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MANAGEMENT OFFICE

eIT Times

Welcome to the eIT

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 eIT PMO received its latest ATO (Authority To Operate) in June, 2011.

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.

Major activities include:

• Actively develop, and manage requirements associated with an IT System;

• Acquire, implement, and test IT capabilities to meet approved requirements;

• Establish product baselines, and maintain them with configuration management controls;

• Support and sustain all delivered IT systems;

• Provide training and help desk support to our user community.

this issue

New Quarterly Newsletter and Website

The Enterprise Information Technology (eIT) Project Management Office (PMO) is pleased to provide you with the first edition of our new quarterly newsletter, the *eIT Times*.

We hope this publication will bring you up to date on our most recent progress with the suite of IM/IT solutions this office provides to USAMRC and its subordinate commands, as well as our collaborative partners in business, academia, and other government agencies.

We plan to include additional information in our publication on topics such as current industry trends, technology solutions, and new software. In future editions, you can expect to see a section for IT Management Tips and Tricks that we hope you will find useful!

Our Website has also undergone a recent transformation! The site now matches our organization name, and has a new URL. You can access the website at: https://eitpmo.amedd.army.mil/ .

The goal of our site is to provide our customers with pertinent information relevant to our products as well as information about the eIT PMO in general. You will be able to access information about a number of items that include, but are not limited to:

- Products in Production:
  - EDMS
  - SAE
  - Medical Dictionaries
- Product under Development
  - EDC-CRDMS
- Account Request Procedures
- Account Request Forms
- Training Descriptions and Links

Both the ***eIT Times*** and the eIT PMO Website are a work in progress, and as such, additional updates may be expected. We welcome your comments and suggestions for further improvements! Please feel free to submit your suggestions for either the newsletter or the site to the eIT PMO at usamrmc.eitpmo@amedd.army.mil .

This Quarter's Product Usage Highlight - EDMS

USAMMDA Division of Regulated Activities and Compliance (DRAC)

In August of 2009, DRAC adopted EDMS as their primary system to store Department of Army, Office of The Surgeon General sponsored regulatory files. DRAC's area within EDMS, better known as Sponsor's Electronic Regulatory Files (SERF), leverages the built in security, version control, and audit trails to be compliant with the Food and Drug Administration regulations for use of computerized systems (21 CFR Part 11). DRAC also utilizes the powerful search engine in EDMS to locate and retrieve documents easily and quickly.

"EDMS for USAMMDA serves as a versatile collaborative tool for document exchange and archive for meeting our organization's mission." *Heidi Moynihan, DRAC Regulatory Systems Manager*

Technology Solutions for Medical Research

Electronic Document Management System (EDMS)

In today's military environment of tightened budgets and staff levels, empowering existing staff to organize, manage, share, and edit documents easily and quickly is critical to the Command's **success**. To maintain maximum **efficiency**, we need to quickly and easily access and collaborate on our **mission-critical information** so we can spend more time doing what we do best and get new medical capabilities to those who need them.

As organizations within the Command evolve, and as individual projects grow and move forward, managing the thousands, or even millions, of paper and electronic documents can be time consuming and costly. Much of this information can become lost or buried within email systems, across shared drives, or even on individual workstations. Consolidating all of our information assets in a secure and centralized repository can significantly reduce the amount of time we spend managing and sharing documents.

EDMS is an existing system, in place and functioning today for USAMRMC, to do just that. EDMS is on the CoN list, and is available for use by the entire Command, at no additional cost.

EDMS is a fully integrated and powerful web based document management system that delivers the capabilities needed for efficient use of mission-critical document assets. **Store, manage, access, edit, and collaborate on** millions of files in a **centrally organized** and **hierarchical** structure tailored specifically to the Command's needs. **Version control** and **audit functions** promote ease of **collaboration** on all content. **Powerful search** functionality allows users to find what they need, when they need it.

Critical information from across your organization can be easily and quickly migrated into **EDMS** using the familiar Windows Explorer interface.

Within **EDMS**, each command or organization in USAMRMC will have the ability to be in **complete control of their content, access to their content, and the storage structure of their content within their organizational areas**. This way, document assets can be stored in a manner that is intuitive to the organization. Content and information can be shared only with whom the organization chooses to share it with. Each user is also given a **Personal Workspace** area, controlled completely by them. It can be customized to suit individual preferences.

Empower yourself, staff, and co-workers with an EDMS account. User and Manager training scheduled for February 8th, March 14th, and April 11th, 2012. Contact the eIT PMO to enroll today!

Our next newsletter will highlight the **EDMS** "apps" available.

EDMS MYTHS

MYTH: "We won't save that much time or money if we cut paper out of our business processes."

Reality: Time is money! Organizations that effectively use their workforce, technology, and innovation can improve efficiency, decision making, and quality of service. Leveraging EDMS can drastically cut the time it takes to get work done, freeing employees to focus on more important organizational activities.

MYTH: "Our document process is already meeting compliance regulations, why change?"

In regulated industries, staying compliant is a cost of doing business even if it can't be directly measured. EDMS helps meet this requirement through features like permissions, digital signatures, and auditable workflows that make annual audits easier and help avoid overall risk.

Other Products

Serious Adverse Events (SAE) System

The SAE system supports USAMRMC's FDA reporting requirements when serious adverse events occur during clinical trials. The system has been in production use since August of 2010. USAMMDA's Safety Division is the primary user of the web based system. SAE is compliant with the FDA's CFR 21 Part 11 guidelines for computerized systems. The system received a CoN (Certificate of Networthiness) from the Army's Network Enterprise Command (NETCOM) in December 2011.

Medical Dictionaries

The eIT PMO manages the licensing and access to two standard medical dictionaries for use by all of USAMRMC.

WHO Drug - an international classification of medicines created by the World Health Organization.
MedDRA - a clinically validated international medical terminology used by regulatory authorities, industry, and DOA.

The dictionaries are made available at no cost to the user or organization. They are viewed using a standard web browser interface. Access options are: individual on-line account access, downloading to your workstation, or they can be imported into other systems, such as SAE and SIRS.

Future Products

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

Details in the next newsletter

eIT PMO
HQ USAMRMC
504 Scott Street, Bldg 844
Fort Detrick, MD 21702-5012

eIT PMO Website: https://eitpmo.amedd.army.mil/
Customer Liaison: 301.619.3488
Product Support: 301.619.7703
Fax: 301.619.0241