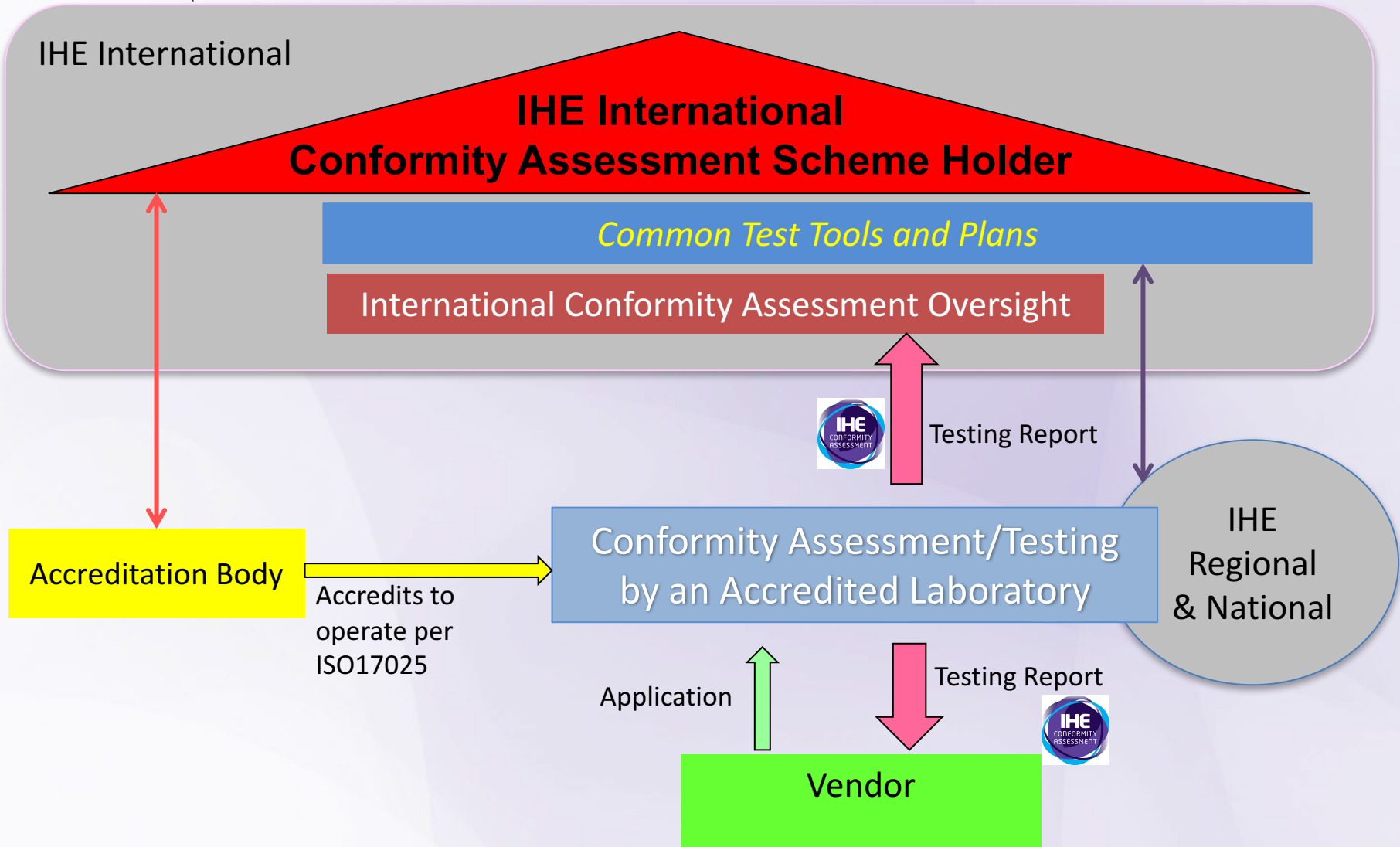# IHE Conformity assessment

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IHE Services Director

Why Conformity Assessment?

- **Widespread adoption of IHE Profiles** by national, regional and hospital eHealth projects

- Many ehealth projects explicitly leverage Connectathon results in their product **tenders/acquisition**.

- Projects report **un-even compliance** to IHE profiles across products and discrepancies between commercial products IHE features and vendor Connectathon results

- Increasing number of national/regional ehealth projects **establish their own conformity testing**. Expected for project specific extensions, but <u>duplicative for IHE profile conformity</u>.

→ Vendor and ehealth projects interested **to avoid duplicative testing of generic IHE Profile conformity**

- Focus on **Testing** (not certification)
  ➔ deliver a trusted *Test Report*

- Enable countries/projects **to require and recognize** these *Test Reports* and perform any additional project specific testing (they may also add a certification process on top of the testing process).

- Ensure **international equivalency** of *Test Reports* and recognition of these *Test Reports* for their trustworthiness:
  - A **single process** ➔ conformity assessment **scheme** (IHE-CAS)
  - The **same test tooling** ➔ provided by IHE International
  - *Test Reports* published ➔ by IHE International

- **Multiple testing laboratories** across the world accredited and authorized by IHE International (competition & convenience)

Concepts of IHE Conformity Assessment

IHE International

**IHE International
Conformity Assessment Scheme Holder**

Common Test Tools and Plans

International Conformity Assessment Oversight

Testing Report

Conformity Assessment/Testing by an Accredited Laboratory

Accreditation Body

Accredits to operate per ISO17025

IHE Regional & National

Application

Testing Report

Vendor

International Consistency, Local Testing laboratories, Trust and Rigor.

Conformity Assessment and Connectathon

Dimensions	IHE Connectathon	IHE Profile Conformity Assessment
Participants	Vendors & Open Source	Vendors & Open Source
Specific Product name and version	No (Vendor self-attestation through Integration Statement)	**Yes**
Testing Profiles (Technical Framework)	Trial Implementation and Final text	**Only Selected Final Text Profiles**
Collaborative and Learning	Yes	**No**
Pre-requisite	None – Only to pass pre-Connectathon tests	Vendor has successfully passed profile tests at an IHE Connectathon
Commitment to commercial availability	No – Pre-product testing OK	**Yes**
Guarantee Interoperability of tested products	No – Reasonable expectation	No – But Clearer expectation for specific product version
Staffing of oversight/jury	Monitored by volunteers	**Monitored by professional staff**
Results	Pass Results published for vendor by IHE	**Test Report published/attested by accredited testing laboratory**

Conformity Assessment, a value-add to Connectathon, not a replacement

The central role of the Gazelle Platform

A shared test platform: Connectathon, Conformity, and ehealth Projects

IHE | Integrating the Healthcare Enterprise

eHealth Projects

Interoperability Specifications

Product

Projectathon

Project Conformity Assessment

Test Report

Profiles

Product

IHE Conformity Assessment

IHE Connectathon

Standards

IHE Gazelle Test Platform

Add project extensions

Enhancing testing rigor and reducing costs and risks on an on-going basis

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IHE | Integrating the Healthcare Enterprise
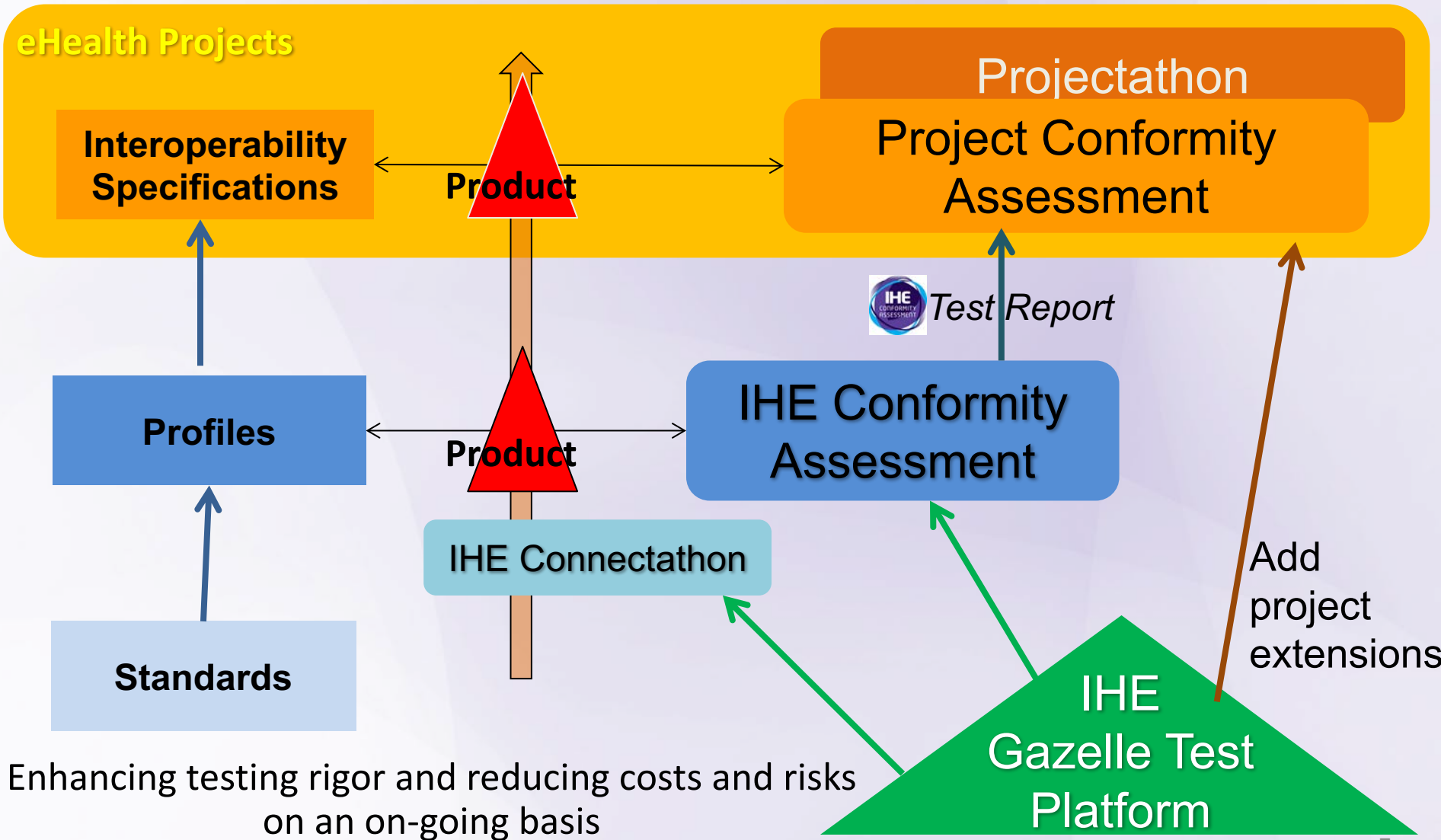
1. The <u>larger eHealth Projects</u> (national, regional, hospital network) that want to engage a broad number of vendors to supply products with IHE profile conformance. Use IHE Conformity Assessment as an entry criteria into procurement and project level lab testing (Projectathon).

2. The care delivery organization (e.g. Hospital/Clinic) with <u>simple interoperability projects</u> (e.g. connecting devices to a Clinical System). Only a few profiles to be combined.

3. <u>Vendors</u> that want to avoid the overhead of retesting in each project at the profile level.

➜ **A Buyer/Vendor win-win !**

Conformity Assessment Deployment

Operational since April 2015:

- IHE International Board Approved Conformity Assessment Scheme (IHE-CAS-vol. 1) in May 2014.

- Kereval (IHE-Europe) and ICSA Labs (IHE-USA) Authorized.

- Initial Set of Profiles selected by IHE-Europe, IHE-USA and IHE Japan in September 2014: **CT, ATNA, PDQ, PDQV3, PIX, XDS**.

- Expanded with additional profiles in April 2016: **XCA, XCPD, DEC, PIV, PIXV3, LAW, PAM**

- 7 vendor products have passed conformity assessment:
  - Lexmark Healthcare   Lexmark Healthcare
  - Tiani "Spirit"   Qvera LLC
  - GE Healthcare   Forcare B.V.
  - A-thon Srl

IHE Profiles included in 2017 CAS

* Profiles offered for Conformity Assessment from **May 2016**
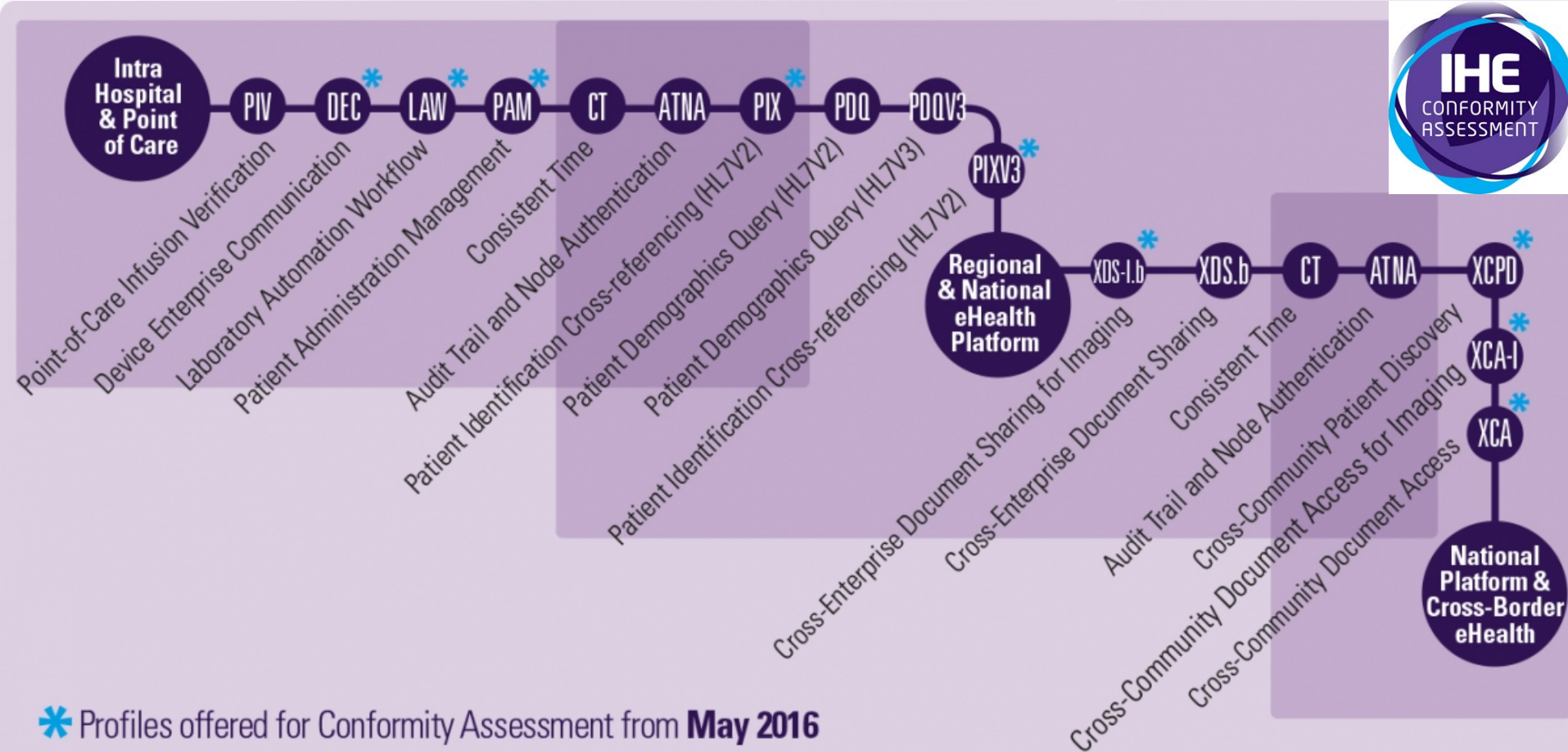
IHE CAS and IHE profiles proposed by EU for procurement

IHE — Integrating the Healthcare Enterprise

XCPD	XCF	XCA
XDR	XDM	XDS.b
CT	ATNA	PIX
PDQ	PAM	BPPC
SVS	XUA	PRE
DIS	XPHR	MS
XD LAB	SWF	PIR
XDS-I.b	SWF.b	LTW
LCSD	LAW	XD-SD

27 IHE Profiles Endorsed by The European Commission

IHE EUROPE — Integrating the Healthcare Enterprise

Information Sharing Infrastructures and Security/Privacy

Cross-Community Patient Discovery (XCPD)
Locates communities with health records of a patient and translates identifiers across communities.

Cross-Community Access (XCA)
Queries and retrieves patient electronic health records held by other communities.

Cross-Community Fetch (XCF)
Fetches a small pre-negotiated list of documents from another community.

Cross-Enterprise Document Reliable Interchange (XDR)
Exchanges point-to-point health documents between health enterprises using a web-service.

Cross-Enterprise Document Sharing (XDS.b)
Shares and discovers electronic health record documents between healthcare organisations.

Cross-Enterprise Document Media Interchange (XDM)
Transfers documents and metadata using USB memory, or email attachments.

Sharing Value Sets (SVS)
Distributes centrally-managed common, uniform nomenclatures.

Basic Patient Privacy Consents (BPPC)
Records a patient's privacy consent acknowledgment to be used for enforcing basic privacy appropriate to the use.

Cross-Enterprise User Assertion (XUA)
Communicates claims about the identity of an authenticated user, across enterprise boundaries - Federated Identity.

Health Information Content

Pharmacy Prescription
Cross-Enterprise Sharing of Medical Summaries (XDS-MS)(PRE)
Records a prescription of medicinal products to a patient.

Pharmacy Dispense (DIS)
Records the dispensing of medications to a patient.

Exchange of Personal Health Record Content (XPHR)
Describes the content and format of patient summary information extracted to/from a PHR or an EHR system.

Cross-Enterprise Sharing of Medical Summaries (XDS-MS)
Describes the content and format of Discharge Summaries and Referral Notes.

Cross-Enterprise Document Sharing for Imaging (XDS-I.b)
Extends XDS to share images and diagnostic reports across a group of care sites.

Laboratory Reports (XD*-LAB)
Describes the content (human and machine readable) of an electronic clinical laboratory report.

Cross-Enterprise Sharing of Scanned Documents (XDS-SD)
Enables electronic records to be made from legacy paper and other unstructured electronic documents.

Basic Patient Identification

Patient Identifier Cross-Referencing (PIX)
Lets applications query for patient identity cross-references between hospitals, sites, health information exchange networks, etc.

Patient Demographics Query (PDQ)
Lets applications query by patient demographics for patient identity from a central patient information server.

Basic Security

Audit Trail and Node Authentication (ATNA)
Basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications.

Consistent Time (CT)
Enables system clocks and time stamps in a network to be synchronised.

Hospital-Wide Patient Management

Patient Administration Management (PAM)
Establishes the continuity and integrity of patient data in and across acute care settings, as well as amongst ambulatory caregivers.

Radiology Scheduled Workflow (SWF.b)
Introduced as a variant of the SWF Profile. It mandates HL7 V2.5.1 for HL7 based transactions and incorporates the transactions of the Patient Information Reconciliation (PIR) Profile.

Departmental Workflows

Radiology Scheduled Workflow (SWF)
Integrates ordering, scheduling, imaging acquisition, storage and viewing for radiology exams.

Patient Information Reconciliation (PIR)
Complements SWF.

Laboratory Testing Workflow (LTW)
Integrates ordering and performance of in-vitro diagnostic tests by a clinical laboratory inside a healthcare institution.

Laboratory Code Sets Distribution (LCSD)
Distributes managed sets of clinical laboratory codes (battery, test and observation codes).

Laboratory Analytical Workflow (LAW)
Supports the workflow of test orders and results with InVitroDiagnosis specimens on laboratory analysers.

National and Regional Deployment

Hospital Workflows

IHE COMMUNITY ASSESSMENT

● Profiles under IHE International Conformity Assessment Programme

Some References

- For general information:

    http:// www.ihe.net/Conformity-Assessment

    - IHE-CAS-1 defines the necessary processes
    - IHE-CAS-2 defines the standardized test methods for each IHE Profile

- For Test Reports:

    http://conformity.ihe.net

- Contact us and Fill the application form, Email us at:

    conformityassessment@ihe-europe.net

Vendor has passed IHE Connectathon for IHE Profiles

Vendor applies for IHE Conformity Assessment testing for specific IHE Profiles

Accredited laboratories tests each product for Conformity

Conformity Assessment Test Report Issued to vendor and published on IHE.net

Thank you for your attention!

Questions?