

IRISS-Forum

eCTD Tool Interoperability Group

February 17, 2010

Agency Updates and Specific Questions:

- FDA (Connie Robinson-Kuiperi / Ginny Ventura)
 - The FDA was closed 4 days last week due to weather related issues. They are currently working through a huge backlog of submissions. Sponsors who submitted via the eGateway on those days will receive a communication soon with clarification on the Receipt Date of their submission.
 - Q: Validation reports
 - Are validation reports being provided to sponsors for every submission? If not, under what conditions are they being provided?
 - A: No. Validation reports are provided for eCTD Sample evaluations. Validation reports are sometimes provided when issues (initiated by the Division, by the sponsor, or by EDR staff) occur with an application to help the sponsor understand what they did wrong. Validation reports are generally not provided with failed gateway guidance compliance test submissions unless the sponsor contacts an ESUB member and the reports may or may not be provided depending what level of detail is needed for the sponsor to understand the errors they made in the test submission.
 - How are they provided (i.e. eGateway account, email, snail mail) and to whom?
 - A: When provided, it is by email.
 - What level of detail is being provided? Are all low level issues being consistently reported?
 - A: The eCTD error code if applicable, description of the error and in certain situations specifics regarding the eCTD location, the xml code, etc. Yes, generally that is the case.
 - There are more detailed responses now with eCTD test submissions, because FDA has more staff to address them. If a sponsor has a concern about something, they are encouraged to email FDA to let them know you will be sending a test submission, send in a test sequence and receive a response from FDA eSub Support. Guidance for test submissions can be found on the FDA website:
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm174459.htm>.

Follow up to previous topic(s):

- Last call for Validation Report examples ... remember to remove all traces of sponsor, application or tool identification!

Interoperability Scenarios of the Month (Group)

- Are sponsors forced to reprocess a submission that has already been sent to an agency if they are bringing it into a new tool?
 - Some tools cannot do life cycle on documents unless sequences are republished. This may cause leaf IDs to change. Subsequent submissions would have a problem at the agency if this were to happen.

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- *Summary for meeting highlights:* Different interpretations of guidance can lead to different requirements, for example, STF file-tags, required vs. implied attributes for CMC. In order to create new sequences, sponsors in some cases have to manipulate the XML backbone. Different scenarios have different solutions, and it is important for sponsor, Agency, and vendor to communicate to resolve issues.
- Not all viewing tools display attributes for "species, route of admin, duration, type of control". The display of these attributes can result in study reports being presented in a different order in different viewing tools.
 - FDA responded that the ordering of M3 caused confusion with the review staff. They are working with GlobalSubmit to have a view with specific ordering. The plan is to make the details of this ordered view available. They have also requested a "Sponsor View" to be available in the reviewing tool which will display reports in the order the sponsor intended.
 - Additional comment was made to remind sponsors to be consistent when entering attributes and metadata ... strongly recommend that these remain the same as previous submissions to the application since modifying the attributes will result in separate nodes for each attribute. It's recommended that sponsors always use where required and do not change during the life cycle of the application.
- Differences in environment between sponsor and agency might lead to different validation reports being produced by the same validation product. As a sponsor, if you encounter this scenario, please be sure to notify the vendor as they may not be aware of the issue.

How do we ...? (Group)

- What should a sponsor do if they acquire an application that is technically incomplete, yet previously accepted by an agency and is not usable by their building/viewing tools? (i.e. missing required attributes)
 - Work with agency and tool vendor to reach an acceptable course of action.
- MHRA (UK) – How are sponsors handling the submission of the application form in regards to optimizing and inclusion in the XML backbone?
 - A participant on the call will research how they have submitted the application form in the past.

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

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))