

IRISS-Forum

eCTD Tool Interoperability Group

April 21, 2010

Attendees (25)

NOTE: The meeting was adjourned early due to degradation of the phone connection. The Interoperability leadership team is investigating an alternative teleconference option.

Agency Updates and Specific Questions:

- EMEA (not represented on the call)
- FDA (Connie Robinson-Kuiperi)
 - They are planning for a release of the GlobalSubmit application(s) later this year, however the date has yet to be determined.
 - Q: Is it acceptable to include a short descriptive title on a leaf with the “delete” operation attribute?
 - A: Confirmation of acceptability is needed before definitively stating “yes” or “no”.
- Health Canada (Vianney Caron)
 - It is OK to follow the naming in the Module 1 Specification for the 3011 form (hc-sc-3011-en.pdf or hc-sc-3011-fr.pdf). The more recent Guidance entitled “Preparation of Drug Submissions in Electronic Common Technical Document (eCTD) Format” which specifies the naming convention as “0001-ca-m122-hc-sc-3011-en[fr].pdf” is not yet being followed.
- Swissmedic (not represented on the call)

Follow up to previous topic(s):

- EU websites provided following the March meeting may not be up to date.

ETICS III Status Update (Harv Martens)

- 12 vendors have expressed interest in participating
- Phase I scope has been confirmed. Numerous tests in addition to tests of regional validation rules will be conducted
- launch date is set for May 17th and vendors will have about 6 weeks to return their results

Best Practice Document (Barbara Jentges, Lalana Dararutana)

- Initial draft review is planned for the May meeting

2010 eTIG Goals (Group)

- Completion of ETICS III – Phase I
 - Design study – small, public domain submissions containing intentional errors that are created by the ETICS team to test viewers and validators
 - Invite vendor participants
 - Evaluate test results – vendor results will be blinded prior to team evaluation
 - Present results at a public meeting
- Increase Health Authority participation on monthly teleconferences with the addition of 2 new regions (Australia is a possibility)

IRISS-Forum

eCTD Tool Interoperability Group

- Gain the confidence of Health Authorities to use IRISS eTIG as a portal for information exchange
 - verbal updates provided monthly regarding new specifications/guidance
 - forewarnings of future changes within the agency
 - written notifications to the public via the IRISS website
- Publish a short best practice-like document based on discussions already held during eTIG meetings
- Create a living document of key discussion points which is searchable (i.e. table of contents, XML tagging, index, etc.)

Interoperability Scenarios of the Month (Group)

- As a result of a partnership, an application has been acquired. As new sequences are being built, the original sponsor's name is pre-populated. Vendors need to ensure that their tools use the most recent envelope information to avoid this situation.
- Acquisition of a compound may result in the new sponsor having to import multiple sequences into their system. Vendors should allow for batch loading capabilities.

How do we ...? (Group)

- Clarification is needed on the new EU Variation requirements that went into effect January 1, 2010. The group would like a general presentation on these new requirements with specifics around the use of the tracking number. The Interoperability leadership team will look into sponsoring this presentation.
- One participant is looking for advice on handling Expert Statement lifecycle. Please send Lenore an email if you have experience with this that you would like to share.

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

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))