

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

Operationalizing the Hybrid Trial: UNC LCCC's Multi-System Compliance and Analytics Framework

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1. Background

Traditional clinical trials offer robust oversight and data control, but they often face patient burden, slow enrollment, and limited accessibility. Hybrid decentralized trial (HDT) approaches aim to make oncology research more accessible, efficient, diverse, and patient-centered by reducing dependence on physical trial sites. However, managing and tracking data can introduce risks when visits occur outside the academic medical center. The Lineberger Comprehensive Cancer Center (LCCC) strives to maintain protocol compliance through real-time data oversight across all HDT studies, using a standardized, compliant Electronic Case Report Forms (eCRF) and system-integrated analytics framework that unifies Advarra eSource+EDC, REDCap, Epic Care Everywhere, and external medical record intake into a single, analyzable data ecosystem.

2. Goals

- Build unified, real-time Tableau dashboards that integrate all data from our enterprise clinical systems into a single analytics environment for seamless tracking and monitoring.
- Track visit activity at UNC-Chapel Hill and HDT location to ensure compliance, quality, and documentation parity, while providing early detection of protocol deviations, external data delays, and changes in visit modalities or types.
- Inform strategic decisions using cross-system analytics to evaluate HDT location performance, identify operational gaps and patient burden, and guide the design of more efficient, compliant, and patient-centered future protocols.

3. Solutions and Methods

The dashboard delivers real-time views across all LCCC HDT studies, Compliance monitoring, demographic, accrual, and location metrics into a unified analytics environment. Compliance monitoring tracks protocol deviation trends by category and root cause, measures time-to-receipt of external patient data across sources and quantifies visit modality distribution — in-person with LCCC-Chapel Hill staff, in-person with local Health Care Provider (HCPs), and remote/telehealth — enabling early identification of workflow bottlenecks before they affect compliance.

Demographic metrics summarize the age distribution, sex, ethnicity, race, income level, education level, and employment type of enrolled participants, helping identify representation patterns and potential gaps within the study population.

Location metrics render distance-based connection lines between UNC-Chapel Hill and each participating in HDT location, annotated with associated visit activity and modality data. Spatial coverage analysis quantifies geographic reach across the trial network, flags underserved patient catchment areas, and supports data-driven decisions about future location placement, and decentralized workflow expansion.

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Accrual metrics quantify HDT locations utilization and visit proportions, enabling performance benchmarking and informed resource allocation across decentralized workflows.

4. Outcomes

Work in progress. The system architecture and standardized eCRF have been implemented, and Tableau dashboards are designed with all required data elements. Metrics collection is ongoing. Anticipated outputs include real-time deviation trends by category and reason, cycle times for external record receipt (Care Everywhere vs. direct submissions), visit types, modalities, and volume/proportion at HDT locations, subject participation, and geocoded visualizations of location distribution across the U.S. These insights will inform HDT workload, engagement, and operational impact.

5. Lessons Learned and Future Directions

Early implementation underscores the importance of standardized data structures and direct system integrations for decentralized oversight. Next steps include full data accrual, metric validation, and comparative analyses to confirm that local/community visits achieve compliance parity with UNC Chapel Hill-only visits, along with continued dashboard refinement to meet evolving regulatory and protocol needs.

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