

Overview of the eIT PMO

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

The PMO facilitates full program coordination to ensure successful acquisition of required IT solutions to support Food and Drug Administration (FDA) compliance efforts.

The eIT PMO maintains a valid DoD Authority to Operate (ATO) Accreditation.

EDMS "Hands On" Training Dates

Classes are held in Bldg 844 at Fort Detrick (DCO available by request).

Basic Functionality Training

14 May 2014

11 June 2014

09 July 2014

Time: 0830-1000

Manager Training

14 May 2014

11 June 2014

09 July 2014

Time: 1000-1130

Enterprise Connect Training

07 May 2014

18 June 2014

23 July 2014

Time: 0900-1030

Advanced Training

28 May 2014

25 June 2014

30 July 2014

Time: 0900-1030

Contact eIT PMO Mailbox to schedule:

(usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil)



In this issue...

eIT PMO Overview & Training **P.1**

In the Spotlight **P.1**

Capabilities Delivered this Quarter **P.2**

Tips & Tricks **P.2**

Product Updates and Future

Capabilities **P.2**

In the Spotlight...

The EDMS Manager Toolkit and the EDMS Knowledge Manager Working Group

The eIT PMO's Electronic Document Management System (EDMS) is currently being utilized by organizations in nearly all of USAMRMC and the Subordinate Commands. Our customers are using the system to store, access, edit, and collaborate on thousands of files in a centrally organized and hierarchical structure, tailored specifically to meet the needs of USAMRMC's Medical Research community.

The FDA compliant system inherently provides version control, audit trails, and powerful search functionality—efficiencies that are not available using USAMRMC network drives. We've helped many of our customers take it to the next level by automating some of their organizational business processes and by providing them with the capability to execute those processes within their own command, across commands, and with their external partners.

While the aforementioned features have resulted in streamlining the work we do here at USAMRMC—which saves both time and money—perhaps one of the most fundamental and important capabilities we provide to our customers is the ability to be in complete control of structure and access within their organizational area.

This control allows information to be stored in a manner that is intuitive to each organization. Content and information is shared only with users who have been granted permissions by the organization. Permission based access to the information in our system becomes especially

important when we consider the extensive collaborative research that is done at USAMRMC. Oftentimes, organizations are working not only with the people within their organization, but with outside organizations, including those outside the DoD and their Foreign National collaborators.

While our EDMS Product Administrators are always here to assist, we encourage organizations to designate one or more of their users to be EDMS Knowledge Managers (KMs). The eIT PMO provides training for these users; enabling them to then serve as the "first line of defense" for access to their organization's information in EDMS.

In EDMS, "groups" are used to control access to EDMS content. Groups are collections of EDMS users. Every EDMS user is a member of at least one group and may be a member of multiple groups. Knowledge Managers maintain "Access Group" membership. Users will not have access to organizational content unless access is granted by the organization's EDMS Knowledge Manager.

As you might imagine, this is a lot of responsibility!

The eIT PMO has released a **Manager Tool Kit** to assist our Knowledge Managers and in turn, to strengthen the security posture of the EDMS.

The Manager Tool Kit consists of (3) reports that EDMS Managers can run:

❖ **Manager Report:** Identifies users that are in their managed groups.

❖ **Group Report:** Identifies which folders are applied to a managed group.

❖ **Folder Contents Report:** Identifies a folder structure in a managed area and identifies the permissions that are applied to specific folders.

We encourage all EDMS KMs to begin utilizing the Manager Tool Kit. EDMS KMs should be running these reports on a regular basis, to determine if the list of users in their managed groups is current and



Technology Solutions for Medical Research

EDMS Manager WG; EDMS KM Manager Toolkit *continued...*

if the group permissions applied to their folders are still relevant. For example, do all users in a group list still have "a need to know" the information they have access to?

Beginning in May, the eIT PMO will be establishing an **EDMS Knowledge Managers (KM) Working Group (WG)**. We plan for this group to meet on a regular schedule to discuss relevant folder management issues and share Lessons Learned and Best Business Practices. Knowledge Managers have a definite impact on the security of this system, so we will be requesting your participation if you have been assigned as an EDMS KM for your organization.

Capabilities Delivered this Quarter

eIT PMO Announces Release of SAS Data Extraction Tool for EDC-CRDMS and Major Update to the SAE System

❖ On 28 February 2014, the USAMRMC eIT PMO released a Statistical Analysis System (SAS) Data Extraction tool for the Electronic Data Capture (EDC) Clinical Research Data Management System (CRDMS).

This tool facilitates the extraction of clinical trial data from EDC-CRDMS into a SAS-friendly format allowing for easy import into SAS for analysis by biostatisticians.

The tool was developed and tested in a joint effort between the eIT PMO, Oracle, and as an improvement to existing data extraction options.

EDC-CRDMS is a 21 CFR Part 11 compliant, fully featured system supporting the life cycle of clinical studies from study inception to study close-out; including, data field definition/specification, data entry, data query, and data transfer/output into stand-alone statistical tools.

❖ On 7 March 2014, the USAMRMC eIT PMO successfully fielded a major update to the Serious Adverse Event (SAE) system.

This update allows SAE to maintain compliance with Department of Defense (DoD) operation orders, specifically by supporting Oracle 11g database software.

As part of the upgrade, all existing SAE data was successfully migrated to new servers. Additionally, the new application version provides improved performance and reporting capabilities and support for Microsoft Excel 2007.

SAE is a 21 CFR Part 11 compliant system for reporting serious adverse drug experiences resulting from clinical trials. The SAE system is used within USAMMDA to meet reporting requirements for USAMRMC investigational drug and therapeutic biologic projects. Additionally, the system has the ability to support electronic submissions (E2B compliant) to the FDA.

Product Updates

Medical Dictionaries

WHO Drug Dictionary updates for 01 March 2014 are now available in SAE and EDC.

SAE upgraded to the latest version. See **Capabilities Delivered this Quarter** for more information.

Future Capabilities

EDMS Workflows in Development

Enterprise Document Routing Workflow

Originally designed for use within the PPA&E Office, this workflow will be available in the near future to **all** EDMS users.

The WF will provide the ability to route any document package thru review, approval, and/or signature cycles as determined by the initiator of the workflow.

Options will include:

- ❖ Ability to utilize one or all of the cycles
- ❖ Ability to provide detailed instructions to participants
- ❖ Ability to select users to participate in each cycle
- ❖ Ability to send documents concurrently or sequentially
- ❖ Ability to repeat cycles

Want More?

If you and/or your organization is interested in learning more about the IT capabilities offered by the eIT PMO, we will be happy to meet with you!

Contact the eIT PMO at: usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil

TIPS & TRICKS

Who Ya Gonna Call??

We've added two new members to our Product Support Team:

❖ Kevin Sanders is a new **EDMS Product Administrator**. Kevin will be creating accounts, applying permissions and troubleshooting general EDMS support issues. He will also be conducting EDMS Advanced and Manager Training.



❖ Melanie Kochel is the new **Customer Support Analyst**. She will be assisting with product training initiatives as well as acting as the eIT PMO point of contact for customer related issues.

Contact the eIT PMO Product Support Team by emailing the eIT PMO Mailbox at: usarmy.detrick.medcom-usamrmc.other.eitpmo@mail.mil

We'd be happy to hear from you!!!

eIT PMO
HQ USAMRMC
504 Scott Street, Bldg 844
Fort Detrick, MD 21702-5012

eIT PMO Website: <https://eitpmo.amedd.army.mil/>
Customer Liaison: 301.619.3488
Product Support: 301.619.7703
Fax: 301.619.0241