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

EDMS "Hands On" Training Dates

All classes held in Bldg 844 at Fort Detrick unless indicated.

Basic Functionality training

11 December 0830-1000

Manager training

11 December 1000-1130

Enterprise Connect training

DCO Training:
12 December 0900-1030

Advanced training

DCO Training
19 December 0900-1030

One-on-one training

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

Training is also announced via the DGSO Milestone Decision Authority Workshop forum.

In the Spotlight…

USAMRMC's 1ST Electronic Common Technical Document (eCTD) FDA Submission

Last month we introduced our newest product in Production, the Electronic Common Technical Document (eCTD), for use by USAMMDA's Division of Regulated Activities and Compliance (DRAC). This FDA 21 CFR Part 11 compliant product became operational on 28 August 2013, enabling the Command to publish electronic regulatory submissions and transfer the information to the FDA in the required electronic submission format.

The true test of the success of this product however, is how it is working for our customer.

Since eCTD became operational, the DRAC Team has been hard at work acclimating themselves to the process changes associated with preparing, publishing, and viewing submissions in the electronic format. We asked members of the team to share their thoughts with us.

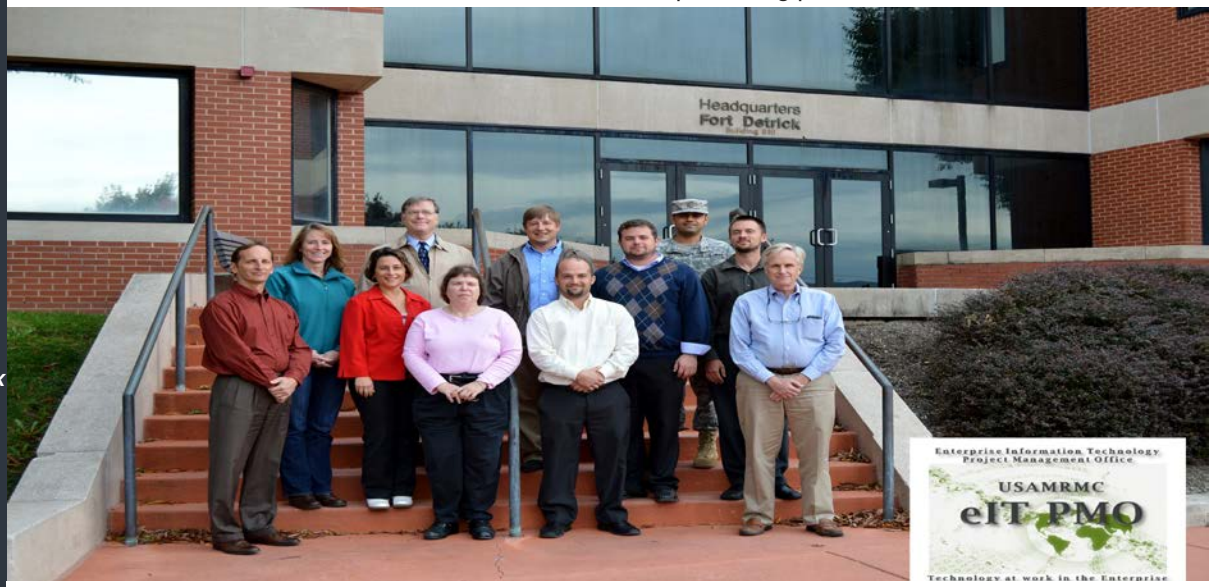
***Q*:** So how has the eCTD experience been so far? Has there been a big 'learning curve'?

A: (*Jennifer Secula, Medical Writer*) There is a significant learning curve; however, we have spent several years bringing the individual documents up to the standards necessary for electronic submissions. We are still learning, but these preparatory steps have proved invaluable. Along the way, we have learned a great deal more about the purpose and content of the individual sections of the CTD.

A: *(Adam Bell, RA Scientist)* Agreed. We are now learning to fully understand and utilize the modular nature of the CTD format. With eCTD, we not only need to think about where all of the information should go, but also how the information is interlinked and can be cross-referenced within the submission.

***Q*:** You store and manage the information for the submissions in EDMS, as well as the final submission itself. Does this integration between EDMS and eCTD provide major benefit to you?

A: *(Jennifer)* We are able to streamline our review and publishing processes thru the EDMS/eCTD



eCTD eIT PMO and USAMMDA DRAC Collaborative Team

eCTD continued…

integration. EDMS enables us to automate the archival process, and ensure both quality control and document version control.

A: *(Adam)* Additionally, having an all-in-house system allows the scientist to be present during the assembly and participate in last minute decisions about content—which isn't possible when the electronic submission is prepared externally or when a large paper submission is in finalization and printing.

***Q*:** What do you see as some of the most beneficial process improvements over previous methods (outsourcing the action and/or paper submission processes)?

A: *(Jennifer)* Performing eCTD publishing in house will significantly improve many of our processes, from project planning through submission archival. Up to this point, it was as if we were building a large jigsaw puzzle without the picture on the box.

A: *(Adam)* With eCTD, when amendments are added, they are fully integrated with previous and subsequent submissions. Over time, a final integrated, single file application for the license of a new drug is created that is easy to navigate and review.

A*: (Tracy Ulderich, Chief, Regulatory Operations)* One of the greatest impacts to USAMMDA is the cost efficiency gained from not having to outsource to a contractor to complete the work. Further, internal review times are streamlined to fit our standard approval process. Working with the eIT PMO as a local resource with a swift response time has also helped us to avoid timely setbacks for IT-related issues.

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On 30 September 2013, the very first eCTD produced by DRAC was successfully submitted electronically to the FDA. The submission was an Investigational New Drug application, sponsored by MILVAX, to evaluate different routes of immunizing soldiers with yellow fever vaccine. A second IND for IMRAS was successfully submitted on 16 October 2013. These two submissions alone have saved the Command thousands of dollars through utilization of internal resources in lieu of contracted support.

***(Dr. Robert Miller, Director, DRAC)*:** *USAMRMC can now produce FDA mandated eCTD formatted submissions cheaper--as much as 40%--than a contractor and retain complete control of the regulatory documents.*

eIT Delivers EDMS Workflow

Workflow 1.D - PPA&E Prepares R-Forms for BES and PB was implemented in Production in early September. This workflow automates many of the business processes for preparing the USAMRMC Congressional Descriptive Summaries (R-Forms) for the Budget Estimate Submission and the President's Budget. This is a semi-annual process to prepare R-Form submissions to Congress, articulating how core Army funding (S&T) is allocated to support DoD goals and guidance from US Army senior leadership.

The workflow is utilized by PPA&E, the RADs, and Systems Biology, in coordination with ASA(ALT). Prior to use of the workflow, staff relied on shared storage drives and email attachments to route the BES submission package documentation through numerous review and approval steps. Tracking work in progress, maintaining an authoritative source, and coordinating document updates was a constant challenge. The implementation of this process ensures the continuity, suitability, quality, and efficiency of R-Form submissions.

Product Updates

Medical Dictionaries

WHO Drug Release 1 September 2013 has been incorporated into both the SAE and EDC systems. It's available for desktop use also.

Future Capabilities

EDMS Workflows in Development

Scheduled for release in the 1st quarter FY14:

A document routing workflow that will be available to all users.

2C – PPA&E prepares Annual Research Execution Plan

1C – PPA&E/RADs Prepare Army RDT&E POM

Updates to three WFs already in Production will be released to provide a consistent look and feel across each WF supporting Financial Management processes.

In the Next Edition

Details on the new workflows being released in the 1st quarter FY14.

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 us at: usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil

TIPS & TRICKS

Mandatory 14 Character Password is Now in Effect for *All* eIT PMO Products

Passwords are an important aspect of computer security for authenticating access to Army Information Systems (ISs). All users with accounts on Army ISs are responsible for taking the appropriate steps to generate and secure their credentials.

Important Password Guidelines to Follow

- **Do not share your password with others—including support staff.**
- **Do not base your password on personal information that someone who knows you may be able to guess, (i.e. your name)**
- **When software programs offer to save your username and/or password, always decline.**

- **Make sure you always log out and close your browser when you are done working.**
- **Protect your passwords and treat them as valuables!**

Creating a 'Strong Password'

A strong password is designed to be complex and therefore, difficult to guess or crack. To be sufficiently complex, the password must:

- **Be a minimum of 14 characters in length.**
- **Include at least two of each: upper and lower case letters, numbers, and special characters (&, %, @, etc.) within the password.**
- ***Tip*: A 'pass-phrase' or sentence is a very secure way of creating a strong password that is both hard for others to crack *and* easy for you to remember. You can substitute numbers/symbols for letters. For example: use $ in place of the letter "s".**

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