Centralised Monitoring Capabilities

Project Scope

Central monitoring is an emerging field with an unclear scope, goals and roles. Central monitoring, if executed appropriately, can have a positive impact on data quality, patient safety and clinical trial efficiencies. This project will work to define central monitoring (including differentiating from data management and other forms of data surveillance), and suggest success measures and best practices to ensure a well-connected end-to-end component of quality risk management. The project will provide insight and guidance to address understanding as well as the current and future needs of holistic central monitoring process and capabilities. Strong central monitoring practices can support early-study risk reduction and, through important trend analysis and mitigation, decrease preventable errors that can have an impact on patient safety or clinical trial conclusions. Our approach will encourage exploration of different approaches versus recommendations so as not to deter sponsor innovation (e.g. points to consider).

In Scope

- Access to study data with the ability to aggregate various data sources to enable oversight of the clinical data and operational data in near real time. This includes frequency of data transfers, audit trails, and facilitating PI oversight of medical care of patients.
- Ideal technology requirements (very broad – patients, sites, CRO–Sponsor connection) and new vendor qualification expectations.
- Cross-functional data review plan (medical review, statistics, data cleaning activities, operational, etc.), with clear defined purpose of what each role is reviewing, what, when and why.
- Definition of robust “monitoring” strategy, as required by the ICH.
- Connection to on-site monitoring, using centralised monitoring to determine on-site monitoring needs, site trends allowing for early, targeted site feedback for CRA to have more focused site engagement.
- Discussion of different data oversight strategies and methodologies and when to consider use of visualisations related to types of data reviewed (visualisations that are focused on critical data only, visualisation, that could contribute to a significant deviation vs. all deviations).
- Facilitated risk mitigation through conducting the trial, ensuring risk linkage to central monitoring oversight.

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Objectives & Deliverables	Timelines
White Paper – Challenges in Central Monitoring Implementation	Q3 2022
White Paper – Defining Central Monitoring Value	Q2 2023

CURRENT STATUS **Q4 2023**

- White Paper #2 is published
- Working to host a community forum in the new year