ISSUE
09
January 2014

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 (DCO available by request).

Basic Functionality training

12 February 0830-1000
12 March 0830-1000
09 April 0830-1000

Manager training

12 February 1000-1130
12 March 1000-1130
09 April 1000-1130

Enterprise Connect training

February 19 0900-1030
March 05 0900-1030
April 16 0900-1030

Advanced training

February 26 0900-1030
March 26 0900-1030
April 23 0900-1030

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

In the Spotlight…

Freeze Dried Plasma
Interview with USAMMDA

Modern warfare can cause severe injuries to our military forces. Severe battlefield injuries often require massive hemorrhage management involving transfusion of red blood cells and plasma. Plasma is the liquid part of blood that contains proteins and clotting factors that are essential for normal blood clotting to occur. Abnormal or deficient clotting often accompanies cases of severe bleeding. Unfortunately, in the challenging environment of the forward battlefield, perishable Fresh Frozen Plasma (FFP) is often an impractical option due to cold storage requirements and the need for immediate use.

The use of **Freeze Dried Plasma** (**FDP**) overcomes these limitations. FDP can be stored at room temperature; therefore, it is more rapidly available to Surgical Teams to manage severe hemorrhage. The current FDP is not licensed by the Food and Drug Administration, but can be used under a special Investigational New Drug (IND) application. This requires that anyone who will use the product must be informed that it is not approved by the FDA. Physicians who are familiar with how to use FDP and its risks and benefits are tasked with administering informed consent to soldiers prior to deployment so they can decide whether they want to receive this product if they are injured.

In early Fall 2013, the US Army Medical Materiel Development Activity (USAMMDA) requested that the eIT PMO develop a controlled-access database to enter, maintain, and track Investigator credentials as they relate to the Freeze Dried Plasma initiative. This system was implemented in Production in October 2013 for use by USAMMDA's Division of Regulated Activities and Compliance (DRAC), allowing them to meet FDA and Institutional Review Board (IRB) regulations for routine monitoring and approval of new Sub-Investigators.

The system is designed to store, track, and maintain credentials for the Principal Investigators (PIs) and Sub-Investigators (SubIs) who are administering the informed consent for the Freeze Dried Plasma clinical study. The minimum credentials required to qualify for informed consent administration include the Medical License, Curriculum Vitae, Human Subjects Protection Training Records, and Good Clinical Practice Training Records. The system provides alerts and email notifications to the Investigators when their credentials are expiring, notifications to the monitoring team when an investigator is in need of review and various additional reporting features.

This was an important and high profile initiative, so we asked USAMMDA's DRAC to share their thoughts with us about Freeze Dried Plasma and this system's relevance to the Command.

Q: Is Freeze Dried Plasma being used today by the US Armed Forces?

A: ***(Dr. Robert Miller; Director, DRAC)***

After working with a regulatory contractor in Florida with no success, the Commander of the US Special Operations, Admiral William H. McRaven, requested the assistance of the US Medical Research and Materiel Command (USAMRMC) in getting an IND submitted to the FDA in order to use a French developed Freeze Dried Plasma product that was already being utilized in Iraq and Afghanistan, but was not approved by the FDA. The French FDP is manufactured by the French military at the Centre de Transfusion Sanguine des Armées (CTSA) (*Translation*: The Armed Forces Blood Transfusion Center). This FDP has been approved by the French Ministry of Health. Completing the IND application required working closely with the FDA to get an expanded use. The IND allows the US Special Operations Command (SOCOM) to deploy with the FDP, but under the same restrictions for its use that any other Investigational New Drug has, including informed consent.

Q: Why is the Freeze Dried Plasma Information System so important to this effort?

FDP Interview *continued…*

A: ***(Dr. Miller)*** The human research Institutional Review Boards (IRBs) are required to review the qualifications of all Principal Investigators (PIs) and Sub-Investigators (SubIs) who conduct the IND study and administer informed consent to study subjects. The fluid nature of the US SOCOM forces requires changing SubIs quite frequently. Without the use of this information system, paper copies would need to be collected for Good Clinical Practice Training, Medical Licenses, and Curriculum Vitaes in order to demonstrate that the SubIs was qualified. Since these documents must be reviewed by the Clinical Monitor in the Clinical Service Support Division (CSSD), the DRAC Regulatory Scientist, and the USAMRMC IRB, it was impractical for the PI to send hard copies to three organizations to obtain approval prior to allowing the SubIs to administer informed consent to new subjects. The information system allows for concurrent approval by CSSD, DRAC, and the USAMRMC IRB. The system also tracks the expiration of Medical Licenses and required training to ensure the Investigators remain qualified to conduct the study and administer informed consent.

Q: What is the most important benefit we are providing the Command by utilizing this system?

A: ***(Dr. Miller)*** It will provide faster turnaround for approving SubIs participation in the FDP study. Since US SOCOM teams deploy on short notice, it is imperative that the SubI's credential reviews are well documented and happen in real time.

Capabilities Delivered this Quarter

Extensive support was provided this quarter to the Plans, Programs, Analysis and Evaluation (PPA&E) Office as part of the ongoing Research Management Enterprise (RME) effort.

The eIT PMO completed enhancements to the following workflows (WFs) that we've recently delivered to PPA&E:

❖**JPCs/PPAE DHP RDT&E Near-Term (NT) Program Plan (PP) Package**. The workflow guides participants through the process of preparing, reviewing, and finalizing the briefings and document templates required to build the NT PP briefing packages.

❖**DHP RDT&E Mid-Term Program Plan Package.** The workflow assists users in preparing the DHP Mid-Term Program Plan Package submissions.

❖**RAD/PPAE prepares Annual Army Funds Distribution and Near/Mid Program Plans (NMP).** The workflow guides participants through the process of preparing, reviewing, and finalizing the briefings and document templates required to build the CBE and NMP briefing packages.

The enhancements we provided to these WFs will minimize the number of steps to complete the processes and provide for enhanced collaboration among the participants. By design, all PPA&E WFs now have a consistent look and feel, making it easier for participants to use these process tools.

Each workflow provides the following:

❖A graphical representation to indicate to the users where they are in the process at each step within the workflow.
❖The ability to capture and maintain questions and/or comments throughout each review cycle within the workflow.
❖Previous review cycle comments may be viewed and/or printed during subsequent review cycles.
❖Final briefing packages and documents are stored in a centralized location in the eIT PMO EDMS for future use and collaboration.

The eIT PMO also delivered two new WFs to PPA&E:

❖**PPAE prepares DHP R-Forms for Program Budget Review (PBR) and President's Budget (PB).** The workflow guides the staff through the process of preparing and editing the R-Forms for the PBR and PB submission. The purpose of the R-Form is to articulate, in non-technical language, the USAMRMC program plan for DHP funds for the various programs to DOD Leadership, the Office of Management and Budget, and Congress.

❖**Document Routing Review, Approval, and Signature Workflow.** Originally designed for use within the PPA&E Office as part of the RME effort, this WF will be made available to ***all*** EDMS users in the near future. The WF will provide the ability to route any document package thru review, approval, and/or signature cycles. The WF initiator may utilize one or all of the cycles, provide detailed instructions for the participants, and assign a suspense date for the completion of the process. The initiator is able to select individual users to participate in each cycle. Documents may be sent through the WF either concurrently or sequentially in each cycle. In addition, each cycle may be repeated as many times as necessary with existing or new participants each time. The WF also provides for optional QA reviews between each of the cycles. Lastly, the initiator will be able to specify where to store the documents in EDMS when the workflow is completed.

Product Updates

The MedDRA 16.1 and the WHO Drug 1 December dictionaries were incorporated into the SAE and EDC systems. They're also free for desktop use.

Both the EDMS and eCTD products, which have Microsoft Office integrated in them, were updated from Office 2007 to 2010

Future Capabilities

SAE: Production implementation of a vendor software upgrade is scheduled for 2nd quarter FY14.

EDC-CRDMS: A new SAS friendly output file will be available for use sometime in the 2nd quarter FY14.

DCO Training Offered

Would you like to attend one of the EDMS trainings that we offer, but you just can't get away from your desk? We can help! You can now attend training via a Defense Connect Online (DCO) link that we will provide. You may enter the training as a guest and participate in the live training from your remote location. Our trainings typically incorporate a slide presentation with a live view of the system.

Want More?

If you and/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

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