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Clarity

With an increasing regulatory focus on risk-based approaches, risk-based quality management (RBQM) is a key area in clinical development. Clarity is aimed at providing a platform to implement your RBQM strategy and drive increased patient safety and data quality .

“Traditional on-site monitoring of each clinical site to evaluate study conduct and perform 100 percent source data verification is highly resource-intensive and may account for up to a third of the total clinical trial cost. But traditional on-site monitoring that is overly focused on source data verification doesn’t guarantee data quality.

Risk-based monitoring, as a component of a sponsor’s overarching quality risk-management systems and trial-specific quality by design programs, can help to provide more efficient oversight of trials, while still protecting human subjects and assuring data integrity.” –
Former FDA Commissioner

Business problem

Given limited resources, emerging biotechs typically outsource clinical development entirely including oversight. Although, this doesn’t absolve the sponsors of the responsibility of ensuring sufficient risk and quality oversight as defined in ICH GCP E6R2, given the impact on patient safety and data integrity. In the long term, the journey of understanding, implementing, and maintaining compliance with ICH GCP E6R2 guidelines requires focused effort driven by a robust process and technology ecosystem.

How does Clarity support you?

A regulatory compliant and seamlessly integrated technology solution with robust central data monitoring capabilities is key to successful RBQM implementation. Clarity is an end-to-end technology solution encompassing clinical data integration, risk and quality management with near real-time analytics. Clarity’s modules address each step across the data journey allowing sponsors to plan, monitor, review, and mitigate risks throughout the development cycle.

Enabled with powerful data visualization at the patient, site, trial, and study-level, Clarity modules help identify data inconsistencies, examine data trends, evaluate systemic errors, and analyse site and patient-level outcomes.

Clarity RBQM

With end-to-end capabilities to synchronize all quality management (QM) steps defined in section 5.0 of ICH-GCP E6 guideline, Clarity RBQM enables the management of quality parameters throughout clinical development.

Powered by a highly configurable integration engine, this module has the ability to pull data from diverse external sources like sFTP, APIs, and work with SAS sources (eg., SAS7BDAT) and exports(eg.,XPT). As per the specified configuration, data can be transformed and loaded with full flexibility to adapt schema and data changes.

Comprised of 5 sub-modules that seamlessly combine, Clarity RBQM helps define and guide the entire risk and quality management process from planning until reporting and remediation. These 5 sub-modules are as follows:

Risk Planning

- A seamless workflow for effective and proactive risk planning
- Built-in standard Transcelerate RACT (Risk Assessment and Categorization Tool) library
- Captures critical data and processes, study-specific risks, risk evaluation and associated controls into the risk inventory
- Custom risk inventory for program level risk management

Risk Control

- Comprises of a detailed Integrated Risk Plan (IRP) template for study teams to draft, review, finalize, and approve
- Tracking and version control of the IRP during the study for trace ability and final reporting

Risk Surveillance

- One-stop solution for central monitoring and analytics
- Data-driven surveillance across all study dimensions- study level (statistical review), site-level (operational and clinical) patient-level (clinical), and QTL monitoring
- Intuitive with robust visualization of clinical and operational data allowing real-time data reviews
- Harmonized with Clarity Connect, the data integration module enabling integration across data sources into the analytics platform

Risk Review

- Facilitates signal management for study teams to create, manage, follow up, and action the risk signals identified
- Signal management workflow for central monitor/data reviewer and action owners to create and manage risk signals at various levels and link to risks identified within risk inventory (RI)

Risk Reporting

- An automated tool integrating inputs from all previous modules through a “push-down” mechanism to generate reports
- Enables study teams to view the final integrated risk plan (IRP), final Risk Inventory (RI), and signal summaries
- Reporter module with custom edits facility to update the structure of reports/summaries as per specific needs

Clarity Patient Insights

The Patient Insights module enables a one-stop view and review of patient data in a visual format. As clinical trials continue to become more dynamic, visualizing patient profiles and trends is a key ask especially while pulling in data from disparate sources for real-time reviews. Focused on critical data analysis driven by risk assessment, Patient Insights facilitates real-time data monitoring thus allowing instant remediation.

This module also has a pre-defined signal trigger algorithm to flag patient-level data anomalies thus reducing reduce manual review burden. In addition, all types of manual reconciliation efforts can be automated using the Patient Insights dashboard. In all, this module is a one-stop solution for visualizing the patient journey through clinical development.

Clarity Site Insights

In course of a clinical trial, understanding the health of the study sites in order to efficiently plan site strategy is key to ensuring timelines are on track. Site Insights helps identify site risks early on using Site Risk Factors or Site Performance Index to set course accordingly. A combination of standard key risk indicators and risk assessment-driven critical data risk indicators, provides a comprehensive site profile for targeted on-site monitoring. The setup of operational KRIs can be customized based on the need of the study and study team, thus giving you metrics that are critical to study conduct.

Clarity Study Insights

Near real-time progress of milestones, regulatory approvals, site contracts, and cycle times to reduce site activation delays are some of the key features available within Clarity Study Insights. To facilitate optimized monitoring, operational and site-level metrics such as enrollment, patient visit compliance and deviations can be readily accessed by study teams.

Also, periodic TMF review and payment reconciliation are built in to ensure regular tracking and issue resolution for faster study close-out.

Clarity Central Statistical Monitoring

This module is aimed at providing basic to advance statistical methods to analyze clinical and operational data, and identify high-risk subjects, sites and domains. The outputs of the Central Statistical Monitoring module can thus be leveraged for optimization of monitoring efforts, focusing on critical data points.

Additionally, early detection of data anomalies from CSM compliments the data cleaning efforts by data management, expediting database lock timelines.

Clarity Quality Tolerance Limit

Identification of deviations in trial conduct with a threshold in place may indicate systemic issues that could impact participants' safety or reliability of the trial results. This module facilitates the definition of QTLs ahead such that assessments can occur on a regular basis throughout the trial. Defining a secondary limit provides study teams with early opportunities to mitigate risks patients and the overall trial outcomes

QTL modules acts as a central repository for issue tracking and follow-up and all QTL deviations identified can be addressed in the risk review module of Clarity RBQM.

Clarity is a strong RBQM tool built by data strategists and statisticians, to help emerging biotechs create a risk and quality-focused ecosystem. Reach us to learn more about how we can help you navigate your clinical quality oversight and expedite study completion.

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