

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

Transforming Regulatory Operations: Driving Efficiency and Quality Through Advarra eReg at a Large Cancer Center

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1. Background

Prior to implementing the Advarra electronic regulatory (eReg) system, clinical trial regulatory documentation at the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) was maintained across shared drives, email, and paper binders. This fragmented model led to inconsistent documentation practices, version control challenges, delayed submissions and study activations, and increased administrative burden. As the portfolio expanded in volume, complexity, and regulatory oversight, averaging 26 percent annual growth in Investigational New Drug (IND) and industry-sponsored trials over five years, decentralized systems heightened operational inefficiencies and compliance risk. Incremental process improvements were insufficient, requiring a coordinated, Cancer Center-wide modernization strategy.

2. Goals

Implementation objectives were to:

- Centralize and standardize regulatory documentation
- Align binder structure, document categorization, and workflows with OnCore CTMS integration
- Reduce time to Internal Review Board (IRB) approval, implementation, Site Initiation Visit (SIV), and Open to Accrual
- Strengthen compliance and audit readiness
- Minimize rework
- Improve onboarding efficiency
- Enhance cross-functional communication
- Establish a scalable model for enterprise-wide adoption

3. Solutions and Methods

UMGCCC executed a structured three-phase approach.

Phase 1 – Strategic Planning and Vendor Selection:

Leadership alignment and definition of nonnegotiable requirements included elimination of hybrid paper–electronic processes, seamless OnCore integration (no custom API), IT compliance, data migration capability, and scalable timelines. An agnostic vendor review and due diligence consultations with 15 U.S. cancer centers informed selection. Advarra eReg was chosen for compliant multi-protocol document management, native OnCore integration, implementation support, strategic services, cost alignment, and staff preference.

Phase 2 – Migration and Implementation:

Policies were revised and a standardized eReg binder structure established. The Advarra Business Operations Support (BOS) team was engaged to support the migration of 38,000 regulatory documents across active and legacy Industry and IND/Food and Drug Administration (FDA)-regulated trials in 10

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structured sprints beginning in May 2023. Each sprint included document inventory and reconciliation, standardized digitization, structured upload with predefined naming conventions, and formal quality control (QC) validation. Studies were prioritized by activation status and regulatory risk. Dual systems were temporarily maintained until QC completion.

Phase 3 – Go-Live and Optimization:

Paper systems were formally retired, eReg use was policy-mandated, and role-based training supported adoption. The system went live to users on December 15, 2023.

4. Outcomes

Two years post-implementation, Advarra eReg serves as the centralized system of record across 566 active protocols. Binder consistency and completeness was markedly improved, with fewer IRB revisions related to missing or outdated documentation and reduced regulatory rework, contributing to more efficient IRB processing and fewer monitoring queries. Document management time decreased, including elimination of duplicate entry between eReg and OnCore. Since go-live, 1,343 external monitoring visits have occurred, with documentation-related findings reduced by 47.5 percent based on internal monitoring review data (6.5 to 3.41 findings per review, 2024–2025). Audit readiness strengthened, with consistent document retrievability.

5. Lessons Learned and Future Directions

Regulatory modernization requires executive sponsorship, clear governance, structured migration controls, and sustained training. This initiative represented operational transformation—not simply technology deployment. The framework developed provides a scalable model for a future enterprise rollout, enhanced analytics, deeper integration with OnCore CTMS and eConsent, and expanded use of Advarra’s connected ecosystem, including CIRBI-to-eReg for IRB document integration.