UMass and RADx Tech: The Clinical Studies Core as a Model for Rapid, Flexible, and Digital Trials in the 21st Century

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Impact Statement: The Clinical Studies Core provided the infrastructure and expertise to rapidly design and implement clinical studies for novel SARS-CoV-2 diagnostic devices in the RADx Tech pipeline.

Abstract: The National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx) Tech initiative to support the development and commercialization of novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) point-of-care test devices. The primary objective of the Clinical Studies Core (CSC) was to perform SARS-CoV-2 device studies involving diverse populations and settings. Within a few months, the infrastructure for clinical studies was developed, including a master protocol, digital study platform, data management system, single IRB, and multi-site partnerships. Data from some studies are being used to support Emergency Use Authorization of novel SARS-CoV-2 test devices. The CSC reduced the typical time and cost of developing medical devices and highlighted the impact of academic and NIH partnership in addressing public health needs at a rapid pace during a global pandemic. The structure, deployment, and lessons learned from this experience are widely applicable to future in vitro diagnostic device clinical studies.

Clinical Studies Core Overview
- All studies based at University of Massachusetts Medical School (UMMS)
  - Prospective sample collection in diverse populations and settings
  - Single IRB
  - Research centers at UMMS, Johns Hopkins, Northwestern, and Practice-Based Research Network (PBRN) sites
- Platform study design
  - Master protocols and consents for all studies
  - Customized amendments for each device study
  - Standard comparator assay used to report test results to participants
- Paperless enrollment through Eureka digital platform
  - Consent process
  - Data entry
  - Survey questions on symptomatology and usability/interpretability

RADx Tech Clinical Studies Core Mission and Approach
- Mission: To design and oversee the process of evaluating point-of-care (POC) devices that advance from Phase 0 to 1 in rigorous clinical studies in diverse populations and settings
- Eureka Digital Study Platform being used for all studies
- Data Safety Board and Single IRB for oversight and safety monitoring
- Robust Research Center Network (POCTRN) serves as core research center network for COVID-19 Test US enrollment with the Practice-Based Research Network (PBRN) sites and Centers for Clinical and Translational Science assisting, as well

Test at Home Feasibility Study Preliminary Findings
- Test at Home Feasibility Study: 200 participants, testing daily for 14 days
  - Is it feasible for participants to use the OTC tests at home without supervision or support from research study staff? How often are participants willing to do the tests?

Digital, Siteless Studies through RADx Clinical Studies Core: Anyone, Anywhere

Digital Accomplishments
- Conducted 6 studies on the performance of SARS-CoV-2 devices; 2 have received EUA
- Compared performance of serial testing of molecular vs antigen tests; data supports updated FDA guidance on recommended frequency of antigen testing - The Journal of Infectious Diseases, jid537, https://doi.org/10.1093/infdis/jid537
- Multi-site biopsory of nasal, saliva, and blood samples – 1000+ participants enrolled
- Test at Home Feasibility Study: 299 participants, testing daily for 14 days
  - Is it feasible for participants to use the OTC tests at home without supervision or support from research study staff? How often are participants willing to do the tests?
- Say Yes! COVID-19 Test: analytics to evaluate distribution of more than 4 million tests and ongoing in NC, TN, MI, GA, HI, IN, and KY
  - Characterize the distribution of OTC tests in different communities and assess association with social determinants and community transmission
  - Understand participant’s behavior for performing risk-based testing using OTC and reporting results to health department over a 12-week period
- Test Us at Home: Nationwide siteless study. Enrolled 600+ participants
  - Evaluate performance of three most popular over-the-counter tests for detecting infection in asymptomatic people when used serially. A collaboration with FDA to inform asymptomatic serial screening guidance.

Conclusions
- Enrollment total as of 11/4/21 – 5,104
- Robust Research Center Network and Centers for Clinical and Translational Science for oversight and safety monitoring
- US and COVID-19 Test US Kids
- Multi-site biorepository of nasal, saliva, and blood samples – 1000+ participants enrolled

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