Making Real World Evidence Analytics work
A guide for Pharmaceutical and Biotechnology executives
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Executive summary

Real World Evidence (RWE), generated outside of randomized clinical trials (RCTs), is leading a new era of innovation in healthcare. Sources of Real World Data (RWD) include electronic medical records, pharmacies, patient reimbursement claims, and web and social networks.

There is plenty of excitement across the healthcare industry for the potential of RWE to improve medical care and lower healthcare costs. However, pharmaceutical and biotechnology companies are faced with a number of RWD-related challenges: limited access to RWD, long delays in processing and analyzing it, inconsistencies in data quality, and limited analytical creativity, to name a few.

Real World Evidence Analytics (RWEA), through a deeper analysis of the “rich” RWD, is poised to deliver on the promise of RWE. The technology is now mature for RWEA to be applied throughout the drug development lifecycle. Specific applications by drug development phase include:

- **Research and development**: population characteristics and clinical development feasibility
- **Growth**: treatment pathways, safety signals, commercial and managed care strategy
- **Maturity**: new indications and natural history of disease

A robust RWEA platform should integrate structured and unstructured data, provide a “data lake” to store both raw and processed data, provide deep analytical capabilities, and offer visualization in a graphical, interactive form.

Biopharmaceutical executives looking to take advantage of RWEA should evaluate the expertise and know-how in their own organizations, define the objectives of an RWE analytics solution, and be prepared with a formal process for vendor selection. Questions to ask a vendor include: does the vendor possess a thorough understanding of data science? How does the vendor address and simplify RWD integration? How is data ingestion automated? And can the vendor leverage a company’s existing IT technology investments?
The scope of and challenges with Real World Data

Real World Evidence (RWE) is derived from medical practice, among heterogeneous cohorts of patients, outside of randomized clinical trials (RCTs). In 2007, the International Society for Pharmaco-economics and Outcomes Research (ISPOR) created a Real World Data taskforce. According to the ISPOR task force, Real World Data (RWD) can be defined as: “Data used for clinical, coverage, and payment decision-making that are not collected in conventional randomized controlled trials (RCTs).”

Massive volumes of RWD are generated every day. Data quality issues, inconsistencies and missing data are inherently present. Many researchers and users of RWD are tasked with the laborious process of cleaning the data, filling gaps and correcting data inconsistencies through methods whose statistical validity may not yet be widely accepted. Because of the complexity of sourcing, normalizing and analyzing RWD, more time and effort is often spent on data acquisition, cleansing and integration than on data analysis or extraction of insights.

More often than not, RWD sources that feed analytics systems are not specifically designed or formatted with RWE in mind. Usually the data is collected for billing purposes, research purposes, or to carry out the daily practice of medicine.
Because of these challenges, and although there is plenty of excitement about RWD throughout the healthcare industry, most pharmaceutical companies report a relatively low level of satisfaction with RWD. According to a survey conducted in December 2015 by Datamonitor Healthcare Consulting on behalf of Saama, the world’s largest pharmaceutical companies see the use of RWD as a formidable challenge.

The top reported frustrations with RWD are:

1. Limited access to the data: RWD is dispersed across systems and geographies. Analytics groups and Health Economics and Outcomes Research (HEOR) groups within the pharmaceutical companies surveyed had no direct access to the data.
2. Long cycle time to insight: it can take days or weeks simply to get results. HEOR and RWE analytics groups have to request RWD from other analysts or expert programmers, often outside their own organizations. And structuring a query can take weeks.
3. Limited visualization: the data is typically displayed in Microsoft Powerpoint or Excel, both of which offer only basic manipulation and visualization tools.
4. Inconsistencies in data quality: non-standard data structures, missing data, and lack of consistent data quality cast doubts in the results of the analysis.
5. Limited analytical creativity: many of the executives surveyed in our study reported dissatisfaction with the lack of analytical know-how and creativity.
6. Lack of predictive ability: according to the executives we surveyed, the ability to make predictions based on RWD, the holy grail of RWD analysis, is still a long way off.

“We might work with payers, like United and then Humana, indirectly. They have the data about their own patients. We will have a project with them, we lay out the research question, and they will do the analysis using their analytical team to be able to answer our question.”

Top 10 biopharmaceutical corporation executive
Why Real World Evidence Analytics? Why now?

Technology

The technology to analyze big data from various sources, including from social media, is mature. Advanced analysis techniques using data science, bioinformatics and machine learning are becoming mainstream. Powerful visualization and end user analysis tools are shortening the time to arrive to insights. The traditional barriers to analyzing Real World Data are disappearing.

Costs

The rise of healthcare costs around the world is a pressing issue, and has been well documented. The average cost to develop a drug, including the cost of failures, is $2.6 billion. RCTs generate data on a restricted subset of the population, under strictly controlled conditions. Lack of efficacy of treatment and the occurrence of adverse events not only impact patient care, they increase the cost of healthcare. Directing healthcare spend to RWE and treatment pathways hold great promise for overall cost reduction and control.

Regulation

In the United States, government regulation is now mandating that healthcare payments be correlated to outcomes. As a result, there is an increased pressure from payers to link reimbursement payments to positive outcomes. This has huge implications for pharmaceutical companies’ go-to-market strategies.

Some pharmaceutical companies have already adopted a proactive strategy, partnering with payers to standardize treatment pathways and improve targeting of therapies to the most appropriate patient cohorts. Focusing on the largest market share in the largest market may not be the optimal strategy when considering costs and payments under the new value-based healthcare paradigm.

“There’s so many different applications. Just to be able to do special analysis that really allows us to dig deeper into the reality of what patients are doing, what physicians are prescribing, takes a long time, often weeks, when you’re trying to piece a story together.”

Top 10 biopharmaceutical corporation executive

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1 Source: Pharmaceutical Research and Manufacturers of America, 2015 biopharmaceutical research industry profile (Washington, DC: PhRMA; April 2015)
The top benefits of Real World Evidence Analytics

Improved healthcare

While randomized clinical trials traditionally impose strict parameters on patient admission to a clinical trial, RWE enables the intelligent processing of enormous amounts of real-world patient data. Larger patient cohorts can be analyzed for evidence-based insights into patterns of drug use. Improved insights carry the potential for better medical decisions and, ultimately, improved healthcare.

Lower healthcare costs

The significant and rising costs of bringing a drug to the market, intensified competitive pressures, and reduced health-care budgets are issues on top of mind for government agencies, pharmaceutical companies and payers. The observations based on RCTs are derived from a restricted subset of the population, under strictly controlled circumstances. RWD and RWEA bring the promise of increased efficacy of treatment and reduced number of adverse events, all of which reduce the total cost of healthcare.

What can Real World Evidence Analytics do?

- Estimate the treatment effectiveness in a variety of practice settings
- Generate information on how a product is dosed and applied in clinical practice
- Compare multiple alternative interventions (i.e. existing versus newer treatments) or clinical strategies, to inform optimal therapy choices beyond placebo comparators
- Analyze data in situations where it is not possible to conduct an RCT (i.e. narcotic abuse)
- Estimate the evolving risk-benefit profile of a new intervention, including the long-term clinical benefits and risks
- Examine clinical outcomes in a diverse study population that reflects the range and distribution of patients observed in clinical practice
- Offer a broader range of outcomes (e.g. PROs and symptoms) than have traditionally been collected in RCTs
- Generate information on resource use for the pricing of healthcare services and economic evaluation
Real World Evidence Analytics in drug development

Real World Data and analytics have applications in every phase of the pharmaceutical life cycle.

Application of RWE Analytics in the Drug Lifecycle

Research and Development
- Population Characteristics
- Clinical Development Feasibility

Growth
- Treatment Pathways
- Commercial and Managed Care Strategy
- Safety Signals

Maturity
- New Indications
- Natural History of Disease

Research and development phase

Analysis of RWD can help expedite the generation of research hypotheses. These hypotheses can sharpen the focus of clinical research, including the design of RCTs. RWD analysis may also accelerate and optimize the recruitment of patients for clinical trials, and be used to reposition existing drugs onto an accelerated development track for new indication approvals.

Applications include:

Population Characteristics: RWD can be analyzed for incidence rate and co-morbidities of a disease and various other metrics across a target population/cohort. The analysis leads to a better understanding of patient segments, which can uncover unmet medical needs, drive future R&D investment, and inform marketing decisions.

Clinical Development Feasibility: RWEA can be used to identify key areas for protocol design improvement, through better definition of cohorts by inclusion and exclusion criteria. Further, RWD analysis can lead to recommendations about the most suitable principal investigators and institutions for cohort enrollment.

Growth phase

RWEA is an invaluable asset and a competitive advantage during this lifecycle phase of drug development.
Applications include:

**Treatment Pathways:** through RWE we can discern and analyze patient treatment switches for a target disease or cohort, and gain insights through comparisons of treatment outcomes.

**Commercial and Managed Care Strategy:** The Affordable Care Act has shifted focus to quality of care and improved outcomes, and outcomes-based contracts rely on RWD for drug reimbursements. As a result, RWE is becoming the center of the conversation between payers and manufacturers, both of whom are racing to gain competitive insights into effectiveness and efficacy of treatment options.

**Safety Signals:** analysis of RWD offers the promise of accelerated detection, substantiation and compliance reporting of potential drug safety signals.

**Maturity phase**

The analysis of RWD of a drug that has entered the mature phase of its lifecycle enables researchers to target new indications, and to address unmet medical needs.

Applications include:

**New Indications:** RWE is slowly entering previously closed regulatory processes, such as the approval of new indications for existing drugs. RWEA is especially valuable for rare or life threatening indications, where RCT studies do not exist. Using careful cohort selection and data science methods, RWEA produces invaluable insights for new indications.

**Natural History of Disease:** RWEA enables researchers to map out the progression of disease from subclinical state to clinical diagnosis and prognosis. Using these insights, we can identify the key combinations of medical indicators to predict onset to outcome under different treatment regimes.

**An analytics platform for Real World Evidence: the guide for bio-pharmaceutical companies**

Real World Data, as described above, comes from a variety of sources. Because the data is sourced in the “real world,” it has inherent gaps in consistency and quality. RWD needs careful mining, processing and interpretation in order to lead to crucial insights.

A Real World Evidence Analytics platform needs advanced capabilities to handle the volume and variety of RWD. Such a platform should integrate and aggregate structured and unstructured data, apply powerful algorithms, and display the results in an effective, user-friendly manner. A powerful RWEA platform arms pharmaceutical and biotechnology companies with game-changing ingenuity.
A modern RWEA platform should provide the following:

- Integration of structured and unstructured data
- Scalability on demand
- A data lake that stores both raw and processed data
- Low-cost storage
- Efficient distributed processing
- Deep exploration capabilities
Real World Evidence Analytics platform architecture

Data ingestion from sources

A key requirement of a RWEA platform is its ability to connect to and ingest RWD from a variety of sources and in a variety of formats. The data ingestion capabilities allow this data—structured, semi structured and unstructured—to be efficiently acquired and onboarded using batch or real-time processes.

Data storage and processing

Storage:
The ingested data is stored in a “data lake”, optimized for storing massive amounts of multi-format data and also capable of performing several levels of processing and cleansing.

Integration and Management:
Raw data undergoes several transformations to:

• Standardize formats
• Integrate across different sources
• Apply business rules and transformations
• Apply and manage metadata and tags for business relevance
• Aggregate into specific metrics for faster retrieval

In addition, data is secured using authentication and authorization services and data lifecycle policies such as retention, archival are enforced

Advanced Analytics:
The ability to process, model and analyze RWD using advanced analytics techniques such as machine learning, forecasting, modeling and prediction is key to a functional RWE Analytics platform. The degree to which these capabilities are part of the integrated architecture (as opposed to a separate silo) is key to the overall efficiency and capability of the system.

Visualization:
The ability to visualize analytics insights for powerful decision-making is key to adoption and business relevance of an RWE Analytics platform. The RWE Analytics platform must enable the user to create metrics and indicators aligned with strategic priorities, embed analytics into business workflow and provide business users with powerful drilling and filtering capabilities to perform self service analysis on data.

RWE Analytics Applications

The applications layer of the architecture are built using the foundational capabilities of the RWEA platform. For more information on specific applications, please refer to the section titled Real World Evidence Analytics in drug development.
Guidelines for RWEA vendor selection

STEP 1: GATHER YOUR OWN INTELLIGENCE FIRST

Ask these questions internally:

- How is Real World Data used in your company today?
- How long does it take you to understand patient treatment pathways and patient switches?
- How do you monitor drug performance?
- Are patient treatment switches for a target disease and resulting outcomes understood and proactively managed?
- Does your organization have a front-end visualization system accessible to the line-of-business?
- Do the business users have dynamic dashboards and live reporting capabilities?
- How does your organization source and integrate data from different geographical markets?

STEP 2: DEFINE GOALS

- Document the desired outcomes from RWEA
- Will you use existing or outside data sources?
- Which existing IT technology investments can you leverage?

STEP 3: QUESTIONS TO ASK A VENDOR

- Does the vendor possess a thorough understanding of big data analytics?
- How deep is the vendor's experience in data science?
- How will they address and simplify data integration?
- Who will automate the analysis, aggregation and provisioning of data sets?
- Will they automate data ingestion, profiling and mapping to OMOP CDM?
- Does the vendor have a global analytics organization?
- Does the vendor have a track record of success and satisfied customers?
What to demand from a RWEA vendor

1. Only look at solutions that are flexible, scalable, share a common data model and have an advanced analytics framework
2. Demand pre-built solutions that can be configured versus custom builds
3. Ensure the capability exists to work with your existing infrastructure or private cloud

What next?

It is doubtful that RWE will supplant randomized clinical trials in the near future. Rather, RWE is generating new forms of evidence that the healthcare industry needs to consider alongside traditional RCT evidence.

RWE adoption has, and will continue to increase at a rapid pace, improving targeting of treatment at the right time, for each individual patient. The potential of RWE can be achieved only if we can overcome the challenges surrounding RWD. As technology continues to improve, more robust, flexible RWEA platforms will become available. Such platforms will need to integrate and analyze RWD from disparate sources, integrate and standardize the Real World datasets for consistency, and use advanced algorithms to produce relevant insights. And as new data sources surface in the future, they should be integrated into the RWEA platforms quickly and efficiently.

As technology improves so will adoption of RWEA platforms. The results will be improved patient outcomes, more patient-centric care, and better-targeted healthcare spending.
Authors

**Sagar Anisingaraju** is the Chief Strategy Officer at Saama Technologies, and the winner of Chief Strategy Officer of the Year award from Innovation Enterprise. Sagar has been instrumental in architecting advanced analytics solutions, used by life sciences companies to derive critical insights in healthcare delivery. He is a frequent contributor to a number of publications, such as Genetic Engineering & Biotechnology, on the use of big data in life sciences. Prior to joining Saama, Sagar was the founder and CEO of InfoSTEP Inc.

**Nikhil Gopinath** is a Senior Solutions Engineer & Life Sciences Lead for Saama Technologies. His focus is big data technologies and applications of data science in clinical research & development. He holds a B.S. in Biochemistry from North Carolina State University and is currently pursuing a Master’s in Biomedical Informatics at Rutgers University.

**Nekzad Shroff** is Vice President of Business Outcomes and Solution Strategy at Saama Technologies. In his role, Nekzad advises pharmaceutical manufacturers on analytics strategies for managed care contracting, payer access management, outcome-based reimbursement, distribution strategy, and commercial sales and account management. He also leads strategic client engagement for Saama’s life science solution implementations.

To learn more about Real World Evidence Analytics visit [www.saama.com/ls](http://www.saama.com/ls)

Connect with Us: Sales@saama.com  
1.888.205.3500 or 1.408.371.1900

**About Saama**

Headquartered in Silicon Valley, Saama is the leading Big Data solutions company delivering Analytics Advantage to Global 2000 clients. Our Fluid Analytics© maximizes existing customer infrastructure, allowing us to focus on the white space between existing capabilities and the critical business questions that need to be answered. We are unique in our ability to combine our Fluid Analytics Engine orchestration with our vertical expertise to drive the rapid adoption of advanced analytics into company-specific business processes in a matter of weeks. Saama has broad experience in industries such as life sciences, healthcare, insurance, financial services, CPG, high-tech and media. Clients include Actelion, Brocade, Broadcom, Cisco, CSAA Insurance Group, Dignity Health, GoPro, Motorists Insurance Group, Otsuka, PayPal and Unilever.