

IHE Proposals for 2013-2014

The submitted proposals

- Update to Lab Device Automation (LDA)
- Harmonization between US realm standards for Lab domain and respective IHE profiles:

Laboratory Device Automation

- Submitters:
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The Problem

- Current IVD analyzer vendors and Laboratory Automation Systems (LAS) vendors have little guidance on how to implement software interfaces between their sample transport systems and IVD analyzers. HL7 and CLSI AUTO3-A provide some direction, but do not provide specific guidance for individual LAS-to-analyzer workflows.

Key Use Case

An IVD analyzer vendor creates an analyzer capable of interfacing with an LAS sample transport track with a point-in-space interface for direct track sampling.

- Lack of guidance for interface implementation
- Unique driver development cycle despite behavioral similarities between analyzers from various vendors
- Recurrent resource burden for typical interface set up
- Desire to leverage an interface that is
Based on real world workflows
- Built on existing standards
- Vetted by key industry representatives
- Promulgated by a respected standards body.

Standards and Systems

Existing systems that could be involved:

- IVD analyzer
- Laboratory automation sample transport track system

Relevant standards to consider:

- HL7
- CLSI AUTO5-A (HL7 Chapter 13)

Discussion

There clearly exists a need for fully specified interface protocols to reduce the time and costs associated with providing LAS-to-analyzer interfaces to clinical laboratories. The IHE-LAB Committee is the appropriate entity to create and promote such solutions. Prior work by the Committee on the LDA profile is testament to that need.

The proposed work item is to continue the original LDA Profile effort, to include sample transport and sample handoff integration profiles between automated sample transport track systems and IVD analyzers.

US Realm Lab IGs – IHE profile Harmonization

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The Problem

- *The following US realm S&I lab related Implementation guides:*
- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm*
- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 - US Realm*
- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2 US Realm*
- *are included in Meaningful Use regulation (MU) in the US, involving product certification testing in order for providers to be eligible for MU payment incentives.*
- *This means that vendors with a customer base in the US will have to support these IGs. It would be beneficial, if the IHE-Lab-Technical Framework and its profiles were congruent with requirements prescribed in these guides.*

Key Use Case

LIS and EHR-S Vendors operate in an international arena – reducing customization as much as possible will reduce system development resource costs for these workflows:

- Place a laboratory order, update a laboratory order*
- Receive results, update results*
- Exchange of the test compendium between the laboratory and the provider*

Standards and Systems

Laboratory Technical Framework – especially the Trial Implementations for Laboratory Testing Workflow (LTW) and the newly proposed Laboratory Clinical Communications (LCC) to:

HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm

HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 - US Realm

Laboratory Code Sets Distribution Profile to:

HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2 US Realm

Discussion

- *Vendor participation in IHE is key to determining the most acceptable denominator. Vendors implementing in the US realm will have to adhere to US regulations – those may not be needed to be ported all the way into the IHE profiles, but the IHE profile and the IG should not require opposite solutions to the same use case.*
- *Harmonize existing profiles with US realm profiles and then republish, where changes were needed. Get Clarifications on different interpretations of the base standard between the US realm IGs and IHE profiles through work at HL7 Orders and Observations WG.*