Use of RWD in Pre-Study Planning and Study Set up:
A Health Plan Perspective
Kevin Haynes, PharmD, MSCE
HealthCore
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.

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- PCORI Awards
- FDA Sentinel
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

*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
HealthCore®

HealthCore Integrated Research Environment

Directly Linking Claims with Other Data Sources
HealthCore Integrated Research Database

- **Eligibility Data**
  - Member Identifier
  - Plan
  - Gender
  - Age
  - Dates of Eligibility

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

- **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

- **Lab Test Results Data**
  - Member Identifier
  - Lab Test Name
  - Result
  - Dollar Amounts
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

Administrative Claims Data - HIRE®
- Site identification and Enrollment, Patient Recruitment using Fully Identifiable Information

Clinical Data (EDC) & Survey Data (eCOA)
- e.g. Medical History/Family History/Severity of Disease
- Reason for Treatment Changes, Physical Exam, Labs, Protocol Specific Assessments, Patient Reported Outcomes, Preference/Data, Provider Questionnaires

Fully Integrated Patient Data Set
- Clinical, Patient Reported, Administrative Claims, Healthcare Utilization and Costs Data

Administrative Claims Data - HIRE®
- Medical Claims Data:
  - Health Care Resource Utilization
  - Direct Medical Costs
- Pharmacy Claims Data:
  - Rx Adherence/Persistence
  - Symptomatic RA Medication
  - Direct Pharmacy Costs

JS-001 + Select PHI
Provider Locations* and Patient Density – All Potentially Eligible T2D Patients, A1c > 7%

*Includes only providers with 10 or more eligible patients

<table>
<thead>
<tr>
<th>Patient count</th>
<th>Provider count</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥10 patients</td>
<td>1,882</td>
</tr>
<tr>
<td>≥15 patients</td>
<td>889</td>
</tr>
<tr>
<td>≥20 patients</td>
<td>480</td>
</tr>
</tbody>
</table>
Examples of Pre-Study Planning
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.

ClinicalTrials.gov: NCT02697916
Health Plan ADAPTABLE Outreach

Patients Eligible
With a history of MI, CABG, or PCI
589,846

Patients Outreached
133,453

Patients Entered Enrollment Portal
878

Patients Enrolled
237
# Examples of HealthCore PCTs

<table>
<thead>
<tr>
<th>Indication/TA</th>
<th>Number of Sites</th>
<th>Number of Patients</th>
<th>Basic Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrinology/Type 2 DM</td>
<td>742</td>
<td>6570</td>
<td>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</td>
</tr>
<tr>
<td>Allergy and Immunology/Severe Asthma</td>
<td>20</td>
<td>150</td>
<td>Registry comparing pre post outcomes of interest</td>
</tr>
<tr>
<td>Psychiatry/MDD, Schizophrenia and BP1 Disorder</td>
<td>60</td>
<td>600</td>
<td>A Multicenter, Randomized, Pragmatic Trial to compare treatment of interest with treatment as usual</td>
</tr>
<tr>
<td>Respiratory/COPD</td>
<td>530</td>
<td>4500</td>
<td>Randomized Pragmatic Clinical Trial conducted in a community based setting comparing treatment of interest with standard of care</td>
</tr>
</tbody>
</table>
THANK YOU.

Kevin Haynes

khaynes@healthcore.com

www.healthcore.com

www.ctti-clinicaltrials.org