eIT Times

Overview of the eIT PMO

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

The office facilitates full program coordination, planning, management, and execution to ensure successful acquisition of required medical IT solutions, to include support of Food and Drug Administration (FDA) compliance efforts.

The eIT PMO received its latest ATO (Authority to Operate) in June, 2011. It's valid until June of 2014.

Upcoming Training Dates

Group classes for EDMS Basic Functionality and Manager Training will be conducted in Bldg. 844 on:

Dec 12
Jan 9
Feb 13
March 13

One-on-one Power User and Basic Functionality training can be scheduled upon user's request.

The DGSO Milestone Decision Authority workshop routinely advertises EDMS Training.

In the "Spotlight"...EDC-CRDMS goes Live!

Electronic Data Capture (EDC) - Clinical Research Data Management System (CRDMS)

Following a successful Milestone C decision, an Acquisition Decision Memorandum (ADM) was issued for EDC-CRDMS. The system was installed in the Production environment and approved to go operational 18 September 2012.

EDC-CRDMS will be available command wide as an FDA compliant system to handle clinical study data. The complete system consists of two COTS products from Oracle; Clintrial and Inform. Clintrial provides for the capture and storage of paper based clinical trials, while Inform is used to capture and store electronic based trials. EDC-CRDMS supports the full life cycle of clinical studies from study inception, through data field/form definitions/specifications, data entry, query resolution, data transfer and export, and study close-out.

The first utilization of EDC-CRDMS will be a three month effort to design and implement a Sentinel Study, as a live test of the system. This will involve a team comprised of developers and data managers from across multiple commands working together. The study selected as the Sentinel study is the Immunization via Mosquito bite with Radiation-Attenuated Sporozoites, or IMRAS. IMRAS will be conducted by the Naval Medical Research Center (NMRC) in collaboration with USAMMDA, USAMRIID, and WRAIR. From the press release, IMRAS is a "phase 1 trial with challenge to assess the safety, immunogenicity, efficacy and biomarkers of protection in malaria-naïve adults of immunization via mosquito bite with radiation-attenuated Plasmodium falciparum sporozoites."

The IMRAS team will be assisted by the eIT PMO and COTS vendor, Oracle, with all aspects of trial design during this period. It is expected that the development of this EDC-CRDMS trial will be complete in December 2012 and the trial will be made ready for data collection in January 2013. The actual clinical trial is tentatively scheduled to begin in late Q1 2013.

Following successful development of the Sentinel Study, the results will be presented to the Milestone Decision Authority in January 2013, to seek approval to allow for full operational use of the system by all of MRMC.

Quarterly Product Highlight - Integrated Product Teams (IPTs) Managing Product Development Information

The IPTs with Decision Gate Projects received a directive in October to use eIT PMO - EDMS to store current and historical product development information. This information will be permanently retained in EDMS. The Decision Gate Support Office (DGSO) approves new IPT file and folder structure in EDMS and coordinates with us to educate and assist IPTs in using EDMS. IPT chairs are to ensure the proper permissions are granted to their information. Please contact us directly at 301.619.7703 or usamrmc.eitpmo@amedd.army.mil for assistance.

Technology Solutions for Medical Research

Medical Dictionaries MedDRA & WHO Drug

The Medical Dictionary for Regulatory Activities (MedDRA) provides quick access to medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products. Using MedDRA to code data provides for consistency across clinical trials and studies. The eIT PMO has integrated MedDRA into both the SAE system and the EDC-CRDMS system.

Similarly, the World Health Organization's (WHO) Drug Dictionary, is a comprehensive source of medical product information used to identify drug names, active ingredients, and therapeutic use in the course of drug safety surveillance. It translates a drug name into useful information used for coding and analysis of drug safety data. Both the SAE and EDC-CRDMS systems have

the WHO Drug dictionary integrated to promote consistent coding of medicines.

The eIT PMO manages the licensing and access to MedDRA and WHO Drug for use by USAMRMC.

To utilize MedDRA right on your workstation, the MedDRA dictionary files and "browser" are available for download from the Public Documents folder in our EDMS system. The EDMS location and steps to install them are as follows:

❖ **Public Documents > Medical Coding Dictionaries > MedDRA > MedDRA Desktop Browser > MedDRA Desktop Browser Version 3.1b Installation File** Once installed, users will need to download the MedAscii (data) files for the version they need for coding: **Medical Coding Dictionaries > MedDRA > MedDRA Desktop Browser > MedDRA MedAscii (Data) Files for Desktop Browser**
❖ **Download files**
❖ **Extract the files**
❖ **Open the Desktop Browser**
❖ **Select the MedDRA version you are using**

❖ **Click File**
❖ **Click Import MedDRA Data**
❖ **Browse to Ascii file location**
❖ **Click ok**
❖ **Click Import**

Alternatively, we can send you a CD with all the files and instructions.. Simply contact us via our email address below.

To utilize WHO Drug on your workstation, web based access is available. All you need is an account, which is created and maintained for the user by the eIT PMO. Contact us via email.

User Manuals for both options are located in the EDMS Public Area Medical Dictionary folder.

The latest quarterly version of WHO Drug and the latest semi-annual version of MedDRA have been loaded into EDMS, SAE and EDC-CRDMS and are ready for use.

We welcome suggestions for either the newsletter or website: https://eitpmo.amedd.army.mil/.

Contact the eIT PMO via email: usamrmc.eitpmo@amedd.army.mil.

Electronic Document Management System (EDMS)

Coming Soon: An EDMS enterprise wide Splash Page will bring a more user friendly look and feel to the Enterprise Workspace. It will be customized for ease of use and accessing personal items of interest. Users will have access to their favorites, work assignments, and most recently used documents, right at their fingertips! (Currently, it takes several clicks to see favorites and work assignments) In addition, users currently do not have instant access to the most recent 10 items they access. With the new Splash page, the user will be able to see these items without having to maneuver through various menus to locate the desired list.

Next Edition:

Details on office use of EDMS; Updates on the EDC product; EDMS Tips and Tricks. and more…

TIPS AND TRICKS / HOW TOs

HOW TO: Set Up Notifications in EDMS

Setting Notifications in EDMS will allow the user to be notified via e-mail when certain events happen within EDMS

1. Log into EDMS
2. Click 'Personal' then 'Notification'
3. Ensure 'EDMS Notification Report –Immediately" is highlighted
4. Click "Modify Settings" to display the Settings Screen:

❖ Ensure "*Enable e-mail delivery of the report*" is "*checked.*"
❖ Ensure your E-mail Address is entered and is accurate.
❖ Ensure "*Plain Body with HTML attachment*" is selected.
❖ Ensure "On these days", "At these hours", and "At these times" are set to the times you wish to be notified. *NOTE: Should be every 10 minutes throughout the day.*
❖ Click "Submit" when finished.
5. Click "Modify Interests" to display the Interest Screen:

❖ Ensure "A Task is assigned to me" is set to – EDMS Notification Report – Immediately.
❖ Ensure "A Workflow I manage has completed" is set to – EDMS Notification Report – Immediately.
❖ Ensure "A Workflow I manage is late" is set to – EDMS Notification Report – Immediately.
❖ Ensure "A Workflow step has arrived in my personal Assignments" is set to – EDMS Notification Report – Immediately.
❖ Ensure "A Workflow Step in my personal Assignments is late" is set to – EDMS Notification Report – Immediately.
❖ Select other interests as desired.
❖ Click 'Submit' when finished
6. Perform Steps 4 and 5 for Daily and Weekly notifications.