

The story is in the REAL data! Preparing and Utilizing Claims and Electronic Medical Records Data for Clinical Research

Laurie Rose, SAS, Cary, NC, USA

INTRODUCTION

Real-world data coming from the healthcare ecosystem is being used in more instances of clinical research. Claims data and electronic medical records often represent a rich source of patient data that can help guide researchers in late phase and post-market studies. When planning analysis of the data, which can be massive in size depending on the source, the techniques to prepare the data will vary from typical clinical trial data. This paper looks at the needs for managing and preparing health care data for research and will provide examples of analyses and visualizations that can be leveraged to get the most value of these additional data sources (Figure 1).



Figure 1

HEALTHCARE DATA SOURCES

Electronic health records (EHR) and **claims data** bring new insights to patient information in clinical research.

The availability of Electronic health records (EHR) and other digital, health-related data has increased the opportunity to advance clinical research. Data sources are becoming more readily available, including device data (fitness, biometric, etc.), socioeconomic, social media and other health behavior data.

Global examples of potential sources of data (Figure 2):

- Electronic health records – partnerships with providers, government entities, third-party data providers (i.e., EHR4CR, Optum)
- Claims – government and private payers, third-party data providers
- Clinical trial registries – EU Clinical Trials Register, clinicaltrials.gov, International Clinical Trials Registry Platform (ICTRP)
- Genomics and electronic medical records – eMERGE Network
- Patient-reported outcomes – patient.info/forums, PatientsLikeMe.com

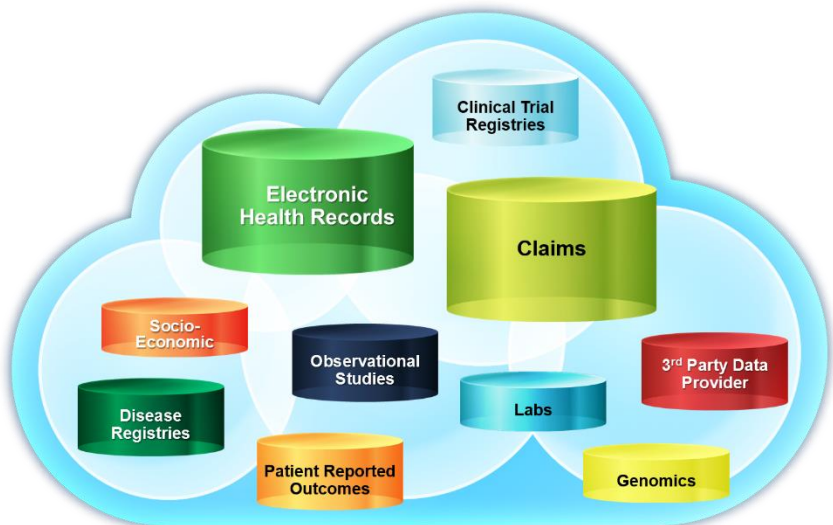


Figure 2

ADDRESSING DATA ISSUES

Managing EHR and claims data brings its own set of challenges and methods. While prepared data can be purchased, many life sciences companies will partner directly with healthcare organizations for data use. New or repeated data elements from multiple EHRs, financial and utilization data from claims, and additional sources of health-related data must be cleansed, reconciled and organized for analysis. Table 1 provides a set of suggested data elements from EHRs to be used in clinical research.

Nr	Data Group	Sample Data Item	Example	Definition
1	Demographics	Date of Birth	10.10.1967	Calendar date on which a patient...
14	Medical History	Menopausal Status	Premenopausal	Stage of female menopause...
24	Diagnosis	Diagnosis Code	C34.1	Code representing a diagnosis...
25	Procedure	Procedure Text	Lobectomy	Textual presentation of a...
29	Findings	Weight	80kg	Weight of a subject
38	Laboratory Findings	HDL in Serum	52 mg/dl	LOINC Code 2085-9
73	Medication	Dosage	100 mg/day	Quantity of an agent such as...
99	Scores/Classification	Hoehn and Yahr	2	Scale used to describe the extent...

Table 1. Suggested EHR data elements used in clinical research (Source: trialsjournal.com/content/15/1/18)

There are a number of considerations when preparing healthcare data for analysis:

- 1) Capacity to correlate **clinical** and **financial impacts** on patient health
- 2) Ability to perform **individual** and **population-based** analytics
- 3) Capability to deliver **real-time** and **historical** information
 - Current medications, historical medications
 - Current vitals, health status, notes
 - Longitudinal disease progression for chronic diseases
- 4) Integration of **multiple** systems
 - Legacy systems
 - Homegrown systems
 - Stand-alone systems
 - Facility-specific systems



In addition, general principals of Information Management should be applied. These include having a comprehensive Data Architecture and Data Governance foundation that is established at an enterprise level. The execution of the architectural design and data governance process are tightly linked to the use of healthcare data across the organization, including data and user access and permissions, clinical, business and technology standards, business rules, and other core components of the information management methodology.

Key methodologies to be implemented with the data architecture include data integration, metadata management, data quality, data security, and master data management. Figure 3 below provides key points to use when putting an information management methodology in place.

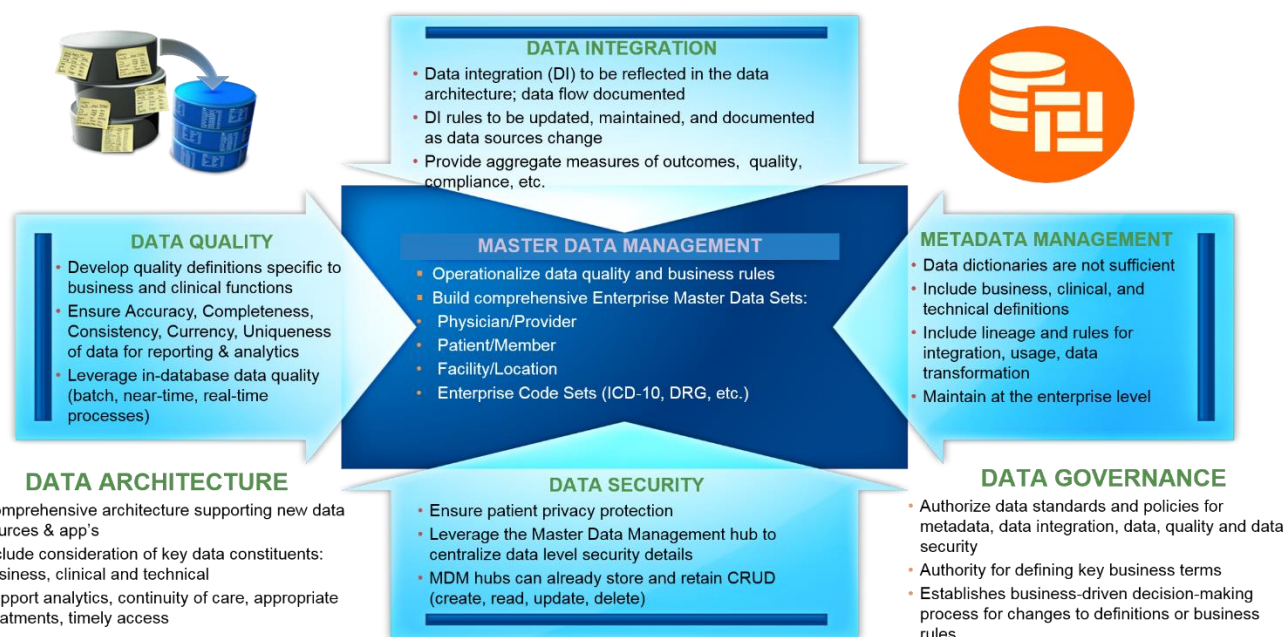


Figure 3. Healthcare information management

ANALYSIS, VISUALIZATION & DISCOVERY

With integrated EHR, claims and other real-world health data available, the opportunity to generate new insights reaches many areas of clinical research and operations. Using modern day capabilities, big data can be visualized and explored in memory with immediate discoveries and results. Predictive models, rules-based analysis, text analysis (medical records, social media), cohort building and episodes of care analysis are all viable methods for utilizing EHR and Claims data to bring greater understanding of patients to the clinical development process.

Examples of leveraging these combined data assets include analysis and exploration of:

- Healthcare cost and utilization
- Episodes of care
- Brand strategy and pricing
- Social media for recruitment
- Effective treatment regimens
- Comorbidities
- Adverse events
- Prescribing-compliance behavior
- Patient cohorts
- Gene-disease associations
- Trial design/execution
- Patient reported medication use

See Figures 4-7 below for examples of interactive explorations supporting several of these initiatives.



Figure 4. Adverse event analysis



Figure 5. Chronic disease analysis

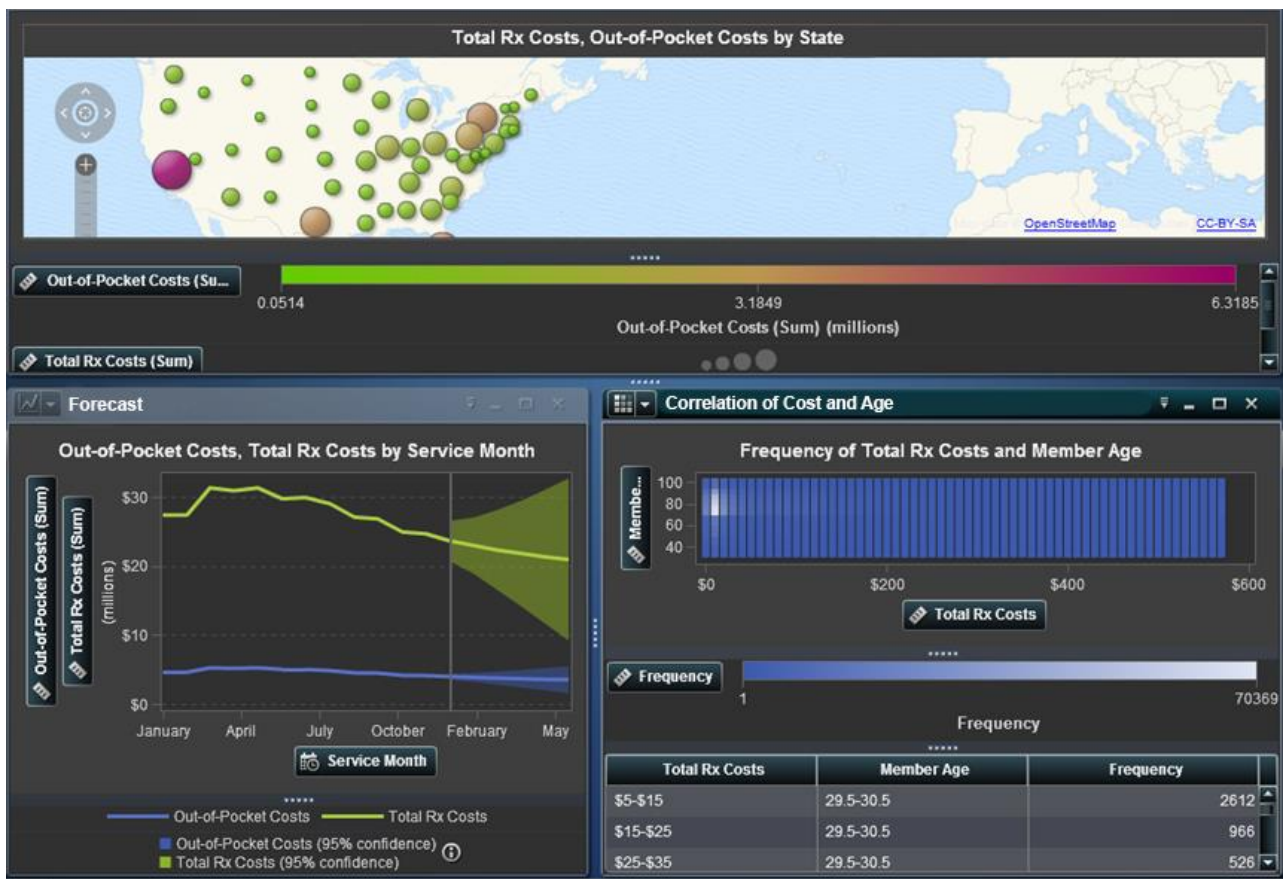


Figure 6. Out-of-pocket Rx costs



Figure 7. Healthcare cost and utilization

CONCLUSION

Collaboration among healthcare organizations and pharmaceutical companies has the potential to greatly influence the **improvement of patient outcomes**.

Benefits from leveraging real-world health care data in clinical research and operations include:

- ✓ Determine outcomes on much broader population
- ✓ Deeper understanding of unmet patient needs
- ✓ Simulate trials based on actual patient outcomes
- ✓ Reduce protocol design time
- ✓ Demonstrate value and safety of treatments
- ✓ Accelerate study patient recruitment

Note

This paper was presented as a poster at the 2015 Annual PhUSE conference in Vienna, Austria. For more details about this topic, please contact the author.

CONTACT INFORMATION

The author welcomes comments and questions. Contact the author at:

Laurie Rose
 SAS Institute
 SAS Campus Dr.
 Cary, NC 27513
 USA
 Phone: +1.919.531.7124
 E-mail: Laurie.Rose@sas.com or linkedin.com/in/laurierose2

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