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IHE / HL7 / FHIR

Overview

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For reasons of legibility, the consistent use of the masculine and feminine form has been avoided. Unless otherwise stated, both genders are always implied.

1 Contents

2 Introduction

For those who are not familiar with the standardisation of health informatics, the interplay of the various standardisation organisations and their functions and roles is often very confusing.

A broad range of standardisation organisations operate in the area of health informatics/interoperability, sharing the field with as few overlaps as possible, such as, for example, HL7[1] for health data communication, SNOMED CT[2] and LOINC[3] for terminologies and DICOM[4] in radiology and medical image processing.

Standards from other non-health-informatics-specific standardisation organisations are also used in health informatics, such as W3C[5], OASIS[6] and IETF[7] for internet standards and IEEE[8] for device communications.

Based on top of these, upstream profiling organisations such as IHE[9] (for general exchange of health data) and PCHA/Continua[10] (for health-related end user devices) are collating the existing standards for health informatics interoperability use cases and facilitating cost-efficient implementation in practice.

This complex picture is completed by international, regional and national standardisation bodies (ISO[11], CEN[12], NIST[13], etc.) which also issue standards while trying to ensure that these are created in collaboration with the above institutions through existing liaisons in order to avoid duplications arising from contradictory standards.

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[1] Health Level 7 (HL7) International, www.hl7.org

[2] SNOMED International, www.snomed.org

[3] Logical Observation Identifiers Names and Codes (LOINC), www.loinc.org

[4] Digital Imaging and Communications in Medicine (DICOM), www.dicomstandard.org

[5] World Wide Web Consortium (W3C), www.w3.org

[6] Organisation for the Advancement of Structured Information Standards (OASIS), www.oasis-open.org

[7] Internet Engineering Task Force (IETF), www.ietf.org

[8] Institute of Electrical and Electronics Engineers (IEEE), www.ieee.org

[9] Integrating the Healthcare Enterprise, www.ihe.net

[10] Personal Connected Health Alliance (PCHA) www.pchalliance.org

[11] International Organisation for Standardisation (ISO), www.iso.org

[12] European Committee for Standardisation, www.cen.eu

[13] National Institute of Standards and Technology US, www.nist.gov

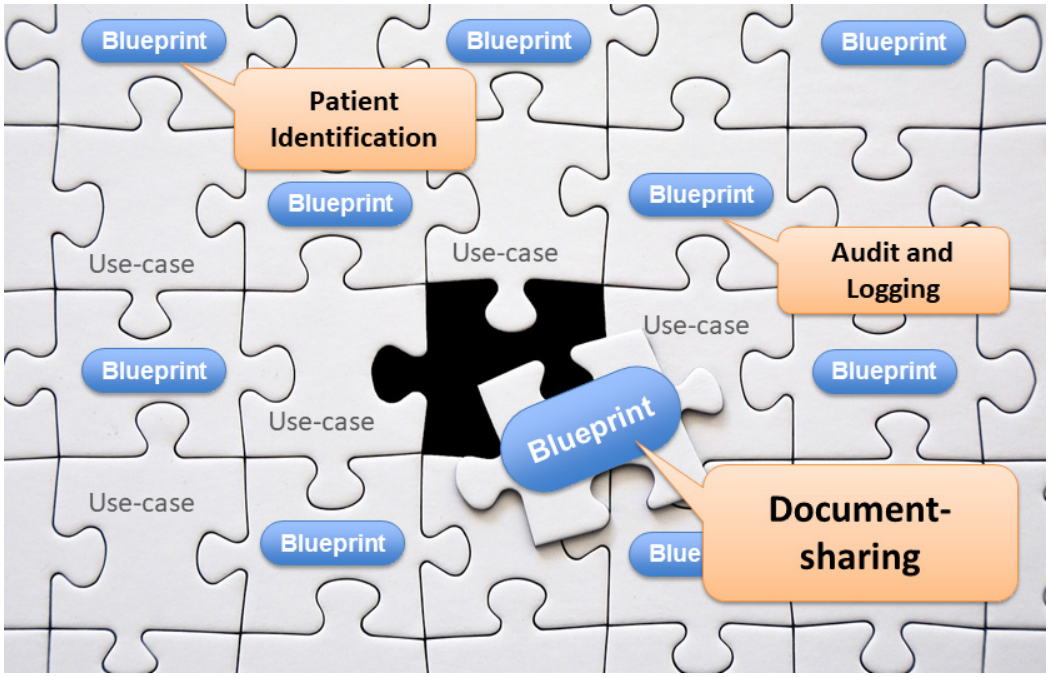
This document explains the basic principles of interoperability and the standardisation process, highlighting in particular the functions and roles of two major standardisation organisations, **IHE** and **HL7**, as well as the position and resulting implications of the upcoming HL7 **FHIR** standard.

2.1 The "global" standardisation process in health informatics

Section 3 ("Foundations of interoperability") of this document describes the standardisation process of use cases in health informatics which has three levels that build on one another and are ideally undertaken in the following sequence:

1. **Developing the base standards**
2. **Profiling the standard for particular communities**
3. **Driving solutions into production in the market**

For use cases that target the "global market", feedback and harmonisation cycles need to be added to the standardisation process described in order to achieve a ***global blueprint for a particular use case.***



A ***global blueprint*** applies if **a particular standards-based solution of an interoperability use case** is eventually recognised as "best practice" because the solution is widely used and there are already a number of products for it, forming a **competitive market**.

A *global blueprint* **includes everything that is "shared or common"**, but still allows room for the respective **national/regional features**.

Of course there may be several such solutions for one use case, in which case a convergence into one solution should be sought.

For instance, of the two competing blueprints for connecting devices to a computer - USB and Firewire - the USB standard eventually emerged as the final *global blueprint* for this interoperability use case.

The development of *global blueprints* must absolutely be pursued in health informatics as well because **use cases in health informatics are very similar across the world** and there is tremendous potential for "global harmonisation" within each use case. Naturally, the interoperability use cases in health informatics are incomparably more complex than in the case of USB and, due to the large number of stakeholders involved (health service providers, legislators, the public sector, vendors, etc.), are also not easy to resolve with an industry standard.

It is therefore a difficult and potentially quite arduous process to attain a *global blueprint.* However, at times when national or even cross-border health data exchange infrastructures are being set up, the potential of these kinds of global solutions must be pursued and utilised because the global market gained through them signifies vendor independence, competition and thus **lower costs and greater sustainability**.

2.2 "National" / project-specific standardisation during implementation

The *global blueprints* mentioned in the previous section are extremely important in ensuring low costs and sustainability because they cover large areas that can be solved uniformly at the international level. This is an invaluable advantage, yet they cannot be applied 1:1 to national eHealth projects because projects of this type generally have to implement more or less national specialities or features.

Thus *global blueprints* generally have to be adapted to the national situation.

This is done in the following steps:

1. Harmonisation of the national situations taking the preliminary global work into account

2. Transfer of these situations into national “interoperability specifications”; these are based on the global blueprints and standards but restrict or expand them further to reflect the national situation.
3. The systems and the test concept are then put out to tender on the basis of these national “interoperability specifications”.
4. Procurement of the systems, testing and deployment

IHE has added volume 4, “National Extensions” to its “Technical Frameworks” in order to include the experience gained from these national specifications. It can be used on a voluntary basis by countries to publicly show others the additions they have made to the standard. This does not expand the underlying IHE profile itself, but it may still be helpful to later countries as a template.

One concrete example is the electronic patient record (EPR) in Switzerland; in the course of its development, the Federal Office of Public Health (FOPH) carried out the further specification work on the Swiss implementation guidelines in cooperation with eHealth Suisse. This was done in collaboration with – and providing feedback to – IHE and HL7, an established method for further improving the base standards in the light of experience from real projects.

Austria and France, for example, took the same approach, the former in the specification of its national eHealth infrastructure (ELGA), the latter for its national specification for laboratory results on the basis of the IHE XD-LAB profile.

2.3 IHE, HL7 and FHIR

In subsequent sections, this document describes the allocation of roles and responsibilities between the two organisations IHE and HL7 in the above standardisation process as well as the changes that are being prompted by the new upcoming HL7 FHIR standard.

The conventional assignment of responsibilities ...

- HL7 at
    - "Level 1: Development of the base standards" and
- IHE at
    - "Level 2: Profiling the standard for particular communities" and
    - "Level 3: Driving solutions into production in the market"

… is becoming less clearly defined with increasing overlaps due to the implications of the FHIR standard.

HL7 and other organisations and even other projects with a broad, international impact are now also starting to operate at Level 2 "Profiling". This is causing a degree of confusion on the market about the responsibilities and core competences of the individual organisations and obstructing a coordinated approach to achieving *global blueprints.*

Furthermore, the hype surrounding FHIR is contributing to increased promises of "simple solutions" with reference to the excessively complex standards that preceded FHIR, such as HL7v3 Messaging and CDA. However, these promises often cannot be kept because the complexity is inherent to the processes and "*does not disappear just because of a new standard*".

All of this poses a problem because the above described message of the need for *global blueprints* (with the concomitant sustainability) and how to achieve them has in many places receded into the background again.

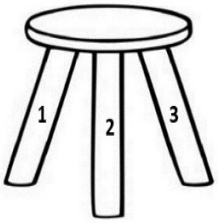
The **organisations IHE and HL7** and others who have identified this as a problem are now **working to counteract** this development (see Section 7, “Solutions and reorientation"). Their aim is to jointly counter the challenges and realign and reposition themselves so that the core competences of both organisations can become optimally effective.

3 Foundations of interoperability

3.1 The three levels of the "global" standardisation process

The health informatics standardisation process consists mainly of three levels that build on each other (see Grahame Grieve's blog "The 3 Legs of the Health Informatics Standards Process"):

1. **Developing the base standards**
2. **Profiling the standard for particular communities**
3. **Driving solutions into production in the market**



These three levels can be viewed as a basic structure for achieving interoperability, i.e. the theoretical pathway to a blueprint for a market. Further feedback and harmonisation cycles within these three levels are usually still needed before a solution is recognised in a market and then emerges as "best practice" and therefore a blueprint in this market or region.

If the target market of the standardisation process is the global market (which it should be!) the solution resulting from this process is a *global blueprint*.

3.2 What is a global blueprint?

"Plug-and-play" is exceptionally rare in health informatics, however, the use cases in health informatics are mostly very similar across the globe.

Depending on the use case, the global level of congruence varies from "identical almost everywhere" (e.g. patient identification and querying, audit processes, etc.) to "identical in the core principles but significant differences in the content" (e.g. exchange of document types, etc.). A use case can therefore always be split into two parts, the areas that are "**globally identical**" and those that include "**national/regional features**". Generally speaking, however, every use case has a fairly large potential for "global harmonisation".

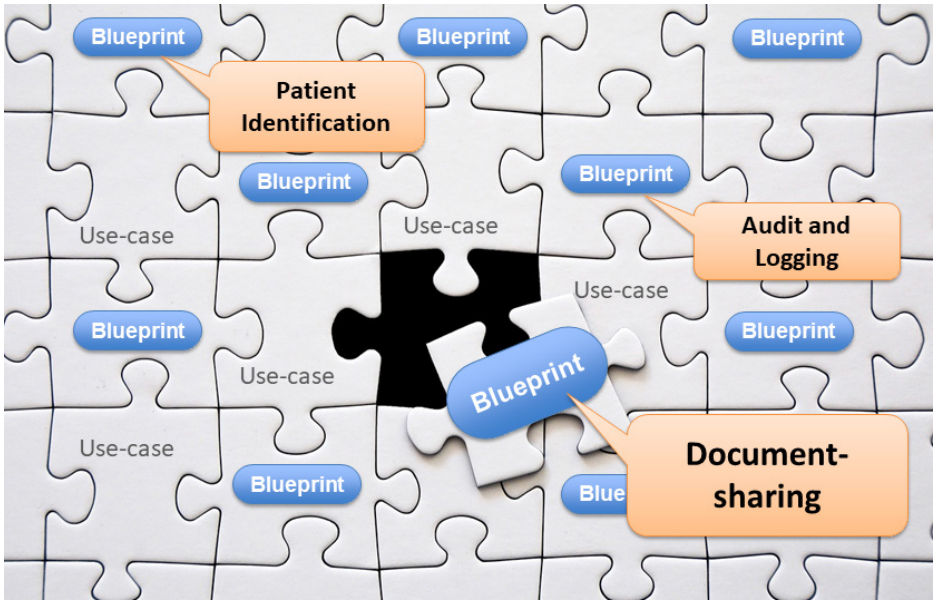
If **a specific standards-based solution for an interoperability use case** is finally recognised as "best practice" because it is widely applied and if a large number of products already exist for it on the market and the market is **competitive**, this is referred to as a ***global blueprint***. There may of course also be multiple solutions for each use case but in

the long term a convergence to a single solution should be sought or may take even come about naturally.

A *global blueprint* **includes everything that is "shared or common"** but still allows room for the respective **national/regional features**.

The use cases in eHealth are manifold, ranging from administrative processes (e.g. patient identification, etc.) to clinical processes (exchange of clinical documents or information, etc.).

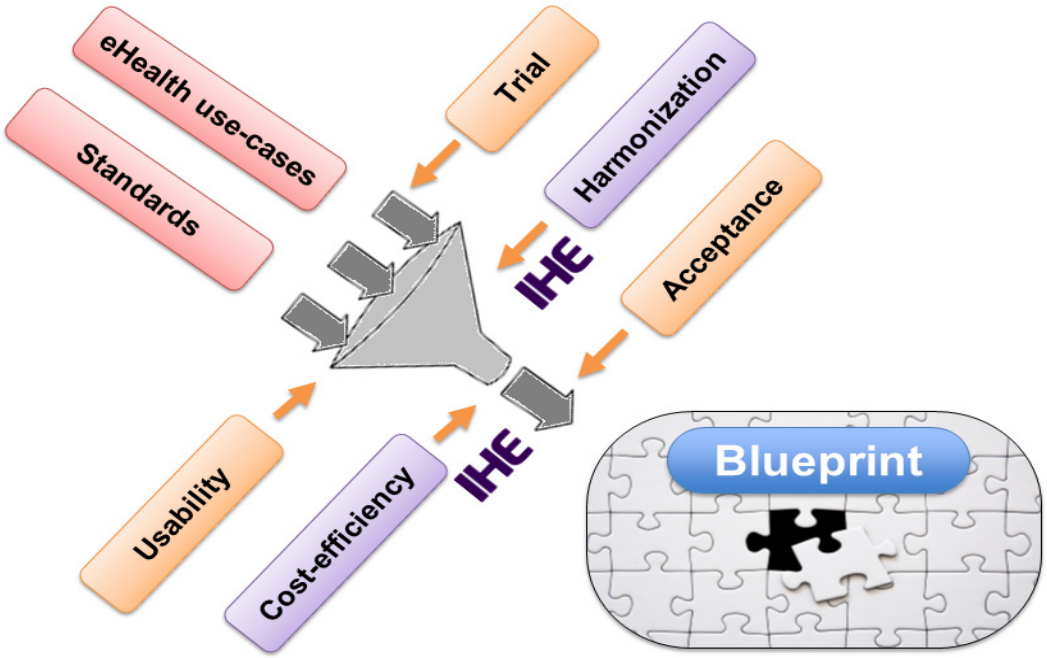
Many of these use cases are based on each other or depend upon each other. In the end, the aim is to develop *global blueprints* for all these use cases, that they be compatible with each other and supplement each other seamlessly.



3.3 How does a global blueprint come about?

The process of achieving a *global blueprint* is quite arduous and not easy. The pathway can be divided into several phases.

The following diagram shows the process from the initial attempts to resolve a use case (various "trial" developments), via the phases in which best practice emerges from global trials (usability and harmonisation) to global acceptance of this solution as the *global blueprint* due to its production maturity and the existence of a competitive market (cost-efficiency and acceptance).



It is evident that the individual phases of this pathway require a certain amount of time to mature and to be run through in an orderly way. While the process can be accelerated through appropriate measures, a substantial amount of time is nevertheless required, otherwise the necessary level of acceptance which ultimately confirms it as a *global blueprint* will not be attained. As a rule it takes several years to achieve this at a global level.

Of course, the appeal being made is not for the whole world necessarily to agree on one solution. Nevertheless, the larger the group, the greater the benefit. And naturally, there may also be several solutions in parallel because continuous development and innovation will repeatedly produce new blueprints:

- either as a more modern solution **for already existing** use cases
  - example: USB 3.0 replaced USB 2.0, same purpose but better
- or **for new use cases** for which a blueprint is developed for the first time
  - example: NFC which made wireless near-field communication possible between mobile phones for the first time

3.4 Why is a global blueprint so important?

Global blueprints are important because the global commonalities are not only captured during the development of the use case but also increased by the global harmonisation effort. The work on the *global blueprint* therefore causes the use case to be solved in a "more

standardised" way at a global level. This presents the potential to solve the challenges **"once and for all"** (or get as close to this as possible).

This, in turn, leads to considerable positive consequences and possibilities. On the one hand, the existence of a blueprint makes writing specifications for a project significantly easier **because the basic solution has already been developed** and large parts of the specification can be copied and pasted[14] from other projects ("borrowed community competence"). On the other hand, the "global market" opened up by a *global blueprint* brings with it vendor independence and competition which ultimately means **faster implementation, lower costs and sustainability**.

A *global blueprint* results in time savings and cost reductions in the following areas:

- **Generating acceptance for the solution among all project participants**
  - In national projects, for example, this is a laborious process which is considerably easier if it is possible to refer to a *global blueprint*
- **Writing the project specifications**
  - This can be done much more quickly because large parts of the specification already exist. Only the project-specific features now have to be added
- **Tendering and procurement**
  - Tenders are considerably less complex and proposals can be compared more easily and more quickly
  - Products are less expensive because the *global blueprint* creates a competitive market with comparable "off-the-shelf" products → instead of customised ones
- **Rollout and testing**
  - *Global blueprints* permit a large part of interoperability testing to be covered at the blueprint level ("IHE Connectathon"), thereby minimising the need for project-based testing (project-specific "Projectathon")
  - This is a large cost factor -> savings in this area, even if only of a few per cent, usually make a big financial difference.

[14] This means that large parts of the solution can be adopted

3.5 Do any global blueprints already exist?

Global blueprints in health informatics exist already, for example for the exchange of clinical documents. These blueprints are widespread and well-recognised thanks to the IHE profile family for cross-document sharing (XDS) including the associated profiles for patient identification (PIX/PDQ) and auditing (ATNA).

In order to achieve solutions of this kind, however, a sufficient number of global participants are required to attain the concomitant and requisite level of "global harmonisation". Furthermore, it is a **fully collaborative process** because the participants must come from both the user side and the vendor side. This naturally involves a large amount of work but it is essential to strive for this process because the potential opened up when national or even cross-border health data exchange infrastructures are established must be utilised.

For example, the European Commission made use of existing *global blueprints* when designing its specifications for the European **eHealth Digital Service Infrastructure (eHDSI)**[15] for the exchange of health data between EU member states (formerly the epSOS project). These were the recognised and proven IHE data exchange profiles in the IHE IT infrastructure domain.

As regards the extension of the eHDSI, **the EC Recommendation on a European Electronic Health Record exchange format**[16] adopted in February 2019 also relies on best practices already proven in these areas:

- Exchange of discharge reports,
- radiology results and
- laboratory results.

[15] European Commission, eHealth Digital Service Infrastructure, https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHealth+DSI+Operations+Home

[16] EC Recommendation on a European Electronic Health Record exchange format: https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

Furthermore, *global blueprints* can be included in **investment plans and procurement catalogues**. For example, the IHE profiles in the EU Recommendation

> *"COMMISSION DECISION (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement"* [17]

were included in the

> *European Catalogue for ICT Standards for Procurement*[18].

[17] European Commission recognises 27 IHE profiles that should be referenced in public procurement documents: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_199_R_0011

[18] https://joinup.ec.europa.eu/collection/ict-standards-procurement/identified-ict-specifications-procurement

4 The IHE and HL7 organisations

This section describes the vision, mission and conventional assignment of responsibilities between the standardisation organisations IHE and HL7.

4.1 Congruent visions, different missions

The visions of the HL7[19] and IHE[20] organisations are almost identical:

HL7	A world in which everyone can securely access and use the right health data when and where they need it.
IHE	Enable seamless and secure access to health information that is usable whenever and wherever needed.

Their missions to achieve these visions, however, are different. **HL7** focusses on "**standards**" and **IHE** on "**specifications, tools and services**":

HL7	To provide **standards** that empower global health data interoperability.
IHE	IHE improves healthcare by providing **specifications, tools and services** for interoperability. IHE engages clinicians, health authorities, industry, and users to develop, test, and implement standards-based solutions to vital health information needs.

4.2 Conventional assignment of responsibilities

As shown in Section 3.1, "The three levels of the "global" standardisation process", the conventional assignment of responsibilities between the two organisations is as follows:

HL7	Level 1 "Basic standards"
IHE	Level 2 "Profiling" (IHE profiles) and

[19] https://www.hl7.org/about

[20] https://www.ihe.net/about_ihe

	Level 3 "Deployment" (testing at the IHE Connectathon and IHE Services[21])

However, this conventional interplay is being increasingly realigned in response to the publication of FHIR. HL7 (and other organisations) are now also operating at level 2 and have level 3 in their sights too.

In this context, a number of occurrences in recent years have repeatedly overshadowed the generally friendly collaboration between the two organisations. For more information on this, see Sections 6, "Problems and challenges" and 7, "Solutions and reorientation".

The conventional assignment of responsibilities detailed above should generally be understood as only a rough orientation. In practice some of the responsibilities were always assigned differently for a number of reasons, mainly in the regional context.

For example, in areas or countries in which things were done differently as a result of long-standing organic structures (e.g. SMART[22] in the USA, which was then continued in SMART-on-FHIR[23]), or in which one of the organisations was not represented and the responsibilities were taken over by other organisations (e.g. countries with no IHE representation).

4.2.1 What is HL7?

HL7 is a non-profit health informatics standardisation organisation which has been writing and publishing standards since 1987. Originally founded in the US, HL7 is now operating as a standards body at international level. Although HL7 standards were previously not free of charge, they have been available for free in recent years.

Well-known HL7 standards include...

- the text-based **HL7v2 messaging standard** which is extensively used mainly in intramural communication between systems.
- the XML-based **HL7v3 RIM** ("Reference Information Model") which was developed on the basis of HL7v2 to serve both message-based and persistent communication.

[21] IHE Services is IHE Europe's operative unit. It offers consulting and testing services relating to IHE. See https://www.ihe-europe.net/deployment/IHE-Services

[22] https://smarthealthit.org

[23] https://docs.smarthealthit.org

Apart from a few exceptions, HL7v3 messaging was not able to establish itself and therefore failed to replace HL7v2. The HL7v3 RIM model was regarded as very powerful but also very complicated and difficult to understand and implement.

- **CDA ("Clinical Document Architecture")** which is based on the HL7v3 RIM model and was developed to encode clinical documents. Combined with, for example, the IHE XDS ("Cross-Enterprise Document Sharing") profile family, the standard has proven itself as suitable for the cross-regional exchange of clinical documents (at regional or national level, i.e. cross-border) and is used in this way.
- **FHIR ("Fast Healthcare Interoperability Resources")** is a completely new development. FHIR describes data formats and elements as resources and offers an interface (API) for their exchange. It has a strong focus on easy implementability. FHIR uses contemporary web-based API technologies, such as the HTTP-based RESTful protocol, HTML, TLS and OAUTH2. Both JSON and XML can be used for data representation.

4.2.2 What is IHE?

Integrating the Healthcare Enterprise (IHE) was founded in the US in 1998 and is a global non-profit eHealth initiative. It is dedicated to improving interoperability in health care informatics.

IHE works with users and vendors on **frequently required eHealth interoperability use cases** to create globally acceptable, detailed and **standards-based specifications**.

Furthermore, IHE supports the use of these profiles through an **open-source test platform** and a **product conformity assessment**.

eHealth interoperability use cases are very similar across the world. IHE's contribution lies in ensuring that these global commonalities are identified in the standards community before they serve as the basis for certain markets or implementations and are potentially supplemented in order to meet local requirements.

IHE profiles the use cases to the largest possible degree of global commonality (around 80-90%, depending on the use case) while making sure to leave the remaining areas undefined. Apart from very few exceptions, the context of the profile users still requires

special adjustments in the remaining percentage range, such as special terminology or data elements, to complete the user's interoperability specification.

This interoperability specification then fully covers the use case in the respective context, as a national specification, for example. These national extensions can then be published in the IHE (Technical Framework, volume 4) for use as a template by other countries.

Users of IHE profiles now only have to **define specific deviations from the profile** when writing their interoperability specifications.

IHE contributes the international profiling work and the coordination of the "global shared part" for the common good, leading to considerable savings in effort for the users of the profiles, who now only have to define specific deviations from the profile.

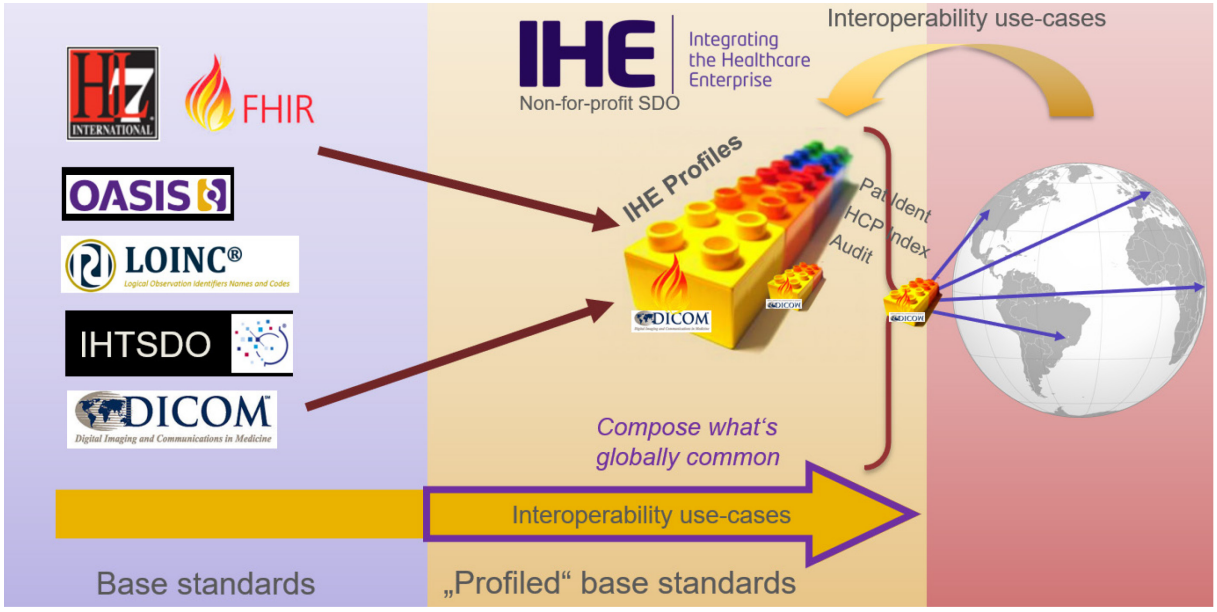
The resulting cost savings are massive, particularly for large businesses. These include ...

- … the creation of interoperability specifications,
- ... the effort of issuing tenders and reviewing them,
- … the required project-specific changes to finished products developed on the basis of the profiles and
- ... the testing process.

The reduction in testing effort is particularly significant in terms of cost efficiency because these costs accrue not only from initial testing before the product launch but throughout the entire duration of the project (onboarding of new participants).

IHE profiles are freely accessible and free of charge. HL7 standards are often used in IHE profiles and, depending on the interoperability use case, other standards are also used, such as DICOM, SNOMED, LOINC, W3C, OASIS, etc.

The following diagram illustrates the Lego building block principle applied in the IHE profiling process which results in standard building blocks to suit the respective use cases.



IHE profiles are designed to complement each other and can, if required, be used in combination to encode more complex use cases. For example, patient identification may be combined with health service provider authentication and a suitable audit/logging function in order to share clinical documents, with all the other use cases that require these basic components using the same building block (e.g. an "audit/logging" building block for all use cases).

Products have already been developed to the point of market maturity using many IHE profiles and are now globally in use (especially in the IHE domains of IT infrastructure and radiology).

5 Collaboration between IHE and HL7

The two organisations have been working together well in the areas conventionally assigned to them for years.

IHE and HL7 have had a "statement of understanding" to mutually support and collaborate with each other for many years. It was renewed as recently as 2018, attesting to the strong and friendly ties between these two organisations.

Even though the organisations are separate and their memberships are different, a number of the people in voluntary standards development are active in both the organisations. Thanks to this personal involvement, collaboration in some areas is even closer.

For example HL7v2, HL7v3 and CDA are HL7 standards that are very often used in IHE profiles. FHIR is also being applied in many IHE profiles; a fact that is not well known. In fact, the majority of new IHE profiles use the FHIR standard. In addition, FHIR-based extension and enhancement profiles are continuously being created for established IHE profiles which use the conventional standards. For more about this see Section 5.2, "FHIR-based IHE profiles".

5.1 The dynamics of HL7 FHIR

FHIR has succeeded in getting a community of young developers excited about standardisation technology.

The ongoing development of the FHIR standard is highly contemporary, tool-driven and therefore attractive to the community. This leads to faster and higher quality standards development and is one of the reasons for FHIR’s success as a standard.

In recognition of this, HL7 has almost entirely moved across to the FHIR standard and the majority of all its current activities refer to it.

The FHIR standard is still being developed, and but with each adopted version, the number of areas already regarded as "normative" increases and the remaining areas also continue to gain stability.

5.2 FHIR-based IHE profiles

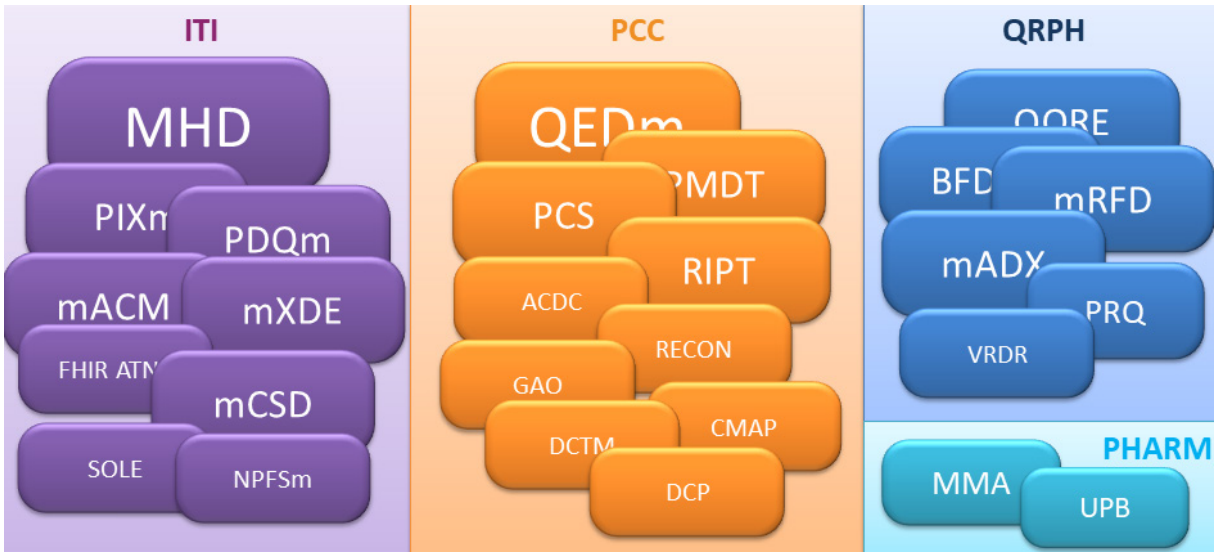
At the time of writing this report, 34 FHIR-based IHE profiles have been implemented. They were published in accordance with the FHIR Implementation Guides on the fhir.org website.

Overview of IHE profiles: https://wiki.ihe.net/index.php/Profiles

(FHIR-based IHE profiles are marked with an FHIR icon)

FHIR IG overview on fhir.org: http://www.fhir.org/guides/registry

To date, FHIR-based IHE profiles have been implemented in the IHE domains ITI, PCC, RAD, QRPH and PHARM. Initially, FHIR-based IHE profiles were created as supplements to existing IHE profiles (e.g. FHIR-based access to patient data via PIXm and PDQm or FHIR-based access to XDS-based document exchange via MHD).



As a rule, it could be said that at present new IHE profile uses cases very frequently use the FHIR standard because it is regarded as a modern and efficient standard that has the potential to replace the existing standards in the long term.

One fundamental difficulty with the profiling of FHIR was that, for a long time, the status of the standard was not stable. The first normative version, FHIR Release 4, was only adopted recently[24], with approximately 3,000 changes[25] (of which > 1,000 were substantial) being made between R3 and R4 alone. The situation has therefore improved greatly but the standard can be expected to remain in flux for some time yet.

This is essentially at odds with IHE's principle of only using "existing", established and proven standards in its IHE profiles in order to ensure the appropriate level of stability in

[24] This means that this version of the standard passed a "normative ballot" for the first time

[25] Source: http://hl7.org/fhir/history.html

products. Due to the great demand for FHIR on the market, however, IHE nevertheless began creating FHIR-based IHE profiles quite early on and continues to update these with each release of FHIR.

6 Problems and challenges

This section describes various existing or new problems and controversies that were caused or exacerbated by FHIR.

The two organisations IHE and HL7 are already working together to jointly address all the issues mentioned.

6.1 FHIR launches the "digitalised" development of standards

Standardisation itself has been "digitalised" by FHIR, and this has had a corresponding impact on the documentation of the standard and on testing too. HL7 Implementation Guides enable content profiles and APIs to be documented as a website and the artefacts generated from this (e.g. as "JavaScript Object Notation" - JSON[26]) to be tested directly.

This point is important less from a strategic than from a practical viewpoint since this new option is having a tremendously positive impact. Apart from the faster implementation of the FHIR standard in products, it is also making the work done by the standardisation community considerably easier and is generating interest and a positive attitude to standards both within the community and among software developers.

In the IHE, the IHE Technical Frameworks / profiles use PDF-based documentation and are facing the challenge of still having to take this digitalisation step. The digital possibilities introduced by FHIR are of course already being used in the IHE to develop FHIR-based profiles, but PDF documentation is still the only form of documentation available in the IHE for many content profiles (especially for CDA-based content profiles). Equally, feedback and public commenting processes are not (yet) handled using digital tools. Here IHE is being forced to begin rapidly modernising its processes.

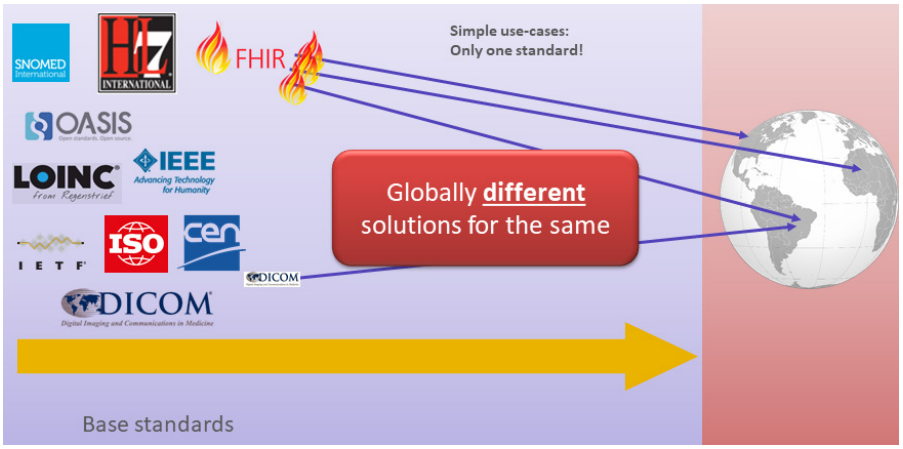
6.2 FHIR helps vendors to create fast <u>but also</u> proprietary solutions

Vendors have always had the option of drawing on any given standards without coordination or governance to implement their own communication solutions in their products. This happened back in the 1990s with the HL7v2 and DICOM standards which meant that, even

[26] https://www.json.org

though products by different vendors were "based on the same international standard", they were not interoperable. This situation prompted the founding of IHE with the aim of preventing precisely this phenomenon on the market. With many years of profiling and persuasion efforts by IHE, this unsatisfactory situation was mitigated for countless important interoperability use cases on the market.

Thanks to the simplicity of FHIR, this practice has again become attractive to vendors. Driven by innovation and commercial pressures to get to market quickly, start-ups and established companies are taking shortcuts by implementing their own FHIR-based communication solutions without coordinating with others. This, in turn, results in increasing duplication, proprietary solutions and thus siloed applications which can only be combined with other systems with additional effort and interfaces.



This approach, which does not include the coordination and profiling of the use case within the standards community, has to be regarded as problematic from a standardisation perspective. Even though these companies are ostensibly trying to promote interoperability (and even applying international standards), they are actually working against standardisation in the long term.

However, solutions like this can also be viewed positively because a “trial” phase is necessary to produce a blueprint (see Section 3.3, “How does a global blueprint come about”). As long as the step of global harmonisation towards a “blueprint” is not forgotten, developments of this kind can certainly be seen as necessary preliminary activities, with their “best-of-breed” providing the basis for a *global blueprint*.

6.3 Overlaps in the fields of activity of HL7 and IHE brought about by FHIR

In terms of HL7's fields of activity and influence, the great success (and hype) of FHIR and its technical simplicity and tool-based development opened up options for courses of action that were previously unavailable, namely in the areas of profiling and testing. Both were originally the sole domain of IHE.

This expansion of HL7's field of activity shook up the conventional assignment of responsibilities and initially caused some controversy between the IHE and HL7 organisations, but ultimately resulted in a realignment and greater collaboration (see Section 7, "Solutions and reorientation").

6.3.1 Profiling the standard for use cases

In the course of the development of the FHIR standard, HL7 also introduced the concept of the "FHIR Implementation Guides" (FHIR-IG)[27] which refer to an interoperability use case and thus are very similar to the IHE profile in terms of purpose. For HL7 this means a step into the area of profiling, although the governance offered by the FHIR-IGs does not go as far as that of an IHE profile and there are other limitations such as the fact that an FHIR-IG only refers to the FHIR standard while an IHE profile is not necessarily bound to FHIR and may combine any number of standards.

In contrast to the IHE profiles, FHIR Implementation Guides can be created by anyone and are therefore not necessarily subject to HL7 governance and quality guidelines. There are also several different platforms on which an FHIR Implementation Guide can be published, including HL7 itself (HL7 FHIR-IG Registry[28]) as well as commercial providers (e.g.: Firely Simplifier[29], etc.).

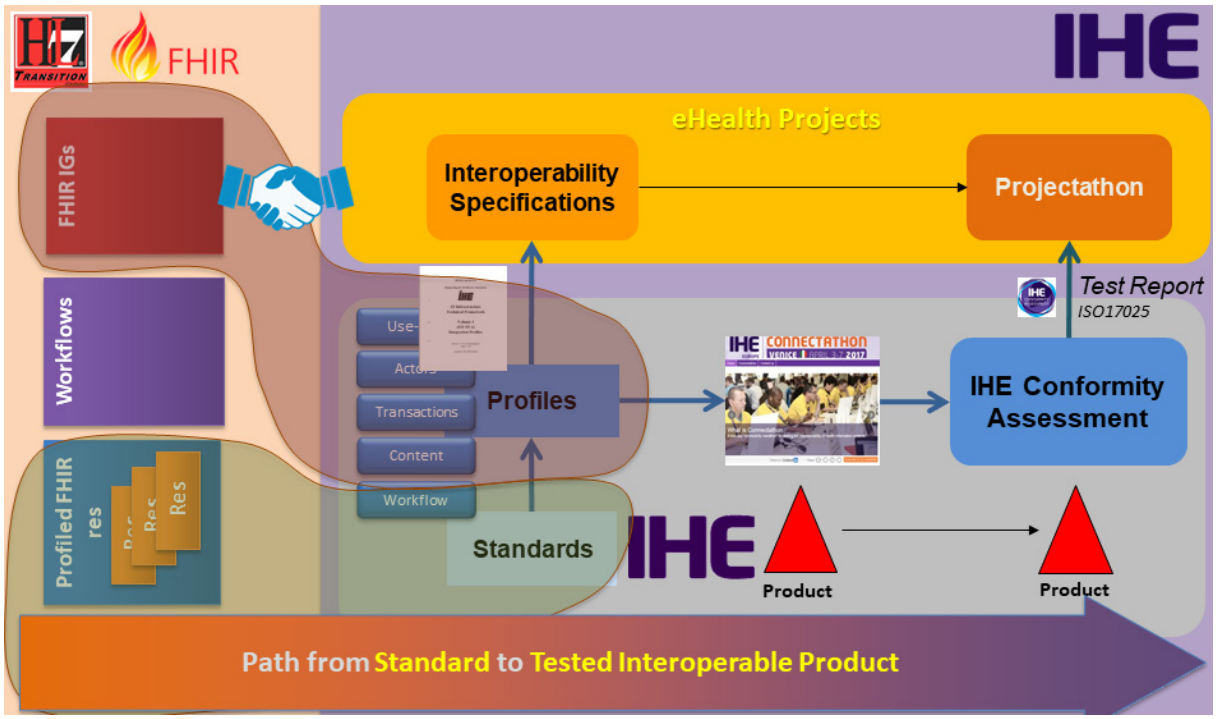
To counter the negative effects of this lack of regulation, HL7 recently launched the "FHIR Community Process" (see Section 7.3).

The following diagram shows the theoretical pathway "from standard to tested, interoperable product":

[27] http://wiki.hl7.org/index.php?title=FHIR_Implementation_Guides

[28] http://www.fhir.org/guides/registry

[29] https://simplifier.net/guides



On this "pathway from standard to tested, market-ready, interoperable product", a FHIR-IG is therefore the end point on the HL7 side, with an IHE profile being the starting point for the other processes in the chain, i.e. software testing at the IHE Connectathon, followed by the product conformity assessment to ensure that the product is market-ready.

The joint IHE/HL7 Gemini project was launched in 2018 to ensure that this pathway does not end with the FHIR-IG but that the process continues to the point of market-ready, tested products (if accepted on the market, this is, in effect, a *global blueprint*) (see Section 7.2).

6.3.2 Testing

The tool-oriented development of FHIR also permitted HL7 to enter the area of software testing, another domain that was previously covered only by IHE.

Organisations close to HL7 and FHIR set up testing events, such as the FHIR DevDays[30] held by a commercial provider and the FHIR Connectathon[31] organised by HL7. Both these events are located in the area of development and prototype testing, with a main focus on mutual "teaching, learning and sharing".

[30] https://www.devdays.com

[31] http://www.hl7.org/events/fhir-connectathon/index.cfm

The introduction of the latter, the FHIR Connectathon, caused some confusion on the market due to the similarity of its name to the IHE Connectathon even though the event has a completely different focus.

For a detailed list of IHE and HL7's various testing events and their respective purposes and target audiences, see Section 7.4, "IHE and HL7 testing events for FHIR".

6.4 FHIR enables other parties to profile too

Thanks to the simplicity of FHIR and the fact that anyone can produce FHIR Implementation Guides without restriction, organisations other than HL7 have also started to publish FHIR IGs.

Examples in the USA include the Argonaut[32] and DaVinci[33] projects which are industry initiatives with the corresponding levels of funding and broad exposure. They cover a wide variety of use cases but do not claim to be "global" as they are focussed on the US market. Nevertheless these initiatives are globally visible and serve as templates for national specifications in many countries. As a result, there may be "replicas" of these specifications in other countries but without the corresponding global coordination.

Of course, the fact that work continues on interoperability even outside standardisation organisations is to be viewed as positive.

However, from the perspective of the aspiration to harmonise "one" generally accepted *global blueprint* (IHE profile / FHIR Implementation Guide) at a global level (if possible) for each interoperability use case, it is problematic if these initiatives act in complete isolation from the standards community.

HL7 is addressing this by working with these initiatives and including them in the HL7 community to create the preconditions for global harmonisation. Due to the simplicity of FHIR, however, these types of projects are emerging in all directions and will, if they are not embedded in the community, continue to change the conventional assignment of responsibilities set out in Section 4.2.

[32] http://argonautwiki.hl7.org/index.php?title=Main_Page

[33] http://www.hl7.org/about/davinci

The FHIR Community Process (see Section 7.3) must also address and channel these kinds of initiatives and be extended in future to include further measures to minimise this issue even more comprehensively (see Section7.5).

6.5 Misunderstanding: "FHIR or IHE" (comparing apples with oranges)

The large number of changes to FHIR, its great acceptance on the market and the new "profiling" and "testing" areas it has opened up briefly led to talk of "FHIR or IHE", thereby evoking the stubborn notion of competition between the two (which is not the case). This comparison is actually not even valid because FHIR is a standard and IHE profiles are a specification for the "application of standards" (including FHIR) for specific use cases.

The problem is further exacerbated because these kinds of statements mean that all other existing standards (DICOM, SNOMED, etc.) are not even considered, which is not correct.

However, there is a simple explanation for this misunderstanding: **IHE is often associated with "document exchange" and FHIR with "data exchange".** The following section explains why.

6.5.1 Fundamental misunderstanding IHE=documents, FHIR=data

The most successful group of IHE profiles by far are those of the XDS ("Cross-Enterprise Document Sharing") family in the ITI domain. Many large-scale implementations are already in operation and there is a large competitive market of products for these profiles. Even the cross-border specifications of the European eHealth Digital Service Infrastructure (eHDSI) for exchanging health data between EU member states (formerly epSOS) are based on this profile family.

While this is essentially positive, it resulted in the unintended side effect of some people associating the IHE organisation and its mode of operation exclusively with its most successful document-sharing profile family.

Although conventional document sharing is regarded as established and suitable for the existing processes in medicine, eHealth is moving towards data sharing which, in turn, is associated with the FHIR standard.

The resulting impression that IHE stands for document sharing (= old school) and FHIR for data sharing (= modern) is, as previously explained, not a valid comparison but rather a sentiment that is largely based on a lack of understanding of IHE and FHIR.

IHE profiled use cases based on data sharing principles even before FHIR came about (example: QED profile - Query Existing Data, etc.) and is, of course, continuing to do so now with the FHIR standard (see Section 5.2, "FHIR-based IHE profiles").

6.6 Misinformation and confusion on the market

All the developments mentioned in the previous sections resulted in significant misinformation and confusion on the market with regard to the distribution of roles between IHE and HL7 and how the development of standards will continue in the future.

A degree of polarisation took place between the contrary stand points that "IHE is the past and the present belongs to FHIR" and "The existing standards profiled by IHE, such as CDA, etc., are proven and IHE must continue to do the profiling. FHIR must first prove its ability to facilitate interoperability".

As a result there is uncertainty on the market about which standards to implement in a project, or whether the existing and proven standards can still be used for certain interoperability use cases or if this would then mean relying on "outdated technology".

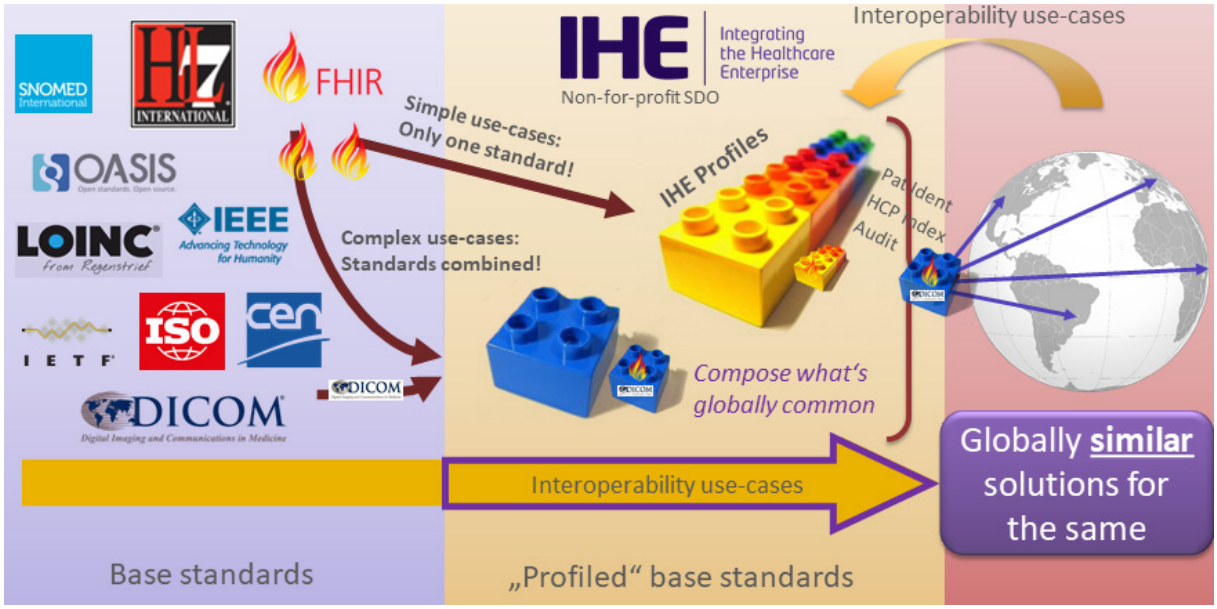
These misconceptions reached a peak in 2018 and were recognised as a problem by both IHE and HL7 who joined forces to introduce appropriate counter measures.

7 Solutions and reorientation

At the beginning of 2018 the issues and controversies discussed in the previous section became so obvious that both organisations felt the need to take action.

7.1 Profiling is still necessary, even with FHIR!

The first maxim jointly announced by the two organisations is that coordination and profiling of standards is necessary for successful, global interoperability, even in the case of FHIR. IHE and HL7 will in future work together in this regard to coordinate the now partly overlapping areas of "FHIR Implementation Guide / FHIR-based IHE profile" and to make the pathway from standard to tested, interoperable product seamless again (see Section 6.3.1, "Profiling the standard for use cases").



The "Gemini" project was launched as a first measure to this end.

7.2 "Gemini" project

The "***Gemini - A Joint Initiative of IHE and HL7 to Advance Use of FHIR for Interoperability***"[34] project is a joint initiative of HL7 and IHE on the topic of FHIR to address the challenges mentioned in Section 6, “Problems and challenges".

[34] https://confluence.hl7.org/display/GP/Project+Gemini

The initiative is driven equally and on an equal footing by the two organisations through a Joint Steering Committee consisting of three people each from IHE and HL7 which supports the collaboration of the various FHIR workgroups that already exist in the two organisations.

The aim is to achieve collaboration and synergies in the following areas:

- ***Area 1: Development and tooling of "FHIR-based IHE profiles"***
  - *FHIR-based IHE profiles remain under IHE governance, but participation and contribution of HL7 shall be encouraged (as well as participation of IHE in HL7)*
  - *This includes collaborative work, alignment of tooling, mutual notification of new work-items, etc.*
- ***Area 2: Publication of "FHIR-based IHE Profiles"***
  - *Align publication of FHIR Implementation Guides and FHIR-based IHE profiles by referencing FHIR-based IHE profiles on fhir.org*
- ***Area 3: Testing***
  - *Positioning of the current testing initiatives, such as HL7 FHIR Connectathons, IHE Connectathons, IHE Conformity Assessment and coordination of the test tooling ecosystem across both organisations*
- ***Area 4: Pilot projects***
  - *Identify, agree and execute joint IHE/HL7 pilot projects and demonstrations*
- ***Area 5: Joint Messaging and Marketing***
  - *Maintain joint messaging/marketing/education on HL7 FHIR and FHIR-based IHE profiles on fhir.org*

The Gemini initiative is a significant new communication channel between the two organisations with regular lively exchanges taking place at this level.

The following two projects have already been accepted as "Gemini projects", particularly in Area 4:

- ***Medical Imaging for Cancer Care***
  - *Seek to make incremental progress over the course of IHE and HL7 Connectathons to develop an interoperability solution built on FHIR and profiles*

- *HL7 work groups Health Care Devices, Image Integration and CIMI, IHE Patient Care Coordination*

- ***Computable care guidelines (CCG)***
  - *Develop CCG profile for workflow, content, actions*
  - *WHO, CDC, HHSC, IHE, FHIR collaboration*
  - *IHE Quality, Research and Public Health, HL7 working groups*
  - *See the following explanation videos:*
    - *CCG in 200 seconds: https://vimeo.com/347427025*
    - *CCG QRPH profile in 300 seconds: https://vimeo.com/356829962*
  - *Project wiki: https://wiki.ihe.net/index.php/Computable_Care_Guidelines*
- ***Device interoperability using SDPi+FHIR***
  - *Cooperation initiative between HL7 Devices WG and IHE Devices Domain to consolidate various device interoperability projects that are focusing on the use of HL7 FHIR or the upcoming IHE service-oriented device point-of-care interoperability (SDPi) technical framework.*
  - *See: https://confluence.hl7.org/pages/viewpage.action?pageId=66926431*

7.3 FHIR Community Process

To address the issues mentioned in Section 6.1, "FHIR launches the "digitalised" development of standards", HL7 is currently starting the "FHIR Community Process (FCP)"[35].

The aim of the FHIR Community Process is to direct all current developments with FHIR onto a specific governance track to minimise the disadvantages of complete development freedom. In this way, the involved parties who are seeking to solve certain use cases with FHIR should cooperate with each other and with other parts of the FHIR community in an orderly fashion with the aim of consulting, deriving reciprocal benefit and avoiding duplication. The outcome of this process is usually published FHIR Implementation Guides.

The objectives of the FHIR Community Process are as follows:

- To introduce a consistent and uniform overall approach to FHIR development for the community
- To permit a multiplicity of approaches to the development of FHIR sub-communities (which reflect different needs)

[35] http://wiki.hl7.org/index.php?title=FHIR_Community_Process

- To minimise incompatibilities in outputs and processes between the different projects (which naturally have overlapping and diverging aspects).

Under the FHIR Community Process, FHIR projects can be notified by members of the FCP (or non-members) who undertake to follow the FCP rules while working on them.

The FCP rules, for example, require that the licensing category of the project is precisely established (preferably Creative Commons Public Domain), that commenting on the project be permitted, that the extent and form of community involvement in the project be defined, and that the project development cycle is clear. The full set of rules can be found on the FCP website.

It is precisely the undertaking to observe the FCP rules in FHIR projects that should ensure that future FHIR developments can proceed with the necessary agreement and thus with the highest possible level of quality and efficiency.

7.4 IHE and HL7 testing events for FHIR

IHE and HL7 both offer testing events for FHIR which, however, differ greatly with regard to target audience and purpose.

While the HL7 testing events focus more on teaching, learning, sharing and development in order to bring the community together and to receive feedback on the FHIR standard, the IHE testing events are geared towards product market readiness.

The maturity of the application or prototype to be tested and the benefits sought for the programming team members to be sent therefore determine which of the testing events is most appropriate.

In terms of purpose and intended target audience, the matrix of the main testing events offered by IHE and HL7 is as follows:

<table>
<tr><th colspan="2">Teach, Learn, Share, Development</th><th>Prototype / Product</th><th>Final Product for Market</th></tr>
<tr><td>FHIR DevDays</td><td>HL7 FHIR Connectathon</td><td>IHE Connectathon</td><td>IHE Conformity Assessment</td></tr>
<tr><td colspan="4">Product Maturity </td></tr>
</table>

7.5 Future positioning of IHE, HL7 and further collaboration: Global Consortium for eHealth Interoperability

Following on from Gemini, the discussions between IHE, HL7 and HIMSS[36] that started in February 2019 have now resulted in the establishment of the "**Global Consortium for eHealth Interoperability (GCeHI)**"[37].

There is a great need for global, vendor-neutral, open and free interoperability standards. National eHealth projects including cross-border initiatives (see the European Union's eHealth Digital Service Infrastructure (eHDSI) or Trillium Bridge), are starting up everywhere and global government initiatives (such as the GDHP, "Global Digital Health Partnership"[38]) are increasingly trying to jointly solve eHealth challenges.

This highly strategic cooperation between the three organisations is intended to reflect this development by merging and using the respective core competencies.

The GCeHI enables national governmental authorities, health systems and their interest groups to use upcoming interoperability standards and the latest implementation guidelines in order to achieve better and lower-cost health outcomes by eliminating obstacles and providing fast, coordinated and efficient API-based interoperable standards.

With the aim of creating a global community, the Consortium is bringing together interest groups all over the world to exchange validated, scalable best practices for point-of-care interoperability in order to ...

- ... support the implementation of secure, usable and effective standards for health data
- ... accelerate the development and introduction of secure and open standard-based APIs
- ... define access for data exchange via APIs

[36] https://www.himss.org

[37] http://globalhealthinterop.org

[38] Global Digital Health Partnership (GDHP): www.gdhp.org

- ... facilitate the formation of implementation communities.

In the final configuration, all types of stakeholder should be able to become members of the GCeHI: **SDOs, ministries, eHealth agencies, health service providers, manufacturers, donor and development aid organisations, NGOs, …**

The intention is not for the Consortium to take over the work of the three founding organisations but to look after everything that is too big or too complex for each of the organisations alone.

The following specific work products will be implemented by the Consortium in future, to the extent that resources are available:

- **Standards Roadmap**
  - Agreed and prioritised roadmap for standard development
- **Global Interoperability Standards Guide**
  - Compilation of established and upcoming standards in health IT
- **Global Interoperability Dashboard**
  - Overview of successful interoperability projects and best practices
- **Regional Health IT Policy Guidance**
  - Relevant regional and national health IT strategies and programmes to provide assistance for other countries
- **Interoperability Measurement/Maturity Models**
  - Maturity models and measurement tools to measure the progress of interoperability activities
- **Global Interoperability Listening Sessions**
  - Exchange of ideas and priorities in health and technology policy
- **Shared use cases, best practices for implementation/deployment**
  - Compilation of use cases and best practices relating to implementation and deployment

The Global Consortium for eHealth Interoperability hopes that this collaboration between these three powerful players in standardisation will enable it to position itself as a partner for entities at a higher strategic level, such as **states (or cooperations between states)**, which are ultimately major users of interoperability standards in their national eHealth strategies.

One of the Consortium's visions is therefore coordinated and efficient **work on new standards, profiles and Implementation Guides**, or in other words the implementation of

the three levels of the standardisation process (see Section 3.1), **in cooperation with the "requesters" and subsequent "users"** of the standards.

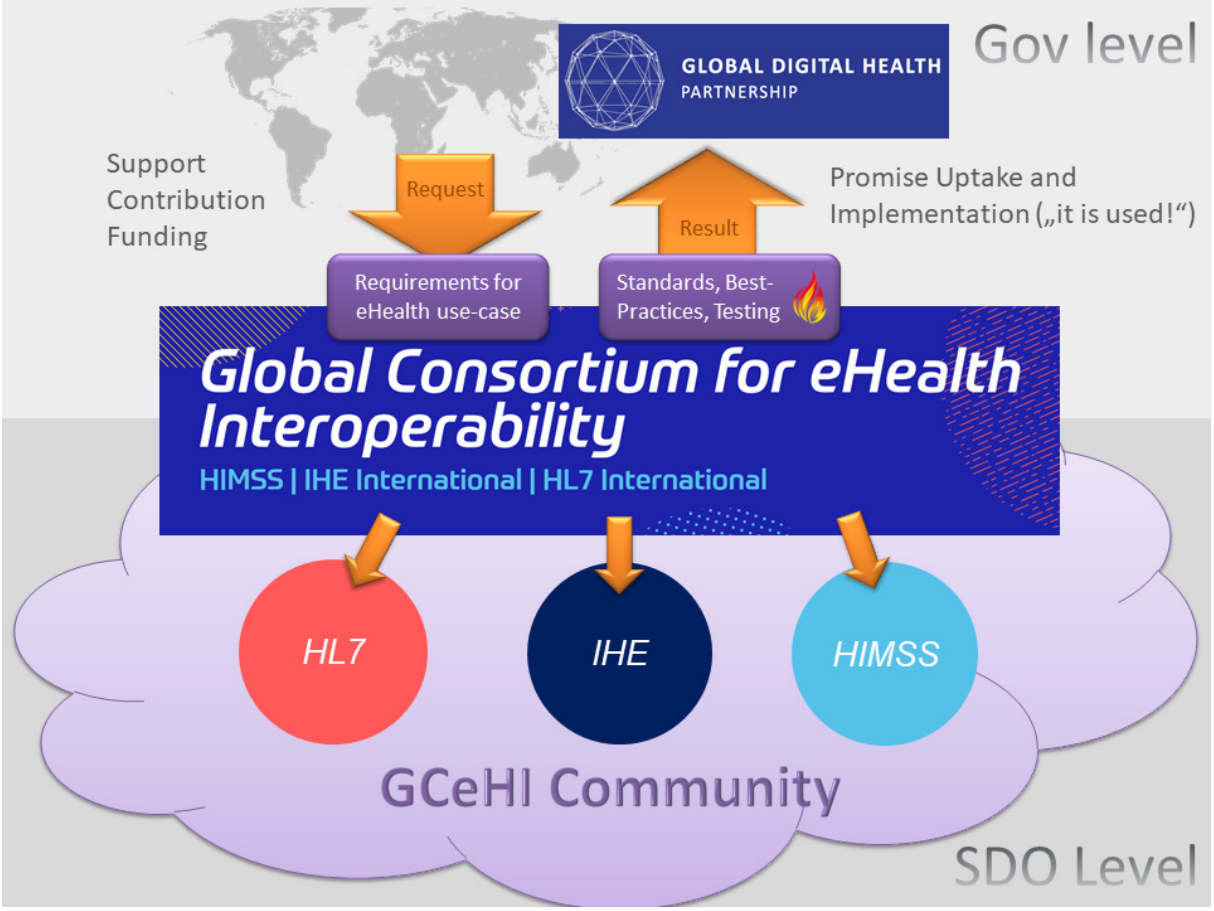
The aim here is to establish cooperation with ministries and institutions such as the Global Digital Health Partnership (GDHP) which are in a position to award the Consortium this type of strategic assignment. One example is the standardisation of a certain eHealth use case in case several GDHP member states would like to implement it and standards or best practices are not yet available.

Undertakings of this magnitude would be too big for each of the individual organisations, but would be feasible if they worked together – this vision was one of the reasons behind the successful foundation of this first-of-a-kind alliance.

In each case the Consortium would not do the work itself but would act primarily as a contact, coordinator and **distributor of work packages within the organisations**, for example in the following form:

- HL7: Work on the FHIR standard and profiling
- IHE: Profiling and development of test tools for deployment
- HIMSS: Distribution, training, certification, etc.

The Consortium is by no means intended to replace the individual founding organisations but rather to add a highly strategic point of access to the alliance.



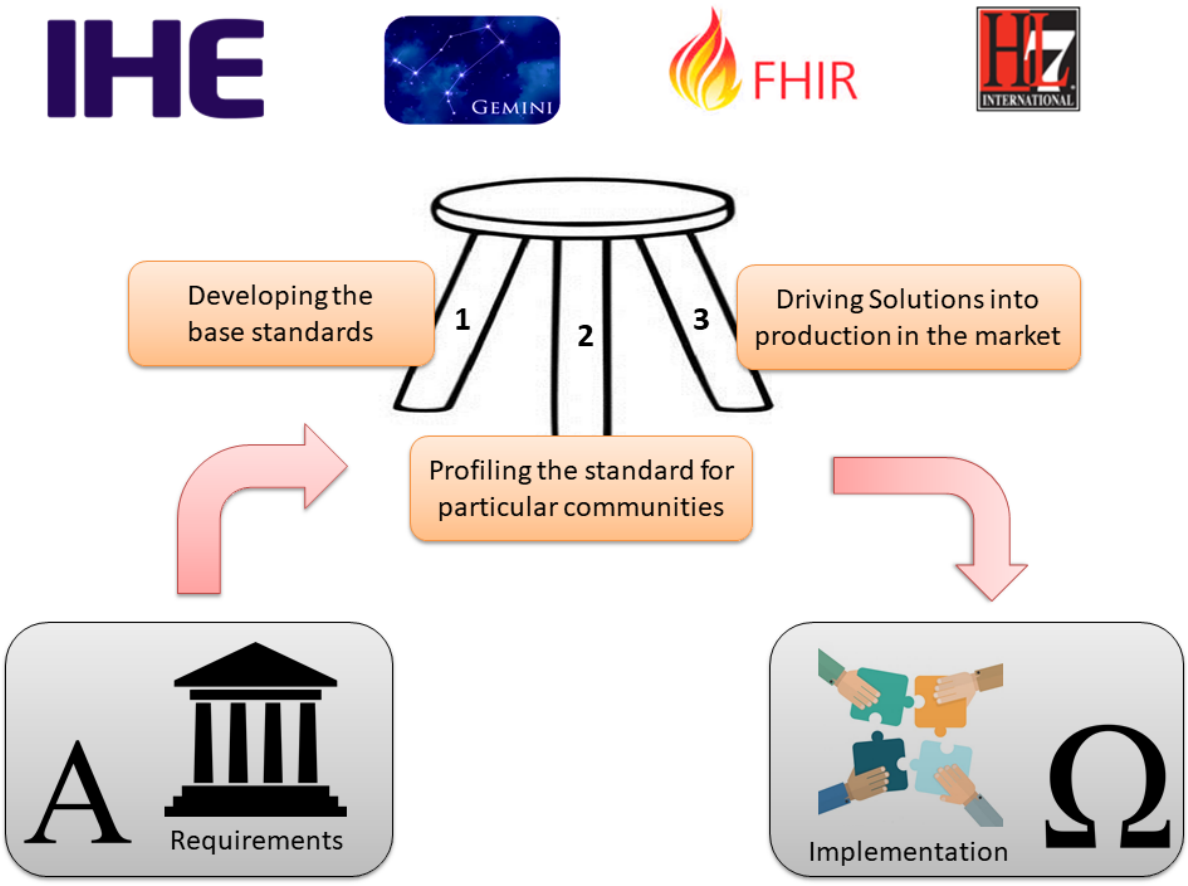
The actual standardisation work should be done in the same way as it has been up to now. In the past, standardisation work has tended to be successful when there were “real” projects behind the use cases that were being standardised.

This enabled standardisation to be done in a more **targeted** and **practice-oriented** manner, making it faster, more efficient and ultimately more useful too.

Switzerland, for example, made a substantial contribution to global standardisation in precisely this way during the work on specifying the medication plan in the electronic patient record. This work was done in cooperation with IHE Pharmacy.

The Consortium needs to create a way to allow the users of the standards to get involved at a high strategic level so that precisely this successful concept can develop positively on a large scale.

See the author's article for more about this: „The 4 aspects that change the game in eHealth Interoperability"[39]:



[39] Article "The 4 aspects that change the game in eHealth Interoperability": https://www.linkedin.com/pulse/4-aspects-change-game-ehealth-interoperability-j%C3%BCrgen-brandst%C3%A4tter

8 References

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- FHIR-based IHE profiles, published as FHIR Implementation Guides on fhir.org: http://www.fhir.org/guides/registry/
- Wikipedia IHE: https://de.wikipedia.org/wiki/Integrating_the_Healthcare_Enterprise
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HL7

- HL7 International: https://www.hl7.org
- Wikipedia HL7: https://de.wikipedia.org/wiki/HL7
- Wikipedia FHIR: https://de.wikipedia.org/wiki/Fast_Healthcare_Interoperability_Resources
- See FHIR IG overview on fhir.org: http://www.fhir.org/guides/registry
- FHIR Community: https://confluence.hl7.org/display/FHIR/FHIR+Community+Process

Joint initiatives

- Gemini project: https://confluence.hl7.org/display/GP/Project+Gemini
- Global Consortium for eHealth Interoperability (GCeHI): http://globalhealthinterop.org

Other

- The 3 Legs of the Health Informatics Standards Process: http://www.healthintersections.com.au/?p=2921
- The 4 aspects that change the game in eHealth Interoperability: https://www.linkedin.com/pulse/4-aspects-change-game-ehealth-interoperability-j%C3%BCrgen-brandst%C3%A4tter
- European Commission recognises 27 IHE profiles that should be referenced in public procurement documents: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_199_R_0011
- GDHP, Global Digital Health Partnership: https://www.gdhp.org