

Wake Forest University School of Medicine

<https://www.wakehealth.edu/>

PCORnet® Network Partner in STAR since 2018

The purpose of this Site Profile is to provide an overview of the basic research processes at Wake Forest University School of Medicine. This profile can help you understand: the types of patients within the electronic medical records; current PCORnet® Study participation; patient recruitment methods and institutional procedures related to Institutional Review Board and contracting; and data linkages.

Table 1. Characteristics of the patient population between January 1 – December 31, 2024

The characteristics of the patient population presented in this table are based on data from the health system’s electronic health records mapped to the PCORnet® Common Data Model as of September 2025 and do not reflect any public-facing or official characteristics reported by the health system or its partners. This data can be used to help inform researchers of the types of patients, care settings, and location data that are available for research.

Unique Patient Records	>1,000,000 [presented as range]
AGE IN YEARS	%
Children 0-9	14 %
Children 10-19	11 %
Adults 20-34	17 %
Adults 35-54	23 %
Adults 55-64	13 %
Adults 65-74	12 %
Adults 75+	10 %
SEX	
Female	57 %
Male	43 %
Unknown	<1 %
Missing	<1 %
RACE	
White	63 %
Black or African American	24 %
Asian	2 %
Multiple race	0 %
American Indian or Alaska Native	0 %
Native Hawaiian or Other Pacific Islander	<1 %
Unknown	8 %
Missing	3 %
HISPANIC	
No	47 %
Yes	4 %
Unknown	11 %
Missing	38 %
CARE SETTING – <i>patients may have more than one encounter type</i>	
Ambulatory Visit	73 %
Emergency Department	33 %
Telehealth	6 %
Inpatient hospital stay	5 %
Emergency to inpatient	7 %
Observation stay	3 %
Non-acute institutional stay	0 %
AREA DEPRIVATION INDEX	
Quartile 1 (Highest Socioeconomic Status)	18 %
Quartile 2	14 %
Quartile 3	34 %
Quartile 4 (Lowest Socioeconomic Status)	23 %
Missing	11 %

RURAL-URBAN RESIDENCE

Metropolitan areas	74 %
Micropolitan areas	12 %
Small town	1 %
Isolated rural area	1 %
Missing	11 %

US STATE*

Georgia	15 %
North Carolina	67 %

*For state data, the site profile report will only list states with $\geq 10\%$ of the patients.

PCORnet[®] Study Leadership (Studies listed below where Wake Forest is the lead site)

Consented Studies (interventional trials & studies with patient-reported data collection)

- TEAMS-BP: Telehealth-Enhanced Assessment and Management after Stroke-Blood Pressure - Feasibility Phase
- TEAMS-BP: Telehealth-Enhanced Assessment and Management after Stroke-Blood Pressure - Full Study Phase

Observational Studies

None

Data Science

None

Engagement (for example, PCORI-funded Science of Engagement projects)

None

PCORnet[®] Study Participation (Studies listed below where Wake Forest is participating)

Consented Studies (interventional trials & studies with patient-reported data collection)

- ACTIV-6: COVID-19 Study of Repurposed Medications
- Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term (ADAPTABLE)
- Clinical Outcomes of Medications Post Anti-TNF: Researching Effectiveness in Pediatric IBD
- Greenlight Plus Study: A Randomized Study of Approaches to Early Childhood Obesity Prevention - Phase 2
- HERO Registry & Trial: Healthcare Worker Exposure Response and Outcomes
- Improving Outcomes and Reducing Disparities for Patients With Inflammatory Bowel Disease Through Epidemiology and Enhanced Disease Management (PROMOTE IBD)
- Pragmatic Evaluation of Events and Benefits of Lipid-Lowering in Older Adults (PREVENTABLE)
- PRECIDENTD - PREvention of Cardiovascular and DiabEtic kidNey disease in Type 2 Diabetes
- REDucing future fractureS and improving ouTcomes of fRagility fracture (RESTORE)
- Tube Size Randomized Trial during Emergency Tracheal Intubation
- VictORION-INCLUSION: Evaluating Inclisiran for Cholesterol Management in Heart Disease (V-INCLUSION)

Observational Studies

- Cardiovascular Multicenter Observational Investigation of Lipid Care in the United States-2 (cvMOBIUS2)
- Characterization of Patients with Heart Failure and Patients with Atrial Fibrillation and Atrial Flutter in PCORnet Data
- Comparing the Benefits and Harms of Three Types of Weight Loss Surgery -- The PCORnet[®] Bariatric Study
- The RECOVER Post-Acute Sequelae of SARS-CoV-2 (PASC) Electronic Health Record (EHR) Cohort Study
- Understanding How Antibiotic Use Affects Childhood Obesity and Growth
- Understanding the Short- and Long-term Effects of Disasters and other Big Events on the Overdose Crisis

Data Science

- Advancing Public Health Use of Electronic Health Record Data

Engagement (for example, PCORI-funded Science of Engagement projects)

None

Participant Recruitment Capabilities

Mechanisms

- Patient portal
 Email
 Post mail
 Schedule-driven clinic intercept

Outreach

- System-wide outreach permitted
 Clinic-specific outreach (physician approval required)

Institutional Review Board (IRB) Policy

- Recruitment messaging with “opt-out” language permitted

Primary Patient Groups

- Adult
 Pediatric
 Safety net
-

Institutional Procedures

Institutional Review Board (IRB) Arrangements

- May rely on single/central IRB for federally mandated studies only
 May rely on single/central IRB for non-federally mandated studies
 May accept commercial IRB review

Order of Activation

- IRB approval required before contract execution
 Contract execution required before IRB approval
 IRB and contract can be executed in parallel

Administrative Efficiencies

- Will accept PCORnet® Master Clinical Research Agreement without redlines for PCORI-funded studies
 Has signed the PCORnet® Master Data Sharing Agreement
 Has contracted directly with Industry funders
-

Linkage with Other Data Sources

Health Plan Claims

- In same or adjacent data mart with common ID
 Established linkage infrastructure and regulatory

Name(s) of Plan(s)

Some claims data from Centers for Medicare & Medicaid Services

Other (non-EHR) Data

- Linked in DataMart*
 Established linkage infrastructure and regulatory

Name(s) of Data Source(s)

Death, Geocoding

*DataMart refers to a specific data source consisting of data collected, captured or otherwise obtained by the health system. Each site’s PCORnet DataMart houses data standardized to the PCORnet® Common Data Model.

Wake Forest University School of Medicine is a Network Partner in PCORnet® which has been developed with funding from the Patient-Centered Outcomes Research Institute® (PCORI®). Wake Forest University School of Medicine’s participation in PCORnet is funded through a PCORI Award (RI-VUMC-01-PS9)]. PCORnet® is intended to improve the nation’s capacity to efficiently conduct patient-centered health research, particularly comparative clinical effectiveness research (CER), by providing a large, highly representative network of health data, research expertise, and patient insights.