ISSUE 19 July 2016

QUARTERLY NEWSLETTER
Enterprise Information Technology
Project Management Office
(eIT PMO)

eIT Times

In this issue...

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).

EDMS "Hands On" Training Dates

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

Basic Functionality Training
Time: 0830-1000
Wednesday 31 Aug
Wednesday 14 Sep
Wednesday 12 Oct

Knowledge Manager Training
Time: 1000-1130
Wednesday 31 Aug
Wednesday 14 Sep
Wednesday 12 Oct

Enterprise Connect Training
Time: 0900-1000
Wednesday 17 Aug
Wednesday 07 Sep
Wednesday 19 Oct

Enterprise Document Routing WF Training
Time: 0900-1000
Wednesday 24 Aug
Wednesday 28 Sep
Wednesday 26 Oct

Contact eIT PMO Mailbox to schedule: (usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil)

In the Spotlight...

eIT PMO Customer Support Analysts are here to Support YOU!

Jennifer Hallberg and Sonia Grover

The eIT PMO would like to introduce the two newest additions to our Product Support Team; Ms. Jennifer Hallberg and Ms. Sonia Grover. Jenny and Sonia are the eIT PMO's Customer Support Analysts (CSAs). They are the first line of support for our eIT PMO product users all over the world. If you've emailed the eIT PMO Product Support Mailbox to request assistance, you have most likely received a reply from one of them.

Our CSAs are knowledgeable about our entire suite of medical IT products and provide prompt and efficient handling of customer-reported incidents or requests. Jenny and Sonia assess and manage incoming requests and can often resolve issues on the spot so you can get right back to work. For requests that require a higher level of support, the CSAs are your interface with our Product Administrators, Developers, and System Administrators. The CSAs track all incoming requests/incidents and will keep you informed of the progress towards resolution.

Our Electronic Document Management System (EDMS) currently has our largest user base with new organizations coming on board all the time. The CSAs are EDMS product experts! In addition to responding to daily customer inquiries, they are here to provide assistance to new users or organizations that are either just getting started in EDMS or want to find out how to make use of all the efficiencies the system has to offer. Jenny and Sonia can walk you through every step of the EDMS implementation process, including helping your organization set up a folder structure with a corresponding permissions set that is tailored to your organizational business needs.

They can answer any questions you may have along the way and help you understand how to maximize your usage and get the full benefits that come with using EDMS.

Once your organization is set up in EDMS, our CSAs can provide individual or group training for new users—either at the eIT PMO office, onsite at your location, or online. Additionally, they provide training for the advanced capabilities our system offers, as well as help you identify opportunities for creating customized solutions that can streamline your business processes.

No request is too large or too small, so if you are interested in learning more about how our Customer Support Analysts can assist your organization, please send an email to us at usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil. We are here to support YOU!

eIT PMO Capabilities on the Horizon

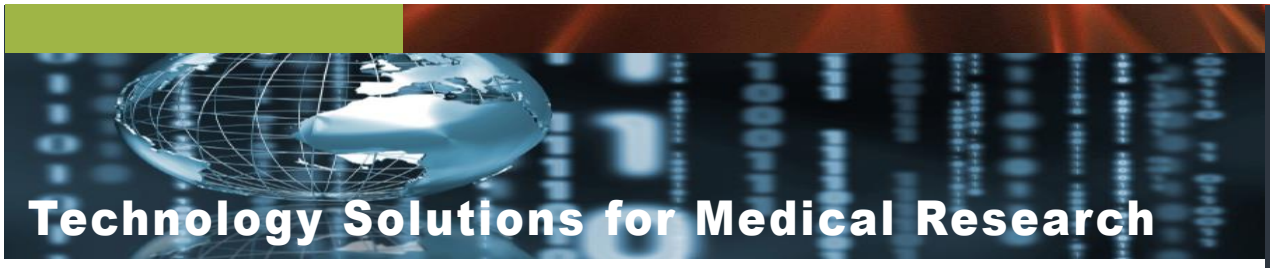
The eIT PMO has two new capabilities that will be ready for delivery to our customers in the upcoming months. Here's a brief 'preview' of what's coming soon!

LOE1

The eIT PMO has been collaborating with the USAMRMC Office of the Principal Assistant for Acquisition and a recently formed Working Group, to field a new IT tool built on the current eIT PMO EDMS product.

In its initial release, the new tool (so new they haven't finalized a name!) will provide capabilities targeted at supporting the Integrated Product Team (IPT) Chairs, IPT Members, Product Managers, the Research Development Acquisition Support Office (RDASO), the Product Lifecycle Review Committee (PLRC), and the Executive Management Committee (EMC).

The 'value added' is that users will now have a



"one-stop-shop" for USAMRMC product development efforts; including the most up-to-date knowledge and content available.

'Phase I' will include two main capabilities.

❖**Information Portal Capability**. Interactive graphics will display USAMRMC's defined business processes. Highlighting and selecting the various graphic elements displayed will provide the user with both high level and detailed definitions, templates, reference links, points-of-contact, and other pertinent information. The initial focus is on the Decision Gate process, associated funding types, and Technology Readiness levels.

❖**Document Management, Project, and Task Features.** Leveraging inherent capabilities in EDMS (document management, version control, workflow capabilities) will enhance collaboration both within the IPT itself and between the IPT and USAMRMC entities such as the RDASO and PLRC. Utilizing the Projects feature, will promote efficiency gains in IPT internal and external coordination and in preparing for In Progress Reviews (IPRs). The tool also offers quick access to document templates and provides reporting capabilities.

Future releases of this tool will target expansion of the Information Portal, to include items such as the USAMRAA Acquisition Process requirements, timelines, and document templates, and FDA related processes and information.

CTMS

The eIT PMO will be conducting an Operational Readiness Review in early August just prior to releasing the newest product in our suite to users. USAMRMC has numerous clinical trial study sites all over the world; however, the Command has never had a single IT system that collects and integrates the information required to manage clinical studies and permits stakeholders at CONUS and OCONUS sites to access information pertaining to the status of a planned or active clinical study.

The FDA compliant, eIT PMO Clinical Trial Management System (CTMS) will fill that gap, saving manpower, time, and effort, and minimizing the delays that are often experienced with the current manual processes. Initially, CTMS will be used by the USAMMDA Clinical Services Support Division to manage the clinical trials conducted by USAMMDA. The web-based system will be hosted on the Army network, but will be accessible for personnel use both here in the states and at the overseas sites for tracking, managing, and reporting clinical monitoring activities for clinical trials.

The following highlights just a few of the features that will be available to CTMS users:

❖**Dashboards:** Features a 'Single Study View-General' to display study identification information, key site and subject accrual metrics, performance, and study milestone timelines and an 'All Sites View-Single Study' to display study identification information, key subject screening and enrollment metrics, site status and site tables, providing totals across multiple record types.

❖**CTMS Home:** Provides users with a study list and displays their alert notifications.

❖**Site Management:** Allows users to control the site initiation process, select applicable regulatory documents, and administer the clinical sites in the study.

❖**Site Monitoring:** Enables users to schedule and manage visits to clinic sites participating in the study, providing calendar and list views and the processing and approval of site visit reports.

❖**CRF Tracking and Verification:** Designed to track the status of CRF pages used to collect experimental data during the course of a study.

❖**Subject Management:** Provides a screening and enrollment log for users to enter subjects into the system and allows users to track the subject treatment events.

❖**Document Management:** Provides users with the ability to upload and track all CTMS related documents and correspondence.

Stay tuned for more on these Capabilities!

Once they have been released and are in use, we'll report back to you with updates and customer feedback!

Product Updates

Medical Dictionaries

The next WHO Drug Dictionary update will be coming in September 2016. The current version of MedDRA is 19.0 and both are available in SAE and EDC.

Released this Quarter

eIT PMO Releases CRF Submit Tool, Greatly Enhancing the Clinical Studies Life-Cycle Process to Deliver Solutions Faster

❖On 30 June 2016, the eIT PMO released the Inform Case Report Form (CRF) Submit tool for the Electronic Data Capture Clinical Research Data Management System (EDC-CRDMS). This tool facilitates the creation of documents in Portable Document Format (PDF) and streamlines file printing from EDC-CRDMS Inform studies, which can then be used for Regulatory submission under International Council for Harmonisation (ICH) and FDA guidance for archiving clinical data for investigative sites.

❖For each study, the tool creates PDF files for subjects and visits and includes CRFs, audit trails, comments, and signatures.

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

Want More?

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

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