Agenda:

Time	Agenda Item
Monday Dec. 15	
09:00 – 09:30	Welcome, roundtable, housekeeping
09:35 – 09:45	Agenda Review
10:00 - 12:00	Production of ILW supplement (F. Macary)
12:00 – 13:00	Lunch
13:30 - 15:30	Production of ILW supplement (F. Macary)
15:30 – 16:00	Break
16:00 - 17:30	Update on Gazelle testing platform project (E. Poiseau)
Tuesday Dec. 16	
09:00 - 10:45	Reporting on IHE LAB connectathons (Japan, Europe, North America) + implementations and projects round world (Japan, Austria, NL, Denmark, Belgium …)
11:00 - 12:00	Newborn screening workflow (F. Macary & M. Marchand)
12:00 – 13:00	Lunch
13:30 – 15:30	Work on simple images in results messages (K. Iguchi)
15:30 – 16:00	Break
17:00 - 18:00	Change Proposals & extensions on LCSD and LBL profiles: Sharing the knowledge on sampling procedures (E. Petit)
	Production of ILW supplement (F. Macary)
evening	Dinner together
Wednesday Dec. 17	
09:00 - 12:00	External Laboratory Order (IHE NL proposal, A. Hamster)
12:00 – 13:00	Lunch
13:10 – 14:20	Decision on NL proposal
14:20 – 14:30	Break
14:30 – 15:30	Scheduling 2009 work for technical committee (All)
15:40 - 16:00	Preparation of next face to face meeting in Kyoto, which will set a planning committee and hold cochairs elections for both committees (Y. Hirasawa, K. Iguchi, K. Bourquard)
16:00 – 17:00	Change proposals work (E. Petit)
17:00	Adjourn

Attendees:

Member	Organization	Country	Mon. 15th	Tues. 16th	Wed. 17th
Karima Bourquard	GMSIH	France	✓		✓
Eric Poiseau	INRIA	France	✓	✓	✓
Filip Migom	MIPS	Belgium	✓	✓	✓
Joost Van Averbeke	MIPS	Belgium	✓	AM	
Jean-Christophe Cauvin	MEDASYS	France		✓	
Emmanuelle Petit	MEDASYS	France		✓	✓
David Escoffier	MEDASYS	France	✓	✓	
Ayman Obeid	MEDASYS	France	✓	✓	
Yoshimi Hirasawa	Techno Medica	Japan	✓	✓	✓
Ken Iguchi	Osaka hospital	Japan	✓	✓	✓
Stefan Sabutsch	JOANNEUM	chair HL7 Austria		✓	✓
Martine Marchand	Paris hospital	France	✓	✓	
Andries Hamster	Forcare	The Netherlands		PM	✓
Ib Johansen	MEDCOM	Denmark	✓	AM	
Margit Rasmussen	MEDCOM	Denmark	✓	AM	
Jean-Christian Hassler	AGFA	France	✓	✓	✓
Ana Estelrich	GIP DMP	France	AM	AM	
Charles Rica	GIP DMP	France	AM	AM	
Charles Parisot	GE	France		PM	✓
Eric Marchand	McKesson	France		✓	
François Macary	GMSIH	France	✓	✓	✓

Details:

1. Agenda review

The agenda was reviewed by the participants and adapted as shown on page 1 of this report.

2. Inter-Laboratory Workflow

(François Macary)

The draft of the future ILW profile was discussed and refined by the group. The revised draft coming out of this process can be downloaded from ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/IHE LAB TF Supplement Inter-Laboratory-Workflow_20081215.doc

The topics discussed during the meeting were:

- This is the first profile from the Laboratory Technical Framework, which deals with an order/results workflow outside of the healthcare enterprise.
    - The messages of this ILW profile shall be close to the messages of the intra enterprise profile (LTW). The message specifications in volume 2 shall express clearly and comprehensively what the differences are.
    - The actor Requester represents the requesting laboratory. We shall consider the possible generalization of this actor to let it represent any ordering healthcare provider placing an order to a community (i.e. non-hospital) identified laboratory.
- The subcontracting laboratory is operated under the responsibility of its director. The results and reports produced are clinically validated (see definition in the LAB TF glossary), and endorsed by the director. However, in some use cases the requesting laboratory may perform a second

clinical validation of the consolidated set of results (observations received together with observations produced locally).

- This profile does not assume that both parties have access to a common patient identity source. Thus the corrections of patient identity are passed from the requester to the subcontractor within order update messages (similarly as in LAB-4 transaction between Order Filler and Automation Manager in the LTW profile). The subcontracting lab manages its patient folders using the patient identity traits (full name, sex, date of birth, address, …) and applying its own business rules.
- The subcontracting process can be iterative and involve more than two laboratories (see figure on page 8 of the draft doc).
- The scope was more precisely delimited with the following items left out of scope:
    - The invoicing process (the profile only provides input to this process)
    - The access by the subcontracting laboratory to the original paper order produced by the physician (this paper order can be attached to the specimen containers)
    - The publication of the reports coming out of this workflow into a document sharing infrastructure (XDS + XD-LAB)
- The various use cases fall within two major categories:
    1. Loose cooperation with a reference lab, on a broad range of tests
    2. Close cooperation between two (private or hospital) labs on a narrow range of tests.

  These two categories were characterized with a set of features shown in table X.2-1, page 9 of the draft. This use case analysis brings three options to the profile:
    - Non coded orders (i.e. test order expressed in plain text)
    - Input for Invoicing (the requesting laboratory provides instructions and information to let the subcontracting laboratory invoice its acts to the proper recipients)
    - Report Fac-simile for Order Group (same option as in transaction LAB-3 of profile LTW)
- Choice of the standard: **HL7 v2.5.1 confirmed as the good choice**. The committee members stated that all related profiles have to leverage a coherent set of standards and versions so that a system playing actors in several profiles of the LAB TF may rely on one single version of the standard for messaging. The other arguments are stressed on page 20 of the draft document.
- Choice of the transport protocol: 4 protocols have been considered

	Synchronous response	**Secure**	**Tools availability**	**Weak point**
Secured email	No	Yes s-mime, esmtp	Widely available	Email is not designed for workflows. Issues of spam blocking
MLLP	Yes	Yes (with ATNA)	API available for java and MS .Net	No possible attachment of an external file, such as the pdf report
Sftp	Not natively	Yes Native	Widely available	Synchronous acknowledgement needs a workaround
web service	Yes	Yes Native	Widely available	IHE has not used web services to carry HL7 v2 messages, so far

As a result of the discussion email and sftp were excluded. The debate went further on between MLLP and web services.

IHE ITI follows the rule of using MLLP transport for all transactions based on HL7 v2 messages, and using web services for all transactions based on HL7 v3 messages, following the guidelines expressed in appendix V of ITI TF-2.

IHE LAB is considering another possible rule: Using MLLP for all intra-institution transactions (e.g. LTW profile), and using web services for all external transactions (e.g. ILW profile).

The choice of the transport remains an open issue in the draft document. MLLP appears more straightforward in that it does not require more specifications than those already applying to the existing profiles of LAB TF. The use of web services will require as pre-requisite the definition of the mapping between the HL7 v2 envelop (MSH, MSA, ERR) and the web service definition.

- **Next steps:**
  - From now on, the main editor of the ILW draft supplement is Jean-Christian Hassler (Agfa Healthcare) ; associated editors are Jan Dols (Academic Medical Center of Amsterdam), Filip Migom (MIPS)
  - François requests Ib Johansen to recruit some Danish stakeholders for this project
  - Conf call in February to have an intermediate milestone
  - Complement the transactions detailed specifications, based on the same message structures as in LTW profile, focusing only on the differences.
  - Complement the "Common segments" section similarly.
  - Having read ITI TF-2:Appendix V, propose a well-argued choice for the transport (MLLP / web service)
  - Build an example for section "Real world examples"

3. Gazelle platform

(Eric Poiseau).

Slides available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/Tools-Connectathon_Gazelle.pdf

Key points:

- Gazelle is an international cooperation between IHE Europe, IHE North America and IHE Japan
- Gazelle is an open source, java, web based platform, to replace Kudu and Mesa Tools
- External Validation Services (EVS) are available for validation of HL7 messages, DICOM objects, CDA documents.
- The test engine and its API are still under development

4. Newborn screening

(Anna Orlova, François Macary, Martine Marchand, Filip Migom)

- **US use case** (downloadable from http://www.hhs.gov/healthit/usecases/nbs.html)

  The brief profile proposal written by Anna Orlova is available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/IHE_Brief_Profile_Proposal_Newborn_Screening_11-21-08.doc

  This document is a proposal to leverage existing IHE profiles (from ITI, LAB, PCC), and if needed to build extensions or new profiles, in order to support a better integration of the systems involved in this newborn screening use case.

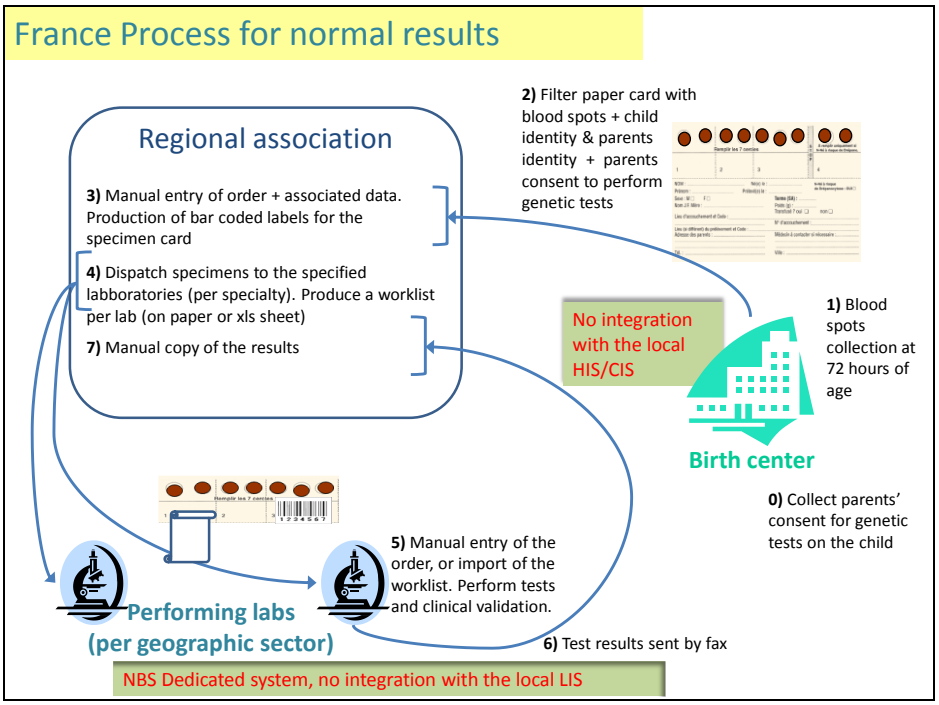
  Main characteristics of the newborn screening program in the US:

  - Newborn screening is mandatory and systematized, administered by state health departments
  - Blood spots collected from newborn at 24-48 hours of child's age by nurse at birthing center, on a state specified specimen filter card providing also the demographics. Tests screening for metabolic genetic and hematologic disorders performed by state public health inner lab or outsourced to commercial lab.
  - Hearing screening performed by birthing center staff to identify permanent conductive, sensory or neural hearing loss using physiologic testing technologies.
  - Organizations and human actors
    - Birthing center: ordering clinician, nurse, audiology service…
    - Public health institution
    - Testing laboratory (public health or commercial)
    - Newborn and parents or guardian or other responsible party for the infant
    - Pediatric clinician or primary care provider of the infant
    - Specialist physician involved in the follow-up treatment of a confirmed case
  - Systems involved:
    1. Hospital of Birth (EHR or ADT system)
    2. Public Health or commercial laboratory systems (LIS)
    3. Public Health blood spot screening & tracking systems including registries on particular conditions, e.g. sickle cell anemia
    4. Public Health hearing screening systems
    5. Primary Care Provider (Pediatrician) EHR
    6. Specialists EHR
  - Level of integration between these systems: minimal.
  - Issues to be solved with better integration:
    - Incomplete and inaccurate data, due to manual data collection and transcription
    - Challenges in follow-up of abnormal results (difficulty to track the newborn)
    - Delay in services and insufficient coordination due to lack of information of the primary care provider.
  - Activities in the US to support this use case:
    - The federal Healthcare IT Standards Panel (HITSP) will work on this use case in 2009.
    - Effort funded by HRSA to develop an HL7 2.5 implementation guide for NBS lab reporting. The draft guide will be developed by the Public Health Informatics Institute.

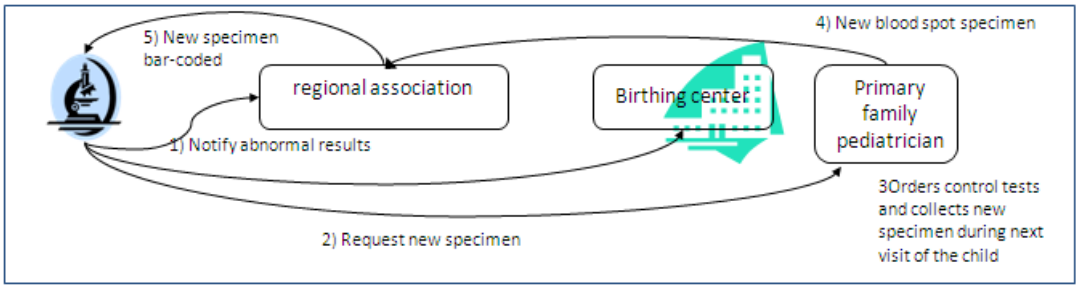
- **Germany use case** (snapshot collected by Filip Migom)
    - Blood spot screening applied to 99% of newborns in Germany.
    - Consent from the parents or guardian like in US and France, but on a flyer distinct from the specimen card
    - 10 performing labs: 3 commercial labs (Munich, Weiden, Hannover), 7 university hospital labs.
    - Privacy requirement for the LIS: Need to mask the identity of the screened patient to most staff of the testing lab
    - Newborn identified with the birth book number from the birthing center
    - Workflow is apparently simpler: Results sent back to the ordering organization, no difference for abnormal results.
- **Austria use case** (snapshot collected by Filip Migom)
    - Various formats of specimen filter cards (some of which formatted for OCR / OMR recognition) providing:
        - A predefined unique number
        - 4, 5 or 6 blood spots depending of the specific card format
        - Newborn and parents demographics
        - Issuing birthing center
        - Additional clinical data (birth weight, blood transfusion, premature, multiple birth, known issues, date&time of specimen collection).
- **France use case** (main source: Martine Marchand, François Macary)
    - Newborn screening is mandatory and systematized, administered by a national non-profit organization: "L'association Française pour le Dépistage et la Prévention des Handicaps de l'Enfant" (http://www.afdphe.asso.fr/). The screening is organized by region (22 regions). Each regional affiliate association plays a role equivalent to the role played by the state health department in the US : Central point for specimen filter cards and lab test results, administration, tracking, follow-up, education…
    - Blood spots collected from newborn at 72 hours of age by nurse at birthing center, on a national specified specimen filter card providing:
        - 7 blood spots (9 in case of born risk of sickle cell anemia)
        - Demographics of newborn and parents, + address and telephone
        - Parents' consent for genetic testing
        - Issuing birthing center (name & code) + birth book number
        - Additional clinical data (birth weight, blood transfusion, premature, risk of sickle cell anemia, date&time of specimen collection).
    - Tests screening for genetic and hematologic disorders distributed to university hospital labs on a predefined geographic basis. 5 analytes tested:

Analyte	Affection	Incidence
TSH	Congenital Hypothyroidism	1 / 3500
17-hydroxy progesterone	adrenal hyperplasia	1 / 14000
TIR	Mucoviscidose cystic fibrosis	1 / 4000
Phenylalanine	Phenylketonuria	1 / 17000
Hemoglobine S	Sickle cell anemia	Depending on population

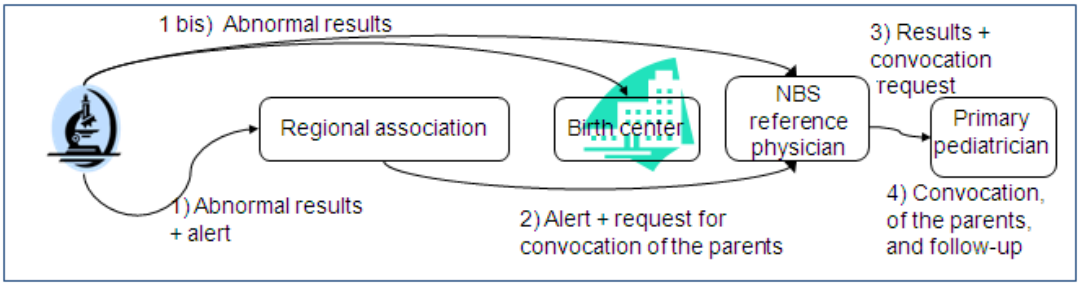
- Organizational actors:
  - Birthing center: responsible clinician, nurse, medical secretary …
  - Regional affiliate of the newborn screening association
  - Testing laboratory (usually in university hospital)
  - "Reference physician": one per NBS pathology and per geographic sector.
  - Pediatric clinician or primary care provider of the infant
  - Specialist physician involved in the follow-up treatment of a confirmed case
- Systems involved: The same as in the US.
- Integration level: Similarly poor if not poorer.
- Normal results workflow:



- Doubtful results workflow:



- Abnormal results workflow:



- Issues to be solved with better integration:
  - The same as in the US.
  - Difficulty to track back the newborn in case of abnormal results: No national identifier for the newborn, sometimes missing first name (not chosen yet), sometimes wrong last name (from the mother, later on changed to the father's name)
- Current activity to improve integration: unknown at this point in time.

- **Temporary synthesis**

  The newborn screening workflows in these countries show some similarities:

  - Newborn screening is the first interaction in the life course of most of us that involves information exchanges between clinical care and public health.
  - Low level of integration, if any, between the systems of the involved organizations (birthing center, central public health, performing labs, primary care pediatricians).

  For what regards IHE LAB:

  - The ordering of a screening test panel narrow and rather fixed in Europe use cases, richer and apparently more flexible in US use case
  - An associated specimen card with a number of blood spots and a unique identifier, and demographics and relevant clinical data.
  - In Europe, the specimen card is the order in itself, with the fixed panel.
  - In the US, a paper order requisition accompanies the specimen card and specifies which tests to perform. Results of hearing screening often accompany the order and specimen.
  - The collection of the parents consent for genetic screening. In France it is collected on the verso of the specimen card.
  - At least in US and France, a central actor collecting the specimens, consents, orders, collecting the results and tracking follow-up for a geographic area (state in the US, region in France).
  - An **assigned** laboratory to perform the tests (possibly a part of the panel, depending on the specialty required). This is another use case of "external lab ordering", in which the performing lab is not chosen by the patient, but rather by the central public health organization.
  - In some cases (doutbtful results, time of first screening, abnormal results) a confirmatory test order, with a new specimen card.
  - The need to reach the primary care physician (pediatrician) for follow-up when abnormal results and a confirmed case.

- **Next steps**

  - Find out whether there is or not a central actor in Germany and Austria, like there is in the US and France. (→ Filip Migom, Stefan Sabutsch)
  - Assess stakeholders' will for a better integration of NBS in France. (→ François Macary, Martine Marchand)
  - Produce a white paper synthesizing the proposals of improvements to these use cases, that could come from a new or existing IHE LAB profile, potentially in combination with existing profiles from this domain and other domains. (→ Anna Orlova, Lori Fourquet, Terese Finitzo, François Macary)

5. Simple images in results messages

(Ken Iguchi)

Slides available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/IHE Simple images in results messages.pdf

- **Key points:**
  - Two categories: simple images (photos taken by analyzers, microscopes or photo device), and graphs (produced by analyzers and workstations)
  - Some images and graphs should appear in the results & report sent to the ordering care provider and other recipients. Some others are of interest only to the biomedical scientists in the laboratory.
  - The need is to upload the images and graphs from analyzer or device to LAS using transaction LAB-23, to carry them from LAS to LIS using transaction LAB-4. Fianally, the images of interest to the ordering physician (e.g. electrophoresis graph, hematology disease picture …) should be able to be transferred from LIS to HIS/CIS, using transaction LAB-3.
  - The choice is to describe this feature as an additional option on transactions LAB-23, LAB-5 and LAB-3.
  - Simple images and graphs will be exchanged in simple file formats (jpg, bmp, png …) referenced by an OBX of type "RP", and retrieved synchronously by the recipient of the results message.
- **Next steps**

Produce the supplement document bringing a new option "**Graphs & Images in Laboratory Results**" **(GIR)** to the profiles LDA and LTW (Editor to be appointed by IHE LAB Japan)

6. Reporting on connectathons

(Eric Poiseau, Yoshimi Hirasawa)

Slides from Yoshimi Hirasawa on Japan connectathon available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/IHE Japan Lab Implementation.ppt

Lab profiles tested at Europe connectathon 2008:

Profile	Actor	Systems
LDA	Automation Manager	1
	Devices	0
LTW	Order Placer	2
	Order Result Tracker	1
	Order Filler	3
	Automation Manager	1
LPOCT	Order Filler	1
	Point Of Care Data Manager	3
	Point Of Care Results Generator	1

Lab profiles tested at North America connectathon 2008:

Profile	Actor	Systems
XD-LAB	Content Consumer	many
	Content Creator	2

Lab profiles tested at Japan connectathon 2008 (by 11 system vendors):

Profile	Actor	Systems
LDA	Automation Manager	4
	Devices	4
LTW	Order Placer	8
	Order Result Tracker	8
	Order Filler	6
	Automation Manager	4
LPOCT	Order Filler	2
	POCDM	1
	POCRG	0
LBL	Label Information Provider	5
	Label Broker	1

Key points:

- The level of participation on Lab domain is low in Europe and North-America, compared to what it is in Japan. We need to enhance our communication to the system vendors of this domain.
- Monthly IHE Japan face to face meetings

The committee decides to allow implementers to test LTW profile without ATNA profiles, in other words **the dependency from LTW to ATNA is not mandatory for connectathons**.

7. Lab projects/implementations in various countries

Austria

(Stefan Sabutsch)

Slides available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/20081216_ELGA_Lab.pdf

Key points:

- ELGA is the Austrian national PHR, leveraging a master patient index associated with a patient smart card, as well as a healthcare provider index associated with a professional smart card.
- ELGA uses a national registry handling decentralized documents repositories (based on XDS).
- First documents to be shared are discharge summary, Lab e-report, Radiology e-report, and e-medication.
- The lab e-report will likely leverage XD-LAB content profile. To that purpose, IHE Austria will build a national extension of that content profile, taking into account all Austrian requirements. Once balloted and approved by IHE Austria this national extension shall be appended to the IHE Laboratory Technical Framework, as part of volume 5.

Denmark

(Ib Johansen)

The url of the slides will be notified soon on the LAB listserv.

8. Change Proposals process

(Emmanuelle Petit)

- CP 140: OM1-31 field for clinical observations (e.g. patient temperature) associated with an ordered test or panel. **Finalized and approved**. **To be published** → François Macary
- CP 141: XD-LAB and telecom format (Sondra). The origin of the format is unclear. **More input expected from Sondra Renly**.
- CP 142: Comment on Order Group: Proposal **to be finalized** to resolve ambiguity between a patient related comment and an Order Group related comment →Ayman Obeid
- CP 143: Volume 1 – make dependency from LTW to ATNA optional, as it has always been considered at all connectathons so far. **Approved. To be published** → François Macary
- CP 144: Sharing the knowledge on specimen collection (type of containers needed, barcode labels). **To be finalized**. The choice is to group LTW with LBL profile for that purpose. Add a use case in Volume 1(LTW): order placer grouped with label broker and order filler with label information provider → Jean-Christophe Cauvin and Emmanuelle Petit
- CP 145: Tuberculosis culture with successive reports: We do not understand the need to carry all these successive observations in one message. Please explain better the problem. **To be finalized**. → Shigeo Hasegawa
- CP 146: OBR-13 & OBR-31: Need to be studied closely. → **Question** by François Macary to be posted to Shigeo Hasegawa, Nobuyuki Edo and Mayu Nagao with mailing list in copy
- Kudu test on microbiology: Don't mandate this test to a system which does not support microbiology (e.g. a system designed for chemistry only). Not really a change proposal. **Accepted**. → Eric Poiseau will updated KUDU test plan accordingly.

9. External Lab Orders

(Andries Hamster)

Presentation

Work item document available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/External Lab Orders Profile Proposal_final.doc

Summary slides available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/IHE Netherlands - Lab working group.pdf

Key points

- 4 organizational actors: The patient, the ordering healthcare provider, the specimen collection center, the performing laboratory.
- The ordering physician is assumed to have no prior knowledge which lab will perform the tests. The patient is free to choose the specimen collection center.
- Notes taken during the presentation.
    - External Lab Order Profile should be a content profile.
    - Create Whitepaper describing dataflow versus workflow. Whitepaper used for international review of use-cases.
    - Take LTW profile into account: how to start internal Lab workflow based on the external order? Include a mapping to an HL7 lab order message, in an appendix of lab TF vol 3.
    - Create a "task force" to work on the content part.

- BSN = Dutch Unique Patient Identifier. UZI-pas = e-card holding digital identity of care professional.
- IHE LAB NL discussions:
    - The order is an electronic document (CDA) owned by the ordering physician.
    - The specimen collection report is a document owned by the phlebotomist, appended to the order document (metadata) and in fulfillment of it (CDA header).
    - The laboratory report is also an electronic document (CDA in content profile XD-LAB) produced in fulfillment of the order document.
- Discussion with Vassil Peytchev available here: ftp://ftp.ihe.net/Laboratory/Face to face meetings/Paris_December_2008/External_Lab_order_comments_vassil_AH.doc

Decision

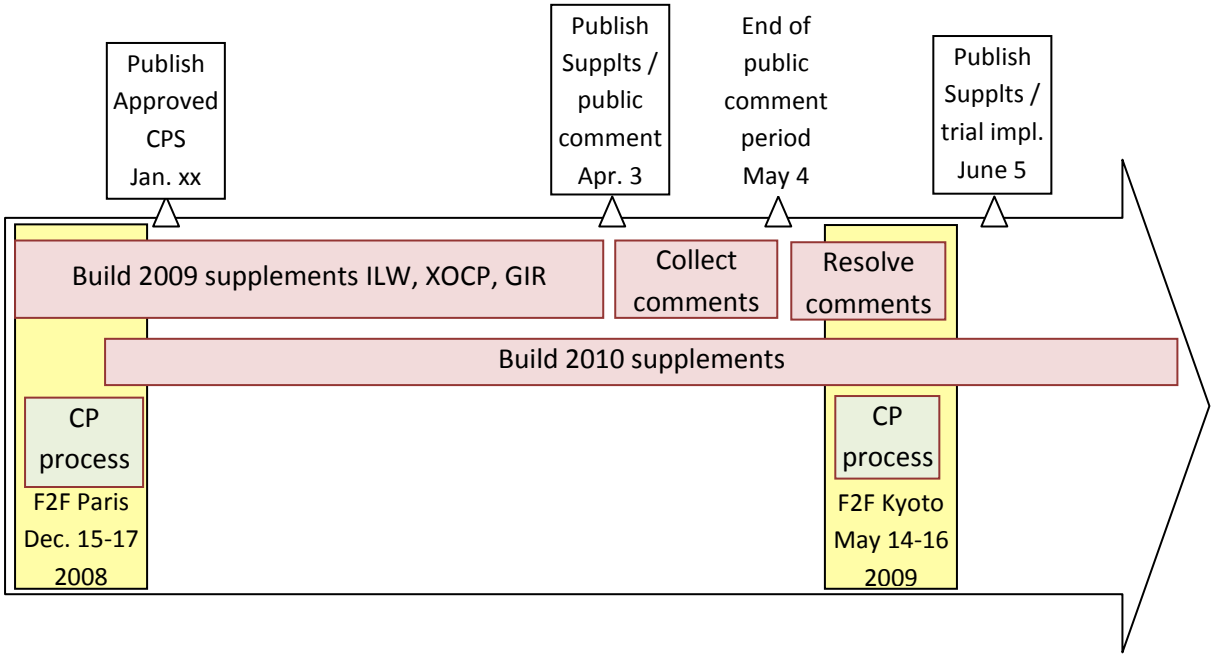
- The IHE LAB international committee decides to adopt the project of a new content profile describing a lab order as a CDA document. The persistency of the order in a registry/repository is needed at least for liability and auditability purposes. This content profile shall be a 2009 supplement to the LAB TF.
- A mapping with HL7v2 messages will complement the profile.
- The usage of this content in the ordering/sampling/reporting workflow will be defined in a separate white paper.

Next steps

- Andries Hamster produces 1st draft of white paper (usage of content in the workflow) in January.
- External Lab Order content profile (XOCP) including mapping with LAB-1 v2.5.1 order message, produced by a task force composed of Andries Hamster, Alexander Henket, François Macary, Filip Migom, someone from Sweden?
- Ftf meeting of the task force end-January, then meetings or conf call once a month.

10. Scheduling work of Technical Committee

The schedule will be updated on this page: http://wiki.ihe.net/index.php?title=Laboratory



11. Lab Domain organization

(Karima Bourquard)

A presentation of the organization of an IHE domain is made, in consistency with the IHE International governance. In each domain, two committees are defined:

- A planning committee whose role is to define the needs and priorities and to select the profiles to be specified on a new yearly cycle.
- A technical committee whose role is to assess the difficulties and workload of each new candidate profiles, then to specify the selected profiles.

Each committee has two cochairs.

Since its birth in 2003 the laboratory domain has had one single committee merging the two functions (planning & technical). The two current cochairs of this committee are François Macary (GMSIH) and Nobuyuki Chiba (A&T).

In January, Karima will send an announcement for a call of candidates for the two committees. The candidates have to send to Karima their candidature with a CV joined.

The list of candidates will be published in March-April.

The election of the cochairs of the two committees will take place during the next face to face meeting in Kyoto, May 14-16, 2009.