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

AT THE FOREFRONT
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BACKGROUND

Clinical trials are vital for advancing treatments and improving health outcomes. The **challenges** in cancer 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, visit scheduling, shipments, and informed consent.

Mock runs (dry runs or 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. At our site, there is limited data on mock runs regarding their effectiveness and perceived value by those involved in the research process.

Our study aims to offer **key insights** into:

- Investigating the importance of mock runs
- Exploring the needs motivating their use
- Evaluating the perceived benefits of mock runs for clinical trial teams in new cancer trials
- Determining the impact mock runs may have on trial efficiency and compliance

HYPOTHESIS

Cancer clinical trials that include mock runs prior to initiation will experience fewer operational challenges, higher preparedness, and improved efficiency compared to trials that do not include mock runs

Objectives:

1. To assess the perceived needs and benefits of mock runs from the perspective of site staff and sponsor personnel.
2. To compare the outcomes of cancer clinical trials with and without mock runs.

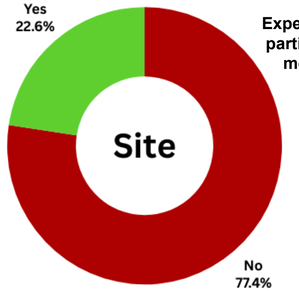
Study Design

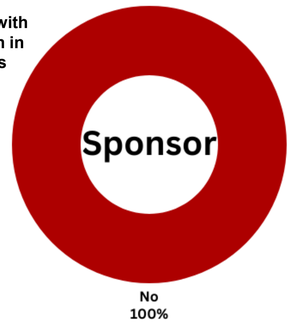
Intervention 1: Administer Questionnaires to site and sponsor personnel
Surveys were distributed electronically to site trial staff and sponsor associates to gather their feedback on past experiences with mock runs, their perceived needs, benefits, challenges and barriers towards integration of mock runs in their new clinical trials.

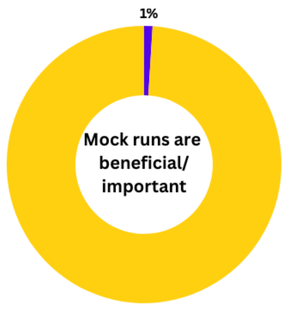
Intervention 2: Randomized Study Design: Mock run vs No intervention
Two studies (A and B) were selected based on similar characteristics, such as type of treatment and protocol complexity. Additionally, both studies are sponsored by the same biotechnology company (Sponsor X) and are monitored by the same CRA. Study B was randomized into the intervention arm. The CRC conducted mock runs on different trial components by involving multidisciplinary teams which are listed on the graph on the right,

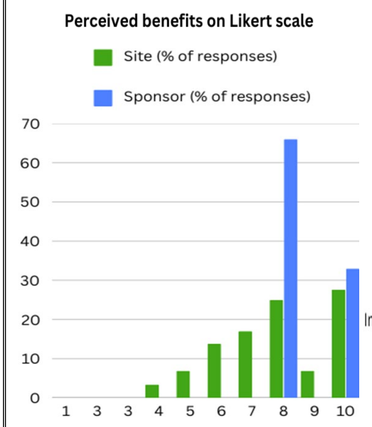
Results

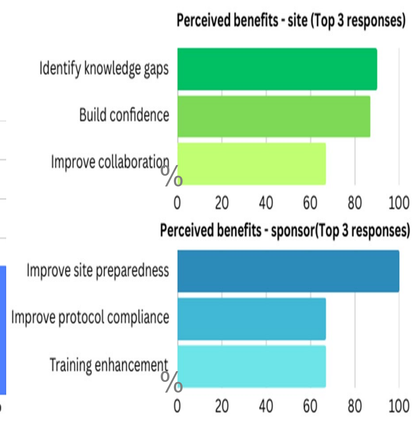
The figures below illustrate key data trends, highlighting our significant findings from Intervention 1.

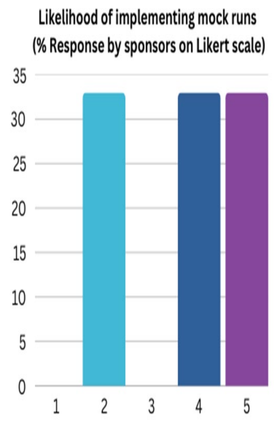




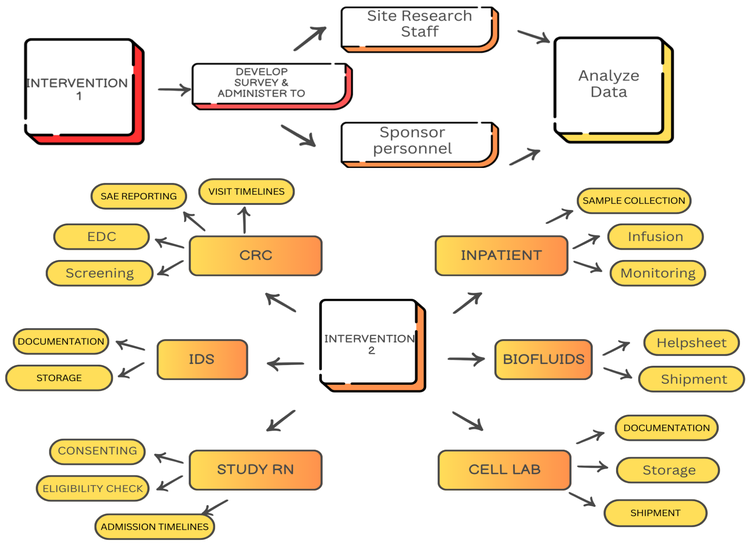








Methods



DISCUSSION AND FUTURE DIRECTIONS

The findings of **Intervention 1** highlight strong support for use of mock runs. Notably, 25% of respondents advocated for mock runs to become a mandatory practice, indicating a desire for integration into clinical trial start up processes.

Upon completion of collecting data for the randomized trial (**Intervention 2**) we plan to analyze and compare the impact of mock runs on trial efficiency and protocol adherence by using specific metrics such as number of protocol deviations -time consumption - number of email correspondences –number of unscheduled patient visits and team satisfaction with NRS. We expect to present **preliminary findings** at future conferences or in follow-up research reports.

Our **future research** will **e**xplore solutions to barriers like **time and financial constraints** to make mock runs more accessible and sustainable. As well as study the **relationship between site staff turnover** and the frequency of mock run implementation.

Acknowledgements

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