All of Us Research Program

Research Opportunity Announcement - Informational Webinar
ROA No. OTA-23-003

Center for Linkage and Acquisition of Data (CLAD)

Date: March 3, 2023; 1:00-2:30 P.M. ET

All of Us Research Program

National Institutes of Health

Today’s Presenters

Chris Lunt
Chief Technology Officer

Lew Berman, Ph.D.
Chief, Digital Health Technologies and Data Branch

Jessica Ely
Team Lead, Awards Management Branch

Webinar Agenda: *All of Us* Center for Linkage and Acquisition of Data ROA

- Provide an overview of the *All of Us* Research Program
- Outline the Center for Linkage and Acquisition of Data (CLAD) Research Opportunity Announcement
- Review the submission requirements and timelines
- Address questions and answers

Webinar Opening

Opening

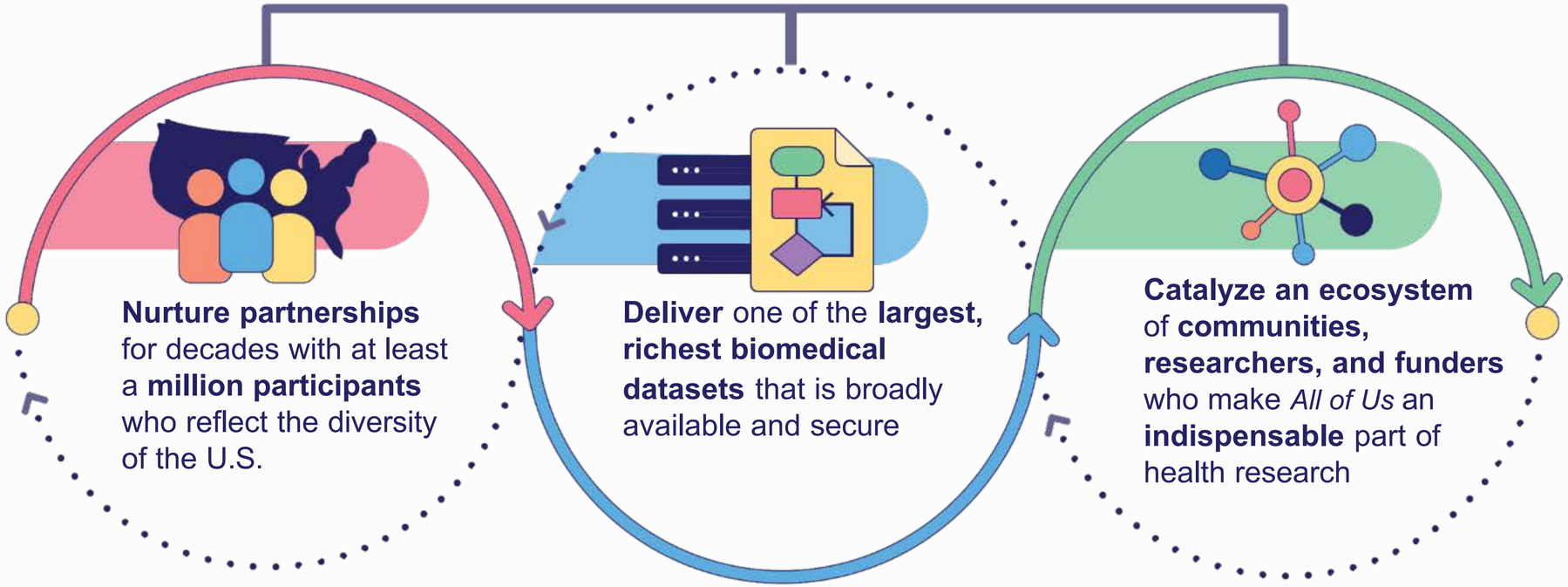
The purpose of this announcement is to solicit and review proposals, evaluate potential partners, and ultimately fund the future *All of Us* Center for Linkage and Acquisition of Data (CLAD).

All of Us Research Program Overview

All of Us Research Program Mission

Our Mission

Accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us



Made possible by a team that maintains a culture built around the program's core values

All of Us Consortium Members *(as of August 2022)*

The Participant Center

Scripps Research Translational Institute · BlueCross BlueShield · SENSIS · SageBionetworks · owaves · Walgreens · MAYO CLINIC · Dedalus · Bloodworks Northwest · CVS Health · Blood Assurance · Gulf Coast Regional Blood Center *Commit for Life.* · careevolution HEALTHCARE TECHNOLOGY · MONTAGE MARKETING · WebMD · active minds · Medscape · patientslikeme · South Texas Blood & Tissue A SUBSIDIARY OF BIOBRIDGE GLOBAL · CASCADE REGIONAL BLOOD SERVICES YOUR COMMUNITY BLOOD CENTER · ACHA American College Health Association advocacy•education•research · SYNC FOR SCIENCE · Quest Diagnostics · San Diego Blood Bank · NATIONAL BLOOD COLLABORATIVE BLOOD SOLUTIONS | TRUSTED SOURCE · fitbit · Mary's Center

Communications & Engagement

WONDROS · PYXIS PARTNERS PATHWAYS TO PROGRESS · RTI INTERNATIONAL · THE UNIVERSITY OF UTAH

HPO Network

(Health Care Provider Organizations)

HPO Lite

UTHealth The University of Texas Health Science Center at Tyler · VCU Health · Washington University in St. Louis

RMCs

All of Us California

UC San Diego Health · UCI Health · UCDAVIS HEALTH · UCSF University of California San Francisco · ECRMC · Cedars Sinai · Keck School of Medicine of USC

Illinois Precision Medicine Consortium

Northwestern Medicine · THE UNIVERSITY OF CHICAGO · NorthShore University HealthSystem · RUSH · THE UNIVERSITY OF ILLINOIS COLLEGE OF MEDICINE PEORIA CHICAGO ROCKFORD URBANA · UI Health UIC · COOK COUNTY HEALTH

All of Us New England

Brigham and Women's Hospital Founding Member, Mass General Brigham · Massachusetts General Hospital Founding Member, Mass General Brigham · Mass General Brigham · BOSTON MEDICAL CENTER

Trans America Consortium

Henry Ford HEALTH SYSTEM · Spectrum Health · Essentia Health · BaylorScott&White HEALTH · RELIANT MEDICAL GROUP Part of OptumCare® · HealthPartners Institute

New York City Consortium

COLUMBIA · Weill Cornell Medicine · NYC HEALTH+ HOSPITALS | Harlem · NewYork-Presbyterian

All of Us Southern Network

UAB MEDICINE · USA HEALTH · THE UNIVERSITY OF ALABAMA | College of Community Health Sciences · University Medical Center · Cooper Green Mercy HEALTH SERVICES AUTHORITY AFFILIATE OF UAB HEALTH SYSTEM · TUSKEGEE UNIVERSITY · The University of Mississippi MEDICAL CENTER · Tulane University · LSU Health NEW ORLEANS

All of Us Southeast Enrollment Center

UJHealth UNIVERSITY OF MIAMI HEALTH SYSTEM | UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE · EMORY UNIVERSITY · MOREHOUSE SCHOOL OF MEDICINE · UF UNIVERSITY of FLORIDA · THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

All of Us Wisconsin

Marshfield Clinic Health System · WISCONSIN UNIVERSITY OF WISCONSIN-MADISON · Froedtert & Medical College of Wisconsin · GUNDERSEN HEALTH SYSTEM

All of Us Pennsylvania

University of Pittsburgh

University of Arizona and Banner Health

THE UNIVERSITY OF ARIZONA · Banner Health · MARIPOSA Your COMMUNITY HEALTH CENTER

FQHCs (Federally Qualified Health Centers)

Cherokee HEALTH SYSTEMS · JACKSON-HINDS COMPREHENSIVE HEALTH CENTER · SAN YSIDRO HEALTH · WAIANAE COAST COMPREHENSIVE HEALTH CENTER · Community Health Center, Inc. · Cooperative Health · Sun River Health

VA Medical Centers

VA · U.S. Department of Veterans Affairs · Veterans Health Administration

Participant Technology Systems Center (PTSC)

vibrent

Biobank

MAYO CLINIC

Data & Research Center (DRC)

VANDERBILT UNIVERSITY MEDICAL CENTER · BROAD INSTITUTE · verily · COLUMBIA UNIVERSITY MEDICAL CENTER · SCHOOL OF PUBLIC HEALTH UNIVERSITY OF MICHIGAN · Northwestern Medicine · UTHealth The University of Texas Health Science Center at Houston

Genomics Partners

Baylor College of Medicine DEPARTMENT OF MOLECULAR & HUMAN GENETICS · JOHNS HOPKINS MEDICINE · UTHealth The University of Texas Health Science Center at Houston · HudsonAlpha INSTITUTE FOR BIOTECHNOLOGY · BROAD INSTITUTE · color · Mass General Brigham · UNIVERSITY of WASHINGTON

All of Us Community and Provider Partner Network *(as of August 2022)*

All of Us Aims to Enroll 1M+ Participants Who Complete Initial Program Opportunities

(Updated 1/25/23)

588,000+

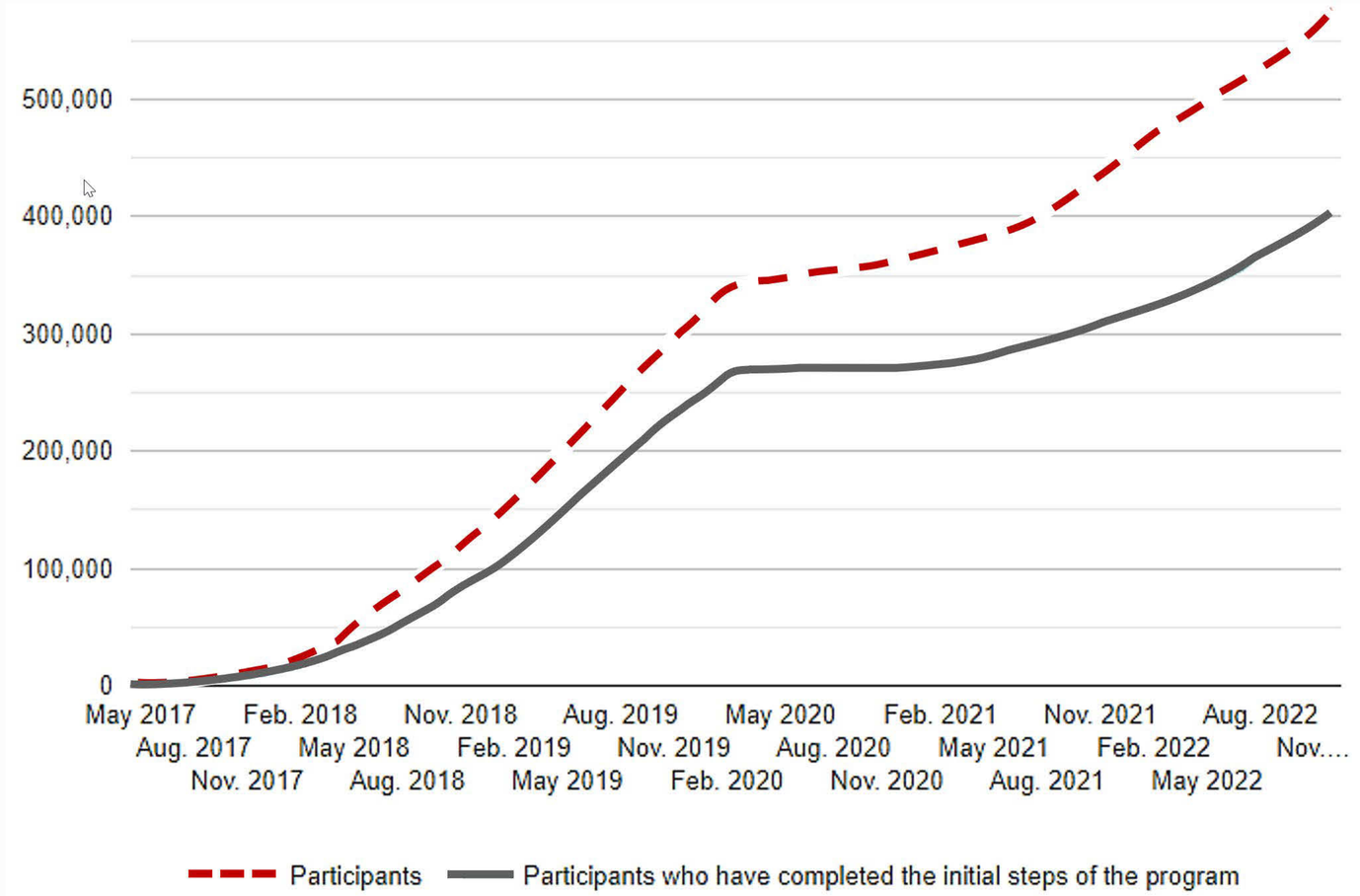
Participants

410,000+

Participants who have completed initial steps of the program

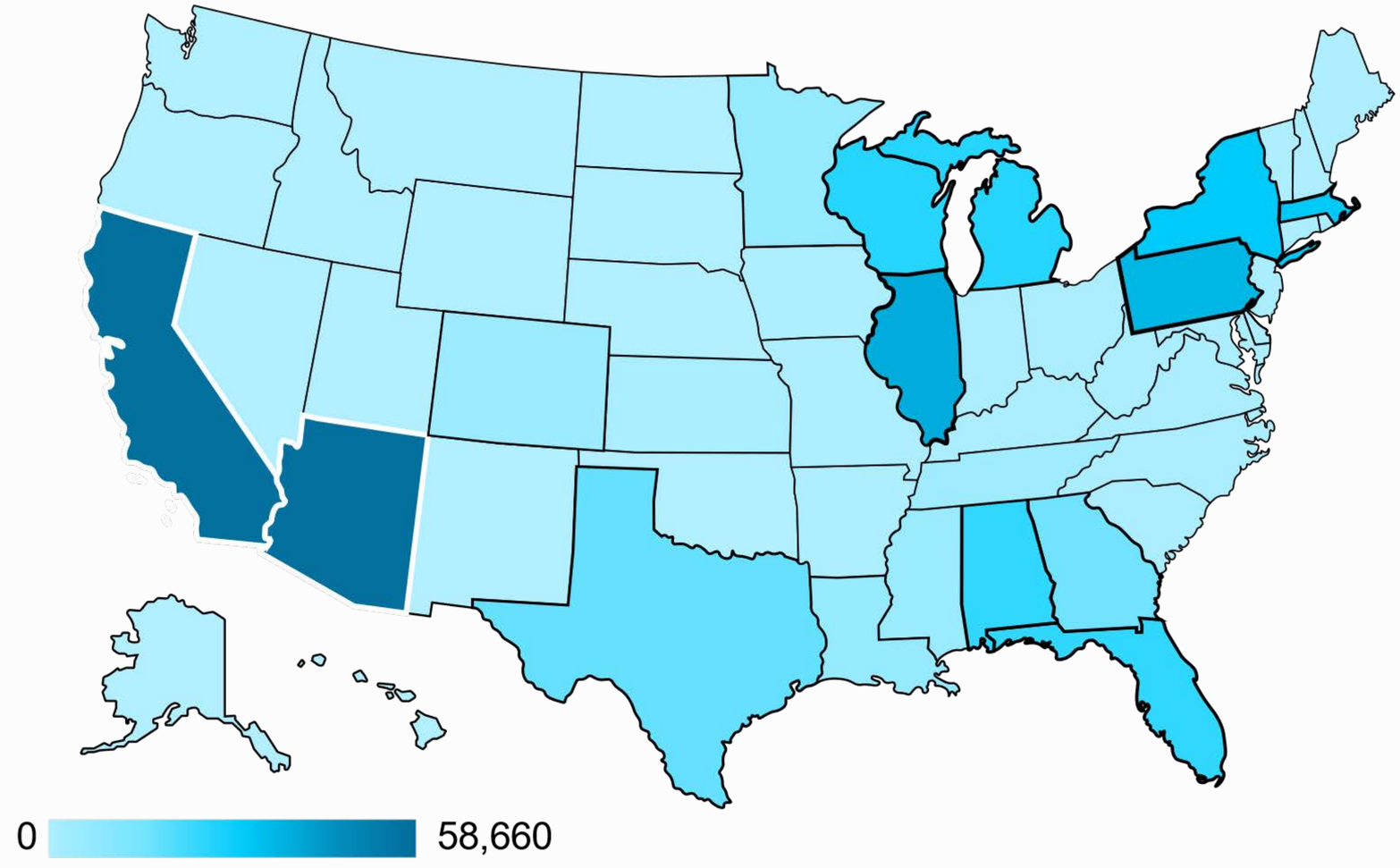
Enrollment Numbers

The following numbers are approximated to protect participants' privacy.
Numbers are updated as of January 25, 2023.



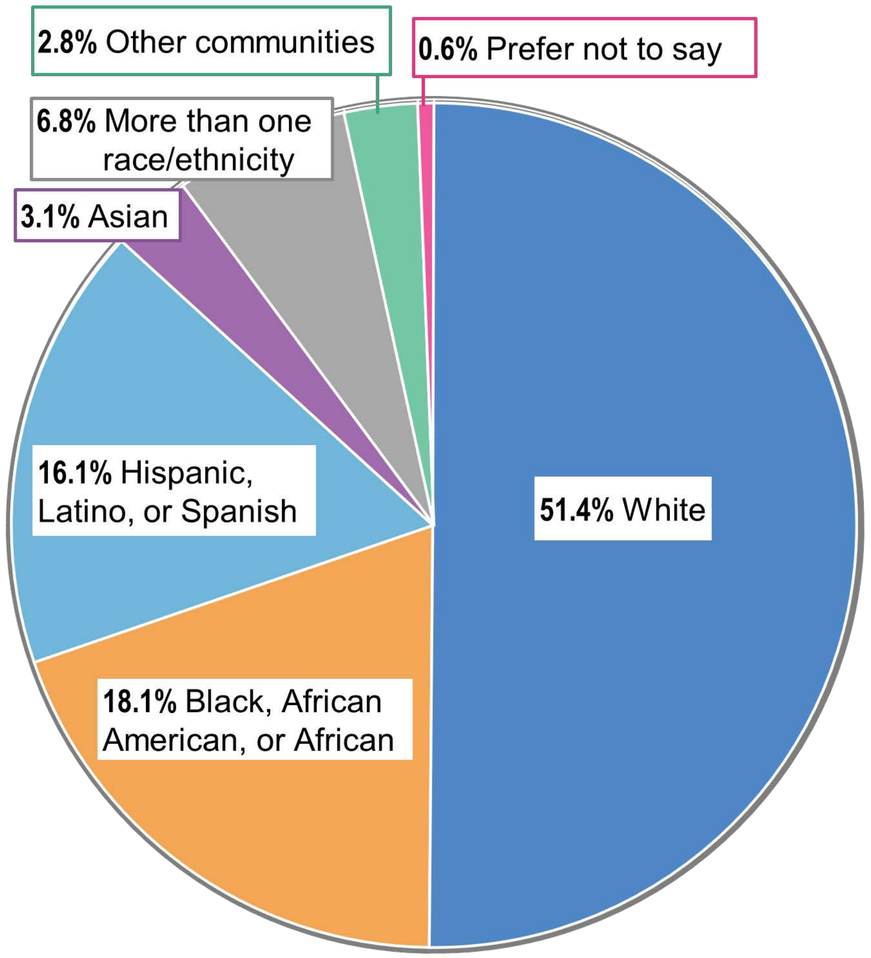
All of Us Supports Regional Enrollment Centers & Nationwide Virtual Participation

All of Us supports nationwide enrollment in all 50 states through a combination of virtual recruitment, regional enrollment centers, and interactive mobile exhibits. Participants can currently enroll and participate in English or Spanish.

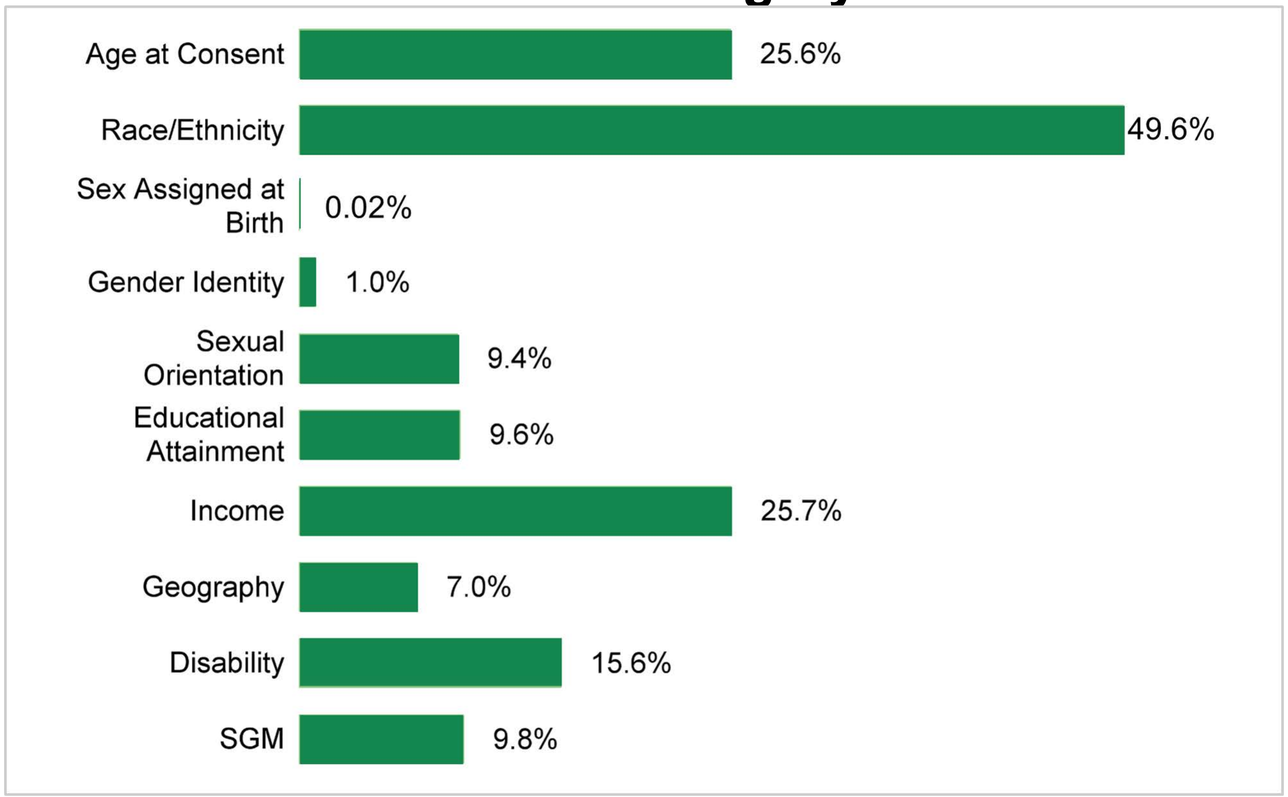


All of Us Strives to Enroll a Cohort that Reflects the Diversity of the U.S.

Race & Ethnicity of Participants



UBR Category



About 80% of *All of Us* participants identify with a group that is underrepresented in biomedical research (UBR)

Numbers current as of January 31, 2023

All of Us Most Talked About Publications of 2022

Metrics as of December 22, 2022

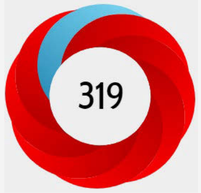
Between December 2021 and December 2022, 100+ articles using *All of Us* data were published in peer-reviewed publications.

Using the holistic reference tool, AltMetric, we see the five studies to the right rose as the most talked about *All of Us* publications of 2022. This serves as a complementary metric to citations, as it shows a fuller view of an article's influence across research, policy, and general public audience.

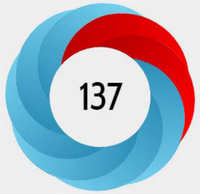
All five of these articles score in the top 5% of all research publications scored by Altmetric. Each of these articles were also amplified through NIH *All of Us* communications tactics and materials to help build additional momentum.

Association of step counts over time with the risk of chronic disease in the *All of Us* Research Program.
Master, H., Annis, J., Huang, S. et al. (2022) Nature Medicine

Association of longitudinal activity measures and diabetes risk: an analysis from the NIH *All of Us* Research Program.
Perry, A (2022) The Journal of Clinical Endocrinology & Metabolism



Revisiting the Latino Epidemiologic Paradox: an analysis of data from the *All of Us* Research Program.
Montanez-Valverde R, et al. (2022) Journal of General Internal Medicine

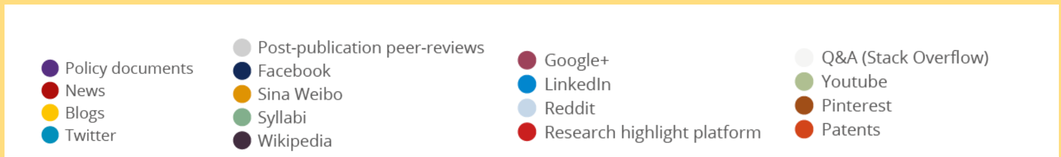


Association of everyday discrimination with depressive symptoms and suicidal ideation during the COVID-19 pandemic in the *All of Us* Research Program.
Lee Younga H, et al. (2022) JAMA Psychiatry

Wearable fitness tracker use in federally qualified health center patients: strategies to improve the health of all of us using digital health devices.
Holko Michelle, et al. (2022) NPJ Digital Medicine (1) 53

Media Outreach | Social Media | Researcher Spotlight | Research Highlights | Research Roundup Newsletter

AltMetric is an indicator of the volume and type of attention a research publication has received. The donut score reports identify how much and what type of attention a publication received.



Data on the Researcher Workbench is Diverse and Longitudinal

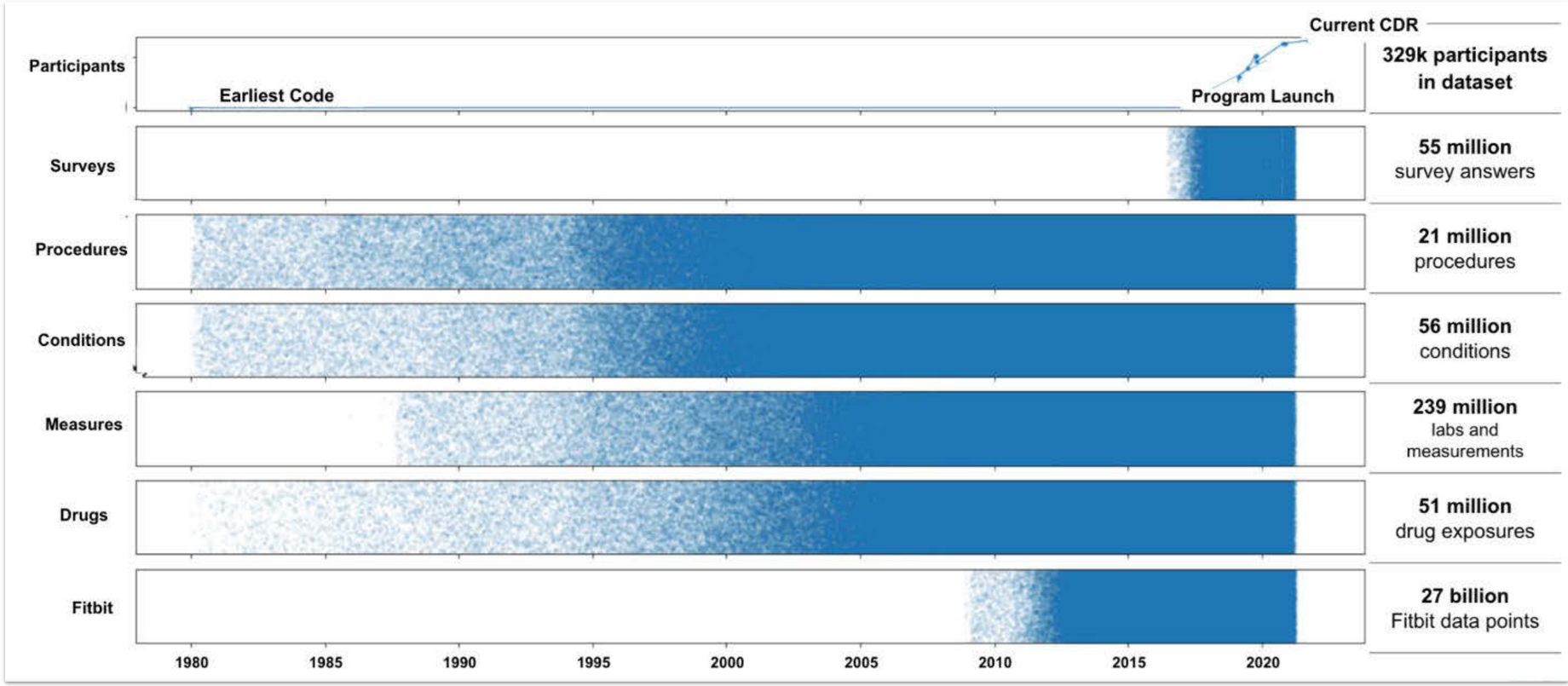
374,000+ Participants

311,000+ Physical Measurements

324,000+ EHRs

372,000+ Surveys

12,880+ Fitbit Records



Center for Linkage and Acquisition of Data (CLAD)

Vision

Current State including Experimental Work

Data Flow

Key functions and Operational Goals

Cores and Staffing

Milestones

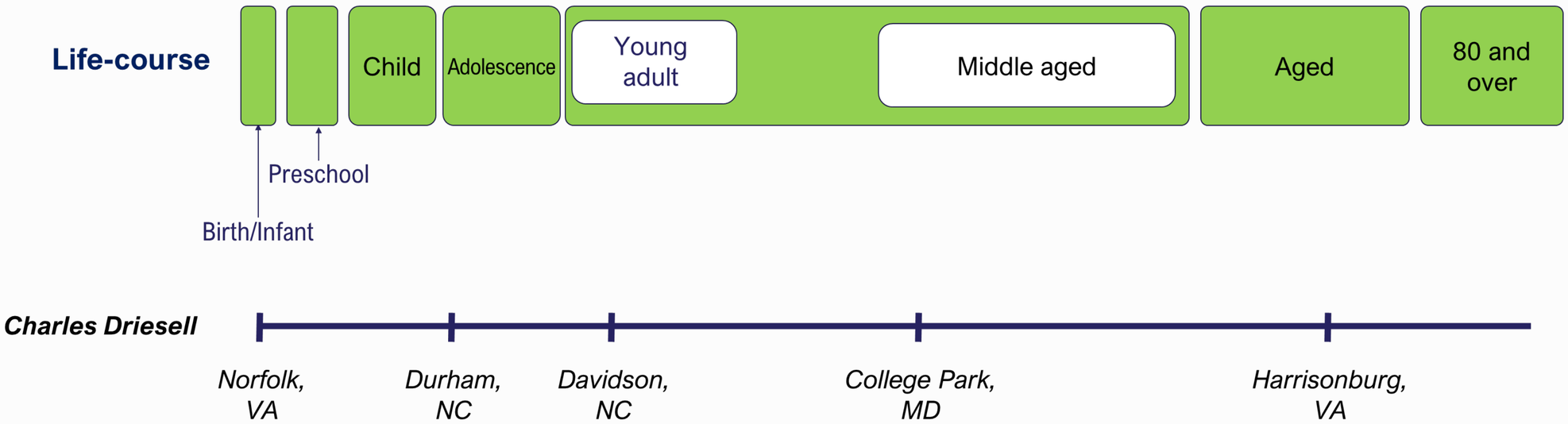
Factors Affecting Data Linkages

Optional Periods

The Overarching Vision for CLAD

A key goal of *All of Us* is to build a broad dataset including behavioral, biospecimen, environmental, health, and other data over an individual's life-course. This data accounts for modifiers of health such as individual mobility, where people live and work, where they seek care, and environmental exposures. An important aspect of this vision is a recognition that new data acquisition methods are needed that reduce participant burden.

Consequently, the vision for CLAD is to expand our understanding of health, increase research utility, align with the expectations of consented participants, and increase retention metrics all through data linkage.



Streams of Data Currently Collected on *All of Us* Participants

Demographics

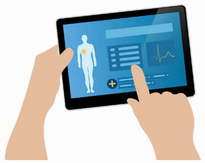
- Participant demographics
- Consent
- HIPAA authorization

Surveys

- The Basics
- Overall Health
- Lifestyle
- Health Care Access & Utilization
- Personal & Family Health History
- SDOH
- COVID

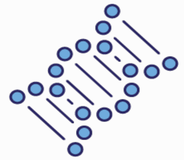
Physical Measurements

- Blood pressure
- Heart rate
- Height and weight
- BMI
- Hip and waist circumference



EHR

- Healthcare Provider acquired data
- Participant health data from portals
- Apple Health



Bioassays

- Assay data from blood, saliva, and urine
- Whole Genome Sequencing and Arrays

Physical Activity Data

- Wearable device data
- Fitbit data

Experimental Work with Privacy Preserving Record Linkages (PPRL)

- Two experiments have been completed and one is planned. The focus has been on cohort discovery, EHR completeness, and EHR acquisition. We are considering a fourth experiment with an imaging repository.

- Some key factors to consider when choosing PPRL technologies and methods
  - Verification of matching accuracy needs to be undertaken / understood
  - Robust tokenization is needed as patient interactions with the health system can result in different demographics

- Some key results
  - *Cohort discovery*: found ~19.5 *All of Us* participants in N3C and a health information network
  - *EHR completeness*: A significant amount of patient activity across diagnoses, procedures and drugs is not in *All of Us* EHR data

Data Linkages During the Base Period

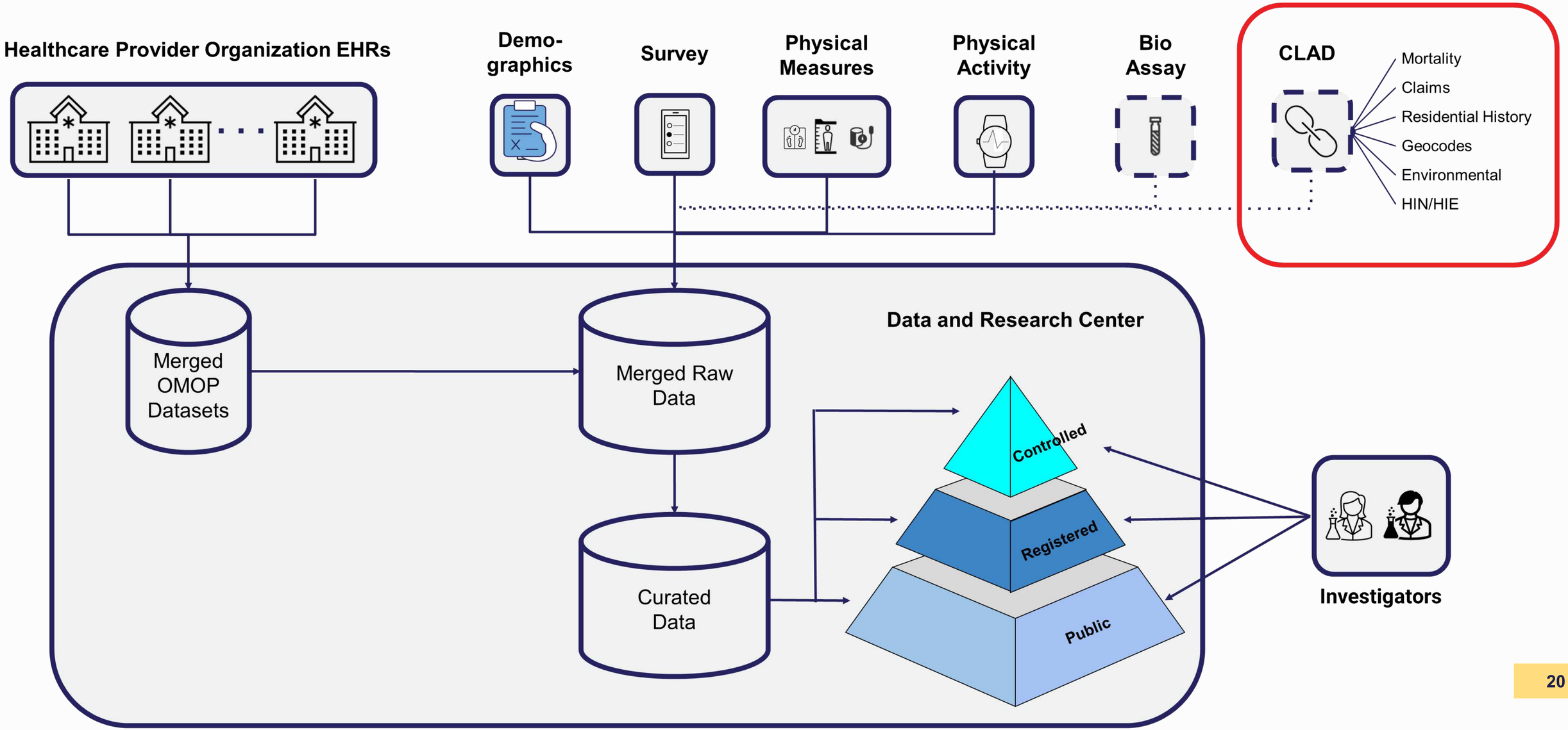
- Initial linkages selected to better understand a participant's health, increase research utility of the data, align with the expectations of consented participants, quality, and to increase retention metrics

- Clinical Data
  - Mortality Data
  - Health Care Claims Data
  - HIN / HIE Pilot for EHR data

- Geospatial Data
  - Residential history - addresses for where study participants have lived
  - Geocodes - home latitude & longitude, Census block / block group, etc.

- Environmental Data
  - Centers for Disease Control and Prevention's Environmental Index

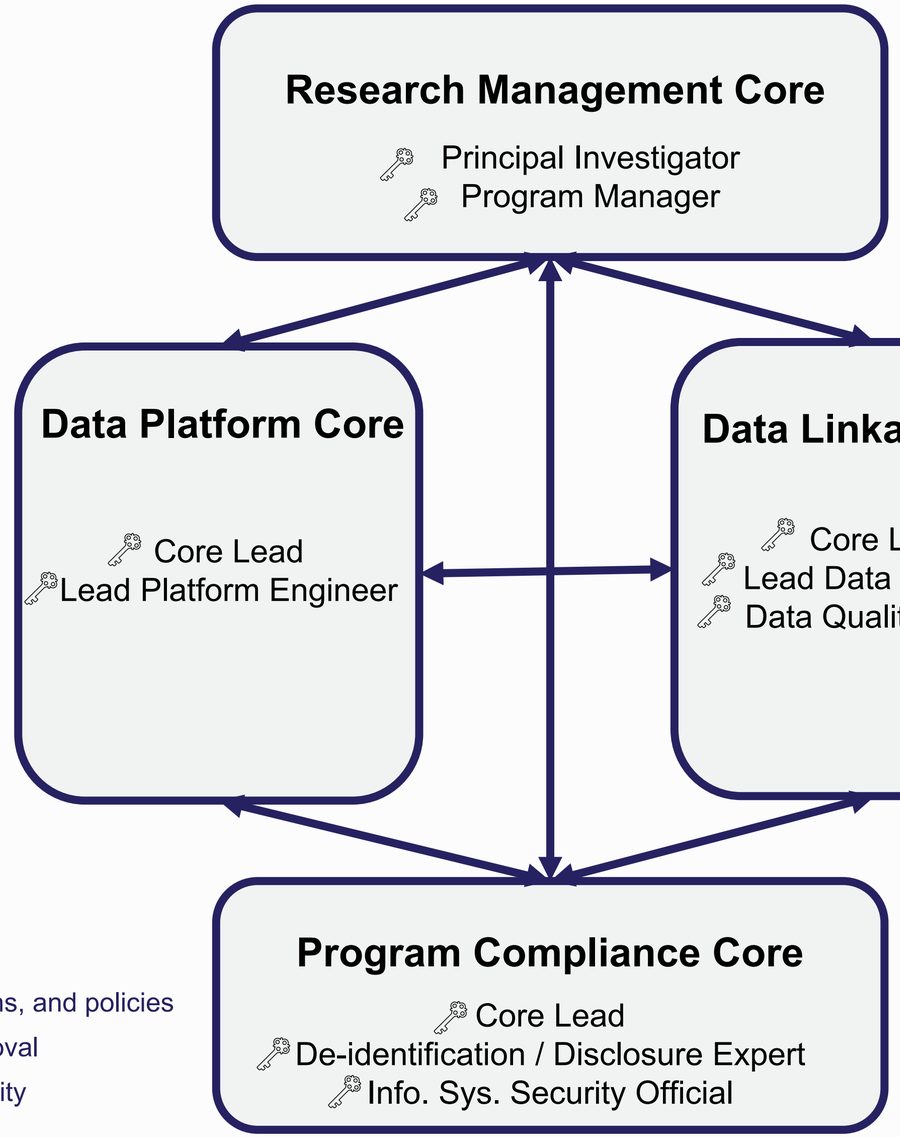
CLAD Data Flow and Researcher Access within the *All of Us* Data Ecosystem



CLAD Operational Goals

- The focus is on developing a ***Center*** (not just a platform) that drives value for researchers using ***advanced methods and technology***
- Provide program management, scientific, and technological ***personnel & services*** for data acquisition, governance & quality, de-identification, and linkage
- Acquire data from ***new data streams*** and from ***existing data streams***, such as electronic health records (EHRs), through new methods
- Matching of linked data to participants with an ***acceptable level*** of sensitivity, specificity, positive predictive value, and negative predictive value
- Build and/or customize and deploy a ***secure cloud-based data linkage platform***
- Produce ***data, documentation, and tools*** for dissemination on the Researcher Workbench

Core Functions and Key Personnel



Research Management Core Functions

- Leadership, management, administration, coordination, and staffing
- Oversight of platform development, linkage efforts, and compliance

Data Platform Core Functions

- Implement and manage the Data Linkage Platform
- Provide Identity Management, Integration and Monitoring Functionality

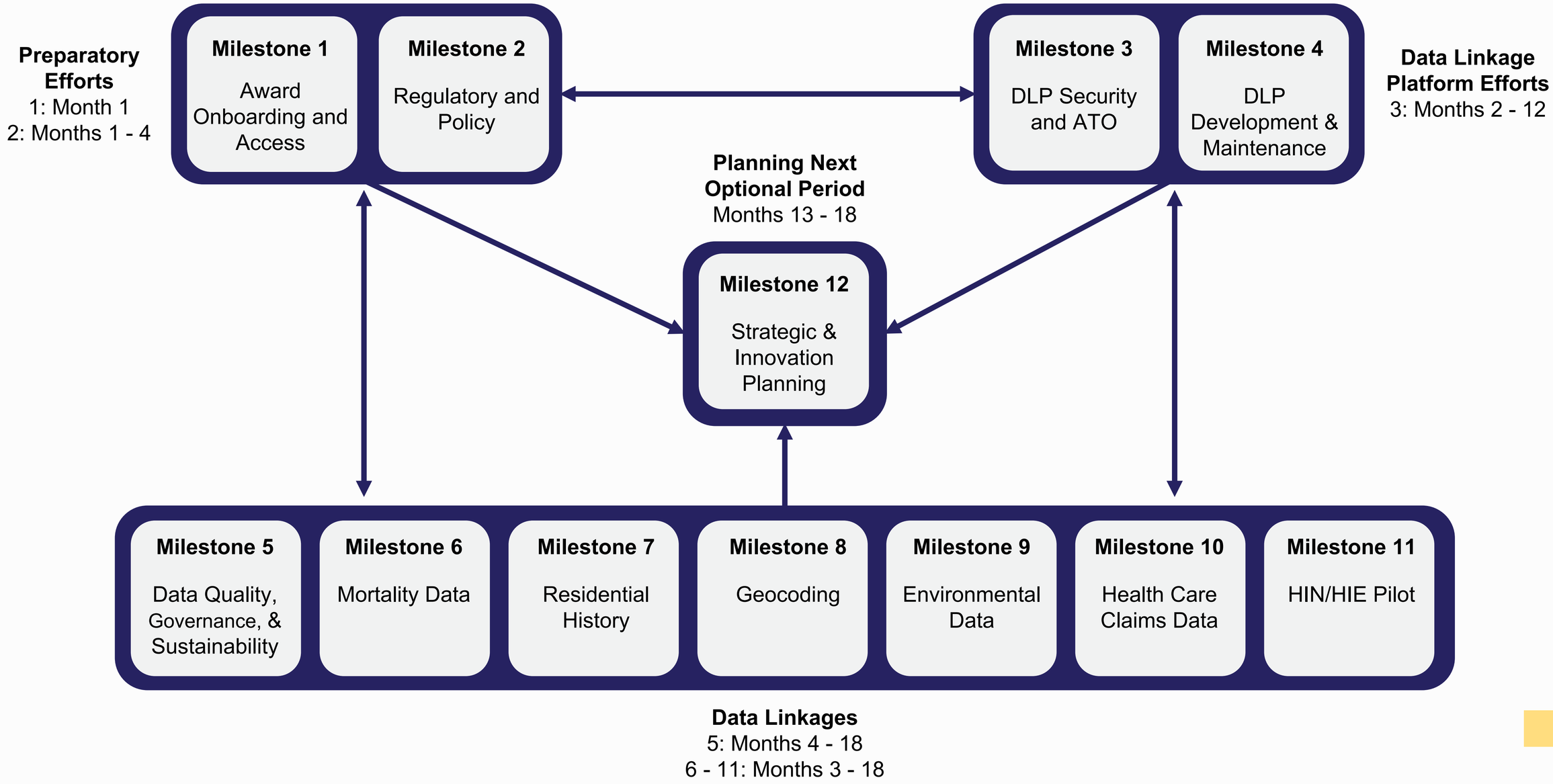
Data Linkage Core Functions

- Data Governance and Quality
- Acquire and Manage Linked Data
- Develop documentation & tools for researchers; support dissemination

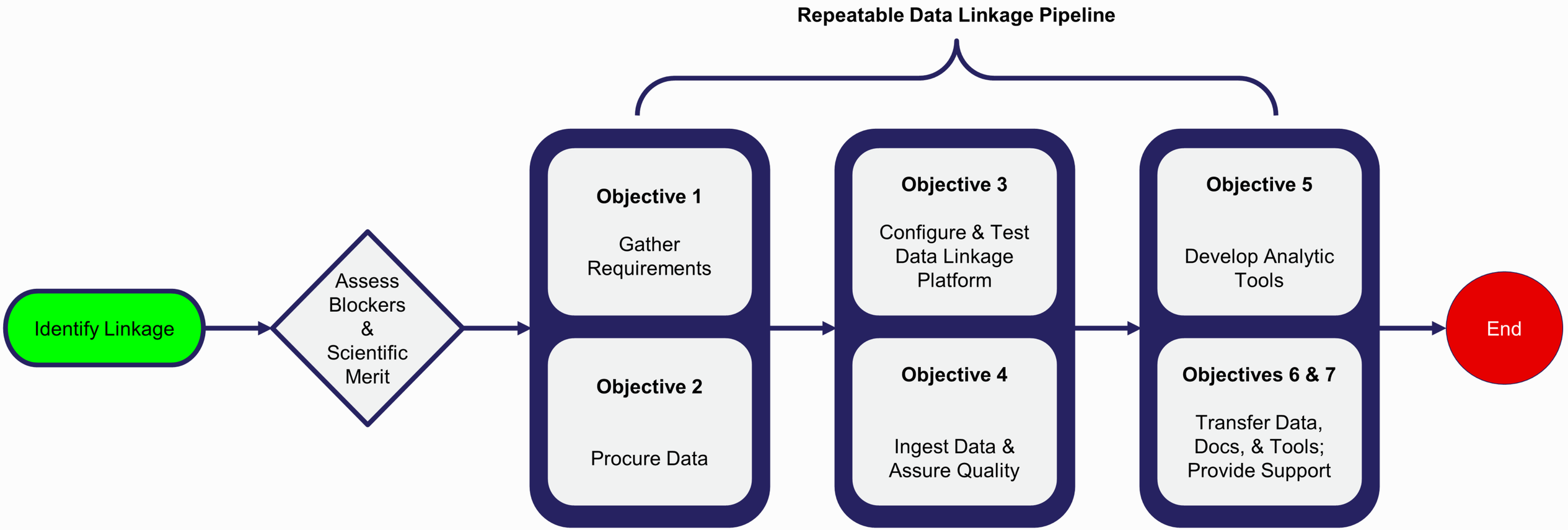
Program Compliance Core Functions

- Ensure compliance with laws, regulations, and policies
- Enable disclosure review and IRB approval
- Safeguard participant privacy and security

CLAD Milestones and Relationships



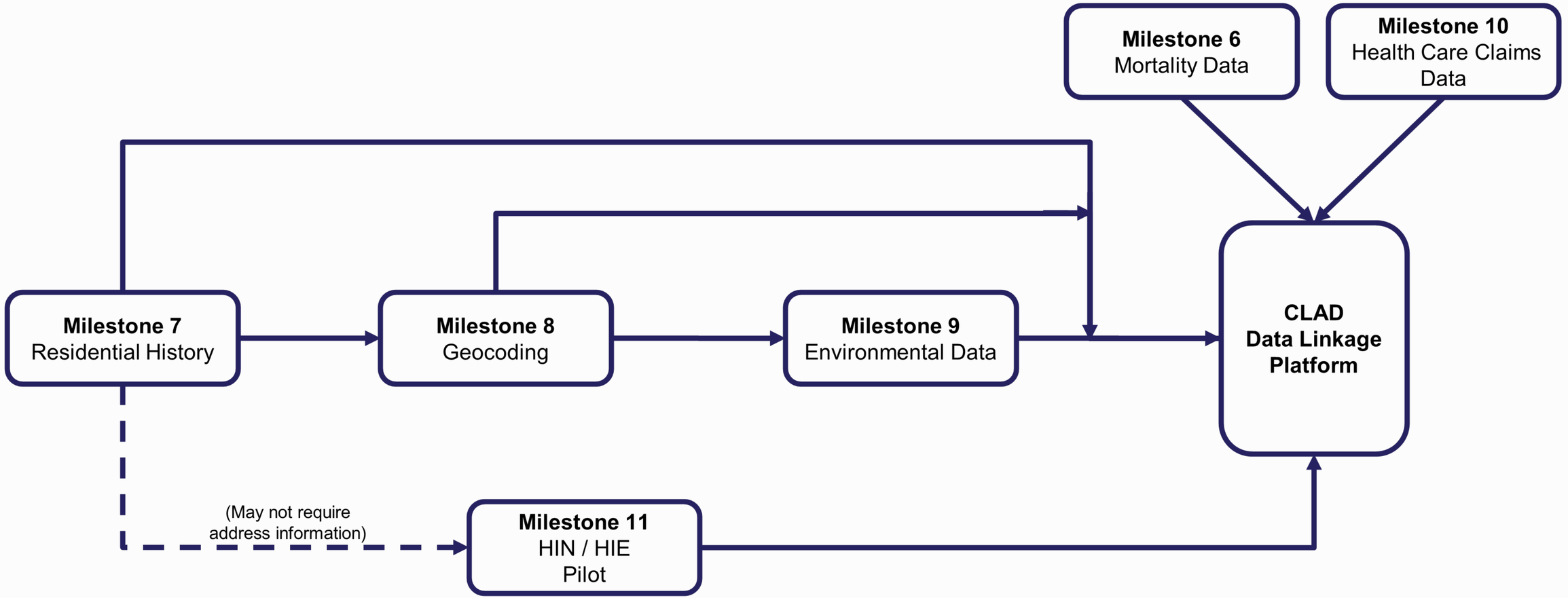
Repeatable Pipeline within Data Linkage Milestones



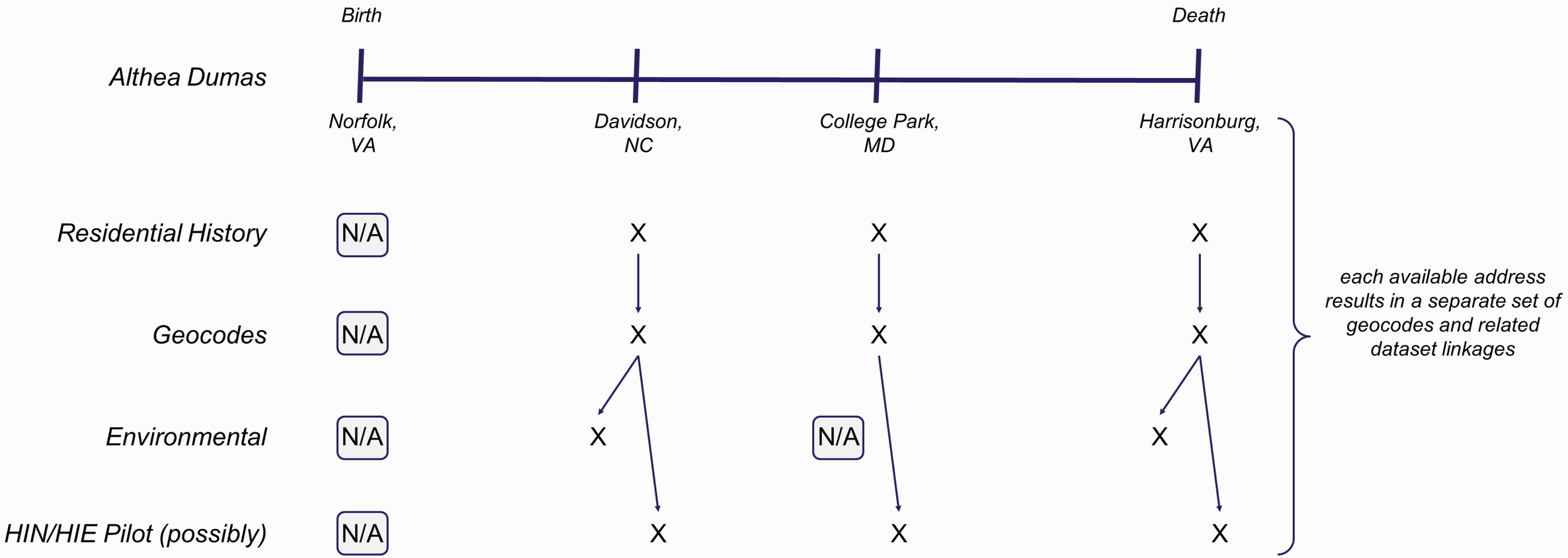
Some Factors Affecting Data Linkages

- *All of Us* IRB submission and approval should be accounted for with each linkage
- ATO must precede acquisition of PII from the DRC and linkage data (unless it is public domain); offerors should be creative however in using approaches (e.g., synthetic data) to advance linkage work before ATO
- CLAD data deliveries need to align with the *All of Us* Data Roadmap which provides for
  - A manifest of which participants are included in a specific delivery of data to the Researcher Workbench
  - Anticipated dates of each (~yearly) curated data release to the Researcher Workbench
- The impact of participants that withdraw from the program in terms of
  - Delivery of data to the DRC
  - Destruction of data within the CLAD data linkage platform

Dependencies within the Baseline Data Linkages



1:M Relationships Exist Between Residential Address and Data Linkages



N/A - no data available

Alignment of Source Data Provider Updates, Data Acquisition, and Data Production

possibly 1 data pull from source provider during the base period

Residential History, Geocodes, EJI

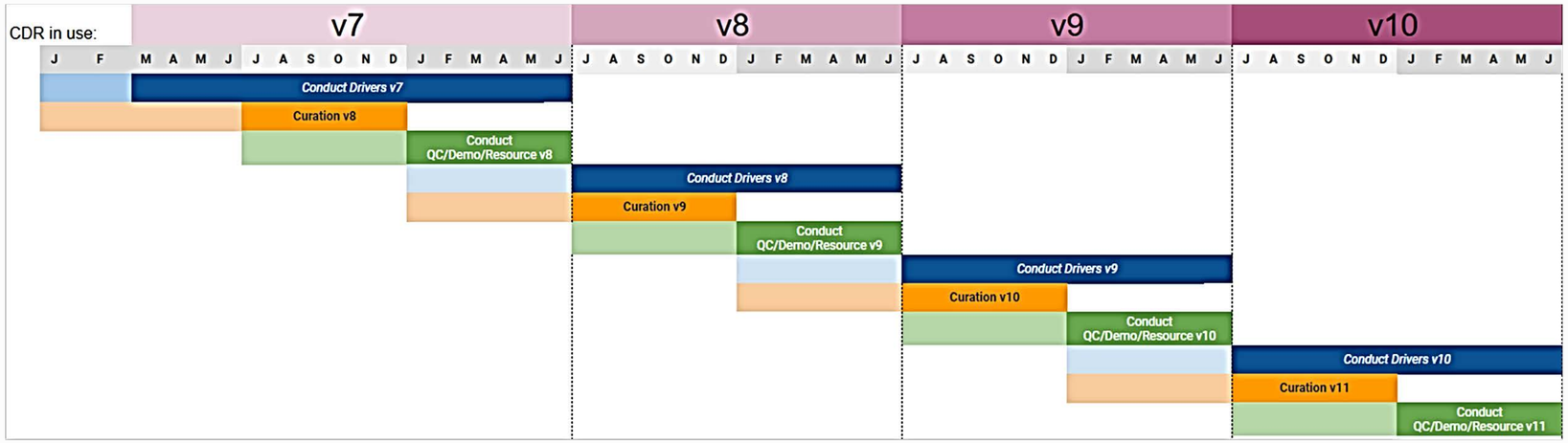
Mortality

Health Care Claims, EHR from HIN/HIE

Less Frequently

More Frequently

possibly > 1 data pull from source provider during the base period



Data production schedule for delivery of data to the Researcher Workbench

Optional Periods

- Examples of future linkages during the optional periods
  - Disease specific areas
  - Environmental data (e.g., air quality, water quality)
  - Occupational history
  - Radiologic & other clinical images (e.g., optical coherence tomography)
  - Registry data (e.g., cancer, immunization)
  - Social Determinants of Health
  - Waveform (e.g., EKG)

- What will drive decisions on the milestones for the optional periods?
  - Research utility, research utility, research utility
  - Funding
  - CLAD Milestone 12 - Strategic & Innovation Planning
  - Partners, Scientific Roadmap, Steering Committee, Science Committee, trans-NIH activities, …
  - *All of Us* Ancillary Studies
  - Participant expectations

Lastly, thank you

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Submission Requirements & Timeline

Award Information

- **Award Type:** Other Transactions (OT)
- **OT Authority:** Public Health Service Act (PHSA) sec. 402(n), 42 U.S.C. sec. 282(n)
- **Budget:** $30 million total costs (Base Period)
- **Period of Performance**
  - 18-month base period
  - Up to four 12-month optional periods

Competition Process

- This Other Transactions Award competition process will include three phases:
  - Phase I - Submission and Evaluation of Full Technical and Cost Proposal
  - Phase II - Data Linkage Platform (DLP) Capabilities Demonstration and Evaluation (Invitation Only)
  - Phase III - Negotiation and OT Award (Invitation Only)
- The NIH intends to down-select at each phase resulting in making one OT award in Phase III
- Depending on program requirements, the NIH reserves the right to omit Phase II, or to combine the Phase submissions as needed
- For selected proposals invited to Phase II and III further instructions will be provided
- Participation in Phase I is required to be eligible for invitation to Phase II and III

Letter of Intent

- Requesting that offerors who intend to submit a proposal in response to the CALD ROA complete the ***Intent to Submit Proposal Form (ROA Appendix E)*** and return to AllofUsDTPDAwardRequirements@nih.gov by **March 15, 2023, at 3pm Eastern Time**

- Letter of Intent is not binding and does not enter into the review of a subsequent proposal

- Letter of Intent is not required but allows the *All of Us* Research Program to estimate the potential review workload and plan the review

Phase I - Proposal Submission Instructions

- Full technical and cost proposal must be submitted via the NIH eRA ASSIST System
- To submit a proposal via ASSIST, the applicant organization must be registered in eRA Commons.
  - Please plan accordingly, as registration approval does not occur immediately upon request.
  - Organizations already registered in eRA Commons do not need to reregister.
  - The individual(s) with the role of Signing Official (SO) and Program Director/Principal Investigator (PD/PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process
- Use the ROA number, OTA-23-003, in the field requesting “Funding Opportunity Announcement #”
- Instructions for submitting a proposal in eRA ASSIST can be found at https://www.era.nih.gov/help-tutorials/assist/era-training-assist.htm
- eRA Technical help is available at https://www.era.nih.gov/need-help

Phase I - Proposal Submission Instructions

- Full technical and cost proposal due **April 17, 2023, at 3 p.m. Eastern Time**
- Proposal Submission Requirements
  - Paper Size: 8.5 x 11 inch paper
  - Margins: 1 inch on all sides
  - Spacing: single-spaced
  - Font: Times New Roman, 12 point
  - Adobe PDF files are required for eRA ASSIST submission
  - No hard copies, facsimiles, zip files, or password protected files
- One proposal submission per offeror

Phase I - Proposal Content Requirements

- Proposal Content
  - Cover page: does not count against page limit
  - Table of Contents: does not count against page limit
  - Abstract: not to exceed 1 page total
  - Specific Aims: not to exceed 1 page total
  - Team Structure and Partnerships: not to exceed 2 pages total
  - Leadership and Management Plan: not to exceed 2 pages total
  - Technical Approach: not to exceed 17 pages total
  - Milestone Plan: not to exceed 3 pages total
  - Relevant Past Experience: not to exceed 3 pages total
  - Key Personnel Overview: not to exceed 3 pages total
  - Appendix A: Key Personnel NIH Biosketches and Resumes
    - Principal Investigator, Program Manager, and the De-identification /Disclosure Expert: for each, a maximum four-page NIH biosketch
    - Other key personnel: for each, either a maximum four-page NIH biosketch or a two-page resume.
    - The biosketches and resumes in Appendix A do not count against the page limit.
  - Cost proposal: does not count against the page limit

Phase I - Proposal Content Requirements

- Cost Proposal must include a cost narrative and cost breakdown to complete each milestone in the milestone plan submitted

- A cost breakdown sample is provided in Appendix F of the ROA

- The breakdown of each milestone cost must include:
  - Personnel Cost
  - Cost for each sub-award
  - Consultant Cost
  - Travel Cost
  - Material/Equipment Cost
  - Other Direct Cost
  - Indirect Cost
  - Fee/Profit, if For-profit institution

- Cost breakdown must show costs allocated to each of the four cores in Section 5.2 of the ROA

Phase I Proposal Evaluation Criteria

- **Proposals will be scored on the following evaluation criteria:**
  - Each core will be assessed along four dimensions including:
    - Team
    - Understanding
    - Science and Technology
    - Past Experience
  - Each Linkage will be assessed along three dimensions including:
    - Data Acquisition Preparation
    - Platform Preparation and Ingestion
    - Effective Documentation, Tools, and Assistance
  - Schedule
    - The milestone plan will be assessed for the ability to satisfactorily meet the schedule of milestones.
- **Cost proposals will be assessed to determine if the cost proposed:**
  - Is within the available funding limits
  - The ability and/or likelihood of the offeror to successfully execute the proposed approach within the financial resources proposed

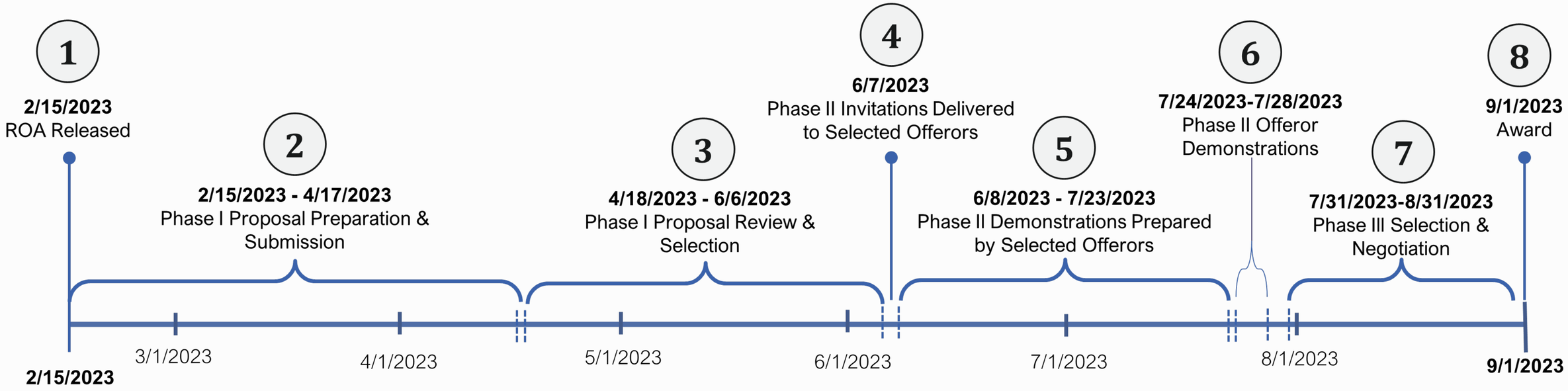
Phase I Proposal Selection

- A numerical scoring system will be used in the technical evaluation of each proposal.
  - Evaluators score each proposal on three elements (cores, linkages, and milestone plan) to produce a composite score for a proposal.
- The overall cost proposed will be given a rating of Insufficient, Sufficient, or Excessive.
- Offerors whose full proposals are deemed to have significant merit may be selected and invited to provide a demonstration in Phase II.
- The NIH does not intend to provide feedback/debriefings on proposal submissions.
- Offerors will receive notification should the *All of Us* Research Program decide not to provide an invitation for the next Phase.

Note: To be eligible for invitation to subsequent Phases and award, offerors must submit a Proposal in Phase I.

Phase II and Phase III

- **Phase II - Data Linkage Platform (DLP) Capabilities Demonstration and Evaluation**
  - This phase is by invitation only
  - The primary purposes for the Phase II Capabilities Demonstration and Evaluation is to better understand the composition and abilities of the offeror's team, to assess security readiness, and to demonstrate the offeror's DLP.
  - Details for requirements of technical demonstration will be provided to the offeror(s) in the invitation for Phase II.
- **Phase III - OT Award**
  - This phase is by invitation only
  - Upon favorable evaluation and available funds, the NIH will proceed to negotiation and award with one offeror to make an OT Award.


1
2/15/2023
ROA Released
2
2/15/2023 - 4/17/2023
Phase I Proposal Preparation & Submission
3
4/18/2023 - 6/6/2023
Phase I Proposal Review & Selection
4
6/7/2023
Phase II Invitations Delivered to Selected Offerors
5
6/8/2023 - 7/23/2023
Phase II Demonstrations Prepared by Selected Offerors
6
7/24/2023-7/28/2023
Phase II Offeror Demonstrations
7
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Phase III Selection & Negotiation
8
9/1/2023
Award
2/15/2023
3/1/2023
4/1/2023
5/1/2023
6/1/2023
7/1/2023
8/1/2023
9/1/2023

All of Us RESEARCH PROGRAM

Questions & Answers

Questions & Answers - Security and Clearances

- **(Chris) Because we need an Authorization to Operate (ATO), does NIH help sponsor this?**
  - An ATO is not FedRAMP certification and does not require “sponsorship.” The offeror may incorporate into their cost breakdown the fees associated with receiving Authorization to Operate (ATO), which includes a third-party controls assessment.

- **(Chris) Is it sufficient for a collaborating entity to have ATO?**
  - The ATO process is specific to the *All of Us* Research Program. So, the CLAD awardee will need to receive ATO from All of Us, regardless of ATO status by the offeror or collaborating entity on other projects.

- **(Chris) Is Public Trust or any higher-level security clearance required for the offeror’s team members working in CLAD?**
  - No. The CLAD award will be implemented through an Other Transaction (OT) award as an extramural research project through the *All of Us* Research Program consortium. No federal clearances will be required for staff.

Questions & Answers - Human Subjects Research Protections

- **(Lew) Will the CLAD offeror be required to have their own Institutional Review Board (IRB) as part of the team?**
  - The CLAD offeror will rely on the *All of Us* single IRB (sIRB). The offeror will need to hold a Federal-wide Assurance (FWA) for the protection of human subjects and have the relevant policies described in the assurance. The awardee is also expected to prepare materials related to each data linkage that is necessary for submission to the IRB. The awardee should be prepared to answer questions that the IRB may have regarding these linkages.

- **(Lew) Will all CLAD team members of the offeror be required to have active Human Subjects Research Protections training/Certification?**
  - The CLAD Principal Investigator, Program Manager, and De-identification / Disclosure Expert and all other personnel who work with identifiable private information on CLAD must have Human Subjects Research Protections (HSRP) training / certification. Training should be updated regularly, according to organization policy but should not exceed five years for recertification. The specific content requirements of the HSRP training are flexible but must at a minimum involve HSRP topics relevant to CLAD and the *All of Us* Research Program.

Questions & Answers - Data Linkage Platform

- **(Lew) The requirement states that data will be exchanged with the Data and Research Center (DRC) implying a bi-directional flow. What data will be coming from the Data Research Center to the CLAD Data Linkage Platform?**
  - The Data Linkage Platform will receive participant personally identifiable information and perhaps other types of data from the DRC that will be needed to link participants to the acquired data. For each data linkage the CLAD awardee will be required to transmit the linked data, documentation, and tools to the DRC so that this data may be moved to the Researcher Workbench after any additional curation by the DRC.

- **(Lew) Does the government have a preferred provider for the data linkage platform and for privacy preserving record linkage tokenization?**
  - No. The government is neutral to the data linkage platform and tokenization. We are open to platforms that are either to be built, ready to go, or need some modification. The platform must satisfy the functions described in the ROA. Moreover, we are not looking for a single tokenization solution. There may be situations where different types of tokens are required. Offerors should consider how best to do this to satisfy the base period linkages and for future growth and opportunities.

Questions & Answers - Data Linkages

- **(Lew) Is the primary cause of death expected on every death record linked? Can NIH provide examples of "other relevant data" that is expected for Mortality Data?**
  - The program is seeking the underlying cause(s) of death for every linked individual. Additional data elements might include the age at death, marital status, and the location of the death. However, the final elements will be uncovered during Milestone 6 Objective 6.1.1 where requirements for the mortality linkage will be gathered.

- **(Lew) Would NIH or the CLAD awardee establish the relationship with the Environmental Justice Index coordinator to link to other *All of Us* Data?**
  - The awardee will establish a relationship with the CDC EJI coordinator. *All of Us* will certainly be involved with the awardee in developing this relationship.

Questions & Answers

- **(Jessica) Regarding the recipient's pre-existing software platform or other trade secrets and materials (part of the recipient's Background Data as defined in the Appendix A Terms and Conditions), the Terms and Conditions contain contradictory terms on whether the NIH is expecting to have use of that software platform, trade secrets and materials only during the term of the agreement, or perpetually. What is NIH's expectation?**
  - Per the ROA, The Terms and Conditions attached in Appendix A serve as a baseline for Other Transactions agreements awarded by the *All of Us* Research Program in Phase III. The NIH may modify these terms and conditions throughout the selection process. Requests by offeror(s) to modify the terms and conditions language will be considered by the NIH on a case-by-case basis and negotiated as deemed appropriate. Discussion/negotiation of agreement terms and conditions will take place with the invitees of Phase II and Phase III.

- **(Jessica) Can the bidders add rows and columns to Appendix F as needed to reflect their accounting system setup and the specific costs elements they're proposing as well as profit/fee?**
  - Yes, the vendor can add as many row and columns needed to reflect their accounting system setup and the specific costs elements they're proposing as well as profit/fee.

Questions & Answers - Cost and Pricing Information

- **(Jessica) Can you also provide clarification on whether fixed price models based on commercial pricing are eligible for the program?**
  - Due to uncertainties and flexibility needed in the project, a fixed price agreement would not be appropriate, therefore a cost-reimbursable or cost-plus-fixed-fee payment agreement would be needed. The offeror can have sub awards with fixed priced labor rate arrangements for commercial services and fixed priced commercial products. Any fixed price cost shall still breakdown labor categories, hours, and itemized list of materials/equipment and travel in proposal.

- **(Jessica) Can the NIH please clarify if all personnel in the Cost Proposal must be named individuals? Can unnamed TBD individuals be included in the cost proposal?**
  - Only Key Personnel must be named. So, unnamed TBD individuals may be included in the cost proposal for non-Key Personnel.

Questions & Answers - Cost and Pricing Information

- **(Jessica) Under ROA Section 8. Milestone Plan it asks for a table with a column for Estimated Total Cost in Dollars. Is the NIH permitting offerors to include costs within their Technical Proposals?**
  - The costs in the milestone table are high-level cost estimates for each milestone and should match directly with the formal and full cost proposal.

- **(Jessica) Can NIH please confirm whether ROA Section 11, Cost Proposal, should be submitted separately as a PDF along with ROA Appendix F in Excel or included with the Technical Proposal as one submission document?**
  - The cost proposal along with Appendix F should be submitted as a PDF and included with technical proposal submission into the NIH eRA ASSIST System.

- **(Jessica) ROA Appendix F only gives a breakdown through Milestone 12 and the first 18 months. Where should the bidders provide optional cost breakdowns?**
  - Cost estimates for optional periods are NOT being requested in Phase I proposals but may be requested in Phase III for planning and budgeting purposes.

Questions & Answers - Eligibility and Partnering

- **(Jessica) Are for-profit entities and small businesses eligible for the CLAD award?**
  - CLAD is open to all entities listed in the ROA Section 6: Eligibility Information, including for-profit organizations and small businesses. There is no specific set-aside for small businesses in this award.

- **(Jessica) Will the program provide potential collaborating partners for applicants?**
  - No, offerors are encouraged to seek out partners for strong solutions, cooperative working relations, and collaboration with the *All of Us* Research Program and program partners.

- **(Jessica) Are applicants expected or required to apply for all cores of the CLAD ROA?**
  - There will only be one award for CLAD so offerors are required to support all four cores. Offerors may apply for the award on their own or as a team. Offerors are limited to one submission but may be included as a partner on more than one submission. Staffing is to be decided by the offeror and partners. This should be done in a way that is logical and supportive of the key functions.

Closing

1. ROA Informational Webinar slides and Questions and Answers will be posted as an amendment on Sam.gov
2. Follow this opportunity on Sam.gov to get notifications to amendments
3. Email any inquires to AllofUsDTPDAwardRequirements@nih.gov
4. Questions must be submitted at least 14 calendar days prior to the proposal due date (April 17) to ensure a response

Thank You!

All of Us RESEARCH PROGRAM

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https://www.joinallofus.org/

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