Title: Evolving Role of Real World Data in Pharmaceuticals

Abstract:

The evolving landscape of big data in healthcare is impacting pharmaceutical companies across multiple facets from research and development, to commercialization, to customer engagement. Of the many forms and facets of data brought about by this, Real World Clinical Data is particularly poised for increasing usage. With the generation of Real World Data burgeoning across both the public and private sector comes the ability to shape the discussion on pharmaceutical products’ benefits and risks by stakeholders throughout the healthcare system. Pharmaceuticals and life science companies will need to shift away from a clinical trials-focused mindset to effectively function and communicate in this new environment.
PRISME: Evolving Role of Real World Data in Pharmaceuticals

October 2013
Agenda

• Big Data in Pharmaceuticals

• What is Health Care Real World Data?

• What is Pfizer Doing in Real World Data?
BIG DATA (including Real World Data) will transform:

- Research & Development
  - Precision Medicine

- Commercialization
  - Market segmentation and targeting
  - Adherence / Compliance

- Dynamics of relationships among patients, providers, payers, and developers of new therapeutics
  - Patient centered research & development
  - Social networking and increasing access to public data sources
What is Big Data in Pharma?

Genomic Imaging
EMR Unstructured Notes

Sensors and Health Monitoring Devices

Learning Healthcare System

Current focus

Claims, Laboratory
EMR, PHR
Surveys: Health Risk
Assessments, Health Status
Assessments
Pt Reported Outcomes
Revealed Pt Behaviors and
Preferences (ex. Purchasing
Habits, Google Trend)

What is Real World Data?

Real World Data is healthcare data used for decision making that is not collected in conventional randomized controlled trials (RCTs).

Sources of Real World Data:

- **Databases**
  - Cross-sectional and longitudinal databases which essentially provide retrospective data but increasingly offer the opportunity to have prospective add-ins.

- **Surveys**
  - Primarily for epidemiological information.

- **EMRs**
  - Used to reflect particular insights in patient management.

- **Cohort studies**
  - What most people would understand by real life studies.

- **Pragmatic clinical trials**
  - Simple experimental trials, where efforts are however made to mimic a real life situation as much as possible.

- **Registries**
  - Analyzing all patients treated at a particular center for a particular condition on a continuous basis.

Why is this considered critical for pharmaceuticals?

- Increasing use of real-world evidence in decision making
  - Shifting emphasis from Efficacy (performance in clinical trials) to Effectiveness (benefit vs harm in a real-life setting)
  - Enhanced role in post-marketing safety surveillance  Comparative Effectiveness, Value-based purchasing Risk-sharing contracts

- Growing universe of developers of real-world Evidence

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Federal agencies
Private orgs
Patients
State/regional initiatives
Integrated delivery systems
Professional societies

Academic centers
FDA
Private payers
PCORI
Health IT providers
Providers
Measure developers
Web-scale pharmacovigilance: listening to signals from the crowd

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ABSTRACT

Adverse drug events cause substantial morbidity and mortality and are often discovered after a drug comes to market. We hypothesized that Internet users may provide early clues about adverse drug events via their online information-seeking. We conducted a large-scale study of Web search query data gathered during 2010. We pay particular attention to the specific drug pairing of paroxetine and protonix, whose interaction was reported to cause hyperglycemia after the time period of the inline logs until in the analytic. We also examine the drug interaction between naproxen and those not associated with hyperglycemia. We find that unreported signals on drug interactions can be mined from search logs. Compared to analyses of other sources such as electronic health records (EHR), logs are inexpensive to collect and mine. The results demonstrate that logs of the search activities of populations of computer users can contribute to drug safety surveillance.

BACKGROUND

The Food and Drug Administration and other organizations collect reports on drug side effects from physicians, pharmacists, patients, and drug companies. 1 These reports provide valuable clues about drug-related adverse events, but are incomplete and biased. 2 As a result, adverse event alerts for single drugs are often delayed as evidence accumulates. 3 These challenges are compounded in the setting of adverse events resulting from multiple drugs that interact in unexpected ways. Given that a significant use of the Internet is for health searches, we hypothesized that Internet users may provide early clues about adverse drug events via their online information-seeking activities. 4 Previous research on tracking seasonal influenza has demonstrated that search logs can form an implicit sensor network for health monitoring. 5 In that work, search logs accurately estimated the weekly levels of influenza activity in different regions of the USA, with a reporting delay of approximately 1 day. The authors showed that health-seeking activity captured in queries to online web search services mirrors trends in data gathered by traditional surveillance methods. The aim of the current study was to test whether Internet search logs can be used to detect unreported adverse drug events or drug interactions.

METHODS

We analyzed the search logs of over 500 million web users who opted to allow Microsoft via the install alog, accessing a 12-month period and submitting searches on Yahoo. An anonymous identifier of the browser address the drugs and symptoms queries were formed over time (note that we distinguish between multiple and machine). Searches for inform drugs are common. We found that 0.34% people (0.34%) pursued information about one of the top 100 best selling including paroxetine and prolixin that we focus on here. 5 By examining words used in search queries we constructed a list of the top 10000 terms associated with hyperglycemia-related terms included in the supplementary text. The list was used to create a list of drug interactions. The list is broad enough to ensure that we covered a majority of related symptoms. Although there are many possible drug interactions, we focus on two drug interactions: a PPI and an SSRI. The PPI is protonix and the SSRI paroxetine.
What is Pfizer Doing?
What is Pfizer doing?
RWDnA Platform Objectives and Value drivers

Vision

- Create competitive advantage for Pfizer in RWDnA
- Achieve enterprise-wide efficiency in the acquisition and use of RWDnA

Value drivers

Competitive advantage drivers

1. Best understanding of value of EMR data
2. Applications of LE Methods to portfolio
3. Strategic Partners (Humana, ESI, Humedica)

Efficiency drivers

4. RWDnA DataMart
5. Central RWDnA licensing
6. Standards and best practices

Learning and Culture drivers

7. RWDnA Steering Committee
8. Analytics and Policy Fora
RWDnA DataMart

Comprehensive resource of Real World Data (patient longitudinal information and cross-sectional patient surveys) accessible by any Pfizer team for clinical research or commercial analysis

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<thead>
<tr>
<th>EMR</th>
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<tbody>
<tr>
<td>HUMEDICA</td>
<td>US: Normalized database of EMR data from 150 US providers</td>
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<td>GE</td>
<td>US: Database of EMR data from GE Centricity customers</td>
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<td>cegedim</td>
<td>UK: THIN database of NHS primary care centers</td>
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<th>CLAIMS, ADMIN.</th>
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<td>OPTUMInsight</td>
<td>US: UnitedHealth database of administrative, claims data</td>
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<td>TRUVEN HEALTH ANALYTICS</td>
<td>US: Formerly Thomson MarketScan administrative, claims data</td>
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<td>PREMIER</td>
<td>US: Administrative, claims data from over 2,000 hospitals</td>
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<td>SDI</td>
<td>US: IMS subsidiary provider-level written Rx</td>
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<td>US &amp; EU-5: Multi-year patient cross-sectional health survey</td>
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Payer Alliances led by RWDnA

- **Open Dialogue:** Ongoing, transparent and timely discussion with payer decision makers on research needs

- **Joint Planning:** Input from decision makers regarding study questions and study design details to more effectively address their specific evidence needs

- **Use of Research Findings:** Commitment by Pfizer to share study results per agreed to protocol/analytic plan for use by payer in their planning and decision making, as desired
Example Uses of Real-World Data in Pharmaceuticals

**MAx / HEOR**
- Disease progression simulations
- Burden of disease or illness (clinical and economic)
- Cohort analysis of comparative treatment effectiveness
- Budget impact assessment

**Safety Strategy**
- Baseline AE rate for class of treatment
- Proactively monitor AE for new product

**Commercial**
- Analysis of clinical factors of payer population for pricing
- Physician messaging given population clinical profile

**WRD**
- Analysis of clinical trial endpoints
- Assessment of patient in-/exclusion criteria