RADx Tribal Data Repository

Tribal Consultation

Susan Gregurick, Ph.D.
Associate Director for Data Science
Office of the Director/NIH

Eliseo J. Pérez-Stable, M.D.
Director
National Institute on Minority Health and Health Disparities/NIH

July 30, 2021

NIH NATIONAL CANCER INSTITUTE

Agenda

- Opening Blessing
- Welcome and Introductions
- NIH RADx Tribal Data Repository
- Tribal Discussion, Comments, Issues, Testimony, Priorities
- Wrap Up and Next Steps
- Closing Prayer

NIH National Institutes of Health

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

- An independent Tribally governed data repository that incorporates and sustains tribal sovereignty
- Supports and promotes AI/AN researchers and programs
- Helps to better understand the impacts of COVID-19
- Provides research support to better inform and develop policies to address health disparities

Communities of Color Are Most Impacted

Rate ratios compared to Whites	American Indians or Alaska Natives	Asian Americans	Black/African Americans	Hispanics or Latinos/as
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

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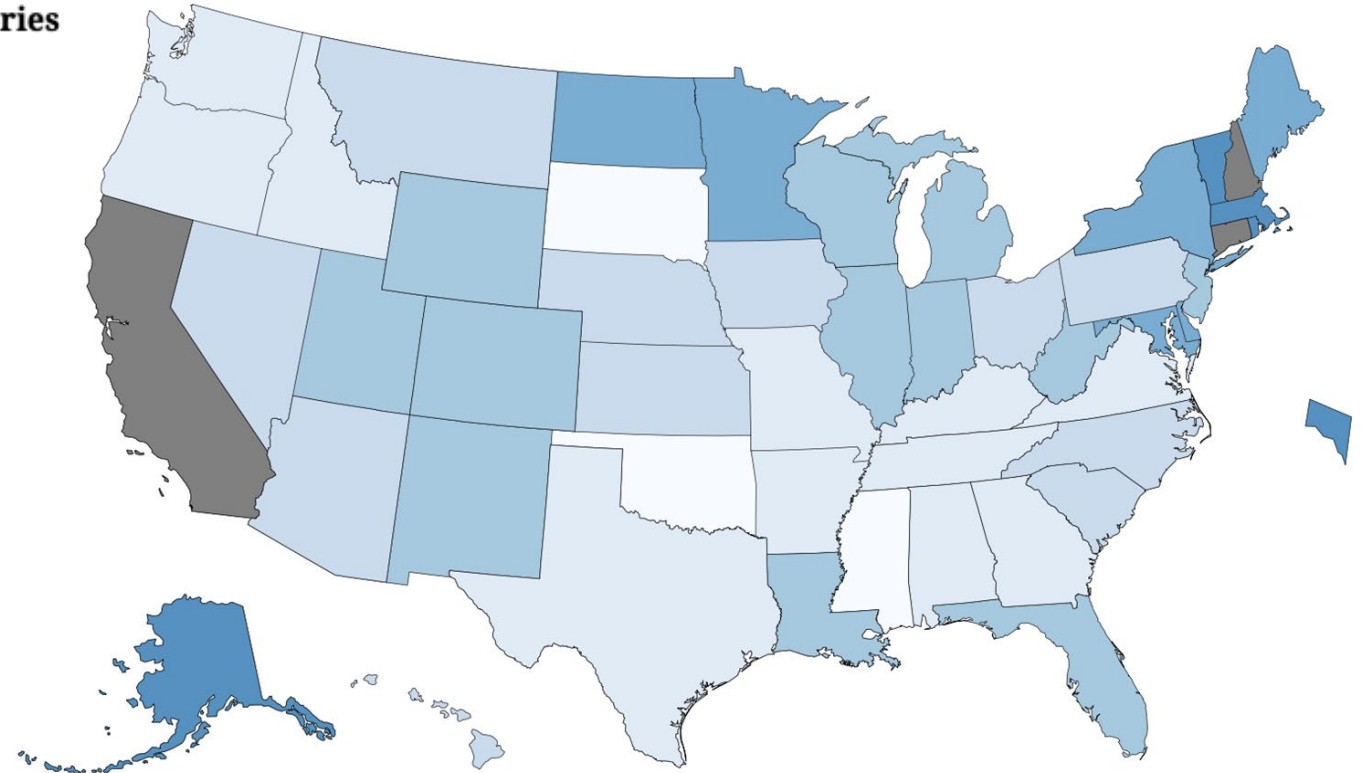
USA
35,842,336
POSITIVE TESTS
CDC Updated: July 6,2021

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

https://www.cdc.gov/covid-data-tracker/index.html
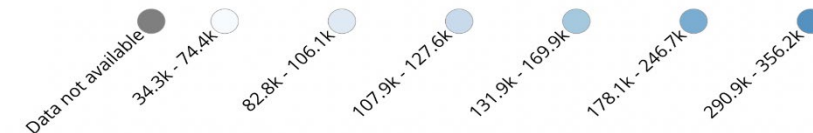
NIH National Institutes of Health

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

Territories
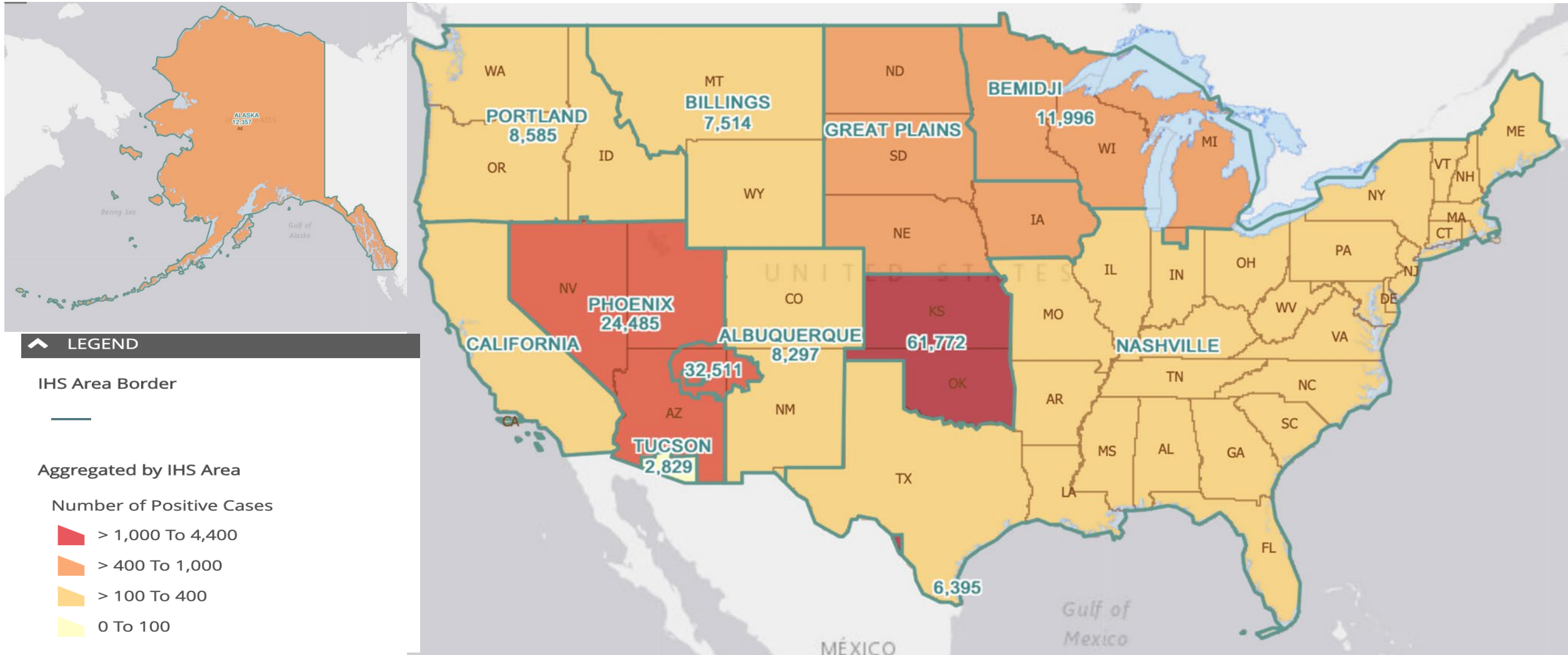
AS	FSM	GU	MP	PW	RMI	VI

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

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

ALASKA 12,357 AK

PORTLAND 8,585 · WA · OR · ID

BILLINGS 7,514 · MT · WY

GREAT PLAINS · ND · SD · NE

BEMIDJI 11,996 · WI · MI · IA

PHOENIX 24,485 · NV · AZ

CALIFORNIA 32,511 · CA

TUCSON 2,829

ALBUQUERQUE 8,297 · CO · NM

61,772 · KS · OK

NASHVILLE · MO · AR · TN · MS · AL · GA · SC · NC · VA · WV · KY · IL · IN · OH · PA · NY · ME · VT · NH · MA · CT · NJ · DE · LA · FL

TX 6,395

NIH National Institutes of Health

Rapid Acceleration of Diagnostics (RADx):

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)

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

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

National Institutes of Health
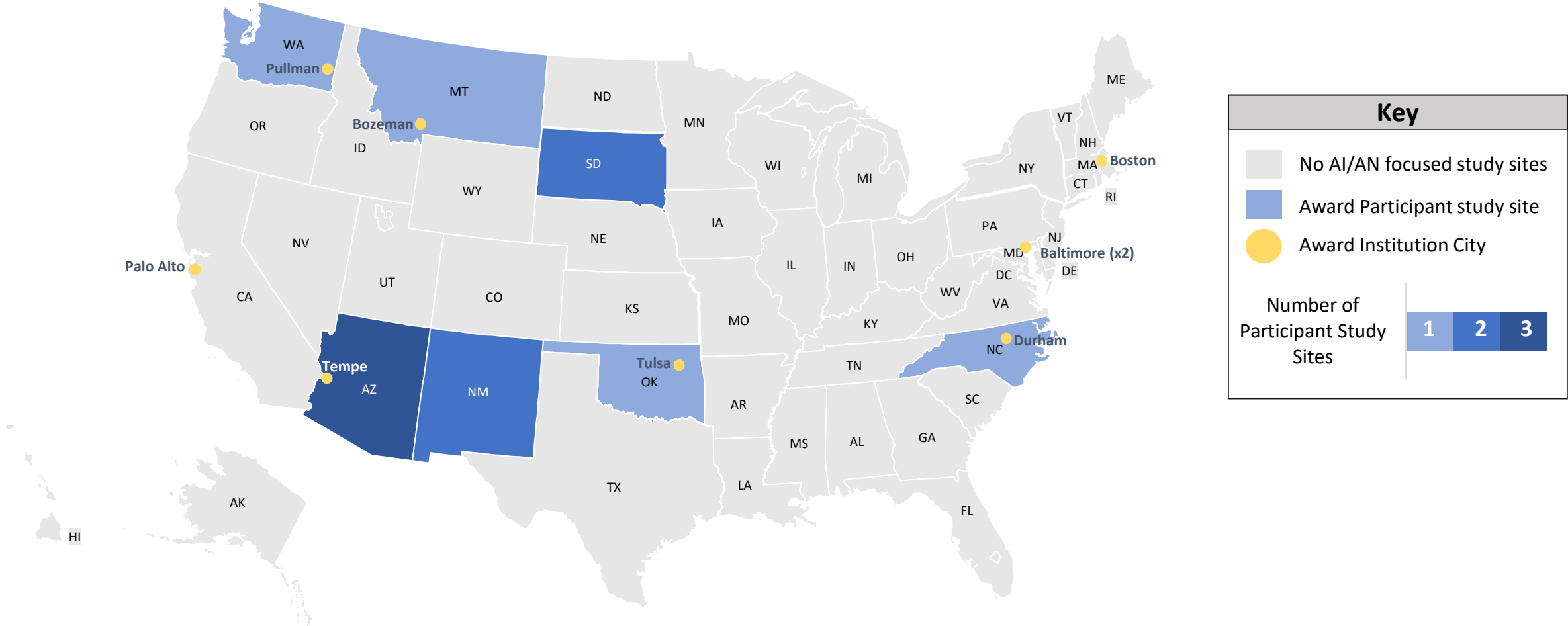
RADx Initiative: Strategy

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

RADx

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

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

National Institutes of Health

RADx-UP Awarded Projects with a Focus on American Indian or Alaskan Native Populations (10 total)
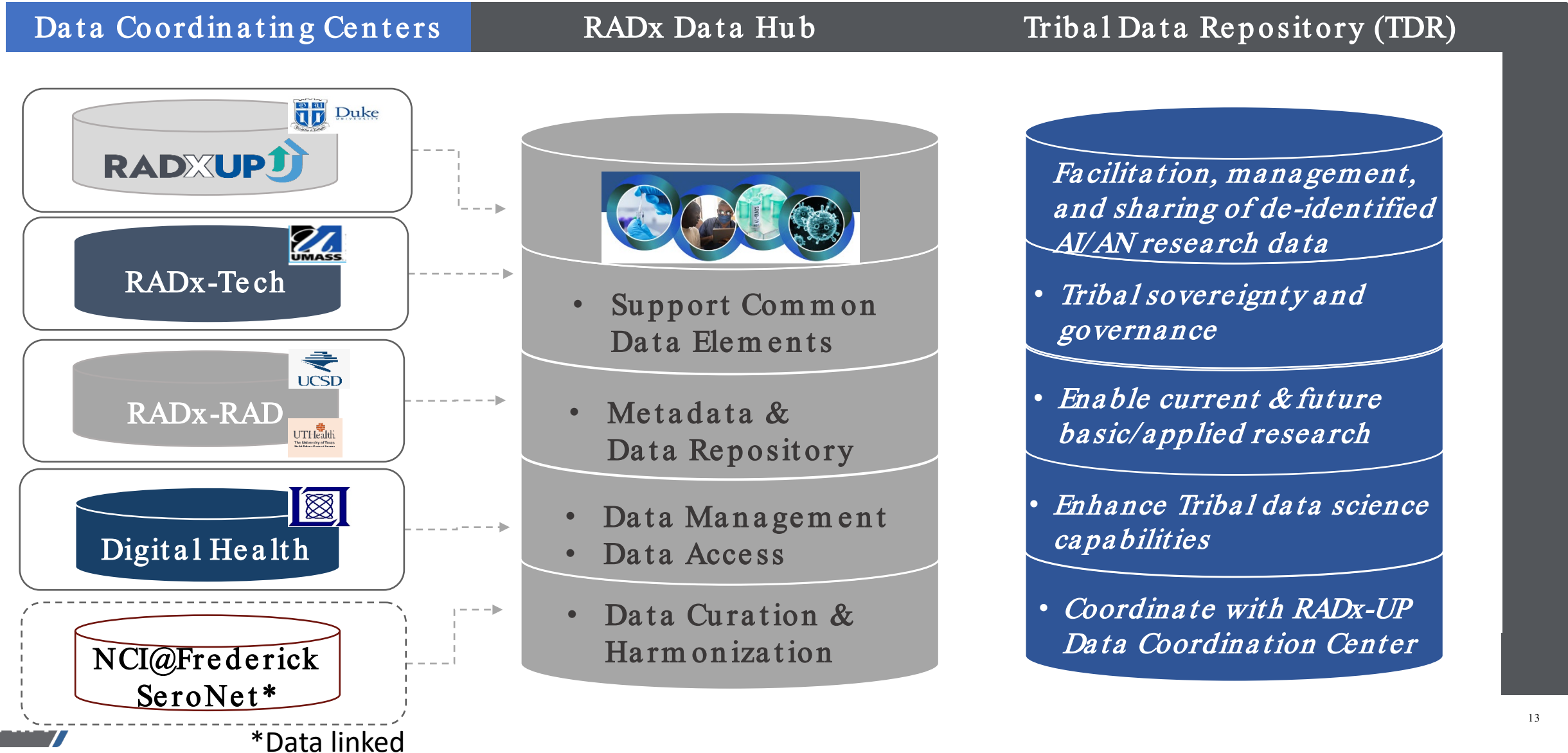
The awarded projects include the RADx-UP Phase I and Return to School Program awarded projects. This map shows projects that focus on AI/AN populations.

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

National Institutes of Health

The RADx Tribal Data Repository will be *an independent Tribally governed data repository* that:

- Incorporates and sustains tribal sovereignty
- Provides AI/AN research data collected across the RADx Initiative
- Provides better understanding of the impact of COVID-19 and data to the tribal health boards
- Informs and supports policies to address current and future pandemics
- Promotes AI/AN biomedical researchers and programs

Issue: The NIH RADx Data Hub **may** 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*

*Data linked

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*

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

PURPOSE: The RADx Tribal Data Repository (RADx-TDR)

- **Support new initiatives** for broad sharing of de-identified Tribal data to address scientific questions concerning testing and vaccination for COVID-19

- **Support** collection of Personal Identifying Information/Protected Health Information (PII/PHI) that would be retained by the RADx-TDR

- **Partner** with the RADx-UP Coordination and Data Collection Center (CDCC)

- **Link AI/AN research data from RADx Programs** and information to the RADx Data Hub and **retain data/tool sovereignty**

- **Provide pathways** to build capacity for big data research skills for Tribal scholars through pre- and post-doctoral mentored fellowships

- **Culturally responsive** to governance and sovereignty issues of Tribal communities regarding data, tools, and algorithms.

- NIH is **collaborating** with THRO, AIHEC, and UND to develop a data science curriculum to be piloted at 3 Tribal Colleges & Universities (TCU) with intentions to expand to all 32 TCUs.

NIH> National Institutes of Health

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?

National Institutes of Health