

IRISS-Forum
eCTD Tool Interoperability Group

August 19, 2009 - 7:30am EDT

Changes for ETIG

- Instead of taking attendance, please identify yourself when speaking
- Highlights of discussions will now be provided instead of detailed meeting minutes

Agency Updates and Specific Questions:

- FDA
 - New physical media transition specifications including expanded formats will be released in the next few weeks (Ginny Ventura)
 - DARRTS v3 Presentation (Gary)
 - An overview of their new internal submission tracking system was provided as an FYI to highlight the benefits and improvements to submission management at the FDA.
 - Allows integration of FDA review tools with the tracking system
 - Capable of tracking submissions across review divisions
 - Initially implemented to support INDs, latest release Includes NDAs and ANDAs
 - Next version which is in the planning phase will include CDER & CBER BLAs
 - Biggest impact with the implementation of v3 is the ability to track applications across review divisions. Therefore, new applications (will be in the 200000 series) and may consist of multiple “original” submission types. The use of Related Sequence must be properly used to allow for accurate review. Agency requested that sponsors be clear in their cover letters when submission applies to multiple supplements.
 - There was discussion around potential interoperability issues with various tools ability to handle multiple original submissions under a single application. Vendors and sponsors would like to see some screenshots of what the agency would see for the life cycle of an active application.
 - Post meeting updates from Gary:
 - At the present time it will apply only to new NDAs.
 - In general, the use of multiple related sequences is still considered an error. The improper use of multiple related sequences has in the past created a great deal of confusion. There are, however, instances where the use of multiple related sequences is appropriate, as in submitting a sequence that applies to more than one pending supplement or original within an application. We will retain error 1578 in our validation document with it's severity level of low. Sponsors receiving this validation error should examine their use of multiple related sequence numbers and ensure it's being used appropriately; the Corrective Action statement for error 1578 describes when it is appropriate. Low errors are not ordinarily used in determining whether

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or not we will accept a submission. At our next revision of this document we will determine whether additional guidance is needed.

- SwissMedic (Stephan Jaermann)
 - They are currently validating their processes and final guidance and specifications will be posted on the website in October. Considerable effort was put into keeping the specifications similar to the EU Module 1.
- Norman Schmuff mentioned that the eCTD/CTD-Q working group at ICH is working on responses to various outstanding Q&As. Note that Swiss Medic, Health Canada and WSMI are participating as observers in this CTD-Q process.

Open eCTD Forum 2009 3 (Barbara Jentges)

- Here is the link to the OPEN eCTD Forum 2009 that takes place from 28-29 Sep 09 in Nice, France: www.openectd.org.

Using Node Extensions in Module 3 (Phyllis Thomas)

- Ginny Ventura stated that the use of node extensions is discouraged in the US because it is a non-standard feature of eCTD that the FDA tool does not support. Sponsors can use node extensions in US submissions, but there is no guarantee what they will look like in the FDA review environment. ETIG participants shared experiences that the use of node extensions can cause unnecessary complexity, may cause interoperability problems when switching tools, and lifecycle can become unmanageable.

Points to Consider Document Update (Terri Boothe-Genthe)

- [Terri](#) is looking for volunteers to work on sections of the document.

Cross Referencing of Information Across Applications (Deanna Murden)

- Discussion on cross referencing of information across applications, particularly when the same change is filed to multiple applications. Though there remain differences between CDER and CBER at FDA on whether multiple 356h forms can be in a single backbone or need to be in separate backbones, the practice of providing multiple copies of the same content is discouraged. FDA would prefer a single instance of the content, referenced through leaf elements in the different backbones.
 - Subsequent discussion on eCTD lifecycle management over time when content location is referenced to be in another dossier via textual statement in cover letter. There is a concern regarding maintaining a complete “current view” of content in any single instance of an eCTD backbone.

Next meeting

- The meetings in 2009 will be held on the 3rd Wednesday of each month ... the next meeting is scheduled for **September 16th @ 7:30am EDT**.