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COMBINING FUNCTIONAL AND INTEROPERABILITY TESTING - RESULTS FROM THE HITCH PROJECT

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Abstract

This report describes intermediate results of the current project HITCH (Healthcare Interoperability Testing Conformance Harmonisation) of the European Commission. Issued by EC DG Information Society, the project invites partners with different approaches regarding specification, testing and certification/labelling to join their methods and establish a roadmap towards an overall functionality and interoperability testing approach in eHealth. The paper explains the existing approaches and a potential synthesis as developed by now.

Keywords – eHealth, Functional specification, Interoperability, Certification, Labelling

1. The HITCH Project

HITCH (Healthcare Interoperability Testing and Conformance Harmonisation) is an EC-funded project with the aim to provide the European Commission with a roadmap (see *Figure 1)* for the future of interoperability testing of IT systems in healthcare. It started on January 2010 and runs for two full years. It has to be said that considerations of intellectual property rights – sometimes referred to as *economic interoperability* – are not in the scope of the rather technical work under HITCH. Also, aspects of placing medical devices onto European markets, as regulated under the Medical Device Directive (93/42/EEC) are not directly in scope. The testing performed for medical device approval aims at patient safety where the approaches described here mainly target system functionality and how it is technically achieved and tested. Of course, the correctness of implementations has direct impact on patient safety and therefore a system that has undergone extensive functional and interoperability testing as described in this paper is more likely to be safe than without. Systems examined as part of testing/certification can be Medical Devices or not, but from a HITCH point-of-view it would make no immediate difference.

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The HITCH project partners (ETSI, EuroRec, IHE Europe, INRIA, MedCom and OFFIS) published various approaches and manage methods and tools towards interoperability testing, labelling and certification. The HITCH project was started in order to write a roadmap in the following areas:

- Interoperability Testing Quality Management System (QMS)
- Testing Tools Strategy
- Quality Labelling and Certification

The results are evaluated at IHE's European Connectathon 2011 (April, Pisa, Italy), being the largest eHealth interoperability testing event in Europe (www.ihe-europe.net).

The approaches presented here especially focus on communicating and preserving semantic aspects of the healthcare domain, such as clinical terminologies and related code sets. Future projects may greatly benefit from the HITCH results, like phase II of the European epSOS project focusing on exchange of medical summaries and e-prescription across Europe [1]. The resulting roadmap (available in July 2011) and its relationship to players in the European eHealth landscape are best described by the following diagram:

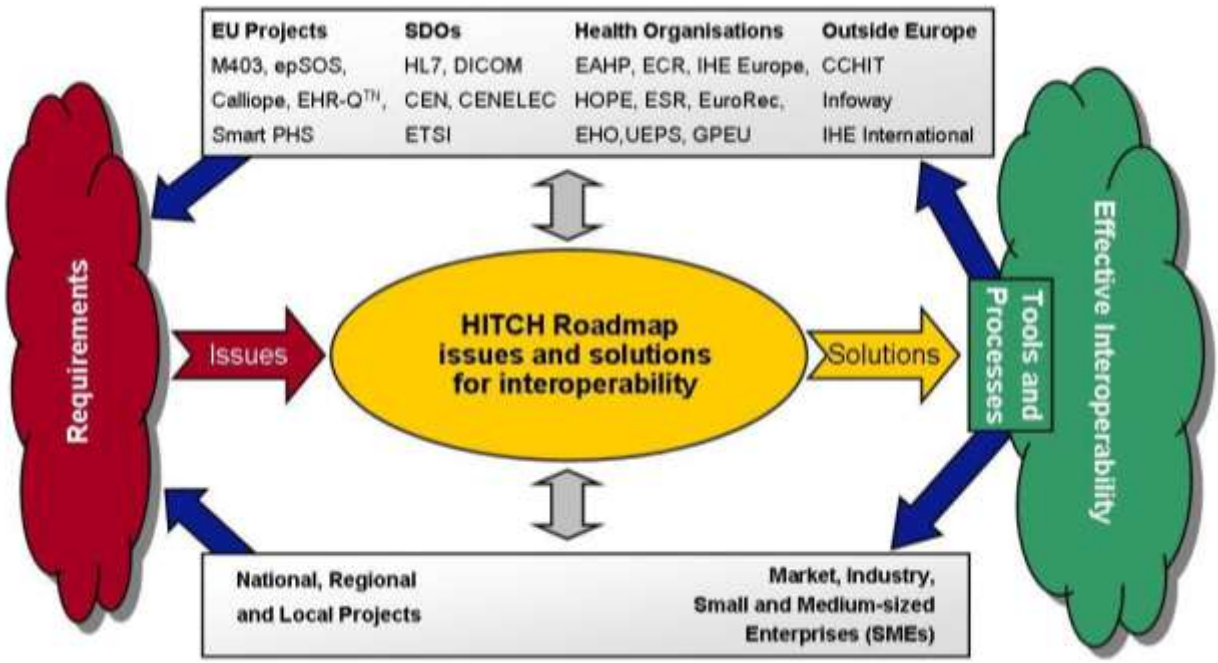

Figure 1: Overview of the HITCH Project

2. Existing Testing Initiatives

This section describes existing work in the area of eHealth testing which was used as input to the HITCH project.

EuroRec – an independent research institute aiming to improve quality of Electronic Health Record (EHR) systems – manages a system-level approach towards functional specification of eHealth applications with the goal to support the use of high-quality EHR systems in Europe. Therefore, EuroRec manages rich multi-lingual databases of Functional Statements and a tool suite [2]. Using these tools, a project coordinator of some eHealth project may create his/her specific subset of Functional Statements that the target system should comply with – by selecting a project-specific

subset of the overall set of Functional Statements. Those Statements do not address how data should be exchanged, but focus on functionality (data entry, data display, content of the record, decision support, care plan monitoring etc…). Communicating health information to other systems is also considered in Functional Statements and should meet "local / national regulations and/or standards" which are not described further. In an auditing process (Functional Testing), an auditor tests the system by validating that every Functional Statement is fulfilled.

Integrating the Healthcare Enterprise (IHE) is an international not-for-profit organization with close to 400 stakeholders members (clinical and IT professional societies, health agencies, national/regional programs, vendors, payors, etc.). IHE publishes Technical Frameworks for all types of health IT systems and devices from hospitals, doctor's offices, diagnostics services, pharmacies, regional/national eHealth infrastructures [3]. Interoperability between such systems is specified by IHE in the form of Integration Profiles (e.g. Cross-enterprise sharing of health documents – XDS) that describe generic, reusable interaction workflow scenarios between systems abstracted as Actors which are communicating through Transactions. A real-world eHealth system might then implement one or more of these Actors. An IHE Transaction specifies services or messages based on standards with drastically reduced optionality to achieve simple and effective interoperable health information exchange. At IHE's connectivity testing events (Connectathons), implementers voluntarily test their implementations of such Actors for conformance and interoperability by connecting with each other and performing dedicated tests corresponding to the Actors they implement [4]. This is called Interoperability Testing. If successful, they receive acknowledgement after having passed a neutral assessment of defined tests. Through IHE Integration Statements vendors can then claim conformity of their IT-products to one or more IHE Profiles (acting as specific IHE Actors), which in turn may be requested in an public tenders.

ETSI – the European SDO focusing on telecommunication standards – has a proven record of very successful telecommunication specifications, including a formalized testing language called TTCN-3 that is being heavily used to test specifications. Also, ETSI developed and organizes test events called Plugfests [5].

3. Discussion: Relations between Functional and Interoperability Testing

The following comparison analyzes these fundamentally different approaches. As a practical presentation of dependencies among these approaches to interoperability, we suggest the ALT-model which distinguishes the Application Level, a Logical Level and a Technical Level (hence the acronym ALT, see *Figure 2*) to better describe dependencies between different aspects of interoperability. The ALT-model has been widely used in Denmark during the past ten years to focus the interoperability discussions [6].

3. 1. Application Level

EuroRec's Functional Statements specify the functionality aspects of the Application Level. Functional Statements provide transparent sets of functionality criteria to select health care IT (HIT) solutions, e.g. for procurement purposes. However, there is no way to predict interoperability of the selected systems (conforming to a given EuroRec Statements subset) with other existing or future IT-systems, since no communication interfaces (Logical and Technical levels of ALT) are specified by Functional Statements. In IHE Integration Profiles, the Application Level is represented by the described Actor concept, where each Actor reflects specific interoperability functionality. For ex-

ample, the Order Filler Actor has the ability to exchange information with the Actor "Order Placer". An EHR system then might claim to conform to any number and kind of Actors.

3. 2. Logical Level

IHE Integration Profiles typically describe common workflows as a composition of Actors that communicate with each other using standardized services and messages (transactions). Only part of the IHE transaction specifications, the content, is relevant to this level (e.g. a laboratory order or results content of the transaction). Vocabularies are partly defined, as they are often country or hospital specific at this time. IHE Profiles focus on the Logical Level of health information content and minimally constrain the application functionality that implements these Actors. Through Integration Statements, HIT product vendors claim conformance to selected Profiles and Actors. Such conformance asserts Logical Level interfacing capabilities, but typically only little application-level functionality.

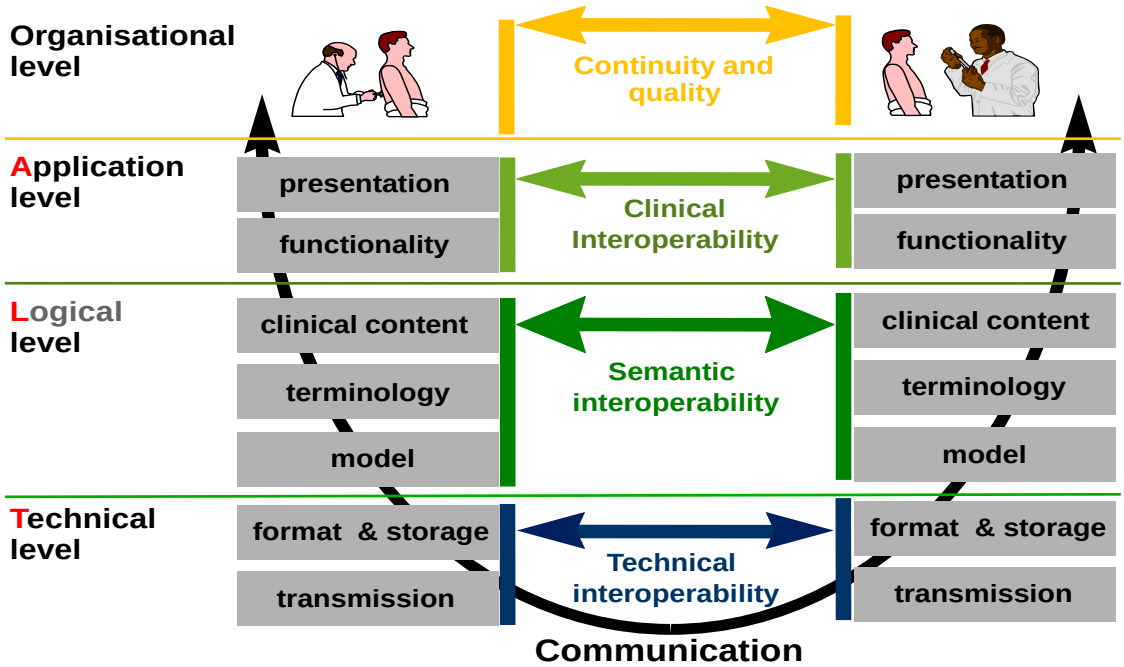

Figure 2: Using the ALT-model to distinguish levels of interoperability

3. 3. Technical Level

This level describes standardized protocol and format of services/messages between IHE Actors. It includes IHE Transactions from Integration Profiles that are content neutral as well as Profiles with Transaction specifications that combine details from the Logical and Technical Level (e.g. a dedicated medical device observation message).

Furthermore, the specific lower-level protocols (in an OSI protocol stack) would be specified here. Depending on the types of communication used – especially in wireless scenarios, ETSI's standards may also play a role at this level. E.g. communication "near the patient" or at a "point of care" is supported through specialized ETSI standards.

Testing at each of these levels is of a different nature:

- Testing at the organizational level is out of scope for HITCH.

- At the Application Level, Functional Testing is limited to auditor observation against textual criteria on the ability to exchange information as observed on a single system.
- At the Logical Level, interoperability testing is a mix of auditor observation (clinical semantics) and the semi-automatic utilization of test tools, data and scripts (workflow and terminology usage).
- At the Technical Level, interoperability testing is based on test tools, data and scripts (format and transmission).

4. Synthesis

When procuring a HIT system, there are mainly two overlapping concerns: First, it must be ensured that capability or behavior of the system supports the users' needs and second, that the system effectively can interoperate with other systems.

Figure 3 shows the process of applying a given set of Statements (with test criteria) to a HIT software product – with (V) denoting validation/verification steps against the related acceptance criteria.

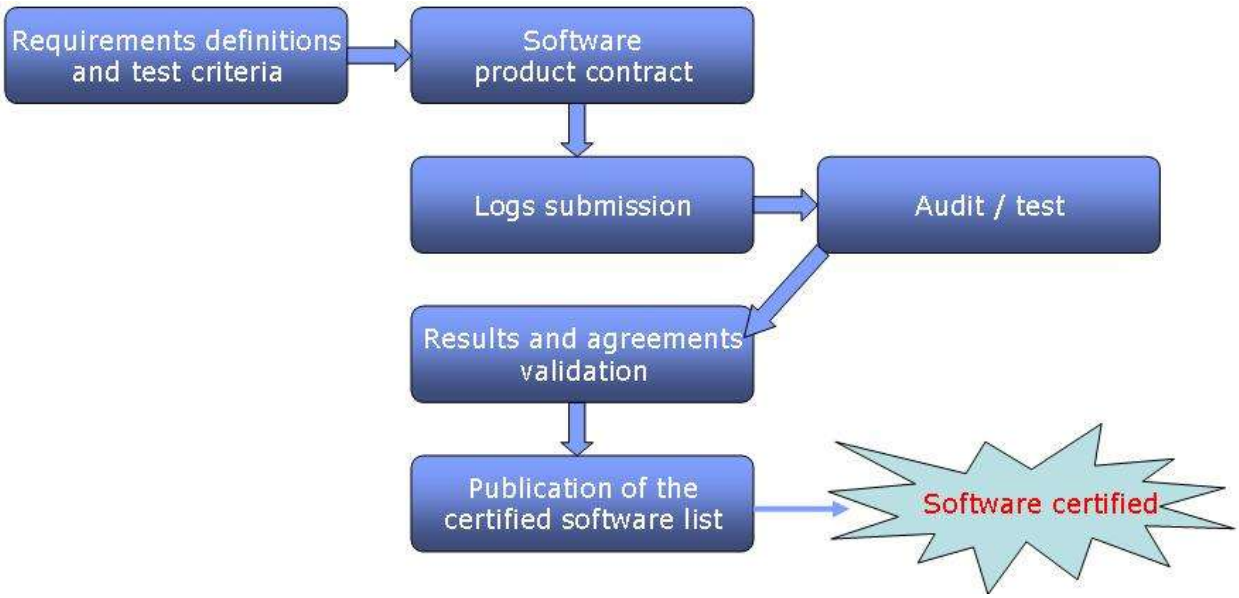

Figure 3: Applying functional statements to a software integration project

As far as internal communication *within* the System-under-test is part of a function, the related *internal* interoperability is covered by that type of testing and certification, too. EuroRec's Functional Statements are describing HIT systems at the Application Level, reflecting only the behavior of the whole IT system with regard to the user. Since workflows, health data records and vocabularies are different not only the nation level but even at the regional level in Europe, no out-of-the box software product can practically meet the exact set of a comprehensive Functional Statements – including all detailed external communication requirements. Rather than suggesting EuroRec's Functional Statements for system procurement, they seem to be most useful for integration contract requirements, effort estimation, project control and contractual acceptance in software integration projects. But HIT procurement has to foresee integrating different existing products. So, IHE profiles are critical to help to practically integrate distinct systems – according to project-specific needs. Such integrated HIT systems are systematically best implemented using IHE Profiles. *Figure 4* shows an

application of IHE Profiles to an integration project where different systems need to be interconnected.

It has to be noted that producing interoperable systems in general requires:
(1) internal / functional ability to produce the content that will be exchanged with other systems (even with decision support tools e.g.)
(2) internal / functional ability to interpret and to use correctly the content "collected from other systems" (applications or devices)
(3) compliance to communication and exchange standards and protocols (including semantic standards).

This list reflects the three perspectives: a sending/exporting application, a receiving application and, a 'set of services' between both. The suggested combination of Functional Statements and Interoperability profiles combines these perspectives in a way suitable for large integration projects.

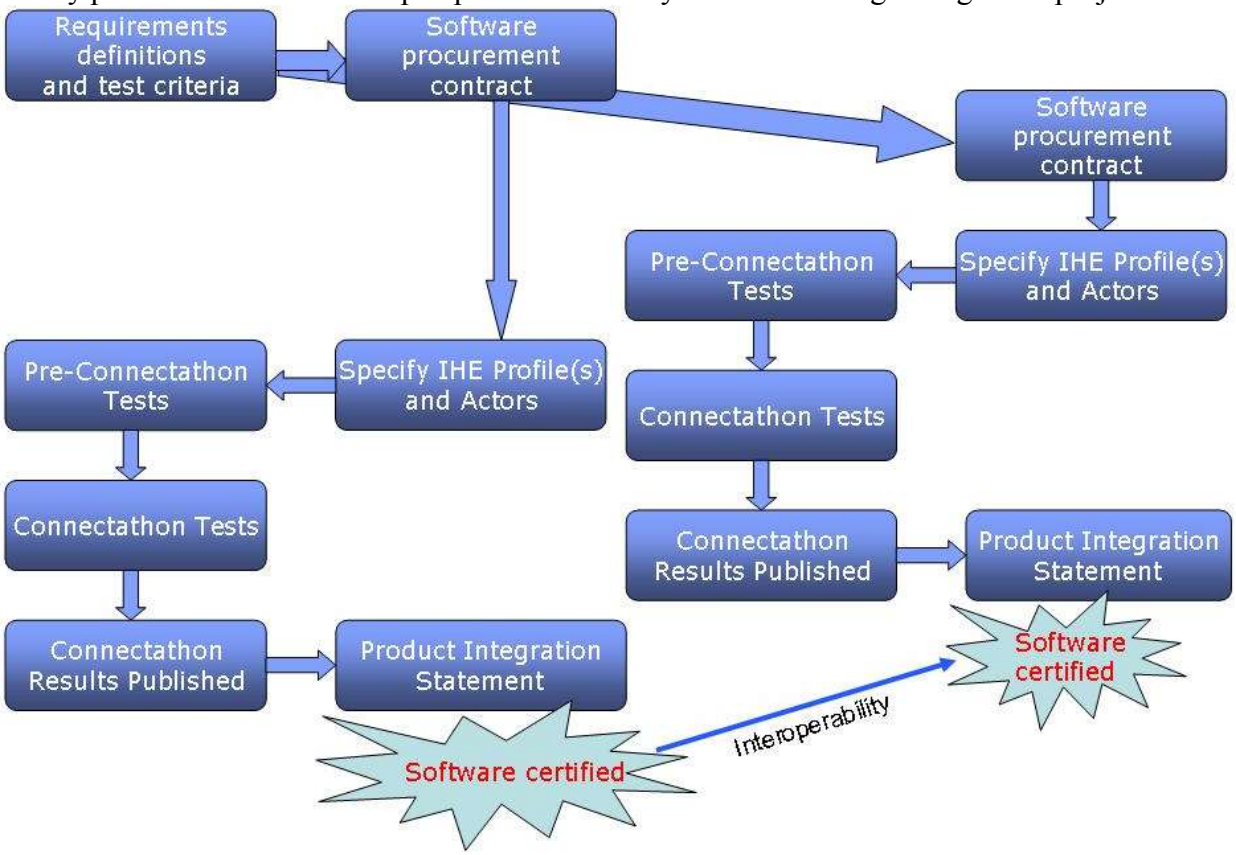

Figure 4 Application of interoperability requirements to interconnect systems

5. Results

One major result of the HITCH project will be a roadmap guiding the combination of interoperability testing and functionality testing in the domain of eHealth. The described approach is the first one combining the initiatives of the biggest European players in this field. EuroRec's Functional Statements serve well for procurement purposes or any other processes where a clear functional description of the system's end user functionality is in focus. These Statements then are amended and filled with life by adding IHE Integration Profiles which clearly define how information must be communicated between different systems by means of existing standards, where possible. Thus,

it has been found that IHE's and EuroRec's approaches perfectly complement each other. In further work (e.g. future HITCH Report, WP4: Integration of Quality Labelling for Interoperability), the link between both has to be defined more thoroughly and in a formalized way.

6. References

[1] JEREMY THORP: Europe's E-Health Initiatives. An Overview of European Interoperability Initiatives, Journal of AHIMA Sept. 2010, AHIMA, Chicago, 2010

[2] GEORGES DE MOOR: Past, Current and Future Initiatives of EuroRec, MIE 2009, (Sarajevo), EFMI c/o MEDIS Munich, 2009, also published under www.eurorec.org

[3] DONELLY J, MARSHALL G, ROTH C: Introduction to IHE - Integrating the Healthcare Enterprise , IHE Int. c/o HIMSS, Chicago, 2010 also published under http://www.ihe.net/Events/upload/2010-IHE-Webinar-Series-1-Introduction-to-IHE-Final-2010_06_08-v5f.pdf

[4] HANKE J: Behind the Scenes at IHE Connectathon, INContext Magazin July 2010, Perceptive Software, Shaawnee (Kansas) 2010; available via http://www.incontextmag.com/article/Behind-the-scenes-at-IHE-Connectathon

[5] About ETSI, http://www.etsi.org/WebSite/document/aboutETSI/ 2010ETSI_Presentation.pdf, ETSI, Sophia-Antipolis, 2010

[6] BERNSTEIN K., BRUUN-RASMUSSEN M., VINGTOFT S., NØHR C., KJÆR ANDERSEN S.: EPJ-Observatoriet - Statusbeskrivelser for EPJ i amterne 2006 (EHR-Observatory – Status Description for EHR by 2006), MEDIQ, Copenhagen, 2006

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