

***IRISS-Forum***  
**eCTD Tool Interoperability Group**

**December 16, 2009 - 7:30am EST**

**eTIG Update:**

- We are going to implement a change to how we interact with the health authority representatives. During the telecon, representatives are encouraged to provide updates to the general eTIG membership as well as pose questions or concerns to the vendor and sponsor communities. I'm sure that they are seeing a lot a questionable or erroneous practices and this is an opportunity for them to find out why sponsors are submitting in a particular manner, etc. In addition, if they are receiving duplicate or similar questions from sponsors, this is an opportunity for them to repeat the question and address it a single time to a wide audience.

Additionally, any one who has a specific question for an agency is asked to submit the question to me at least one week in advance of the meeting. The question will be reviewed to make sure that it relates to interoperability (which is really quite a broad category) and then passed along to the appropriate agency. This will allow them time to research and prepare a response. So the sooner you send in your question, the better chance you have of it being addressed at the next meeting.

**Agency Updates and Specific Questions:**

- EMEA – not represented on the call
  
- FDA
  - The FDA received their 100,000<sup>th</sup> eCTD submission this week!
  - There is a possibility of a revised Module 1 in 2010 to include elements for DDMAC submissions and new forms.
  - Remember to use the related-sequence-number element for IND amendments!
  
- Health Canada – not represented on the call
  
- Swissmedic (Stephan Järmann)
  - Release of Specification v1.0.1 and statement by agency that they will be supporting both v1.0 and v1.0.1.

**Follow up to previous topic(s):**

- In an effort to get clarification on the FDA's validation criteria, the eTIG leadership team is **asking the sponsor community to provide snippets of the validation reports** they are receiving from the agencies with which there is confusion or disagreement. The examples will be scrubbed of company name and application number, collated, and sent to the appropriate agency for clarification. You can [send](#) the error reports along with what you are questioning.

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### **Q & A v1.18**

- New Q&As (#65-70) are in response to Module 3 questions that have been submitted.
- CTD-Q IWG will be looking at new change requests related to Module 3. These should be submitted via the [ICH Change Request](#) process. Clarification questions (e.g. “How would you like this situation handled?”) should be sent to [esub@fda.hhs.gov](mailto:esub@fda.hhs.gov).

### **Points to Consider (PtC) Document Update** (Lenore Palma)

- After a lengthy discussion and careful consideration of what is in the best interest for IRISS, it has been decided to hold off on the release of the eTIG PtC document by year end. We’re going to try a different approach, so during each month’s teleconference we’ll discuss as a group a few interoperability specific scenarios and once a consensus approach has been reached or a concise list of pros/cons for handling the scenario in a multitude of ways has been achieved, it will be documented and combined with the other topics that we’ve discussed in the past (e.g. Q&As #48-57). Once we think there is sufficient material, we’ll then look to formally produce a PtC document.

### **Interoperability Scenarios of the Month** (Group)

- There was discussion regarding the inconsistencies displayed by the agency’s viewing tools under the following scenario:

Seq #	Leaf Title	Operation Attribute	Current View at ...	
			FDA, EU, & Swissmedic	Health Canada
0000	NewLeaf	new	NewLeaf	NewLeaf
0001	AppLeaf	append	NewLeaf AppLeaf	NewLeaf AppLeaf
0002	DelLeaf	delete NewLeaf in 0000	AppLeaf	<blank>

- According to the EU TIGes “*Guidance for Industry on Providing Regulatory Information in Electronic Format: eCTD electronic Submissions*” document dated May 2009, non-PDF required formats (e.g. MSWord, RTF) should not be added as leaf elements within the eCTD structure. They should be provided in a separate folder called, e.g. “<sequence>-workingdocuments”. According to the example in the guidance document, this folder should be at the same level as the sequence number folder. In general, validation tools check to make sure that folders listed under the high level folder (e.g. application number) are valid submission folders with a valid sequence number name. How are sponsors handling this during validation of their applications?
  - The response was that the “<sequence>-workingdocuments” folder is stored separately from the sequence folders and only joined together under the high level folder when put onto the hard media.

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- Question for the agency is “what will happen in the future with submissions done through a gateway?”

**2010 Teleconference Schedule** (3<sup>rd</sup> Wednesday of the month):

20-Jan (7:30 am (US Eastern Standard Time, GMT -5))  
17-Feb (7:30 am (US Eastern Standard Time, GMT -5))  
17-Mar (7:30 am (US Eastern Daylight Time, GMT -4))  
21-Apr (7:30 am (US Eastern Daylight Time, GMT -4))  
19-May (7:30 am (US Eastern Daylight Time, GMT -4))  
16-Jun (7:30 am (US Eastern Daylight Time, GMT -4))  
21-Jul (7:30 am (US Eastern Daylight Time, GMT -4))  
18-Aug (7:30 am (US Eastern Daylight Time, GMT -4))  
15-Sep (7:30 am (US Eastern Daylight Time, GMT -4))  
20-Oct (7:30 am (US Eastern Daylight Time, GMT -4))  
17-Nov (7:30 am (US Eastern Time, GMT -5))  
15-Dec (7:30 am (US Eastern Time, GMT -5))