IPE Event – Leiden
Block 2: IHE Closer observations

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Agenda

- IHE Pillar 1: Profiling
  - Detailed explanation of a profile
    - Structure of the document
    - What are the most important parts
  - How a profile is created
    - Which persons are needed and how are they collaborating
    - What are the cycles
    - Further development, maintenance, versioning
- IHE Pillar 2: Testing
  - Details on Connectathon, Projectathon, Conformity Assessment

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Technical Framework

- A **Technical Framework** summarizes profiles in “Final Text” status

- Consists of a maximum of 4 volumes
  - Volume 1: Integration Profiles
  - Volume 2: Transactions
  - Volume 3: Cross-Transaction and Content-Specifications
  - Volume 4: National Extensions

Structure of a TF: Volume 1

- **Volume 1: Integration Profiles**
  - „for the user“
  - Chapter 1
    - Introduction
  - Chapter 2
    - Brief description of all profiles included
    - Dependencies of the profiles on other profiles
  - Chapter n: Detailed descriptions of the profiles
    - Actor/Transaction description
    - Options
    - Process Flow
      - Description of at least one use-case
    - Security Considerations

Structure of a TF: Volume 2

- **Volume 2: Transactions**
  - „for the developer“
  - Chapter 3
    - Description of each transaction defined in the profiles
      - Scope
      - Use case roles
      - Referenced standard
      - Interaction diagram
    - For each transaction, the transaction number is also the number of the subchapter
      - z.B. Transaction ITI-18 is described in chapter 3.18

Structure of a TF: Volume 3

- **Volume 3: Cross-Transaction and Content-Specifications**
  - „for the developer“
  - Chapter 4: Cross-Transaction Specifications
    - Specifications that apply to multiple transactions
  - Chapter 5: Content-Specifications
    - Transactions should not contain "content“
    - This chapter contains content specifications that are referenced in the transactions

Structure of a TF: Volume 4

- **Volume 4: National Extensions**
  - „for the developer“
  - Includes national extensions to the profiles
  - Usually encouraged by National Deployment Committees

Close look

Let‘s look into a Technical Framework

Profile

- **A „profile“ is the fundamental concept in IHE**
  - … it resolves a very particular interoperability use-case of the user
  - … it uses a mechanism to resolve the problem (= IHE methodology)
  - … but is yet flexible and allows project-specific specialities
  - … it may have dependencies or may be grouped to other profiles
  - … shall be seen as „sellable unit“
    - *„if software is installed on different systems based on the same IHE profile, there should be some basic interoperability “*

Profile

- **A profile consists of chapters which will later be added to the Technical Framework:**
  - Short description of the profile
  - Dependencies to other profiles
  - Detailed description of the profile
    - Actor/Transaction description
      - Options
      - Process Flow
        - Description of at least one use-case
      - Security Considerations
  - Description of each transaction defined in the profile
    - Scope
      - Use case roles
      - Referenced standard
      - Interaction diagram

- **Types of profiles**
  - Integration profile
  - Content profile

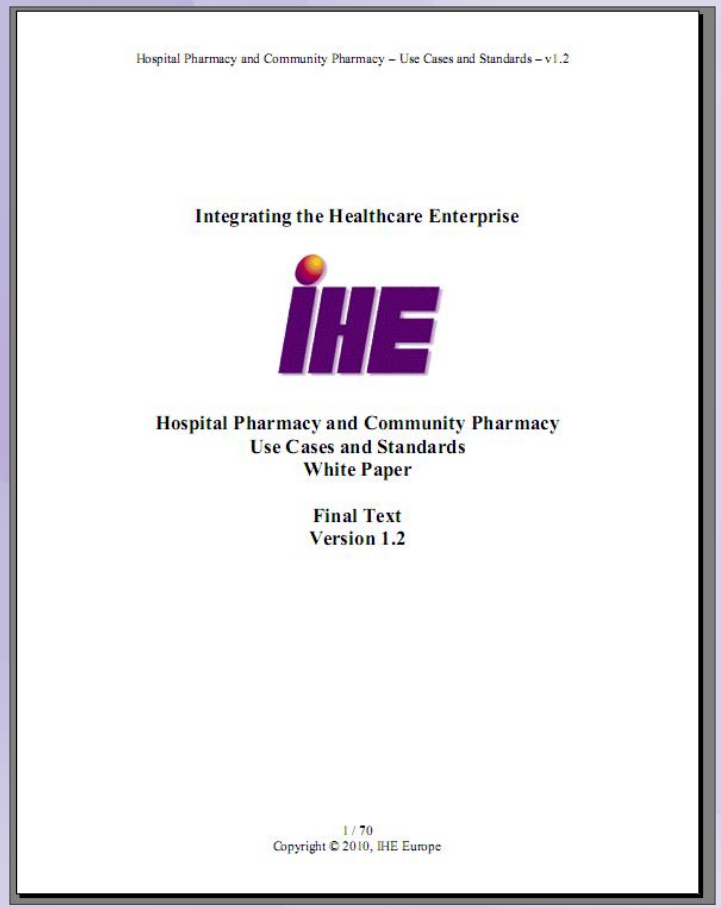
Profile in detail

As demonstration,
let‘s view the profiles of …

IHE Pharmacy

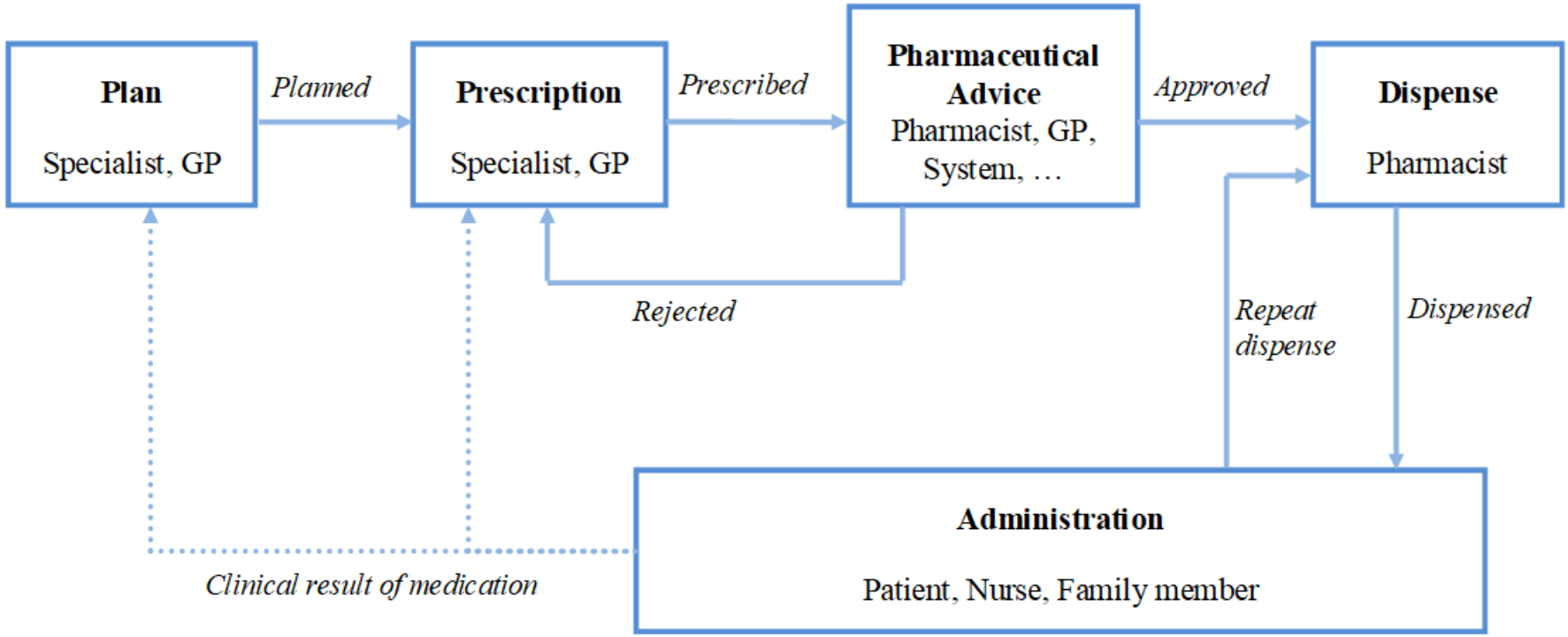
The White Paper

- IHE White Paper
  - Foundation of all current profiles
- Final version
  - Released in early 2010
- 78 pages
  - Community Pharmacy use cases
  - Hospital Pharmacy use cases
  - Harmonization of actors definitions



Current version:
ftp://ftp.ihe.net/Pharmacy/White%20Paper/IHE_Eur_Pharmacy_White_Paper_Final_Text_1.3.3.pdf

IHE Pharmacy – Key process



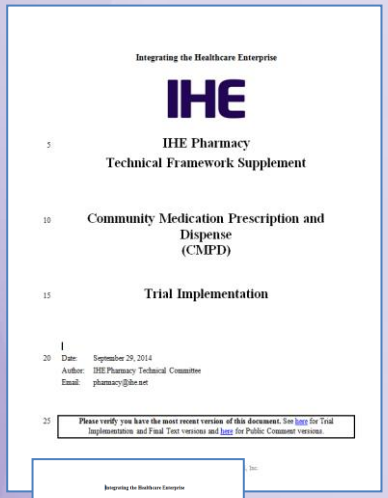
Community Pharmacy profiles

Workflow

- **Community Medication Prescription and Dispense (CMPD)**
  - Technical Integration, Actors, Transactions, based on IHE ITI XDS

Content (based on HL7v3 CDA extended with HL7 Medication CMETs)

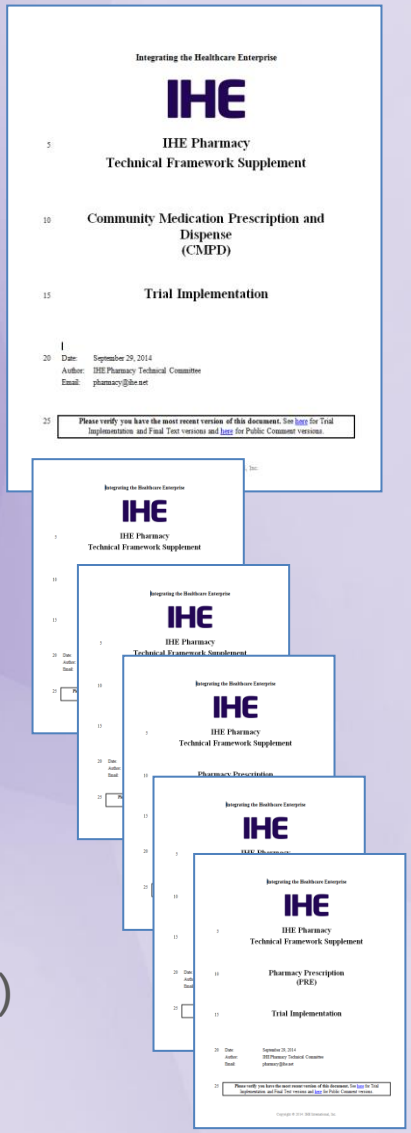
- **Community Prescription (PRE)**
  - Information on prescribed medication of a patient
  - In sync with upcoming ISO DTS 17523 “Requirements for electronic prescriptions” and ePrescription guideline of the EU / eHGI
- **Community Dispense (DIS)**
  - Information on dispensed medication of a patient
  - In sync with upcoming ISO DTS 19293 “Requirements for the record of Dispense Medicinal Products”
- **Community Medication Administration (CMA)**
  - Information on administered medication on a patient



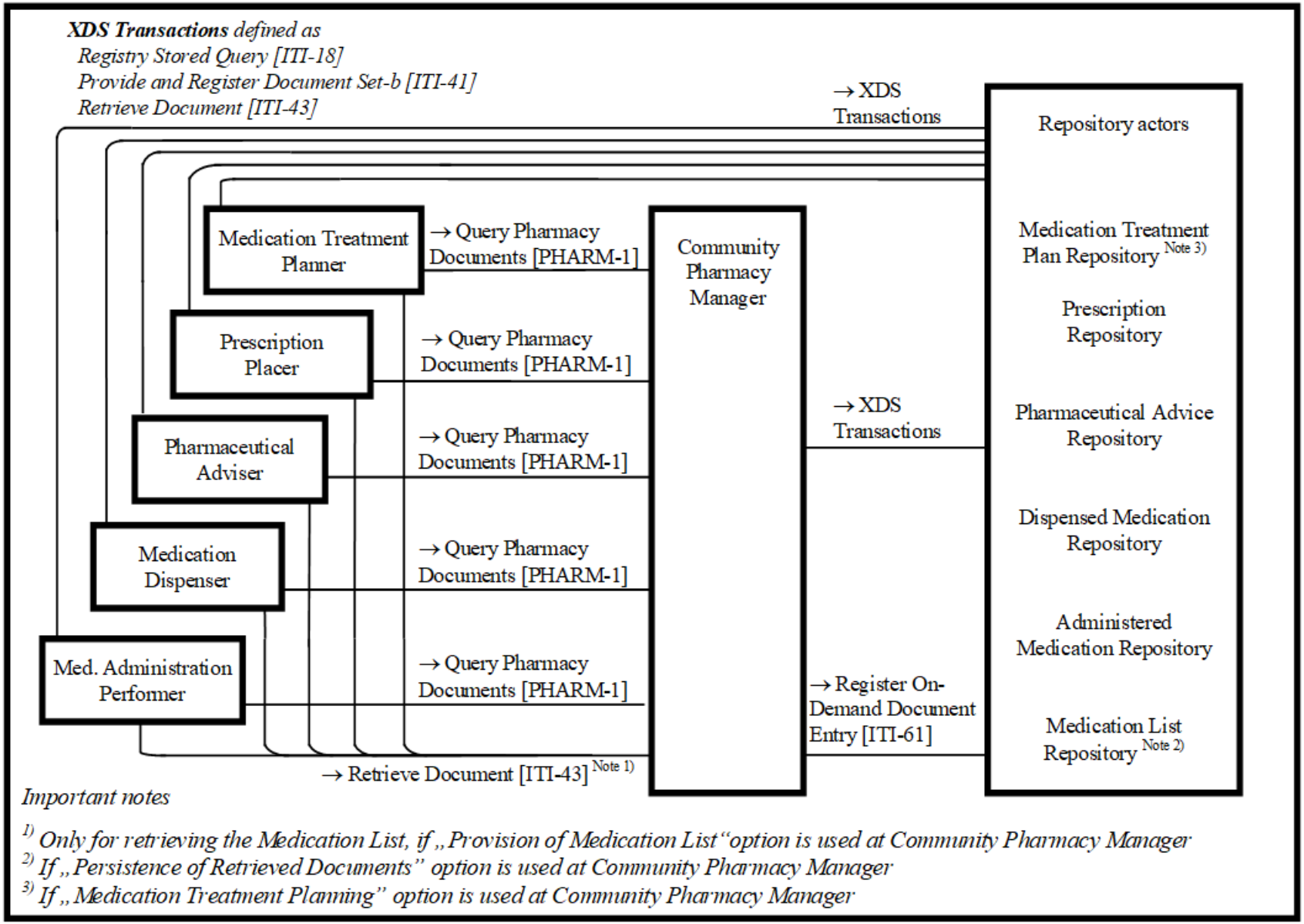
Community Pharmacy profiles

Content (based on HL7v3 CDA extended with HL7 Medication CMETs)

- **Community Pharmaceutical Advice (PADV)**
  - Used for …
    - Validating a prescription
      - » e.g., Medication Interaction Checking Issue Management
    - Managing of prescriptions and dispenses (Change, Cancel, …)
      - » Always related to PRE, DIS or MTP
- **Community Medication List (PML)**
  - Information on prescribed and dispensed medication to a patient
  - Contains Prescription-, Dispense-, Pharmaceutical Advice Items
  - „On-demand“ document
- **Community Medication Treatment Plan (MTP)**
  - Information on planned medication to a patient
  - Contains Medication Treatment Plan Items (alike PRE items)
  - Prescriptions and Dispenses may be referencing MTP



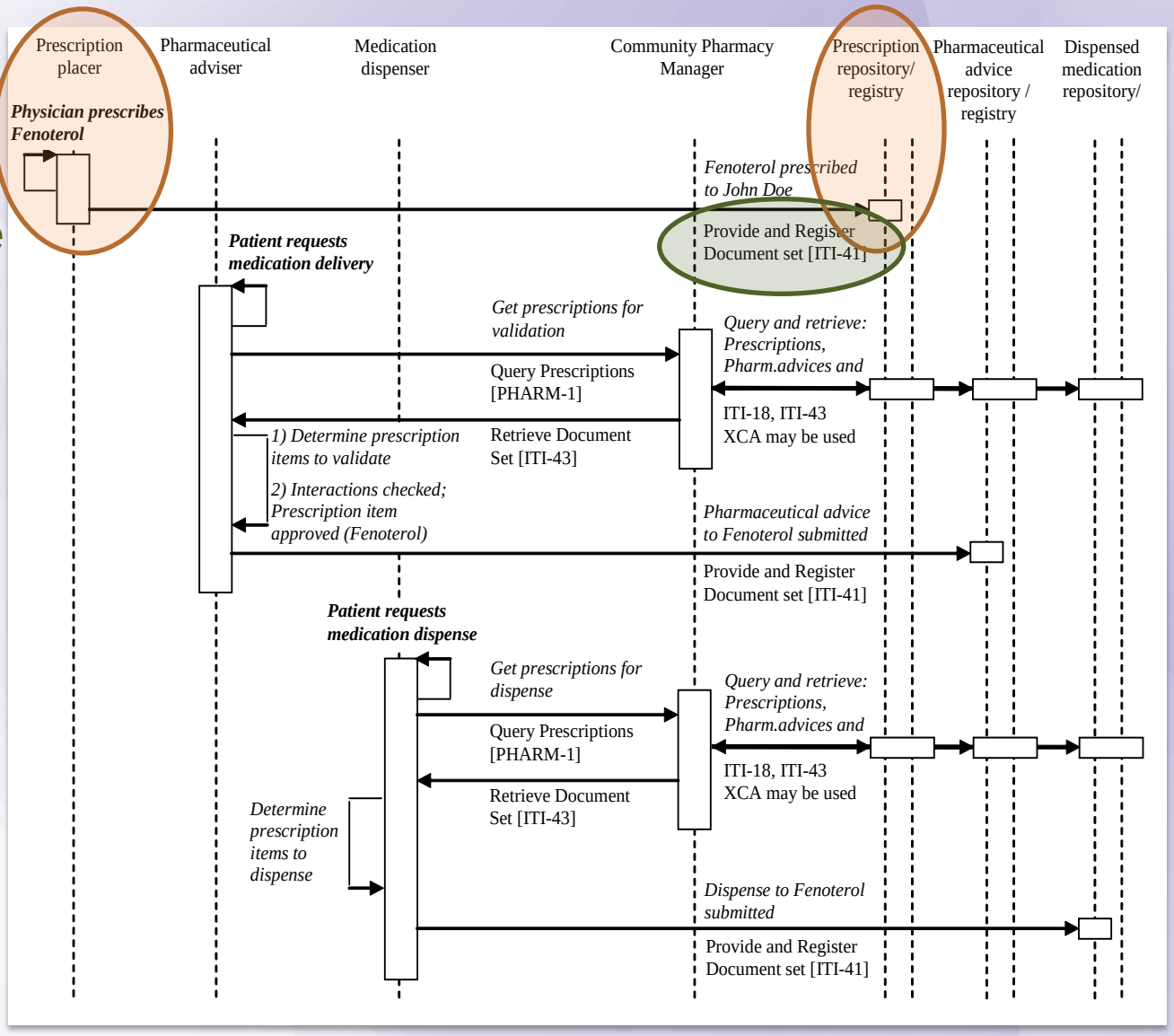
CMPD actor diagram



CMPD Process Flow

Two actors

Perform one transaction



Close look

Let‘s look into a Profile

May sound familiar to you:

Supply chain

Supply – areas covered

Manufacturer

Distributor

Hospital

Dispensing Systems

Point of care

Catalog maintenance

Selection of vendors | Pricing & Contracts | Update product data

Internal data (Clinical data, internal prices, usage rules, usage instructions)

Consult product data

Inventory management

Availability and recall

Permissions, availability, recall

Orders and returns

Stock orders and bulk orders

Point of care ordering & order processing

Consignment items

Usage report & tracking

Consignment items

Patient usage

Stock status, consumption

Billing

Patient charges / intra-hospital charges

Hospital billing

Profiles for Supply of Products for Healthcare

These profiles will provide the interoperability mechanisms for the supply of items, not only inside Pharmacy flows, but also for / from other domains.

Order and Delivery Management

Handles the mechanisms for ordering and delivery of H care products in the context of the supply chain, such as "Orde Product delivery", "Product recall", etc.

Inventory Management

Handles the interop nagement of inventory of H "Consumption", "Consignme

Uniform Barcod

In several tra "Uniform Barcode Processing" is crucial to make sure the ed information from the barcode is used by the actors in the tr actions we designed. We distinguish three organizations that deliver this standardized information on product Id, batch number, expiry date, serial number, location number, patient and staff identification: GS1, HIBC en ICCBBA. By incorporating the 'uniform barcode processing' element in the defined transactions we support inventory management, order, administration of pharmaceuticals and use of medical devices on patients.

Synergy?

ftp://ftp.ihe.net/Pharmacy/yr9_2017-2018/Technical_Committee/Whitepapers/Supply%20of%20products%20for%20healthcare/IHESupply%20v38.docx

Questions?

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    - Structure of the document
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IHE Profiling cycle

Participate IHE's Profile Cycle

- **Committee work follows the IHE Profile Cycle**
  - Annual cycle
    - Sep – Dec: Call for proposals
    - Dec – Jun: Working on work-items
    - Jun – Jul: Public comment
    - Jul – Aug: Ballot & Release
- **Opportunities for IHE members (and non-members) to participate in cycle**
  - Register at Google group of the domain

Meetings are F2F and TCons

Who is creating a profile

- **Persons involved**
  - **Users**
    - They know the process from a non-IT perspective
    - Submit the use-case
    - Describe the use-case in the profile (Volume 1)
  - **Vendors (IT, developers)**
    - They know the base standards and IT landscape
    - Help users to formulate the use-case
    - Divide the use-case in actors and transactions
    - Pick the right base standards
    - Write the technical part (Volume 2+)

- **Champion and funding needed**
  - Creating a profile needs at least one person, who signs him/herself responsible
  - Creating a profile is a minimum of one-year effort -> usually needs funding

Who is creating a profile

- **Ideal proceeding (usually leads to success)**
  1. A real-world project runs into an interoperability problem
  2. It submits a profile proposal to IHE to resolve it
  3. It funds a person or team to accomplish the work within the respective IHE development domain
  4. They drive forward the creation of the profile …
     - … in collaboration with the other members of the domain
     - … in a neutral way (= stripping away all project-specific aspects)
  5. After the profile is published, the team creates the project specifications by …
     - … taking the just created profile as basis
     - … and adding the project specific aspects

- **Positive outcomes of this proceeding:**
  - The community has got a new interoperability use-case profiled
    - Others will take up and do the same
  - The project may declare that it is based on an international standard, others are using as well
    - **Without much more costs!**

How a profile is created

Stage 1

Description of the use case

How a profile is created

- Step 1.1: Identification of an **interoperability use case**
  - … is usually reported by users
    - Health Authorities, Hospital providers, eHealth projects, etc.
  - … created by the „proposal editor“
  - … in form of a „work item proposal“
  - … by the „Brief Proposal Template“
    - http://wiki.ihe.net/index.php?title=Brief_Proposal_Template
  - … during the „call for proposals“ phase
  - … to the Planning Committee of a domain

How a profile is created

- Step 1.2: Planning
  - … is carried out by the "Planning Committee" of a domain
  - … after the „call for proposals“ phase
  - … Acceptance or rejection of the work item
  - … Assignment to an "editor"
    - Usually to a person of the „users“ category

How a profile is created

- Step 1.3: Preparation and formulation of the use case
  - … by the editor
  - … in collaboration with the entire working group of the domain
  - … usually in the form of a white paper
  - … under the responsibility of the "Technical Committee" of the domain

How a profile is created

- Step 1.4: Publication of the whitepaper for "Public Comment“
  - … on the IHE homepage
  - … for at least 1 month
  - After that:
    - Incorporation of the comments

How a profile is created

- Step 1.5: Vote the whitepaper
  - … Ballot for at least 1 month
  - … Voting rights according „roster“
    - Minimum participation / participation required
  - Adoption of the whitepaper as "Final Text“
  - After that:
    - Publication on the IHE homepage

How a profile is created

Stage 2

Technical elaboration of the profile (Trial Implementation)

How a profile is created

- Step 2.1: Formulation of the **proposal for a new profile**
  - … from another „proposal editor“
  - … contains an overview of the new profile to be created
  - … to illustrate the application technically
  - … during the “call for proposals" phase
  - … to the Planning Committee of a domain

How a profile is created

- Step 2.2: Planning
  - … is carried out by the "Planning Committee" of a domain
  - … after the „call for proposals“ phase
  - … Acceptance or rejection of the (new) profile
  - … Assignment to a profile "editor"
    - mostly from the group of vendors

How a profile is created

- Step 2.3: Elaboration of the profil
  - … by the editor
  - … in collaboration with the entire working group of the domain
  - … on the basis of the “new profile template”
  - … under the responsibility of the "Technical Committee" of the domain

This is the most extensive work!

How a profile is created

- Step 2.4: Publication of the profile for "Public Comment“
  - … on the IHE homepage
  - … for at least 1 month
  - After that:
    - Incorporation of the comments

How a profile is created

- Step 2.5: Vote on the profile
  - … Ballot for at least 1 month
  - … Voting rights according „roster“
    - Minimum participation / participation required
  - Adoption of the whitepaper as “Trial implementation“
  - After that:
    - Publication on the IHE homepage
    - Vendors start with the implementation

How a profile is created

Stage 3

Further development of the profile (Trial Implementation)

How a profile is created

- Step 3.1: Formulation of a **change proposal** to a profile
  - … from another „proposal editor“
    - user or vendor
  - … contains concrete changes to a technical framework / profile
  - … to correct errors or to add missing functionality
  - … to the Planning Committee of a domain

How a profile is created

- Step 3.2: Planning
  - … is carried out by the "Planning Committee" of a domain
  - … throughout the season
  - … Acceptance or rejection of the change proposal
  - … Assignment to a profile "editor"
    - mostly from the group of vendors

How a profile is created

- Step 3.3: Preparation of the change proposal
  - … by the editor
  - … in collaboration with the entire working group of the domain
  - … contains all changes to a technical framework / profile
  - … under the responsibility of the "Technical Committee" of the domain

How a profile is created

- Step 3.4: Vote on the Change Proposal
  - … Ballot for at least 1 month
  - … Voting rights according „roster“
    - Minimum participation / participation required
  - After that:
    - Incorporation of changes in the profile
    - Release of the new profile version

Close look

Let‘s look into a Change Proposal

How a profile is created

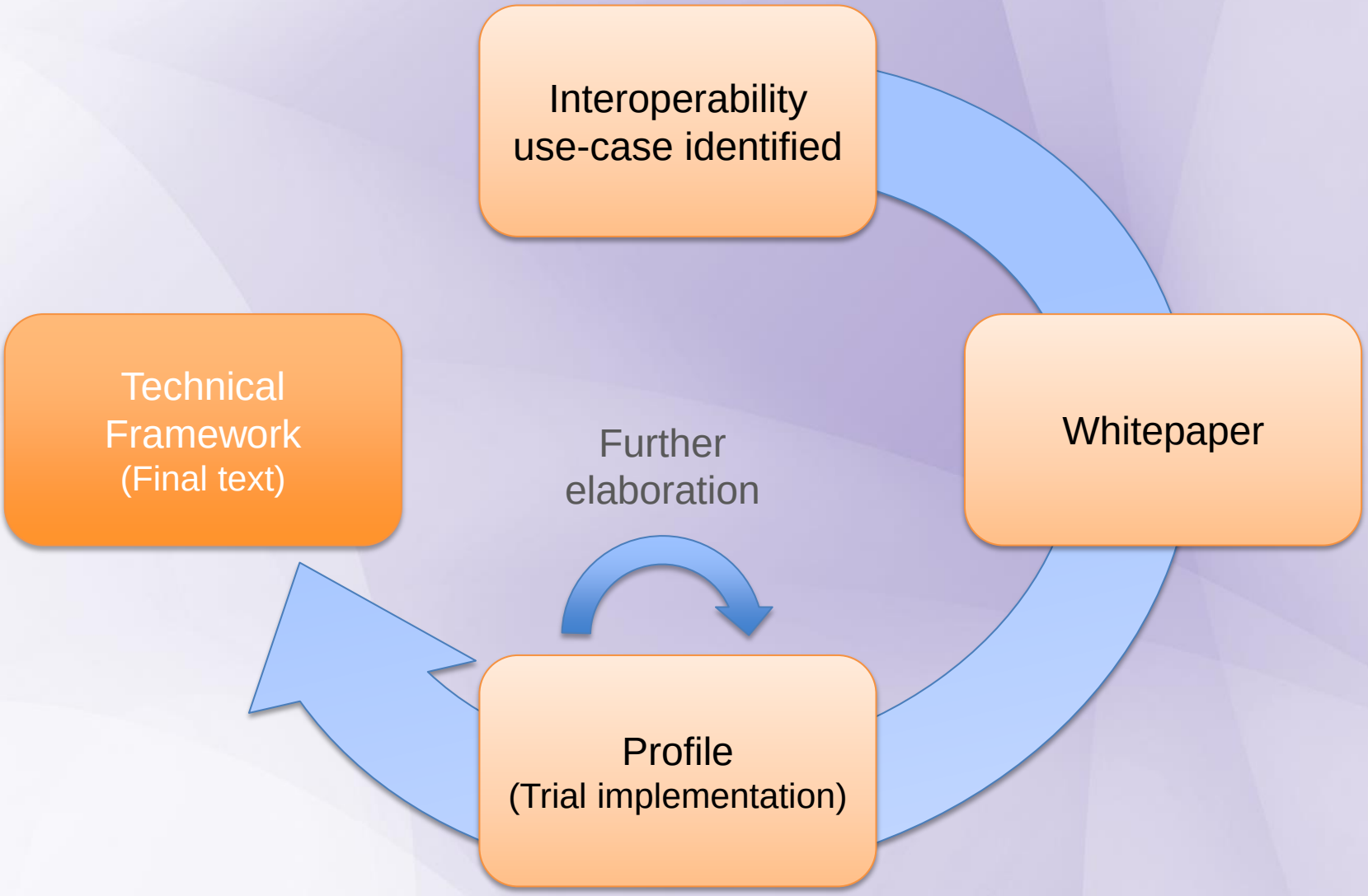
Stage 4

Finalization of the profile (Final text)

How a profile is created

- Schritt 4.1: Proposal
  - … The Technical Committee proposes **forwarding the profile to "Final Text"**
    - Have all „Open issues“ been resolved?
    - Is the specification stable enough?
    - Has it been adequately tested?
      - Minimum: 3 different vendors at 2 different places each
  - … Vote in „Planning Committee“
  - … Acceptance of the profile as "Final Text"
  - After that:
    - Incorporation of the profile in the Technical Framework

How a profile is created



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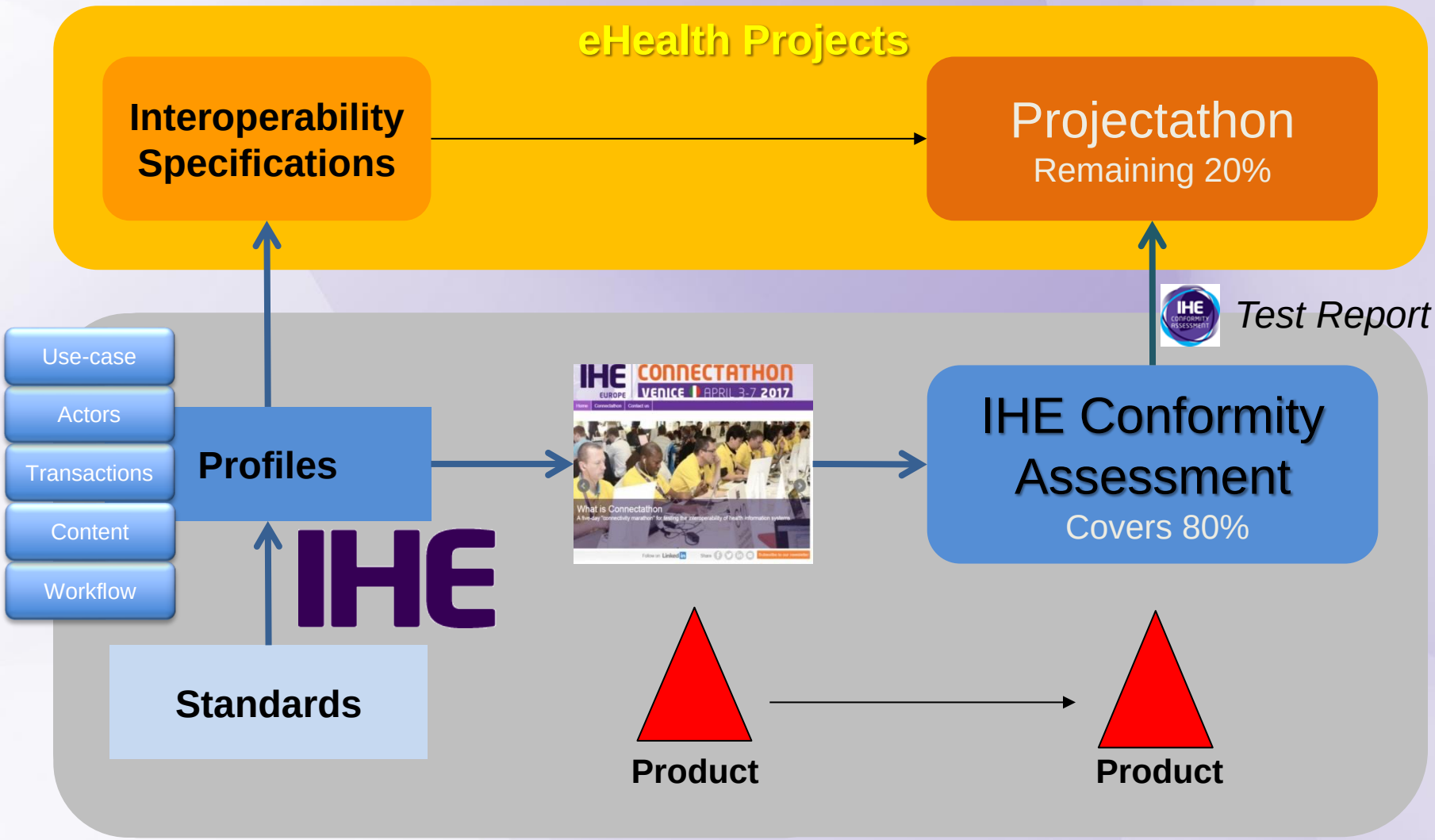
Conformity and eHealth Projects



IHE EUROPE

CONNECTATHON

VENICE APRIL 3-7 2017

What is Connectathon

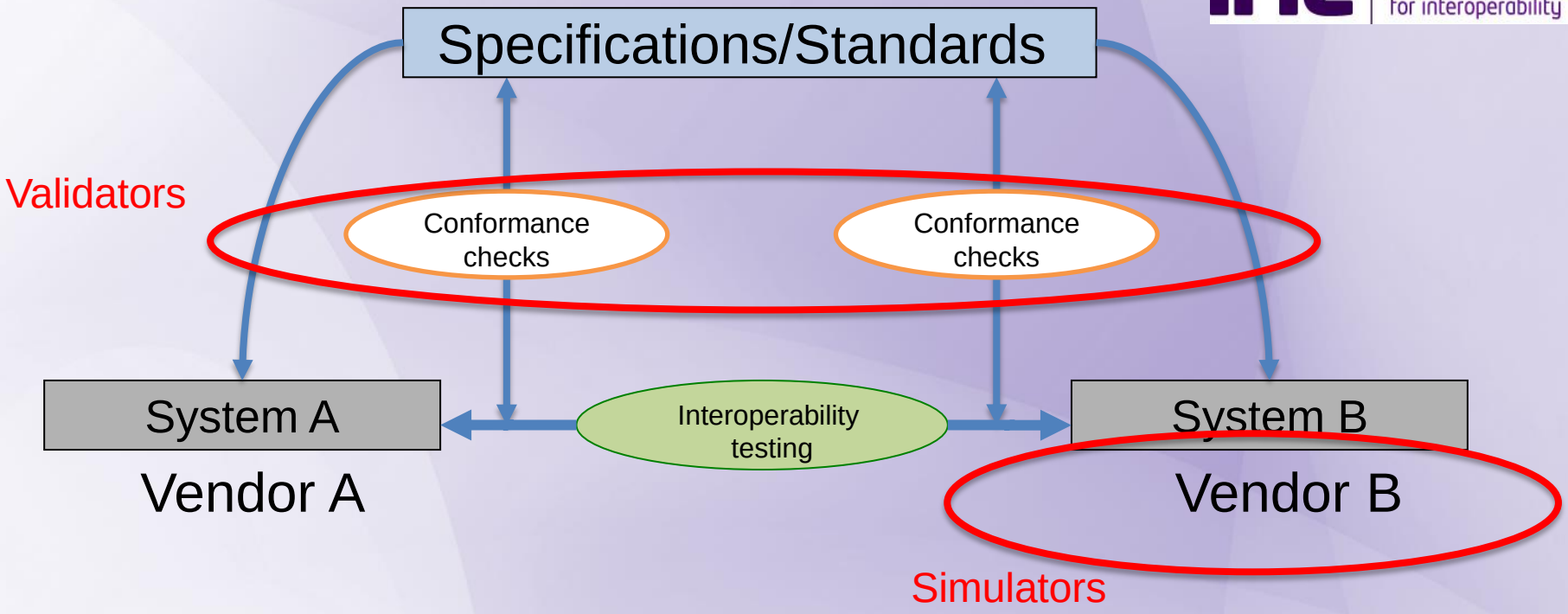
A five-day "connectivity marathon" for testing the interoperability of health information systems.

CAT key figures

~300	230+	30+	50+	2400+	90+
Participants 75 Companies	engineers from participating organizations	committee members	monitors	tests performed	systems

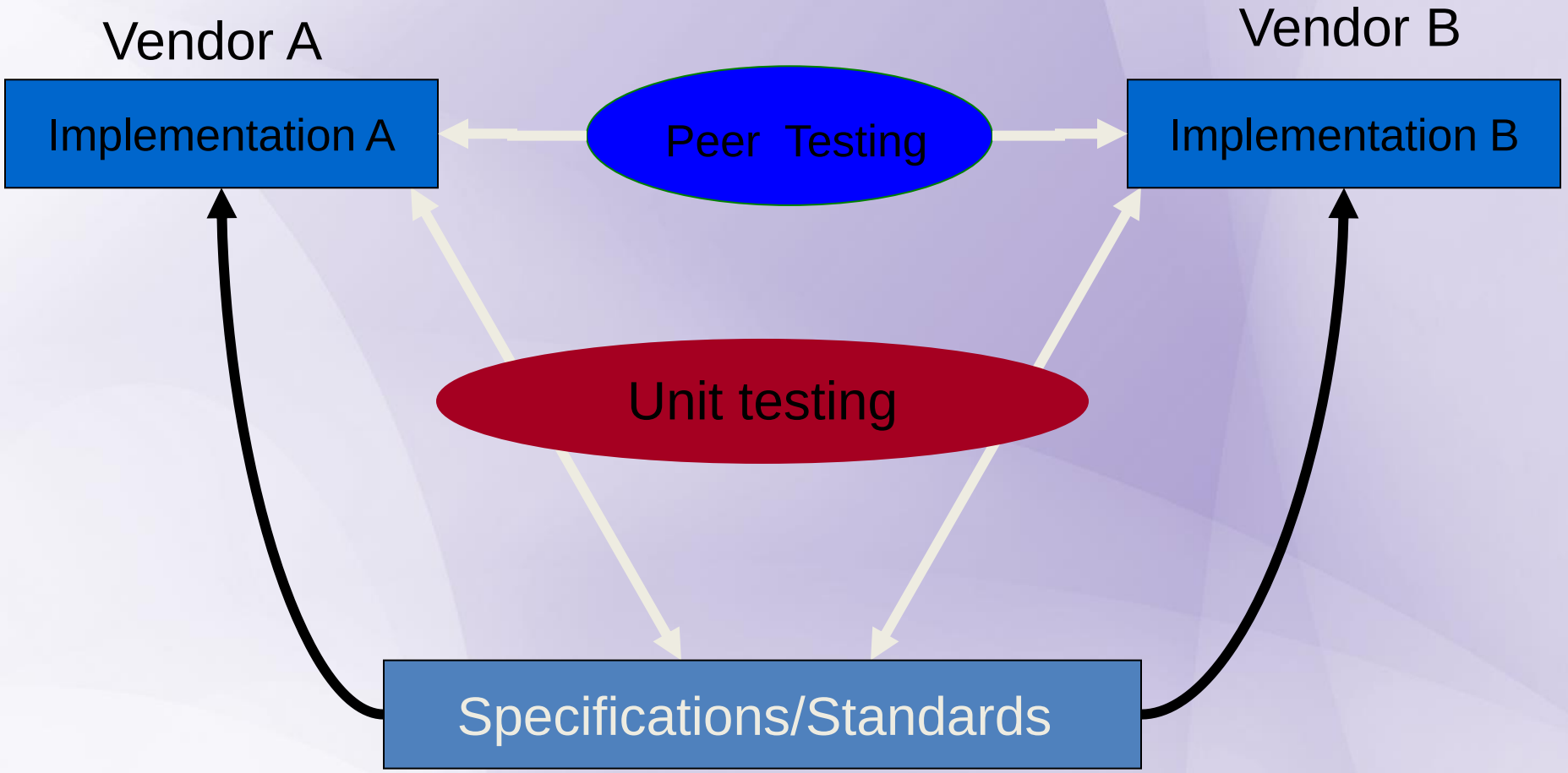
~370	~310	30+	55	3000	114
Participants 83 Companies	engineers from participating organizations	committee members	monitors	tests performed	systems

Gazelle Test Framework



- Test management tool oriented toward interoperability and conformance testing
- Suite of conformance testing tools
- Suite of simulators tools

Unit Testing & Peer Testing



Performs a combination of peer-to-peer (during connectathon) and unit/conformance testing (pre and during connectathon)

CAT outcome

„Stars“ at the CAT result matrix
https://connectathon-results.ihe.net/

Vendors may issue Integration Statements in Product registry
https://gazelle.ihe.net/content/product-registry

		Document Administrator	On-Demand Document Source	Patient Identity Source	Document Registry	Document Consumer	Document Source	Document Repository
メタキューブ					*	*	*	*
Adaptive TechSoft						*	*	
AEGIS.net, Inc.					*			*
AGFA Healthcare				*	*	*	*	*
ALERT Life Sciences Computing		*	*		*	*	*	*

Conformity Assessment

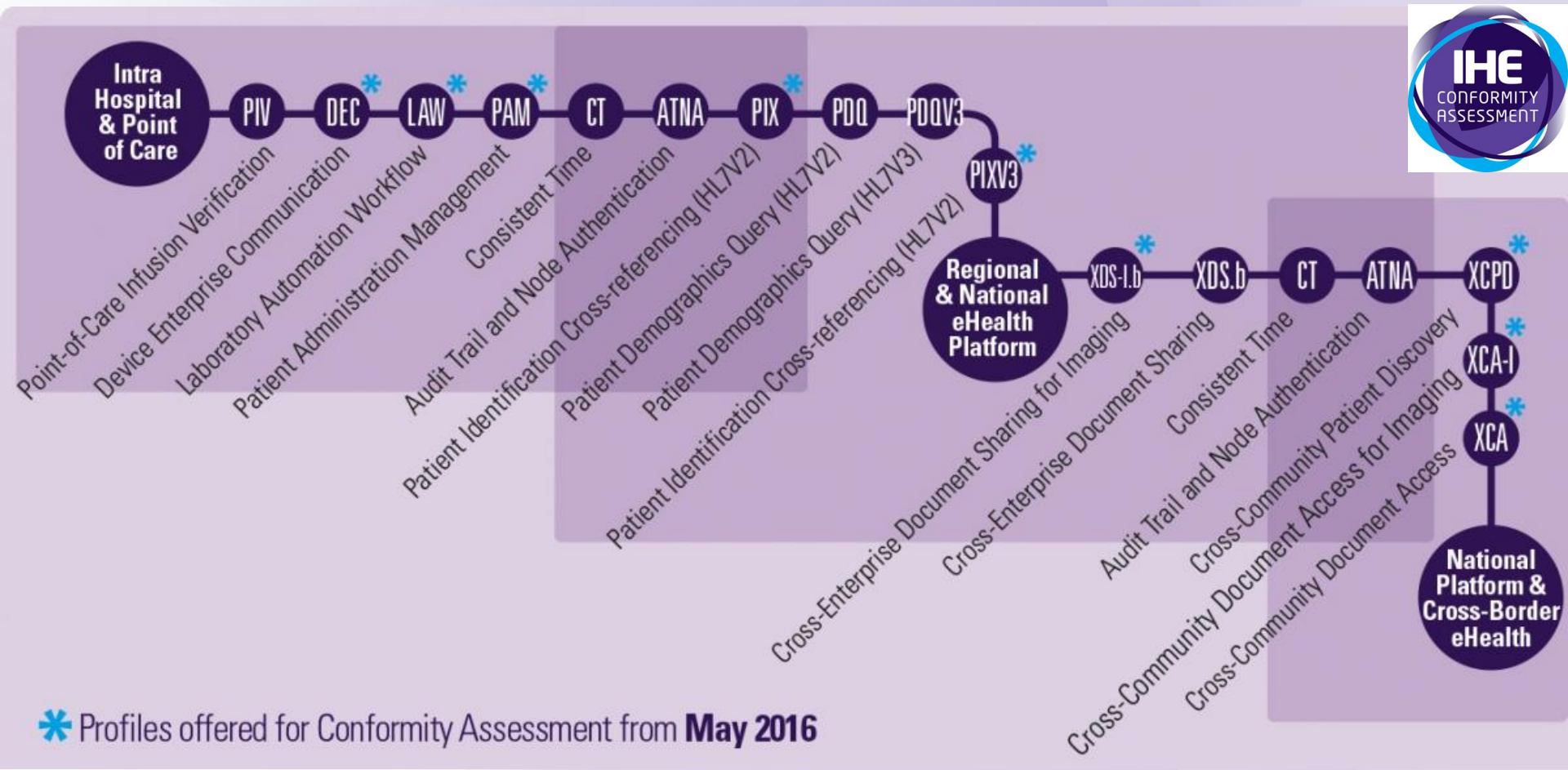
- **IHE International Conformity Assessment** program was launched in 2015 and is the next step in testing rigor
  - More rigorous testing process
  - Assessment at product level
  - Stronger assurance of interoperability to marketplace

- Based on an internationally recognized quality system
  - Testing for specific IHE Profiles is performed by Testing Laboratories **ISO17025 accredited**

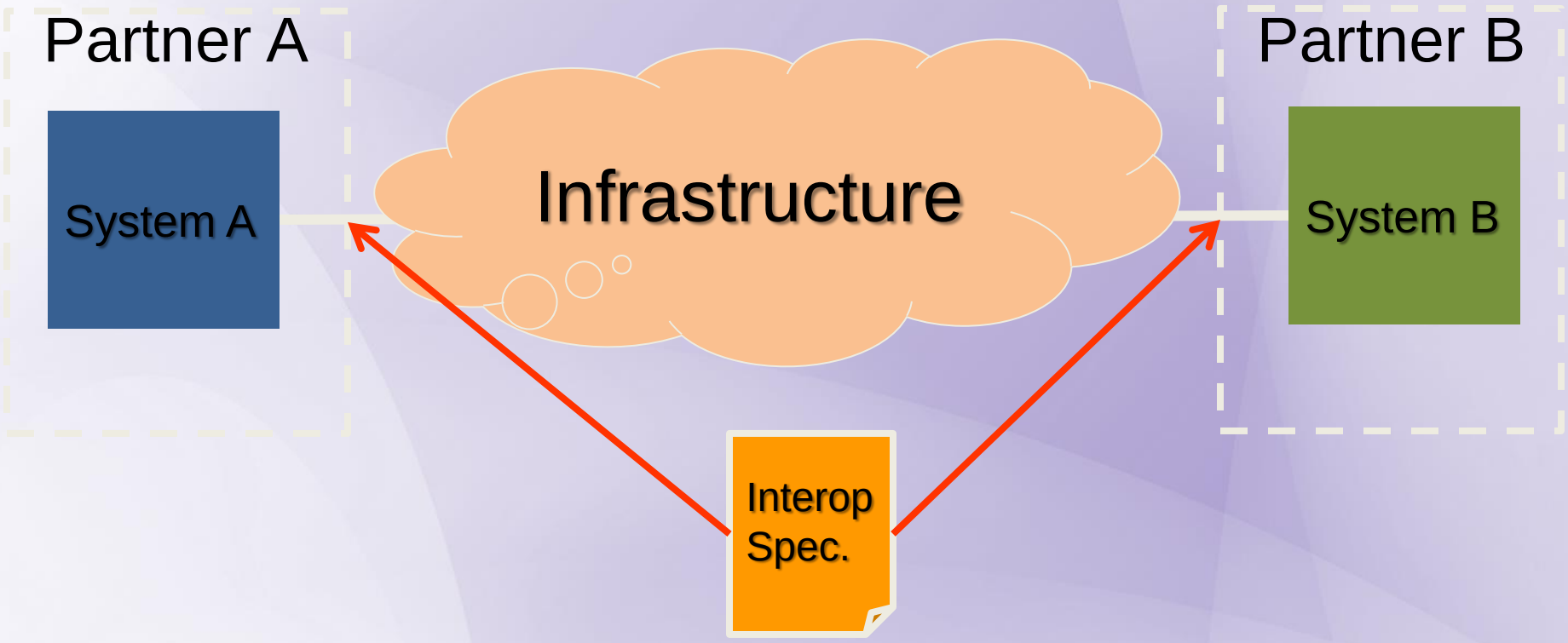
- Conformity assessment scheme
  - **Ensure world-wide equivalence**

How Conformity Assessment works in IHE

IHE Conformity Assessment Scheme



A typical project

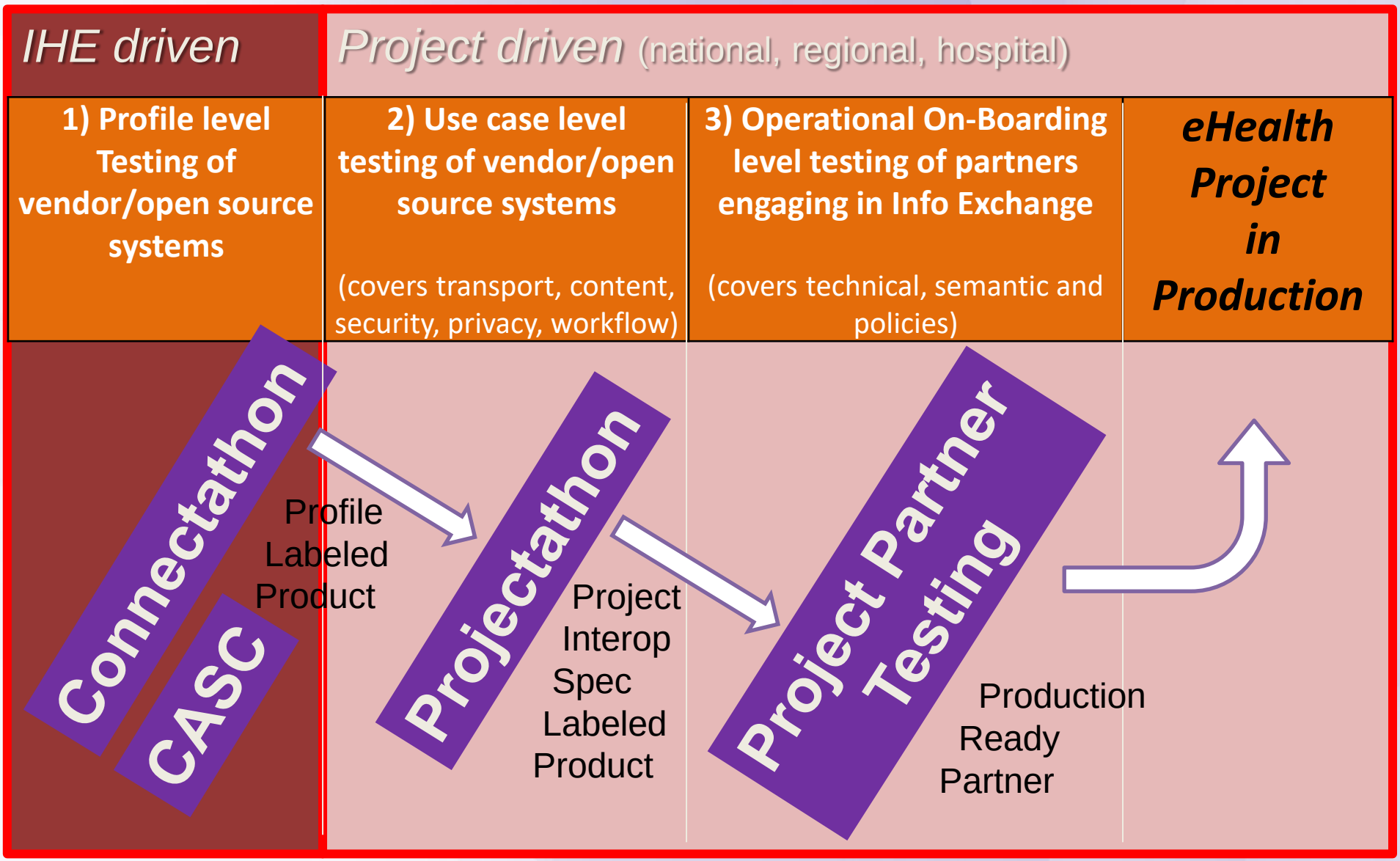


Project Interop Spec = Combined set of Profiles

Need to test systems installed by partners

How to test that? Solution: Projectathon

Phases of Interoperability Testing



Questions?

IHE | Integrating the Healthcare Enterprise

Changing the Way Healthcare CONNECTS

http://www.ihe.net

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