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.

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

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.

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

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)

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

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