RADx® Underserved Populations - CDEs

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Duke Clinical Research Institute

UNC | SCHOOL OF MEDICINE
Center for Health Equity Research

RADx-UP is Part of a $1.4 Billion NIH Initiative

RADx Tech

Speed innovative point-of-care, home-based, and clinical laboratory tests for COVID-19

- -

BUDGET
$908 Million

RADx Advanced Technology Platforms (RADx-ATP)

Identify testing platforms that are far enough advanced for rapid scale-up or expanded geographical placement

- -

BUDGET
$230 Million

RADx Underserved Populations (RADx-UP)

Understand and reduce the disparities in COVID-19 morbidity and mortality for those disproportionately affected by COVID-19

- -

BUDGET
$533 Million

RADx Radical (RADx-rad)

Support new, non-traditional approaches to address current testing gaps, and non-traditional applications of existing approaches

- -

BUDGET
$187 Million

## This is us

RADXUP

RADx-UP is Community-Engaged Research

Overarching goal is to evaluate strategies to increase uptake and access to COVID-19 tests in underserved populations

- NIH started RADx-UP in September 2020, with awards in phases:
  - Fall 2020: Phase 1 (69 projects) and CDCC
  - Spring/Summer 2021: Say Yes! COVID Test and the Safe Return to School Diagnostic Testing Initiative (16 projects)
  - Fall/Winter 2021: Phase 2 (21 projects) and Supplemental (21 projects)
  - Fall 2022: Additional Phase 3 projects added
  - Fall 2023: Additional Phase 4 projects added

- RADx-UP projects build on **existing community-academic** infrastructure, processes, and **trusted relationships**

Take home messages

- The RADx-UP Coordination and Data Collection Center (CDCC) is a **joint collaboration** of DCRI, UNC Chapel Hill, and the Community-Campus Partnerships for Health. **Started in September 2020.**

- RADx-UP CDCC leverages the **Secure Duke Azure Cloud**

- We coordinate **135+ NIH funded projects**

- We partner with many communities throughout the country and **use data to drive and enhance** those relationships

- **CDEs** are central to our data sharing mission.

What is RADx-UP?
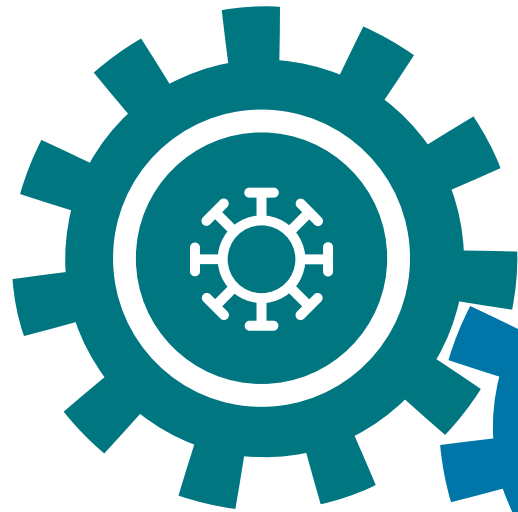
DIAGNOSTIC TESTING EXPERTISE to **shape public health responses** under dynamic regulatory frameworks
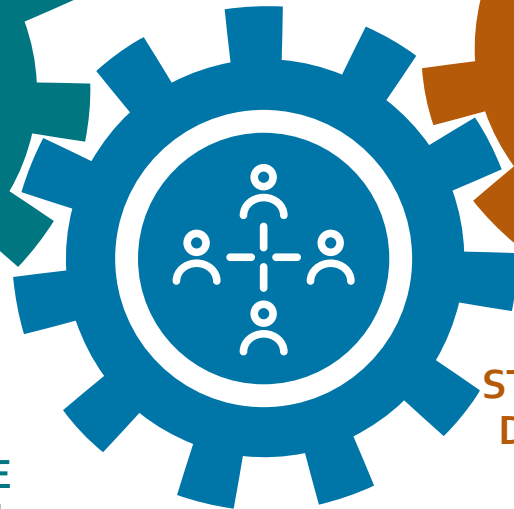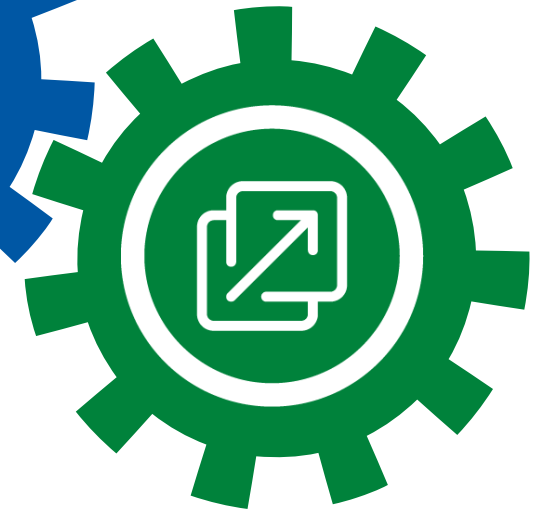
COMMUNITY-ENGAGED RESEARCH STRATEGIES that are diverse, multiple, localized, and heterogeneous

STANDARDIZED CDE DATA COLLECTION harmonization, sharing, and dissemination across all populations
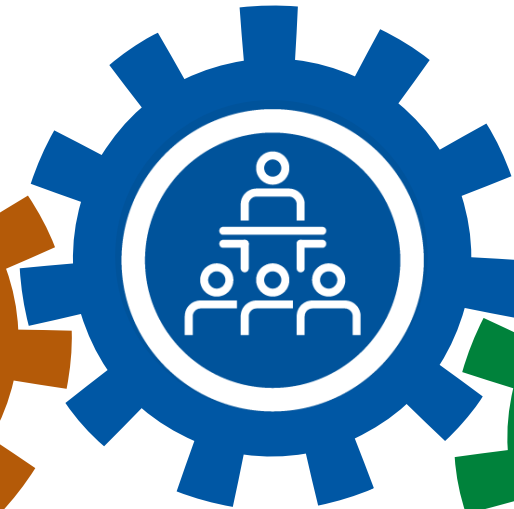
RESEARCH PLATFORM to engage communities through the entire life cycle of research studies

LOCALIZED LEARNING, NATIONAL TRANSLATION via a community of practice

RADXUP

A functional RADx-UP Community of Practice

Community Collaboration Grants

> Support to community partners to advance capacity, training, more

COVID-19 Equity Evidence Academy

> Annual interactive conference, presentations of what's working in community engagement
> Data Profile with scholarship, project profiles

RADx-UP Scientific Meeting

> Annual program for data results, lessons learned, community engagement approaches

Partnering for Impact

> Writing groups collaborating on consortial publications

Working Groups

> Building Community Capacity and Impact
> Engaging Black/African Americans
> Social, Ethical and Behavioral Implications
> Community Health Worker
> Engaging Hispanic / Latino / Latinx Populations
> Sexual and Gender Minorities
> Understanding Social Determinants of COVID-19
> Child Health

Community Connections

> Quarterly gathering of RADx-UP community partners

Engagement Resource Center

> Library of 250+ community-engagements resources

RADx-UP Image Bank

> 700+ images that reflect the rich mosaic of identities and experiences of RADxUP

> CDCC Community Engagement Framework
> RADx-UP Health Equity Policy Framework
> Community Health Worker Symposium
> RADx-UP Long COVID CDEs
> Causal loop diagrams

LOCALIZED LEARNING/NATIONAL APPLICATION

RADXUP

NUMBER OF PROJECTS SERVING SPECIFIC POPULATIONS*

80
Hispanic / LatinX

73
African American

36
Other

32
Asian

26
Older Adults
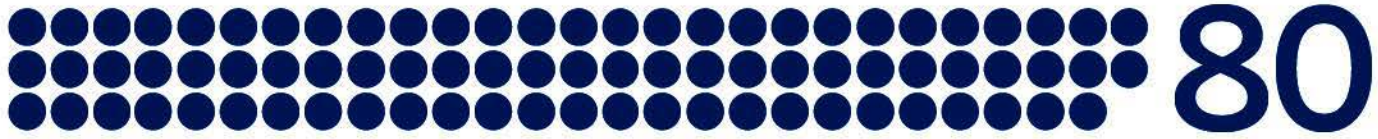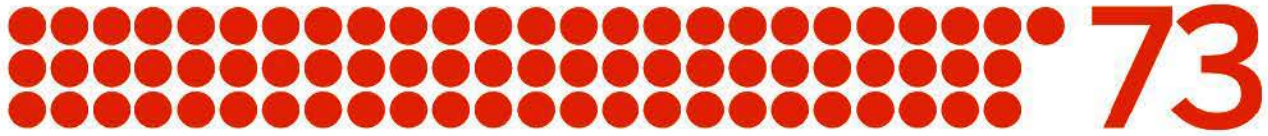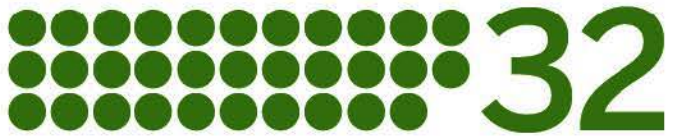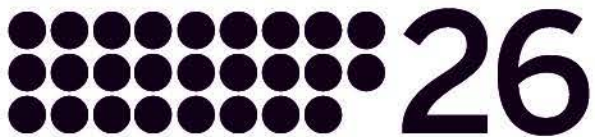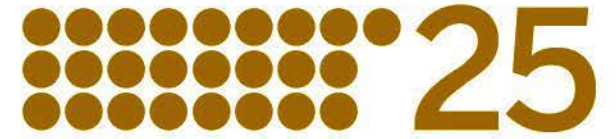
25
Low income populations

17
Hawaiian / Pacific Islanders
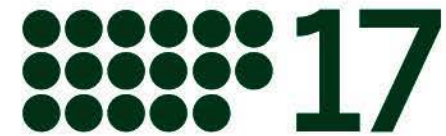
17
Rural Populations

16
American Indians
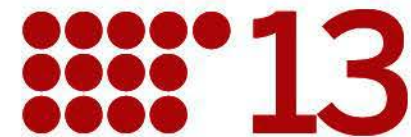
13
Pregnant Women

*Phase I, II, III and Supplements, data as of 6/30/2023 from REDCap project summaries

RADXUP

NUMBER OF PROJECTS SERVING SPECIFIC POPULATIONS*

12 Immigrants

10 Alaska Native

7 Substance Users

7 Low income housing

6 Federally Qualified Health Centers (FQHCs)

5 People Experiencing Homelessness

4 Intellectual and Developmental Disabilities

3 LGBTQ/ Sexual and Gender Minority (SGM)

3 People living with HIV/AIDS (PLWHA)

3 Pediatric Only Communities

2 Testing Deserts

2 Incarcerated People

2 Farm Workers

1 Coal Miners

*Phase I, II, III and Supplements, data as of 6/30/2023 from REDCap project summaries

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NUMBER OF PROJECT SETTINGS FOR COVID-19 TESTING

48	42	41	34	27	19	5	2	1
Community health center	In-home	Urban	Rural	School*	Public housing	Nursing home or long-term care facility	Any setting	Prison or correctional facility
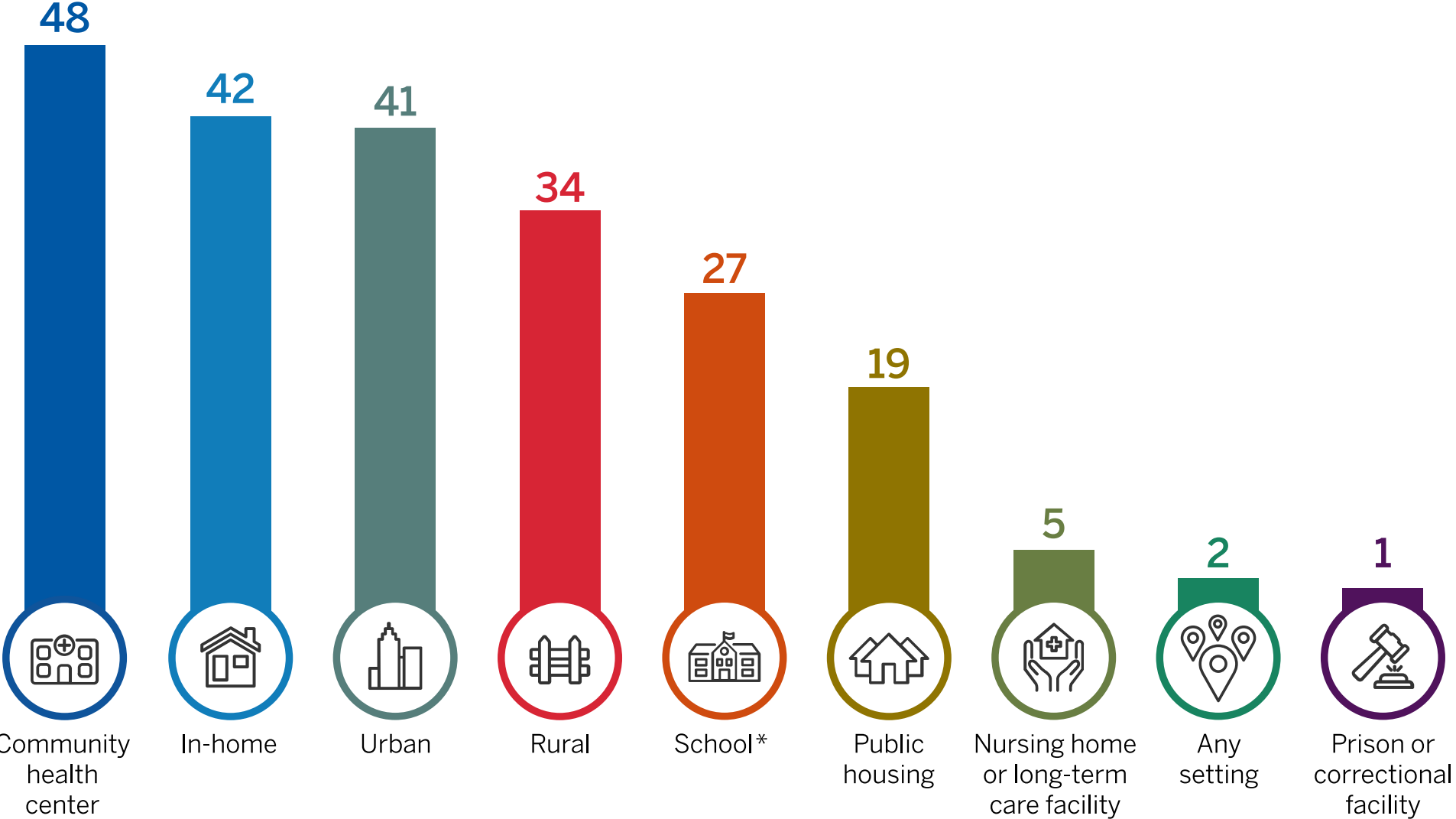
RADX UP

*Includes 16 research projects in the **RADx-UP Safe Return to School Diagnostic Testing Initiative**
Source: Phase I, II, III and Supplements, data as of 6/30/2023 from REDCap project summaries.

RADx-UP Awardee Locations (142 Projects Phase I-IV)

SEATTLE, WA
PULLMAN, WA
STAYTON, OR
EUGENE, OR
(7 awards)
BOZEMAN, MT

SACO, ME
BOSTON, MA
(4 awards)
BURLINGTON, VT
PROVIDENCE, RI
(5 awards)
ROCHESTER, NY
NEW HAVEN, CT
(3 awards)

MILWAUKEE, WI
(2 awards)
MADISON, WI

DAVIS, CA
(2 awards)
SAN FRANCISCO, CA
(3 awards)
STANFORD, CA
(3 awards)
NORTHRIDGE, CA
LOS ANGELES, CA
(3 awards)
IRVINE, CA
LA JOLLA, CA
(3 awards)
SAN DIEGO, CA
(6 awards)

SALT LAKE CITY, UT
(3 awards)
DENVER, CO
OMAHA, NE

CHICAGO, IL
(7 awards)
CHAMPAIGN, IL
(2 awards)
KANSAS CITY, KS
(2 awards)
KANSAS CITY, MO
(2 awards)
ST. LOUIS, MO (6 awards)

LAYFAYETTE, IN
COLUMBUS, OH
MORGANTOWN, WV
(2 awards)

NEW YORK, NY
(9 awards)
NEWARK, NJ
PHILADELPHIA, PA
(2 awards)
DOVER, DE
BALTIMORE, MD
(11 awards)
COLUMBIA, MD
WASHINGTON, DC
NORFOLK, VA
(2 awards)
DURHAM, NC
(6 awards)
CHAPEL HILL, NC
WINSTON-SALEM, NC

ALBUQUERQUE, NM
(4 awards)
TAHLEQUAH, OK
OKLAHOMA CITY, OK
(3 awards)
TEMPE, AZ
(4 awards)
LITTLE ROCK, AR
(2 awards)
BIRMINGHAM, AL
(4 awards)

DALLAS, TX
JACKSON MS
TUSKEGEE, AL
(2 awards)
BATON ROUGE, LA
(2 awards)
EL PASO, TX
(2 awards)
HOUSTON, TX
(5 awards)
NEW ORLEANS, LA
(3 awards)

HONOLULU, HI
(3 awards)

TAMPA, FL
MIAMI, FL
(3 awards)

SAN JUAN, PR
PONCE, PR

LEGEND

Phase I – IV* Project Institutions

1-2 3-4 5-6 7-8 9+

LOCATION OF INSTITUTION WITH PROJECT GRANT

*Phase IV projects do not yet include awards for RFA-OD-23-051.

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RADX-UP at a glance

Data as of 01/17/2024

138 COVID-19 testing and SEBI projects

53 States, territories, and D.C.

1 Coordination & Data Collection Center

273 Community-engagement resources in the RADx-UP library

127 Projects submitting CDEs to CDCC

408,599 Enrolled participants (direct participants)

448,647 COVID-19 tests conducted (direct participants, CDEs only*)

13 Partnering for Impact writing teams

25 Rapid Research Pilot Awards

70 Community Collaboration Grants

283 Published research articles

*Count reflects common data elements data only, not actual tests conducted in the program (in the millions)

January 2024
Newsletter

news from the CDCC

Coordination and Data Collection Center

VOL 4 NO 1

PHOTO COURTESY RADx-UP IMAGE BANK

RADXUP

152
Home Test Assays in the updated RADx-UP Quick Reference Guide

55M+
CDE data points uploaded to Data Hub

16
Core Analytic Data Set domains available

RADXUP

RADx-UP Tier 1 CDE Categories Presented in Data Dashboard

Tier 1 CDE Category	Data Dashboard Page
Consent (and other date CDEs)	Enrollment Over Time
Location	(Used on Data Linkage Dashboard)
Sociodemographics	Demographics, Socioeconomic Status
Housing Employment and Insurance	Employment, Health Coverage Status and Insecurities, Social Vulnerability, COVID-19 Pandemic Insecurities
Work PPE and Distancing	Work PPE and Distancing
Medical History	Medical History
Health Status	Overall Health Status
Vaccine Acceptance	COVID-19 Vaccine Acceptance and Concerns, COVID-19 Vaccine Acceptance Over Time, Flu and COVID-19 Vaccine History and Acceptance, COVID-19 Vaccination (1+ Dose) Over Time and Rate
Testing	COVID-19 Testing Access and Impact, COVID-19 Testing History
COVID Test	COVID-19 Tests Performed Over Time, COVID-19 Test Results and Positivity Over Time, COVID-19 Test Characteristics, Time to Test Results
Symptoms	COVID-19 Symptomology
Alcohol and Tobacco	Alcohol and Tobacco

RADx-UP Challenges

- There have been 5 waves of funded projects (phase 1, 2, 3, supplements, and 4).
  - As we have gone from the earliest projects to the latest, we have gotten better at understanding and communicating the data sharing expectations. This was a major challenge for phase 1, as the expectations were still being defined.
  - The Terms and Conditions of Award for each wave have continued to evolve and become clearer, helping everyone to be pulling in the same direction.
  - Having different data sharing expectations and different versions of the CDEs over the waves of projects made data quality and conformance processes more complex.

RADXUP

RADx-UP CDE Timeline
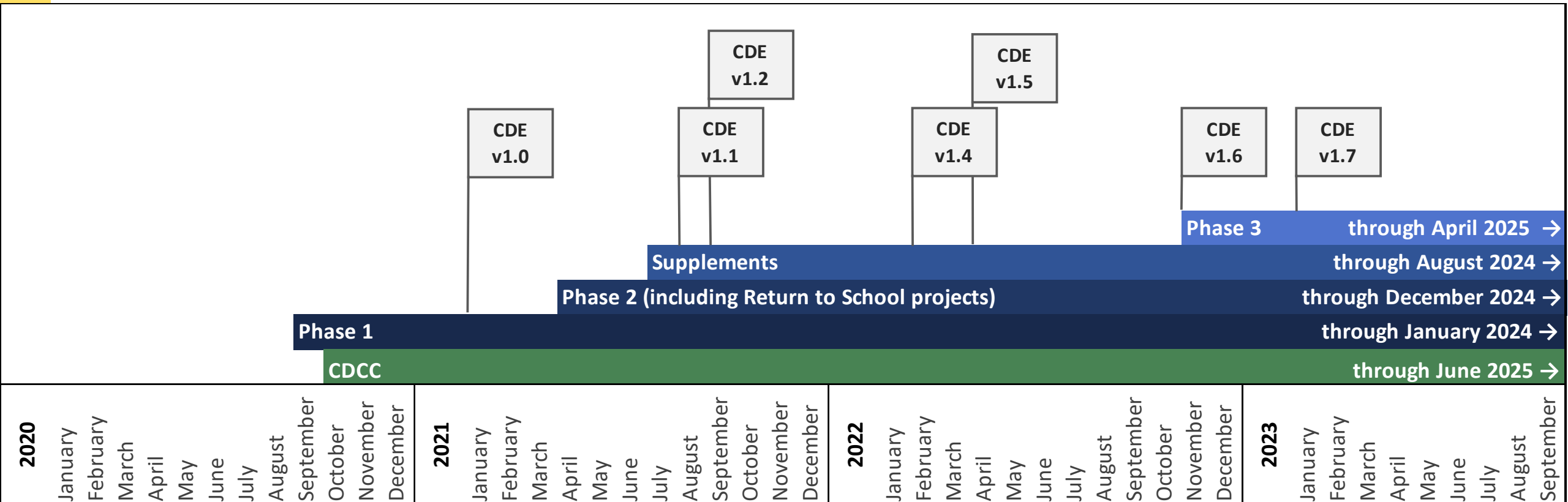
Data Flow

DATA SOURCES

RADx-UP Projects
- Individual-level data
- **NIH Common Data Elements**

External data sets
- Individual-level data
- U.S. Census data, American Community Survey data, electronic health records, National Death Index, CMS

LINKAGES

Aggregating, merging, and de-identifying data

DATA REPOSITORIES

CDCC participant re-contact repository
- Identifiable individual-level demographic data

CDCC data repository
- Participant data is coded
- De-identified individual-level data

NIH data repository
- De-identified individual-level data

NIH RADx-UP Common Data Elements leading to CDEs v1.0

Development process:

1. NIH provided *RADx-UP Data Harmonization Guidance*

2. CDCC met with NIH, NLM, DR2 to discuss recommended RADx and RADx-UP CDEs

   – *initial Tier 1 version had 752 items*

3. CDCC revised CDEs, sent to NIH, NLM, DR2 for review

4. CDCC updated CDEs based on feedback

   – *new version had 66 items*

5. CDEs sent to RADx-UP projects for review and feedback

6. NIH RADx-UP CDEs posted to the Toolkit web page Jan. 4, 2021

Data Toolkit   −

National Institutes of Health (NIH) Common Data Elements (CDEs) - Jan. 4th, 2021

- REDCap Data Dictionary Codebook PDF
- RADx-UP Data Dictionary Codebook CSV (updated Jan. 11th)
- RADx-UP PDF form for paper data collection
- RADx-UP Word Document form for paper data collection
- Spanish REDCap Data Dictionary Codebook PDF
- Spanish REDCap Data Codebook CSV *
- Spanish RADx-UP PDF form for paper data collection

If you have questions about the NIH CDEs, or are interested in learning more, select here to visit our CDE Questions with Dr. Kibbe series, which includes short podcasts as well as written key points.

RADX UP

Explaining the CDEs

- Projects needed to understand how and why the NIH RADx-UP CDEs were to be incorporated into research studies

- We produced a CDEs explainer graphic (at right)

- We also addressed the most pressing questions & concerns in a series of audio segments with Dr. Kibbe

- https://radx-up.org/radx-up-cdes/

- Dr. Eliseo Perez-Stable discussed the CDEs at the July 2021 Project-wide Meeting

CDE EXPLAINER - TIER 1 VS. TIER 2

TIER 1

Required from all testing Projects	Two components: • CDEs recorded by the participants or Project teams • CDEs recorded by the Project teams	REDCap Data Dictionary Codebook PDF – items #1 – 170 (pages 1-22)	RADx-UP Data Dictionary Codebook CSV – Column B, rows 2-158	RADx-UP PDF form for paper data collection – pages 1-22

- Consent
- Location
- Demographics
- Housing
- Employment

- Spoken Language
- Family Income
- Work PPE and Distancing
- Medical History

- Health Status
- Vaccine Acceptance
- Testing
- Symptoms

- Alcohol and Tobacco
- Identity (name, address, contact information, date of birth)

TIER 2

Recommended additional CDEs	REDCap Data Dictionary Codebook PDF – items #171 – 265 (pages 22-32)	RADx-UP Data Dictionary Codebook CSV – Column B, rows 159-241 (form name starts with "tier2_")	RADx-UP PDF form for paper data collection – pages 23-38 (form name starts with Tier2)

- Sociodemographics
- Medical History
- Vaccine Acceptance
- Testing

- Medications
- Alcohol and Tobacco
- Drug Use
- Disability

- Food Insecurity
- Housing
- Trust
- Identity – SSN and MRN

RADX UP

Version 1.1 released

- Version 1.1 with wording, responses, and branching logic fixes released on Aug. 12, 2021

- All changes are Tier 2 and fully compatible with version 1.0

- Additional vaccine CDEs to be released shortly

- Initial Pediatric version of the Tier 1 CDEs designed to be asked of parents and/or teachers

- https://radx-up.org/learning-resources/cdes/

CDE and ICF Files

NIH RADx-UP CDEs Version 1.1

- NIH RADx-UP CDEs v1.1 REDCap Codebook PDF file—This document contains all current CDEs in PDF form.
- NIH RADx-UP CDEs v1.1 Codebook CSV file—This file contains all current CDEs as a REDCap consumable data dictionary (CSV file). Note that variables are now less than 32 characters in length to be SAS-compliant. See change log for details on synonym substitutions.
- NIH RADx-UP CDEs v1.1 Change Log—This document details the changes between CDEs 1.0 and 1.1, as well as providing guidance for understanding these changes.

NIH RADx-UP CDEs Version 1.1 - Modified for Pediatric/Child Health Use

- NIH RADx-UP CDEs v1.1 Pediatric CSV file—This file contains a subset of the NIH RADx-UP CDEs v1.1, but with a column for questions modified to ensure relevance to children.

NIH RADx-UP CDEs Version 1.0

- REDCap Data Dictionary Codebook PDF
- RADx-UP Data Dictionary Codebook CSV (updated Jan. 11th)
- RADx-UP PDF form for paper data collection
- Spanish REDCap Data Dictionary Codebook PDF
- Spanish REDCap Data Codebook CSV *
- Spanish RADx-UP PDF form for paper data collection
- Chinese REDCap Data Codebook CSV**

*The Spanish version of the NIH CDE CSV file includes special characters which, when loaded into REDCap, will convert to the correct Spanish language characters. The form names themselves would not accept the special characters, so will remain in Spanish with regular character substitutions.

RADX UP

Sample Adult vs. Pediatric CDEs (Version 1.1) vs. NIH Pediatric CDEs

RADx-UP Tier 1 Adult CDEs	RADx-UP Tier 1 Pediatric CDEs	NIH Pediatric CDEs

- What was your sex assigned at birth on your birth certificate?

- Are you currently living in transitional housing, staying in a shelter, or experiencing homelessness?

- Did you lose health coverage because of the COVID-19 pandemic?

- What was your child's sex assigned at birth on their birth certificate?

- Is your child currently living in transitional housing, staying in a shelter, or experiencing homelessness?

- Did your child lose health coverage because of the COVID-19 pandemic?

- What was the participant's sex assigned at birth?

- Have any of the following occurred during the COVID-19 pandemic (since March 2020)? Loss of your housing, or becoming homeless since March 2020?

- During this pandemic (since March 2020) has this child had a change in their health insurance coverage?

RADX UP

Long-COVID CDE Community Engaged Focus Group 2022!

CDE Focus Group: Primary Goals

Goal #1: Produce long-COVID CDEs that are appropriate for the RADx-UP Community

- **Short term:**
  - Engage Community Partners, research staff, and investigators for review and feedback of tier 2 CDEs
  - Set clear expectations about engagement plan for the development of long-COVID CDEs for RADx-UP (and broader research community)
- **Long term:** Contribute to national banks of CDEs

Goal #2: Develop a smaller team to generate best practices for rapid development of CDEs using a community engagement approach

The 4 Ds of Success

FOCUS ON **DIVERSITY**
- Have a diverse focus group

FOCUS ON DATA
- Deliver a set of measures for the consortium so that all projects have a way to capture information about long COVID
- Data is consistent and comparable between multiple projects
- CDEs are answered as a set, not hand-picked as individual CDEs

FOCUS ON DEVELOPMENT
- Facilitate a process with a clear timeline and support at each step
- Accomplish task on time
- Process serves as example of how a network can rapidly engage community partners to solve a problem

FOCUS ON **DELIVERABLES**
- Document that we have increased trust and engagement across RADx-UP Community Partners
- Document process on best practices
- Deliver CDEs to NLM for the world to use

RADX·UP

An opportunity to improve the process

Per JAMIA article (2022):

- Some RADx-UP projects felt the CDE drafting process was rushed, insensitive, and may have inadequately considered community concerns

- Many found the initial CDEs to be culturally incompatible, with the possibility of worsening stigmas among marginalized communities who may already perceive academia in an unfavorable light

- **Key lessons learned from our CDE process include the importance of clear messaging, stating intent, assessing local factors, and providing more direct communications with stakeholders in the community**

- Researchers must foster trust and mutual respect, balance expertise across communities, and overcome barriers through better understanding of the populations they serve

Carrillo GA, Cohen-Wolkowiez M, D'Agostino EM, Marsolo K, Wruck LM, Johnson L, Topping J, Richmond A, Corbie G, Kibbe WA. Standardizing, harmonizing, and protecting data collection to broaden the impact of COVID-19 research: The Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) initiative. J. Am. Med. Inform. Assoc.2022: ocac097. doi: 10.1093/jamia/ocac097

Long COVID CDE Focus Group

- **~20 volunteers, faculty, and staff from the RADx-UP community** reviewed the "starter pack" of common data elements (CDEs), offered feedback via online surveys, and met up to discuss results and further refine the CDEs

- Comprised of:
  - Community members
  - Community partners
  - Long-COVID patients
  - CDCC staff
  - Principal investigators and clinicians

Focus Group: 3-Month Timeline

FOCUS GROUP members provided feedback on Long COVID CDEs via survey

CDCC and **FOCUS GROUP** members joined Zoom sessions, discussed survey results, and provided key takeaways

CDCC prepares *draft* Long COVID CDEs

CDCC and **FOCUS GROUP** members agreed on final set of Long COVID CDEs for tier 2 data collections

2022				
October 6	OCT 7-17	Oct 20 & 27	Nov 1-Dec 2	Dec 5- Jan 6

FOCUS GROUP members joined orientation session about the review of Long COVID CDE Starter Pack

CDCC and **FOCUS GROUP** members agreed on direction for creating a set of Long COVID CDEs for tier 2

CDCC sent Long COVID CDEs to Data Core for upload to tier 2, and to **RADx-UP Community** with educational component

RADX UP

Long COVID CDEs: Final Set

The Long COVID CDEs are *optional* tier 2 questions comprising 27 questions in three sets:

- Introductory (baseline), including a working definition of "Long COVID"
- Symptom-based (the most critical symptoms), and
- Quality of life (or "everyday" life)

RECOVER
CDEs
= 2,000

RADx-UP
Starter Pack
= 198

RADx-UP
Long COVID
=27

RADX UP