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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 maintains a valid DoD Interim Authority to Operate (IATO).

## EDMS "Hands On" Training Dates

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

**Basic Functionality Training**

**Time: 0830-1000**
**Wednesday 13 May**
**Wednesday 10 June**
**Wednesday 08 July**

**Manager Training**

**Time: 1000-1130**
**Wednesday 13 May**
**Wednesday 10 June**
**Wednesday 08 July**

**Enterprise Connect Training**

**Time: 0900-1030**
**Wednesday 20 May**
**Wednesday 17 June**
**Wednesday 15 July**

**Enterprise Document Routing WF Training**

**Time: 0900-1030**
**Wednesday 06 May**
**Wednesday 03 June**
**Wednesday 22 July**

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

## In the Spotlight..

### Major New Release for EDC-CRDMS

A major undertaking to upgrade the Electronic Data Capture - Clinical Research Data Management System (EDC-CRDMS) is now completed. In Production since September 2012, the EDC-CRDMS provides a full featured clinical research data management system supporting the life cycle of clinical studies from study inception, through data field definition/specification, data entry, data query, and data transfer/output into stand-alone statistical tools and study close-out. The system is compliant with the FDA Title 21 CFR Part 11 requirements. The main objectives for the upgrade were to transition EDC-CRDMS to the latest versions of the vendor software (Inform GTM version 6.0 and Central Designer 2.0), as well as to bring all servers onto the latest MEDCOM standard Windows Server Operating System (Windows Server 2008 R2).

EDC-CRDMS can be described as a 'System of Systems', meaning the applications that make up the EDC-CRDMS create a new, more complex system, offering optimized functionality and performance. The effort to upgrade Inform GTM required upgrades to all of the software applications that make up the EDC-CRDMS product; Inform, Inform Adapter, Central Designer, Cognos, Central Coding and Directory Services.

The following list provides an overview of some of the new capabilities:

- ❖ Users can accelerate data collection and will notice an improved site experience, with interface enhancements to handle repeating data as well as new dynamic data entry displays in Inform.
- ❖ New itemset types for submitting multiple rows of data on a form at one time: Add Entry itemsets for variable rows and Repeating Data itemsets for fixed rows.
- ❖ Users will improve productivity by eliminating redundant source data verification with advanced targeted source verification enhancements, including item-level partial source verification.
- ❖ Users can view, identify, and manage study priorities and accelerate data cleaning with enhanced Data Viewer displays.
- ❖ Utilizes mobile technology to allow access to Inform from iPad and Android devices.
- ❖ Increased flexibility for mid-study changes with advanced batch calculation rules options.
- ❖ Simplified and automated data exchange utilizing the CDISC Operational Data Model (CDISC-ODM) standard to import data to InForm through a new Clinical API.


❖ New Central Designer enhancements further streamline the process for designing and building EDC studies.

❖ New web-based client for Central Designer.

❖ Dynamic prompts for faster electronic edit checks and rules writing.

❖ Offline translation speeds the translation process for multi-language studies.

One of the biggest challenges for the EDC-CRDMS upgrade was the migration of the existing studies/protocols and associated data to the new version. To accomplish this, the old servers were taken offline on Friday morning, 27 March 2015. Over the next two and a half days, the clinical studies and associated clinical data for more than 40 trials were migrated to the new servers. The system was up and running for use on Monday morning, 30 March 2015.

## New Release for eCTD

The Electronic Common Technical Document (eCTD) product, in Production since August 2013, is scheduled for an upgrade to version 5.1 in May 2015.

eCTD provides comprehensive and scalable submission publishing capabilities and produces output that is compliant with all current regulatory agency requirements. Specifically, eCTD provides submission planning, publishing, viewing, and registration management capabilities. One of the biggest benefits this new version provides is removing the current desktop browser limitation, allowing user workstations to be upgraded to Internet Explorer 9. See additional features in the Future Capabilities Section.

## TIPS & TRICKS

### Internet Explorer Tips and Tricks when using the EDMS Web Browser

Ever feel frustrated when working in the EDMS Web Browser and you want to open a new tab to get to another location in EDMS—but when you do—you are taken to the EDMS Log In page and have to log in again before you can get where you want to go?? There's a little trick to getting around that issue!

❖ When you log in to EDMS, go to a location within the system that you access frequently (i.e. the Enterprise Workspace, your organizational folder or one of the subfolders beneath).
❖ Create a bookmark or Favorite to that location in Internet Explorer.
❖ Now when you open a new blank tab during your browser session, you can use your bookmark or Favorite to get to your favorite spot immediately! No need to log in again!

If that helps you—here's a couple more IE tips/tricks that you might find useful!

❖ Ctrl + K will duplicate the current tab you are on.
❖ Ctrl + T will open a new blank tab (If you are still in the same browser session, use your 'Favorite' to get to your favorite spot!).
❖ Print or diagram too small to see? Ctrl + the scroll button on your mouse will zoom in (and out!) OR use Ctrl + plus/minus sign.
❖ Ctrl + Tab will let you scroll through open window tabs.

## Product Updates

### Medical Dictionaries

WHO Drug Dictionary update (March 2015) and MedDRA (18.0) are available in both SAE and EDC.

## Future Capabilities

### eCTD Version 5.1

### New Features!

❖ The Product selection process has been simplified, allowing users to select Applications, then Products. This significantly reduces the Product list, making the user's search less time consuming.

❖ The DMS Browse Tree has been enhanced to include the display of additional attributes for documents, eliminating the need to click multiple documents to view the attributes.

❖ The eCTD Module 1 Assembly Template 3.3 is available, allowing submissions to be created with the most current FDA accepted Module 1 file structure.

❖ Details on all new features, and any bug fixes, can be found on the vendors website at: http://help.liquent.com/InSight_5-1-0/1613-DSY/1605-DSY/7647-DSY.html

## 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!

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

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