INNOVATING CLINICAL TRIALS: Aggregating Clinical Data for Easy Access and Brilliant Insights

There are increasing pressures for life-sciences companies to look aggressively for ways to decrease costs and bring new products to market more quickly. Sponsors want to leverage their clinical data to support critical decisions. To do this clinical data need to be easily accessible and integrated for sponsors to have a complete view of the efficacy and safety of a treatment.

Today most sponsors are only able to review siloed data components, which limit their ability to identify trends and information to empower their decision making. A clinical data repository (CDR) standardizes, aggregates, and integrates clinical data from multiple systems and sources to support insightful analyses that drive impactful actions. Without a CDR, performing cross-trial analyses is a daunting and costly task that requires programmers and developers to manually integrate data, which is a time-consuming and error prone endeavor.

Analytics and Insights

There are cost-effective and robust CDR platforms available to aggregate clinical trial data from multiple sources and provide insights quickly, easily, and in a format that enhances decision-making. A CDR enables team members across the life-sciences organization to gain actionable insights. Advanced analytics capabilities bring data visualizations to enhance the ability of companies to identify quality issues or detect safety signals more quickly and efficiently.

Visualizations and dashboards automatically update as clinical data are integrated into the CDR. A best-in-class CDR will provide a robust set of standard reports that provide meaningful insights for various roles.

Executive Managers

» Identify potential trial operations problems early in the trial by accessing metrics, such as investigator recruitment rates, patient enrollment rates by site, and site retention rates
» Identify potential safety issues for the product with alerts
» Expedites the go/no-go decision-making process
» Share pooled data results with potential partners and investors

Clinical Operations Personnel

» Trends to detect site fraud
» Identify potential problems early with access to metrics such as number of potential patients that failed trial screening, subjects with protocol deviations, etc.
» Review data and provide CRO oversight in a timely manner
» Identify the number of subjects enrolled in the study that did not meet inclusion/exclusion criteria
» Track trial budgets and review cost and site metrics with projected versus actual expenses

Drug Safety/Medical Monitors

» Access necessary data in preparation for the Data and Safety Monitoring Board review
» Determine the percentage of patients with elevated liver function tests
» Easily review serious adverse events and adverse events information
» Monitor patient disposition information
» Evaluate the adverse events risk ratios for the most frequent adverse events
» Access information for patient narratives
» Leverage insights for developing and implementing a risk mitigation strategy

Data Managers

» Review data for safety trends and outliers
» Identify trends and query the sites for efficient data cleaning
» Access legacy trials for insights into what worked and did not work as the next protocol is developed
» Generate and review patient profiles for quality assurance
» Confirm consistency of adverse events with relevant data across the trial (eg, adjudication, end points)
» Take action on discrepancies identifying potential protocol deviations
» Review data for protocol defined inclusion/exclusion criteria

Contributed by

RAJ INDUPURI
Executive VP, Principal Partner
eClinical Solutions

Aggregation, Standardization, Visualization, and Analytics

One of the ways companies can access and interact with all of their clinical data is by using a clinical data repository that empowers their teams and provides them with complete access to all of their collected data, aggregated and standardized, for analysis and visualization — from cross trial/program views to the individual patient level.

Using cloud-based architecture, a scalable clinical data repository platform can be implemented for storage of clinical data as well as

powerful visualization and computing for reporting and analysis.

Data that have been integrated and standardized in a platform are instantly accessible through advanced analytics and visualizations. These visualizations enable users to interact with their data for views of adverse events, lab results, patient profiles, and more. Drill down capabilities give users complete transparency and empower them to interact with their data.

The benefits of clinical data repository are:

- Increased transparency and real-time visibility into clinical trial operations and data.
- Enhanced collaboration between investigators, sponsors, and partners.
- Increased efficiency and speed to conduct trials and prepare submission-ready data sets.
- Enhanced capabilities to support effective risk-based monitoring strategies.
- Establish governance models for data, systems, and standards to ensure compliance with regulatory requirements.
- Decreased frustration and costs in completing trials.

Best Practices for Successfully Implementing a CDR

An important first step is to develop an implementation plan that includes these areas:

1. Identify a cross-functional team to lead the initiative
2. Identify and align the organization to the ultimate goal
3. Implement a governance process
4. Develop and implement a change management plan that encompasses…
   - **a.** Communication plan
   - **b.** Knowledge transfer and training

Implementing a CDR requires effort, time, and planning to be successful. These four critical success factors ensure advanced technologies are successful in transforming clinical trial processes for an organization.

Options for Implementing a CDR

Sponsors can build their own systems, which can be very expensive and time consuming, or can use existing cloud-based systems.

A best-in-class platform will enable team members across the organization to interact with data, run ad hoc queries, and access data visualizations to analyze clinical and operational data across multiple trials and use this information as part of their monitoring strategy.

A key feature of a best-in-class platform is the use of advanced extraction, transformation, and load (ETL) technologies to enable data mapping and standardization according to a defined data model based on CDISC standards.

Additionally, platforms that leverage technology in an integrated manner offer scalable warehousing, efficient data computing capabilities, a document management system, and a communication portal between information consumers. PV

Case Study

Mid-market pharmaceutical company implements a CDR and sees its data in a new light

A mid-size pharmaceutical company with a growing pipeline had both legacy and ongoing clinical trial data in different formats and systems. In the current state, the data were of limited use without significant programming efforts.

Additionally, multiple functional groups such as biostatistics, clinical operations, and clinical data management wanted to interact with the clinical data for different reasons. Although the organization standardized its EDC system, the use of multiple data management partners, including internal resources, resulted in clinical data being in disparate structures and formats.

The client set out to find a partner and platform that would integrate its clinical trial data and data from its CTMS system into a platform that could aggregate the data and standardize it using CDISC's SDTM. The goal was to implement a technology platform that would centralize the data, and allow the various stakeholders to analyze and visualize their data for a single trial or across trials to gain meaningful insights and make decisions.

The answer to the client's problems was to implement a clinical data repository to aggregate and standardize the clinical data by using CDISC standards and mapping its legacy data by leveraging next generation ETL capabilities. Using Web services, the client's ongoing clinical data is now integrated in near real time, in the defined standard.

A series of custom visualizations and dashboards helped the client's various functional stakeholders visualize their data. In addition, training users on the integrated business intelligence capabilities allowed them to build views of their data through the development of reports, graphs, patient profiles, and dashboards. Through the visualizations and dashboards, the client's various stakeholder groups can perform analyses and accesses multi-dimensional clinical data views by role, for example data managers, safety analysts, biostatisticians, medical monitors, and clinical trial managers.