvals in place if relevant?

Gaps/hurdles

WHAT OTHER EXPERTISE DO YOU EXPECT TO NEED?

What are the major gaps and risks you will have to overcome?