

JIC Executive Meeting

Wednesday 22nd July 2015

20:00-21:00 UTC

Minutes of Meeting

Location: Teleconference via GoToMeeting

Meeting documentation: <https://csfe.aceworkspace.net/sf/go/docf4908>

1. Welcome, Apologies.

The Chair welcomed the Council members to the meeting. Apologies are noted above.

2. Minutes of last meeting (20150722)

Approved. An abbreviated ‘Record of Discussion’ will therefore be posted on the JIC website.

3. Agenda approval, requests for AOB

Agenda approved. No new items were requested.

4. Review of actions from previous meeting

Action list: <https://csfe.aceworkspace.net/sf/go/doc12556>

Outstanding Actions:

- 2015-04-19: Update on International Patient Summary [Action: JQU to get an HL7 update on IPS following TSC tomorrow and to circulate]

A representative of HL7 reported that he had spoken with one of the co-chairs of the HL7 Structured Document Working Group. He then looked at the ballots in progress. He found that the IPS was part of the ballot that was just completed so they will be working on it over the next 30 days for resolution of the negatives. He stated that this is directly tied to the Trillium Bridge Project in general. He was asked what the scope of the ballot document was, as he hadn’t seen anything that related to it? He thought that the white papers had been balloted, but not the IPS itself. The HL7 rep replied that there is a list of balloted items on the Structured Document Working Group’s home-page. He invited those on the call to speak with him offline if they had further questions.

- 20150624-01: Updating the Charter [RDH to complete the final document and circulate for final approval. IHTSDO will work to coordinate getting everyone's signatures].
The Chair stated that the Charter had been circulated electronically and no change requests were received so he had therefore signed two hard copies for each SDO via courier by IHTSDO's head office. Now waiting for appropriate signatures from all SDOs.
ACTION UPDATE: The Chair asked everyone to email him to confirm receipt and check progress on signing. The group agreed.
- 20150624-05: Trillium Bridge - Advancement of International Patient Summary [DSW to circulate a statement of endorsement by the JIC for electronic approval by the Executives, with 5 working days to review. Council members should also seek to obtain endorsements from their own organizations and send them to CCH directly].
The JIC Executives endorsed the Trillium Bridge recommendation.

Other outstanding actions were listed as agenda items below...

5. Development of Starter Set

5.1. Update on progress and next steps

See document: <https://csfe.aceworkspace.net/sf/go/doc12753>

A sub-group of the JIC had met twice since the last meeting and now have fortnightly calls scheduled. The paper linked above (*Patient Summary Global Standard Set - Draft Scope and High Level Use Cases: A Foundation Report*) had an executive summary of what they are doing.

An executive said that there were several statements in the Executive Summary that were setting a really good direction as the sub-group has identified what a Standard Set is as well as identifying the topic, the target work, the approach, and the primary use case. Another executive agreed, saying that it was building off the good work done in San Francisco. They stated that the sub-group had tried to find one of the most common clinical problems they are all working to solve, in order to assist many different jurisdictions. They did define that initial use case but they are open to having ideas submitted. Everyone agreed that it has to be able to be used for both a national and international transaction.

The Chair thanked everyone on the sub-group and urged those on the call to provide feedback. He asked if the JIC should post a progress document on the website at this stage, or was it too early? An executive replied that he thought the piece of work was excellent, however he thought we should wait until after the sub-group's next meeting before sharing it publicly. He said he thought the case for dropping "international" was made well, however he hoped that the JIC would still gain something that had the structure and flexibility to be able to be used across borders and

jurisdictions. Others agreed, saying they would like for the sub-group to decide when the document is ready for publication. There also needs to be a statement added about the ISO work (as mentioned below) included in the Report.

5.2. JIC Standard Set & ISO bundle

Documentation: <https://csfe.aceworkspace.net/sf/go/doc12754>

An executive stated that they had tried to outline a background of why the JIC and ISO need to demonstrate what these two initiatives mean and how they will link. The Chair stated the document linked above was meant to be complimentary to the Standard Set Report as it provides clarity and link to the work that TC215 is doing under the ISO banner as well as what the JIC is doing, so it should help to eliminate confusion in the ‘real world’ about what is happening.

There was a request that it be made clear in any published documentation that it is only ISO *TC215* that is involved, rather than the broader organization (which could be inferred from any abbreviations).

Action 1	The JIC was asked to provide feedback on the Foundation Report & ISO Bundle briefing by the CoB of Wednesday 29 th July 2015. Report feedback should go to JMI, and ISO feedback to MGL. The sub-group would then recommend timing for when the document could be published on the JIC website.
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6. JIC involvement in ISO 80003 ballot (update)

Documentation: <https://csfe.aceworkspace.net/sf/go/doc12758>

A representative from ISO elaborated on the briefing summary linked above. At the May 2015 JIC meeting ISO TC215 leadership indicated that it might request a letter of support from the JIC regarding the concerns around the 80003 series, which has been an ongoing concern of ISO TC215 for since 2012. It has now been decided that the executive leadership of ISO TC12, ISO TC215 (Chair and Secretaries) will meet with ISO/CS to enable productive work of both TCs on standardization of quantities and units in healthcare. Based on the positive outcomes from this ISO/TC12 meeting as described, ISO TC215 do not feel that a letter from the JIC is needed at this time. LSP will keep the JIC posted as this matter progresses.

7. Unique Device Identifier (UDI)

Documentation: <https://csfe.aceworkspace.net/sf/go/doc12748>

A representative from GS1 said that they had previously sent the above document to HL7 but had not yet received a response.

The IMDRF (International Medical Device Regulators Forum) has defined new rules for medical devices under the name of UDI (Unique Device Identifier). This guidance focusses on manufacturers and their representatives, to secure appropriate, unambiguous identification is labelled on medical devices with a data carrier (such as a bar code) and also human readable text. Once medical devices are identified, a minimum set of product information has to be published in a database maintained by the regulator.

The first implementation of this international guidance occurs by the US FDA. It will be followed by similar rules in Europe and in other jurisdictions. In that respect UDI requires a globally harmonised approach.

It was stated that they were requesting that the JIC:

“Develop guidance -which is in no way a standard- to demonstrate the capacity of JIC SDOs to collaborate. It should pass appropriate approval process in the involved SDO so that each of them can add the guidance to its publications.”

It is not a US specific issue, but rather a general one, and it would therefore be a good opportunity for the JIC to provide some “foot-prints” in this space where various standards have to work together.

A representative from DICOM asked to be sent some documentation as they had a change proposal that had been sitting ‘on hold’ pending the other standards being ready to harmonise. They wished to make sure their coding format aligned. They were advised that the full guidance document was not yet written, but at this point the briefing note and some other items could be shared.

Action 2	GSI to share UDI documentation with DICOM.
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The Chair said that IHTSDO would be happy to provide guidance as IHTSDO has an agreement with GMDNA where they have been putting device content (in the form of SNOMED ID's) into SNOMED. He could reach out to GMDNA to provide guidance, if the JIC wished? He stated that it would certainly be appropriate from a European perspective. An executive replied that it was his opinion only the active JIC members should be involved, although he was pleased that IHTSDO are involved with GMDNA as they are very important (more strongly on the regulatory side, rather than on the clinical side where SNOMED plays a much more important role).

An executive said that he thought it was a good idea for the JIC to have a guidance document on this topic. He would be interested to see the process of how this document comes together, as the patient summary world will no doubt need written implementation guidance soon too.

It was stated that it had been over two weeks since there had been any activity from the US FDA, so those at HL7 were still waiting on a response to see if there would be any need to make changes from the current status. An executive replied that they shouldn't need to change the

current status. Instead, there needs to be visible endorsement of a solution, and he was not sure that the solutions HL7 were providing was absolutely ideal. He said, however, that it was not appropriate to speak further on it at this stage, and it was agreed that the issue was still pending a response.

The Chair asked how things would move forward? Would GS1 lead in keeping the JIC updated, working with the identified SDOs to bring back a framework for the guidance? Should each SDO send on their guidance ideas that GS1 could then shepherd into one document? Or should the JIC wait for the US FDA to make updates to what they are requiring in this area? The representative from GS1 replied that his preferred way forward would be for the interested SDOs to nominate one person each to then work together to develop the guidance. This approach was agreed.

Action 3	The Chair to distribute a note to relevant SDOs asking them to nominate an appropriate contact for developing the guidance document.
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8. New Business

No new business was raised.

9. Confirmation of next face-to-face meeting

Agreed as Thursday 5th November 2015 (18:00-21:00 local time), during the ISO meeting in Bern, Switzerland.

10. Adjournment

The meeting was adjourned after the Chair thanked the attendees for their time.

11. Next meeting

September 9th 2015 (20:00-21:00 UTC)

(Combined August/September meeting earlier in September to avoid clashes)