CLINICAL TRIALS TRANSFORMATION INITIATIVE

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Use of RWD in Pre-Study Planning and Study Set up: A Health Plan Perspective

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Disclaimer

- The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.
- The presenter is an Employee of HealthCore a Research Subsidiary of Anthem. Salary support comes from grants and contracts:
  - PCORI Awards
  - FDA Sentinel

Anthem: A Health Benefits Leader

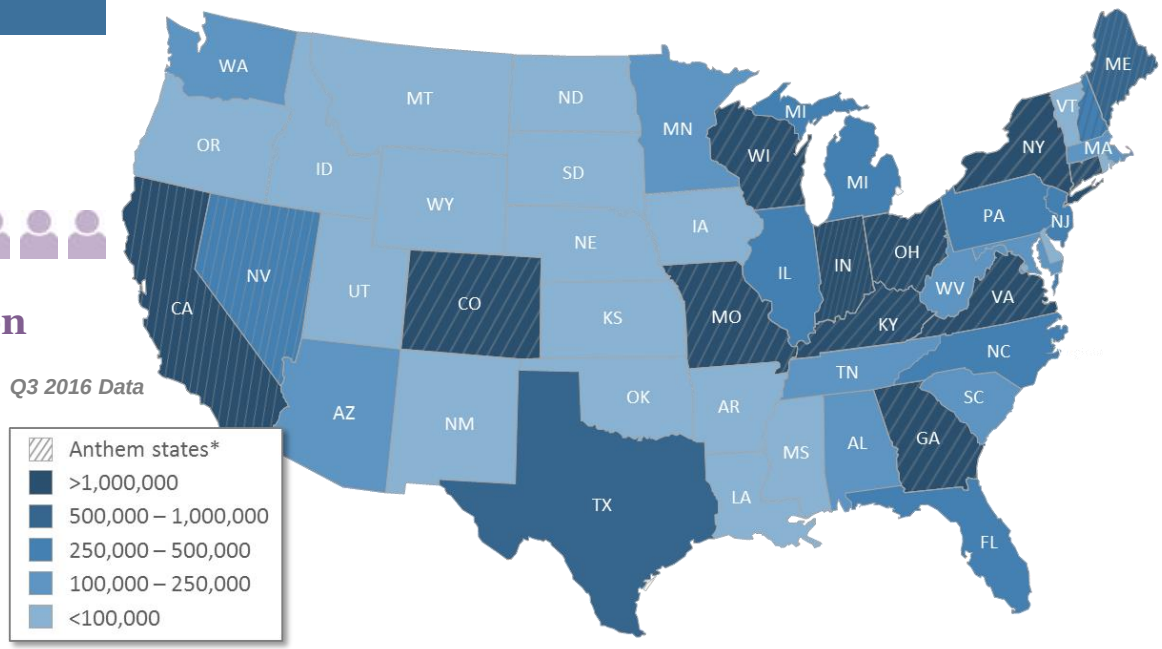
OVERVIEW & MEMBERSHIP

1 in 8 Americans

40 million
total medical members in affiliated health plans

over 73 million
total lives served

1 in 12 births in the US



SUBSIDIARIES

CareMore – It's what we do.
DeCare Dental
Amerigroup RealSolutions in healthcare – 19 states Medicaid presence
simply healthcare
National Government Services
AIM SpecialtyHealth
HealthCore

*Anthem Blue States (14): California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, Wisconsin

HealthCore

- Real-World Evidence (RWE) development company
- 220 associates
- Offices in Wilmington, Delaware; Watertown & Andover, Massachusetts and Alexandria, Virginia
- Founded in 1996 through an asset purchase from BCBS of Delaware
- Acquired by WellPoint Health Networks in 2003
- WellPoint acquired by Anthem in 2004
- Acquired New England Research Institutes in 2017

Rapidly Evolving Landscape

National Frameworks for Evidence Generation

IMplementation of a randomized controlled trial to imProve treatment with oral AntiCoagulanTs in patients with Atrial Fibrillation (IMPACT-AF)

- **Direct mailer to health plan members and providers with Afib at high risk for stroke and no oral anticoagulant treatment**

ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness)

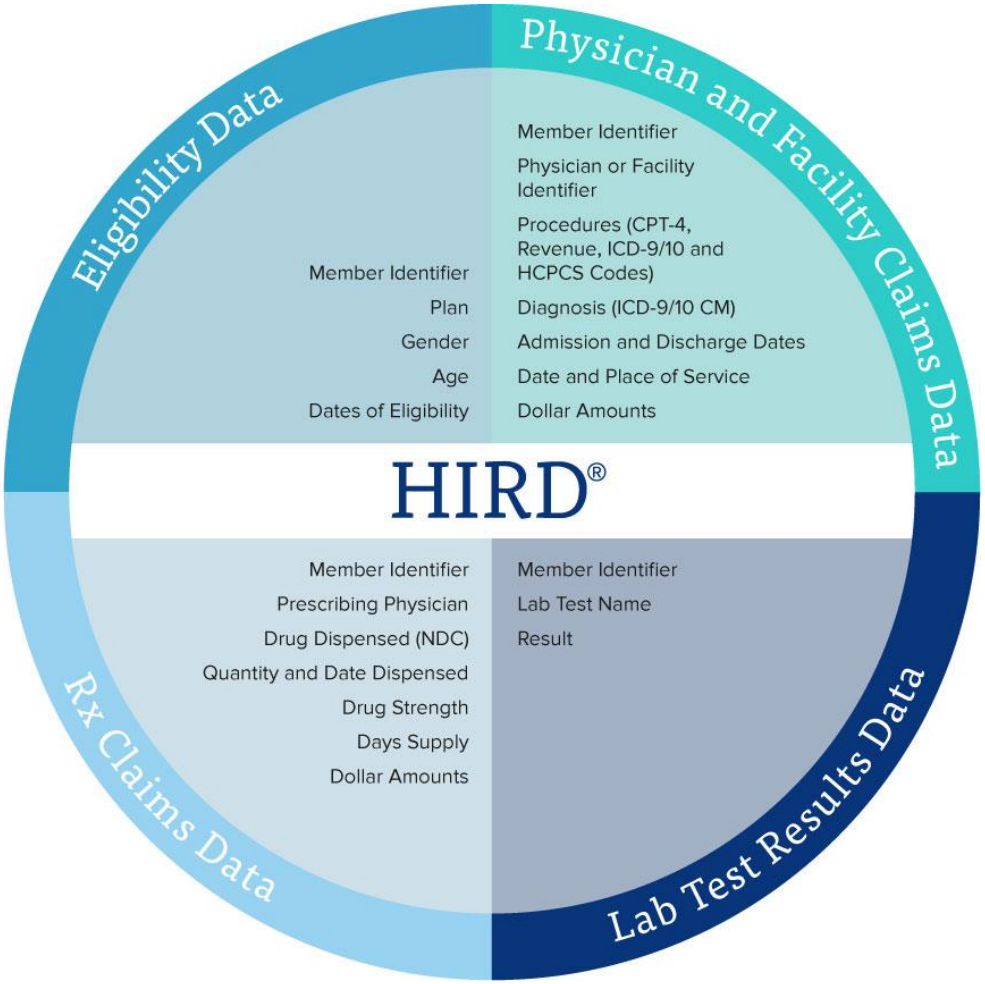
HealthCore has enrolled 239 members with additional outreach waves planned

HIRE®

HealthCore Integrated Research Environment

Directly Linking Claims with Other Data Sources

HealthCore Integrated Research Database



Claims Data Availability

63.9 million researchable lives total with medical eligibility

47.1* million researchable lives total with both medical & pharmacy eligibility

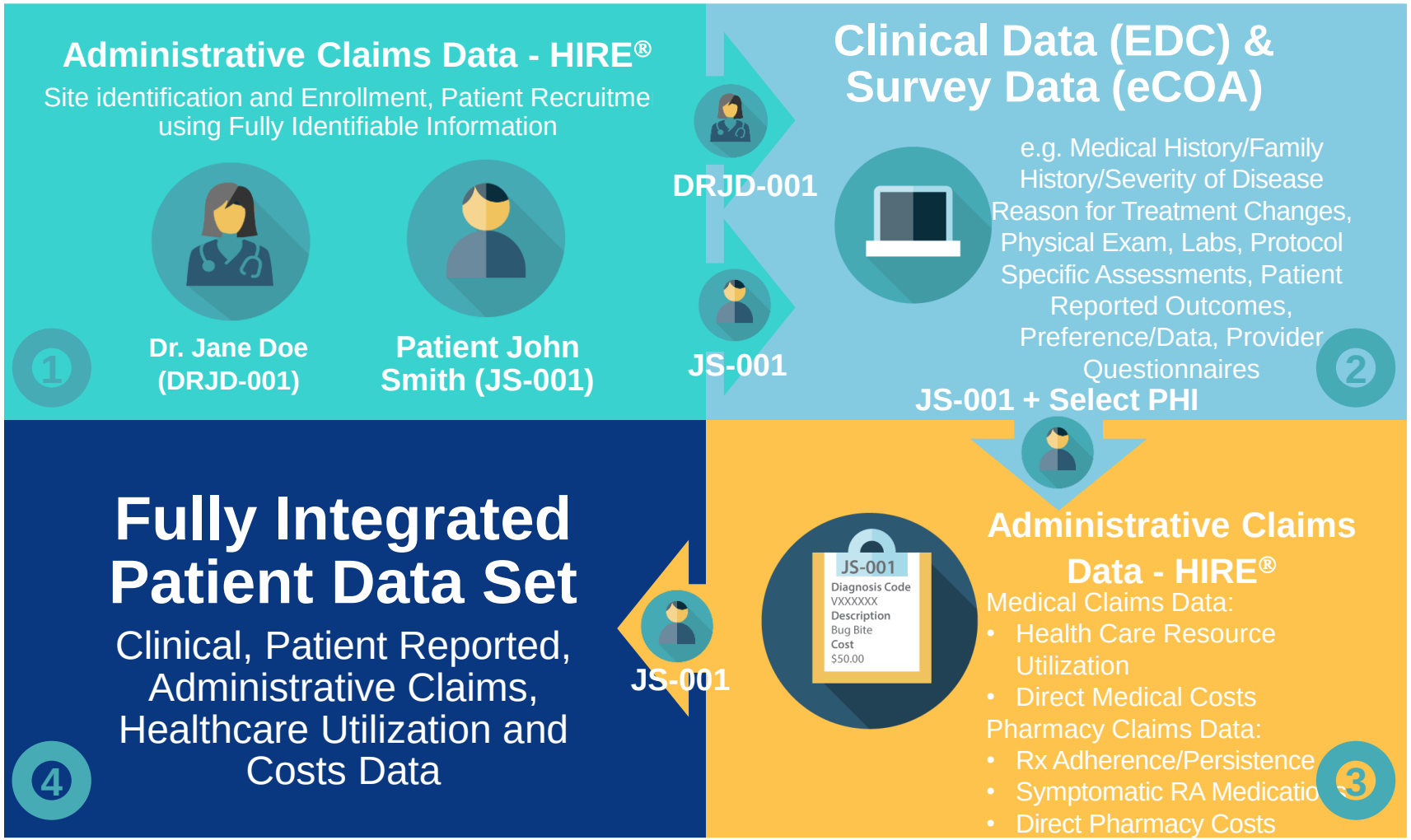
Millions with continuous eligibility for:

1 year:	32.3
2 years:	22.7
3 years:	16.5
4 years:	11.4

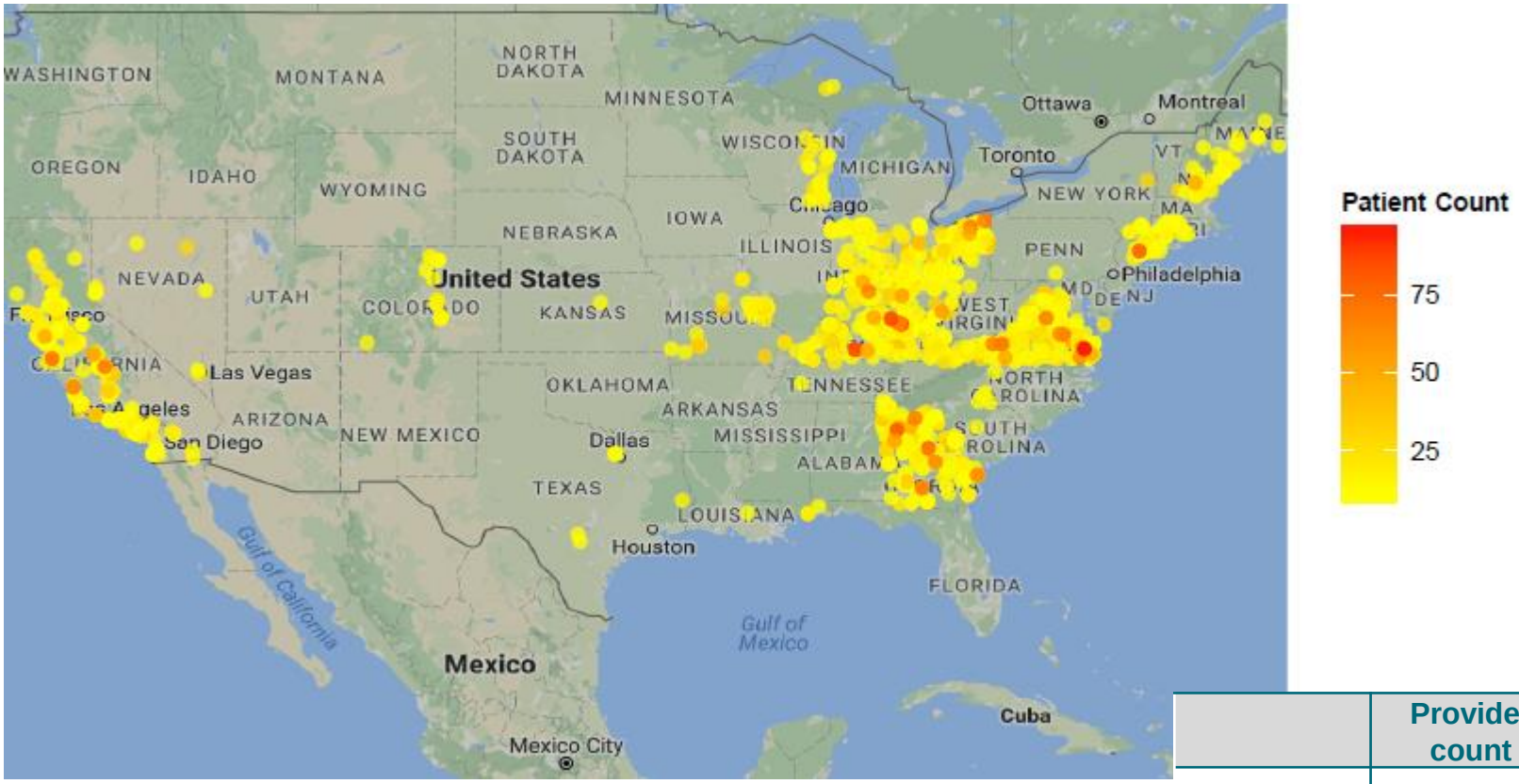
* Includes Carve-out Pharmacy Data

14.6 million lives with electronic outpatient laboratory result data

Data Integration Via Direct Linkage



Provider Locations* and Patient Density – All Potentially Eligible T2D Patients, A1c > 7%



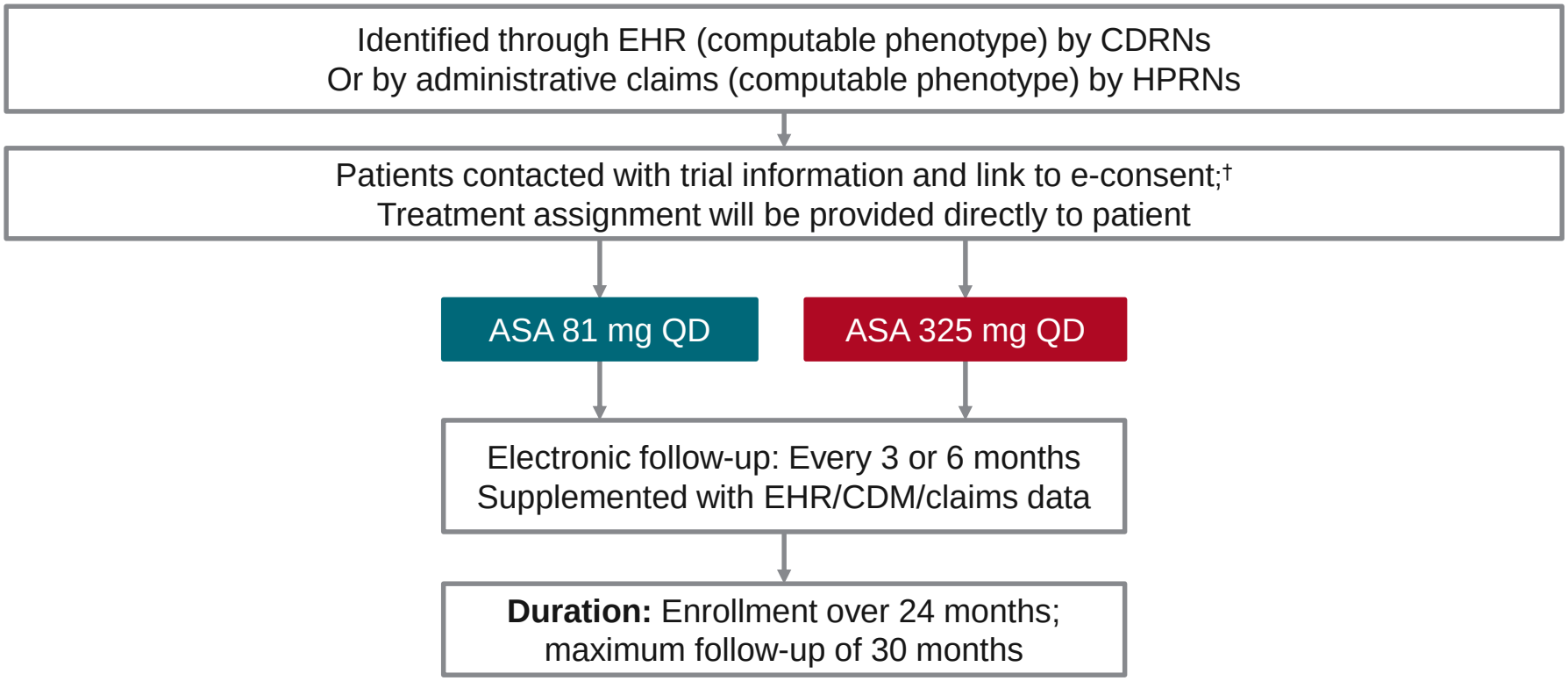
**Includes only providers with 10 or more eligible patients*

	Provider count
≥10 patients	**1,882**
≥15 patients	889
≥20 patients	480

Examples of Pre-Study Planning

ADAPTABLE Study Design

Patients with known ASCVD + ≥ 1 "enrichment factor"



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

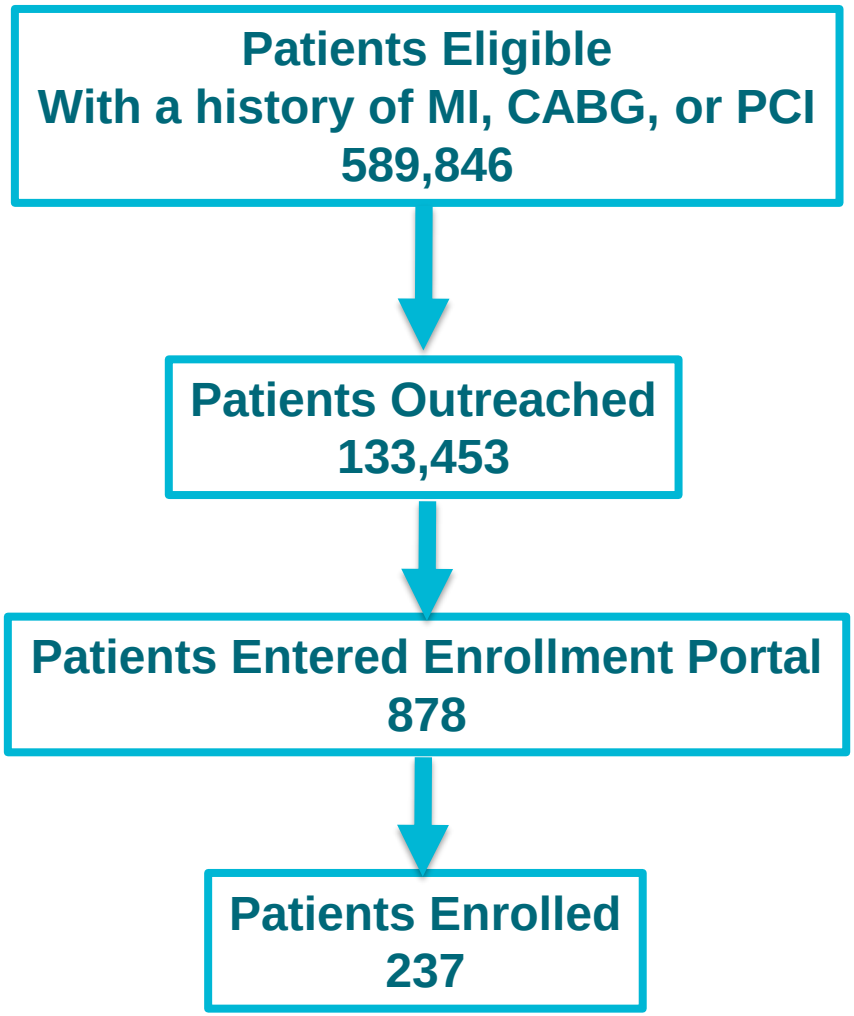
Primary safety endpoint:
Hospitalization for major bleeding

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

ClinicalTrials.gov: NCT02697916

CTTI

Health Plan ADAPTABLE Outreach



Examples of HealthCore PCTs

Indication/TA	Number of Sites	Number of Patients	Basic Design
Endocrinology /Type 2 DM	742	6570	Pragmatic Clinical Trials comparing the Real-World Use of treatment of interest vs Standard of Care Cluster randomization by site or randomization between treatment options used
Allergy and Immunology /Severe Asthma	20	150	Registry comparing pre post outcomes of interest
Psychiatry/ MDD, Schizophrenia and BP1 Disorder	60	600	A Multicenter, Randomized, Pragmatic Trial to compare treatment of interest with treatment as usual
Respiratory/COPD	530	4500	Randomized Pragmatic Clinical Trial conducted in a community based setting comparing treatment of interest with standard of care

THANK YOU.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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