

IRISS-Forum

eCTD Tool Interoperability Group

March 18, 2009 - 7:30am EDT

Attendees (11)

Glenn Austin, Ian Child, Kathy Clark, Joel Finkle, Leah Kleylein, Shy Kumar, Harv Martens, Lenore Palma, Leigh Sandwell, John-Paul Smith, Tom Smith

IRISS Topic Groups

- Two additional topic groups are forming and will begin authoring their Concept Papers shortly
 - *Lifecycle - led by Shy Kumar*
 - *section will be added to the IRISS website soon*
 - *during the initial definition phase, this topic group is not currently open to a broader audience*
 - *Metadata - led by Don Palmer*

Best Practice Document

- *Topics will be accumulated into a single document*
- *Bookmark Best Practice*
 - *Sample was provided by Lillian Reilly to Terri Booth-Genthe*

Update on Preparation of Change Request for Q&A #55 - PDF Document Properties (Security tab)

- *The plan is to submit a Change Request prior to the June ICH M2 meeting in an effort to get further clarification on the Security tab settings of PDF documents*
- *The change request has begun with outlining the process and providing samples by Terri*
- *It will ask for clarification on how to handle secured Application Forms during validation ... as a warning or should forms be an exception and errors reported only on other documents*
- *Also looking for clarification on Published Literature from online sources as it is generally protected. Many sponsors print the article and then scan it to eliminate the protection. This eliminates the ability for copy/paste functionality by the reviewer.*

Update on FDA Website Link Destination

- *Raj Maitra received confirmation from Valerie Gooding (OBPS-Division of Regulatory Review Support) of the following changes*
 - *file-tags "nonclinical-data" and "individual-subject-data-listing" have been removed from the valid-values list*
 - *"eCTD Backbone File Specification for Modules 2 through 5 version 1.1" was replaced with ICH eCTD specification 3.2.2*

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- *FDA Implementation of Study Tagging File Specification 2.6.1 (6/3/2008) (23 pages) which was US specific is now replaced by ICH M2 EWG The eCTD Backbone File Specification for Study Tagging Files 6/3/2008 (22 pages)*
- *The STF style sheet provided on FDA website is v2.2 and the one present on ESTR1 website is 2.2a and comes along with MD5 value. It is recommended that sponsors use the 2.2a stylesheet . The FDA eCTD website is in the process of being updated. It's recommended you use the 2.2a.xsl stylesheet however, if your software has not yet been updated, then using the 2.2 xsl style sheet is acceptable, but could only be temporary.*

Physical file location of CRFs (5.3.7 vs. Study folder)

- *ETICS results led vendors to believe that CRFs should not be physically located in m5/m53-clin-stud-rep/m537-crf-ipl in US submissions but should be located with the other study documents.*
- *Canada's validation criteria indicates that the CRFs should be located in m537-crf-ipl/study-1*
- *IRISS - ETIG will request clarification from the FDA as to the preferred physical location of the CRF files within the folder/file hierarchy*

Stylesheet

- *Some tools will report a validation error for a different US M1 stylesheet*
 - *Stylesheet is not an ICH requirement, only the FDA is requiring it*
 - *FDA was returning errors if named incorrectly*
 - *Kathy stated that the FDA does not use the stylesheet that is submitted*
- *Canada does not provide a standard M1 stylesheet; if you include a custom stylesheet, they do not return an error*
- *ETIG recommendation is to use the Region specified stylesheet. Validation tools should only report a low level warning (no error) when deviations occur*

ICH M2 June - 2 New Issues to be Considered by the SENTRI subgroup of the ICH M2

New PDF version recommendation

- *Moving from PDF version 1.4 to a higher version will be considered*
- *Impact on all regulatory agencies to be taken into account*
- *will look at v1.7 as it is an ISO standard*

XML Documents

- *A white paper will be prepared on the subject of standards for submission documents in XML format*
- *Harv will update the IRISS ETIG with new information and will welcome feedback as this white paper progresses.*

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- *Depending on what ICH M2 decides to do with this issue at the June meeting, there may be a place for another IRISS topic group to study this matter.*

What should the leaf title be when using the Delete operation attribute?

- *The intention of the ICH M2 group was to have no title value*
- *FDA validation error occurs if title exists*
- *Shy will author a Change Request stating that title is a required attribute with explicit examples of how it should be implemented and validated*

Interoperability topics

- *Topics will be organized and presented at the next meeting*
 - *SAS file extension*
 - *additional foldering in M3 for*

Next meeting

- The meetings in 2009 will be held on the 3rd Wednesday of each month at **11:30am GMT** ... the next meeting is scheduled for **April 15th**.