RECOVER Data Repositories and Mobile Health Platform Research Opportunity Announcements Technical Assistance Webinar

July 15 2021

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Researching COVID to Enhance Recovery

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Zoom Orientation

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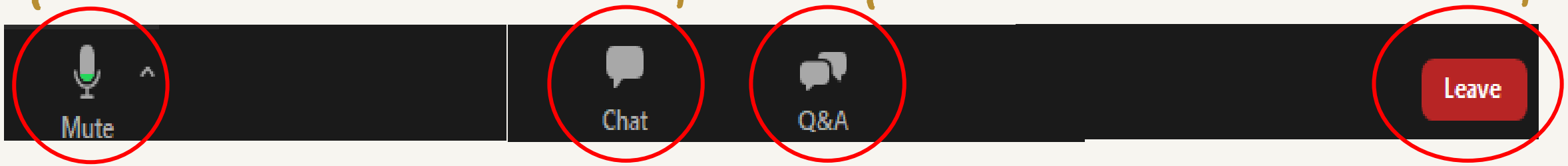

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Technical Assistance Webinar (TAW) Overview

Purpose

To enhance potential applicant understanding of the RECOVER initiative, the Data Repositories and Mobile Health Platform Research Opportunity Announcements (ROAs), and to facilitate preparation of responsive applications.

Objectives

- ❑ Gain an understanding of the vision and specific objectives of the **RECOVER** initiative
- ❑ Outline the **key scientific & research elements** of the ROAs—including the specific research components
- ❑ Review the **OTA framework**, application process, and requirements
- ❑ Address **prospective applicant questions**

Agenda

1	**Technical Assistance Webinar (TAW) Introduction**	Amy Patterson	5:00 - 5:03
2	**NIH RECOVER Initiatives**	Amy Patterson	5:04 - 5:14
3	**Components of RECOVER Data Repositories**		5:15 – 5:36
	Data Repository Overview	Susan Gregurick	
	Clinical and Observational Data Repository	Alastair Thomson	
	Imaging Data Repository	Rui Pereira De Sa	
	Pathology Data Repository	Stephen Hewitt	
4	**Digital Health Data Repository and Mobile Health Platform Strategy**		5:37 – 6:04
	RECOVER Mobile Health Platform Strategy	Andrew Weitz	
	Digital Health Data Repository	Andrew Weitz	
	Mobile Health Platform	Audie Atienza	
9	**Other Transaction Authority Framework Overview**	Jeffrey Snyder	6:05 - 6:10
10	**Q&A**		6:11 - 6:27
11	**Closing Remarks & Next Steps**		6:28 - 6:30

NIH Researching COVID to Enhance Recovery (RECOVER) Initiative on Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)

Overview

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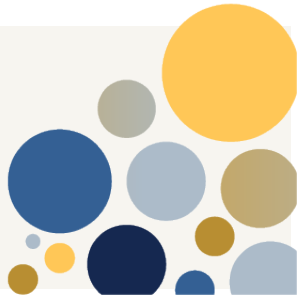


Why Study PASC?

- Patients vary in the timing and extent of their recovery from SARS-CoV-2 infection:
  - Many recover quickly while others may experience important **p**ost-**a**cute **s**equelae of SARS-**C**oV-2 Infection (PASC)
    - Reported symptoms range from mild to incapacitating, may involve multiple organs and systems, and can adversely affect overall quality of life
    - In some cases, timing of infection is linked to new symptoms and findings but emerge subsequently and evolve over time
- The public health impact is currently unknown, but potentially large given the numbers of individuals across the age spectrum who have been/will be infected

NIH PASC Research: Toward Recovery from SARS-CoV-2 Infection

Goal

Rapidly improve our **understanding** of and **ability to treat and prevent** PASC

Key Scientific Questions

1. What are the clinical spectrum of and biology underlying recovery from acute SARS-CoV-2 infection over time?
2. For those patients who do not fully recover, what is the incidence/prevalence, natural history, clinical spectrum, and underlying biology of this condition? Are there distinct phenotypes of patients who have prolonged symptoms or other sequelae?
3. Does SARS-CoV-2 infection initiate or promote the pathogenesis of conditions or findings that evolve over time to cause organ dysfunction or increase the risk of developing other disorders?

Recovery Cohort

Acute SARS-CoV-2 Infection Cohorts

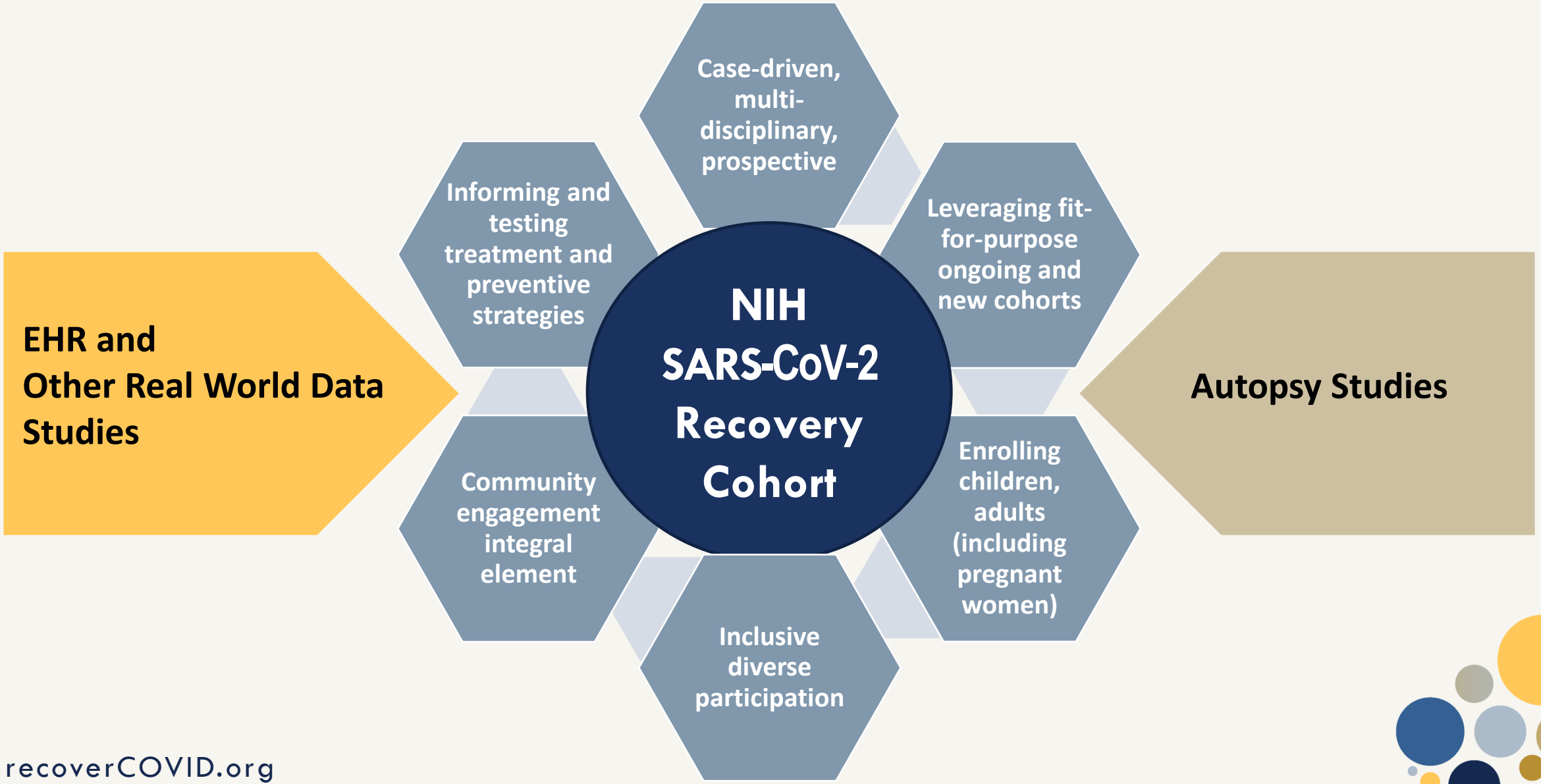
Post-Acute SARS-CoV-2 Infection Cohorts

Goal: *To understand and be able to treat and prevent PASC*

Aiming for a national, inclusive, diverse patient population that spans the life cycle.

RECOVER Research Approach

RECOVER Research Approach (*continued*)



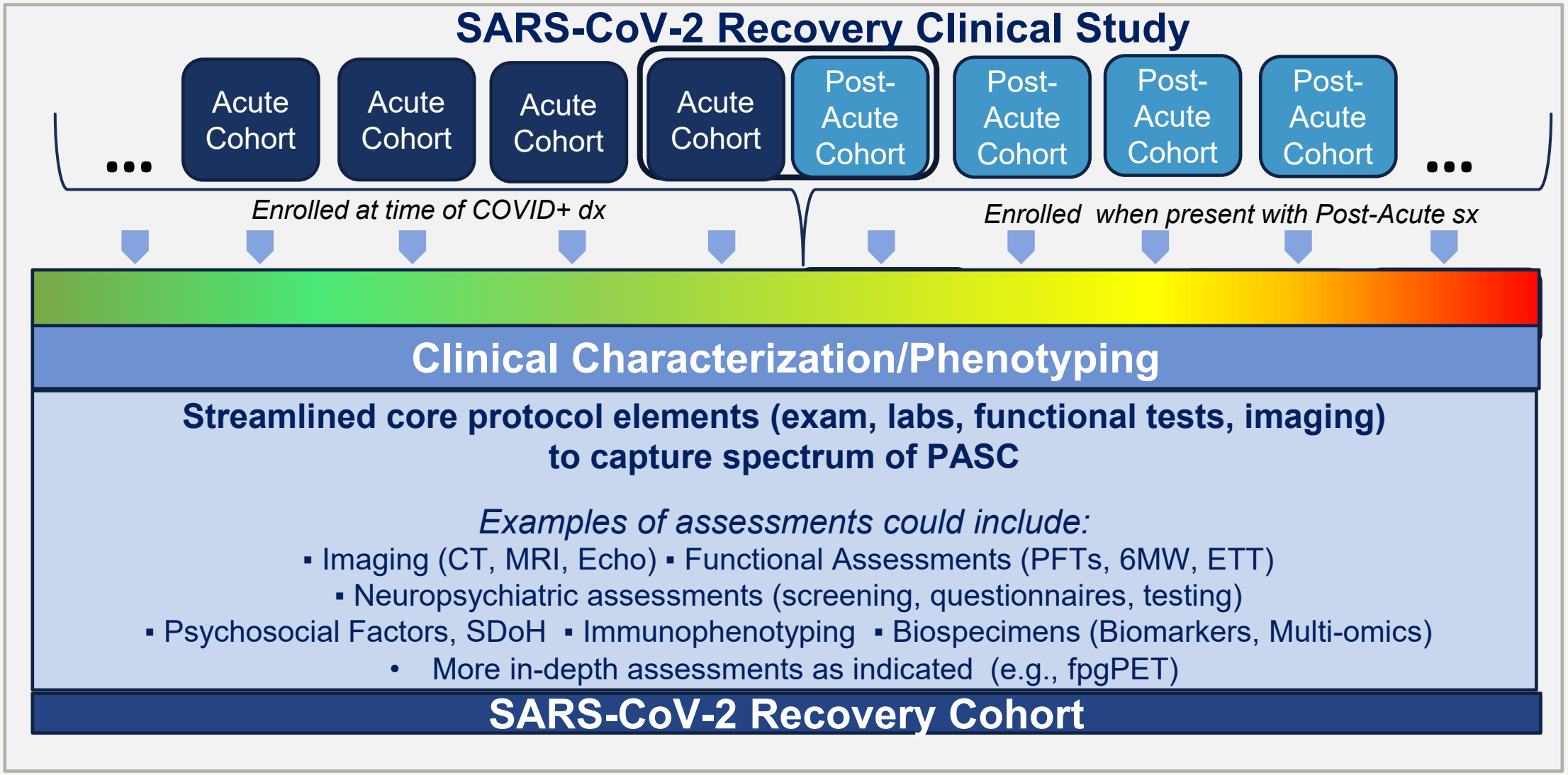
PASC Characterization Strategy

Notes:

Includes Peds & Pregnancy Cohorts Studies

Includes new and leveraged ongoing studies

Broad Spectrum of Recovery Phenotypes



RECOVER Initiative Components

SARS-CoV-2 Recovery Meta-Cohort

- Clinical Recovery Cohort (Adult, Peds, and Pregnancy)
- Autopsy Cohort (Acute and PASC)
- EHR-/ Other Real-World Data-Based Studies

Investigator Consortium

- **Cross-disciplinary investigator teams** will work together to:
  - Achieve **speed and scale/breadth**
  - Set of common core protocol elements
  - Conduct systematic screening and **in-depth follow-up evaluations**

Clinical Science Core | **Data Resource Core** | **Biorepository Core** | **Admin Coord. Ctr**

Additional Key Features

- **Collaborative community/patient/stakeholder involvement at multiple levels**
  - Listening Sessions
  - Community Advisory Board (CAB)/Community Based Organization: Study level
  - RECOVER CAB
  - Participation in Consortium activities
- **Mobile Health/Digital technology to enable broader outreach to patients and facilitating participation**
  - Reporting symptoms
  - Receiving updates/notices
  - Personal sensor technology

Additional Key Features (*continued*)

- **Longitudinal follow-up**
  - Vary in depth/intensity as well as duration
  - Will need to adjust plans as results become available
- **Adapt and innovate** as science evolves
- **Clinical Trials** are an important component

Key Dates and Review Process for Data Repositories ROA

Apr 19

NOITP issued

July 8

Research Opportunity Announcement issued

July 15

DR & MHP Technical Assistance Webinar

July 16

Letter of Intent due

July 23

Invitations sent out requesting full proposals

August 13

Full proposals due

Sept-Oct

Awards made

Key Dates and Review Process for Mobile Health Platform ROA

Apr 19

MHP NOITP issued

July 8

Research Opportunity Announcement issued

July 15

DR & MHP Technical Assistance Webinar

July 30

Proposal due

Late Aug - Early Sept

Virtual interviews (select applicants)

Sept - Oct

Award made

Data Repositories Research Opportunity Announcement (ROA)

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RECOVER Data Repositories Overview

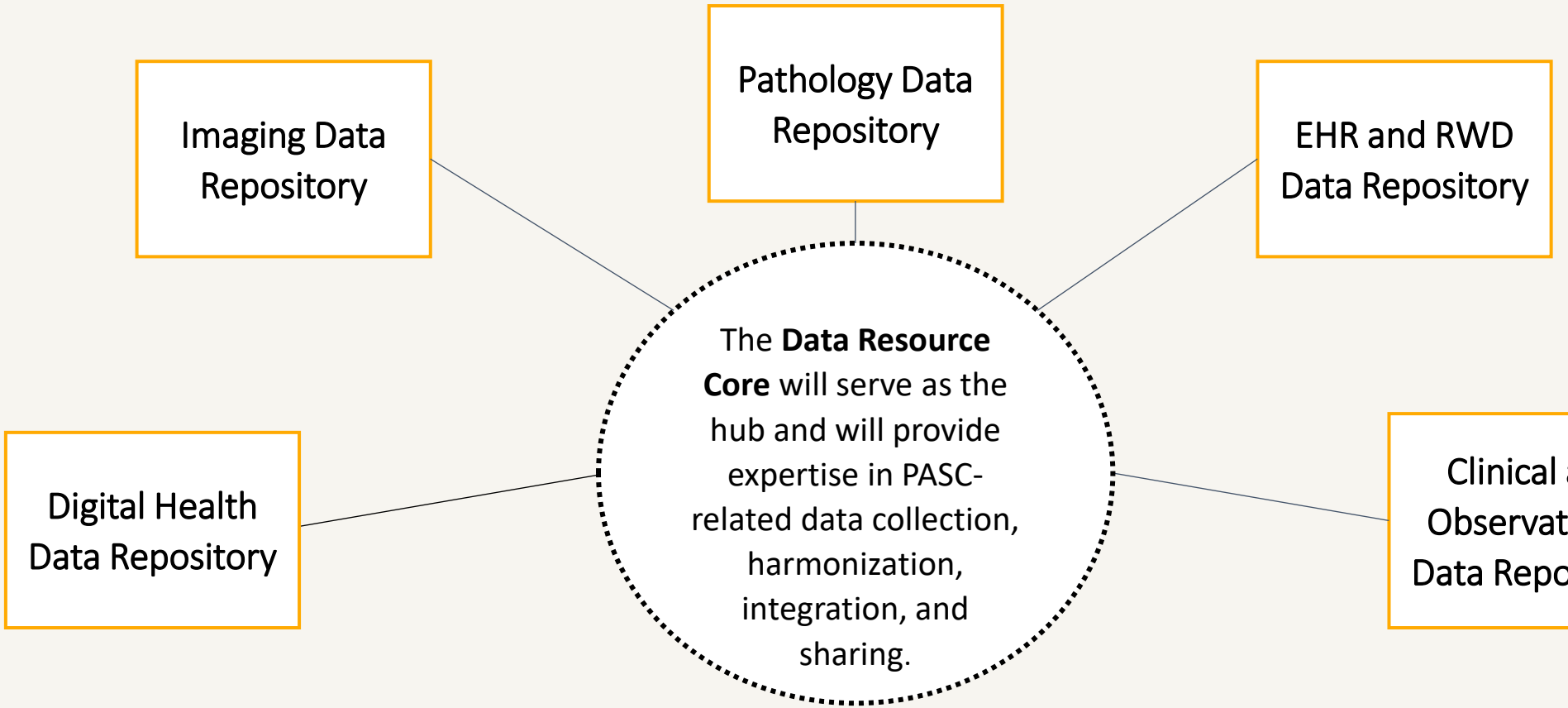
VISION

The RECOVER Data Repositories will work closely together as integral partners with the rest of the RECOVER Consortium to rapidly and flexibly deploy, manage and grow a robust, secure digital infrastructure that can meet near-term and long-term needs of the program.

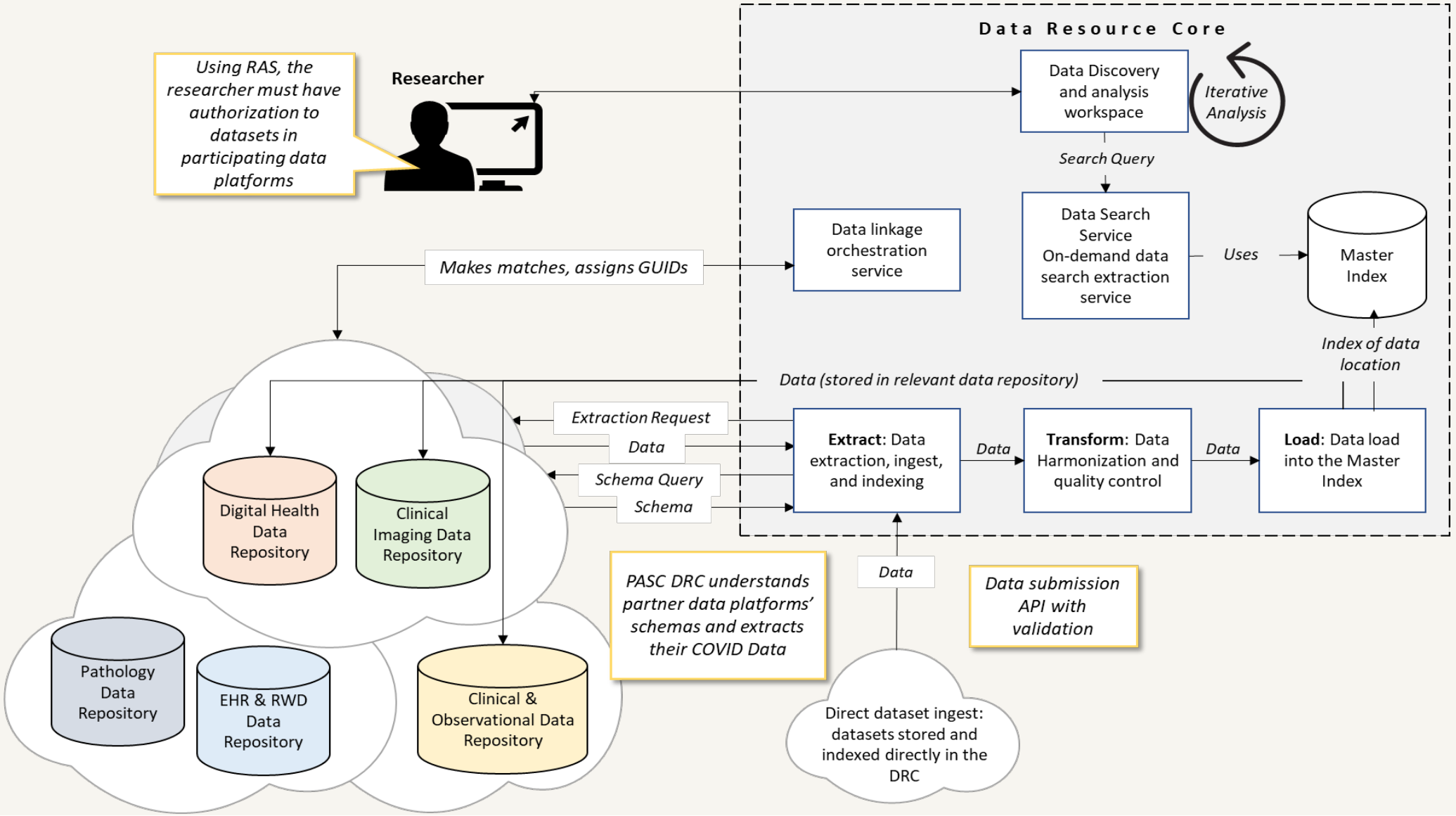
1. Overall requirements for **each RECOVER Data Repository**
2. Overview of the **Clinical Data Repository**
3. Overview of the **Imaging Data Repository**
4. Overview of the **Pathology Data Repository**
5. Overview of the **Digital Health Data Repository**

RECOVER Data Repositories Overview 1/2

In this vision, the RECOVER data repositories are the spokes in a hub and spoke model, with the PASC Data Resource Core acting as the coordination hub:



RECOVER Data Repositories Overview 2/2



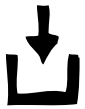
Requirements for All Data Repositories

Data Curation, Metadata, Provenance

- ❑ Data Curation and Mapping
- ❑ Common Data Model Adherence
- ❑ Data De-Identification
- ❑ Data Provenance Tracking
- ❑ Data QA/QC Checks
- ❑ Unique persistent identifier (PID) assignment
- ❑ Data Retention Policies

Data Ingestion & Sharing

- ❑ Data Management & Linking Model
- ❑ Data Use Tracking
- ❑ Data Sharing & Collaboration



Data Management & Linkage

- ❑ Consent Groups Data Ingestion & Linking
- ❑ Secure Data Ingestion via API
- ❑ Completion of Institutional Agreements and Certifications (DTAs, DUAs)
- ❑ Data management services & expertise
- ❑ Integration with Researcher Auth. Services (RAS)

Other Requirements *(See ROA for more details)*

❑ **Collaboration**

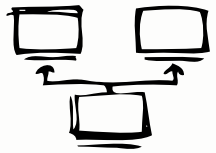
with DRC, CSC, consortium to data harmonization and scientific research

❑ **Cloud Capabilities**

Cloud-based technology and best practices

❑ **Security**

Comply with all necessary standard security protocols



❑ **Resources**

Documentation, analytical tools, and other resources to support researchers

Clinical and Observational Data Repository

Purpose:

- Facilitate the collection, annotation, harmonization, curation, and sharing of clinical data generated by structured observational studies and clinical trials

Objectives:

- Collaborate with the PASC Data Resource Core to support scientific collaboration
- Utilize Common Data Elements (CDEs)
- Provide a user-experience-focused web portal to enable data discovery
- Provide cloud based collaborative workspaces for researchers using common tools such as Jupyter notebooks, RStudio, SAS and Python
- Provide the ability to safely archive workspaces encapsulating data, code, documentation etc. to facilitate reproducibility
- Provide integration with data in other data repositories including linking study participants using GUIDs provided by the DRC
- Provide secure access to clinical, genotypic and -omics data using APIs and the NIH Researcher Auth Service (RAS)

Imaging Data Repository

Purpose:

- Facilitate the collection, annotation, harmonization, curation, storage, and sharing of digital human medical imaging data in support of SARS-CoV-2 Recovery Cohort studies and other PASC-related initiatives

Objectives:

- Ingest, curate, perform QA/QC, aggregate, and securely store digital imaging data and metadata
- Provide support for submission and analysis of a wide range of imaging data (multiple imaging modalities, organs and systems, …)
- Employ an extensible and versatile data dictionary
- Provide for data de-identification
- Facilitate data harmonization for PASC imaging data
- Provide a means to link the imaging data to clinical, observational and pathology data
- Enable access to imaging data through a secure portal and API
- Provide imaging-specific software tools (e.g. DICOM viewer, support for annotations, …) in an interoperable manner

Pathology Data Repository

Purpose:

- Facilitate the collection, annotation, harmonization, curation, and sharing of pathology imaging data collected, including but not limited to histopathology, whole slide imaging being collected by the SARS-CoV-2 Recovery Cohort studies and other PASC-related initiatives as appropriate

Objectives:

- Maintain and document an enterprise information management strategy for all types of histopathology imaging data
- Provide for data de-identification
- Ingest, curate, perform QA/QC, aggregate, and securely store the digital images generated using a pathology imaging modalities
- Provide a user-experience-focused web application and API
- Provide investigator support for data analysis
- Enable the consortium access imaging data through a secure portal
- Ensure database design and implementation can facilitate querying of imaging datasets

Digital Health Data Repository and Mobile Health Platform

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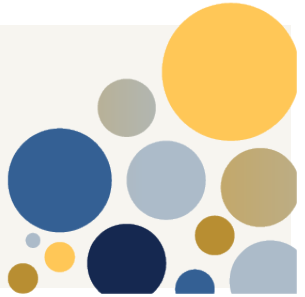


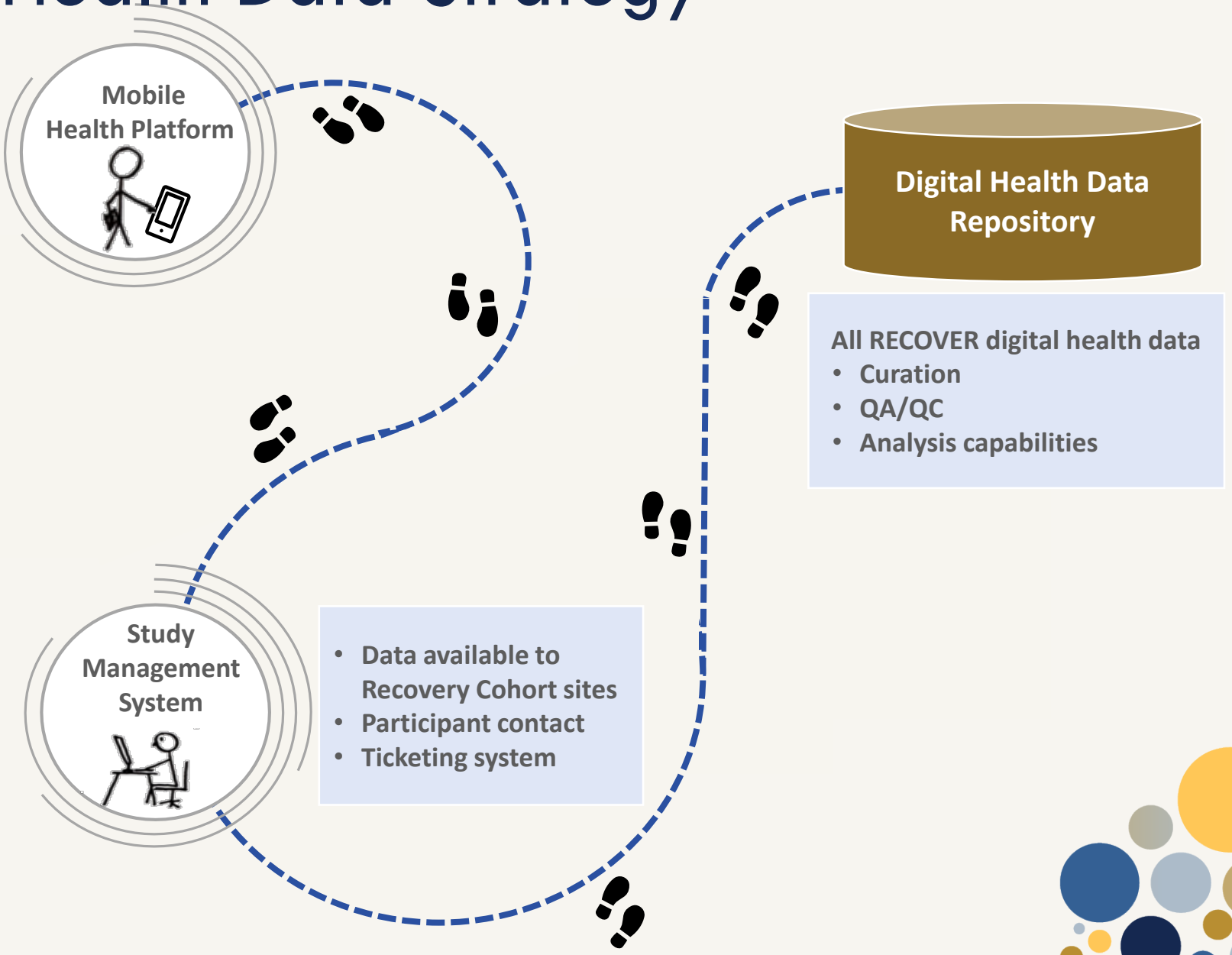
Why Mobile?

Advantages of mobile health include:

- Timely and real-world assessments of the PASC symptoms, trajectory and recovery
- Enable capture of person-centered data (e.g., ePROs)
- Reducing burden on fatigued patients with mobile health sensors and/or mini-surveys
- Ability to collect data from sensors integrated with the platform chosen
- Enable recruitment of non-hospitalized, under-served, and/or rural populations
- Empower and engage patients by returning personalized information
- Capture Social Determinants of Health and other contextual factors (e.g., environment) that may contribute to PASC

RECOVER Mobile Health Data Strategy

The Mobile Health Platform (MHP) and Digital Health Data Repository (DHDR) will facilitate the collection, annotation, harmonization, curation, and sharing of digital health data collected via mobile apps and/or sensors by the RECOVER Initiative Investigator Consortium to augment existing clinical, EHR, and other real-world data.



Key Features of Digital Health Data Repository

Purpose:

The Digital Health Data Repository (DHDR) will host the mobile and digital health data being collected by SARS-CoV-2 Recovery Cohort studies to assess trajectory of acute SARS-CoV-2 infection and PASC over time.

Objectives:

- Host all digital health data (mobile app surveys, wearable sensor data, etc.) collected by the Recovery Cohort studies (Mobile Health Platform, potentially other apps and devices)
- Conduct cleaning, QA/QC, curation, and aggregation of all mobile and digital health data
- Harmonize sensor data and health measures collected from different devices
- Enable computational pipelines, workflows, and analyses to be run on the data

Digital Health Data Repository Requirements

- Define a common data model, minimum metadata and Para data standards, and QA/QC metrics
- Ingest data from the Mobile Health Platform (MHP) and non-MHP apps and sensor devices
  - Support graphical, command-line, and application programming interfaces (APIs)
- Leverage approaches for data fusion to harmonize sensor data and health measures collected from different devices
- Ensure all sensor data are cleaned and usable by addressing issues of signal quality, missing data, erroneous recordings, etc. (data-janitoring)
- Implement de-identification approaches for sensor data, adhering to best-in-class approaches for preventing re-identification (e.g., GPS-derived measures)
- Provide sophisticated analytics capabilities, enabling users to develop and deploy computational pipelines, workflows, and analyses over the data

Key Features: Mobile Health Platform

Purpose:

Develop customized iOS/Android-compatible, mobile and web-based applications capable of collecting and aggregating RECOVER patient digital health data, which can be analyzed and leveraged in order to understand and eventually mitigate PASC symptoms.

Topics:

- General Requirements
- Platform Device Integration & Procurement Requirements
- Harmonization/Standardization
- Security and PII management

Mobile Health Platform Requirements 1/2

- Deployable on multiple interfaces, including mobile devices (e.g., iOS and Android), mobile, tablets, and desktop web browsers, etc.
- Collect sensor data from consumer wearable devices
- Securely store all data before sharing it with the Digital Health Data Repository
- RECOVER study management system with interfaces for participants and study staff, including:
  - Participant recruitment, electronic consenting, and onboarding
  - Ticketing system to track and respond to technical issues
  - Making the data collected through the MHP available to the Recovery Cohort investigators
  - Real-time data collection and reports
  - Return of results to participants
  - Contacting participants via email, text/SMS, and mobile system alerts for push notifications/alerts and survey questions and responses

Mobile Health Platform Requirements 2/2

- Software integration with commercial or research-grade devices
- Ask core questions about the symptoms experienced by patients to chart recovery or worsening over time in symptoms and quality of life
- All websites and mobile applications are Section 508 compliant in accordance with HHS regulations.
  - Providing customized interfaces that are multilingual, culturally adaptable and accessible to diverse age groups and populations
- Creation of a configurable survey engine that includes:
  - Ability to deploy a standardized/harmonized of digital health measures across all Clinical Recovery Cohort studies
  - Ecological momentary assessment (EMA) including a customizable task queue for real-time mobile surveys
  - Randomization engine of survey items including the number of questions and the specific questions to be asked as to reduce respondent burden

Platform Device Integration & Procurement Requirements

The MHP will work with the Clinical Recovery Cohort studies to procure and distribute consumer wearable devices to participants that collect information relevant to PASC, such as:

- heart rate
- skin temperature
- sleep
- respiration rate, etc.

- Integrating data from COVID-19 testing, including serial at-home COVID-19 antigen testing to monitor possible reinfection

- MHP budgets should include the costs for procuring and deploying up to 10,000 wearable devices across sites. Deployment costs could include but are not limited to training and support, device software licenses, and postage for mailing/returning devices.

Harmonization/Standardization

The MHP will use standards-based methodologies to support the interoperability and exchange of data across the RECOVER initiative studies, with the Digital Health Data Repository and with the Data Resource Core.

- The MHP will work with the RECOVER Clinical Science Core, Data Resource Core, and Consortium to:

  - Standardize/harmonize a set of digital health measures to be collected from PASC patients for assessing the trajectory of acute COVID-19 and PASC over time

  - Share all data collected through the MHP, including data obtained through device and app integrations, with the Digital Health Data Repository using privacy and security safeguards

  - Be easily adapted to support a wide range of standardized and validated measures and instruments

  - Design and customize the MHP in a manner that enables the data it collects to be combined with the clinical data collected by the Recovery Cohort studies

Security and Privacy (PII management)

The MHP will maintain integrity, confidentiality, privacy, and security of participant study data collected. This requires the creation and maintenance of System(s) of Record (SOR) to securely contain personally identifiable information (PII)

The SORs will adhere to a Federal Information Security Management Act (FISMA)-moderate level of security controls:

- Incorporates evolving data security standards and best practices
- Conforms to regulations that ensure privacy, confidentiality, integrity, and security - particularly for data transfer
- Provides cloud storage that is HIPAA- and FISMA-compliant
- Provides capability for eConsent (e.g., adult, children, waiver of consent)
- FedRAMP authorized and compliant
- Compliant with 21 CFR Part 11
- GDPR addressed in the FAQ document: *https://recovercovid.org/docs/ota21015cd_faq.pdf*

Other Transaction Authority (OTA) Framework

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Other Transaction Authority (OTA) Framework

An Other Transaction Authority provides the NIH **greater flexibility to identify and engage nontraditional research partners**, to **engage traditional partners in new ways**, and negotiate terms and conditions that will **concentrate their efforts**, **spur innovation**, and **facilitate collaborative problem solving**.

Defined in the negative:

- Not a grant
- Not a contract
- Not a cooperative agreement

Defined in the positive:

- Is an agreement between the government and a legal entity
- Is used primarily for R&D
- Is funded from the NIH *(usually)*

OTA Framework Considerations

Proposal Formatting:

- OTA review prioritizes content of proposal and focuses evaluation on requirements as outlined in the ROA.
- Responses should focus on addressing the requirements spelled out in the ROA and the accompanying OTA package, but note that the format requirements do not limit you to requirements associated with a grant application (such as an R01).
- An important note, when submitting into ASSIST **enter OTA-21-015 and within the proposal specify** if applying to **OTA-21-015C** or **OTA-21-015D**. If you include the final letter, you will receive an error.

Proposal Content:

- The ROA and accompanying OTA submission instructions package provide guidance on what must be addressed by the proposal.
- With this mechanism, if not otherwise specified, you have flexibility to make formatting decisions as long as the content requirements are addressed. For example, the key personnel requirement could be satisfied by submitting a standard NIH biosketch template, resume, or CV.
- Additional content in the proposal such as biosketches, appendixes, or letters of support will not count towards page limits.

OTA Framework Considerations (*continued*)

Budget and Negotiation:

- There is no predetermined level of support established for any individual proposal. Each proposal's budget will be evaluated based on need, number of applications selected for award, and reasonableness of the cost based on proposal justifications along with a number of other factors that will be set forth in the published ROAs.
- OTAs are typically milestone driven. In addition to an annualized budget, applicants will be asked provide Operational Milestone-based Payment Schedules, generally this refers to a percentage of overall budget "unlocked" based on deliverable/milestone schedule. See ROA for details.
- MHP and DR awards are anticipated to be issued as sub-OT awards of the RECOVER Data Resource Core.
- What you propose may not be what we fund. NIH reserves the right to negotiate various elements of award.

Q&A

Please Post Questions in the Q&A Box

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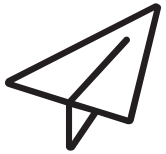
Submitting Additional Questions

For questions related to **eRA submission**, you may contact the **eRA Service Desk** through the website, email or phone.

- All contact information can be found at: **https://grants.nih.gov/support/index.html**.



For any questions related to the **ROAs**, you can reach out to **NHLBI_OTA@mail.nih.gov**

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Closing Remarks & Next Steps

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For More Information on the ROAs:

RECOVER Data Repositories ROA:

ROA: https://recovercovid.org/docs/ota21015d.pdf

FAQ: https://recovercovid.org/docs/Data-Repositories-ROA-FAQ.pdf

Mobile Health Platform ROA:

ROA: https://recovercovid.org/docs/ota21015c.pdf

FAQ: https://recovercovid.org/docs/ota21015cd_faq.pdf

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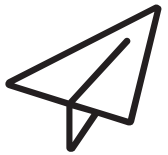
Staying connected with the RECOVER Initiative

Visit the **Research Initiative website**



Email the team at **RECOVER@nih.gov**

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