

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

**January 20, 2010**

**Agency Updates and Specific Questions:**

- EMEA (Claire Holmes)
  - Q: Validation reports
    - Are validation reports being provided to sponsors for every submission? If not, under what conditions are they being provided?
      - A: Validation reports are not provided to sponsors as a matter of routine - they are only provided upon request, or if there is a technical issue with the submission that is reported.
    - How are they provided (i.e. eGateway account, email, snail mail) and to whom?
      - A: The reports are provided via secure mail (Eudralink), to the EMA's product contact at the company.
    - What level of detail is being provided? Are all low level issues being consistently reported?
      - A: The level of detail provided is as presented by default by our validator from Extedo (we have a new version of the validator that now supports EU M1 v1.4 - this was made available in December). Category A, B and C issues are reported and labelled accordingly so that they can be addressed or taken as information as appropriate, and the exact dossier location of the issue is indicated.
- FDA
  - Q: Validation reports
    - A: A response was not provided during the meeting.
- Health Canada (Vianney Caron / Irena Pastorekova)
  - Q: Validation reports
    - Are validation reports being provided to sponsors for every submission? If not, under what conditions are they being provided?
      - A: A report is sent for every submission including sample submissions
    - How are they provided (i.e. eGateway account, email, snail mail) and to whom?
      - A: It is sent via email to the technical contact if provided, otherwise to the person who signed the cover letter. Many times an email address is not provided for anyone.
    - What level of detail is being provided? Are all low level issues being consistently reported?
      - A: Errors are categorized as Error, Warning, Pass, Informational. In the past, links to another sequence were being reported as bad links. Named destination links will be corrected in the next version of eValidator by DocuBridge ... anticipated to be around January 29<sup>th</sup>.
  - Q: A few sponsors are stating that the agency does not want a node extension created for a study if only a single document is being submitted. Is that really what the agency is requesting? What happens with life cycle of the study when additional

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

documents may be added to the study? You would end up with some documents outside of the node extension and some within.

- A: Originally reviewers were annoyed by having to open additional folders for a single document. Now after gaining some life cycle experience, they understand the benefit provided by node extensions. They recommend that the node extension title consist of the study ID and the full study title, keeping the document leaf titles short.
- Q & A document – The current version is outdated. They were planning to revise, but it is not moving too quickly due to a lack of resources.
- For hybrid submissions where M1&2 are in paper, M3-5 are eCTD, a response to a Clarifax should be submitted together as a single package. A summary of the response may be faxed to the reviewer if it is critical that they get the response that day. It is assumed that the summary will be sent after completing the package.
- Swissmedic (Stephan Järmann & Claudia Zerobin)
  - Q: Validation reports
    - Are validation reports being provided to sponsors for every submission? If not, under what conditions are they being provided?
      - A: Since we are now starting with eCTD, we provide the reports for every submission. At a later stage (after July 2010) based on our experience we are going to reconsider this. The scope and extent of the feedback may then be modified. In case of validation issues, the applicant will receive a validation report identifying validation results including errors, warnings and notifications. The validation report states in more detail the reasons for rejection and/or additional comments. The feedback policy will be revised after an initial phase (End of June 2010), the scope and extent of the feedback may be modified.
    - How are they provided (i.e. eGateway account, email, snail mail) and to whom?
      - A: Swissmedic provides the report in paper to the applicants contact address of the applicant deposited in Swissmedic's address database.
    - What level of detail is being provided? Are all low level issues being consistently reported?
      - A: Currently we provide the full report including all the low level issues. The applicant gets the report that Swissmedic also uses to evaluate the technical quality of the eCTD.
  - Swissmedic has received three official eCTD (January 26, 2010) and three test eCTD submissions so far. We are in the process of the technical validation and feedback is provided to the applicants. Swissmedic uses DocuBridge and EURS is Yours validators. Links were updated on our website on the 18<sup>th</sup> of January, indicating how to get both validators. We have seen cases of different results of the technical validation from each validator, reasons are currently being evaluated.

# ***IRISS-Forum***

## **eCTD Tool Interoperability Group**

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

- Validation report examples that are unclear
  - We have 2 samples to date, so please send more examples, but remember to remove all traces of sponsor, application or tool identification!!!

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

- Are sponsors linking across applications? Please either share your experiences with this approach or tell the group why you've chosen not to take this approach.
  - FDA - Some companies are doing cross application linking. It is recommended to include a table under 1.4.4 indicating where cross-referenced documents can be located. It is also recommended that the leaf title indicate that the leaf cross refers to application # / sequence #.
  - HC – The reviewing tool does not handle cross application linking, therefore it is not supported.
- What is the definition of path length? Some tools start at the application number folder and some at the sequence number folder. What was intended by ICH? What is required by the agencies?
  - ICH never defined where the path length should begin. ETICS defined as starting with the sequence #.
  - FDA – Awaiting confirmation that it starts at the sequence # folder.
  - HC – Starts with the application # folder and is limited to 230 characters.
  - Swissmedic – Starts with the application # folder and is limited to 180 characters. A change request is being written to start at the sequence # folder, so an eCTD will not be rejected if the root folder length puts the total path length over the 180 character limit.
- In general, eCTD building tools do not allow for a replaced or deleted leaf to have an action (append, replace, delete) applied to it. Are there any regulatory scenarios under which this type of action is possible?
  - Per ICH, replaced and deleted leaves are not meant to have a life cycle applied to them.

### **2010 teleconference schedule (3<sup>rd</sup> Wednesday of the month):**

- 17-Feb (7:30-9:00 am (US Eastern Standard Time, UTC/GMT -5 hours))
- 17-Mar (7:30-9:00 am (US Eastern Daylight Time, UTC/GMT -4 hours))
- 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))