RADx Radical to RADx Tech Work Package Application

Pre-submission Documentation for Awardees

Information for Awardees

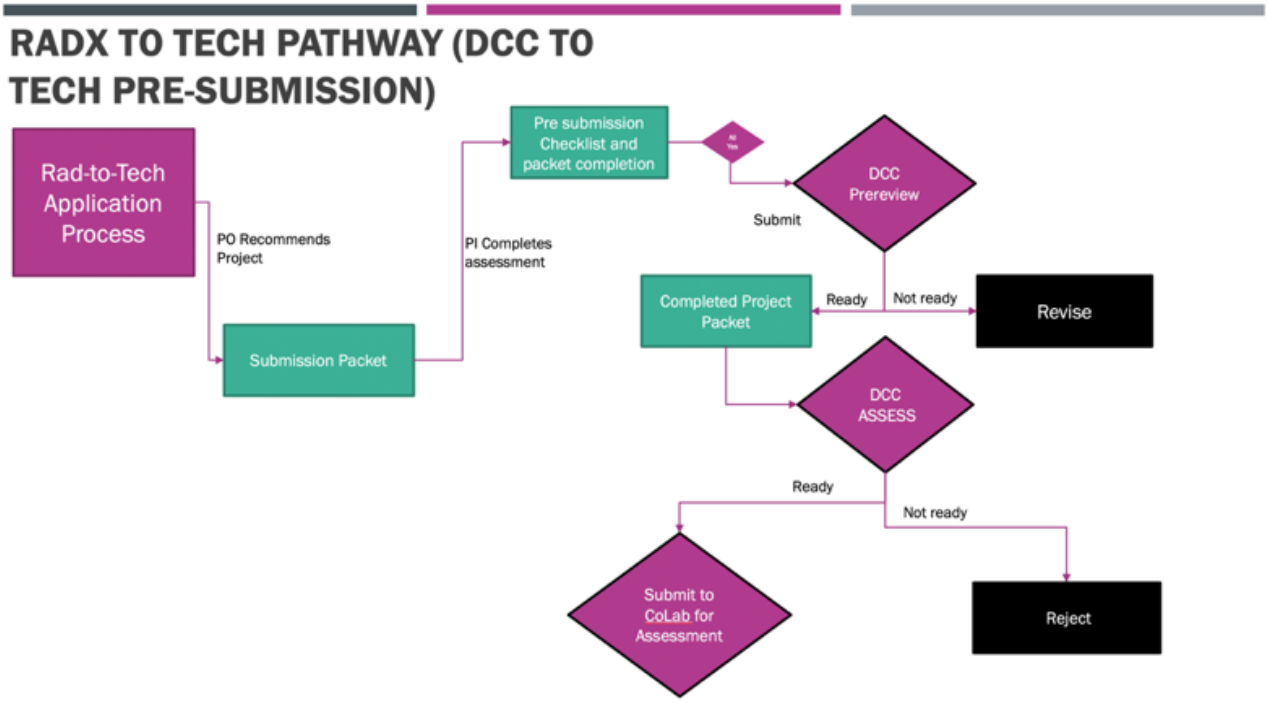
The NIH RADx Radical (RADx-rad) program supports innovative technologies for the diagnosis and surveillance of COVID-19 and emerging infections. RADx-rad has a diverse portfolio of research projects and some of the projects may be best suited for future applications while others may be ready to move forward with commercialization and deployment within 2021. As part of the Phase II development plans, RADx-rad intends to support and fund the commercialization efforts of selected mature technologies that are ready to accelerate their development. This will be done by partnering with the RADx Tech program and leveraging its well-established workflow for scaling existing RADx technologies. The NIH RADx-rad and Tech programs will be collaborating and coordinating their efforts to evaluate and select projects that have minimized development risks (de-risked) and are highly likely to attract external investment towards commercialization by the end of 2021. All funding to access the RADx Tech innovation funnel will be provided by RADx-rad upon approval by the RADx Executive Committee. This process will be facilitated by the RADx-rad Data Coordination Center (DCC).

Program overview

- The Rad-to-Tech pathway offers a **three-stage process** to apply for a Tech transition work package:
    1) Preliminary Proposal will be screened by the DCC.
    2) Full proposal will be evaluated by the Point-of-Care Technologies Research Network (POCTRN) via the CoLab grants management portal.
    3) A Deep Dive, preparation, proposal revision will be screened by the Tech Viability Panel to decide which projects which projects get support to move into the Work-Package process.
- There is limited availability of funding awards, so only mature technologies with a high chance of reaching the market will be selected for this process.
- There is a significant amount of documentation and preparation associated with this process. RADx-rad teams must be prepared to complete the documentation and have sufficient resources to dedicate to the process.
- Applications will be processed by the RADx-rad DCC on a rolling basis, beginning on July 6, 2021, and will continue to be accepted until funds are spent.
- Projects that pass DCC review will be invited to apply for a review by the RADx Tech CoLab. Proposals that pass this review will then be assessed by the RADx Tech Viability panel and approved by the RADx-rad Executive Committee.
- Selected projects will then be awarded up to $25,000 to support a RADx Tech deep dive-assisted preparation of a full Work-Package submission to the RADx Tech Investment panel (Tech Viability).

- For those projects that are recommended by the panel and approved by the RADx Executive Committee to proceed to the Work Package, funding will be awarded in the amounts of between $250,000-$1,000,000 with a timeline of 4 to 6 months.

To apply, RADx-rad awardees should work with their NIH representative (PO) to review this pre-submission document and complete the readiness self-assessment included. If the answer is yes to all or majority of the questions, you are encouraged to submit a “pre-proposal” for assessment to the RADx-rad DCC. Proposals will be assessed for completeness and basic awardee readiness. Selected awardees will then be asked to apply to the CoLab system (see information below for awardees selected to submit full proposals) where you will enter information from the short proposal as well as additional information requested by RADx Tech. Awardees that are not selected may revise their submissions and reapply pertaining to availability of funds.



Readiness Self-Assessment Checklist

- ❑ Is the intended use of my program/product aligned with at least one of the following strategic categories? Categories include home testing, bedside monitoring, point of care use, symptomatic or asymptomatic testing, convalescent testing, and/or surveillance such as droplet/aerosol detection, touchscreen/surface or wastewater monitoring) (**Intended Use** is the general purpose of a medical device or its function - what you "claim" a medical device does).
- ❑ Does my technology diagnose/screen the most prevalent circulating COVID 19 virus/variants (with supporting data).
- ❑ Can my technology provide advances in the detection/ surveillance of other diseases or pathogens?
- ❑ Will my approach reduce barriers to national testing capacity?
- ❑ Does my technology improve the state of the art compared to what is available or coming soon?
- ❑ Can I perform the clinical/real-world studies (obtain the resources, carry out the study, analyze the data) needed for EUA if a diagnostic / screening test, or other regulatory validation for surveillance technology? Can my technology be scaled (e.g., tens to hundreds of thousands of tests or people screened per day) in a cost-effective way?
- ❑ Is my technology likely to be de-risked* sufficiently to obtain external investment by the end of 2021? See the following link: Healthcare Innovation Cycle PDF Checklist, you should be able to reach **level 5** by the end of 2021.

*Given funding, can I overcome the many risks (including supply chain limitations, regulatory hurdles, intellectual property / freedom-to-operate, business case, usability, validated performance, etc.) to obtain external investment in 2021?

You should be able to answer YES to all of these questions. If you have answered YES, you may now prepare and submit your brief proposal.

Proposal Instructions:

The following instructions cover the first phase of submission for a RADx Tech Work Package. Submitted proposals will be screened by RADx-rad DCC for completeness and readiness to submit to RADx Tech. RADx Tech is different from most solicitations in that it was created to provide a rapid response to the massive and unique challenges created by the COVID-19 crisis, and therefore seeks to fund projects that can obtain external investment and be taken to market quickly.

- Your initial proposal can be submitted online via this proposal submission link (also sent out via email on Tuesday, July 6, 2021)22.
- Proposals will be checked for completeness and reviewed by the DCC within 14 days.
- *Selected proposals will be returned to PIs and their PO with instructions to submit full proposals to the POCTRN/RADx Tech CoLab grants portal.

*Proposals awarded under this solicitation will be treated as a subaward to a cooperative agreement (see PAR-17-453) and are required to comply with all of the NIH Standard Award Terms and Conditions available at this LINK .

If you have any questions or need assistance with your proposal, please contact Eli Aronoff-Spencer earonoffspencer@health.ucsd.edu and/or Alexandra Hubenko ahubenko@ucsd.edu at the RADx-rad DCC.

Brief Proposal

Please submit a proposal with the information outlined below. Note that word limits apply and proposals over the limit will be asked to revise. Upon submission, the RADx-rad DCC will acknowledge receipt and review all proposals within 2 weeks. Selected proposals will be notified and given instructions to submit further information to the CoLab system.

Applicant Information

- *Proposal PI / Team Lead*
- *Project Title*
- *Award number*
- *NIH Program Officer*
- *Team / Company Name (website)*
- *Point of Contact Information (Name, Role, Email, Phone Number)*

Proposal Information

Nature of the Solution (<250 words)

Please indicate if your proposed solution is standalone or is needed to make another solution deployable at scale.

Overview (<250 words)

Please provide an overview of your proposed solution to help reviewers quickly understand your proposal - more detail will be asked later.

Solution Maturity (<250 words)

Download the Healthcare Innovation Cycle PDF Checklist, complete it as best as you can indicating your current status, and then upload the completed version.

Key performance parameters
Please indicate the demonstrated performance parameters of the test's performance as accepted by the FDA.

Prototype performance
This section asks for a summary of key test performance parameters expected when the work is completed. Below please indicate the status of prototypes in delivering these results today.

Sampling methods
Describe the planned specimen and sampling type (select all that apply).
- ☐ Saliva
- ☐ Sputum
- ☐ Fecal
- ☐ Nasal swab
- ☐ Oral swab
- ☐ Blood
- ☐ Wastewater
- ☐ Aerosol/Breath
- ☐ Secretions (e.g., Sweat)
- ☐ Olfactory or Other Sensory function
- ☐ Other

Expected Level of Detection (LoD)
Please select the LoD units and then input the appropriate value.
LoD in genome equivalents (copies/ml). *[leave blank for solutions that do not detect virus directly]

Expected Sensitivity %
Use whole numbers for the %, so for 30% enter 30, not 0.30.

Expected Specificity %
Use whole numbers for the %, so for 30% enter 30, not 0.30.

Expected time to run a test (TaT)
How long does a test take to run (in minutes/seconds x.xx) from the time a sample is handled until read-out?

Expected Capacity
What is the expected current throughput capacity of the test (tests/hr)?

Expected capital costs
Please estimate the total cost to make any hardware needed to conduct the test (not the price of the test itself), in dollars.

Expected cost per individual result
Please estimate the average cost of consumables per individual result test (in dollars).

Prior Work Upload

Please create and upload a document that succinctly describes your proposed solution. This should briefly describe its significance and key innovation, its intended use, capital and operating costs, expected performance, connectivity, and results to date to convince reviewers that your proposed solution is viable**.**

***Note: we will ask about the work you plan to do later. Limit this prior work document to **4 pages, with 1-inch margins on all sides, Times New Roman font size 10 minimum**. Only the essential references are to be included, with no hyperlinks to webpages.

Regulatory (<250 words)

Please provide an overview of your status in seeking FDA approvals and CLIA status. Describe if you plan to file for Emergency Use Authorization (EUA) and if a CLIA waiver will be required for your intended use case.

Implementation (<250 words)

How do you plan to make your solution available - and what progress have you made to date?

Companion Activities

Are there other things that need to be in place for your solution to be deployable? (i.e., information systems, etc.)

Key Risks and Mitigation (<250 words)

What do you see as the biggest risks to commercialization and reaching market in a scalable way and how can they be managed? Examples include supply chain and cost barriers, freedom to operate (patents of others), regulatory, and usability barriers.

Brief Modular Budget and Timelines

- Requested Funding ($250,000-$1.5M) for Period of Performance __ (*specify up to six months)
- Investigators & Staff, Services, Supplies & Equipment
- Key tasks and milestones (Gantt chart)