

RADx Radical to RADx Tech Work Package Application

*Pre-submission Instructions for Awardees
Updated 18 October 2021*

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 in a relatively short timeframe (~6 months). 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 within 6 months of award date. 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).

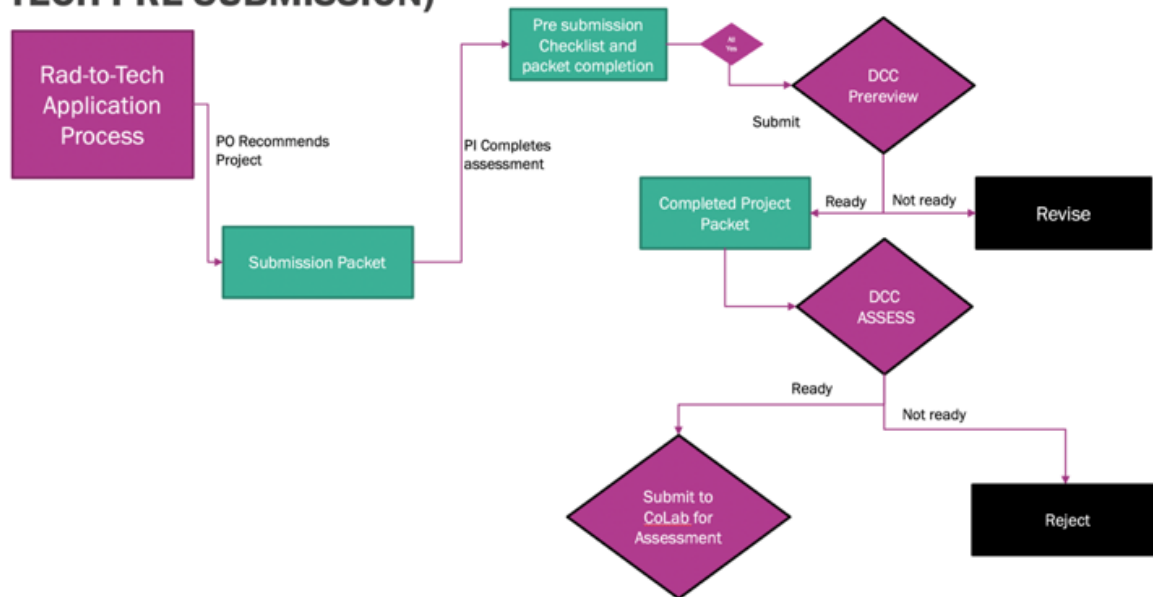
Program overview

- 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, and proposal revision will be screened by the Tech Viability Panel to decide 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 and are approved by the RADx Executive Committee 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.

- As part of the application, applicants submit a budget plan that outlines estimated project-specific costs for salaries and materials for product design, prototyping, testing, and/or data preparation. The total budget for these costs is capped at \$500,000. Support for design and building of manufacturing equipment and the procurement of materials to support prototype builds and verification testing are all allowable costs. However, please note that expenses related to the following activities are not allowed and will not be supported by NIH:
 - Procuring materials for commercial production
 - Manufacturing product for commercial production
 - Sales and marketing
- Projects approved by NIH for the Deep Dive evaluation will receive valuable consultation and support from technical advisors with expertise in validation, de-risking, and commercialization. Working with these advisors, they will prepare a full Work Package submission for consideration by the RADx Tech Investment Panel, including a proposed final budget that covers the necessary activities for validation and commercialization.
- Projects that are recommended by the Panel and approved by NIH will proceed to the Work Package stage. As determined by the Tech Investment Panel and upon approval by the NIH, costs for the validation and commercialization activities will be covered by the RADx-rad program, subject to available funds.

To apply, RADx-rad awardees should work with their NIH program officer (PO) to review this pre-submission document and complete the readiness self-assessment included below. If the answer is yes to all or majority of the questions, you are encouraged to submit a “pre-proposal” including the budget plan (see above for allowable/unallowable costs) for assessment to the RADx-rad DCC. Pre-proposals will be assessed for completeness and basic awardee readiness. Proposals may be sent back to applicants with reviewer comments and revision may be requested. Revised/ready proposals will be approved by NIH and 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. For the pre-proposals not selected by the DCC, awardees may revise their submissions and reapply, subject to availability of funds.

RADX TO TECH PATHWAY (DCC TO TECH PRE-SUBMISSION)



Readiness Self-Assessment Checklist

- ☐ Is the intended use of the program/product aligned with one of the following strategic categories? (symptomatic or asymptomatic testing, convalescent testing, or surveillance monitoring in home use or point of care environments)
(**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 also provide a significant advancement in the detection/surveillance of non-COVID diseases, such as influenza A and B, or do we have a plan for the technology to be utilized and/or be expanded to new and other emerging infections and diseases?
- ☐ 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 6 months from the date of award? See the following link: [Healthcare Innovation Cycle PDF Checklist](#)- you should be able to reach **level 5** in the next 6-8 months.

*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 6 months from the date I receive a RADx Tech grant?

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 the proposal process encourages applications from projects that can obtain external investment and be taken to market quickly.

- Your initial proposal can be submitted online via [this proposal submission link](#).
- Proposals will be checked for completeness and reviewed by the DCC within 14 days.
- Applicants will receive reviewer comments/assessment. If revisions are requested, applicants will have 2 weeks (10 business days) to re-submit their revisions.
- Revisions will be screened by DCC to ensure reviewer comments were addressed
- DCC sends application packets, reviewer comments, and revised proposals to NIH RADx leadership for review.
- Selected proposals will be returned to PIs and their PO with instructions to submit full proposals to the POCTRN/RADx Tech CoLab grants portal.

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.

Proposal Submission:

Please submit a proposal with the information outlined below. Please notify your NIH Program Officer about this submission. 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.

Period of Performance (specify up to 6 months)

Budget (Maximum \$500,000) and Budget Justification

Estimate project-specific costs for salaries and materials for product design, prototyping, testing, and/or data preparation. Allowable costs: support for design and building of manufacturing equipment, procurement of materials to support prototype builds and verification. Unallowable costs (will not be supported by NIH): procuring materials for commercial production, manufacturing product for commercial production, sales and marketing expenses.

Key tasks and milestones (Gantt chart)