

## **MHEALTH:** JOINT RECOMMENDATIONS FOR AN EFFECTIVE DEPLOYMENT

April 2021





## **TABLE OF CONTENTS**

INTRODUCTION	3
EXECUTIVE SUMMARY	4
1. THE CURRENT MHEALTH DEPLOYMENT STATE	5
2. CHALLENGES AND OPPORTUNITIES FOR INTEROPERABILITY IN mHEALTH	7
2.1 CHALLENGES	7
2.2 <b>OPPORTUNITIES</b>	8
3. EXAMPLES OF CONCRETE MHEALTH USE CASES THROUGH IHE PROFILES	9
3.1 ACCESS TO CLINICAL DATA THAT ARE STORED IN DIFFERENT REPOSITORIES	9
3.2 PUBLICATION OF CLINICAL DOCUMENTS TO THE NATIONAL EHR	10
3.3 ACCESS TO A PATIENT IMAGE STUDY WITHIN AN ENTERPRISE	10
3.4 PATIENT AT HOME	10
4. JOINT RECOMMENDATIONS FOR EFFECTIVE DEPLOYMENT OF mHEALTH	11
ANNEX A COCIR AND IHE EUROPE'S SEVEN-STEP APPROACH TO INTEROPERABILITY IN AN EFFECTIVE DEPLOYMENT PROJECT	13
ANNEX B INTEROPERABILITY STANDARDS TO SUPPORT mHEALTH	14
B.1 IHE	14
B.2 PCHAlliance	14
B.3 DICOM	15
B.4 HL7	15





## INTRODUCTION

In its 2018 Communication on the digital transformation of health and care,<sup>1</sup> the European Commission set out to deliver citizen's secure access to, and sharing of, health data across borders. This will provide better data for advancing research, prevention and personalised care and for creating digital tools that empower citizens and provide person-centred care.

Deploying mHealth can help make the digital transformation of health and care a reality, and will support the Commission in delivering on its ambitions.

The ubiquitous availability and use of mobile devices, such as smartphones and connected personal health devices, can accelerate patient-centred care. However, standards-based interoperability will be essential in deploying mHealth to the maximum effect.

To allow mHealth to truly deliver genuine clinical value and support a patient-centred care model, the core applications must be able to communicate with the full range of systems used in day-to-day medical practice.

The importance of interoperability of Electronic Health Records (EHRs) was clearly acknowledged by the European Commission in its Communication, where it proposed to use open exchange formats to drive this as a priority.

COVID-19 has accelerated the uptake of digital health solutions, but there is a risk that the measures taken are time-limited and non-structural. Many mHealth apps for instance are not able to connect and update electronic health records. More interoperablity is needed between mHealth solutions and the broader health ecosystem.

To build the recovery and resilience of our health systems large investments will be made. It is important that funds will be effectively used. Public procurement rules should consider best value and include clear requirements on interoperability.

This document sets out recommendations for ensuring and advancing mHealth interoperability. However, mHealth addresses the "last mile" to the patients and the health professionals. Its successful implementation depends on a wellestablished eHealth infrastructure. This will ensure that the information flows freely between the various participants in the patient care pathway and that it is available to the mHealth applications. Therefore, a number of the recommendations made in earlier COCIR publications remain relevant for the implementation of mHealth.<sup>2</sup>

Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society
 We are all in this together: Advancing eHealth Interoperability (May 2017)





## **EXECUTIVE SUMMARY**

Mobile devices and applications in health – mHealth - have an increasingly important impact in the growing trend towards digitising various aspects of healthcare. mHealth offers a channel for reaching out to the citizen or the patient during their day-to-day lives. It can provide access to both personal and generic health-related information, engaging the citizen and soliciting responses, or encouraging changes that will contribute to a better health.

mHealth also has an increasingly important role in exchanging data between different stakeholders. It provides rapid access to real-world data, reports on outcomes and allows patients to take active control of their health data and share it with others as they see fit.

We first reviewed the most common approaches to interoperability and took stock of the existing challenges and opportunities, which identified the need for a more strategic approach. We also analysed what has been learned in eHealth over the last 20 years.

In this new edition COCIR has worked with IHE Europe<sup>3</sup> in order to include concrete use cases to demonstrate how the use of IHE Profiles enables and improves the interoperability of mHealth solutions.

We make several recommendations that are specific to the topic of interoperability for mHealth. These, we believe, will accelerate deployment of mHealth-centric projects by reducing the risks and costs generated by uncoordinated approaches to interoperability.

These recommendations take into account the fact that various stakeholders are already engaged in deployment projects. In particular, they recognise that the policy maker perspective may have assumed – possibly prematurely - that health-centric applications differed little from existing consumer applications.

### COCIR AND IHE EUROPE RECOMMEND THAT THE EUROPEAN COMMISSION, MEMBER STATES AND OTHER KEY STAKEHOLDERS:

- 1. COLLABORATE with each other, and with local stakeholders, on steering mHealth interoperability in individual Member States or at EU level.
- 2. SET stakeholder engagement rules by fostering a use case-based approach to interoperability.
- **3. DEFINE** for each use case, a brief interoperability specification referencing IHE profiles or open, international interoperability standards that can be recommended for use in tendering and procurement.
- 4. EDUCATE stakeholders, such as mHealth architects, project leaders, manufacturers, start-ups and care providers.
- 5. **IDENTIFY** based upon high-priority use cases, the organisational and policy changes needed to effectively deploy and foster implementation of mHealth.

3. https://www.ihe-europe.net





# **R**<sup>o</sup>

## **1. THE CURRENT STATUS OF mHEALTH DEPLOYMENT**

When assessing the maturity of mHealth deployment, many mobile-based services have been introduced in silos. These have often adopted limited pilot deployments that, in many cases, have not seen subsequent broader deployment.

The European Commission published a Green Paper on mHealth<sup>4</sup> in 2014. This forecast rapid adoption, stating that:

"As for mHealth revenues, a joint analysis by GSMA and PwC projects that the global mHealth market will reach the equivalent of US\$ 23 billion in 2017, with Europe accounting for US\$ 6.9 and Asia-Pacific for US\$ 6.8 billion, ahead of the North American market of US\$ 6.5 billion. According to that report, remote monitoring treatment solutions constitute almost 60% of the total mHealth deployments in Europe. Solutions that increase the efficiency of healthcare workforce and systems make up nearly 15% of overall deployments, alongside health and wellbeing apps."

Subsequently, it has become clear that although there has been some progress, it did not proceed at the predicted rate.

### The three areas that saw the greatest growth were:

- Personal wellbeing apps on smartphones, which allow users to self-monitor specific vital signs and assist patients in managing a specific condition or disease. Here, uptake has expanded rapidly.
- Health professional mobile apps that extend existing health IT systems (hospital medical records, RIS/PACS), or that make mobile phone-based diagnosis devices, such as ultrasound scanners, available.
- Patient access to hospital or regional portals through smartphone browsers, or via mobile phone apps provided by the portal or EMR vendor.

The barriers to further growth were clearly identified in the European Commission's 2014 mHealth Green Paper. It is now worthwhile reconsidering these barriers and assessing those that remain:

**ENSURING DATA PROTECTION**, including the security of health data, in the light of an unclear EU legal framework.

• The implementation of the General Data Protection Regulation (GDPR) has provided some clarity. Unfortunately the rules for the processing of health data are complex and inconsistent across Member States<sup>5</sup>. Next to that, considerable technical and organisational challenges to compliance remain, some of which call for standardised / interoperable solutions.

### LIABILITY, PATIENT SAFETY AND TRANSPARENCY OF INFORMATION

• With the Medical Device Regulation (MDR) entering into force on 26 May 2021, the new requirements for medical device software will provide tangible progress.

### **mHEALTH ROLE IN HEALTHCARE SYSTEMS AND EQUAL ACCESS**

This is one of the areas that has seen little progress, except for some national initiatives (e.g. in Germany, where
a new legislative framework was created for digital health applications). This demonstrates that integration of
mHealth and patient-centred care still present a major organisational challenge.

### **REIMBURSEMENT MODELS**

• There have been a number of national initiatives piloting new reimbursement models<sup>6</sup>, however, most insurance systems have taken a cautious approach.

<sup>4.</sup> European Commission - Green Paper on mobile Health ("mHealth")

Assessment of the EU Member States' rules on health data in the light of GDPR (February 2021)
 <u>COCIR publication - Market Access Pathways for Digital Health Solutions</u> (November 2020)

COCIA publication - Market Access Pathways for Digital realth Solutions (November 2020)





### INTEROPERABILITY

- The interoperability of the various mHealth and eHealth applications is essential for the broad deployment of mHealth. Unfortunately, in practice this continues to present a substantial challenge, despite the existence of applicable standards and IHE Profiles / guidelines. These challenges, along with a series of recommendations to address them, will be addressed in greater detail in the following chapter.
- The European Commission should lead concerted efforts on a recommendation for a European EHR exchange format,<sup>7</sup> a common semantic strategy<sup>8</sup> and investment guidelines.<sup>9</sup> If adopted by the eHealth Network, this will allow national eHealth infrastructures to improve their interoperability in the future. Preparatory work on a European EHR exchange format for imaging, lab results and hospital discharge reports is currently being undertaken by the EU-funded X-eHealth<sup>10</sup> project.
- One area that has seen significant progress is in developing standards that are more mobile platform-friendly, such as HL7 FHIR and DICOMweb. However, many challenges remain to their broad, uniform deployment.



- 7. Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format
- 8. https://ec.europa.eu/health/ehealth/events/ev\_20191128\_en
- 9. eHealth Network Guidelines to the EU Member States and the European Commission on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe
- 10. https://www.x-ehealth.eu/





### 2. CHALLENGES AND OPPORTUNITIES FOR INTEROPERABILITY IN mHEALTH

### **2.1 CHALLENGES**

COCIR and IHE Europe have identified the following interoperability challenges facing mHealth deployment:

Despite the existence of appropriate standards, care providers are finding it hard to define their interoperability requirements in their tenders, in terms of selecting appropriate standards and demanding compliance to them. In addition, in the event that buyers do articulate their needs, these can be highly diverse, as currently there is no effective mechanism for coordination. As a result, vendors have few incentives to actually adopt interoperability standards.

- The corpus of healthcare IT interoperability standards is continuously evolving, as the underlying ICT technology develops and needs of the care provision sector change. This increases the difficultly for care providers to articulate their requirements in their specifications.
- Deployment projects predominantly focus on mobile applications that are presented to users. This poses problems when addressing the level of interoperability required to integrate these with healthcare IT systems in such a way that the associated health services can access and liberate the data. This results in unproductive systems that in turn lead to a low return on investment and frequent rejection by health professionals.
- Interoperability standards coming from traditional healthcare IT fields are not well understood by most entrepreneurs active in mHealth. They often lack the experience required to allow mHealth interoperability in health systems.
- Mobile applications, and the service they connect to, are designed as closed systems (no standard APIs), which means that:
  - 1. Buyers are deprived of healthy, competition-driven innovation, as the introduction of apps or devices from alternative suppliers which could potentially offer better services for patients are blocked.
  - 2. They are difficult or impossible to integrate with multiple health services, and also make it difficult for patients to switching between them.
  - 3. Care organisations need to invest in specific integrations for each application, which is costly and complex and leads to high ICT maintenance costs. As mobile applications and services mostly use non-standard APIs, health providers relying on a range of offerings will have to interface their health IT with each different API. This requires a huge effort and investment and also poses a risk to the integrity and security of the health providers' IT infrastructure.
- If the popular apps used by patients do not build on a commonly agreed set of interoperability standards, it will make it more complicated for those health record-sharing platforms that want to offer access via mHealth applications.

These issues outlined above demonstrate how bespoke systems act as a brake on the independent procurement and evolution of mobile health apps, software platforms and healthcare IT systems. The lack of standardised interfaces causes unnecessary complexities, which in turn erects barriers to establishing the best mHealth ecosystem for their needs.





### **2.2 OPPORTUNITIES**

What opportunities could make interoperability a visible priority for technology providers and deployment architects in the mHealth market?

- **Create** a strong and homogeneous demand pull for solid interoperability solutions as an integral part of vendor mHealth offerings. This can be done by aligning and clearly articulating the needs of providers, payers, project architects and patients.
- **Educate** those companies entering the mHealth market from outside the sector on existing interoperability standards / IHE Profiles used in the health domain. This will avoid creating proprietary mHealth interfaces.
- **Encourage** mHealth companies and mHealth users to become active within the healthcare standard and profiling bodies (IHE, PCHA, DICOM, HL7, etc.). This can be used to develop IHE and Continua profiles suitable for mHealth.
- Incentivise these companies to participate in collaborative interoperability test events in mHealth, such as plugathons, Plugfest and IHE Connectathon<sup>11</sup>.







## 3. EXAMPLES OF CONCRETE mHEALTH USE CASES THROUGH IHE PROFILES

To benefit of the deployment of mobile devices in eHealth, clinical data and other relevant information should be exchanged or shared in a trusted and interoperable environment. The following use cases have the objective to demonstrate how the use of IHE Profiles simplifies the implementation of necessary mHealth functionalities in an internationally proven interoperable way.

### **3.1 ACCESS TO CLINICAL DATA THAT ARE STORED IN DIFFERENT REPOSITORIES**

A healthcare professional needs access to the latest medical reports (e.g. patient summary, hospital discharge letter, laboratory results) before examination of a given patient at home. He uses his mobile device to access to the patient's EHR, a service which is widely deployed in the country.

At first, the user has to obtain authorised access for the documents he wants to see. After having received the authorisation, the healthcare professional requests the identifier of the patient using demographic data (last name, first name, date of birth) in order to request the clinical documents that are stored in different repositories.

After obtaining the patient identifier, he accesses with his authorisation and access rights the different repositories hosted in the different organisations (clinics, hospitals, etc) the patient was in contact with during the past weeks. The healthcare professional is able to request the clinical documents or to query data elements extracted from clinical documents. In the end, he displays reports or a set of extracted data being represented on his device as a curve or table with the data covering a specific period of time.

To execute this use case, several IHE Profiles are orchestrated in the mobile application. An IHE Profile describes specific solutions to interoperability problems based on the actors and transactions. All IHE Profiles used in this use case provide RESTful interfaces, which are in general widely deployed in mobile devices:

- Patient Demographics Query for Mobile (PDQm) provides a transaction for mobile devices to query a patient demographics' supplier on the basis of user-defined search criteria and to retrieve a patient's demographic information such as a patient identifier;
- **Patient Identifier Cross-reference for Mobile (PIXm)** provides a transaction for mobile devices to query the Patient Identifier Cross-reference Manager for a list of cross-referenced patient identifiers from different types of organisations;
- Mobile Health Document (MHD) provides transactions to find document entries containing metadata based on query parameters in order to obtain a copy of a specific document;
- Query for existing data for mobile (QEDm) provides queries for clinical data elements including
  observations, allergy and intolerances, diagnostic results and medication. This IHE Profile is used together
  with the Mobile Cross-enterprise Document Data Element Extraction (mXDE). These two IHE Profiles
  allow access to a sharing platform, that is generally based on Cross Enterprise Document Sharing (XDS),
  that extends the services to mobile applications.
- Internet User Authorisation (IUA) provides user authorisation. It provides the authorisation token that is
  incorporated into HTTP RESTful transactions and presented for access decision to the resource services
  where the clinical documents are stored;





### **3.2** PUBLICATION OF CLINICAL DOCUMENTS TO THE NATIONAL EHR

After the examination of the patient at home, the healthcare professional writes the prescription, the laboratory order and the report of the patient examination directly into the mobile application. He already knows the patient identifier as described in the previous use case.

The mobile application creates the user input as clinical documents and submits these documents, together with the relevant metadata, to be recorded in the repository for the authorised healthcare professional.

Because the same infrastructure is being used, the **Mobile Health Document (MHD)** is the main IHE Profile that provides the transaction for the publication of the clinical documents.

### **3.3** ACCESS TO A PATIENT IMAGE STUDY WITHIN AN ENTERPRISE

A senior radiologist using a mobile device has been asked to review images for a patient in emergency care. He would like to access the available studies for the patient within the hospital. In his EMR client, the radiologist looks up the patient's clinical detailed information and makes a query for the image studies using the patient identifier provided by the EMR. Multiple entries are being sent, one per matching study. After selecting the one the radiologist is looking for, the mobile device retrieves the instances and displays them.

The main IHE Profiles to be used in this case are the following:

- Patient Demographics Query for Mobile (PDQm) provides a transaction for mobile devices to query a patient demographics supplier on the basis of user-defined search criteria and retrieves a patient's demographic information such as a patient identifier;
- Web-based Image Access (WIA) profile brings the interoperability solution that solves this use case. It defines methods for image sharing and interactive viewing of imaging studies using RESTful interfaces, such as WADO-RS<sup>12</sup> and QIDO-RS<sup>13</sup> which are based on DICOMweb services.

### **3.4 PATIENT AT HOME**

M. John Wright, 66, is working in his garden when he suddenly feels very bad. Currently, he suffers from hypertension and is at high risk for stroke. He used to monitor his vital signs (blood pressure, weight, oxygen, etc).

He wants to call his doctor, but on Sunday the doctor is not available. Instead, he decides to find the doctor on call using a mobile application that was recommended by his doctor and which provides PHR services.

One of the services offered by this mobile application allows him to search easily a practitioner that is available in his city, closest to his home. To facilitate the diagnosis of his health problem by the doctor who does not know him, he uploads the latest patient summary from his PHR. He is now ready to receive the doctor.

The main IHE Profiles needed are the following:

- **Personal Health Device Observation Upload (POU)** describes a standardised means of representing a Personal Health Device's data as FHIR Resources;
- Mobile Care services Discovery (mCSD) provides RESTful queries for supporting discovery of care service resources such as organisation, location, facilities, practitioners and health services;
- International Patient Summary (IPS) provides the content of the Patient Summary based on CDA or FHIR implementation guide. This IHE Profile as a content profile is supported by the profile IHE MHD.

12. https://www.dicomstandard.org/dicomweb/retrieve-wado-rs-and-wado-uri 13. https://www.dicomstandard.org/dicomweb/query-qido-rs





## 4. JOINT RECOMMENDATIONS FOR EFFECTIVE DEPLOYMENT OF mHEALTH

COCIR and IHE Europe have actively promoted interoperability in eHealth, where the focus is on allowing health data created by health professionals to follow the patient as they move through health systems. In addition, the patient has access to their health data. As previously discussed, eHealth is essential for patient-centred care; when extended with mHealth, it offers the potential for patients and other care givers (e.g. family and friends) to engage in their care more directly.

We believe that the effective eHealth approaches developed over the past 20 years can also be applied to mHealth, particularly as there must be seamless integration of mHealth and eHealth from an interoperability perspective. The sevenstep approach widely used in eHealth remains a valuable resource for mHealth projects architects (See Annex A).

We would like to stress that interoperability in mHealth must rely on open standards. Otherwise, proprietary approaches will lock buyers in and thus restrict competition, stifling innovation and making it difficult to reduce costs. Indeed, there is already an immense range and number of sources and users of health data and a huge array of different IT systems and platforms, such as mobile apps and devices. Each of these has been designed and procured by different health related organisations or the patient.

The relevance of profiling, as discussed in the jointly published document entitled, 'We are all in this together: advancing eHealth interoperability",<sup>14</sup> also applies to mHealth interoperability. It also stresses the importance of adopting standards facilitators such as IHE and PCHA.

Large-scale interoperability needs an adoption and testing ecosystem capable of rapidly delivering the robustness and quality needed to allow users and healthcare professionals to build trust in eHealth technology.





## COCIR AND IHE EUROPE RECOMMEND THAT THE EUROPEAN COMMISSION, MEMBER STATES AND OTHER KEY STAKEHOLDERS:

- 1. COLLABORATE with each other and with local stakeholders, on steering mHealth interoperability in individual Member States or at EU level. This was the case for eHealth in sharing health records in recent years.
- 2. SET the stakeholder engagement rules by fostering a use case-based approach to interoperability.
  - The EU Commission should engage the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) reference networks in developing a consensus on two or three initial use cases. This should be coordinated by IHE and PCHA, both of which are experienced<sup>15</sup> in this type of process and in selecting supporting IHE Profiles<sup>16</sup> and Standards.
  - Member States could further leverage the outcome of this European-level process, bringing the benefits of a shared approach to interoperability in mHealth throughout the Digital Single Market for the most common use cases.
  - Care providers, payers and patient representation organisations should be encouraged to be part of this process.
- 3. DEFINE for each use case, a brief specification<sup>17 18</sup> that references IHE profiles or open, international interoperability standards (when IHE Profiles are not available) that can be recommended for use in tendering and procurement<sup>19</sup>. These should be aligned at national, and preferably European, levels.
- **4. EDUCATE** stakeholders such as mHealth architects, project leaders, manufacturers, start-ups and care providers. They should understand where and how to find and use existing interoperability specifications and, where necessary, how to define such specifications themselves.
- **5. IDENTIFY** based upon high-priority use cases, the organisational and policy changes required to address roadblocks to effectively deploy and foster the implementation of mHealth.



15. We are all in this together: Advancing eHealth Interoperability (May 2017)

- https://wiki.ihe.net/index.php/Profiles
   <u>COCIR eHealth Toolkit 2013</u> (chapter on mHealth)
- 18. COCIR eHealth Toolkit 2015 (chapter on Interoperability)
- 19. https://www.ihe-europe.net/sites/default/files/2018-08/Flyer\_27\_profiles.pdf





### ANNEX A COCIR AND IHE EUROPE'S SEVEN-STEP APPROACH TO INTEROPERABILITY IN AN EFFECTIVE DEPLOYMENT PROJECT

COCIR has previously developed guidance on how to incorporate interoperability, which has already proved effective, for example in Austria and Switzerland<sup>20</sup>.

IHE Europe refines the guidance with a use case driven methodology<sup>21</sup> that has proven its robustness in various countries such as Ireland, Greece and Gabon.

In synthesis, COCIR and IHE Europe define the seven steps to achieving interoperability:

### 1. Identify use cases

Aligned with the policy on interoperability, describe the proposed functionality in medical terms, avoiding any technical language and prioritise your use cases by establishing an interoperability roadmap

### 2. Select IHE Profiles and standards

Identify existing IHE Profiles and standards that may support the use case. For example, the 27 IHE profiles that are identified for the hospital, regional, national and cross border levels and recommended for the public procurement

### 3. Refine data content

Design the messages and data structure required in the use cases.

### 4. Write the interoperability specifications

Assemble the components and scenarios, building on existing standards to fit to the interoperability architecture defined for the implementation of the use case.

### 5. Organise testing

Design the testing processes and testing events (e.g. Projectathon). Prepare test cases and an environment for implementers to demonstrate component interoperability in scenarios with multiple implementers.

### 6. Educate end-users on interoperability

Develop communication materials that help end-users become familiar with the benefits and impact of interoperability.

#### 7. Organise the interoperability governance

Create an organisation that supports the evolution of the sustainable eHealth interoperability framework.

We are all in this together: advancing eHealth interoperability (May 2017)
 https://www.ihe-europe.net/ihe-in-europe/use case implementation





## ANNEX B INTEROPERABILITY STANDARDS TO SUPPORT mHEALTH

Interoperability will be key to the success of mHealth applications. This can best be achieved by using internationally defined, open and freely available interoperability standards that represent a consensus between the medical community and those vendors providing the applications. This will ensure true interoperability, a broad selection of potential vendors and a better coverage for the needs of the medical community.

Various groups have already created such profiles and standards for mHealth, and are working relentlessly to expand their coverage and adoption.

### **B.1** IHE

Integrating the Healthcare Enterprise (IHE)<sup>22</sup> is an initiative by healthcare professionals and industry designed to improve how computer systems in healthcare share information. Communication standards such as HL7, DICOM, IETF, OASIS, SNOMED and LOINC usually provide a number of options for achieving a specific clinical goal, particularly where they need to be used in combination. IHE therefore creates detailed specifications, the so-called 'IHE Profiles',<sup>23</sup> setting out how to use the standards in a coordinated way to reach these goals. Vendors can verify their implementation of IHE Profiles at Connectathons, which are annual face-to-face interoperability-testing events organised by IHE.

IHE has created, and continues to create, profiles that specifically address mHealth scenarios, including Mobile Access to Health Documents (MHD), Patient Demographics Query for Mobile (PDQm), patient Identifier Cross-referencing (PIXm), mobile Cross-enterprise Document data-element Extraction (mXDE), Query for Existing Data for mobile (QEDm), Device Enterprise Communication (DEC), Internet User Authorisation (IUA), Web-based Image Access (WIA), mobile Care Services Discovery (mCSD) and Mobile Health Document Sharing (MHDS).<sup>24</sup>

IHE has developed a testing methodology for interoperability with tools and processes:

- "IHE Plugathon"<sup>25</sup> and PCHA Plugfest<sup>26</sup>, a hackathon dedicated to interoperability of Apps and APIs;
- "Connectathons"<sup>27</sup>, where testing is planned at the profile level;
- "Projectathons", where end-to-end testing of the various scenarios covered by the use case, in the regional or national deployment context, are covered.

IHE offers and maintains an interoperability test platform, "Gazelle" (https://gazelle.ihe.net), to support and automate each of these testing phases.

This methodology has already proven highly effective in rapid, large-scale deployment, without major problems, in several European countries as well as around the world. It currently covers more than 200 million patients.

### **B.2** PCH Alliance

The Personal Connected Health Alliance<sup>28</sup> is a non-profit organisation formed by HIMSS. The Alliance publishes and promotes the adoption of the Continua Design Guidelines. These guidelines are recognised by the International Telecommunication Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices.

- https://www.ihe.net/
   https://wiki.ihe.net/index.php/Profiles
- https://wiki.ihe.net/index.php/Category:FHIR
   https://connectathon.ihe-europe.net/plugathon
- 26. https://www.pchalliance.org/value-and-benefits-plugfest
- https://connectathon.ihe-europe.net/
   https://www.pchalliance.org/





### **B.3 DICOM**

DICOM (Digital Imaging and Communications in Medicine)<sup>29</sup> is the international standard for transmitting, storing, retrieving, printing, processing and displaying medical imaging information. It is supported by virtually all medical imaging devices. DICOM is published by the US National Electrical Manufacturers Association (NEMA) in close collaboration with manufacturers and clinical community.

In order to make medical images more easily accessible for mobile devices, DICOM has standardised an additional, lightweight transfer mechanism: DICOMweb. Similar to FHIR from HL7, DICOMweb uses RESTful<sup>30</sup> services that can be effortlessly integrated into today's development environments for mobile applications.

### B.4 HL7

Health Level Seven International (HL7)<sup>31</sup> is a non-profit, ANSI-accredited standard developing organisation providing standards for exchanging, integrating, sharing, and retrieving electronic health information (with the exception of medical images, which are covered by DICOM). All stakeholder groups involved in the electronic processing of health information are contributing to creating HL7 standards. To make health information more easily accessible, HL7 has begun to create Fast Healthcare Interoperability Resources (FHIR).<sup>32</sup>

FHIR Resources represent granular clinical concepts that can be accessed via RESTful services, thus lending themselves to processing on mobile devices.

HL7 standardised the first FHIR Resources with the release of R4 in 2019. It will continue to add further as they mature.

<sup>29.</sup> https://www.dicomstandard.org/

<sup>30. &</sup>lt;u>https://restfulapi.net/</u> 31. https://www.hl7.org/

<sup>32.</sup> https://hl7.org/fhir/



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.

1 001 0011

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.

### **ABOUT COCIR**

We provide a wide range of services on 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)**.

### WWW.COCIR.ORG

0011 0011 0





Integrating the Healthcare Enterprise

The mission of IHE Europe is to improve patient care by advancing the interoperability of healthcare IT systems and the appropriate sharing of relevant information.

Towards that end, IHE Europe conducts education, testing, demonstrations and other activities promoting the deployment within Europe of systems compliant with the IHE Technical Frameworks developed by IHE International.

### **ABOUT IHE EUROPE**

IHE Europe also recruits healthcare professionals and solution developers to participate in the development of these specifications and promote their appropriate use in Europe.

IHE Europe interacts with relevant governmental and nongovernmental organisations in Europe. It also maintains close contacts with similar initiatives around the world.

### WWW.IHE-EUROPE.NET

