

IRISS-Forum

eCTD Tool Interoperability Group

March 17, 2010

Agency Updates and Specific Questions:

- EMEA (not represented on the call) – eTIG leadership will attempt to get clarification on the following:
 - Sponsors are receiving validation reports from the individual EU agencies with errors that appear to be caused by the agency not loading the prior sequences into their systems. Are sponsors receiving other types of errors as well?
 - Sponsors are also receiving validation reports with errors that contradict the severity level of an error with the EU validation criteria. It appears that some health authorities are configuring certain errors to be at a higher level which is of concern to sponsors.
- FDA (Connie Robinson-Kuiperi / Ginny Ventura)
 - FDA confirmed that SPL component files (e.g. JPG files, etc.) should be included in the XML backbone
 - There was discussion around the STF category attribute. Further clarification will be provided at the April meeting.
- Health Canada (not represented on the call)
- Swissmedic (Stephan Järmann)
 - Currently using 2 validation tools to ensure appropriate errors are being reported. They are trying to stick closely to the EU validation criteria. Sponsors are being provided with validation feedback. Most of the eCTDs being submitted are technically correct.
 - They have received many change requests. It is foreseen to forward the change requests to the EU. Swissmedic will implement them in accordance with EU.

Follow up to previous topic(s):

- Validation report examples will be sent to the agencies by the end of the month.
- MHRA (UK) – How are sponsors handling the submission of the application form in regards to optimizing and inclusion in the XML backbone? – an eTIG member is waiting for information from his colleagues

ETICS III Status Update (Harv Martens)

- The sub-team has 26 members broken up into 3 regional teams (Canada, EU, US).
- There have been 11 vendors that have agreed to participate in the study so far. A reminder email will be sent soon to the remaining vendors.
- There are 44 items to test in addition to the regional validation rules.
- Phase I
 - scope will be finalized by the end of March
 - samples are being created
 - email to vendors on how this phase will be conducted will be going out soon as well

2010 eTIG Goals (Group)

- ETICS III – Phase 1
- Increase Health Authority participation with the addition of 2 new regions to the monthly teleconference
- Publish a short best practice-like document based on discussions already held during eTIG telecons (pull from meeting minutes)

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Interoperability Scenarios of the Month (Group)

- With the recent release of the Study Data Specifications v1.5.1, sponsors are having issues with the creation of the new folder(s) under analysis and tabulations. Current eCTD building tools do not allow for this additional level of foldering.
 - FDA representatives will provide additional information on these and other changes at the April meeting.

How do we ...? (Group)

- The FDA has stated that any change to an STF's Study ID, Study Title or Type of Control (5.3.5.1) will result in a new study being displayed in their viewing tool. Their recommendation to correct any of this information in an STF is to delete all leafs associated with the original STF (do not delete the STF leaf itself), create a new STF with the correct information, and associate cross-reference leafs to the new STF.
 - There is a similar issue with node extensions in the EU.
- Questions as to the national acceptance requirements in the EU were partially answered by the distribution of several URLs. Please note that these websites may not contain the most recent information.
 - [Heads of Medicines Agency \(HMA\) Directory](#)
 - [Requirements on electronic submissions for new applications within MRP, DCP or National procedures](#)
 - [Requirements on electronic submissions for renewals & variations within MRP, DCP or National procedures](#)
 - [HMA special press release on e-submissions](#)
 - [Dossier requirements in MRP/DCP and national procedures for medicinal products for human use](#)
- Discussion was held regarding the operation attribute generally used for the Application Form. The general consensus was that in most cases, "new" is used.

2010 teleconference schedule (3rd Wednesday of the month):

21-Apr (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
19-May (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
16-Jun (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
21-Jul (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
18-Aug (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
15-Sep (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
20-Oct (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
17-Nov (7:30-9:00 am (US Eastern Time, UTC/GMT -5 hours))
15-Dec (7:30-9:00 am (US Eastern Time, UTC/GMT -5 hours))