

# ***IRISS-Forum***

## **eCTD Tool Interoperability Group**

**October 21, 2009**

### **Agency Updates and Specific Questions:**

- SwissMedic
  - An update was provided on the 3 phased approach to accepting eCTDs beginning January 1<sup>st</sup> 2010 with new applications. The final version of the DTD will be posted on their website at the end of October
  - Informational meetings are planned to assist with the implementation. Details will be posted on the website.
- EMEA
  - Forward questions specific to M1 v1.4 to Claire Holmes prior to a Nov. 13<sup>th</sup> meeting with EMEA, member states and Industry during which questions will be discussed with the intention to produce a Q&A (technical and procedural) by the end of the year.
  - Question: Will there be a harmonized procedure created for MRP/DCP?
    - Response: This would be handled by the CDM(h) group. Since member states have implemented at different rates, a practical guidance document will be posted on the CMD(h) website.
- FDA – the Electronic Submission Support Group was not represented on the call.
- Health Canada – Not represented on the call

### **Points to Consider Document Update**

- Brief update was provided on the progress of the document.

### **IRISS ETIG eCTD Tools Interoperability Study**

- This is expected to be a minimum 6 month process led by Industry with agency and vendor participation
- The objective will be to produce an eCTD Tool Validation Test Suite.
  - For example, for building tools:
    - Source files → Instructions → Expected Outcome
    - Sample eCTDs → Import → Add Sequence → Expected Outcome
  - Allows vendors to self-validate their tools
- A request was made for sub-team participation (ETICS II had a large team of people)
  - Sponsor leadership of sub-team and participation is desired with expected vendor participation near 100%.

### **Interoperability Scenarios of the Month**

- This is a new agenda item that will appear each month. Members have been asked to come to the telecon prepared with an example of an interoperability issue that they've experienced recently. It doesn't have to be solved yet as this is an excellent forum to get the perspective of others and possibly a way to resolve the issue. For vendors, it is an opportunity to discuss issues that came up in the

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ETICS II study and ask other vendors what approach they may have taken on a particular topic. Product and vendor names will be kept out of the discussions.

1. As the result of a merger, applications created in one tool needed to be migrated to a different tool. In the process it was discovered that the old tool allowed for folder names to be different from the recommended folder names. The tool being migrated into restricted folder names to the recommended names, thus the import failed. Discussion ensued around resolution.
2. Discussions are taking place at the CTDQ IWG regarding the content of module 3 overlapping within the eCTD. Excipients are the next attribute to be dealt with and the focus being on the optional nature of the values. Some discussion was held on Drug Product attributes being optional in the DTD. Grouping of information under a general attribute value could be a potential problem with eCTD NMV and RPS.
3. For CMC information in an eCTD format IND, be practical with granularity choices. Information which is too granular does not make sense (e.g. 7 individual documents submitted which had they been combined would have been ½ page). Sponsors should consider combining the information into a single document, at the heading element level which is fully allowed by the DTD.

#### **Has anyone had this happen?**

- This is another new standing agenda item where members are given an opportunity to ask about how a particular situation should be dealt with in the eCTD world. There is a tremendous amount of experience on the call and it's a great opportunity to tap into that knowledge base. These questions should be related to potential interoperability issues, such as how another viewing tool might display something in the submission, importing a submission created in another tool, what to keep in mind when submitting basically the same information around the globe, etc.
1. You've acquired a product from another company. When trying to bring it into your tool you encounter what you believe to be a fairly serious problem with an STF in one submission which has carried on through the life cycle of that study. In a sequence from the early days of eCTD acceptance, the agency accepted an STF leaf with no modified-file attribute value. This has caused the following STF leaves to be disassociated with the initial set ... kind of a branching of STFs so to speak. When you look at the study in some viewers, it appears that you have two separate studies.
    - a. The recommendation is to contact the agency to determine if they made corrections and you should do the same or if steps could be taken to make the correction.

#### **Next meeting**

- The meetings in 2009 will be held on the 3rd Wednesday of each month ... the next meeting is scheduled for **November 18<sup>th</sup> @ 7:30am EST.**