

The story is in the REAL data!

Preparing and Utilizing Claims and Electronic Medical Records for Clinical Research

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1 INTRODUCTION

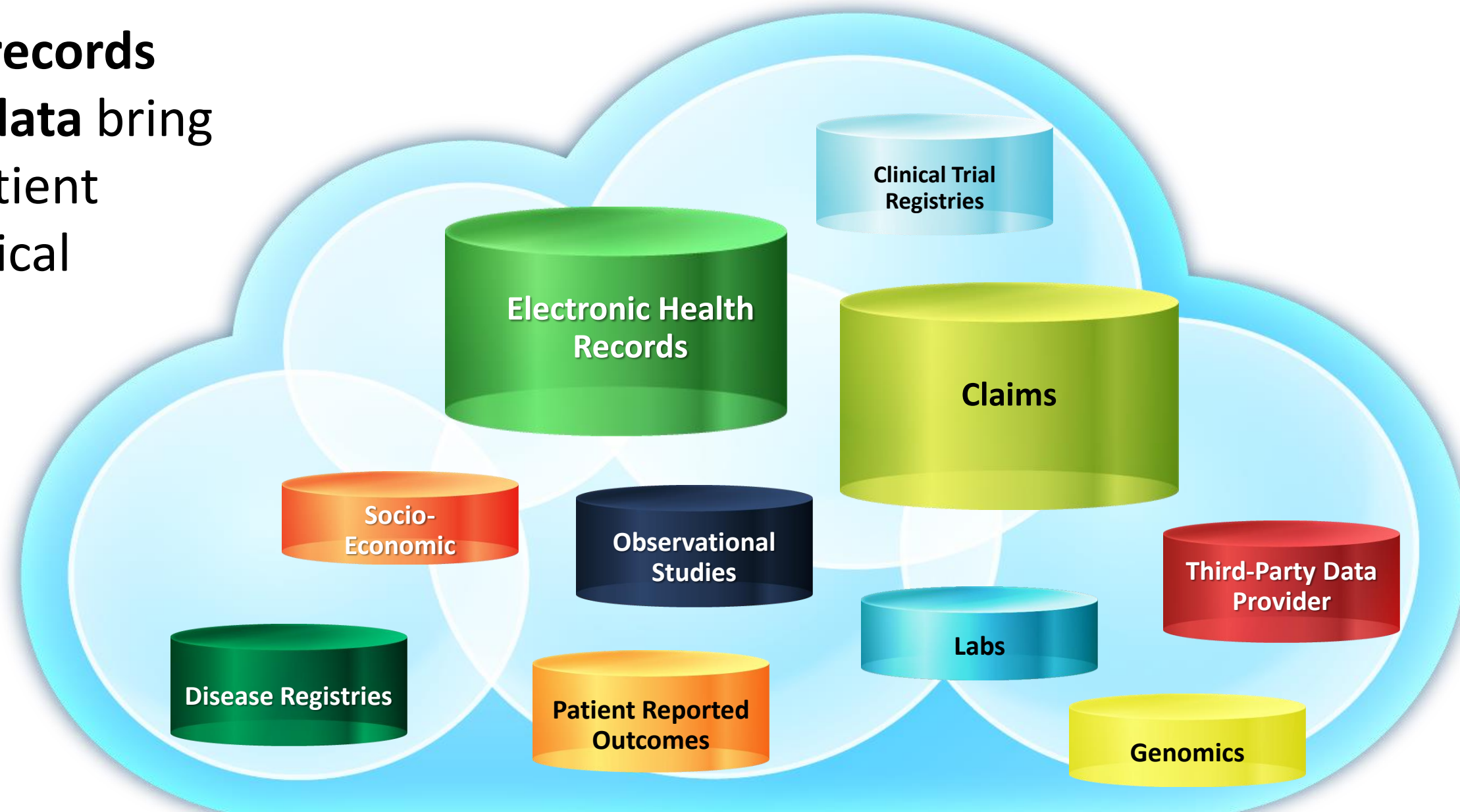
Real-world data coming from the healthcare ecosystem is being used in more instances of clinical research. Claims data and electronic medical records often represent a rich source of clinical, administrative and financial data that can help guide researchers in late-phase and post-market studies. Using this data can lead to tremendous advantages in both the development and commercialization of therapies.



Availability
of Real-
World Data

2 HEALTHCARE DATA SOURCES

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



The availability of EHRs 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:

- 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

3 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 (Table 1), financial and utilization data from claims, and additional sources of health-related data must be cleansed, reconciled and organized for analysis.

No.#	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...

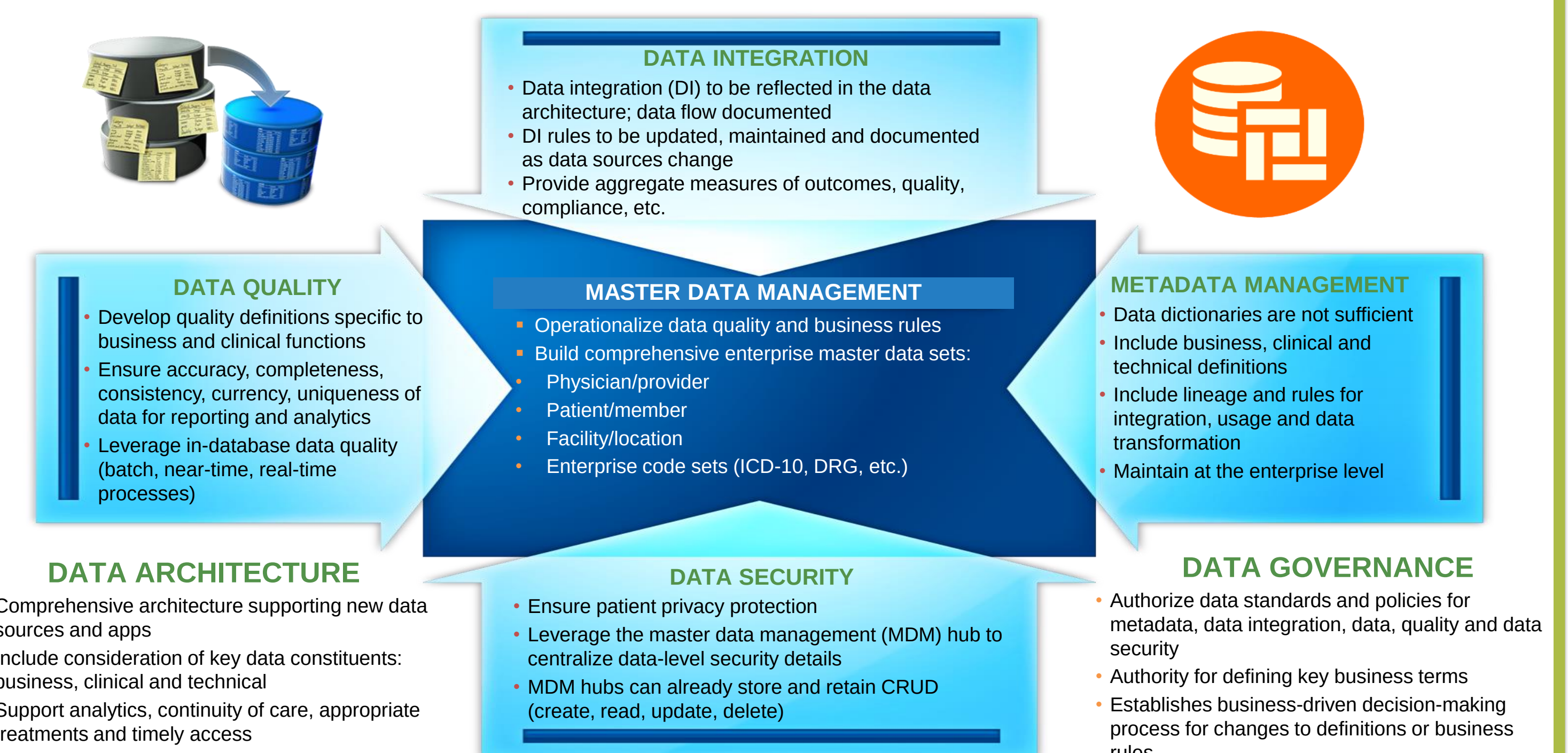
Table 1. Suggested EHR data elements used in clinical research (Source: trialsjournal.com/content/15/1/18)

Considerations when preparing healthcare data for analysis:

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



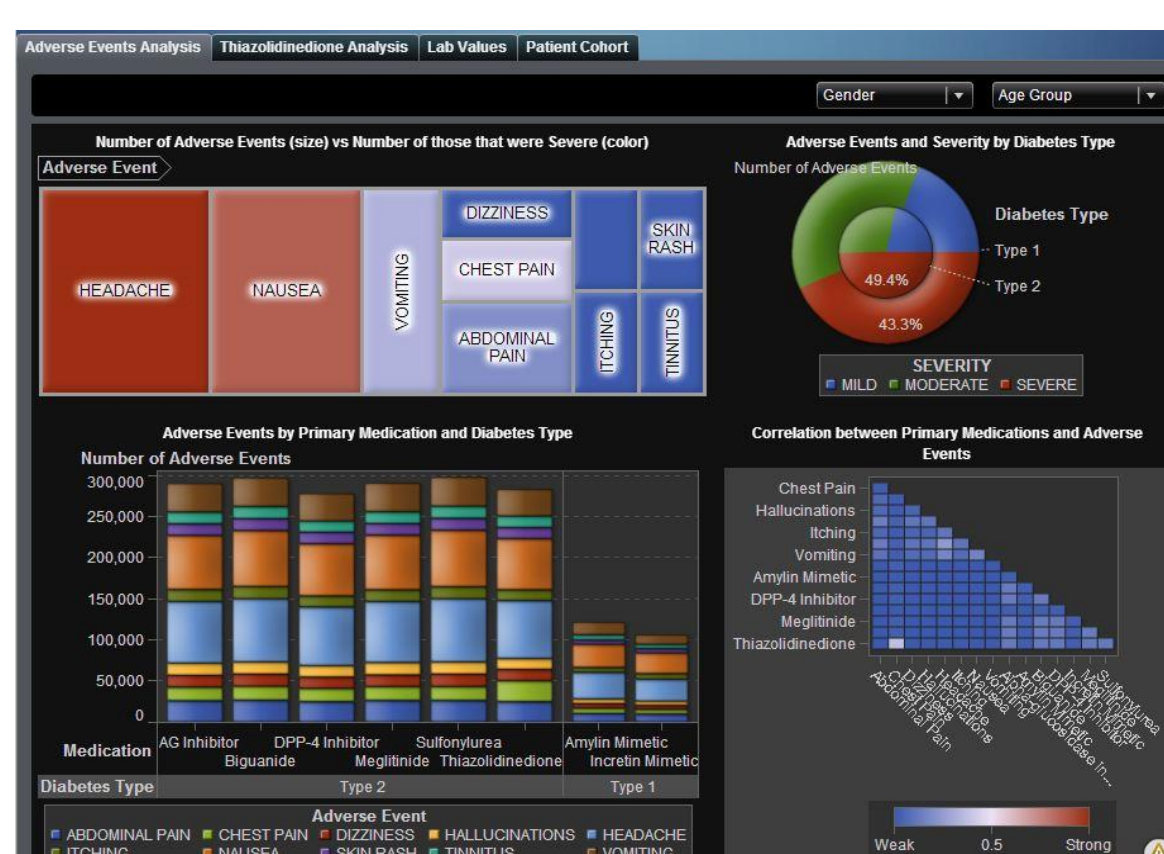
Comprehensive information management practices to be applied:



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

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



Adverse event analysis



Chronic disease analysis



Out-of-pocket Rx costs



Healthcare cost and utilization

5 CONCLUSION

Collaboration and data-sharing among healthcare organizations and pharmaceutical companies has the potential to greatly influence the **improvement of patient outcomes**. Benefits from leveraging real-world healthcare data in clinical research and operations include:

- Determine **OUTCOMES** on much broader population
- SIMULATE TRIALS** based on **ACTUAL PATIENT OUTCOMES**
- Demonstrate **VALUE** and **SAFETY** of treatments

- DEEPER UNDERSTANDING** of unmet patient needs
- Reduce **PROTOCOL DESIGN** time
- Accelerate **PATIENT RECRUITMENT**