Health Plan Research Networks (HPRN): Data Linkage Activities to Facilitate Longitudinal Pragmatic and Observational CER
What is PCORnet?

PCORnet is a national patient-centered clinical research network developed by the nonprofit Patient-Centered Outcomes Research Institute (PCORI). PCORnet seeks to improve the nation’s capacity to conduct clinical research by creating a large, highly representative, national patient-centered network that supports more efficient clinical trials and observational studies.

Patient-Powered Research Network (PPRN)
Clinical Data Research Network (CDRN)
Health Plan Research Network (HPRN)
Introductions and Outline

HealthCore-Anthem Overview
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  - PI: HealthCore/Anthem Research Network (HCARN)

Humana’s Comprehensive Health Insights Overview
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  - PI: HUMnet

ADAPTABLE Trial Support
- Longitudinal Data Support
- Recruitment Support at Specific Sites
- As a Recruitment Site

Obesity Observational Studies
“Payers probably have the most complete data set but it's not timely. Doctors have the most acute data but it’s not complete. And patients have most relevant data, but it's not actionable.” – Craig Samitt, Executive Vice President and Chief Clinical Officer of Anthem
Anthem: A Health Benefits Leader

- ~71M individuals served
- 1 in 9 Americans
- 39.5 million total medical members in affiliated health plans
- $213 billion benefits paid

Map of the United States showing BC or BCBS licensed commercial plans (14)

- Local Group: 40%
- National Accounts: 19%
- BlueCard®: 14%
- Medicaid: 14%
- Individual: 5%
- FEP: 4%
- Medicare: 4%

1 in 9 Americans served.

39.5 million total medical members in affiliated health plans.

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Map of the United States showing BC or BCBS licensed commercial plans (14).
HealthCore Integrated Research Environment - HIRE

HIRD

Anthem Health Plans & Affiliated Businesses
Anthem, BCBS, Empire, Other Blues

Clinical and Scientific Expertise

Provider Community
Physician Practices
Hospitals
Integrated Delivery Systems
Pharmacies
Ancillary Services

Member/Patient Community
Surveys
Focus Groups
Medical Charts
Registries

Actionable Information

Physicians, Industry, Health Plans, Employers, Regulatory, Patients
HealthCore Integrated Research Database

HIRD℠

Administrative Claims Data
- Member Identifier
- Plan
- Gender
- Age
- Dates of Eligibility

Physician and Facility Claims Data
- Member Identifier
- Physician or Facility Identifier
- Procedures (CPT-4, Revenue, ICD-9/10 and HCPCS Codes)
- Diagnosis (ICD-9/10 CM)
- Admission and Discharge Dates
- Date and Place of Service
- Dollar Amounts

Rx Claims Data
- Member Identifier
- Prescribing Physician
- Drug Dispensed (NDC)
- Quantity and Date Dispensed
- Drug Strength
- Days Supply
- Dollar Amounts

Lab Test Results Data
- Member Identifier
- Lab Test Name
- Result
Claims Data Availability

62.5 million researchable lives total with medical eligibility

40.2 million researchable lives total with both medical and pharmacy eligibility

Millions with continuous eligibility for:

- 1 year: 26.8
- 2 years: 18.7
- 3 years: 13.3
- 4 years: 9.6

13.8 million lives with electronic outpatient laboratory result data
HIRD - Researchable Population Density by State

Medical and Pharmacy

Anthem states*

- California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, Wisconsin

*California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, Wisconsin
HIRD vs US Census - Demographic comparison

Age group distribution

![Graph showing age group distribution for HIRD and US Census]

- HIRD Total
- HIRD Male
- HIRD Female
- US Census Total
- US Census Male
- US Census Female

Demographic comparison between HIRD and US Census for various age groups.
PCORnet Sustainability
Comprehensive Health Insights
A Humana Company

Data. Evidence. Insight.
CHI is a wholly owned subsidiary of Humana, conducting research studies for clients using access to Humana real world data.

CHI delivers research, financial and decision making information to clients.

**Research Team** CHI staff is made up of research professionals with either Master’s or Doctoral degrees.

- **Doctoral Degree**
  Over 73% of the team hold doctoral or other advanced professional degree

- **Masters Degree**
  Over 97% of the team have one or more Master’s degrees
Distinguishing Humana’s Data

CHI accesses Humana’s extensive claim-based data set, the 2nd largest Medicare population with >3 Million Medicare Advantage and >6 Million Medicare Part D members. We regularly access medical, pharmacy, and lab claims derived from traditional claims processing, ePrescribing, charts, and increasing visibility and connectivity to electronic medical records.

Our datasets include medical (inpatient, outpatient, emergency room, office, etc.) pharmacy, and laboratory claims for its served populations. In addition, continuous enrollment, formulary and benefit design, physician arrangements, and member cost share are frequently available.

Unique Member Identifier

- A single unique identifier is assigned to every member
- It remains constant regardless of any change or gap in enrollment
- Transitions between lines of business

Additional Member Data

- Eligibility
- Benefit Design
- Demographics
  - Geography
  - Race / Ethnicity (direct for Medicare and by Geocode proxy for Commercial)
- Complementary consumer data (e.g. census education level, estimated household income)
- Humana Behavioral Segmentation
Integrated Data: Consumer and Reported Outcomes

**Consumer Data**
- Different Levels of Matching
- Consolidated (100%) Table
- Refreshed every 2 months

**Reported Outcomes**
- Providers
- Caretakers
- Patients

**Unique Identifier**

**Source Data**
- EMR / HIE
- Consumerism Data
- Medical Claims
- Laboratory Claims
- Pharmacy Claims
Data Identification

CGX: Clinical Guidance Exchange

Utilization Management (UM)
- The process of evaluating the necessity, appropriateness and efficiency of health care services.

Case Management (CM)
- A method of managing the provision of health care to members that will coordinate the care to improve both continuity and quality of care and to lower costs.

- Contains data on Humana members starting from 2011
- Examples: assessment answers, clinical review data, authorization information
- Multiple types of authorizations – prior, post, concurrent
- One member can have multiple authorizations
Integrated Claims for Research

- Medical
- Pharmacy
- Laboratory

Distinct Members with claim activity

Distinct members by claims source

Two-way integration

Full integration

Membership from 1/1/2007-9/30/2016
Humana Research Database Population - Historical As of 9/30/2016
Geographic Breakout by line of business for current members (as of 9/30/2016)

Humana Research Database Population - **Commercial** as of 9/30/2016

Humana Research Database Population - **Medicare** as of 9/30/2016
Principles for Conducting Pragmatic Clinical Trials in Learning Health Care Systems

- Leverage available medical data from electronic health records (EHRs) and **administrative claims** to identify eligible patients.
- Ascertain endpoints as part of routine healthcare delivery and **administrative claims**.
- Simplify baseline and follow-up data collection through **systematic direct patient contact** (patient-reported outcomes) and **multiple data sources**.
- Recruit large samples of patients within healthcare systems to limit selection bias and provide more generalizable results.
- ADAPTABLE is the **first large scale pragmatic** trial conducted via PCORnet in **learning health care systems**.

ClinicalTrials.gov: NCT02697916
CDRNs and Health Care Systems Participating in ADAPTABLE

This map depicts the coverage of health systems within Clinical Data Research Networks (CDRN) participating in ADAPTABLE.
ADAPTABLE Study Design

Patients with known ASCVD + ≥ 1 “enrichment factor”

- Identified through EHR (computable phenotype) by CDRNs
- Or by administrative claims (computable phenotype) by HPRNs

- Patients contacted with trial information and link to e-consent;†
  - Treatment assignment will be provided directly to patient

- ASA 81 mg QD
- ASA 325 mg QD

- Electronic follow-up: Every 3 or 6 months
  - Supplemented with EHR/CDM/claims data

- **Duration:** Enrollment over 24 months;
  - maximum follow-up of 30 months

**Primary endpoint:**
- Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke

**Primary safety endpoint:**
- Hospitalization for major bleeding

† Participants without internet access will be consented and followed via a parallel system.
Endpoint Ascertainment

Patient Reported Hospitalizations

ADAPTABLE Patient Web Portal

ADAPTABLE Trial Endpoints

Event algorithms

Match?

Call Center verification

Yes

No

PCORnet

EHR

Supplemental Linkages

Medicare Claims

Private Health Plan

Yes

No
Bariatric Obesity Observation Study

**Aim 3:** What is the frequency of major adverse events following these three different bariatric surgical procedures at 1, 3, and 5 years?

- HPRNs have longitudinal data access to assess outcomes
- Identify rehospitalizations and reinterventions that occur outside the initial hospitalization
- Also death that occurs in an outside hospital admission can be captured in HPRN data environments

Early work can characterize populations of interest without data sharing to identify meaningful collaborations
Pediatric Antibiotic Obesity Observation Study

Issues of misclassification of antibiotic exposure
- CDRN data is prescribing, not dispensing, data
- HPRN data lacks prescribed but not dispensed or cash paid dispensings

Prescription data probably overestimate dispensings, and the overestimate is likely not related to excess weight gain.
- However CDRNs lack the prescription data from external health systems and so can not truly conclude that a single health system data overestimates dispensings

Early work can characterize populations of interest without data sharing to identify meaningful collaborations
HPRN Sustainability Discussion

- Founding partners in the Sentinel FDA
  - Vast experience with the Common Data Model
  - Has lead to other CDM collaborations
    - NIH Collaboratory Distributed Research Network
    - RUF-IMEDS
    - AMCP-BBCIC
- Active engagement with PCORI and PCORnet
- Exploring sustainable collaborations with networks
- Engaging the leadership with the People Centered Research Foundation (PCRF)