UroGen Streamlines Clinical and Regulatory Operations

Vault Connection speeds business processes and improves access

UROGEN – AT A GLANCE

- Corporate Headquarters: Princeton, NJ
- Employees: 170+
- Primary Therapeutic Areas: Urology and Uro-oncology

With users working in both Vault RIM and Vault Clinical Operations, UroGen maintained separate repositories for their regulatory and clinical data and documents. This made cross-functional processes like preparing an IND update rather cumbersome as teams had to download documents from one system, upload them in another, and track version numbers and status in a spreadsheet. These manual steps were time consuming, error prone, and resulted in the same file existing in multiple places.

Automatic Information Sharing

To alleviate this challenge, UroGen decided to implement the Vault Clinical Operations to RIM Connection, which seamlessly transfers data and documents between application suites. For example, when the clinical team approves trial records like an audit certificate or Form 1572, the documents are automatically shared in Vault Submissions. As a result, the regulatory team can more easily assemble IND updates and clinical study report appendices with confidence that nothing is missing. Similarly, when the regulatory team approves a protocol change, the update is automatically shared in Vault eTMF, which helps clinical keep the TMF and study sites current.

Streamlined Processes

By leveraging the Vault Clinical Operations to RIM Connection, UroGen has eliminated the manual transfers and tracking that raised the risk of delays, omissions, and duplicate files. The company has built a single source of truth with two-way information sharing that increases the visibility, quality, and speed of clinical and regulatory activities—a real advantage now that UroGen's first global phase three clinical trial is underway.

Moving forward, UroGen will leverage the established connection framework to include new document types and processes as they expand their global footprint.

> *"We have already seen benefits from the connection between clinical and regulatory as we support the new global phase three trial."*
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> *– **Dominick Gagliostro,** Senior Director of Project Management and Regulatory Operations, UroGen*