Impact of Structured Mock Runs on Trial Execution: A Comparative Study of Two Cellular Therapy Protocols

Mohamed Iburahim Haja Maideen MD CCRP, Amrinder Kaur MD
Cellular Therapy/ Transplant Program

AT THE FOREFRONT
UChicagoMedicine
Comprehensive Cancer Center

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.

Prior stakeholder assessments at our institution demonstrated strong interest in implementing structured mock runs to improve trial readiness, highlighting a gap between current practices and perceived operational needs.

However, quantitative real-world evidence evaluating the operational impact of mock runs remains limited. This study builds upon a prior quality improvement initiative that initiated a comparative evaluation of trial start-up with and without mock runs. The present analysis reports finalize outcomes from this comparison.

OBJECTIVES

1. To evaluate the operational impact of structured mock runs during clinical trial initiation
2. To compare operational and data outcomes between trials with and without mock runs
3. To assess the role of mock runs as a quality improvement strategy in cellular therapy/ oncology trials

STUDY DESIGN

This quality improvement study evaluated two cellular therapy clinical trial protocols matched for complexity (complexity score of 6 out of 6) and operational requirements. Both studies were conducted at the same academic research site (University of Chicago), monitored by the same clinical research associate (Sr. CRA), and sponsored by the same study sponsor (U.S. based clinical biotech company focused on T-cell therapies).

The two studies were randomized to receive or not receive a mock-run after SIV and prior to first subject enrollment. Outcome data were collected retrospectively from institutional trial records (Timepoint ICF Signing until Day 28) and summarized descriptively
Study A: Standard trial initiation (no mock runs)
Study B: Structured mock runs prior to trial execution

RESULTS

Figure A: Operational quality outcomes

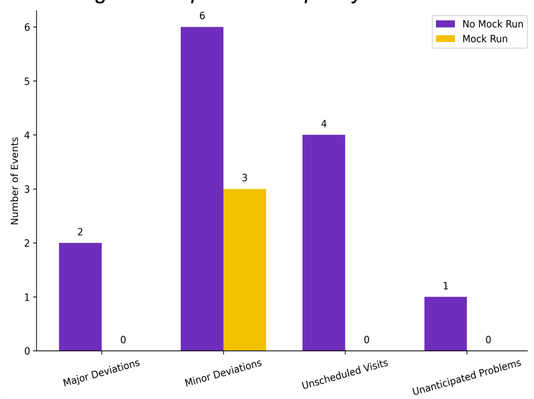
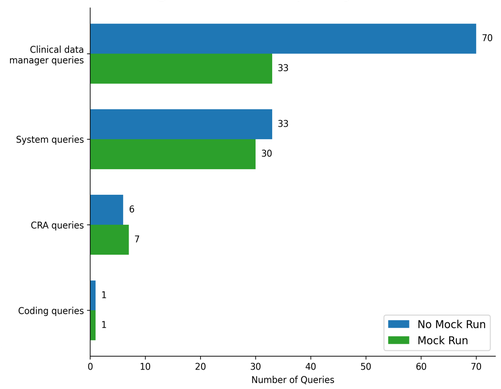


Figure B: Data quality outcomes



Key Findings:

*100% reduction in major PD and UP
*50% reduction in minor PD
*Complete elimination of UNS study visits
* Significant reduction in data queries

METHODOLOGY

Structured mock runs were designed by the author and coordinated by the primary clinical research coordinator, with multidisciplinary participation from investigators, nursing staff, laboratory personnel, pharmacy, regulatory teams and sponsor representatives (including the CRA).
Mock runs simulated full trial workflows using a standardized approach. A synthetic “mock” patient profile was generated using AI and tailored to protocol-specific eligibility criteria to enable realistic scenario-based testing.
Simulated processes included:
•Eligibility assessment and screening workflows
•Visit scheduling and protocol adherence
•Lab sample collection, processing and shipment logistics
•IP handling and administration
•Source documentation and EDC workflows

During each mock run, operational gaps, protocol ambiguities and communication challenges were identified and documented, with real-time stakeholder feedback used to refine workflows and improve trial readiness prior to study initiation.

DISCUSSION AND LIMITATIONS

Structured mock runs were associated with a reduction in both the frequency and severity of protocol deviations, as well as elimination of unscheduled study visits. These findings suggest that mock runs improve trial readiness by identifying workflow gaps, clarifying protocol interpretation and strengthening coordination across multidisciplinary teams prior to patient enrollment. Importantly, this approach represents a **proactive quality improvement strategy**, shifting trial operations from reactive issue management to anticipatory risk mitigation.

Findings are limited by single-site design, comparison of two protocols, descriptive analysis, and potential unmeasured operational factors.

CONCLUSION

Incorporation of structured mock runs was associated with fewer protocol deviations and improved operational efficiency compared with standard trial initiation practices and they are a feasible and scalable quality improvement strategy to enhance preparedness in complex oncology clinical trials.

Ongoing implementation across additional protocols will further clarify their broader impact and sustainability.