

NATIONAL INSTITUTE OF ALLERGIES AND INFECTIOUS DISEASES (NIAID) USES LIVELINK TO SUPPORT WIDE ARRAY OF ELECTRONIC DOCUMENT AND RECORDS MANAGEMENT INITIATIVES

Description of Challenge

By 2007 the Malaria Vaccine Development Branch (MVDB) of the National Institute of Allergies and Infectious Diseases (NIAID) had accumulated six years worth of data supporting eight investigational new drug applications and twelve master protocols. This equated to more than 17,000 data files, more than 1,000 animal and laboratory protocols, 128 associated standard operating procedures (SOPs) and at least 50 different users accessing the data on a daily basis. MVDB's use of network shared drives and a combination of Microsoft Office documents including Word and Excel to manually manage its business process and associated data caused inefficiencies and put the organization at risk for data loss.

The Solution

To meet MVDB's needs, Momentum developed a robust and highly secure Livelink Electronic Document and Records Management System (EDRMS). The EDRMS features:

- A document/data repository with metadata tracking
- Automated document creation, number assignment, and approval process
- Secured role-based permissions
- The ability to support current regulatory requirements as well as future 21 CFR Part 11 compliance for electronic records and signatures

While the MVDB focus was on protocols and standard operating procedures, the overall process and key functions are common to a variety of business activities found in most organizations. For example, the majority of documents follow these steps: Create, Review, Use, and Manage. Prior to implementation of the EDRMS system, MVDB handled all of these steps and their associated tasks manually. That meant tracking in MS Excel and Word; numbering documents and versions by hand; and authorizations involving hard copy reviews and ink signatures.

With the EDRMS, managing protocols (their associated documents and data) and standard operating procedures (SOPs) can now be done through Livelink. This means that key information can be used to search, track, and manage the protocols. Search result lists can be sorted a variety of ways and functions can be determined by user roles and permissions. From the search interface, users can also link directly to the protocol repository.

Similarly, Livelink enables auto-numbering, updates, and the check-in/out functions, eliminating the manual document creation and revision process. For example, a typical protocol document is an MS Word file. With the MVDB system, its header and signature block data are automatically updated when the draft protocol is created and whenever its status changes within the workflow. Existing protocols

can be used as templates as well as to create master folder structures. The system also includes an SOP certification module that identifies staff members that are certified to work on specific protocols.

In addition, protocol reviews have also been streamlined, allowing the entire approval process to be conducted and tracked electronically. This includes the ability to view and edit documents from email links, so that document approval and rejection does not have to be done solely from within Livelink or the MVDB application.

In total, the MVDB system implementation involved the migration of 17,000 files, migration of 128 standard operating procedures, and staff training. Key to the project's successful implementation was the training of lab and staff members—which went so smoothly and easily that it quickly boosted user acceptance of the new system.

In addition to implementing the MVDB application, Momentum Systems architected and implemented an enterprise-wide content management system based on Livelink. The enterprise infrastructure includes Livelink / SharePoint integration modules that give NIAID the ability to support a variety of business requirements.

RIMS: Solicitation Package Development

The RIMS project supports a new and innovative method of creating, reviewing and managing NIAID's grant and contract initiatives for external research. The Institute funds in excess of \$10B in annual these research and development activities. Each year, NIAID creates approximately 50 new initiatives; each managed by a team with dozens of members; each handling the creation and review up to 19 large document sets.

Prior to the implementation of the Livelink system, the Institute used SharePoint and email to control the collaboration and review of the initiative documents. In addition to the challenges in tracking the status of any given document in its lifecycle, this technology made version control extremely difficult.

The Livelink application provides a tailored environment for each team using reusable components which support the team's interactions and collaboration. Advanced workflow, security, compound document control, and versioning have been integrated and support the teams' need to accurately and securely draft and track the content deliverables.

Clinical Research Agreements

The Office of Regulatory Affairs (ORA) maintains clinical trial agreements (CTAs) with clinical research organizations (CROs), pharmaceutical, and biotechnology companies engaged by NIAID. These are agreements are confidential documents that previously routed via email and hardcopy for review and approval. Document tracking (for example, when an agreement is mailed to a company for execution) was done manually and via an MS Access database. A Livelink repository for CTAs and related documents was created and existing documents were migrated to the repository. Livelink workflows manage the creation, review, approval, and tracking of new and amended CTAs.

Electronic Remote Access Authorization Process

The electronic Remote Access Authorization Process (eRAAP) is used to manage staff requests for remote access to NIAID's network and computing facilities. Security and privacy requirements demand

that remote access be reviewed, granted, monitored, and revoked in an efficient and auditable fashion. The initial version of eRAAP was built using the BizFlow workflow system. It was migrated to Livelink in order to support new functionality and as part of an initiative to implement all NIAID workflows in Livelink.

Animal Care and Use Committee

The ACUC is the institutional animal care and use committee at NIAID. Its activities are mandated by the U.S. Animal Welfare Act and Public Health Service Policy. The ACUC is charged with reviewing and approving all proposed uses of live vertebrate animals in teaching and research. A large number of people are involved in these activities, with different subsets of the group involved with different protocols. Protocol creation, distribution, review, and approval processes were previously handled via emails and physical distribution of hardcopy documents. Livelink workflows and a custom “dashboard” interface have been created to support the review process from the initial draft through final approval and tri-annual reviews. Approved protocols are securely maintained in a Livelink repository along with all drafts and review packages submitted to the ACUC. Legacy ASPs were migrated to the Livelink repository and made accessible to committee members, staff, and researchers.

Division of Intramural Research Repository

The Division of Intramural Research (DIR) conducts basic and clinical research in a wide range of disciplines related to immunology, allergy, and infectious diseases. The DIR is comprised of more than 20 laboratories that conduct peer-reviewed research. The laboratories create and maintain a number of common documents related to their administration and financial management. The documents have been historically stored in a variety of locations and formats making it difficult to quickly and reliably locate key information. As the DIR has grown and the complexity of its administration increased, a well-defined system for creating, reviewing, tracking and managing large numbers of documents and change requests has become a necessity.

Implementation of the Livelink DIR Repository the creation of a flexible nomenclature, construction of a large repository (containing sub-repositories for each laboratory), and the development of workflows for division financial, operational, and change management processes.