

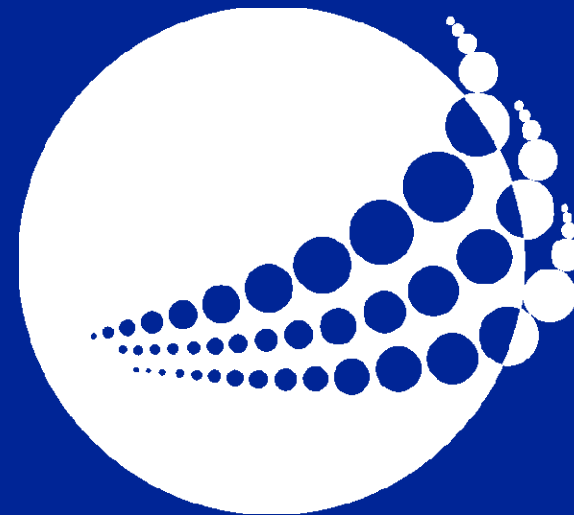
Title: Evolving Role of Real World Data in Pharmaceuticals

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



Enhancing Real World Insights Together



REAL WORLD DATA & ANALYTICS

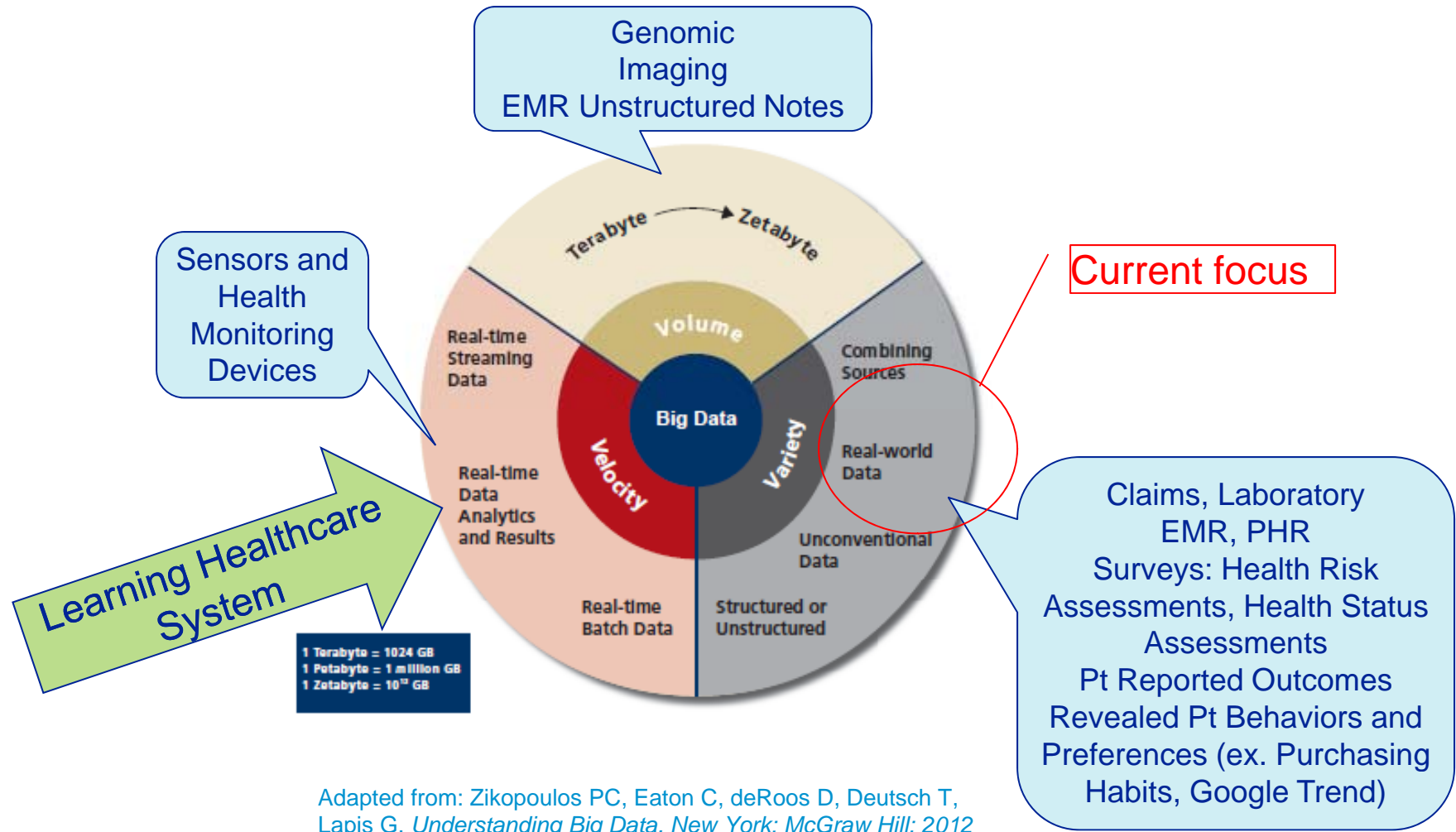
Agenda

- 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?



Adapted from: Zikopoulos PC, Eaton C, deRoos D, Deutsch T, Lapis G. *Understanding Big Data*. New York: McGraw Hill; 2012

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:

Focus for Today

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.

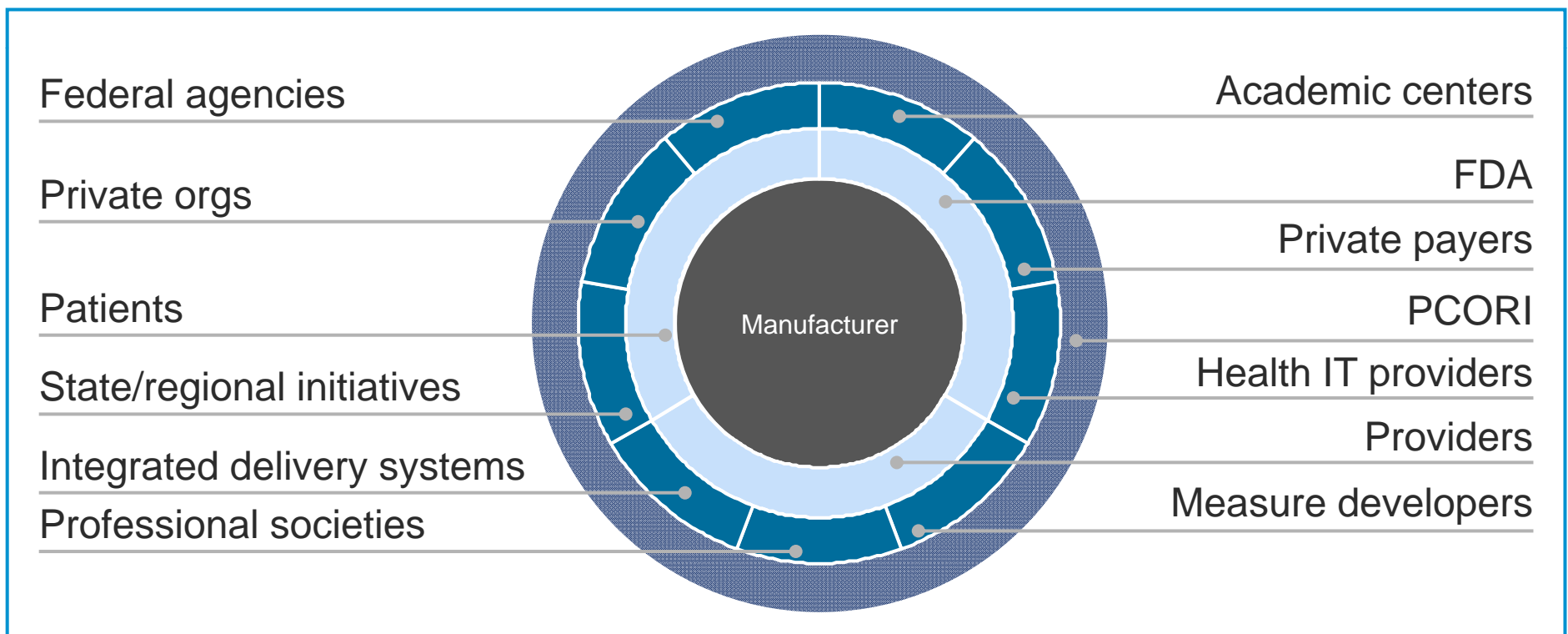
Registries

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

- “Using Real-World Data for Coverage and Payment Decisions: The ISPOR Real-World Data Task Force Report,” Value in Health, Volume 10, November 5, 2007.
- Annemans, L., Aristides, M., Kubin, M. “Real-Life Data: A Growing Need,” ISPOR Connections 2007.

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



A Glimpse of the Future

J Med Info Assoc

Brief communication

Web-scale pharmacovigilance: listening to signals from the crowd

Ryan W White,¹ Nicholas P Tatonetti,² Nigam H Shah,³ Russ B Altman,⁴ Eric Horvitz¹

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/amiqjnl-2012-001482>).

¹Microsoft Research, Redmond, Washington, USA

²Department of Biomedical Informatics, Columbia University, New York, New York, USA

³Department of Medicine, Stanford University, Stanford, California, USA

⁴Departments of Bioengineering and Genetics, Stanford University, Stanford, California, USA

Correspondence to Dr Ryan W White, Microsoft Research, Redmond, WA 98052, USA; ryenw@microsoft.com

Received 9 November 2012
Revised 8 January 2013
Accepted 13 January 2013

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 log data gathered during 2010. We pay particular attention to the specific drug pairing of paroxetine and pravastatin, whose interaction was reported to cause hyperglycemia after the time period of the online logs used in the analysis. We also examine sets of drug pairs known to be associated with hyperglycemia and those not associated with hyperglycemia. We find that anonymized 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 US Food and Drug Administration and other organizations collect reports on drug side effects from physicians, pharmacists, patients, and drug companies.¹⁻³ These reports provide valuable clues about drug-related adverse events, but are incomplete and biased.⁴⁻⁶ As a result, adverse event alerts for single drugs are often delayed as evidence accumulates.⁷⁻⁸ 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.⁹ Previous research on tracking seasonal influenza has demonstrated that search logs can form an implicit sensor network for health monitoring.¹⁰⁻¹¹ 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 trad-

itional surveillance systems. 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 log data gathered during 2010. We pay particular attention to the specific drug pairing of paroxetine and pravastatin, whose interaction was reported to cause hyperglycemia after the time period of the online logs used in the analysis. We also examine sets of drug pairs known to be associated with hyperglycemia and those not associated with hyperglycemia. We find that anonymized 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.

METHODS

We analyzed the search logs of internet users who opted to share their search history with Microsoft via the install add-on, spanning a 12-month period and comprising searches on Google, Microsoft and Yahoo!. An anonymous identifier instance of the browser add-on was used to identify the drugs and symptom queries formed over time (note that we distinguish between multiple users on a single machine). Searches for information on drugs are common. We found that 0.43% of people pursued information on one of the top 100 best-selling drugs, including paroxetine and pravastatin that we focus on here.¹⁵

By examining words used in searches for information on paroxetine and pravastatin over time (2010) we found a higher frequency of hyperglycemia-associated words in searches for only one of the drugs, paroxetine. The hyperglycemia-related terminology included in the supplementary material (table S1, available online at <http://dx.doi.org/10.1136/amiqjnl-2012-001482>) was derived from a review of the literature. The list is broad to ensure that we covered a majority of related symptoms. Although there are many pos-

The New York Times

March 6, 2013

Unreported Side Effects of Drugs Are Found Using Internet Search Data, Study Finds:

“Using data drawn from queries entered into Google, Microsoft and Yahoo search engines, scientists at Microsoft, Stanford and Columbia University have for the first time been able to detect evidence of unreported prescription drug side effects before they were found by the Food and Drug Administration’s warning system.”

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

EMR

-  **HUMEDICA** • US: Normalized database of EMR data from 150 US providers
-  • US: Database of EMR data from GE Centricity customers
-  **cegedim** Strategic Data • UK: THIN database of NHS primary care centers

CLAIMS, ADMIN.

-  **OPTUMInsight™** • US: UnitedHealth database of administrative, claims data
-  **TRUVEN**
HEALTH ANALYTICS™ • US: Formerly Thomson MarketScan administrative, claims data
-  **PREMIER** • US: Administrative, claims data from over 2,000 hospitals
-  **SDI** • US: IMS subsidiary provider-level written Rx

KANTAR • US & EU-5: Multi-year patient cross-sectional health survey

Payer Alliances led by RWDnA



Pfizer, Humana form research pact on elderly health

By Lewis Krauskopf
Thu Oct 13, 2011 7:50pm EDT

(Reuters) - Pfizer Inc has formed a partnership with health insurer Humana Inc to research ways to improve healthcare for the elderly.

The five-year partnership, announced on Thursday, will focus initially on three chronic conditions: pain, cardiovascular disease and Alzheimer's disease.

Humana is one of the largest providers of plans under Medicare, the U.S. government health plan for the elderly. Pfizer is the world's largest drugmaker.



OCTOBER 26, 2011, 5:15 P.M. ET

Pfizer, Medco collaborating on precision medicine

Associated Press

NEW YORK — Drugmaker Pfizer Inc. is partnering with prescription benefits manager Medco Health Solutions Inc. to find ways to match individual patients with the best treatment for their disease.

- **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

QUESTIONS?

