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

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1. 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). The previous system supported secure storage, system-generated audit trails, and compliant electronic signatures, but relied on manual file stewardship, such as maintaining "Current" and "Archived" subfolders and preparing updated delegation of authority (DOA) PDFs outside the system before uploading and routing revised documents for signature. These structures required sustained regulatory coordinator effort to ensure the appropriate version appeared active and to monitor completion of required signatures. This approach introduced opportunities for version ambiguity, delayed signature visibility, and reliance on individual coordinator vigilance to maintain regulatory currency.

eReg offers built-in version control, real-time document status indicators, and an integrated DOA module that captures staff updates and electronic signatures entirely within the system. Visibility into outstanding signatures and expiring documents extends to all users with binder access, and automated email reports can be scheduled. The migration provided an opportunity to streamline document lifecycle management, enhance transparency, and increase regulatory operations efficiency.

2. Goals

The goals of the transition were to:

1. Reduce manual effort associated with maintaining current/archived document structures;
2. Provide visibility of document status indicators to the entire study team;
3. Centralize DOA task updates and signatures within a single system workflow;
4. Support timely completion of signatures and identification of expiring documents through enhanced transparency; and
5. Strengthen audit readiness by shifting lifecycle management from coordinator-dependent oversight to system-supported governance.

3. Solutions and Methods

A cross-functional working group mapped regulatory workflows and identified steps requiring manual oversight in the prior system. During the eReg configuration and rollout—implemented through a rolling go-live by disease group—the team prioritized features that would shift document management from a repository-based model to a structured, lifecycle-oriented framework. These included:

- Built-in version tracking, eliminating the need to maintain "Current" and "Archived" subfolders;
- System-generated document status indicators (e.g., "Signature Needed," "Expired") visible to any user with binder access;
- An integrated DOA module enabling delegated staff updates and electronic signatures within the system; and

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- Automated scheduled reports providing regular summaries of outstanding signatures and upcoming expirations.

4. Outcomes

Early observations demonstrate a structural shift in how regulatory oversight is operationalized. Version tracking is now system-managed, reducing opportunities for parallel active versions and removing the need for manual archiving steps. Transparency has increased, as all users with binder access can readily view outstanding signatures and expiring documents without relying on regulatory coordinators to identify gaps. DOA updates occur directly within eReg, allowing staff changes and required signatures to be captured in a unified workflow. Automated reports support proactive oversight and audit readiness.

5. Lessons Learned and Future Directions

The migration underscores the operational impact of transitioning from a repository model to a lifecycle-oriented regulatory management system. Early benefits include reduced manual version stewardship, improved transparency, and more consistent system-supported processes. Planned next steps include continued collection of quantitative data on quality indicators, gathering structured qualitative feedback from users across study teams, and evaluating opportunities to further optimize reporting and cross-protocol monitoring to support sustained regulatory stability.