RADx Tribal Data Repository

Pre-Tribal Consultation

Informational Webinar

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NIH NATIONAL CANCER INSTITUTE

Agenda

- Introduction: What NIH Proposes

- COVID-19 Landscape

- Response to COVID-19: The RADx Initiative

- Tribal Data Repository

A RADx Tribal Data Repository will provide American Indian and Alaska Native (AI/AN) data collected across the RADx Initiative and beyond to:

- Better understand the impacts of COVID-19
- Support research to better inform and develop policies to address current and future pandemics
- Support and promote AI/AN researchers and programs

What could researchers do with these types of data?

Better understand transmission and infectivity

Evaluate Treatments & Interventions

Predict Long-term effects from COVID-19 Infection

Link Social Determinants of Health with COVID-19 related data and exposures

Examine the impact on Child & Maternal Health

Resolve Technical & Implementation issues

The Harvard Gazette

For Native Americans, COVID-19 is 'the worst of both worlds at the same time'

The Skywalk over the Grand Canyon was closed by the Hualapai tribe to increase social distancing measures during the pandemic.

Stan Lawrimore/Unsplash

The Striking Racial Divide in How Covid-19 Has Hit Nursing Homes

Homes with a significant number of black and Latino residents have been twice as likely to be hit by the coronavirus as those where the population is overwhelmingly white.

Rural America Could Be the Region Hardest Hit by the COVID-19 Outbreak

Black Americans Face Alarming Rates of Coronavirus Infection in Some States

Data on race and the coronavirus is too limited to draw sweeping conclusions, experts say, but disparate rates of sickness — and death — have emerged in some places.

Many Who Need Testing For COVID-19 Fail To Get Access

April 3, 2020 · 5:00 AM ET

COVID-19 in Prisons and Jails in the United States

Laura Hawks, MD[1,2]; Steffie Woolhandler, MD, MPH[2,3]; Danny McCormick, MD, MPH[1,2]

» Author Affiliations | Article Information

NIH National Institutes of Health

[Courtesy: T Schwetz, NIH, 2020 https://dpcpsi.nih.gov/sites/default/files/NIH_Tribal_Consultation_on_COVID-19_508.pdf]]

Communities of Color Are Most Impacted

Rate ratios compared to White persons	American Indian or Alaska Native, persons	Asian, persons	Black/African American persons	Hispanic or Latino persons
Cases[1]	1.8x	0.6x	1.4x	1.7x
Hospitalized[2]	4.0x	1.2x	3.7x	4.1x
Deaths[3]	2.6x	1.1x	2.8x	2.8x

National Institute on Minority Health and Health Disparities

Emergency Department Visits for COVID-19 in 13 States, October–December 2020

Race or Ethnicity	ED visits per 100,000 population
White	333
Black/African Am	463
Latino/a	588*
AI/AN	570*
Asian/PI	234*

National Syndromic Surveillance Program, MMWR-April 16, 2021; 70(15);566-569

COVID-19 Testing Across the U.S.
(circa July 09, 2021)

United States Laboratory Testing
Commercial and Reference, Public Health, and Hospital Laboratories

USA

472,527,865
TESTS REPORTED
CDC Updated: July 6,2021

USA

35,842,336
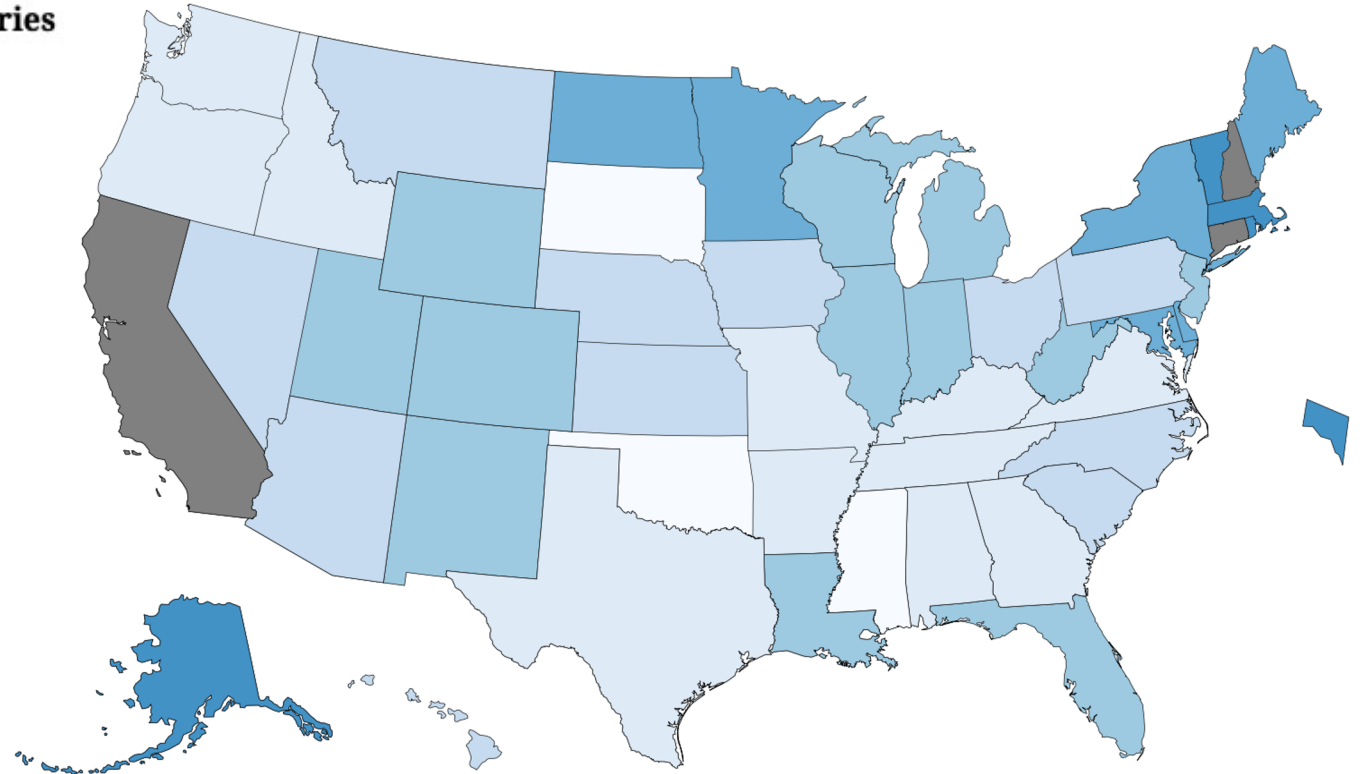## POSITIVE TESTS
CDC Updated: July 6,2021

USA

3%
OVERALL % POSITIVE
CDC Updated: July 6,2021

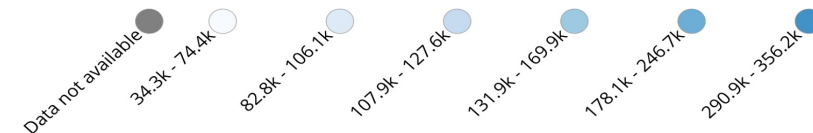https://www.cdc.gov/covid-data-tracker/index.html

Preliminary data: Reported by U.S. Laboratories including Commercial and Reference, Public Health, and Hospital
Totals may include antibody data from some states

Territories

| AS | FSM | GU | MP | PW | RMI | VI |

Cumulative Tests Performed per 100,000

Data not available | 34.3k - 74.4k | 82.8k - 106.1k | 107.9k - 127.6k | 131.9k - 169.9k | 178.1k - 246.7k | 290.9k - 356.2k

National Institutes of Health

COVID-19 Reported Cases by Indian Health Service Area[1]
(circa through July 09, 2021)

LEGEND

IHS Area Border

Aggregated by IHS Area

Number of Positive Cases

- > 1,000 To 4,400
- > 400 To 1,000
- > 100 To 400
- 0 To 100

Map labels:
- ALASKA 12,357
- PORTLAND 8,585
- BILLINGS 7,514
- GREAT PLAINS
- BEMIDJI 11,996
- PHOENIX 24,485
- ALBUQUERQUE 8,297
- 32,511
- 61,772
- NASHVILLE
- TUCSON 2,829
- 6,395
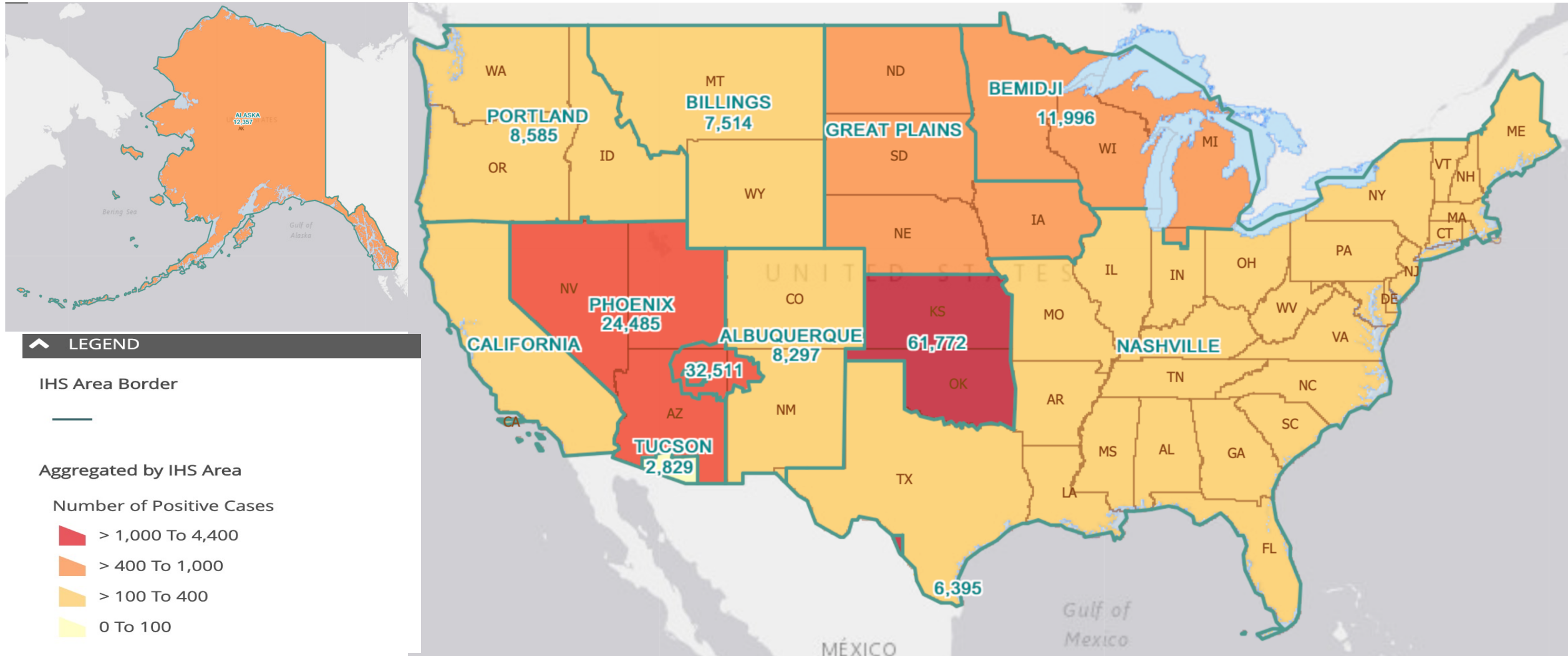
(RADx) Initiative: Goal and Approaches

Goal:

- Accelerate innovation in and development, commercialization, and implementation of COVID-19 testing

Approaches:

- Fund early innovative diagnostic technologies
- Advance late-stage diagnostic technologies to expand testing infrastructure
- Identify effective testing implementation strategies in underserved populations
- Work with other government agencies (FDA, BARDA, CDC)

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Rapid Acceleration of Diagnostics (RADx) Programs

Program	Description
RADx-Tech	Competitive, rapid three-phase challenge to identify the best candidates for at-home or Point-of-Care COVID-19 tests
RADx-Advanced Technology Platforms (RADx-ATP)	Rapid scale-up of advanced Point-of-Care technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities
RADx-Radical (RADx-rad)	Develop and advance novel, non-traditional approaches, or new applications of existing testing approaches
RADx-Underserved Populations (RADx-UP)	Interlinked community-engaged projects on implementation strategies to enable and enhance COVID-19 testing in underserved and/or vulnerable populations

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RADx Underserved Populations Project: (RADx-UP)

Coordination and Data Collection Center (CDCC)

- Provide leadership and project management
- Data harmonization, storage, management
- Coordinate governance

Collaborative Clinical Research Network

- Interlinked community-engaged implementation strategies and intervention projects to COVID testing of underserved, under-resourced, underrepresented, rural, and/or vulnerable populations

Social, Ethical, and Behavioral Implications

- Understand social determinants and ethical, social, and behavioral issues associated with testing/diagnostic technologies and information/data collection and sharing
- Conduct outreach and dissemination activities

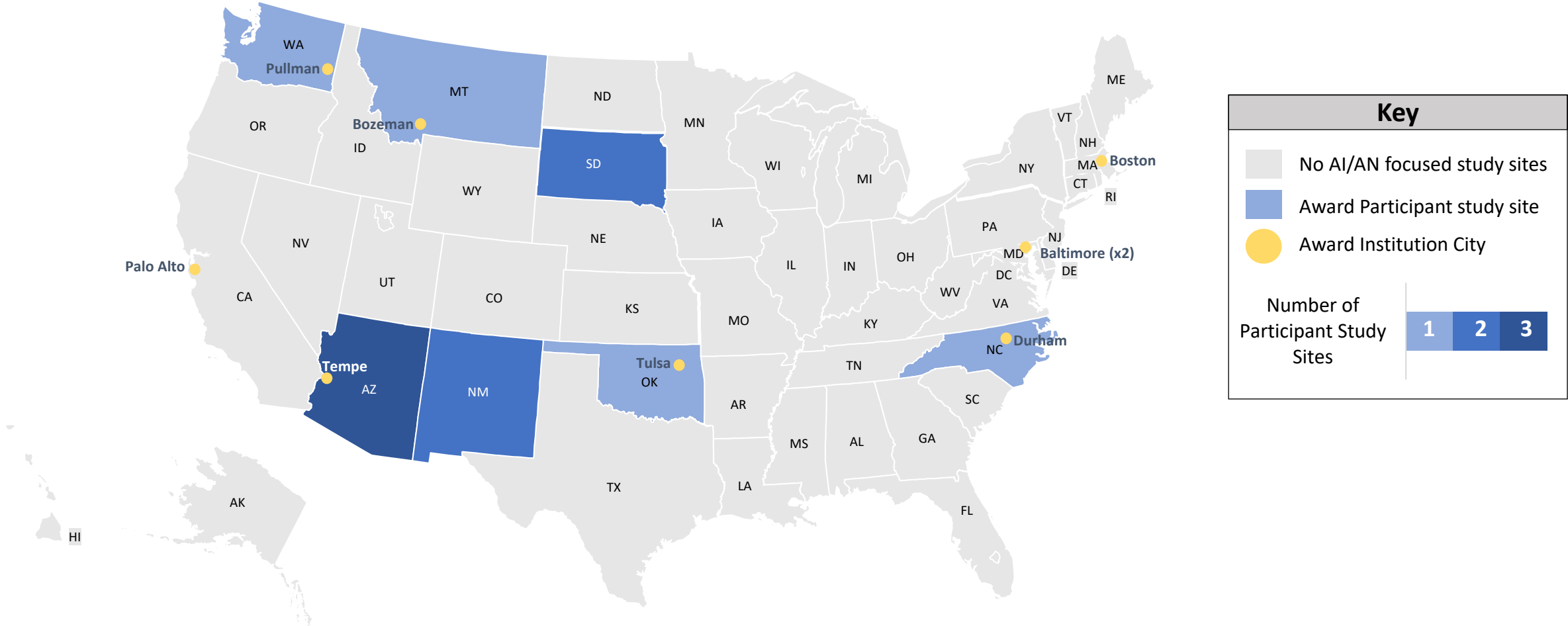# RADx-UP Phase I Awards

Testing Participant Locations

Note: Cities listed are not exhaustive, as some projects only provided state-level information.
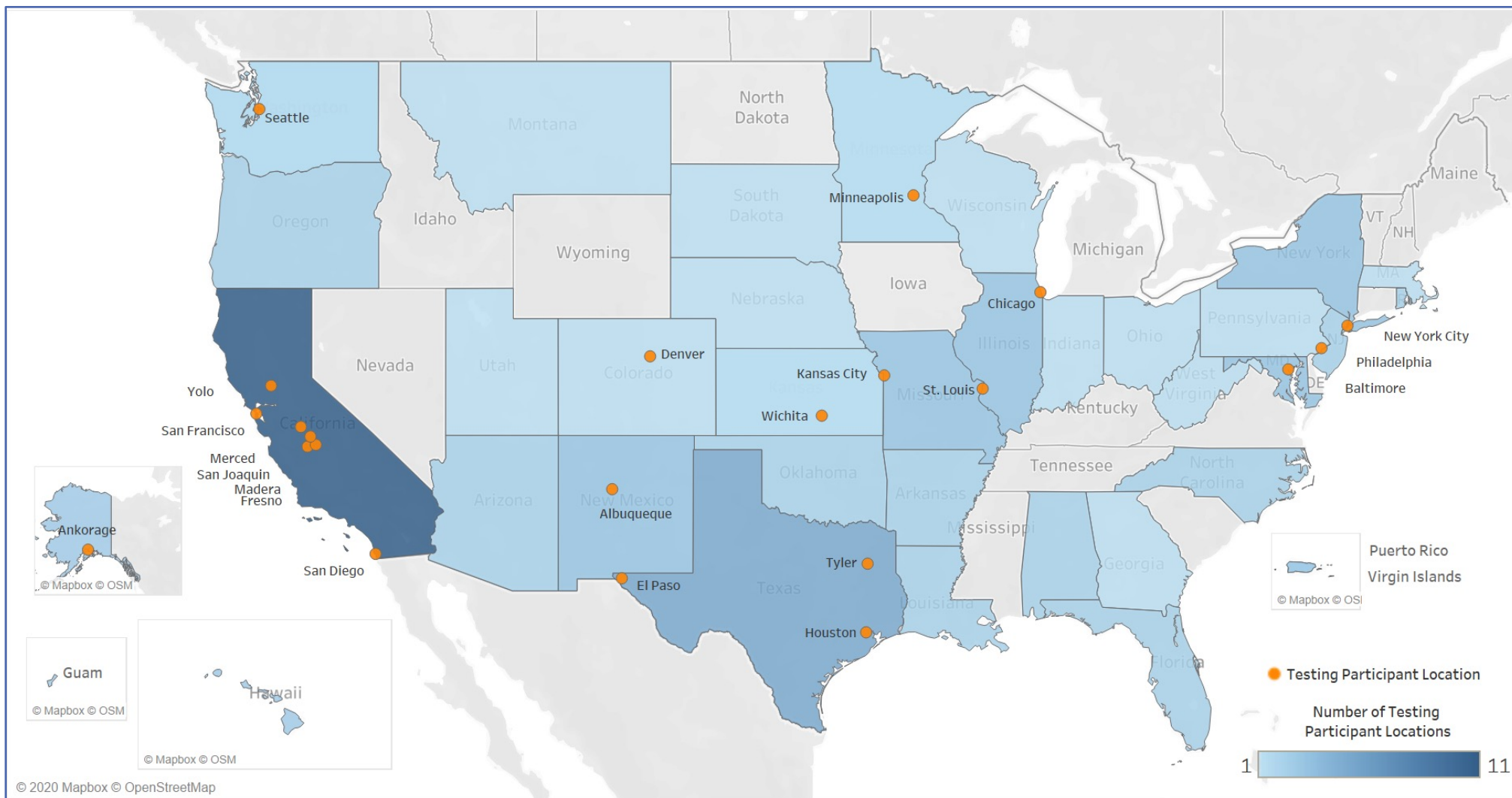
RADx-UP: Strategy

Provide access to de-identified RADx and related data, algorithms, and other capabilities to address compelling questions

RADx

- ➢ The RADx Initiative supports nine adult and pediatric studies collecting exclusively American Indian/ Alaska Native (AI/AN) data

- ➢ The RADx Tribal Data Hub (RADx-TDH) will be a collaborative resource for researchers working with RADx AI/AN data

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RADx-UP Awarded Projects with a Focus on American Indian or Alaskan Native Populations (9 total)

The awarded projects include the RADx-UP Phase I and Return to School Program awarded projects. This map shows projects that focus on AI/AN populations.

Key

	No AI/AN focused study sites
	Award Participant study site
●	Award Institution City

Number of Participant Study Sites

1	2	3

Note: Four projects have studies across multiple states; the total number of participant study sites does not add up to the total number of projects represented

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• Project Information

• The chart below highlights the RADx-UP projects focusing on American Indian and Alaska Native populations

Contact PI	Project Summary	Institution	Study Locations
MARSIGLIA, FLAVIO FRANCISCO	This study will perform targeted SARS-CoV-2 testing within defined testing deserts in Arizona and will compare a subset of affected individuals who undergo the proposed testing and educational protocol with those who receive the same testing through standard systems available in the state.	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	Arizona
KHAN, SOHAIL	This study will enhance understanding of COVID-19 within the significantly and disproportionally impacted residents of Cherokee Nation. The researchers will perform rapid point-of-care testing, antibody testing, and contact tracing, and will develop educational materials for the community. Rapid data analysis will be used to nimbly move testing sites to areas of need.	CHEROKEE NATION	Cherokee Nation (NE Oklahoma)
CWIK, MARY	This study will address high rates of morbidity and mortality due to COVID19 among American Indian (AI) and Navajo Nation (NN) communities in the US. The goal of this study is to increase and speed up the testing among those with symptoms and improve adherence to recommended strategies.	JOHNS HOPKINS UNIVERSITY	East Central Arizona and Western New Mexico
ARMSTRONG, KATRINA	This research will perform a phased study of three Lakota tribes in South Dakota to address attitudes and access to testing.	MASSACHUSETTS GENERAL HOSPITAL	Western South Dakota
ADAMS, ALEXANDRA K	This study will use pragmatic randomized testing to evaluate home based testing through comparing community health workers with mail in at-home testing and their related feasibilities.	MONTANA STATE UNIVERSITY - BOZEMAN	Flathead Reservation in MT and Yakima Valley in WA

Project Information

- The chart below highlights the RADx-UP projects focusing on American Indian and Alaska Native populations

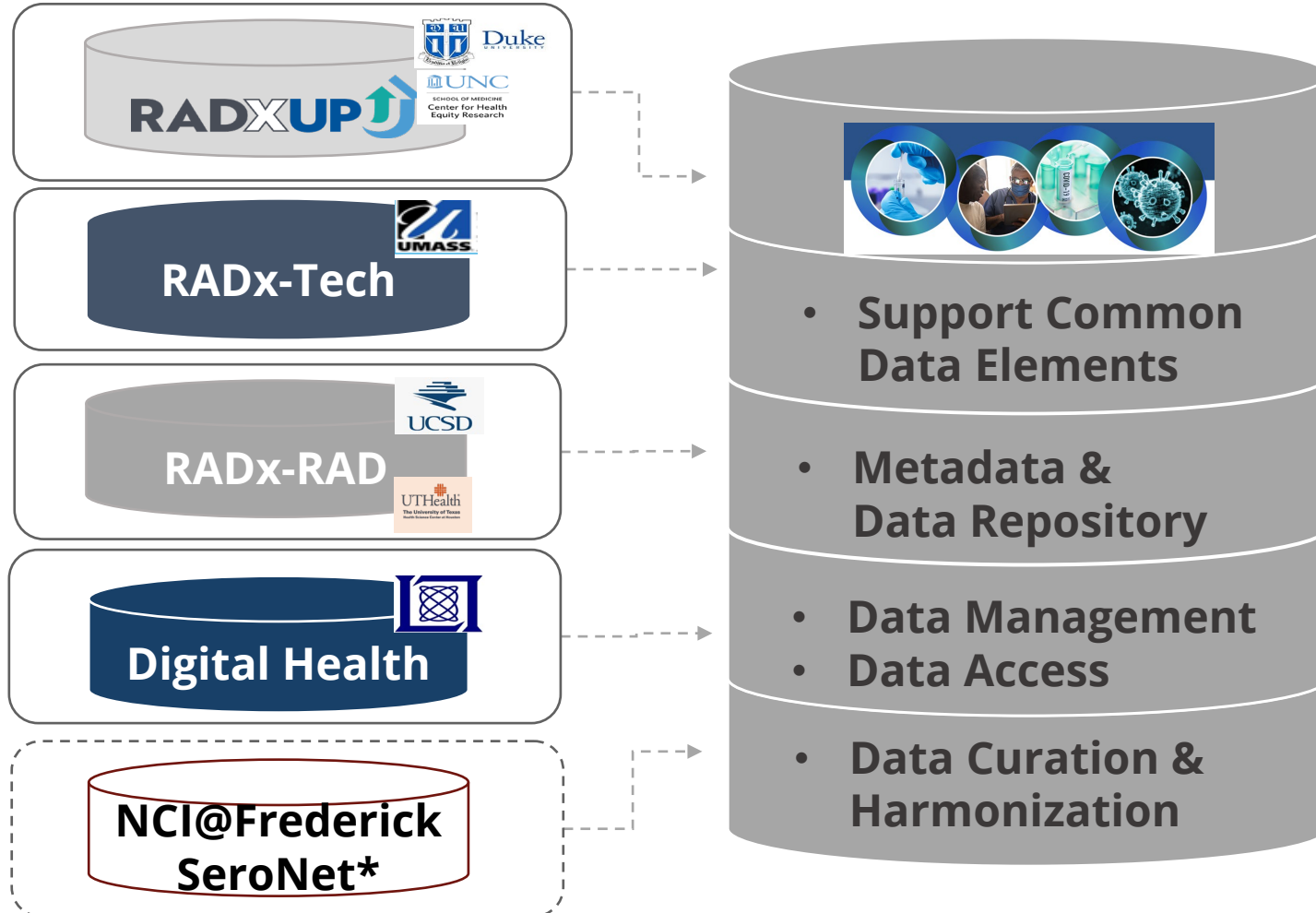| Contact PI	Project Summary	Institution	Study Locations
KUMAR, DEEPAK	This study will evaluate the impact of work to increase testing uptake for American Indians in North Carolina.	NORTH CAROLINA CENTRAL UNIVERSITY	Lumbee Tribe of North Carolina, In Robenson, Scotland, Hoke and Cumberland
MALDONADO, YVONNE A	This study will upgrade and sustain local capacity at the Native BioData Consortium (NBDC) with training and development of Personal Protective Equipment (PPE) and Lab Protocols to improve COVID-19 testing and outcomes for Tribal populations by creating an improved diagnostics lab/local data resource and by testing the use of wearables on early diseases detection.	STANFORD UNIVERSITY	South Dakota, Locota Territory
BUCHWALD, DEDRA S	This study focuses on satellite centers that partner with six geographically contiguous Urban Indian Health Programs (UIHPs) across the United States to launch studies under Community Organizations for Natives: COVID-19 Epidemiology, Research, Testing, and Services (CONCERTS). The overarching goal is to remove barriers and increase SARS-CoV-2 testing among urban American Indian/Alaska Native populations by offering an array of testing options that cover a wide geographical area.	WASHINGTON STATE UNIVERSITY	National
BARLOW, ALISON	The proposed study will utilize a community-based participatory research process to understand implementation barriers to in-person school instruction and various testing strategies (e.g., students vs. teachers; screening vs. surveillance; at-home vs at-school) in schools that serve Native American students ages 3-16 years.	JOHNS HOPKINS UNIVERSITY	Arizona, New Mexico

RADx Initiative Goal: Single access point to de-identified RADx data and related data, algorithms, and other capabilities generated by various digital health solutions and technologies

Data Coordinating Centers	RADx Data Hub	Analytics Environment

Data Coordinating Centers:
- RADXUP
- RADx-Tech (UMASS)
- RADx-RAD (UCSD, UTHealth)
- Digital Health
- NCI@Frederick SeroNet*

*Data linked

RADx Data Hub:
- Support Common Data Elements
- Metadata & Data Repository
- Data Management
- Data Access
- Data Curation & Harmonization

Analytics Environment:
- **RAS Authentication Portal**
- **Query & analyze RADx data**
- **Data tools for analytic use (e.g., Jupyter Notebooks, R, and Python)**
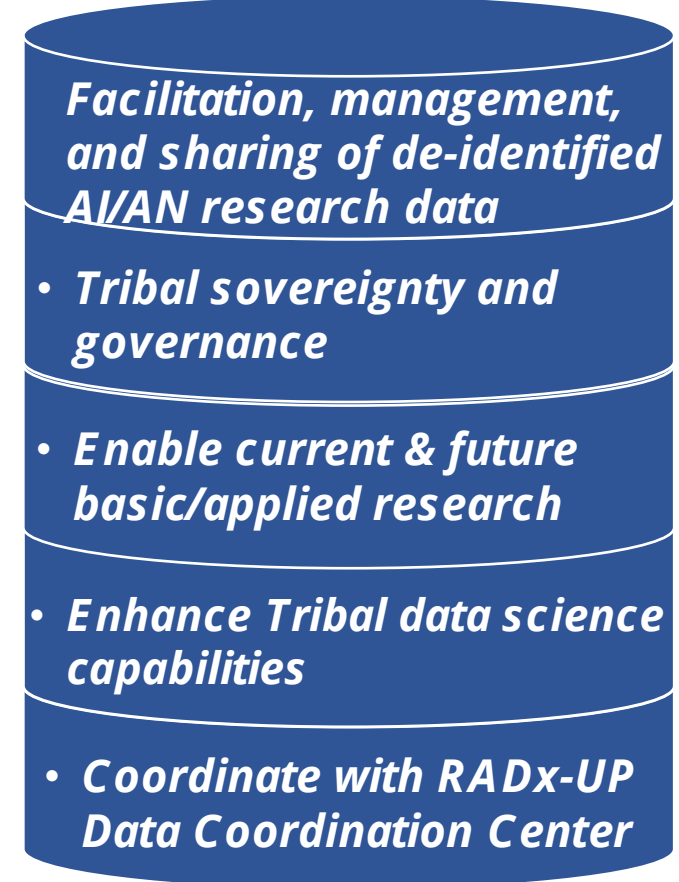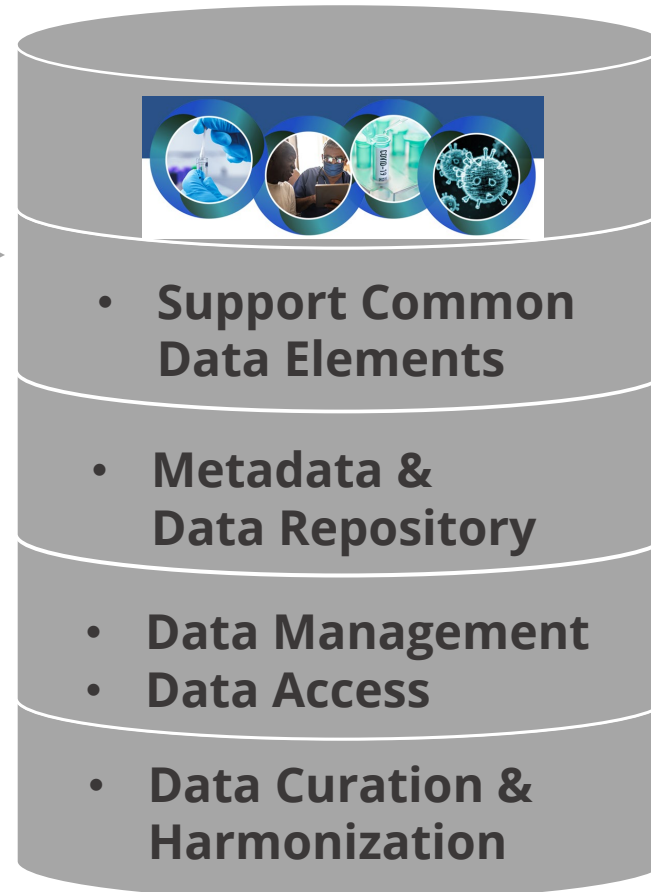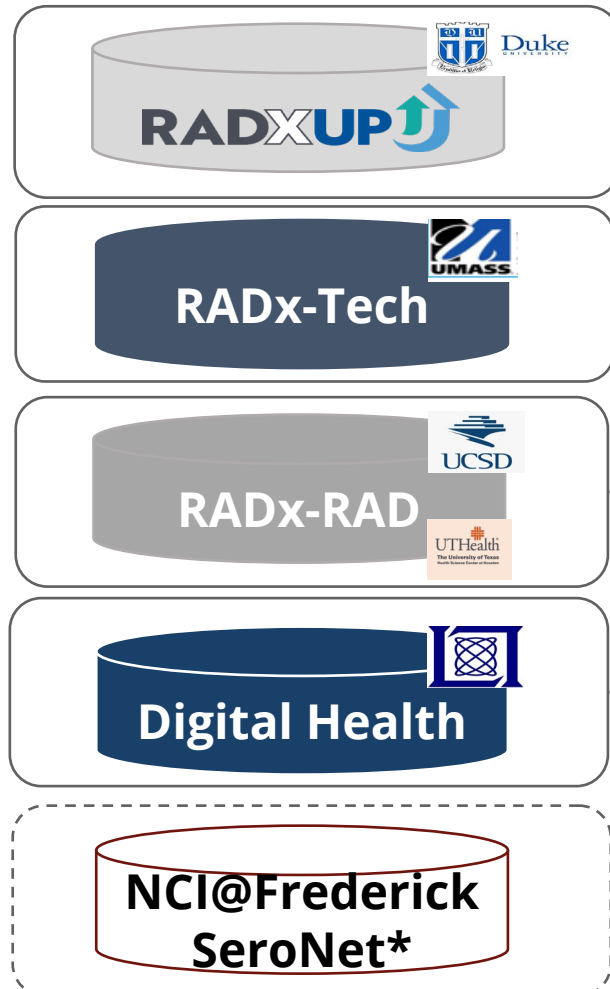- **Workbench enabling researcher collaboration**

Issue: The NIH RADx Data Hub <u>may</u> not meet cultural, governance, and sovereignty needs and expectations to support and share American Indian/Alaska Native (AI/AN) research data

Data Coordinating Centers	RADx Data Hub	Tribal Data Repository (TDR)

Data Coordinating Centers:
- RADXUP (Duke University)
- RADx-Tech (UMASS)
- RADx-RAD (UCSD, UTHealth)
- Digital Health
- NCI@Frederick SeroNet*

RADx Data Hub:
- Support Common Data Elements
- Metadata & Data Repository
- Data Management
- Data Access
- Data Curation & Harmonization

Tribal Data Repository (TDR):

Facilitation, management, and sharing of de-identified AI/AN research data

- *Tribal sovereignty and governance*
- *Enable current & future basic/applied research*
- *Enhance Tribal data science capabilities*
- *Coordinate with RADx-UP Data Coordination Center*

*Data linked

Rapid Acceleration of Diagnostics (RADx): Some Points Considered

F.A.I.R[1]

Findable Accessible Interoperable Reusable

C.A.R.E[2]

CARE

Collective Benefit   Authority to Control   Responsibility   Ethics

NIH TRIBAL HEALTH RESEARCH OFFICE[3]

- Strengthen Engagement built on Trust Between Researchers and Tribal Nations
- Train Researchers to Responsibly and Respectfully manage and share AI/AN Data
- Ensure Research Practices Align with Laws, Policies, and Community Partners

[1] F.A.I.R. https://static1.squarespace.com/static/5d3799de845604000199cd24/t/5da9f4479ecab221ce848fb2/1571419335217/CARE+Principles_One+Pagers+FINAL_Oct_17_2019.pd

[2] C.A.R.E https://static1.squarespace.com/static/5d3799de845604000199cd24/t/5da9f4479ecab221ce848fb2/1571419335217/CARE+Principles_One+Pagers+FINAL_Oct_17_2019.pdf

[3] TRIBAL CONSULTATIONS:DATA SHARING https://dpcpsi.nih.gov/thro/tribal-consultations/draft-policy-for-data-management-and-sharing COVID RESEARCH https://dpcpsi.nih.gov/thro/tribal-consultations/covid-19

Rapid Acceleration of Diagnostics (RADx):
Suggested Topics to Consider

- How should the Tribal Data Repository be established to incorporate and sustain tribal sovereignty for data collected and stored?
- What are your expectations for data ownership? Data stewardship?
- What are your expectations for data governance and data access?
- What are your expectations for sustainability of the RADx Tribal Data Repository once the initial RADx Initiative has ended?
- What is your guidance to address data ownership, stewardship, and governance issues for rural, urban, or non-reservation dwelling individuals who self-identify as American Indian/Alaska Native?

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