COVID-19 DIABETES ASSESSMENT

The COVID & Diabetes Assessment (CODA) Study

The NIH COVID-19 Diabetes Assessment (CODA) Study: Leveraging PCORnet for a Novel Cohort Study

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Across the Lifecourse (CoRAL)

Unite data and communities for faster, more targeted research

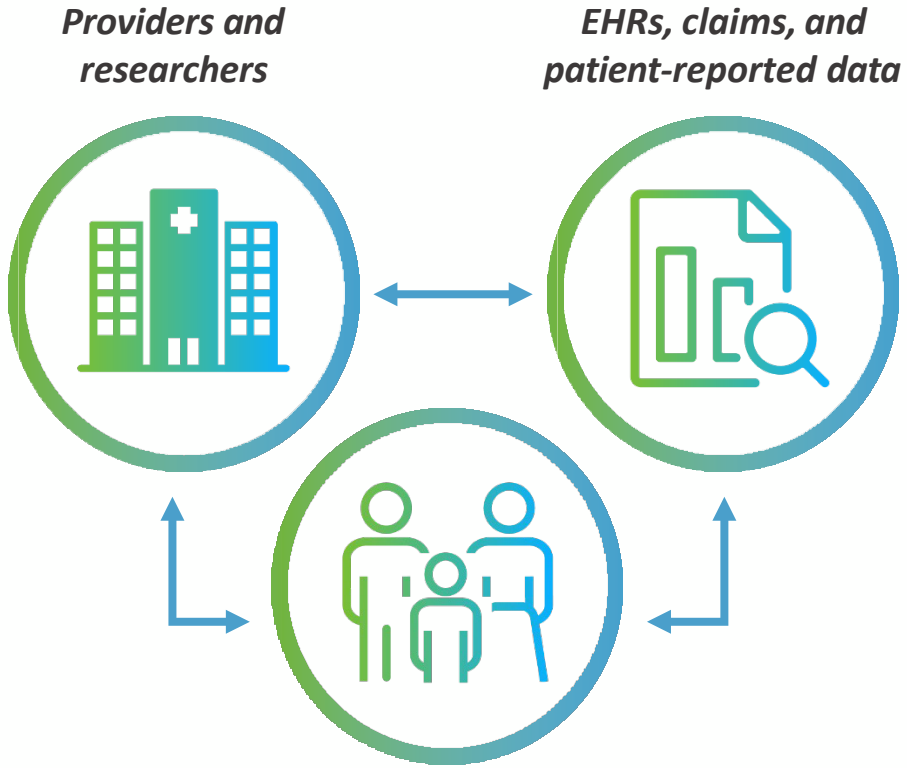
One PCORnet®, Many Possibilities

PCORnet is a national resource, funded by PCORI, where high quality health data, patient partnership, and research expertise deliver fast, trustworthy answers that advance health outcomes.

- **Real-world evidence studies**
- **Comparative effectiveness research**
- **Population health research**
- **Pragmatic research**
- **Health systems research**
- **And more**

More Than a Data Network

Access to patient partners and **thousands of clinicians** with expert knowledge of PCORnet-enabled data = meaningful research targets and faster answers.



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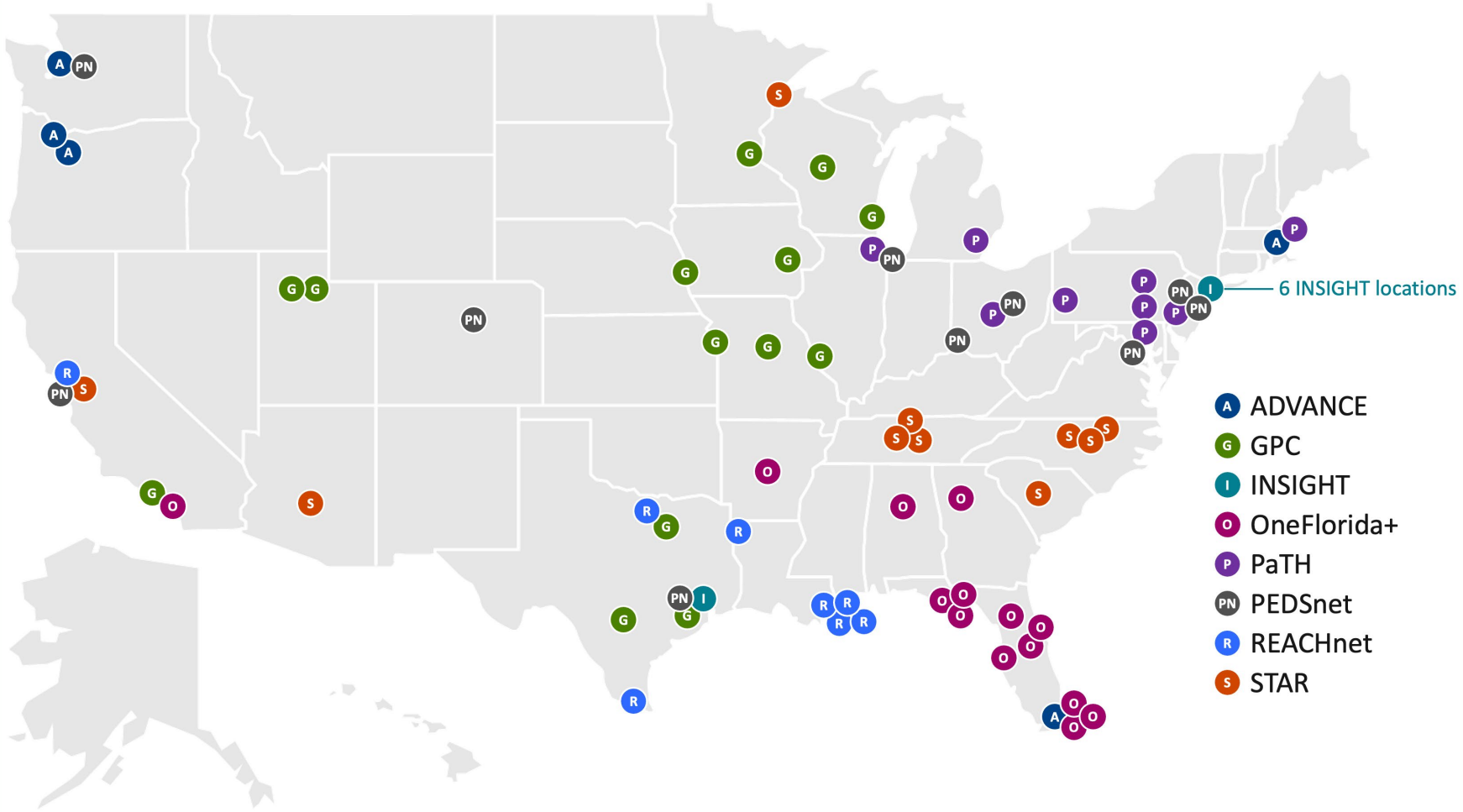
PCORnet® Clinical Research Network locations

PCORnet infrastructure offers access to real-world data through partnerships with Clinical Research Networks (CRNs)



What are Clinical Research Networks?

CRNs are groups of diverse healthcare institutions across the U.S., from large academic health centers to local community clinics, united by a commitment to speed patient-centered research via PCORnet.

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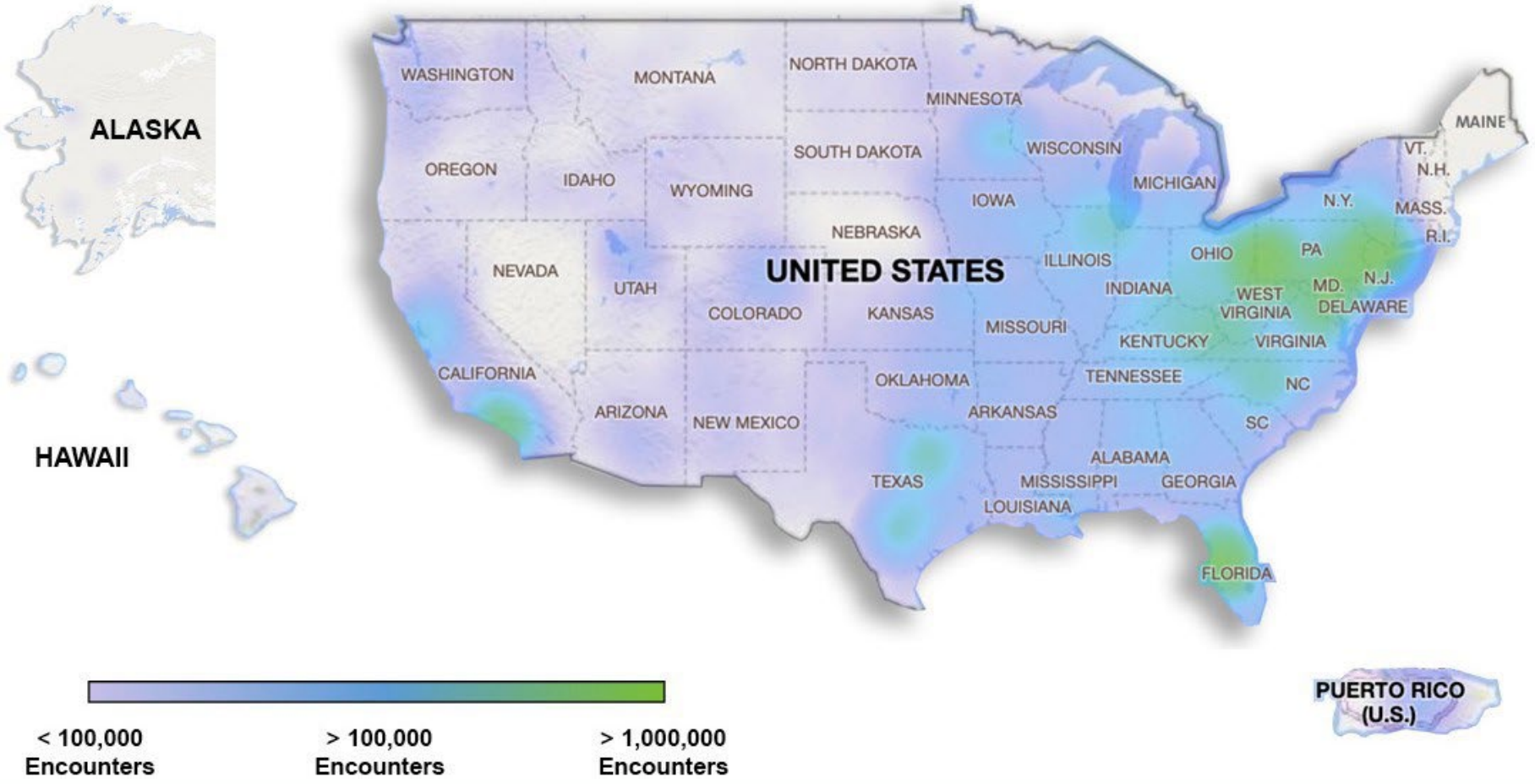
Scope of PCORnet-accessible data

PCORnet represents data from **everyday health care encounters with more than 30 million people** across the U.S. each year.



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**The data density maps illustrates single addresses that are associated with individual PCORnet Network Partner encounters.*

The PCORnet® Common Data Model

For data to be useful, it has to be standardized across systems. Frequent data curation and a single language enabled by the PCORnet® Common Data Model delivers fast insights.

Ready for Research			Available, But Still Evolving		
Demographics	Diagnoses	Procedures	Immunizations	Tumor Registry	Biosamples
Vital Signs	Labs	Clinical Observations	Social Determinants of Health	Patient-Generated Data	Genomic Results
Medication Orders & Administrations			Patient- Reported Outcomes	Natural Language Processing Derived Concepts	

Data available from Clinical Research Networks, in the PCORnet® Common Data Model and ready for use in research

Data available at some Clinical Research Networks, may or may not be in the PCORnet® Common Data Model and require additional work for use in research

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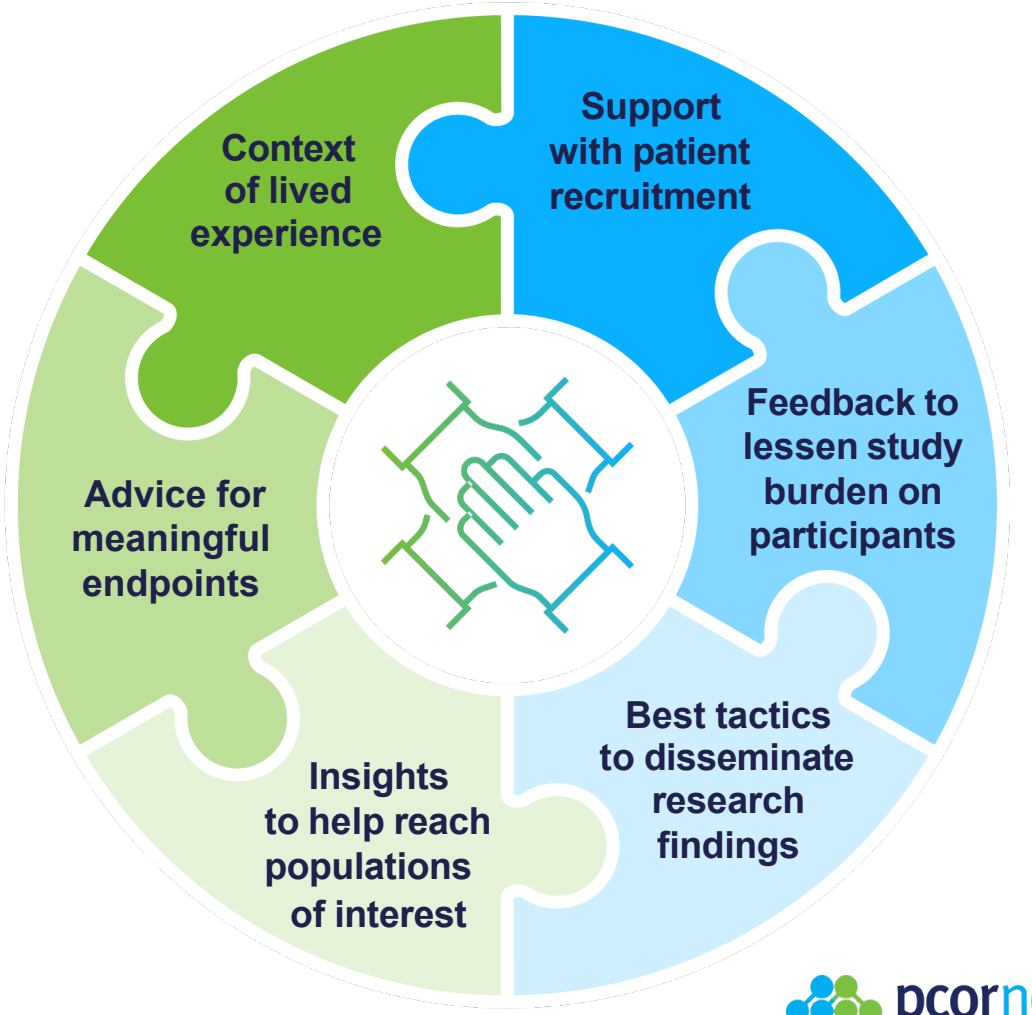
Engaged communities drive better, faster research

What do we mean by “communities”?

- **Patients and caregivers**, who have a seat at the table of every PCORnet® Study, engaging as coequal collaborators with health professionals
- **Clinicians/Clinic Staff**
- **Insurers**
- **Policymakers**
- **Others**

“Good studies consider all relevant evidence — and no evidence is more relevant than the community experience.”

— PCORnet Steering Committee Member



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The PCORnet® Front Door

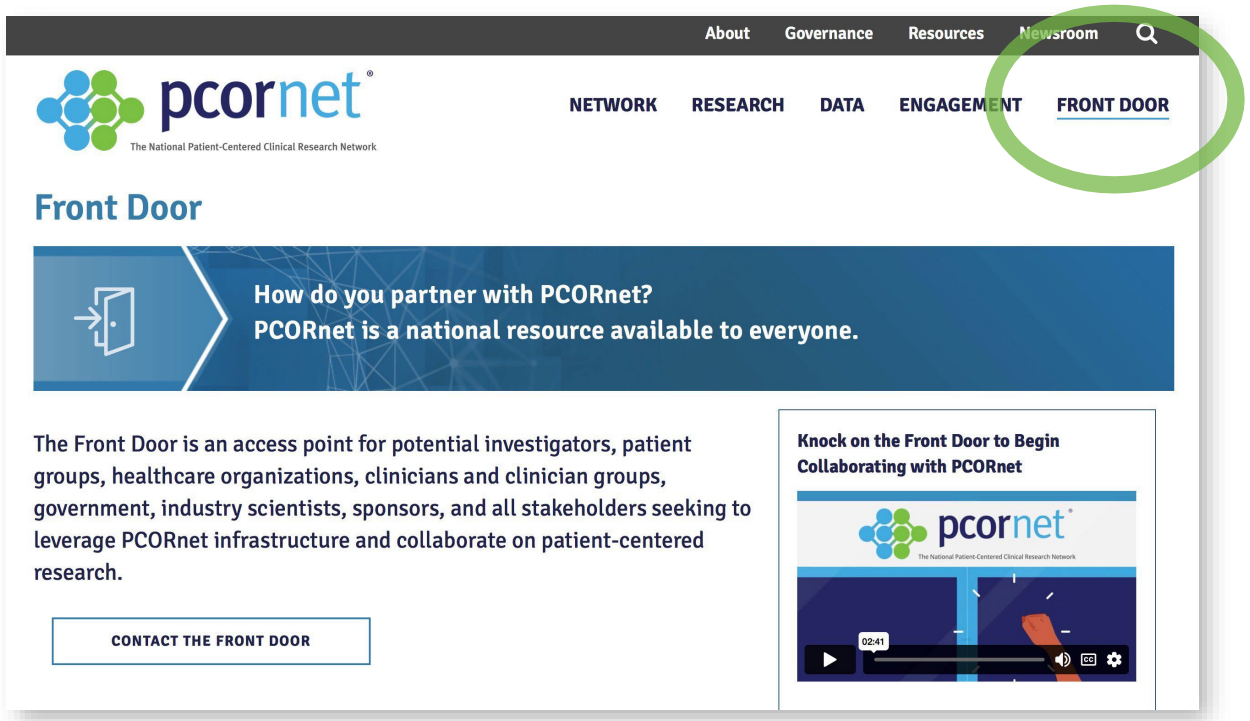
The Front Door is the Access Point for PCORnet Resources & Services

A "knock" on the Front Door can also support:

Study Design
- Preliminary data for proposals, effect sizes and potential study power

Connections to Network Collaborators
- Partners to co-design research
- People with specific expertise

PCORnet Study Designation Support
- Deeper partnership with PCORnet provides access to best practice sharing, patient engagement, and transparent quality improvement initiatives



Learn More About the Front Door

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Key PCORnet Resources for CODA Study

- Work with Front Door to rapidly identify diverse sites across PCORnet for the Study
- PCORnet CRN lead sites and their individual sites help to support identified site investigators with study start-up
  - Can run “prep-to-research” queries to understand potential participant eligibility in the study
  - Can help investigators navigate initial contracting, single IRB, budgeting and other administrative and regulatory issues
  - Can help investigators identify Partners for engagement
- PCORnet CC and CRNs help with study implementation
  - Oversight of site performance including monthly progress reports
  - Develop queries that use the PCORnet Common Data model for participant identification and for collection of participant EHR data and analyses
  - Can help optimize informatics tools including:
    - PCORnet queries or EPIC/CERNER approaches for identification and contact of study participants (based on local policies)
    - Use of REDcap for e-consent, survey collection, reminders (ex. twillio)
  - Can help with engagement and dissemination activities

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Covid and Diabetes Assessment (CODA) Study

- NIH/NIDK U01 ($28M over 4 years)
- PIs: Russell Rothman, Al Powers, Jonathan Schildcrout, Jason Block (Harvard)
- Will recruit and follow a cohort of 1600 adult and pediatric participants with recent diagnosis of T1D or T2D to examine the relationship between SARS-Cov-2 exposure and glycemic control, metabolic function, inflammation, cardiovascular risk, and patient-reported outcomes.
- Will explore the role of genomic/social/environmental factors on glycemic control, inflammation and metabolic function
- Will also leverage EHR data from 38 PCORnet health systems across the country participating in the NIH RECOVER program to explore role of COVID-19 infection on diabetes development and progression.

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The COVID & Diabetes Assessment (CODA) Study

Study Rational

- Some epidemiologic evidence suggests increases in the incidence of Type 1 and Type 2 diabetes in both adults and children + possible worsening of preexisting disease after COVID-19 infection
- Mechanisms may include direct effects on pancreatic beta cells that produce insulin, increase in inflammation, immune dysregulation, and other metabolic changes caused by infection with SARS-COV-2
- Other factors may also contribute to increased rates of diabetes and worsening of disease including social factors, environmental stressors, health disparities, and other issues.

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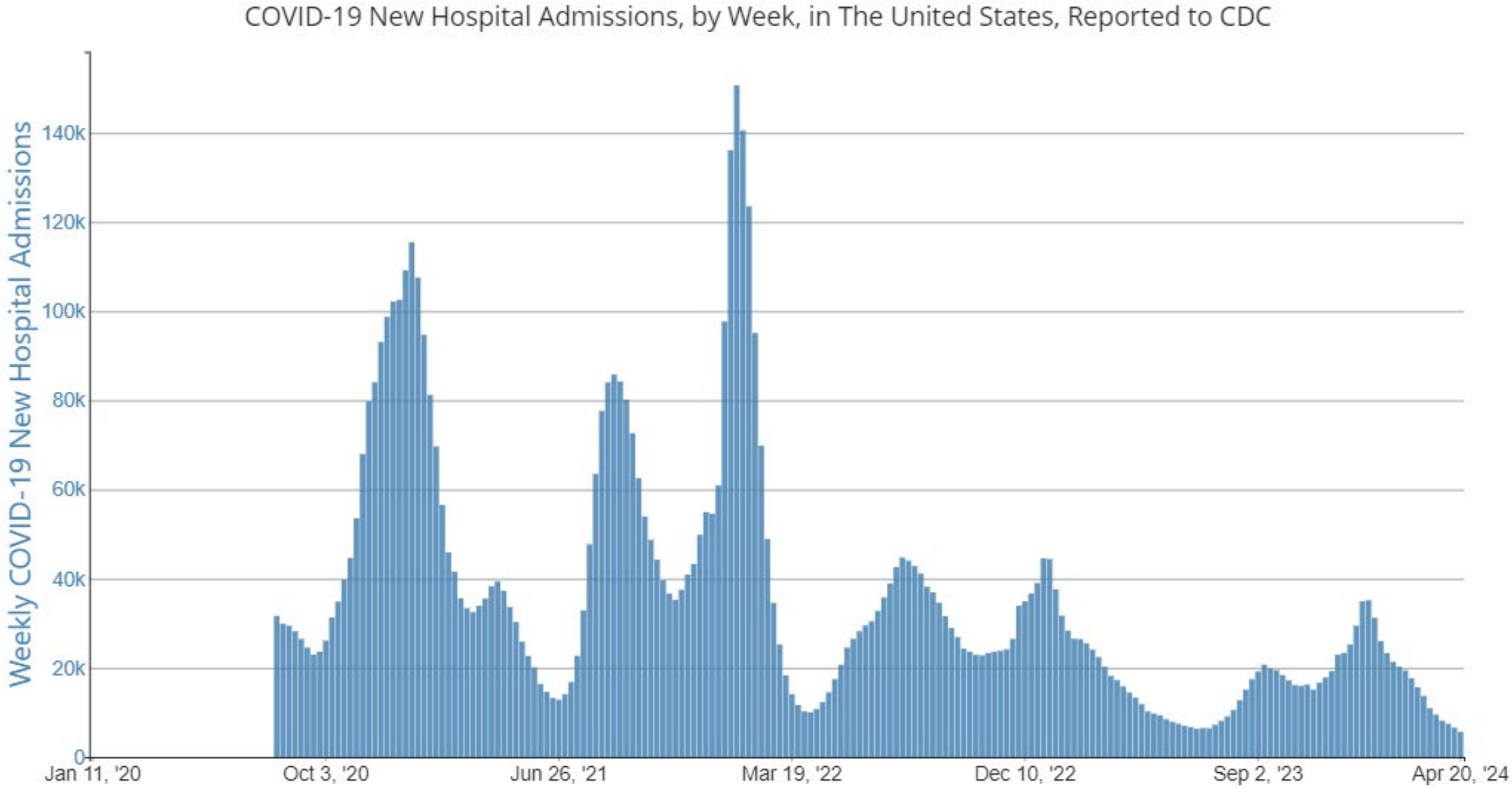

Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2024, May 01. https://covid.cdc.gov/covid-data-tracker

Study Aims

- **Aim 1:** Examine if patients with recent T2D who have recent COVID exposure are more likely to have worse glycemic control, increased inflammation and increased insulin resistance than patients without recent COVID exposure.

- **Aim 2:** Examine if patients with recent T1D who have recent COVID exposure are more likely to have worse glycemic control, increased inflammation and more rapid reduction in beta cell function than patients without recent COVID exposure.

- **Aim 3:** In a subset of patients with diabetes examine if COVID exposure is associated with worse vascular function, increased mechanistic evidence of inflammation and hypercoagulability.

- **Aim 4:** Explore the role of genomic/social/environmental factors on inflammation and metabolic function

- **Aim 5:** Integrate and leverage supplement EHR data to explore role of covid on diabetes development and potential remission (in T2DM).

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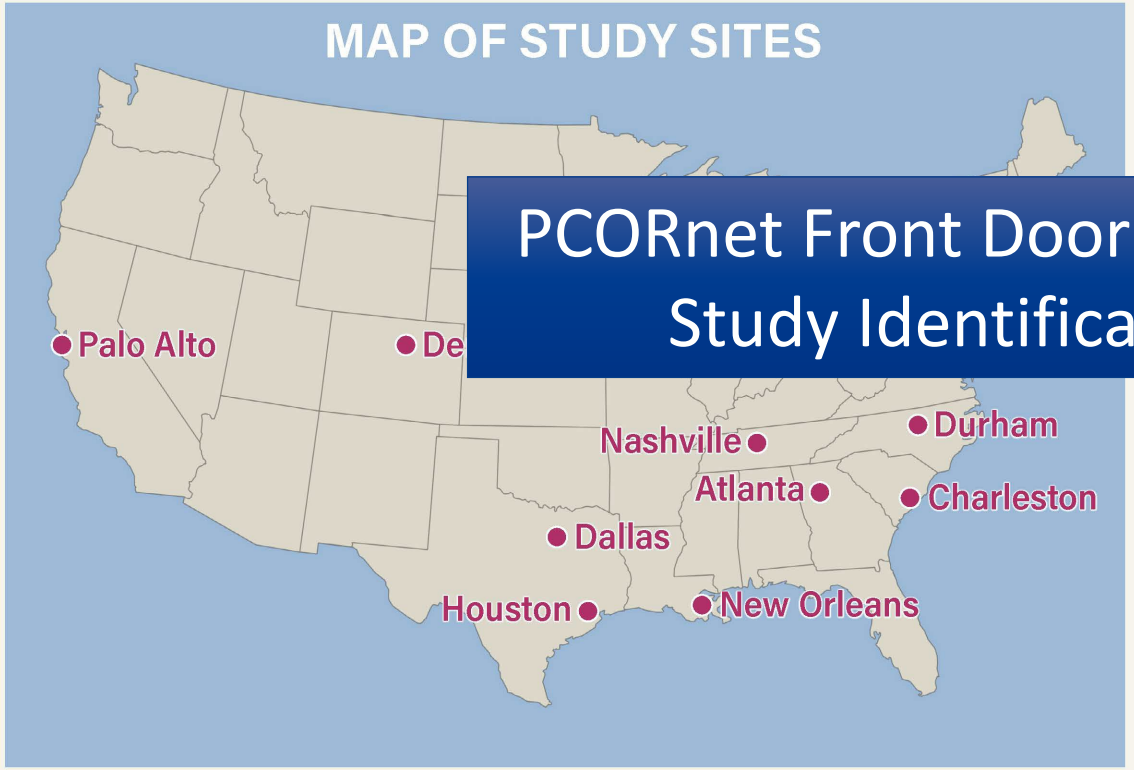
Where will this study take place?

This map shows the locations of all the CODA study sites. City names in the adjacent list, that also includes the participating medical facilities, link to that study site's section on the Study Sites page in this website.



PCORnet Front Door and CRNs helped with Study Identification and Start-Up

- **Atlanta, GA:** Emory University
- **Baltimore, MD:** Johns Hopkins
- **Charleston, SC:** Medical University of South Carolina
- **Columbus, OH:** Nationwide Children's Hospital
- **Dallas, TX:** Baylor, Scott & White Health
- **Denver, CO:** Children's Hospital Colorado
- **Durham, NC:** Duke University
- **Houston, TX:** Texas Children's Hospital – Baylor College
- **Nashville, TN:** Vanderbilt University Medical Center
- **New Orleans, LA:** Ochsner Health System
- **Palo Alto, CA:** Stanford Children's Hospital
- **Philadelphia, PA:** Children's Hospital of Philadelphia
- **Pittsburgh, PA:** University of Pittsburgh Medical Center
- **Rochester, MN:** Mayo Clinic

CODA COVID-19 DIABETES ASSESSMENT

Study Design

Baseline Data:
Genomics
Social Factors, Environmental Factors
Lifestyle Factors, Baseline health characteristics
T1D antibodies
SARS-CoV-2 Antibodies
Metabolic, Inflammatory Markers

- New T1D or T2D in past 90 days with +COVID within 180 days prior to diagnosis (~50% of sample)
- New T1D or T2D in past 90 days with +COVID within 180-365 days prior to diagnosis (~10% of sample)
- New T1D or T2D in past 90 days with –COVID within the past 365 days

1-2 years

Trajectory analysis of T1D or T2D and metabolic factors

A1C, HOMA-IR (T2D), MMTT (beta cell function), Inflammatory/Coagulopathy markers, Lipids, BP, Weight, Medications, Lifestyle, etc.
Data collection every 3-6 months

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Inclusion Criteria

1. Diagnosis of T1D or T2D in the past 90 days made by a clinician (per medical record of new elevated A1C, diabetes specific medications and/or new diagnosis of diabetes) **and**
2. Diabetes not related to ongoing steroid use, or pancreatic insufficiency from cancer, cystic fibrosis, or other infiltrating disease (per patient report),
3. COVID+ defined as a documented case of SARS-CoV-2 infection (with positive SARS-CoV-2 by PCR or rapid antigen, including home tests or prescriptions/dispensing for paxlovid, remdesivir, molnupiravir, or a monoclonal antibody used for treatment) in 365 days prior to diagnosis (ideally within 180 days) of diabetes diagnosis OR COVID- defined as no known history of COVID-19 and no use of a COVID-19 treatment in the past 365 days,
4. Willing to participate for 2 years,
5. English or Spanish speaking,
6. Age 11 years and older.

*Patients who report COVID- status will also have SARS-CoV-2 nucleocapsid antibody tests performed at enrollment and results will be batched and analyzed as part of the study
**"Past 90 days" means within 90 days of first contacting the participant, not at the time of enrollment

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Exclusion Criteria

1. Life expectancy less than 2 years
2. Insulinoma
3. Active pregnancy at enrollment or within 6 months prior to enrollment
4. Sickle cell anemia or other hemoglobinopathy
5. Dialysis dependence (**for Extensive Level engagement only**)

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Target Enrollment

Subset	COVID + (<=180 days preceding diabetes diagnosis)	COVID - (>180 days preceding diabetes diagnosis or no known COVID history)
T2DM (Adult)	400	400
T2DM (Child)	100	100
T1DM (Adult)	100	100
T1DM (Child)	200	200

Level	Total # of Participants (includes overlap)
Base Level (all surveys and basic labs +/- genomic testing)	N=1600 • 1000 T2 (500 Covid+, 500 Covid-) • 600 T1 (300 Covid+, 300 Covid -)
Moderate Level (Base Level + 4 MMT measurements)	N=400 • 200 T2 (100 Covid +, 100 Covid -) • 200 T1 (100 Covid +, 100 Covid-))
Extensive Level (Moderate Level + Biomarkers + Vascular Ultrasound	N=200 • 100 T2 (50 Covid+, 50 Covid-) • 100 T1 (50 Covid+,50 Covid-)

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Schedule of Events

Event	Population	Baseline	3 mos	6 mos	12 mos	18 mos	24 mos
Informed Consent/Assent	All	X					
Demographics	All	X					
Weight, Height, WHR, BP	All	X	X	X	X	X	X
Electronic Health Records Query	All	X			X		X
Record Type 1 antibodies (anti-gad, anti-insulin, anti-islet cell ab) from EHR	Type 1 Diabetes only	X					
Blood collection for Central Laboratory[1]	All	X	X	X	X	X	X
Adverse Event Assessment	All	X	X	X	X	X	X
Self-reported concomitant medications, medical history, vaccine history, care utilization, & death	All	X	X	X	X	X	X
Participant Questionnaires	All	X	X	X	X	X	X
Optional Procedures							
Mixed Meal Tolerance Test (MMTT)	Subsample	X	X	X	X		
Vascular Integrity (SphygmoCor)	Subsample	X			X		
Continuous Glucose Monitoring (CGM)[2]	Subsample	X	X	X			

[1] Collect One of each 10 mL EDTA, 6 mL Na Citrate, 6 mL serum at each visit.

[2]Participants with existing CGM may consent for CGM data to be shared with the study team. A subset of participants will be asked to wear a masked CGM for a 10-day period. Participants who develop COVID during the study who agree to have a CGM placed will be mailed 2 masked CGM devices for data collection.

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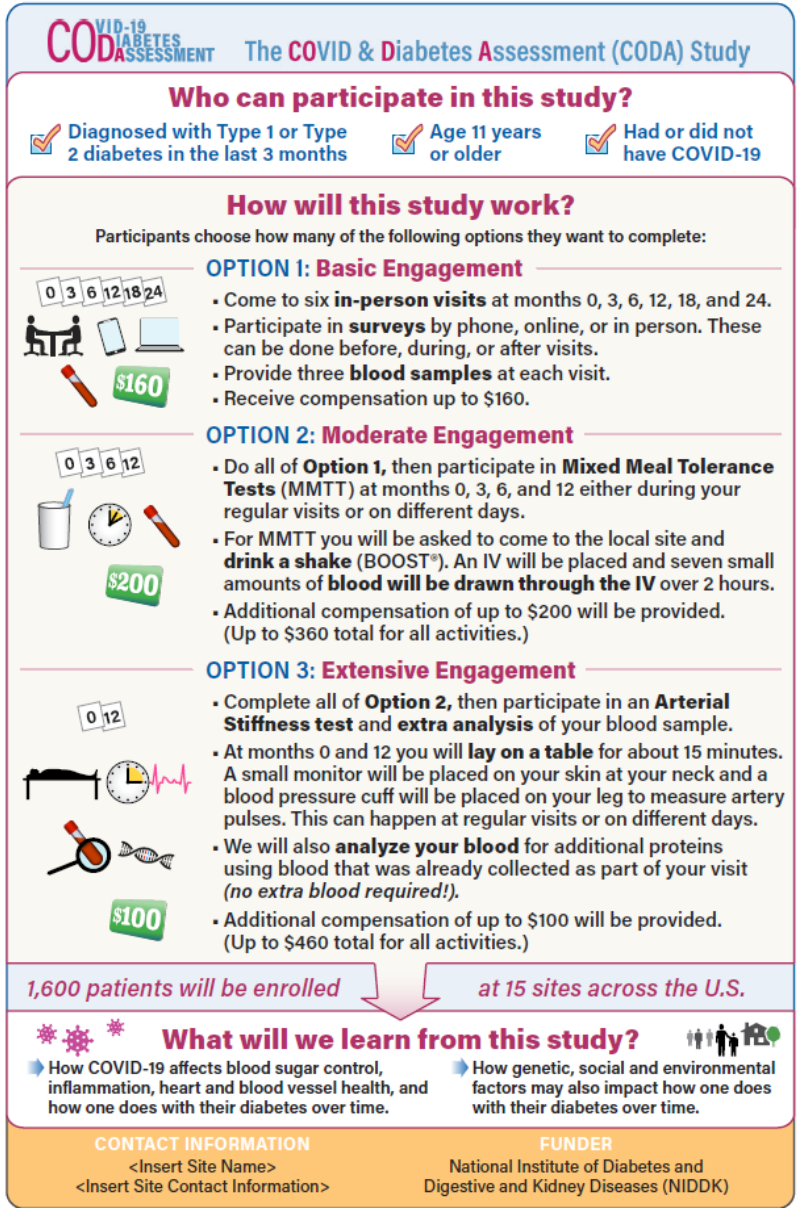
Data Element	Population	Baseline	3 mos	6 mos	12 mos	18 mos	24 mos
Demographics, Socioeconomic status, Residential characteristics, Health literacy/numeracy	All	X					
Weight, Height, WHR, BMI, BP	All	X	X	X	X	X	X
Life stressors, including discrimination, loneliness, food insecurity	All	X	X	X	X	X	X
Behaviors, including physical activity, smoking, diet, sleep	All	X	X	X	X	X	X
Functional and mental well-being (e.g. PROMIS)	All	X	X	X	X	X	X
Adverse Event Assessment	All	X	X	X	X	X	X
Self-reported concomitant medications, medical history, vaccine history, care utilization, & death	All	X	X	X	X	X	X
Electronic Health Records Query	All	X			X		X
Hemoglobin A1C	All	X	X	X	X	X	X
Complete Metabolic Panel (CMP)	All	X			X		X
HOMA-IR (fasting insulin and glucose)	Type 2	X	X	X	X		X
hs-CRP	All	X	X	X	X		
Type 1 antibodies (anti-gad, anti-insulin, anti-islet cell ab) (from EHR)	Type 1	X					
SARS-CoV-2 nucleocapsid antibodies	All	X			X		X
Genome Array	Subsample	X					
Mixed Meal Tolerance Test (MMTT)	Subsample	X	X	X	X		
Inflammatory & Coagulopathy Markers	Subsample	X			X		
Arterial Stiffness (Sphygmocor)	Subsample	X			X		
CGM Data*	Subsample	X	X	X			

Recruitment and Enrollment

- Identify participants based on local sites, including
  - EHR or Research Data Warehouse
  - [redacted]
  - [redacted]
- Consent via Phone with email/docusign
- Participants are considered enrolled after assent/consent and completion of baseline surveys and blood collection

CRNs can use PCORnet CDM, EPIC, or CERNER tools for patient identification

Many CRN sites have "Opt-out" Consent Procedures



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Study Activities

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Participant Procedures

Basic Level (1600 participants)

- Surveys of participants/parents/children
- Blood draws
- Possible CGM on subsample of participants
  - At 0, 3, and 6 months
  - During acute episode of COVID
- Evaluation of serum for genetic information (600 participants)

Moderate Level (Basic +MMTT) (400 participants)

- Basic Level, and
- 2-hour Mixed Meal Tolerance Test at 0,3,6,12 months

Extensive Level (Moderate Level+ Vasc US + Proteomics)

- Moderate level, and
- SphygmoCor Device to assess Arterial Stiffness at 0, 12 months
- Evaluation of proteomics from baseline blood (from baseline blood draw)

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Surveys and Physiologic Assessments

- Surveys at 0,3,6,12,18,24 months
  - Can be completed online or via mobile device or at F2F visit
  - Vanderbilt Survey Core available to phone participants who do not complete surveys (20%)
  - Available in English and Spanish

- Physiologic Assessments
  - Height, Weight, and Waist-to-Hip Ratio (using WHO guidelines)
  - Blood Pressure (using automated blood pressure machine and WHO guidelines)
  - Blood Draws

- Medication reconciliation and targeted chart abstraction for labs
  - Labs for chart abstraction: A1c, autoantibodies, insulin, c peptide; doesn't have to happen at the visit
  - Medication reconciliation for all active medications; should happen at visit

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Blood Draws

- Occur at each face-to-face visit (0,3,6,12,18, and 24 months)
- Need to fast for 8 hours overnight and then present for morning blood draw.
- Ask them to bring food that they can take after they are done with the blood draw and any other procedures (ex. MMTT and Sphygmocor)
- Type 1 participants should continue their insulin as normal, and treat lows as needed
- Type 2 participants need to hold blood sugar lowering medications (See next slide)
- Phone, Email, and Patient Portal Scripts are available for Fasting Recommendations

Mixed Meal Tolerance Test (MMTT) Overview

- Only collected on subset of 400 participants that agree to MMTT
- Perform at 0,3,6, and 12 months in Moderate/Extensive Participants
- Requires Clinical Research Center or Similar Facility
- Participants with the Ilet pump (autonomous) are EXCLUDED
- Requires:
  - Fasting overnight and potential holding of medications
  - Check of BG in am prior to procedure to confirm eligibility (preferably at home)
  - Placement of IV (for collection of samples)
  - Provision of Boost per protocol (to be provided locally)
  - Collection of 7 blood samples
  - Processing of **samples**; batching and shipping samples to Vanderbilt Hormone Assay Core

NOTE: This is a separate sample collection from the main study labs. *Will be reviewed later in this presentation.*

Time (min)	Blood Sample Taken
-10	X
0	X
Boost® High Protein	
15	X
30	X
60	X
90	X
120	X

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SphygmoCor

- SphygmoCor measures Carotid-Femoral Pulse Wave Velocity (cfPWV) to assess arterial stiffness

- Methodology
  - Measures time delay of the pulse wave between two arterial sites and divides this time by the distance between sites
  - Easy to administer and reproducible

- Clinical relevance
  - Increased cfPWV indicated reduced arterial elasticity and CV risk

- Will perform at 0 and 12 months
- Perform right before MMTT
- EXCLUDE participants on hemodialysis

Targeted query of EHR data

- Will supplement information captured through in person visits and survey by querying participants' EHR data using the standard PCORnet processes for capturing this information.
- Utilize a modular SAS program to pull patient-level data available in the PCORnet Common Data Model, a standardized version of clinical data entered into the EHR.
- Will capture longitudinal weights, heights, medications, and A1c measures; will supplement this with target chart abstraction for laboratory measures and medication reconciliation..
- Process will require mapping done by sites to identify participants on whom to run the query; PCORnet uses a patient identifier (PATID) that will need to be mapped to the medical record number to facilitate data query.

Leveraging PCORnet to Collect More Comprehensive Participant Data

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Potential Additional Procedure:
Continuous Glucose Monitoring

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CONTINUOUS GLUCOSE MONITORING

- CGM may help to detect signs of beta cell deterioration in early T1D, or signs of worsening glucose tolerance/insulin resistance in patients with T1D or T2D.[1]

- In addition, several recent studies have suggested that an increase in glucose variability (GV) may be associated with increased risk for deterioration in glycemic control, cardiovascular disease, and even mortality.[2]

- Recent studies have also shown that evaluating CGM can help to better identify glucose abnormalities such as time in range, (TIR) or time above range (TAR), or hypoglycemia that may not be appreciated in a Hemoglobin A1C measure that is the average glucose control over 2-3 months

PROPOSE 3 APPROACHES TO ADD CGM

<u>Approach 1:</u> Collect CGM Data from Participants Already Using Them.

- For enrolled patients who already have a CGM they will share via the manufacturer data sharing platform (ex. Clarity, LibreView)

<u>Approach 2:</u> Provide Blinded CGMs to a Subset of T2DM Participants at 0, 3, and 6 Months.

- Provide blinded Dexcom CGMs to a subset of 300 participants with T2D (150 COVID+ and 150 COVID-) at baseline, 3 and 6 months. CGM sensor placement at the study site during a scheduled visit

<u>Approach 3:</u> Provide blinded CGMs or collect CGM data from participants who develop COVID during the CODA study.

- Participants with a CGM (predominantly T1D and a few T2D): we will ask them to share their data electronically.
- Participants without a CGM (predominantly T2D) will be mailed 2 Dexcom G6 pro CGM sensors to collect a 20-day profile (10 days each sensor) *Will provide instructions and video on how to insert the CGM.

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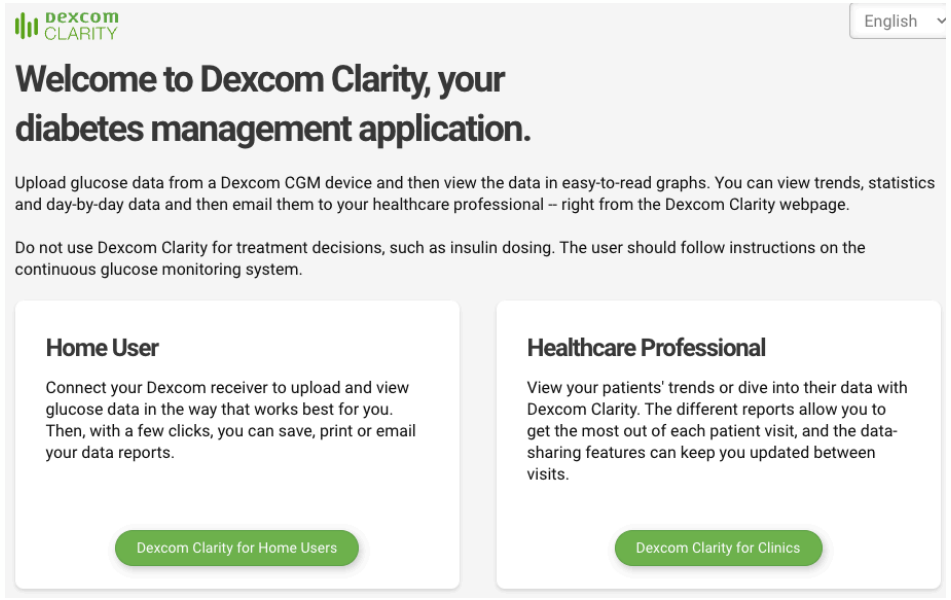
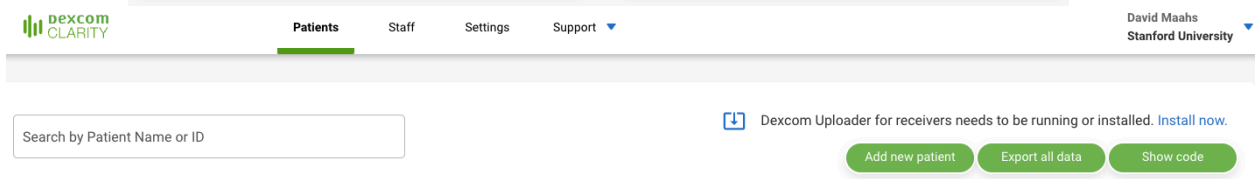
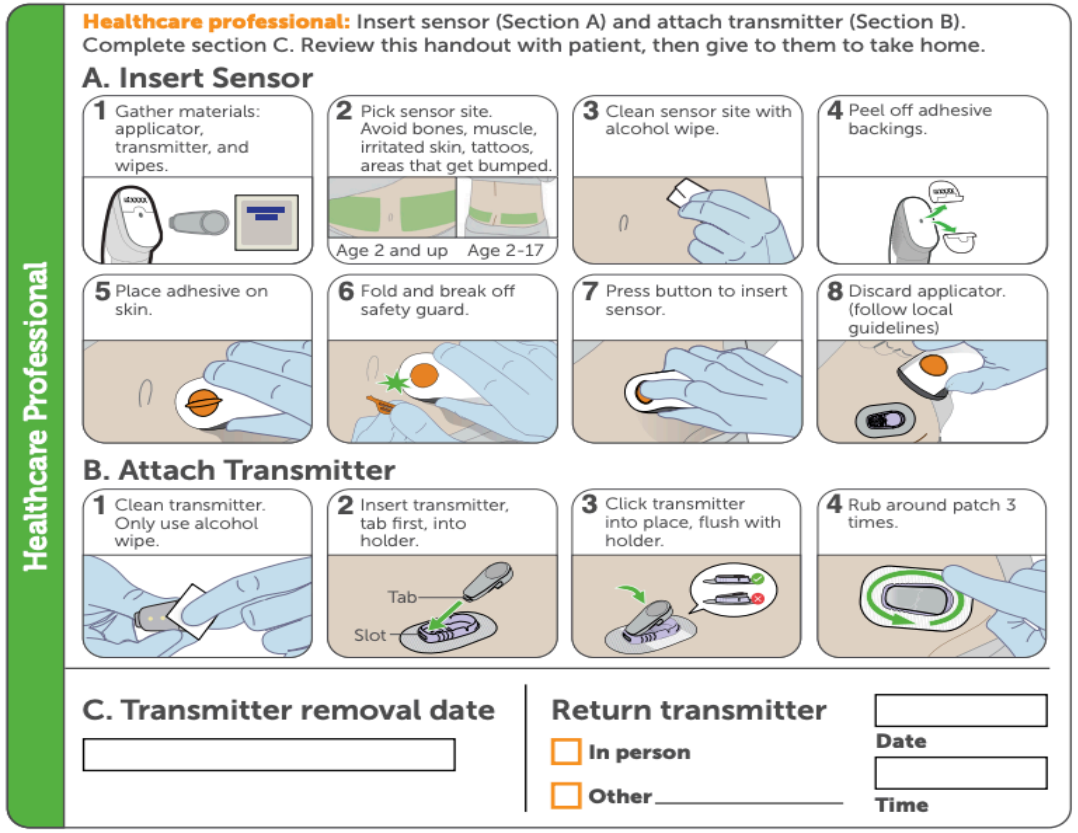
CGM Study Materials to Support Activities

- Information about setting up accounts
- Information and handouts about sharing data
- Information and handouts/videos about placing and removing devices
- Information and handouts about mailing devices







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Aim 5 – EHR-only based analysis in RECOVER data enclave

- 5a: Among those with SARS-CoV-2 testing, assess association of SARS-CoV-2 infection (vs. not) with incidence of diabetes (1 and 2) after SARS-CoV-2 infection by SARS-CoV-2 variant
- 5b: Among those with incident diabetes, assess association of SARS-CoV-2 infection (infection vs. not) with diabetes outcomes (A1c, utilization, # meds, insulin)
- 5c/d: Among those who test positive with SARS-CoV-2, assess
  - Incidence of diabetes (1 and 2) after treatment with paxlovid vs. no treatment
  - Diabetes outcomes after treatment with paxlovid vs. no treatment

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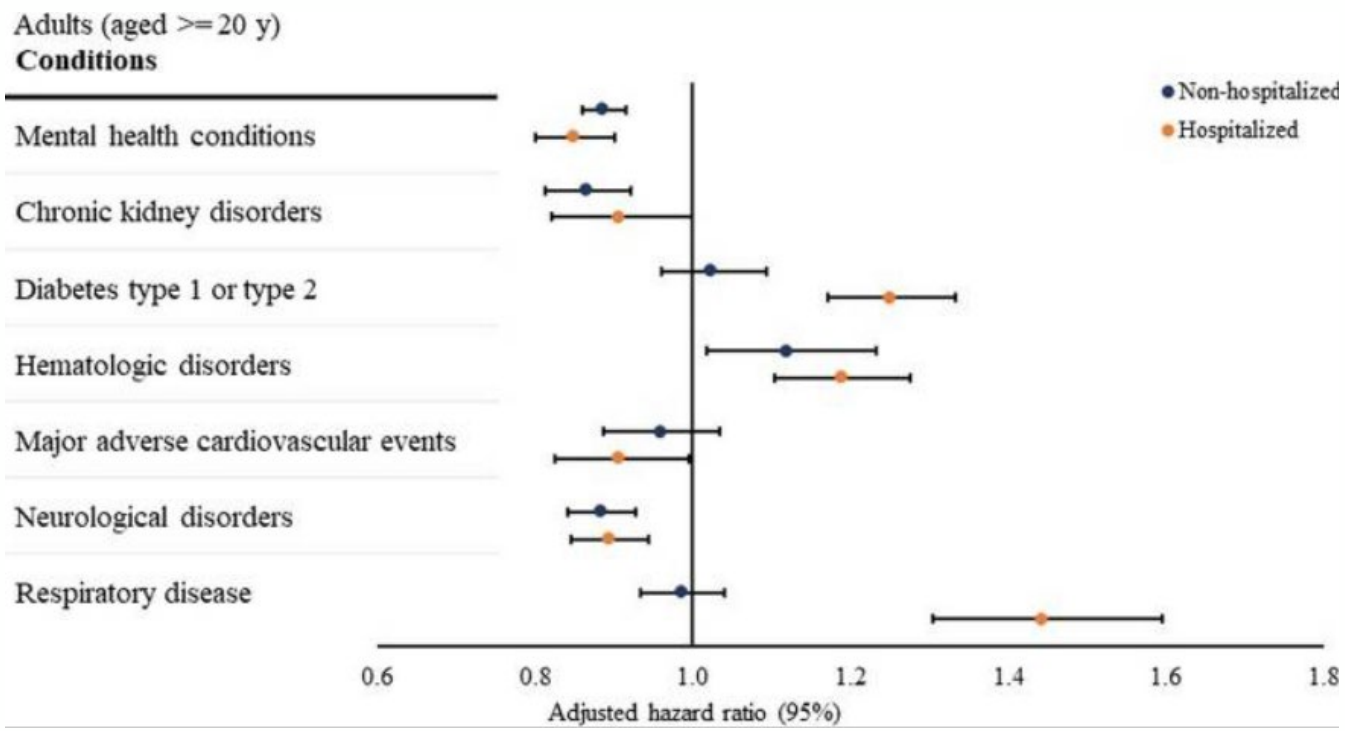
Prior Study in PCORnet on Post-COVID Diabetes

- Study funded by contract with CDC for COVID-19 surveillance with involvement with RECOVER team
- Investigated association of SARS-CoV-2 positive test with selected conditions and symptoms
- Utilized data from March 2020-May 2021 on 316k SARS-CoV-2 + and 2.8 million SARS-CoV-2 -



Zhang, et al., BMC ID, 2023.

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Aim 5a: Differential incidence of DM by variant period

- Ancestral: March 2020-Sept 2020
- Winter 2020/21: Oct 2020-Feb 2021
- Alpha: March-June 2021
- Delta: July-Dec 2021
- Omicron: Jan -Dec 2022

Aim 5a inclusion criteria

- Will limit to those who were seen in the emergency department or inpatient setting
  - Outpatient testing very limited, especially “negative” testing

- Require at least 2 encounters within 3 years (or 1 encounter in 1 year) prior to testing and 1 encounter in the year follow exposure (“loyalty cohort” or “medical home”)

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5a: exposure, outcome, sensitivity analysis

- Exposure: covid + (exposed) vs. covid - (unexposed), 3/2020-12/2022
  - Would remove those with COVID dx code within 180 days from the COVID negative group
- Outcome: diabetes in the 31-to-180 day period after index
  - A1c ≥ 6.5%; meds excluding insulin inpatient/metformin/SGLT2/GLP1; DM diag code (2 outpatient, 1 inpatient or with med)
- Sensitivity analysis could examine 1) patients who were COVID + or received COVID meds (not COVID dx codes) and 2) only patients who had hemoglobin A1c <6.5%

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The COVID & Diabetes Assessment (CODA) Study

Baseline confounders to include

- Demographics and healthcare utilization; presence of A1c
- Prior COVID infections (for those with >1), prior vaccination (missingness?)
- COVID severity and use of therapeutics
- Baseline BMI within 90 days of index; possibly weight trajectory
- Underlying conditions
- Use of metformin, SGLT2, GLP1

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Aim 5b and differences in approach

- Population will be limited to patients who are diagnosed with diabetes
- Outcomes to be assessed will be a range of continuous, count and binary measures: A1c measurement, use of insulin, number of DM medications, hospitalizations, remission from diabetes
- Plan to use a similar approach here perhaps with survival analyses for some of the outcomes (use of insulin, hospitalizations, remission from diabetes) and linear/Poisson models for outcomes of a1c and numbers of DM meds
- In models, would likely need to include some weights for likelihood of followup

Aims 5c/d – role of COVID medications on incidence of diabetes and diabetes-related outcomes

- Aims will be focused on whether prescriptions of Paxlovid, monoclonal antibodies, molnupiravir and possibly remdesivir are associated with incidence of T1D and T2D (similar to Aim 5a) and diabetes-related outcomes (similar to Aim 5b)
- Aims will only include patients who have tested positive for SARS-CoV-2, some of whom received medications
- Will compare patients who received medications to those who did not receive medications on the outcomes of diabetes incidence (Aim 5c) and diabetes-related outcomes (Aim 5d)
  - In this case, we are asking a causal question and can use inverse probability weighting for likelihood of receiving a medication and for follow-up, with marginal structural models

Summary

- PCORnet is a national network available for a broad array of research including pragmatic trials, real world evidence research, and cohort studies
- PCORnet has a wide array of resources and capabilities to enhance research including:
  - PCORnet Common Data Model
  - Informatics Tools and experience leveraging tools for research
  - Administrative efficiencies
  - Partner Engagement
- Opportunities to leverage the PCORnet Common Data Model for direct collection of data from enrolled study participants, and for ancillary/complementary research

CONTACT INFORMATION FOR CODA

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- **Can also contact:**
  - **Jessica Marlin** – Sr. Project Manager for VUMC Admin Core for Research Issues
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DISCUSSION & QUESTIONS

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