**MOTIVATION**

- Although randomized, controlled clinical trials remain the gold standard for assessing the efficacy of pharmaceuticals, biologics, and medical devices, they are inadequate for addressing questions about the long-term effectiveness and safety of these interventions.
- Today, as payers and other stakeholders expect interventions to be safe and effective as well as provide good value for money, the focus is increasingly on how these interventions perform in the “real world” and whether or not they add value to the healthcare system.
- Real-World Evidence (RWE)-based approaches are increasingly becoming the “new normal”—practical and necessary for bringing a product to market, ensuring its relevance in clinical practice, and sustaining its value throughout the lifecycle of the product. However, RWE studies bring with them their own special considerations, including study design, analytical approaches, and sources and quality of data.
- A part of RWE that remains to be fully explored is the hybrid study, which merges retrospective and prospective data to save time and money in evaluation and assessment of investigational as well as marketed pharmaceuticals, biologics, and medical devices.

**PROCESS**

- **Data Selection and Capture**
  - Efficacy/Effectiveness
  - Resource Utilization
  - Costs/Claims
  - PROs/Utilities
  - Safety?

- **Analysis**
  - Individual Data Sets
  - Pooled Data Sets

- **Database Merging**
  - Size
  - Format

- **Data Merging From Multiple Sources**
  - Standardize coding, event definitions, and outcomes
  - Common data model for harmonization across multiple sources
  - Storage system to enhance accessibility of individual databases from common platform as anonymized data at appropriate level

**HYBRID STUDY DESIGN**

- **Formulate Hybrid Study Design**
  - Study Design: Every endpoint must be supported
  - Data Collection Feasibility, avoiding superficial data collection

- **Target Data Management and Analysis**
  - Data Access: Increase
  - Data Quality: Enhance

**FUTURE CONSIDERATIONS**

- How can hybrid studies facilitate product development?
- How can combined retrospective/prospective data management systems be used to demonstrate and predict value?
- How can hybrid studies demonstrate market leadership while enhancing and maintaining flexibility in an ever-changing market?
- How can retrospective data from prospective patients drive understanding of market access and a product’s life cycle?

**REFERENCES**


**CONSIDERATIONS**

- **Logistics**
  - Start-Up
  - Ongoing
  - Regulatory

- **Data Management**
  - Single-use vs. multi-use datasets
  - One-time vs. multi-year analysis
  - Quality of data: Availability Consistency Validity

- **Analytics**
  - Type of analysis
  - Research objectives
  - Retrospective vs. Prospective data

**OVERVIEW**

- Target Population
- Selection
- Historical/Retrospective Data
- Comparisons of Endpoints Between Two Data Sets