Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Shifting Data Management Upstream: A Scalable Framework to Optimize Capacity, Quality, and Efficiency in Bone Marrow Transplant and Cell Therapy Trials

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1. Background
Oncology clinical trials continue to grow in complexity, with expanding eligibility criteria, extensive data demands, and higher regulatory and quality expectations. At the same time, data management teams across cancer centers face persistent capacity constraints related to hiring limitations and competing priorities in growing study portfolios.

In practice, many downstream data quality issues, delays in data entry, and coverage challenges emerge when shared operational knowledge, standardized tools, and consistent preparation are not yet fully established during early study execution.

Traditional responses to these challenges have focused on incremental staffing increases or post-hoc quality checks, approaches that are increasingly unsustainable. There is a growing need for scalable, upstream strategies that enhance early protocol understanding and enable data management teams to deliver high-quality, compliant data within existing resources.

2. Goals
The goal of this initiative was to implement an upstream, standardized data management framework that strengthens early protocol comprehension, promotes proactive inquiry, enhances coverage clarity, and surfaces protocol nuances and amendment-driven changes.

3. Solutions and Methods
Four integrated, manager-led solutions were developed and implemented:

1. **SIV Data Management Notes Template:** A structured tool was developed to support Site Initiation Visit (SIV) efficacy by guiding early protocol review, targeted questioning, and clarification of eligibility criteria and data requirements. The template enables early identification of operational and documentation gaps, supporting early alignment before study execution.
2. **Data Management (DM) Study Reference Guide for Coverage:** A centralized study reference designed to support planned and unplanned coverage and handoffs by consolidating key study information and capturing protocol nuances and amendment-driven updates over time.
3. **Data Deliverables Execution Template:** A standardized, phase-based framework that structures early planning, clarifies accountability and escalation pathways, and coordinates cross-functional effort to support timely, consistent execution of data milestones across complex oncology trials.
4. **Co-DM Model:** A structured dual-DM operating model applied to high-enrollment studies with intensive safety and data oversight to promote shared study ownership and distributed protocol knowledge. In practice, this approach supports faster onboarding, effective cross-coverage, and consistent execution of data entry and safety reporting without increasing staffing.

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4. Outcomes

Over multiple years of implementation, these integrated frameworks improved data quality, simplified coverage and onboarding, reduced reliance on individuals, increased data manager role satisfaction, creating operational capacity to absorb additional studies while sustaining efficient, resilient team performance.

5. Lessons Learned and Future Directions

- Upstream, standardized data management frameworks are most effective when treated as living tools, periodically reviewed to reflect evolving study portfolios and operational demands.
- Structured integration of data manager perspectives through quarterly tool reviews, operational milestone debriefs, and systematic incorporation of monitoring findings to sustain relevance and drive measurable operational impact.
- Sustained leadership engagement is critical to embedding these frameworks into long-term operational practice.
- Future efforts will focus on expanding shared resources into a centralized, evolving knowledge repository to support consistency, onboarding, and team-wide growth.