Impacting R&D through pharma-payer collaboration: the AstraZeneca-HealthCore Partnership

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Outline

• Challenges faced by pharma R&D and the need for Real World Evidence (RWE)

• Gap in use of Real World Evidence (RWE) data for R&D

• How can we build data assets that can generate useful RWE?

• Case examples where RWE data have helped R&D
Challenge I: Lack of Translational Science

• In FDA’s view, the applied sciences needed for medical product development have not kept pace with the tremendous advances in the basic sciences.
• The new science is not being used to guide the technology development process in the same way that it is accelerating the technology discovery process.

Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products. FDA, March 2004
Challenge II: Costly Attrition in Late Stage Development

- Chance of new compounds entering Phase I & reaching market decreased to 8% as compared to 14% 15 years ago
- For drugs completing phase 2, the failure rate in phase 3 has increased to 50% as compared to 20% 10 years ago
- Cost for launching a successful drug keeps increasing
Challenge III: Long-term Safety – Needs Real World Evidence (RWE)

- Some drugs have been withdrawn from the market because of unexpected adverse effects that were not detected during Phase III clinical trials and were only apparent from long-term surveillance data from the wider patient community.
Challenge IV: Comparative Effectiveness – Needs Real World Evidence (RWE)

• Need to demonstrate comparative effectiveness
  - Cost effectiveness – Payer's willingness to pay
  - Clinical effectiveness (long term efficacy and safety) – CER research and patient reported outcome for decision making by healthcare providers and patients

• Other related issues:
  - Lack of standardization of data (EHRs/EMRs) and analytical methods
  - Uncertainty in data quality and completeness in EHRs/EMRs
  - Uncertainty in regulatory environment
Potential Use of RWE in Pharma R&D

- Community Health Workers
- Primary Healthcare
- Diagnostic Labs
- Hospitals
- Pharmacies
- Patients / Consumers

Payers

Electronic Health Record

Pharmas

D&I

Proactive Pharmacovigilance

PHC

Cost Effectiveness

Drug Repositioning /New Indications

Patient recruitment

EBM

CER

Clinical Trials

Cost

Vendor

Payers

Pharmas
The RWE capability provides dedicated RWE analytics capability with enhanced data access for robust decision support.
AstraZeneca, WellPoint To Work On 'Real-World' Health Studies

Drug maker AstraZeneca PLC (AZN) and health insurer WellPoint Inc. (WLP) have teamed up to conduct what they're calling "real-world" studies to determine the most effective and economical treatments for chronic illnesses and other diseases. The partnership is part of a movement toward greater use of comparative-effectiveness research...

Feb 3rd, 2011

AstraZeneca, HealthCore Launch Outcomes Data Project, Seek Multi-Stakeholder Consortium

AstraZeneca and Healthcore, WellPoint's clinical outcomes research unit, have begun an evidence-development partnership to generate "real world" data on the most effective and economic ways to treat disease, with a focus on chronic ailments ..., but also addressing areas such as oncology...
Key Contributors to Evidence Gaps

- Little to No Evidence
- Unstudied co-morbid conditions
- Varying severity of disease
- Differing concomitant medications
- Varying levels of compliance – i.e. < 80%

Clinical Trials

Conceptualization

FDA Approval

Off-label indications

Variance in population characteristics from what was studied

Post-Marketing Studies

Utilization

Differing age groups – elderly, pediatrics

Race, ethnicity, gender variances

Real World Evidence | April 10, 2015
Shifting Landscape

Traditional Environment for Decision-Making

To Innovate
To Approve
To Prescribe
To Adhere

Industry
FDA
Physician
Patient

Evidence
Clinical Efficacy
Safety SAE & Overall Tolerability
Cost Direct cost of product acquisition
Shifting Landscape

Emergence of the Payor in the Decision-Chain & the need for Industry to develop products that will get reimbursed

- To Innovate
- To Approve
- To Pay for
- To Prescribe
- To Adhere

Industry
FDA
Government
Physician
Patient
ID Systems

Evidence Demands
Clinical Effectiveness
Safety
Population Safety/Long-term Safety
Total Cost of Care Impact
Direct cost of product acquisition

Evidence Used
Clinical Efficacy
Safety
SAE & Overall Tolerability
Cost

Clinical
Safety
Cost
The value of RWE data to customers

Strong correlation between data integration and RWE value

Data richness and integration

- Disease background
  - Treatment in single care setting
- Comparative Effectiveness
  - Research & safety in limited care settings
  - Patient adherence
- Health outcomes
  - Costs of chronic disease care

Value of RWE analysis

- Claims, Rx fulfillment and cost
- Lab values and longitudinal
- Clinical
Data integration is key to quality of RWE results

Integrated View of the Patient

Outpatient EMR/EHR

Inpatient EMR/EHR

Patient Reported Information

Claims

A Strong, Aligned, Collaborative Working Relationship With Our Health Care Community
The RWE capability provides dedicated RWE analytics capability with enhanced data access for robust decision support.

- **RWE front-end**
  - AstraZeneca
  - Internal AZ customers
  - Hub partner
  - Licensed databases

- **RWE back-end**
  - Primary data sources
  - Add-on partners
    - Health Information Exchange
    - Integrated Delivery Networks
    - Community Physicians
    - Pharmacy Benefit Managers

**Key Partners**
- Payers and regulators
- Internal AZ customers
- Hub partner
- Primary data sources
- Add-on partners

**Data Sources**
- NHS
- MacCare Medical Association
- WELLPOINT
- HUMANA
- Blueprint Health Group
- IQWiG Institute for Quality

**Insight**
- Collaboration
- Insight
- Analytic capabilities
- Data access
Data Environment - Elements

HealthCore data

Administrative 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 & Facility Claims
- Member identifier
- Physician or Facility identifier
- Procedures (CPT-4, revenue codes, ICD-9 and HCPCS codes)
- Diagnosis (ICD-9-CM)
- Admission and discharge dates
- Date and place of service
- Dollar amounts

Lab Test Results Data
- Member identifier
- Lab Test Name
- Result

Enhancements

Chart Reviews
Patient Reported Outcomes
Physician Surveys
Benefit Design Insights

AstraZeneca
HealthCore
Real World Evidence
April 10, 2015

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Advancing Outcomes Research
Patient 360° Proof of Concept *

Member and Provider 360° View

Eligibility Data
HRA Data
Intervention Data
Cost of Care Delivery Data
Lab Results Data
Claims Data

EHR Data

Enhance/Accelerate ECC Clinical Healthcare Services Capabilities

The value-chain

Data Acquisition
Data Cleansing/Data Validation
Data Integration
Data Enrichment
Data Analysis & Transformations

De-identified extractions
Data Exchange
Analytics
Collaborative Research
Benchmarking
Practice Pattern Analysis

Understand true costs vs. reimbursed cost – risk based contracts
Understand drivers of never events
Insights into appropriate coding
Systematic justification for denial of care
Screen/identify/prevent population disease burden

* Potential HealthCore service offerings subject to legal review and approval, and mutual agreement
Use of RWE for R&D

Case Examples:

• Early drug development team requires data on treatment patterns in oncology to assess ‘line of therapy fit’ for their compound

• Market sizing for potential indications requires deep understanding of ‘unmet’ need- example: not all hyperlipidemics may be potential targets for a new compound but only those with unmet need/experiencing treatment failure may be targeted

• Comparative effectiveness studies on competing products enable R&D to assess value proposition potential of compounds