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

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Disclaimer

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- 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

Q3 2016 Data

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
HIRE®
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, 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

HIRD®
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

JS-001 + Select PHI

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 Medications
  - Direct Pharmacy Costs

Dr. Jane Doe (DRJD-001)
Patient John Smith (JS-001)

1

2

3

4
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>Provider count</th>
<th>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: 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.

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www.healthcore.com

www.ctti-clinicaltrials.org