

# Initial Contribution on European Commission recommendation

On a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning the application mobile applications and the use of anonymized mobility data

## Shaping a vision for interoperability

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## 1. Introduction on the EU recommendation

The European Commission is working on a recommendation for developing a common approach referred to as a toolbox to use digital means and, more specifically, **in support of mobile applications** to help address the COVID-19 crisis. This recommendation applies to Member States to better coordinate actions in concordance with the Union law and without prejudice to the competence of each Member State.

Member States and industry have been developing a variety of mobile and/or other types of applications in support of the barrier actions and care processes for the COVID-19 such as

- Developing telemedicine and patient follow-up with symptoms by the general practitioner;
- Alerting the suspected patient by providing questionnaires (self-diagnosis and follow-up) and information to cut the chain of contamination;
- Monitoring a confirmed COVID-19 patient and enforcement of his quarantine period;

- Monitoring citizen distance;
- Information reporting to the Public Health and statistic;
- Availability of ICU bed and resources;
- etc

The European recommendation highlights the necessity of a pan-European approach for the use of mobile applications that will include the interoperability of those applications with respect of privacy and data protection.

IHE-Europe supports the European Commission in their recommendation and with the present document contributes to the development of an interoperability framework that supports some of the needs described in the Commission recommendation on common approach and toolbox. The second part of the document provides recommendations regarding the interoperability conformity assessment based on existing work in this domain, including different types of testing sessions such as connectathon or dedicated projectathon sessions (as presently done already by the EU Commission under the eHDSI Application Provider).

## 2. IHE-Europe

IHE-Europe, a non-profit association with 20 years of experience in the eHealth domain, is dedicated to interoperability in health information technology (HIT). IHE-Europe is a deployment committee of IHE International – the organization that develops integration specifications for implementers called IHE Profiles. Today 27 IHE profiles have been identified by the European Commission in 2015 for referencing in public procurement.

The mission of IHE-Europe is to

- Promote the adoption of IHE profiles and supporting open standards;
- Provide support to countries in operationally deploying eHealth services relying on IHE profiles;
- Provide tools and services in support of interoperability testing in practice to accelerate deployment.

For over twenty years, IHE-Europe conducts test sessions called **Connectathons** (connectivity marathon) that bring together more than 120 systems of over 80 companies in Europe to verify their ability to interoperate with IHE profiles specifications of different health domains (radiology, cardiology, laboratory, pharmacy, etc.). For one week, these companies will verify compliance of their products and solutions with those of peers executing under supervision test plans prepared ahead of the event. To successfully realize this event, IHE-Europe has developed the **Gazelle platform** for event management and testing tools, simulators, and validators and to manage more than 3200 tests achieved by all companies presented during the event.

The members of IHE-Europe are either

- a) **IHE National initiatives** (France, Belgium, Luxemburg, Germany, Italy, Switzerland, The Netherland, Austria, ...),
- b) European associations of vendors and users as well as
- c) companies.

IHE National initiatives are IHE organizations that support domestic stakeholders to deploy IHE profiles and use testing tools developed by IHE.

Many national and regional ehealth deployments across Europe have chosen to align their interoperability specification on IHE Profiles, in order to take advantage of the robustness of

these specifications and of the testing methods made available by IHE. This is the case in the EU Cross-border eHDSI deployment of ePrescription and Patient Summaries services.

### 3. Meeting the interoperability needs For COVID-19 pandemic

For many years IHE has been developing a use case driven approach that is now widely adopted by eHealth deployments across Europe and beyond. It guides the identification of standards and profiles that fit the needs and helps specify IHE profiles. Regarding the initial needs identified by the commission, IHE proposes to identify through a COVID-19 related use cases and to identify a defined set of profiles and standards that can be used viewed from the “mobile application” angle.

#### 3.1. Context

The short text below describes a common situation related to the COVID-19 outbreak.

*After five days of illness, a person is diagnosed COVID-19 as an asymptomatic patient. The patient filled out a self-diagnosis questionnaire when he suspected he was probably carrying the illness. He did a PCR laboratory test and a CT scan and this was confirmed by his family doctor.*

*He does not feel not very ill, but he may be in the beginning stage of his illness. The family doctor instructs the patient to take care of himself and his family, and to stay confined at home.*

*The patient uses thermometer and pulse oximeter to monitor his condition at home and every day he fills out a questionnaire with standard questions for his COVID-19 illness that is sent/shared to /with his family doctor. Depending on his answers, a system algorithm will potentially send an alert to the family doctor.*

*In the case where his status is stable, an appointment with his family doctor is planned every two days using a telemedicine session during the next two weeks for the follow-up of his illness.*

*In the case where an alert is sent, if he has any new complaints or if he feels worse, a call with the doctor using the telemedicine tool is immediately planned. If the patient needs to go immediately to the hospital, the doctor requests a referral along with the patient history information to the emergency department for admission.. When the patient arrives at the hospital, the emergency doctor looks at the ICU bed availability and completes the patient admission.*

*In the case where the patient is declared virus-free, the family doctor ends the care episode and writes the report triggering the end of the containment (Immunity passport).*

*The COVID-19 status for this patient needs to be tracked by the Public Health Service of the patients Country of Residence.*

*For all cases, the doctor sends information to the emergency setting in case the patient needs to go immediately to the hospital and involved healthcare practitioners should report to their respective national COVID-19 registries.*

*The citizen is free to go back to work or to travel. Before travelling, he may upload information to a “contact tracing application” deployed in his home country. At a European level, citizen*

*mobility for business or leisure is critical. EU member states decide on a common set of guidelines to monitor contact tracing in data privacy by design approach. At the host country, after a few days, a visitor may not feel very well, he follows the host country COVID-19 protocol and a COVID-19 test is performed. He receives an alert in his apps on the results with clear guidance on how to deal with his clinical condition. The travellers is using a EU validated contact tracing application to and get information on possible infected contacts he had and also to provide information on his status, enabling other citizens that were in his proximity anonymously that they need to follow the epidemiological protocols immediately.*

### 3.2. Interoperability use cases

The context, as presented above, is broken down into several interoperability use cases available for mobile application implementation. They are presented in the following sections

Note 1: the tracing contact use case is developed in [section 3.4](#).

Note-2: the use cases described below can be detailed in the future and be stored in the use case data repository (<https://usecase-repository.ihe-europe.net>) by IHE-Europe.

Note-3: Patient consent should be taken into consideration; it is mandatory for mobile applications to be properly deployed. IHE BPPC and APPC profiles are applicable here.

Note-4: ENISA has published an analysis of standards in areas relevant to the potential EU candidate cybersecurity certification schemes<sup>1</sup>. An overview of cybersecurity landscape applicable to the EHR is provided with respect to existing standards, architecture models, and best practices. IHE Profiles listed in this document are also provided in the table.

#### 3.2.1. Use cases for a citizen travelling in other EU countries

Title	Access to the lab report (COVID-19)
Context	A CPR laboratory test or a serological test is prescribed to a foreign patient suspecting of having the COVID-19. The laboratory performs the test and send the results at the national Public Health authorities (option: when positive). The national authority informs the country of residence of the patient. The lab results/report are sent directly to the PHR/EHR of the patient using the Cross border exchange infrastructure. The patient receives an alert from the contact tracing (or his PHR) that the results are available. He displays the report on his mobile application
Information	Patient demographics Lab results/report Diagnosis Notification Patient Summary informations
Pre-requisite	Cross Border exchange infrastructure National infrastructure Security infrastructure

<sup>1</sup> <https://www.enisa.europa.eu/publications/recommendations-for-european-standardisation-in-relation-to-csa-i>

Profiles and standards (for Patient Apps)	<i>PIXm, PDQm</i> <i>XD-LAB</i> <i>MHD, MHDS</i> <i>QEDm</i> <i>NAV</i> <i>ATNA (on FHIR)</i> <i>CT</i> <i>IUA</i> <i>mCSD</i>
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Title	Access to the CT Scan and the radiology report
Context	A CT scan is prescribed to a foreign patient suspecting of having the COVID-19 in the host country. The Radiology department performs the CT Scan and the radiology report is sent to the country of origin of the patient using the cross border exchange infrastructure (with the prescription). The images are stored in the Imaging platform (national/regional/local). The patient receives an alert from his PHR that the report is available. He displays the report on his mobile application from his PHR/EHR.
Information	Patient demographics Radiology report Images Diagnosis Notification
Pre-requisite	Cross Border exchange infrastructure National infrastructure Security infrastructure
Profiles and standards (for Patient Apps)	<i>PDQm PIXm</i> <i>QEDm</i> <i>WIA (if images are available)</i> <i>Radiology report</i> <i>NAV</i> <i>ATNA (on FHIR)</i> <i>CT</i> <i>IUA</i>

### 3.2.2. Effort coordination among EU countries

Title	Use of standardized forms for COVID-19
Context	Various documents are actually used to follow the pandemic at the national level such as <ul style="list-style-type: none"> <li>• <i>COVID-19 self-diagnosis questionnaire</i></li> <li>• <i>COVID-19 Follow-up questionnaire</i></li> <li>• <i>Immunity passport</i></li> <li>• <i>Revised case report form confirmed novel coronavirus COVID-19</i></li> <li>• <i>etc</i></li> </ul> Some of the forms are derived from the WHO templates. See for example <a href="https://www.who.int/docs/default-source/coronaviruse/2019-covid-crf-v6.pdf?sfvrsn=c5ff90c6_2">https://www.who.int/docs/default-source/coronaviruse/2019-covid-crf-v6.pdf?sfvrsn=c5ff90c6_2</a>

	The patient with his mobile application can access to these questionnaires. In the case of follow-up questionnaire, the patient is able to receive an alert in the case where the answers are not normal
Information	Patient demographics AI algorithm Diagnosis (Coding system) HP directory Other information to be identified depending of the questionnaire
Pre-requisite	National infrastructure Security infrastructure
Profiles and standards	<i>Content standards</i> <i>mRFD, RFD</i> <i>SDC (a future extension on FHIR is in progress)</i> <i>ATNA (on FHIR)</i> <i>CT</i> <i>IUA</i> <i>XDS-SD</i>

**Note 1:** To follow the pandemic evolution public healths from European countries can develop a common standardized reporting for a better coordination. Very recently The IHE Quality Research and Public Health is launching a work on future IHE profile “ADX-for-COVID-19”, a content profile on the case report based on *IHE ADX profile* and on WHO template and other resources.

### 3.2.3. Other national use cases

Title	Remote Patient Monitoring
Context	Patient uses thermometer and pulse-oximeter to monitor his condition at home. The information that are collected can be used to fill the COVID-19 follow-up questionnaire.
Information	Patient demographics Clinical-grade Temperature Blood oxygen Heart-rate
Pre-requisite	Security infrastructure
Profiles and standards	<i>ITU H.810</i> <i>Interoperability design guidelines for personal health systems (PCHA)</i> <i>IHE PCD profiles</i>

Title	Send an alert to the family doctor
Context	The patient fills the questionnaire (COVID-19 or Follow-up). The questionnaire are analysed by the mobile application. If the case where the results of the analysis is not normal or not acceptable, an alert is sent directly to the family doctor.
Information	Patient demographics HP directory Mobile alert report

Pre-requisite	Security infrastructure
Profiles and standards	<i>mACM</i> <i>SVSm</i> <i>mCSD</i> <i>IUA</i> <i>EUA</i> <i>ATNA (on FHIR)</i> <i>CT</i>

Title	<i>Appointment for COVID-19 consultation</i>
Context	<i>An appointment is made by the patient with his GP who can visualize the appointment list in his own EMR. The patient use an appointment service available in his country.</i>
Information	Patient demographics <i>Appointment</i> <i>HP directory</i>
Pre-requisite	Security infrastructure
Profiles and standards	<i>mCSD</i> <i>FHIR standard</i> <i>ATNA (on FHIR)</i> <i>CT</i> <i>IUA</i> <i>EUA</i>

Title	ICU bed Management within hospital
Context	<i>The anesthesist is able to follow the availabilities of the ICU bed directly in his mobile application (delivered by the hospital) and can manage the list of beds in the ICU setting</i>
Information	<i>Hospital organization</i> <i>ICU bed identification</i>
Pre-requisite	HIS
Profiles and standards	<i>mCSD</i> <i>BED (hospital)</i> <i>ATNA (on FHIR)</i> <i>CT</i> <i>IUA</i>

### 3.3. Profiles

ATNA (FT): [Audit Trail and Node Authentication](#) Basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications. (RESTFUL mod in TI)

EUA (FT): [Enterprise User Authentication](#) enables single sign-on inside an enterprise by facilitating one name per user for participating devices and software.

BED (TI): [Bed Management](#) augments ITI PAM to communicate bed management for admissions.

CT(FT): [Consistent Time](#) synchronizes system clocks and time stamps of computers in a network (median error less than 1 second).

IUA (TI): [Internet User Authorization](#) provides user authorization for RESTful interfaces.

NAV (TI): [Notification of Document Availability](#) supports out-of-band notifications of documents of interest between systems or users.

mACM(TI): [Mobile Alert Communication Management\(mACM\)](#) provides a RESTful interface to an alert infrastructure

mADX (TI): [Mobile Aggregate Data Exchange \(mADX\)](#) supports interoperable public health reporting of aggregate health data

ADX (TI): [Aggregate Data Exchange](#) captures and communicates information for birth and fetal death reporting for vital registration purposes.

mCSD (TI): [Mobile Care Services Discovery \(mCSD\)](#) provides a RESTful interface to discover Care Services: Organization, Location, Practitioner, and Health Services.

MHD(TI): [Mobile access to Health Documents](#) provides a RESTful interface to Document Sharing including XDS.

MHDS: [Mobile Health Document Sharing \(MHDS\)](#) provides a Document Sharing using only FHIR. In progress

PDQm(TI): [Patient Demographics Query for Mobile \(PDQm\)](#) provides a RESTful interface to a patient demographics supplier.

PIXm(TI): [Patient Identifier Cross-Reference for Mobile \(PIXm\)](#) provides a RESTful interface to patient identifier cross-references.

[QEDm] [Query for Existing Data for Mobile](#) queries for clinical data elements (e.g. observations, allergies, conditions, diagnostic results, medications, immunizations, procedures, etc)

SDC (FT): [Structured Data Capture](#) retrieves and submits forms in a standardized and structured format.

SVSm (TI): [Sharing Valuesets, Codes and Maps \(SVCM\)](#) provides a RESTful access to ValueSets, CodeSystems, and ConceptMaps.

XD-LAB (FT): [Sharing Laboratory Reports](#) describes the content (human and machine readable) of an electronic clinical laboratory report.

SD (FT): [Cross-enterprise Sharing of Scanned Documents](#) shares unstructured electronic documents including scanned legacy paper and film.

ITU H.810: Multiple manufacturers from all around the world need to produce billions of sensors and platforms that can automatically communicate with one another where ever they are deployed. This is where interoperability is essential. ITU H.810 provides a home to hospital solution that guides manufacturers on how to quickly implement open standards-based solutions that allows any sensor to connect to any gateway and any clinical health record system. Implementation software allows rapid implementation. Test tools provide conformity assessment to assure interoperability.



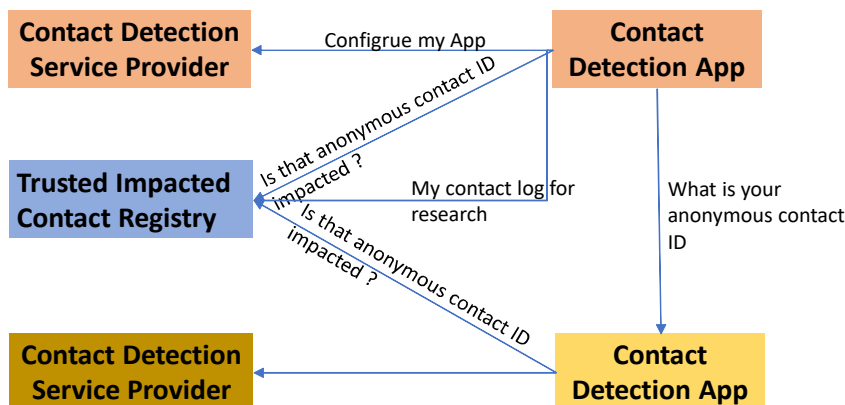
FT: Final Text

TI: Trial Implementation

### 3.4. Contact Tracing

For Mobile applications related to contact tracing, the use case and confidentiality model need to be defined and addressed with a standard-based interoperability profile.

The Commission document is a good baseline, but likely not sufficient to reassure European Citizens. An open business model is needed to allow for multiple contact detection Service Providers, each with their respective mobile application. However, the knowledge that a contact has been identified as “infected” needs to be strictly controlled and released only to a Contact Detection application by a Trusted Impacted Contact Registry (to be further analyzed). The database of contacts accumulated by an authorized Contact Detection App is likely to remain within the App, unless the App user chose to contribute its contact log for other purpose such as cross border exchange or research. An example of transactions to be standardized to ensure open interoperability is shown below (architecture neutral):



Additionally an analysis of the solution proposed by Apple and Google<sup>2</sup> as well the PEPP-PT<sup>3</sup> should be analyzed.

Other protocols are developed: [ROBERT](#)<sup>4</sup>, [DP^3T](#)<sup>5</sup>, [BlueTrace](#)<sup>6</sup>, etc. See also [COVID-19 apps](#).

IHE has not yet developed such a profile related to the above use case, but can engage this process with the goal to reach a “Public comment” version. The IHE process is proven and

<sup>2</sup> <https://www.apple.com/newsroom/2020/04/apple-and-google-partner-on-covid-19-contact-tracing-technology/>

<sup>3</sup> <https://www.pepp-pt.org/>

<sup>4</sup> <https://github.com/ROBERT-proximity-tracing/documents>

<sup>5</sup> <https://github.com/DP-3T>

<sup>6</sup> <https://en.m.wikipedia.org/wiki/BlueTrace>

well known at the European and international levels. IHE delivers the quality and the testing environment (test tool and projectathon) necessary such as the one provided to eHDSI. IHE Europe is collaborating with PCHA on providing end-to-end testing encompassing also ETSI and other telecommunication standards.

### 3.5. Other needs not covered by the recommendations

Other elements that should be included in the EU Commission COVID-19 Toolbox are based upon the European Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of ‘Integrating the Healthcare Enterprise’ profiles for referencing in public procurement of interoperable solutions. Several of these profiles have proven their readiness for an efficient coordination of care for COVID-19, to power, in an open way, key interoperability use cases proven in existing deployments with an ability to be deployed rapidly at the regional and national levels:

- The teleconsultation and referral workflow
- The sharing of Laboratory Reports at regional and national scale.
- The sharing of imaging reports and images at regional and national scale.

Profiles supporting → the following Interoperability Use Cases ↓	XDS/XCA + MHD*	ATNA /CT	XUA/B PPC	XDS-MS/ XPHR	PIX/ PDQ	XDS-SD*	XDM/ PDI	XD-LAB	XDS-I	XDW* + XBeR-WD*
Teleconsultation workflow and hospital referral	X	X	X	X	X	X				X
Sharing of Laboratory Reports	X	X	X					X		
Sharing of imaging reports and images	X	X	X				X		X	

Note: profiles shown with an \* have been released after the Commission Decision.

Note for overview of Profiles see: <https://wiki.ihe.net/index.php/Profiles>

Note that IHE engaged a large consultation in Europe and world-wide to identify additional interoperability needs effective in the support of pandemics such as COVID-19.

## 4. Testing and Conformity Assessment

The “use-case driven approach” unfolds a lot of cost-effectiveness and sustainability by having access to the “global community knowledge” as an additional resource. But to fully harvest the benefits of the approach, the testing and conformity assessment of products must be addressed. A huge effort was developed during the last past years at the international level (IHE CAS<sup>7</sup>) but also at the European level with the EURO-CAS<sup>8</sup> project, a European project

<sup>7</sup> [www.IHE.net](http://www.IHE.net)

<sup>8</sup> [www.EURO-CAS.eu](http://www.EURO-CAS.eu)

dedicated to the establishment of the Conformity Assessment Scheme for Europe that is consistent with the international effort in this domain (IHE CAS, Continua Alliance certification). To sustain such an initiative is the way to harmonize and to deploy better interoperability among Member States, allowing the care continuum that many stakeholders are waiting, including industry and secondary use organizations (research, public health etc).

Establishing a Conformity Assessment Scheme for Europe and testing products for their conformance is the arm of interoperability for better clinical data quality.

Additionally, IHE-Europe plans to set up the **Connectathon 2020 in November 2-6** in Brussels. Companies developing mobile applications are encouraged to test their products during this face to face test session.

Additionally, IHE Europe recommends to extend and use DG Santé IHE Gazelle infrastructure to create test plans and test tools to

1. Provide hands-on support to mobile application developers to harmonise their solutions against EU recommendations;
2. Test and enhance information exchange semantic and technical interoperability specifications;
3. Align the results of this COVID-19 outbreak as an asset to the already existing cross border healthcare infrastructure.