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# eIT Times


## this issue



## Overview of the eIT PMO

The USAMRMC Enterprise Information Technology (eIT) Project Management Office (PMO) is responsible for providing medical IT solutions to USAMRMC in accordance with DoD and Army/MEDCOM Policies and Regulations.

The office facilitates full program coordination, planning, management, and execution to ensure successful acquisition of required medical IT solutions, to include support of Food and Drug Administration (FDA) compliance efforts.

The eIT PMO has a valid ATO (Authority to Operate).

## Upcoming Training Dates

Group classes for hands on EDMS Basic Functionality training and Manager training will be conducted in Bldg. 844 on: ***May 8 at 9 (basic) & at 1 (Manager). June 19th*** will be the next EDMS training held in 844.

***EDMS Advanced "hands on" training*** is scheduled ***May 16th*** from 9-11 in Bldg 1520. Training is advertised via the DGSO Milestone Decision Authority Workshop.

One-on-one, Power User and Basic Functionality training can be scheduled upon user's request.

## In the "Spotlight"…

### EDC Full Operational Capability!

From the initially identified requirements for clinical trial data management software in 2006 until today, development of an Electronic Data Capture-Clinical Research Data Management System (EDC-CRDMS) available to the entire command has been a long wait. The wait ended on 22 April 2013 with the approval for Full Operational Capability from the USAMRMC Principal Assistant for Acquisition. This approval means that EDC-CRDMS is available for command-wide use. The system meets all the requirements of the multi-disciplinary, multi-organizational EDC Working Group and was independently reviewed and approved by USAMRMC's Quality Management Office.

EDC-CRDMS will promote efficient and consistent clinical trial process execution across the various USAMRMC commands. It can be used for all phases of clinical trials and can also be used under the animal rule qualification model. If you are interested in utilizing EDC-CRDMS, please contact the eIT PMO at: usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil or the USAMMDA Clinical Services Support Division for additional information.

### EDMS – Can it be an Asset to your Organization? How about a Demo or Implementation Plan for your Office?

The eIT PMO office has put together an EDMS Demo for anyone interested in learning more about the system. The demo is not meant to be a training session. Instead, its purpose is to demonstrate functionality while also highlighting how USAMRMC organizations are using the system today. Beyond the obvious benefits and efficiencies that EDMS provides, we can give you real world examples of organizational content structure, customized tools, and customized workflows for the automation of business processes. We have numerous examples of each that may give your organization ideas on improving effectiveness.

The eIT PMO office has also put together an Implementation Plan template to assist organizations that are new to EDMS in getting started. It's simple and straight forward, and can be adjusted to fit your exact needs. We'll work with you, side by side, if you decide to take advantage of the EDMS system. Simply send us an email at: usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil and we'll be glad to coordinate a demo and/or informational briefing.

## Quarterly Product Highlight – EDC-CRDMS

"Clinical Data Management is an integral part of any given research study. Having the right clinical data management system is an absolute necessity for any organization submitting study data to regulatory bodies and other partners. The clinical data management teams within USAMRMC (USAMMDA, WRAIR, NMRC at Bethesda, USAMRIID, USARIEM) have been privileged to take part in the planning, testing, and validation of EDC-CRDMS. This new system will be a critical asset for clinical and non-clinical data management activities across USAMRMC. Improved processes will be a direct result from the implementation of EDC-CRDMS; including, efficient Case Report Form (CRF) design, study database development, data entry and management, edit specifications development, data review and query management, medical coding with MedDRA and WHO-Drug, quality control, and data reconciliations. It has been a long but fruitful process for the clinical data management teams and USAMRMC as a whole."
*Dixion Rwakasyaguri, CDM Section Lead, Clinical Services Support Division, USAMMDA*

# Technology Solutions for Medical Research

## EDMS Workflows in Production

By now, organizations that have chosen the eIT PMO EDMS for their content storage needs have come to realize the benefits of using this system. The ability to store, manage, access, edit, and **collaborate** across commands and with our external partners on mission critical files in a central, web based location is a key asset to the medical research conducted at this command. The system inherently provides **version control, audit trails, and powerful search functionality**--efficiencies that are not available using network drives.

The eIT PMO is now taking several of our customers to a new level with **AUTOMATED WORKFLOWS.** Or, another term you might hear used instead is, **Automated Business Processes**. No matter the term, workflows provide many benefits:

❖Streamlined and consistent process execution.
❖Reduces the amount of time users spend on performing tasks by minimizing manual actions, thereby removing bottlenecks.
❖Accurate tracking of progress and timelines.
❖Transparency in players, roles, and approval chain of command.
❖Framework intuitively guides users, minimizing errors and ensuring the correct outcome.
❖Auditing, reporting, and versioning capabilities.
❖Capability to execute business processes within commands, across commands, and with externals.

**In this environment of tightened budgets and reduced spending, streamlining our work just makes sense.** Take a look at just a few of the Automated Workflows/Business Processes we are providing USAMRMC organizations today:

❖**DRAC Regulatory Submission Workflow.** Researchers route INDs for review, approval, and electronic signature prior to submission to the FDA. The initial request is captured and automatically routed to the appropriate staff based on the defined process. Automated emails alert staff when they have an assignment. Errors that occur in the submission are identified during the review. Signature designation is determined and a customized email is available to notify the Sponsor's Representative when the package has been submitted to the FDA. At the end of the workflow, the system moves the package to the appropriate area in EDMS with appropriate metadata applied. *Approximately 200 submissions have been processed using this workflow!*

❖**PPAE Annual Command Budget Estimate Near-Mid Program Plans Briefing Workflow.** This workflow was designed to assist the RADs in preparing the briefs presented at the Board of Directors (BOD) meeting. Briefing templates and documents are routed to the appropriate RADs based on selections made when the process is initiated. The process includes three review and approval cycles as well as a meeting minute review that occurs subsequent to the briefing. Comments and questions from the RADs to PPAE are captured as well as PPAE's responses and are available in future cycles for reference. A graphic illustration is provided to show the user where they are in the process. At the conclusion of the workflow, the system moves the documentation to the appropriate area in EDMS. *The first official CBE/NMP process is currently in process using this workflow!*

❖**PPAE Near-Term Program Plans Workflow.** This workflow was developed for DHP and the JPCs. It contains three review cycles and is similar in style to the CBE/NMP Workflow. Templates and documents are added to participant's folder and are routed to the appropriate JPC for completion. *The first official use of the workflow is currently underway!*

❖**DGSO Lessons Learned - Best Practice DB.** This unique capability is both a workflow and a searchable database. Users have the ability to submit lessons learned or best practice ideas for review, approval, and publishing to the database. The initial submission is routed thru DGSO. Without changing the original submitted entry, they can edit as needed for publishing. Users are then able to search the database for information.

❖**Document Routing Workflow** The eIT PMO is using this workflow for our internal processes based on our Approval Matrix. The initiator selects either a defined process or 'other', allowing them to select who should review and sign the document. Comments and approval status are captured throughout the workflow. At the conclusion, the system automatically places the document in the appropriate area within EDMS

These are just a few examples of the type of business process automation we can help you achieve. If you or your organization is interested in learning more about automated workflows, we will be happy to meet with you! Contact the eIT PMO at: usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil

## Other Products

### Medical Dictionaries

This quarter: MedDRA and WHO Drug March updates are both now available.

### Serious Adverse Events (SAE) System

This quarter: Loaded the MedDRA and WHO Drug March updates.

## Future Products

### Electronic Common Technical Document (eCTD)

The eIT PMO has begun the process of standing up this new capability. eCTD will interface directly with EDMS and enable the DRAC division of USAMMDA to build properly formatted electronic submissions to the FDA. It also brings the submission process "in-house" and eliminates the need to contract out for this service, reducing costs in the process.

System implementation is on schedule. Formal operational & validation testing has begun, with production availability slated for the fourth quarter of FY13.

## Next Edition:

Streamline online editing in EDMS for Office documents.

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