ISSUE
16
October 2015

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
Thursday 12 Nov
Wednesday 09 Dec
Wednesday 13 Jan

Manager Training
Time: 1000-1130
Thursday 12 Nov
Wednesday 09 Dec
Wednesday 13 Jan

Enterprise Connect Training
Time: 0900-1030
Wednesday 18 Nov
Wednesday 16 Dec
Wednesday 06 Jan

Enterprise Document Routing WF Training
Time: 0900-1030
Wednesday 25 Nov
Wednesday 30 Dec
Wednesday 20 Jan

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

In the Spotlight..

eIT PMO IT Systems Supporting USAMRMC Product Development from the Laboratory Bench to the Soldier

The USAMRMC has six laboratory commands executing various areas of basic and applied research and six more commands focused on advanced development, logistics, and contracting; all in support of its mission to create, develop, deliver, and sustain medical capabilities for our Soldiers. Not only do we have Military, Civilian, and Contractor scientists and staff diligently working these efforts, the Command also manages numerous extramural contracts, grants, and cooperative research and development agreements from academia, industry, and other government organizations.

It can conceivably take 12 years or more for the development of a drug to travel from the research "benchtop" to the patient. The number of people involved in the process of bringing a product from the beginning stages of its lifecycle through development and delivery may only be surpassed by the extraordinary number of processes (not to mention the overwhelming number of documents!) it takes to execute each stage.

The development and approval process for a new drug is rigorously monitored and regulated by the Food and Drug Administration (FDA), and is one of the most challenging processes the command faces.

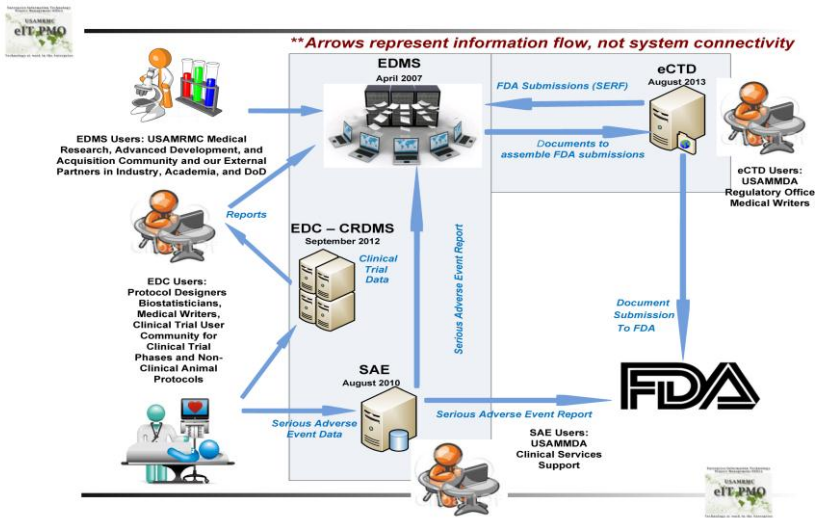
While the FDA's crucial role occurs once human clinical trials begin in the drug development lifecycle, the documentation generated during the pre-clinical research phase (which could span three years or more) will support an Investigational New Drug (IND) application to the FDA if a drug candidate shows promising results during animal or in vitro testing.

So with disparate organizational structures, mission areas, and internal processes, how is the Command able to manage all of this medical research information as it travels through such a complicated and lengthy process *and* maintain it according to rigid FDA standards?

The eIT PMO tackles this challenge head on by integrating several commercial-off-the-shelf (COTS) IT products using a virtual enterprise infrastructure. Our suite of medical IT solutions simultaneously provides USAMRMC with interagency and external collaboration capabilities, confidentiality, integrity, and availability of research data related to the drugs, biologics, and devices that are being developed by the Command. We work closely with the US Army Medical Materiel Development Activity (USAMMDA) to provide the only suite of DoD and FDA compliant IT products. The systems managed by the eIT PMO must meet compliance standards for both the FDA and DoD acquisition, while ensuring a stringently cyber secure environment.

Heidi Moynihan, (USAMMDA Regulatory Systems Manager) was able to provide us with a 'condensed' example of how USAMRMC research teams and Advanced Development utilize our systems as a prospective drug or biologic moves through its development lifecycle.

Technology Solutions for Medical Research



"Prior to the clinical stage, researchers will use the eIT PMO's Electronic Document Management System (EDMS) to store, manage, and collaborate on the extensive documentation gathered during pre-clinical development. Once a product shows potential for human clinical use, a team will work collaboratively in EDMS, developing the protocol, informed consent document, investigator brochure, etc. in preparation for clinical trial and the IND. As the protocol is being finalized, the Clinical Data Managers will begin creating case report forms (CRFs) that define the data that will be collected in the clinical trial in order to support the researcher's claims of safety and efficacy. The CRFs will eventually be built into an electronic protocol in the eIT PMO Electronic Data Capture-Clinical Research Data Management System (EDC-CRDMS).

The protocol, investigative product detail, and supporting documentation will be finalized in EDMS, and sent through the EDMS automated DRAC Submissions Workflow. This package will be used to produce an IND in the eIT PMO Electronic Common Technical Document (eCTD) Publisher system. The eCTD Publisher will output the submission file in the specified format for transmission to the FDA via the FDA's Electronic Submissions Gateway. For each product, several submissions to the FDA will occur over the lifecycle, and DRAC is currently the only DoD regulatory team who has the capability to create these electronic applications 'in house'. At this point, although a product is still investigational, it is most likely on a development pathway to licensure or approval.

As the clinical study is conducted, researchers will collect data from the trial subjects. The clinical site personnel will enter subject data directly into EDC-CRDMS, or in the case of remote areas with no internet access, paper CRFs will be used and later transcribed via the EDC-CRDMS double data entry module. Data Managers will query and clean the data in EDC-CRDMS over the course of the clinical study.

If a subject has an adverse event classified as serious, that data will be entered into eIT PMO's Serious Adverse Event (SAE) system. If the event is required to be reported, the system will generate a safety report that will be sent to the FDA. A product may have numerous studies associated with it and each study could have multiple SAEs.

Once the study is complete, the clinical data is exported from the EDC-CRDMS and sent to biostatisticians who will analyze it against the outcome measures defined in the protocol. The data analysis reports will be loaded into EDMS where medical writers will collaborate with the subject matter experts to draft formal reports that will be published using the eCTD system and sent to the FDA via the Electronic Submissions Gateway.

These actions occur over and over while a product is investigational as the eCTD continues to grow with each submission to become the final FDA application.

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The eIT Times is published by the eIT PMO.

Once a product's investigation supports a claim for licensure, a New Drug Application (NDA) or Biologics License Application (BLA) is prepared. The application combines summaries of the clinical research and supports market approval of the product. Preparation of an NDA/BLA occurs within EDMS, is published in eCTD, and is sent to the FDA via the Electronic Submissions Gateway.

The completed FDA submission is then automatically moved to a restricted area in EDMS called the Sponsors Electronic Regulatory Files (SERF), for long term storage. SERF meets the FDA's strict requirements for access, storage, and retrieval; necessary because they can choose to audit this information at any time."

The benefits the Command sees from using the eIT PMO systems are real. Our business processes are streamlined and we are able to collaborate on medical research not only across this command, but also with other DoD agencies and our external partners all over the world, in a secure, reliable, centralized location. The cost savings is notable as well. Contracted services such as archived storage of paper files can be greatly reduced or eliminated, and the reduction in time and resource manual processes is substantial. Of the FDA submissions process, DRAC Director, Dr. Robert Miller noted, "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."

Ms. Moynihan further compared the now automated eCTD process with the previous manual one.

"Previous paper process to submit an initial IND to the FDA consisted of four bound paper copies; three of which were sent via FedEX to the agency. Each page of each copy had to be hand checked for completeness and quality.

- ❖ It took 2-3 people approximately 15 days to prepare a submission for printing.
- ❖ The printing had to be contracted out because it was so large. It would take up to two weeks to get the printed material back.
- ❖ It would take 2-3 people up to three days to put everything in proper binders and perform quality checks on each and every page.
- ❖ Each binder could only hold 300 pages and each copy consisted of 3-4 three inch binders, plus three copies had to be prepared and submitted,with additional copies if the FDA reviewer requested it.
- ❖ The entire process took 5+ weeks and involved multiple individuals.

Now with eCTD, it takes one person about 5 days to prepare and publish an electronic submission—and one other person just minutes to submit it through the FDA Electronic Submissions Gateway to the FDA. Only one copy is required because the FDA reviewers can view the same submission electronically; plus, the entire application lifecycle is viewable—not just the most recent submission."

Dr. Miller offered his endorsement by adding, "Although the systems are COTS solutions, the seamless integration by the eIT PMO—developed with rigid requirements documents and an integrated plan—have yielded an FDA compliant system unique within the DoD; supporting over 70 open applications to the FDA and over 300 eCTD submissions per year, with products ranging from the treatment of severe malaria to the prevention of enteric diseases."

In a previous article, we provided a checklist to determine if the eIT PMO's systems could work for you or your organization.

If you can answer "Yes" to any of the following questions, contact us at the eIT PMO Mailbox (usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil). ***We'd be happy to meet with you!!***

- ❖ Do you need to share and collaborate on information, not just within, but outside of your command?
- ❖ Do you work with industry and/or academia?
- ❖ Do you have a difficult time tracking document updates and inputs?
- ❖ Do you send documents back and forth via email, and run into mail system space limitations?
- ❖ Do you know if you are using the latest version of a form or document?
- ❖ Have you ever had a document "accidentally" deleted from a shared drive by someone else?
- ❖ Does your data need to reside on an FDA-compliant system?

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