



INTEROPERABILITY OUT-OF-THE-BOX? ASSESSING FHIR

June 2021



TABLE OF CONTENTS

INTRODUCTION	3
EXECUTIVE SUMMARY	4
THE RISE OF HL7 FHIR	6
HOW FHIR CAME TO BE	6
FHIR IN THE UNITED STATES	6
FHIR IN EUROPE	8
RECENT DEVELOPMENTS AT EU LEVEL	9
FROM FHIR RESOURCE TO IMPLEMENTATION	10
CHALLENGES AND OPPORTUNITIES	12
CHALLENGES	12
OPPORTUNITIES	13
CONCLUSION AND RECOMMENDATIONS	15
ANNEX - REFERENCES	16



INTRODUCTION

Interoperability of healthcare IT systems remains a challenge, even though huge efforts have been put into it over the years. As COCIR already stated in the eHealth Toolkit 2015, eHealth has the potential to revolutionise healthcare, but a lack of interoperability hinders market development and delivery of eHealth's promised benefits.¹

Recently a new standard being developed by HL7 International has promised to come to the rescue: the “**FAST HEALTHCARE INTEROPERABILITY RESOURCES**”, better known as **FHIR**.²

Despite being still in development FHIR has gradually attracted a large community. And today essentially every project or vendor who wants to exchange health data is looking at how this could be done more easily with the use of FHIR.

In contrast to older standards for the exchange of health data FHIR has been designed with a very strong focus on implementation. Additionally, it leverages contemporary web standards, has good tooling support and is licensed for free use without restrictions.

Together with the base domain model of modular FHIR “Resources”, like Patient, which every clinician can relate to, software developers can create useful, interoperable applications in hours instead of weeks. This makes it very attractive for healthcare delivery organisations, companies and governing bodies to make use of FHIR to address their communication needs of health data.

However, the seemingly ease of use also comes with a drawback: when not used in a properly coordinated way it is very easy to create FHIR based systems which are nevertheless not interoperable.

Since the ambition for FHIR is to be able to cover most common healthcare workflows, the base resources are defined on a very generic healthcare domain model. For specific healthcare use cases the FHIR resources need to be extended and adapted. This is done by the creation of FHIR Profiles, which can be – and are - created by anybody. This poses a high risk of creating incompatible FHIR Profiles for the same or similar healthcare use cases.

Additionally, the first parts of FHIR have only been published as a normative standard at the end of 2019. Many projects using FHIR have thus based their specifications on draft versions of the FHIR specifications which are not in all aspects compatible with the normative version. It poses a challenge for system developers to address these differences.

Within this paper we first introduce how FHIR came to be. We learn of various initiatives that have helped FHIR to gain traction within different regions. We provide a brief overview on how FHIR resources are built into applications. We then consider the challenges and opportunities of FHIR development and deployment, and how it impacts interoperability. Lastly, we offer several recommendations to help improve healthcare interoperability.

¹ COCIR eHealth Toolkit 2015” (chapter on interoperability) https://www.cocir.org/uploads/media/15013.COC_2.pdf

² *FHIR for the C-Suite*

EXECUTIVE SUMMARY

First released by HL7 in 2014, FHIR (Fast Healthcare Interoperability Resources) has over the years become very attractive for healthcare delivery organisations, companies and governing bodies to address their communication needs of health data.

FHIR provides interoperability out-of-the-box, has computer processable specifications, good tooling support, free to use implementation libraries, and the standard itself is licensed to be free without restrictions. Several initiatives within the United States as well as in Europe have led to a wider uptake.

FHIR resources are however only the basic building blocks to build an application. Additional steps are necessary in order to fit a particular context of use, but that level of customisation also has some drawbacks.

On top of that there are other challenges: issues of fragmentation and maturity affect compatibility; the proliferation of initiatives result in inconsistencies undermining the reusability and sustainability; and the creation of different “dialects” leads to inefficient use of resources within the developer community and risks confusing the users in understanding the best specifications and requirements for their environment.

Nevertheless, the introduction of FHIR has led to a new and strong drive in standardising healthcare data. Awareness on the topic of interoperability, both on the demand and the supply side, is on the rise. With healthcare increasingly moving beyond the walls of traditional healthcare facilities, such as through the use of sensors, wearables and consumer equipment, new possibilities and use cases for health data exchange emerge as well.

The use and exchange of health data is fundamental for providing equitable high-quality care. The digital transformation of health and care will bring many benefits to patients, healthcare professionals and society. The use of FHIR can make a tangible contribution, but only if all involved stakeholders are properly informed and educated on how to safeguard interoperability when developing and deploying FHIR-based solutions.



To achieve this COCIR makes the following recommendations:

COCIR RECOMMENDS THE EUROPEAN COMMISSION AND EU MEMBER STATES TO:

1. **UPDATE** the *EC endorsement* of IHE Profiles to include FHIR-based profiles
2. **CHART** an interoperability roadmap that will guide future creation of Implementation Guides and Profiles for specific domains
3. **BUILD UPON** existing initiatives that foster international dialogue on interoperability, such as the *Global Digital Health Partnership* or the *Global Consortium for eHealth Interoperability*
4. **PROMOTE** and **SUPPORT** (financially) open source and/or publicly available tools for interoperability testing
5. **STIMULATE** interoperability through tendering and procurement processes
6. **INVEST** in digital skills to build a strong and knowledgeable developer community

COCIR RECOMMENDS THE VENDOR AND DEVELOPER COMMUNITY TO:

1. **COLLABORATE** on a governance structure for Implementation Guides and Profiles specific to a certain domain
2. **FAVOUR** the use of Implementing Guides and Profiles, or derived ones, at the highest possible level (international – European – national – regional)
3. **EVALUATE** the maturity of existing Implementation Guides and Profiles before supporting or using them
4. **ADDRESS** inconsistencies in the use of terminology and avoid reinventing the wheel
5. **CONSIDER** the potential and value of the FHIR Community Process³
6. **SUPPORT** standardisation efforts and good development practices, including on documentation and versioning
7. **PARTICIPATE** in testing events to validate effective integration
8. **ENGAGE** with purchasers and other relevant stakeholders on the topic of interoperability

³ <https://confluence.hl7.org/display/FHIR/FHIR+Community+Process>



THE RISE OF HL7 FHIR

Arguably the most widely implemented standards for the exchange of medical information are HL7 version 2 (HL7 v2), and for medical images, DICOM. Both have been released in initial versions around 1990.

HOW FHIR CAME TO BE

Despite the uptake of HL7 v2 it was soon recognised by HL7 that certain deficiencies of the pragmatic HL7 v2 make the implementation in the field difficult and require considerable amount of effort and expertise at each individual site where it is used.

Therefore, already in 1995 work on a successor to HL7 v2, based on a formal methodology and object-oriented principles was started: HL7 Version 3 (HL7 v3).

Due to the complexities of trying to cover all of healthcare in a Reference Information Model as a cornerstone of HL7 v3 it took 10 years to publish an initial version, which then was too complicated to find much interest. ⁴

In order to improve the situation HL7 initiated the Fresh Look Taskforce to start again from scratch and think about how an easy-to-implement specification for the exchange of health data needs to be designed. In 2011 Grahame Grieve created a proposal based on web technologies and RESTful services, ⁵ the same approach which brought companies like Facebook and Google a thriving developer community.

This eventually led to the publication of FHIR as a draft standard for trial use in 2014, combining the best features of HL7 v2, HL7 v3 and applying a tight focus on implementability.

FHIR provides interoperability out-of-the-box, has computer processable specifications, good tooling support, free to use implementation libraries, and the standard itself is licensed to be free without restrictions. FHIR comes with a base domain model of modular FHIR "Resources", like Patient, which every clinician can relate to, and software developers can easily combine into working applications that solve real-world problems at a fraction of the time and cost of existing alternatives.

In addition to document-level based mechanisms, FHIR resources allow to exchange and make use of health data on a much finer level of granularity.

To address the variability caused by diverse and evolving healthcare processes FHIR defines a simple framework for extending and adapting the FHIR resources which are exchanged between systems. The framework enables the documentation of the extensions as computer processable FHIR Profiles and Implementation Guides. This allows all FHIR systems, on whatever platform, to work with these extensions using the same mechanisms that manage the primary resources.

Thus, FHIR has become very attractive for healthcare delivery organisations, companies and governing bodies to address their communication needs of health data. A number of initiatives have been started to specify FHIR Profiles and Implementation Guides for specific use cases, even before a normative release of the FHIR standard.

FHIR IN THE UNITED STATES

FHIR has historically been more popular in the United States. Offering a bigger and less complex market compared to Europe, there has been more funding available for development and implementation.

⁴ Only the Clinical Document Architecture (CDA), another outcome of the HL7 v3 initiative, is widely used today, especially for nation-wide exchange of health data, like for instance in the [ELGA](#) system in Austria.

⁵ Adam Grieve, [Resources For Health: A Fresh Look Proposal](#)

Strong impulses for developing FHIR were given by the government, mainly through the *ONC 21st Century Cures Act Final Rule*⁶ and the *CMS Interoperability and Patient Access Final Rule*.⁷

- The **ONC 21st Century Cures Act Final Rule** implements the interoperability requirements outlined in the Cures Act,⁸ that aim to give patients and their care givers secure access to electronic health information. The Office of the National Coordinator for Health Information Technology (ONC) released this final rule to extend its 2015 *Meaningful Use Health IT Certification* criteria with a technical focus on FHIR-based API data access. The ONC also provides funding to HL7 International and partnered with the MITRE Corporation⁹ to develop tooling, hence supporting further FHIR developments.

The FHIR R4 US Core¹⁰ implementation guide implements data classes established by the ONC in the United States Core Data for Interoperability.¹¹

A cooperative agreement between ONC and IHE USA was announced to create FHIR-based IHE Profiles as an alternative or a complement to existing IHE document-based exchange specifications, and to support testing activities.¹² Prior to the cooperative agreement IHE had already made IHE Profiles available which made use of FHIR¹³ and is continuing to do so.

- The **Interoperability and Patient Access Final Rule** issued by the Centers for Medicare & Medicaid Services (CMS) puts patients first by giving them access to their health information. This final rule focused on driving interoperability and patient access to health information by liberating patient data using the CMS authority to regulate payers.

Also prior to these initiatives, there was already a vibrant FHIR scene. One well-known early initiative has been the Argonaut project,¹⁴ a private sector initiative comprising of leading technology vendors and provider organisations that develop FHIR-based specifications to enable extended information sharing for electronic health records.

Argonaut specifications have been taken up by large implementation health information exchange projects in the US like Carequality¹⁵ and Commonwell.¹⁶ Even Apple has integrated Argonaut-based functionality directly into the iPhone.¹⁷

Numerous other initiatives have been running under the HL7 FHIR Accelerator Program¹⁸, like Da Vinci¹⁹, CARIN²⁰, the Gravity project, CodeX or Vulcan²¹ defining functional use cases. The ONC itself has convened the FHIR at Scale Taskforce²², to identify FHIR scalability gaps and accelerate FHIR adoption at scale.

By now essentially every health IT vendor in the US either already offers FHIR based interfaces or will do so in the near future, including traditional IT infrastructure providers, such as Microsoft, Google or IBM.

⁶ <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>

⁷ <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

⁸ <https://www.congress.gov/114/plays/publ255/PLAW-114publ255.pdf>

⁹ <https://github.com/onc-healthit/inferno>

¹⁰ <https://www.hl7.org/fhir/us/core/>

¹¹ <https://www.healthit.gov/curesrule/>

¹² <https://www.iheusa.org/story/onc-and-ihe-usa-announce-cooperative-agreement-support-advancements-health-it-standards>

¹³ <https://wiki.ihe.net/index.php/Category:FHIR>

¹⁴ <https://argonautwiki.hl7.org/>

¹⁵ <https://carequality.org/carequality-seeks-community-input-as-it-expands-governance-to-fhir/>

¹⁶ <https://www.commonwellalliance.org/news-center/commonwell-news/commonwell-becomes-first-national-network-use-argonaut-projects-fhir-specifications/>

¹⁷ <https://www.apple.com/healthcare/health-records/>

¹⁸ <http://www.hl7.org/about/fhir-accelerator/>

¹⁹ <https://www.hl7.org/about/davinci/>

²⁰ <https://www.hl7.org/carin/>

²¹ <http://www.hl7.org/vulcan/>

²² <https://oncpjecttracking.healthit.gov/wiki/pages/viewpage.action?pageId=43614268>



FHIR IN EUROPE

Similar to how healthcare is structured and organised at national level, in many countries within Europe FHIR-based specifications are developed at country level, in isolation of the other FHIR communities. These “dialects” rely on a mix of different FHIR versions (DSTU2, STU3, R4), prescribe different terminologies, and establish unique extensions.

GERMANY²³

The uptake of FHIR in Germany is mainly driven by subsidised projects, although overall coordination has been lacking. Some specific governmental initiatives that have spurred FHIR developments are:

> Medical Information Initiative (MII)²⁴

The German Federal Ministry of Education and Research launched its medical informatics funding scheme to make data from healthcare and research more useful and meaningful. It provides around 180 million Euros with the aim of strengthening medical research and improving patient care. All of Germany’s university hospitals have joined forces with research institutions, businesses, health insurers, and patient advocacy groups to create a framework that harnesses research findings to the direct benefit of patients.

> Patientendaten-Schutz-Gesetz

As part of the Patientendaten-Schutz-Gesetz²⁵ the German Law has changed: as of 1 January 2021, the health insurance companies should make the electronic patient records available, which will be gradually developed and made usable. The aim is to enable secure, user-friendly and barrier-free digital communication between treating staff and patients and thereby to simplify everyday treatment processes.

THE NETHERLANDS²⁶

The country has standardised on HL7 v3 for communication between healthcare institutes. On the other hand, the government stimulates so-called Personal Health Environments²⁷ (PGOs), a digital means for patients and citizens to bring together their digital medical information. MedMij is looking after the standardisation for this initiative and has published implementation guides.²⁸

Implementation is however heavily relying on governmental temporary grants, mainly through the accelerator programme for information exchange between patient and healthcare professional (the so-called VIPP programme²⁹).

UK

NHS Digital is promoting FHIR. NHS Digital helped to deliver a HL7 UK / INTEROPen FHIR approach called ‘Care Connect’ which was England-centric. These profiles were established in May 2017 in STU3 and published in November 2018.

With the adoption of FHIR R4 there is now an opportunity to create a unified approach to interoperability across England, Scotland, Wales and Northern Ireland. This will enable consistent information flows across borders to improve health and care outcomes for all citizens.

In the UK, NHS Digital makes extensive use of FHIR in delivering the Personalised Health and Care 2020 strategy as published by the National Information Board.³⁰

FINLAND³¹

The national authorised Finnish Kanta service incorporates a personal health record (PHR) platform³² of which the data content is based on FHIR. The data content is open, published online and thus available for all. There is a specific Finnish PHR Implementation Guide.

²³ <https://simplifier.net/basisprofil-de-r4/>

²⁴ <https://www.medizininformatik-initiative.de/>

²⁵ <https://www.bundesregierung.de/breg-de/aktuelles/patientendaten-schutz-gesetz-1738402>

²⁶ <https://simplifier.net/nictizstu3-zib2017>

²⁷ <https://www.medmij.nl/en/>

²⁸ https://informatiestandaardn.nictiz.nl/wiki/MedMijV2019.01_FHIR_IC

²⁹ <https://www.vipp-programma.nl/over-vipp>

³⁰ <https://digital.nhs.uk/services/fhir-apis>

³¹ <https://www.kanta.fi/en/system-developers/kanta-phr>

³² <https://www.kanta.fi/en/system-developers/the-national-finnish-kanta-phr-data-content>



ELSEWHERE IN EUROPE

Developments in other regions are happening at various speeds. For instance in **France, Belgium and Norway** uptake and deployment is happening at a slow pace. In **Switzerland** electronic patient records are still based on HL7 CDA, but work is under way to transition to FHIR.³³

RECENT DEVELOPMENTS AT EU LEVEL

FHIR has recently gained considerable traction and its use is accelerating at enormous speed. As a demonstration we would like to highlight three particular initiatives, coordinated at the European level, where FHIR is playing a central role.

> Patient Summaries

On European level CEN, HL7 and IHE Europe have worked together to create the European Standard EN 17269:2019 “The Patient Summary for Unplanned, Cross-border Care” (CEN IPS) and an accompanying FHIR Implementation Guide.³⁴

The CEN IPS is seen as a possible basis for the future European Electronic Health Record Exchange Format which is currently being defined through the EU-funded X-eHealth³⁵ project. Recently the International Patient Summary has been adopted by ISO as ISO 27269:2021. Consequently the CEN version will be discontinued in time.

> Person-centred Electronic Health Records

The InteropEHRate³⁶ project funded by the European Commission aims to develop exchange protocols for a mobile patient-controlled EHR application.

The project is using FHIR to develop communication protocols and a reference implementation, in order to support health data exchange scenarios, in particular device-to-device, exchange with research centres and remote sharing and retrieving.

> Vaccination and COVID Certificates

With the aim of restoring economic and social activities there has been a plethora of initiatives at various levels – international, European, national and even more local – looking into the creation of vaccination- or COVID-related certificates.

At the European level, the EU institutions have agreed upon an EU Digital COVID Certificate.³⁷ This certificate will confirm whether a person has been vaccinated, tested negative or shows proof of recovery.

Technical specifications for interoperability³⁸ have been agreed and prior to the official application date of 1 July 2021 already 17 Member States are operational.³⁹ A specific EU Digital COVID Certificate FHIR implementation guide⁴⁰ has been created.

At the World Health Organisation level similar discussions have taken place with an initial initiative on Smart Vaccination Certificates now also being broadened to Digital Documentation of COVID-19 Certificates⁴¹ (DDCC). The DDCC specifications will also include an HL7 FHIR Implementation Guide, including example software implementations.

³³ <https://www.fhir.ch/>

³⁴ <https://www.ehealth-standards.eu/en/projects/international-patient-summary-ips-project/>

³⁵ <https://x-ehealth.eu/>

³⁶ <https://www.interopehrate.eu/>

³⁷ Regulation (EU) 2021/953 on EU Digital COVID Certificate

³⁸ https://ec.europa.eu/health/ehealth/covid-19_en

³⁹ https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

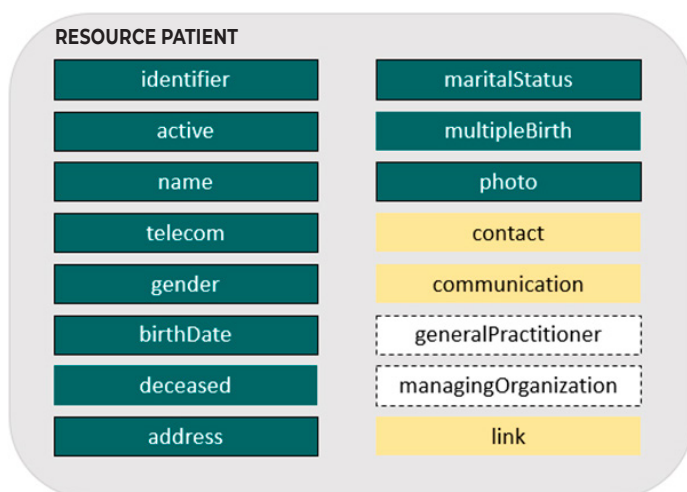
⁴⁰ <https://build.fhir.org/ig/hl7-eu/dgc/profiles.html>

⁴¹ <https://www.who.int/news/item/04-06-2021-revised-scope-and-direction-for-the-smart-vaccination-certificate-and-who-s-role-in-the-global-health-trust-framework>

FROM FHIR RESOURCE TO IMPLEMENTATION

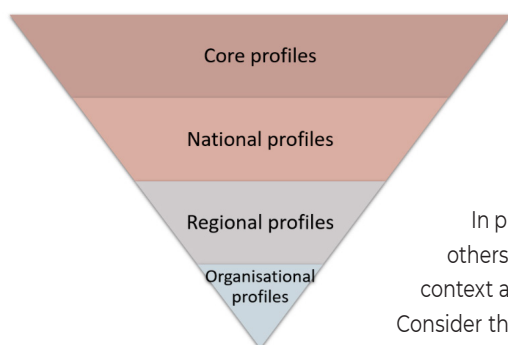
It doesn't take a trained eye to distinguish between a house and a pile of bricks. What sets them apart is how the bricks are structured, positioned and adapted to fit the construction. Clearly a plan and instructions are needed to ensure that the final result lives up to the designer's or user's needs in terms of design and functionality.

Within the context of FHIR, and in analogy with abovementioned example of building a house, a base FHIR resource represents a simple standard brick.



FHIR Resources contain a set of structured data items and can be specifically identified. Resources are used to exchange or store certain data. Additional elements and properties can be defined for each resource, such as metadata or extensions.

The Resource **Patient** for instance covers patient data relevant for administration. Not all concepts are included (such as race or nationality for instance). Some are defined in other Resources and can be linked through extensions. Others are more specific and are rather used at the national, regional or organisational level. In such cases, even if the same names and valuesets would be used, the concepts would not be similar enough to be able to map and exchange the data in a meaningful way between different structures.



In order to fit a particular context of use 'profiling' is done to describe or specify additional rules for resources. FHIR Profiles can extend or restrict resources. They will contain either a differential statement (indicating only the differences compared against the base resource), a 'snapshot' of the resulting structure or both.

In practice, several layers of profiles exist as new profiles may be derived from others in order to cater to the specific national, regional or even organisational context and use case.

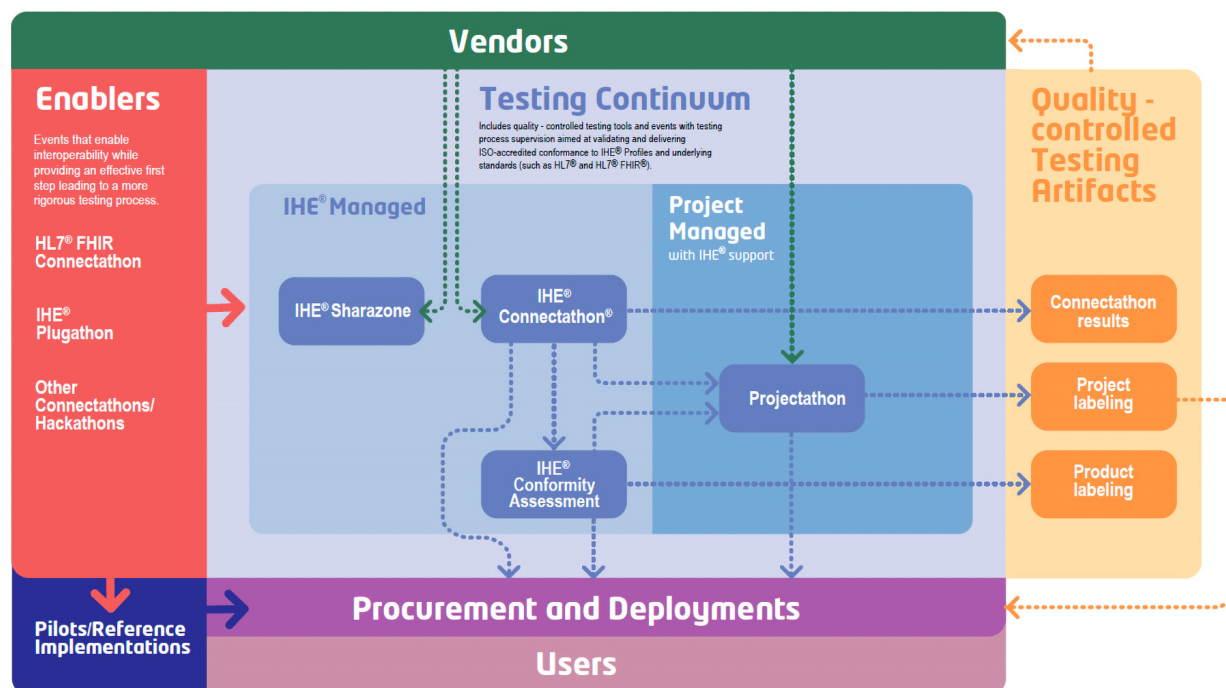
Consider this the cutting of a brick to its right dimension and shape in order to perfectly fit within the whole construction.

Bringing everything together an Implementation Guide specifies a set of rules about how FHIR resources are used or should be used to solve a particular problem. Accompanying documentation helps to better understand the logical content and usage of the resources within an implementation.

Implementers can test their FHIR implementation against base specifications or any published implementation guide. Testing can focus on the resource content, the server's behaviour on inputs or the client-side application's behaviour. While some testing may be automated, there are cases where manual testing is needed.

United in their quest to advance healthcare interoperability HL7 and Integrating the Healthcare Enterprise (IHE) are working together to realise the full potential of FHIR standards. As a consequence, IHE has produced already a range of FHIR-based integration profiles⁴² that define how to achieve interoperability in specific medical use cases. These are also being tested during dedicated events.

While the FHIR Connectathons offered by HL7 are the place to learn how to implement aspects of FHIR and advance the FHIR specification by trying out options, the IHE Connectathons are the established interoperability testing event for getting independent and impartial verification of the implementation of FHIR based IHE Profiles. The IHE Conformity Assessment allows ISO 17025 accredited assessment of individual products.



⁴² <https://wiki.ihe.net/index.php/Category:FHIR>

CHALLENGES AND OPPORTUNITIES

FHIR has been gaining attention as it is contributing to liberate data out of proprietary silos. Some consider it as a silver bullet, although FHIR implementation may not always lead to better interoperability or lead to unjustified dismissing of established technologies.

Herewith we would like to provide a balanced view highlighting the challenges of and opportunities in using FHIR.

CHALLENGES

> Limited standardisation

While FHIR is usually referred to as a standard, only recently and to a limited extent have FHIR resources been made normative. FHIR considers normative content a prescriptive part of the standard that is “locked”⁴³ and remains backwards compatible with existing implementations. FHIR contains many elements that are considered Trial Use content that may be subject to significant changes that are not backward compatible. As a consequence, many existing implementations are still making use of Trial Use content, which often leads to interoperability issues as content definition changes, or becomes normative.

FHIR also defines different methods for exchanging data, whereby not all methods – for instance the messaging exchange framework or the document-based exchange framework - are as well-established and well-developed as the RESTful API.

> Moving from needs to solutions

It is burdensome to build a logical model as it requires a lot of interaction with clinicians and other involved actors. Furthermore, there is no easy way to reflect the logical modelling of the clinical needs and domains into FHIR resources. A clear concept from HL7 is missing on how to do this.

> A fragmented reality

Developers have the freedom and flexibility to make use of FHIR resources, even if some may not yet be mature and stable. With different versions in use, compatibility issues may arise. Although there are some strategies to prevent this issue, forward and backward compatibility are not guaranteed by FHIR.

Different terminologies that are being used across applications and implementation guides will further break down semantic interoperability.

Ultimately there is also a sustainability issue as there may be a lack of resources for organisations or individuals to keep all resources updated over the longer term.

> The double-edged sword of customisation

In any project there will always be the need to cover the “last mile” as FHIR has been developed to cover the most common elements. FHIR offers the developer quite some flexibility in self-defining and profiling resources. This level of customisation does cut both ways as developers may be unaware of available solutions and will try and reinvent the wheel.

The proliferation of FHIR profiles may increase the unclarity and inconsistency of definitions being used throughout these resources. On top of this, the use of profiles is also becoming inconsistent. More effort will be needed to build implementations that combine or integrate different versions and profiles.

⁴³ <https://www.hl7.org/fhir/versions.html>



Without a clear implementation guide or profiling governance mechanism it will also be difficult for others to further use or re-use existing resources in other projects.

> **Implementation and integration into workflows**

Technology is not a means in itself and as such, any implementation and integration should bring tangible value to the patient, the healthcare provider or the health system.

FHIR resources are not always well-adjusted to pathways for clinical information. Heavy profiling may be necessary to address specific use cases. The extensive need for testing is not always fully considered from a budgeting or project approach.

Developers may face issues when trying to reconcile implementation guides, taking into account different FHIR versions.

Lastly, existing shortcomings of FHIR may require developers to turn towards additional or external resources in order to build necessary supporting features. As an example, current FHIR profiles are not able to fully handle subscription and notification tasks, which may be essential for workflow messaging.

> **Dispersion and confusion**

There are too many different initiatives running in parallel within the FHIR community. These rapid evolutions not only lead to inefficient use of resources within the developer community, it also risks leading to different “dialects” being created by the different projects. This in turn will make it confusing for users to understand the best specifications and requirements for their user environment.

OPPORTUNITIES

> **Promising growth and development**

The introduction of FHIR has led to a new and strong drive in standardising healthcare data. This is a vital aspect in unlocking the full potential of the digital transformation of health and care.

The standardisation of FHIR resources has been an ongoing process and the iterative approach to increase the maturity is building a strong foundation for future developments.

> **Increased awareness on the need for digitalisation and interoperability**

In years past there has been an increasing awareness that in order to address current and future health challenges it is crucial to digitalise healthcare. The COVID-19 pandemic crisis has starkly highlighted the urgent need. Public health authorities are accelerating their intentions and will make significant investments in the years to come.

Interoperability is considered an essential element in any digital health strategy. Authorities are setting up big implementation projects based on FHIR architecture. Next to that, they are also pushing interoperability through public procurement and tendering.

> **Market potential and low barriers for entry**

Healthcare is increasingly moving beyond the walls of traditional healthcare facilities. Sensors, wearables and consumer equipment are just a few examples of how health-related data is being collected and exchanged in new ways.

The ecosystem is changing and there is a growing influence of platforms driven by bigger technology players. Their support and shift towards FHIR implementation is guiding the market.

In addition, FHIR focuses on mainstream features, only including elements if it will be implemented by 80% of systems (the 80/20 rule). This takes away some of the complexity that is common in other established health data exchange technologies.

With the technology being available free for use, having a strong focus on implementation and designed to support web-based functionality, it is also more accessible to non-healthcare IT and it makes perfect sense that FHIR has been strongly embraced by the wider software development community.





CONCLUSION AND RECOMMENDATIONS

The use and exchange of health data is fundamental for providing equitable high-quality care. The digital transformation of health and care will bring many benefits to patients, healthcare professionals and society. The use of FHIR can make a tangible contribution, but only if all involved stakeholders are properly informed and educated on how to safeguard interoperability when developing and deploying FHIR-based solutions.

From a policy perspective strong signals are needed that interoperability by design is the way to go. Incentives should be put in place that guide and stimulate both the demand and the supply side.

From a process perspective this will require coordinated efforts to improve the governance of interoperability standards. Healthcare is not the environment to *move fast and break things*. More attention should go to the quality, consistency and sustainability of code development. Robust testing is essential to validate the implementation and integration into the wider ecosystem.

COCIR RECOMMENDS THE EUROPEAN COMMISSION AND EU MEMBER STATES TO:

1. **UPDATE** the *EC endorsement* of IHE Profiles to include FHIR-based profiles
2. **CHART** an interoperability roadmap that will guide future creation of Implementation Guides and Profiles for specific domains
3. **BUILD UPON** existing initiatives that foster international dialogue on interoperability, such as the *Global Digital Health Partnership* or the *Global Consortium for eHealth Interoperability*
4. **PROMOTE** and **SUPPORT** (financially) open source and/or publicly available tools for interoperability testing⁴⁴
5. **STIMULATE** interoperability through tendering and procurement processes
6. **INVEST** in digital skills to build a strong and knowledgeable developer community

COCIR RECOMMENDS THE VENDOR AND DEVELOPER COMMUNITY TO:

1. **COLLABORATE** on a governance structure for Implementation Guides and Profiles specific to a certain domain
2. **FAVOUR** the use of Implementing Guides and Profiles, or derived ones, at the highest possible level (international – European – national – regional)
3. **EVALUATE** the maturity of existing Implementation Guides and Profiles before supporting or using them
4. **ADDRESS** inconsistencies in the use of terminology and avoid reinventing the wheel
5. **CONSIDER** the potential and value of the FHIR Community Process⁴⁵
6. **SUPPORT** standardisation efforts and good development practices, including on documentation and versioning
7. **PARTICIPATE** in testing events to validate effective integration
8. **ENGAGE** with purchasers and other relevant stakeholders on the topic of interoperability

⁴⁴ Cf. the United States where ONC is sponsoring the Inferno testing suite (<https://inferno.healthit.gov/>)

⁴⁵ <https://confluence.hl7.org/display/FHIR/FHIR+Community+Process>

ANNEX - REFERENCES

Adam Grieve, *Resources For Health: A Fresh Look Proposal*, <http://healthintersections.au/?p=502>

Apple, *Empower your patients with health records on iPhone*, <https://www.apple.com/healthcare/health-records/>

Carequality, *Carequality seeks community input as it expands governance to FHIR*, <https://carequality.org/carequality-seeks-community-input-as-it-expands-governance-to-fhir/>

CEN/TC 251 Health Informatics, *International Patient Summary (IPS)*, <https://www.ehealth-standards.eu/projects/>

CMS, *Interoperability and Patient Access Final Rule*, <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

COCIR, *eHealth toolkit 2015*, https://www.cocir.org/uploads/media/15013.COC_2.pdf

CommonWell Health Alliance, *CommonWell becomes first national network to use the Argonaut Project's FHIR specifications*, <https://www.commonwellalliance.org/news-center/commonwell-news/commonwell-becomes-first-national-network-use-argonaut-projects-fhir-specifications/>

Deutsche Bundesregierung, *Patientendaten-Schutz-Gesetz*, <https://www.bundesregierung.de/breg-de/aktuelles/patientendaten-schutz-gesetz-1738402>

European Commission, *eHealth and COVID-19*, https://ec.europa.eu/health/ehealth/covid-19_en

European Commission, *EU Digital COVID Certificate*, https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

EUR-LEX, *Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic*, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.211.01.0001.01.ENG

HL7, *Argonaut Project*, https://argonautwiki.hl7.org/Main_Page

HL7, *Da Vinci Project*, <https://www.hl7.org/about/davinci/>

HL7, *EU Digital Green Certificate FHIR Implementation Guide*, <https://build.fhir.org/ig/hl7-eu/dgc/profiles.html>

HL7, *FHIR Accelerator Program*, <http://www.hl7.org/about/fhir-accelerator/>

HL7, *FHIR Community Process*, <https://confluence.hl7.org/display/FHIR/FHIR+Community+Process>

HL7, *FHIR for the C-Suite*, <http://www.hl7.org/documentcenter/public/standards/FHIR/FHIR%20for%20the%20C-Suite.4Sep19.pdf>

HL7, *FHIR US Core Implementation Guide*, <https://www.hl7.org/fhir/us/core/>

HL7, *FHIR Version Management Policy*, <https://www.hl7.org/fhir/versions.html>

HL7, *HL7 Deutschland Basic Profile DE (R4)*, <https://simplifier.net/basisprofil-de-r4/>

HL7, HL7 Switzerland – Swiss Implementation Guides, <https://www.fhir.ch/>

HL7, The CARIN Alliance, <https://www.hl7.org/carin/>

HL7, Vulcan, <http://www.hl7.org/vulcan/>

IHE, Overview HL7 FHIR items, <https://wiki.ihe.net/index.php/Category:FHIR>

IHE, ONC and IHE USA announce cooperative agreement to support advancements in health IT standards, <https://www.iheusa.org/story/onc-and-ihe-usa-announce-cooperative-agreement-support-advancements-health-it-standards>

InteropEHRate, EHR in people's hands across Europe, <https://www.interopehrate.eu/>

Kanta, Kanta PHR, <https://www.kanta.fi/en/system-developers/kanta-phr>

Kanta, The national Finnish Kanta PHR data content, <https://www.kanta.fi/en/system-developers/the-national-finnish-kanta-phr-data-content>

Medizininformatik Initiative, Medical Informatics Initiative Germany, <https://www.medizininformatik-initiative.de/>

MedMij, MedMij FHIR Implementation Guide, https://informatiestandaarden.nictiz.nl/wiki/MedMij:V2019.01_FHIR_IG

MedMij, Personal health data in the palm of your hand, <https://www.medmij.nl/en/>

NHS Digital, Fast Healthcare Interoperability Resources, <https://digital.nhs.uk/services/fhir-apis>

Nictiz, Repository of FHIR STU3 conformance for HCIM Release, <https://simplifier.net/nictizstu3-zib2017>

ONC, 21st Century Cures Act, <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>

ONC, 21st Century Cures Act Final Rule, <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>

ONC, FHIR at Scale Taskforce (FAST), <https://oncprojecttracking.healthit.gov/wiki/pages/viewpage.action?pageId=43614268>

ONC, Inferno GitHub repository, <https://github.com/onc-healthit/inferno>

ONC, Inferno information page, <https://inferno.healthit.gov/>

ONC, ONC's Cures Act Final Rule information page, <https://www.healthit.gov/curesrule/>

VIPP, Accelerator Programme Information Exchange Patient and Professional, <https://www.vipp-programma.nl/over-vipp>

World Health Organisation, Revised scope and direction for the Smart Vaccination Certificate and WHO's role in the global health trust framework, <https://www.who.int/news/item/04-06-2021-revised-scope-and-direction-for-the-smart-vaccination-certificate-and-who-s-role-in-the-global-health-trust-framework>

X-eHealth, Exchanging Electronic Health Records in a common framework, <https://www.x-ehealth.eu/>

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

COCIR COMPANY MEMBERS:



NATIONAL TRADE ASSOCIATIONS MEMBERS:



COCIR *How to join us*

COCIR aisbl | Bluepoint Building | Boulevard A. Reyerslaan 80 | 1030 Brussels | Belgium
Tel +32 (0)2 706 89 60 | Email info@cocir.org | www.cocir.org | [@COCIR](https://twitter.com/COCIR)