

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 has a valid DoD Information Assurance Certification ATO (Authority to Operation)

EDMS "Hands On" Training Dates

All classes held in Bldg 844 at Fort Detrick.

Basic Functionality training

10 August 2013

04 September 2013

9 October 2013

Time:

Manager training

14 August 2013

04 September 2013

9 October 2013

Time:

Advanced training

21 August 2013 9-11:00

One-on-one training

Power User and EDMS training can be scheduled



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In the Spotlight...

MAJ Sumesh Sagar

Deputy Project Manager and
Customer Liaison Officer

The eIT PMO welcomes MAJ Sumesh Sagar who is a familiar face around USAMRMC. He has been with the U.S. Army Medical Service Corp for over nine years, most recently serving as the USAMRMC Headquarters Company Commander. Prior to being the Company Commander, he served as the Aide-de-Camp to Major General James K. Gilman, former USAMRMC Commanding General.

MAJ Sagar is replacing CPT Bruce Barnes as the Deputy Project Manager, Information Assurance Manager, and the Customer Liaison Officer for the eIT PMO. As the Liaison Officer, MAJ Sagar will provide face to face coordination with individuals and/or organizations. We anticipate MAJ Sagar will be very busy, as more organizations utilize eIT PMO systems to automate their business processes. If you would like to discuss your organizational needs with MAJ Sagar, please send an Email to: usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil.

Quarterly Product Highlight - EDMS WORKFLOWS

A quote from Sheila McFarland, Economist with the PPAE Office at USAMRMC:

"For Defense Health Program funding, we used an EDMS workflow designed to streamline PPAE processes to collect, review, and finalize Near-term Program Plans from the Joint Program Committees. Having a single location to store files in EDMS eliminated large email attachments, ensured up-to-date version control, and maintained a chain of review and approval."

Electronic Common Technical Document (eCTD) Product

The eIT PMO **eCTD Product** will soon be USAMRMC's interface with the U.S. Food and Drug Administration (FDA) for the transfer of regulatory information in the FDA required format.

With ever evolving regulations, USAMRMC must continually reassess standards, processes, and technology to be operationally positioned to meet emerging FDA requirements. As of 01 Jan 2008, the FDA announced that the Electronic Common Technical Document standard is the required format for electronic submissions.

The eCTD System is specifically intended for use by USAMMDA's Division of Regulated Activities and Compliance (DRAC) for preparation and life cycle maintenance of electronic regulatory submissions originating from OTSG/Army sponsored investigational product development.

The FDA is expected to announce the date in 2014 in which they will **only** accept submissions electronically. The eCTD system allows the DRAC to handle submissions in-house saving the expense of outsourcing this service. **eCTD Continued next page...**



Technology Solutions for Medical Research

eCTD continued...

The eCTD system consists of two major parts: a *publisher* which creates the submission packages, and a *viewer* which allows users to view the submission packages. Both the publisher and the viewer components of eCTD will interface with the eIT PMO Electronic Document Management System (EDMS). Documents managed within EDMS will be available for direct inclusion into the electronic regulatory filings created using the eCTD publisher. The eCTD system is managed by the eIT PMO and is integrated into the projects Common IT Infrastructure.

A Production Readiness Review (PRR) for eCTD was held on 11 July 2013. The PRR provided results from the formal testing and system validation activities. The outcome of the PRR was a recommendation for the eCTD product to proceed into the Production and Deployment Phase of the eIT PMO Product Development Lifecycle. Full implementation into the production environment is targeted for QTR 4 of FY13.

Decision Gate Support Office

Lessons Learned Database

The DGSO has created a Lessons Learned Database to collect lessons learned and share best practices pertaining to USAMRMC activities. This online tool can be used by anyone with an EDMS account to conduct a search on published lessons learned and/or best practices. This information can be accessed for general information, planning and analysis purposes. Users may also submit suggestions for review and approval by the DGSO.

EDMS Edit Function is Available!

The online **Edit Function** has been enabled in EDMS without having to install Livelink Explorer or Enterprise Connect. This function streamlines editing and is recommended for edits taking less than 30 minutes. See the Tips & Tricks section below for **HOW TO:** instructions.

NOTE: Enterprise Connect Version 10.3 is now available and recommended! Contact ESD at: 1-800-USAMITC to have it installed!

Other Products

Medical

Dictionaries

MedDRA and WHO Drug updates are available for desktop users. Updates have also been incorporated in the Serious Adverse Events (SAE) System.

Future Capabilities

EDMS Workflows in Development

* PPA&E is using an automated workflow for preparing R-Forms for Budget Estimate Submissions, Program Budget Review, and the President's Budget for both Army & DHP Funding. These workflows provide a standard automated process to collect, review, approve, store & maintain this data.

* PPAE/RADs are preparing the Army RDT&E POM cycle document review & approval workflows which will be available enterprise wide upon completion.

TIPS & TRICKS

HOW TO: Instructions For Using Online Editing

1. EDMS Web Version View Edit Directions

- ❖ In EDMS, navigate to the document that you wish to edit.
- ❖ Click the Edit link to the right of the document, or from the Functions drop down menu, click Edit.
- ❖ The message, "Opening your editor and returning to Content Server.." is displayed while the document is opening for editing.
- ❖ The document will be opened in its associated program for editing. It will be automatically marked as 'Reserved' in EDMS (Note: Refresh your screen to see the Reserved Check Mark.
- ❖ When you have finished editing the document, click the 'X' in the upper right corner of the program.
- ❖ You will be prompted to Save the Changes.



2. Enterprise Connect or Livelink Explorer View Directions

- ❖ Locate the document you wish to edit and Right Click and select Edit from the Functions menu or Double Click on the document name.
- ❖ The document will be opened in its associated program for editing. It will be automatically marked as 'Reserved' in EDMS.

3. When Editing is Complete (All Views)

- ❖ Click the 'X' in the upper right corner of the document. In the Save Dialog Box:
- ❖ Click Yes to Save the Changes to EDMS as a new Version and un-reserve the document.
- ❖ Click No to Discard the Changes, close and un-reserve the document.
- ❖ Click Cancel to Return to the document and continue editing. Note: At this point, you can click File-Save to save the document to your workstation.

In the Next Edition

EDMS Workflows

Want More?

If you 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:

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