

From Repository to Lifecycle Management: Transforming Regulatory Oversight Through eReg Implementation

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Background

In 2024–2025, the Wilmot Cancer Institute transitioned from a repository-style electronic regulatory binder system (Complion) to a lifecycle-oriented regulatory management platform (Advarra eReg).

Although the prior system supported compliant electronic signatures and audit trails, regulatory oversight remained highly manual. Coordinators maintained “Current” and “Archived” folders, created updated delegation of authority (DOA) PDFs externally, routed revised documents for signatures, and tracked expirations and incomplete signatures.

This approach relied heavily on individual coordinator vigilance and created opportunities for version ambiguity, delayed visibility of missing signatures, inconsistent oversight workflows, and limited transparency across study teams.

eReg introduced system-managed version control, real-time status indicators, integrated DOA workflows, shared binder visibility, and automated reporting, shifting regulatory oversight from coordinator-dependent maintenance to system-supported governance

Goals

The implementation aimed to:

1. Reduce manual document stewardship
2. Increase transparency of document status across study teams
3. Centralize DOA updates and signatures within a unified workflow
4. Improve visibility of expiring documents and outstanding signatures
5. Strengthen audit readiness through lifecycle-based oversight

Solutions and Methods

Implementation Approach

A cross-functional working group evaluated existing regulatory workflows and identified areas requiring sustained manual oversight.

The eReg rollout was implemented through a phased go-live by disease group.

Implementation Priorities

- Reduce dependence on manual coordinator tracking
- Increase team-wide transparency
- Standardize oversight workflows
- Improve audit readiness

Table 1. Transition from Repository-Based Document Storage to Lifecycle Management

Document Repository Model (Before)	Lifecycle Management Model (After)
Manual “Current/Archived” subfolders	System-managed version control
DOA PDFs created externally	Integrated DOA module
Coordinator tracks signatures	System-generated status indicators
Email follow-up for expirations	Automated reports + shared visibility
Oversight = individual vigilance	Oversight = embedded in system

Shift: Coordinator-Dependent Oversight → System-Supported Management

Outcomes

- **Eliminated manual maintenance** of “Current” and “Archived” folders and reduced coordinator-dependent version tracking
- **Increased transparency** through shared visibility of outstanding signatures, expiring documents, and workflow status indicators
- **Centralized DOA updates** and signatures within a unified system workflow
- **Improved proactive oversight** and audit readiness through automated reporting and embedded lifecycle controls

Lessons Learned

Transitioning from a repository model to a lifecycle management framework shifted regulatory oversight from a person-dependent process to a system-supported operational structure.

Key implementation considerations included:

- Workflow mapping before migration was critical
- Shared visibility improved accountability across study teams
- Standardized lifecycle controls reduced variation in document management practices
- Phased rollout supported adoption and troubleshooting

Future Directions

Next steps include:

- Collection of quantitative quality metrics
- Structured user feedback across disease teams
- Evaluation of operational efficiency gains
- Expansion of reporting and cross-protocol monitoring capabilities

Potential future metrics include:

- Signature completion turnaround time
- Expired document rates
- Coordinator time spent on maintenance activities
- Audit findings related to document oversight

Key Takeaway

Implementing lifecycle-oriented eReg functionality shifted regulatory oversight from manual coordinator-dependent stewardship to system-supported operational governance, improving transparency, consistency, and audit readiness.

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