Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Enhancing Clinical Trial Success: The benefits of Mock Runs in Trial Preparation and Execution

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1. Background

Clinical trials are vital for advancing treatments and improving health outcomes. The challenges in trials include complex protocols, strict requirements, and coordination between multiple teams. The misinterpretations of protocol by site staff and communication gap with study sponsors can lead to inconsistent implementation in areas like eligibility, lab work, scheduling, shipments, and informed consent. Mock runs (practice simulations) are recognized as valuable tools for identifying problems and improving trial preparedness. Mock runs allow trial teams to simulate processes, identify logistical issues, assess resources, and ensure readiness before the actual trial begins. Despite their proven potential, the importance and impact of mock runs are underutilized in the research community. In general, there is limited data on mock runs regarding their effectiveness and perceived value by those involved in the research process.

2. Goals

- Investigating the importance of mock runs.
- Evaluating the perceived benefits of mock runs for clinical trial teams in new cancer trials.
- To compare the outcomes of clinical trials with and without mock runs.

3. Solutions and Methods

Intervention 1: Administer Questionnaires to site and sponsor personnel

Surveys were distributed electronically to site staff and sponsor associates to gather their feedback on past experiences with mock runs, their perceived needs, benefits and barriers towards integration of mock runs in their new clinical trials.

Intervention 2: Randomized Study Design: Mock run vs No intervention

Two studies (A and B) were selected based on similar characteristics, such as type of treatment and protocol complexity. Additionally, both studies are sponsored by the same biotechnology company (Sponsor X) and are monitored by the same clinical research associate (CRA). Study B was randomized into the intervention arm. The clinical research coordinator (CRC) conducted mock runs on different trial components by involving multidisciplinary teams. The topics covered- informed consent form (ICF), screening, eligibility, sample collection, investigational product (IP) administration, shipment logistics, electronic data capture (EDC), severe adverse event (SAE) reporting. Collection of data will occur from date of consent up until a day after IP administration (Endpoint). The data metrics to be measured includes number of protocol deviations, time consumption, number of email correspondences, number of unscheduled patient visits and team satisfaction with NRS.

4. Outcomes

Intervention 1: The findings highlight strong support for use of mock runs. Notably, 99 percent of respondents agreed that mock runs would be beneficial, with 25 percent advocating for them to be mandatory. This highlights the need to integrate mock runs into clinical trial startup processes.

Intervention 2: Upon reaching endpoints for both study A and study B, we plan to analyze and compare the impact of mock runs on trial efficiency and protocol compliance using the data metrics mentioned. We expect to present preliminary findings at future conferences or in follow-up research reports.

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5. Learned and Future Directions

Our future research will explore solutions to barriers like time and financial constraints to make mock runs more accessible and sustainable. Additionally, study the relationship between site staff turnover and the frequency of mock run implementation.

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