Analyzing real-world data: Generate new scientific insights to increase patient and medical product understanding

Business Impact

"The issue of new drugs and biologics not being taken up by the market is that health technology assessment (HTA) bodies want different data than the regulatory agency is using to approve the drugs, such as robust analytics on real-world data to determine rare adverse events and long-term efficacy."

A senior medical officer of a regulatory agency, March 2016

Challenges

- **Managing and storing complex real-world data**. Vast amounts of data change over time, are not structured according to a standard data model, and come from different health care systems and contexts.
- **Collaboration among different stakeholders**. Managing and analyzing real-world data requires different skill sets and reports from data managers, statisticians, data scientists, epidemiologists, clinicians and other users from clinical development, health economics and outcomes research, epidemiology and commercial brand teams.
- **Analyzing big data sets**. Real-world data is typically very large, and not in a structure ready for creating and analyzing patient cohorts. Large amounts of new data arrivals make updating analytical and reporting techniques and cohorts difficult.

Pharmaceutical manufacturers want better insights into real-world use of their medical products since this additional information complements data gathered during the development phase. A primary objective is to better measure the value that the medical product (device, medicine or vaccine) brings to the patient in a clinical real-world setting that is often different than the evaluation of patients included in randomized clinical trials.

Life sciences organizations are finding real-world data from different providers and sources: commercial data providers that repackage clinical and financial health care information; disease registries; safety and complaints data; hospital and lab information; wearable device data; physician notes; social media; and more. The challenge for pharmaceutical companies is to respond in a timely manner to questions from commercial and brand teams, research and development, regulatory authorities or reimbursement agencies.

The process requires finding the right data source, getting the data in a format that can be queried, and preparing the analytical environment to analyze the large amounts of divergent patient-related data. Then scientific and repeatable evidence can be generated – and questions answered based on real-world evidence.

Our Approach

SAS provides a scalable analytics platform that gives statisticians and data scientists an environment they can trust and easily use. We provide software and services that help you:

- **Manage data**. Cleanse, standardize, load and integrate real-world data prior to using it.
- **Integrate Hadoop**. Profile, integrate, cleanse and move data stored in Hadoop with an intuitive interface that doesn't require coding.
- **Provide access to any user**. Directly interact with complete patient populations, quickly determine feasibility of studies based on the number of patients meeting criteria, and reduce time and resources extracting patient populations interactively.
- **Visualize and analyze cohort data**. Easily explore and understand cohort characteristics and evidence obtained in data and make that accessible for in-memory analysis and visualization in SAS® or other technologies of choice (R, Python, third-party visualization tools).

SAS delivers best-in-class data integration, high-performance analytical capabilities and visualization solutions so that users can gain insights across your life sciences organization. Achieve faster time to insight from real-world big data to real-world evidence and gain a competitive advantage for product development, marketing, market access and commercialization decisions.

The SAS® Difference

SAS is the only solution that provides all the capabilities you need to glean insight from real-world evidence – from data management to cohort extraction to advanced analytics.

- **Data management**. Collect internal or external data from point-of-care systems, electronic health records, insurance claims, patient-reported outcomes, trusted third-party data providers and others. Develop process automation to map data to a common data model and refresh cohorts and outputs as new data arrives.
- **Cohort building**. Identify research cohorts without coding; complex queries can go beyond simple subsetting to selecting criteria with multiple temporal relationships and Boolean logic. Quickly see the effect each inclusion/exclusion criterion has on the patient population to determine study feasibility. Reuse and modify criteria against other real-world data assets to compare across populations, reducing time and improving efficiency.
- **Analytics**. Access an analytics library of methodologies that includes simple descriptive statistics, predictive analytics and machine learning methods. Third-party analytics and visualization tools work on the defined cohorts.
- **Visualization**. Explore, visualize and report on real-world data sources to generate insights to support decisions on treatment regimens, gaps in care, reimbursement, formulary access or support clinical development decisions. Pre-define characterization of cohorts and do ad hoc exploration. Extensive and advanced visual analysis lets users understand the therapeutic area, medical product or device, and longitudinal effects of the therapy on the patient.
- **Speed and agility**. Navigate and explore massive data sources with little or no lag time from a point-and-click interface. With high-performance analytics, calculations on millions of rows of data can happen in seconds, rather than minutes, hours or days.

Case Study: A Global Pharmaceutical Company

Situation

A pharmaceutical company's marketed drug will be losing patent protection in a few years, putting the company at risk of losing its major revenue source. With new drug compounds in various stages of discovery and development, the executive team wants to know how the market value of a current in-market drug can be expanded through extending the customer base or identifying new indications. Therefore the marketing team wants to explore claims, laboratory, survey and social media data to better understand the drug's utilization, performance, adherence and preference.

Solution

Using SAS Data Management, data from numerous sources – including proprietary, commercial and unstructured – is now transformed and loaded into SAS Real World Evidence.

Results

The data is now available for defining patient cohorts using complex queries and applying medical terminologies to narrow down to the right patient subsets.

- Marketing teams can learn how the product is used by patients and physicians so that it can best be positioned before the patent is lost.
- Development teams can gain insights about drug effects by looking into the laboratory data and identifying potential new indications or design next-generation clinical trials on follower product categories.
- Statisticians can program rich, accurate reports that are integrated with scientific and regulatory reports.
- Clinical and scientific teams can look at simple visual reports that translate analytical complexity of observational health care data into visual explorations and reports.

What if you could …

- **Improve safety**: Identify subpopulations demonstrating unique risks.
- **Obtain real-world product insights**: Understand broad population clinical effectiveness, adherence, comparative effectiveness and overall patient outcomes over time.
- **Improve marketing**: Improve brand planning and position new medicines.
- **Establish economic value**: Analyze preference and performance data to quantify product/service market value and improve price negotiations.

SAS Facts

- SAS solutions are the industry standard for data analysis and reporting in clinical trials.
- For 40 years, life sciences companies have used SAS to derive greater insight from information.
- Our software is installed at more than 83,000 business, government and university sites.

Learn more about SAS software and services for life sciences at: sas.com/rwe.

To contact your local SAS office, please visit: sas.com/offices

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