

IRISS-Forum
eCTD Tool Interoperability Group

February 18, 2009 - 8:00am EST

Attendees (19)

Terri Booth-Genthe, Jimmy Chen, James Errico, Joel Finkle, Gary Gensinger, Ted Hanebach, Brent Jones, Leah Kleylein, Harv Martens, Deanna Murden, Lenore Palma, Don Palmer, Lillian Reilly, Connie Robinson-Kuiperi, Leigh Sandwell, John-Paul Smith, Tom Smith, Patrick Thomas, Phyllis Thomas

Review of Group Bookmark Discussion

- Review of Group Bookmark Discussion (see attached)
 - *Gary and Connie stated that all bookmarks should take you somewhere*
 - *There have been several submissions to the FDA containing bookmarks with no action. Several sponsors stated that they had not received any feedback.*
 - *James commented that this would lead to an inconsistent approach to bookmarking*
 - *A Best Practice document will be formulated on this topic.*
 - *Samples to help clarify this concept will be provided by Terri, Lillian and James by February 27th for inclusion in a Best Practice document.*
 - *No action bookmarks would be a validation error by the Canadian health authority, although the submission would still be accepted*

Discussion of Q&A responses for Questions #55-57

- Continuation of Q&A #55 - The eCTD specification recommends that the PDF 1.4 is the only acceptable version in all regions. Does the ICH have any recommendations for other PDF Document Properties?
 - *Further clarification is needed on the Security tab settings*
 - *Application forms are secured to prevent changes*
 - *How should this be handled during validation? as a warning or should forms be an exception and errors reported on other documents?*
 - *Published Literature from an online source is generally protected. Current process for many sponsors is to print the article and then scan it to eliminate the protection.*
 - *This eliminates the potential for copy/paste functionality by the reviewer*
 - *Further documentation will be gathered in an effort to submit a Change Request prior to the June ICH M2 meeting.*
 - *Terri will initiate this process by outlining the process and providing samples*
- Q&A #56 - How should the application version attribute in the leaf description be used?
 - *The application-version attribute was intended to provide the version of the file format and thereby inform the receiving system of the software tool(s) needed to open the file*
 - *For leafs referencing non-PDF files, the application-version attribute should not be provided*

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- *Results of ETICS II indicated that eCTD tools are applying different rules around this attribute*
- *Currently the acceptable PDF version in all regions is 1.4*
- Q&A #57 - Can clarification be provided on the correct usage of the xml:lang attribute?
 - *This was a result of ETICS II*
 - *Several validation tools are enforcing that this attribute be used*
 - *Ted Hanebach commented that in Canada where there are two languages, there is a need to distinguish which document uses which language*

FDA Website Link Destination

- Phyllis questioned if the change in destination of the [eCTD Backbone File Specification for Modules 2 through 5 3.2.2](#) link on the FDA's eCTD website was intentional?
- New destination is http://www.fda.gov/cder/regulatory/ersr/eCTD_Specification_v3_2_2.pdf
- Previous link was <http://www.fda.gov/CDER/REGULATORY/ersr/module2-5spec.pdf>
- Connie will research this change and provide the answer

Next meeting

- The meetings in 2009 will be held on the 3rd Wednesday of each month at **7:30am** EST/DST ... the next meeting is scheduled for **March 18th**. Please be aware that the U.S. switches to DST this Sunday, March 8th.