

IRISS-Forum
eCTD Tool Interoperability Group

September 16, 2009 - 7:30am EDT

Agency Updates and Specific Questions:

- swissmedic (Stephan Jaermann)
 - M1 specification v0.93 is available by contacting [Stephan Jaermann](#)
 - v0.95 will be posted on the website towards the end of September
 - Final v1.0 will be posted mid to end of October
- Health Canada (Glenn Austin)
 - Implementing Lorenz' DocuBridge v5 this fall
 - In the process of an enterprise architecture review; this is a 5 year mission with the goal of having one common system across all regulatory systems

Points to Consider Document Update (Terri Boothe-Genthe)

- Draft Table of Contents is available on the IRISS ETIG website
- Next meeting will be Sept. 23rd at 9:00 ET
- Please submit the form found at the bottom of the ETIG webpage and include "Points to Consider" in the subject line if you are interested in participating on this sub-team ... volunteers are still needed
- Region specific section will be addressed first

Related sequence view

- Currently there are only a few viewing tools that offer a related sequence view
- FDA, EMEA, Health Canada and swissmedic use the related sequence element
- FDA is expecting that related sequence is used for all "amendment" submission types
 - IND applications – amendments should be related to the "original-application" sequence; "other" submission type should not be related, but will automatically be grouped together by the viewing tool
- What happens to those sequences which have already been submitted without a related sequence specified? Is some form of correction needed and/or possible?

Next meeting

- The meetings in 2009 will be held on the 3rd Wednesday of each month ... the next meeting is scheduled for **October 21st @ 7:30am EDT**.