

Board Report: IHE Anatomic Pathology/Laboratory Domains

Sponsors:

- College of American Pathologists (CAP)
- French Agency of Share Healthcare Information Systems (ASIP Santé)
- Japanese Association of Healthcare Information Systems (JAHIS)

Leadership:

- AP (prior) domain
 - Mary Kennedy, CAP (mkenned@cap.org) - secretary
 - Raj Dash, CAP - planning & technical cochair (currently the only cochair of AP)
- LAB (prior) domain
 - Carolyn Knapik, CAP - secretary
 - Riki Merrick, Vernetzt, LLC - planning cochair (currently the only planning cochair of LAB)
 - François Macary, ASIP Santé - technical cochair
 - Yoshimi Hirasawa, Techno Medica - technical cochair

Activity:

The IHE Anatomic Pathology (AP) and IHE Laboratory (LAB) domains request approval from the IHE Board to merge into one domain to be known as “Pathology and Laboratory Medicine” (PaLM).

The collaboration between the two domains, IHE AP and IHE LAB, has occurred since the creation of the AP domain, and is demonstrated by the reuse of materials (Transactions, Content Modules, Actors, value sets) from one domain to the other. A few joint meetings have occurred as well and there is a common Secretariat for both assumed by the College of American Pathologists.

As of April 2015, in thinking strategically of future work and profiles, and in the spirit of reinforcing this collaboration, the co-chairs from IHE AP, IHE LAB, and together with their Secretariat, have recommended a consolidation of the two working groups into one group. Consequently we have held meetings together, both face to face as well as via conference calls, and continue to review work in common on future integration profiles where the scope covers both domains.

In general, we think a merger of the two domains into a single one will:

- Help streamline processes for profile creation
- Better address the emerging common needs such as specimen processing automation, molecular genetic testing or flow cytometry
- Produce common assets usable in a broadened scope

- Benefit both systems vendors and systems users.

On-going discussions between the two domains have produced a number of practical reasons for merging including:

- A common general workflow of ordering and reporting diagnostic observations performed on in vitro specimens
- Common organizations in some countries (e.g.; in US, LAB and AP are in the same institution and pathologists cover both anatomic pathology and clinical pathology).
- Some common systems, and thus common software vendor stakeholders: EHR-S vendors, LIS vendors, middleware vendors, in vitro diagnostic device vendors
- Several use cases and integration profiles already in common like inter-laboratory workflow, laboratory device automation, structured reporting ... and we want to simplify users and vendors experiences by providing common solutions to common use cases.
- An opportunity to redesign, in light of the new domain's scope, some existing profiles that, due to lack of adoption by implementers, had failed to reach the Final Text status
- A will to broaden the visibility and enforce the activity of the merged domain, leveraging existing successful assets from LAB or AP
- A will to have a more consistent strategy in the design of the semantics within the merged domain, and more formal relationship with the owners of reference terminologies.

We understand that there are always risks associated with such a merger and have raised and discussed these issues. These include:

- Risk of reduction of the involvement of the users or vendors of one of the two communities due to the dilution of their specific needs in the broadened scope of the merged domain
- Risk of decreasing joint meetings with some domain specific working groups (e.g.; DICOM WG 26 or HL7 AP)
- Risk of neglecting the standardization workflows specific to one of the two domains (e.g.; the in vitro imaging workflow when the digital pathology area is emerging)
- Risk of jeopardizing the existing "final text" profiles implemented and used in the field.

To mitigate these risks, the planning and technical committees of the merged domain will:

- Clearly define the scope of each new project and tag it with the specialties addressed (e.g.; "surgical pathology", "cytology", "flow cytometry", "chemistry", "molecular", "bacteriology", "anatomic pathology", "laboratory medicine", "all specialties" ...)
- Organize the agendas of virtual and physical meetings of the committees so as to sort the time slots of projects of common scope, and schedule dedicated calls for more specific projects when needed

- Clearly present the schedule of those meetings, with the time window and scope allocated to each project
- Reach out to all potential stakeholders of the AP domain so they can catch the opportunity of the merger to get involved in the newly merged AP & LAB domain.

Merger process steps

As we worked through this merger process, we took and will take the following steps:

- May 19-22, 2015: First combined face to face meeting in Paris.
- Since then, all monthly conference calls are held jointly and discuss common projects
- June 23, the merger was discussed in the Domain Coordination Committee, which provided encouragement and advice to make it a success.
- July 22, the merger proposal was explained during an IHE NA webinar, held jointly by the planning co-chairs of both domains.
- July 31, formal intent to submit the merger proposal to the Board was announced to the Board Chair/IHE Director.
- During summer, the planning co-chairs of AP reach out to AP stakeholders in Europe, Japan and North-America, to get them involved in the future merged domain.
- August 7: This merger proposal is sent to the membership of each domain to request their formal vote (with the voting period ending September 16th).
- Voting is tallied by Secretariat and reported to all co-chairs
- October, Affirmative unanimous results are announced to both domains
- October 1, the proposal to merge is voted on by the IHE Board Operations Committee (BOC).
- November 11, the vote is sent to the IHE Board for approval.
- November/December, if merger affirmed by the Board, the call for profile proposals of the new domain is launched. The co-chairs of both AP and LAB keep their positions until staggered elections are held.
- November /December 2015, begin process of creating new wiki pages and deprecating former IHE AP and IHE Lab wiki pages. Former wiki pages are retained for informational and historical purposes. Both new and former wiki pages have pointers to each other. Other IHE administrative changes are handled by the Secretariat working with IHE staff.
- January 2016: New domain is technically established.

Voting Process:

There have not been any previous mergers of two IHE domains. As a result, we created a merging process and a voting procedure that was approved by the IHE Director. Here are the steps we took to ensure the most accurate voting parameters were followed:

1. Reviewed IHE voting criteria: to vote, a representative must have attended 3 of the last 5 meetings of the domain and cannot have missed more than two meetings in a row.

2. Members: Even though there is now a membership fee, we used the official membership list that is on the IHE website (as of September 2015) to determine if a voting participant belonged to a member organization. We do not know if the member organizations have paid their membership fees so we went strictly by the member organizations listed as official IHE member organizations.
3. Quorum: Our last 3-4 meetings (including the F2F) were joint meetings so it was difficult to know what quorum for each domain really was. Per Chris Carr, we needed four affirmative votes to reach quorum.
4. Final results: Based on all the above criteria of those eligible to vote, we ended up with eight affirmative votes and no negative votes of eligible voters. We did receive on one negative vote; however, that was not an eligible voter based on IHE criteria.
5. As a result of our process, we declared a unanimous vote in favor of the merger.

Definition of the scope of the new PaLM domain

The scope definition below is an outcome of the recent joint face to face meeting of the two domains in Tokyo, October 2015.

The PaLM domain covers:

- the representation and exchange of digital structured data, digital documents, digital images related to ordering, scheduling, performing and reporting diagnostic observations on in-vitro specimens collected from a patient or a non-living subject
- the representation and exchange of digital structured data related to specimen management (preparation, transportation, handoff, etc.)
- the secondary use and exchange of the observation results
- the diagnostic storage and reuse of specimens in bio banks

when a pathology laboratory is involved and in charge of the production of the observation report following diagnostic/prognostic/screening tests, this laboratory having at least one of the specialties listed below.

Specialties of a pathology laboratory:

Anatomic pathology specialties: Surgical Pathology, Autopsy, Cytopathology, Image Cytometry, Immunohistochemistry.

Clinical pathology specialties: Clinical Chemistry, Hematology, Coagulation, Blood Gas, Microbiology (bacterio, parasito, myco, viro), Immunology (allergy, auto-immunity, serology), Transfusion Medicine (blood bank testing), Human Leukocyte Antigens (transplant compatibility testing, Fertility, Assisted Medical Procreation, Cytogenetic (karyotype, molecular cytogenetic), Drug monitoring and toxicology, Flow cytometry

Molecular pathology specialties:

- In oncology: gene mutations in tumor cells

- In microbiology: genetic identification of virus or bacteria
- In genetic: characterizing and diagnosing genetic disease

Summary of Future Plans:

If the Board approves the merger proposal, we will immediately initiate work under the new name and acronym. We have developed a spreadsheet/checklist of all the steps we need to accomplish for a smooth transition from two domains into one. This includes changes on the IHE sponsored web pages as well as internal decisions on the best approach to maintaining consistency in existing profiles.

We expect issues to arise as we begin the practical aspects of merging the two domains and anticipate that the full merger will take a couple of years. As we progress towards one domain, our focus will be on any issues related to the merger that arise as well as the development of new profiles under the PaLM domain name.