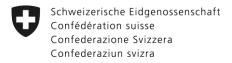
Abteilung Digitale Transformation



Swiss Interoperability Conformity Assessment Scheme (SIAS)

Edition 1.8 1. June 2023

| 1. | Introduction | 5 |
|-----|--|----|
| 1.1 | Purpose of this document | 5 |
| | Document life cycle | |
| 1.3 | Contact for inquiries about SIA and SIAS | 5 |
| 2. | References | 6 |
| 2.1 | Legislative texts (German version) | 6 |
| 2.2 | Specifications | 6 |
| 3. | Scope of the SIA | 7 |
| 4. | Resources | 7 |
| 4.1 | Execution test reports | 7 |
| | Testing tools | |
| 5. | SIA actors and responsibilities | 9 |
| | Requirements | |
| 6.1 | Requirements for the FOPH | 10 |
| 6.2 | Requirements for the certification body | 11 |
| | Requirements for test laboratories | |
| 6.4 | Requirements for the communities and reference communities | 12 |
| 6.4 | | |
| 6.4 | .2 Preparation before the assessment | 12 |
| 6.4 | .3 Test plan | 14 |
| 6.4 | .4 Test cases description and related tools | 21 |
| | Annexes | |
| | Certification Test System and Test Tools | |
| 7.2 | Execution test report summary (sample) | 40 |
| | Detailed test report (Template example) | |
| 8. | Changelog | 48 |

Glossary

| Term | Abbr. | Definition | Source |
|---|-----------|--|---|
| Certificate | | Third-party attestation related to products, processes, systems or persons. | ISO/IEC 17000 |
| | | A certificate is delivered to the communities that meet the criteria set out in articles 9 to 13 of the EPRO and to the reference communities that meet the criteria set out in articles 9 to 21 of the EPRO. | Art. 30 ff. EPRO (SR 816.11) |
| Certification | | Communities and reference communities are subject to certification. | Art. 11 a EPRA (SR 816.1) |
| Certification Body | СВ | "Certification body" is defined as an accredited external body issuing written assurance (the "certificate") that it has audited and verified that the product or software conforms to the requirements of the EPRA and its ordinances. Requirements for the certification body in the con- | ISO 9001:2008 ISO 14001:2004 Art. 11 a EPRA (SR 816.1) Art. 28 and 29 EPRO (SR 816.11) |
| | | text of the EPR are specified in Art. 28 and 29 EPRO (SR 816.11). | |
| Certification Test System | CTS | Test system provided by the FOPH to examine the transfer of data between and inside communities or reference communities during an SIA. | Art. 28 para. 4 EPRO (SR 016.11) |
| Community | | Organisational unit of health professionals and their institutions. | Art. 2 d EPRA (SR 816.1) |
| Conformity | | Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. | ISO/IEC 17000 |
| Conformity Assessment Scheme | CAS | Conformity assessment system related to specified objects of conformity assessment to which the same specified requirements, specific rules and procedures apply. | ISO/IEC 17000 |
| Electronic Patient Record | EPR | A remotely archived virtual record which allows data from a patient's medical history relevant to their treatment or data that the patient has recorded themselves to be retrieved in the event that the patient requires treatment. | EPRA (SR 816.1) |
| EPR Platform | | Central IT infrastructure of a community or reference community. | |
| Execution Test Report | | Document recording the test execution conditions and the final test results performed by an EPR platform of a specific community. | |
| FDHA Ordi- nance on the Electronic Pa- tient Record | EPRO-FDHA | The ordinance of 22 March 2017 completes the Federal Act on the EPR by providing technical requirements in its nine annexes. | EPRO-FDHA (SR 816.111) |
| Federal Act on the Electronic Patient Record | EPRA | The Federal Act on the Electronic Patient Record, in force since 15 April 2017, regulates the conditions of introduction and dissemination of the EPR. | EPRA (SR 816.1) |
| Federal Ordi- nance on the Electronic Pa- tient Record | EPRO | The ordinance of 22 March 2017 completes the Federal Act on the EPR by providing organisational, functional and certification requirements. | EPRO (SR 816.11) |
| Integration Profile | | An integration profile is a guideline for implementation of a specific interoperability process, which provides precise definitions of how standards shall be implemented to meet specific requirements for exchanging or sharing clinical data. | IHE |
| Primary System | | IT infrastructure of the health institution (hospital, pharmacy, nursing home, etc.) | 13.050 Dispatch on the Federal Act on Electronic Patient |

| Term | Abbr. | Definition | Source |
|---|-------|--|---|
| | | | Record of 29 May 2013; chapter 1.1.4 |
| Reference Community | | Community that performs additional tasks (e.g. administering patients). | Art. 2 e EPRA (SR 816.1) |
| Scheme Owner | | Person or organisation responsible for developing and maintaining a specific certification scheme. | ISO/IEC 17065 |
| Secondary System | | Infrastructure of the EPR that holds data provided by the primary systems. | 13.050 Dispatch on the Federal Act on Electronic Patient Record of 29 May 2013; chapter 1.1.4 |
| Swiss Interoperability Conformity Assessment | SIA | Process demonstrating whether the Swiss interoperability requirements as defined in the EPROFDHA, annex 2, chapter 2.9, have been fulfilled by the community or the reference community. | |
| Swiss Interoperability Conformity Assessment Scheme | SIAS | Provides the technical and operational requirements as well as rules by which the Swiss Interoperability Conformity Assessment will be executed. Conformity requirements are derived from annex 2; annex 3; annex 5; annex 5, amendment 1 and amendment 2; and annex 9 of the EPRO-FDHA. | |
| System Under Test | SUT | "System under test" is a system implementation that is tested against the Conformity Assessment Scheme. | IHE CAS |
| Test Case | | A set of test scripts including values, execution pre-conditions, expected results and execution post-conditions, developed for a particular objective or test condition, such as to exercise a particular programme path or to verify compliance with a specific requirement. | IEEE 610 |
| Test Laboratory | | Organisation that carries out the SIA by means of the certification test system and according to the rules defined in the SIAS. | |
| Test Method | | A definitive procedure that produces a test result using a combination of test cases, procedures, test data references and test tools. | EURO-CAS |
| Test Procedure | | A step-by-step implementation of a test method contained in an automated test tool or defined via manual step. | EURO-CAS |
| Test Scripts | | Test procedures that describe the sequence of actions for the execution of a given test procedure. | ISTQB |
| Test Specifications | | A collection of test procedures for a particular functional area, including the background, approach, procedure and possible results for a test. A test specification is an aggregation of test descriptions. | EURO-CAS |
| Test Tools | | An automated implementation of one or more test procedures. | EURO-CAS |

1. Introduction

1.1 Purpose of this document

This document describes the Swiss Interoperability Conformity Assessment Scheme (SIAS) for assessing the electronic patient record platform (EPR platform), under the operational responsibility of a community or a reference community¹. It provides the technical and operational requirements as well as rules by which the conformity assessment will be executed. Conformity requirements are derived from annex 2; annex 3; annex 4, annex 5; and annex 5, amendment 1, amendment 2.1, amendment 2.2 and amendment 2.3, of the FDHA Ordinance on the Electronic Patient Record (SR 816.111 EPDV-EDI).

The document is available in English only.

1.2 Document life cycle

This document is periodically updated by order of the FOPH. Reasons to update this document include but are not limited to updates of

- the EPRO-FDHA and its annexes,
- the test cases, data and tools used for assessing the SUT and included in the CTS.

The most current edition of the SIAS is available on the FOPH website at https://www.bag.ad-min.ch/epra.

1.3 Contact for inquiries about SIA and SIAS

If you have any question about this document and SIAS, please contact the FOPH via email to ehealth@bag.admin.ch

SAS accredited certification bodies are published on the SAS website at https://www.sas.ad-min.ch/sas/en/home/akkreditiertestellen/akkrstellensuchesas.html

¹ In the remainder of this text, references to "community" always mean community AND reference community, except if stated otherwise.

2. References

2.1 Legislative texts (German version)

- <u>SR 816.1 Bundesgesetz vom 19. Juni 2015 (Stand am 15. April 2020) über das elektronische Patientendossier (EPDG)</u>
- SR 816.11 Verordnung vom 22. März 2017 (Stand am 1. April 2019) über das elektronische Patientendossier (EPDV)
- <u>SR 816.111 Verordnung des EDI vom 22. März 2017 (Stand am 15. April 2021) über das</u> elektronische Patientendossier (EPDV-EDI)
 - Anhang 2 der EPDV-EDI (Zertifizierungsvoraussetzungen Gemeinschaften und Stammgemeinschaften) Ausgabe 6 Inkrafttreten 01.06.2023
 - o Anhang 3 der EPDV-EDI (Metadaten für den Austausch medizinischer Daten) Ausgabe 5 Inkrafttreten 01.06.2023
 - o Anhang 4 der EPDV-EDI (Austauschformate) Ausgabe 2 Inkrafttreten 01.06.2023
 - Ergänzung 1 zum Anhang 5 der EPDV-EDI (Nationale Anpassungen der Integrationsprofile) - Ausgabe 6 - Inkrafttreten 01.06.2023
 - Ergänzung 2.1 zum Anhang 5 der EPDV-EDI (Nationale Integrationsprofile) Ausgabe
 Inkrafttreten 01.06.2023
 - Ergänzung 2.2 zum Anhang 5 der EPDV-EDI (Nationale Integrationsprofile) Ausgabe
 4 Inkrafttreten 01.06.2023
 - Ergänzung 2.3 zum Anhang 5 der EPDV-EDI (Nationale Integrationsprofile) Ausgabe
 Inkrafttreten 01.06.2023
 - o Anhang 9 der EPDV-EDI (Metadaten für den Dienst zur Abfrage der Gesundheitseinrichtungen und Gesundheitsfachpersonen) Ausgabe 3 Inkrafttreten 01.06.2023

2.2 Specifications

- Legally binding specifications are available on the FOPH website at https://www.bag.ad-min.ch/epra, tab "Dokumente" (Documents).
- Most current specifications (status: in process and not in force, respectively) are available on the eHealth Suisse website at http://www.e-health-suisse.ch/specs.
- Additional resources (e.g. XSD schemas, examples) are available on the FOPH website at https://www.bag.admin.ch/epra.

3. Scope of the SIA

The scope of the SIA is defined by EPRO-FDHA, annex 2, chapter 2.9.

For all transactions listed in chapter 2.9, a community must demonstrate during a SIA that these transactions are supported by its EPR platform according to the corresponding specifications. If a community decides not to implement one or more of the transactions defined in chapter 2.9, the community has to inform the test laboratory and the certification body at least four weeks prior to the SIA and has to document the identified deviations. The document provided by the community must list all the missing transactions, and for each of them a rationale explaining why these transactions have not been implemented. (See also chapter 6.4 note for document "Technical guidelines for SIA testing".) After analysis of the provided information, the certification body together with FOPH will then decide whether it is acceptable not to support those transactions.

4. Resources

4.1 Execution test reports

Two execution test reports describe the test results:

- An execution test report summary of the community EPR platform. The report provides a summary of the test results for each SUT of the EPR platform. An example is provided in annex 7.2.
- A *detailed test report* of the community EPR platform. The report provides detailed test results for each SUT of the EPR platform. An example is provided in annex 7.3.

4.2 Testing tools

The testing tools used for the execution of the test cases are classified in different categories as described in Antilope Project D3.1 deliverable²:

Table 1: SIA testing tools overview (based on Antilope D3.1)

| Test tool category | Description |
|-----------------------|--|
| | A test management tool needs to facilitate the execution of tests but may include additional functionalities that would be useful in performing the tests and collecting the results. This document will focus on two distinct groups within the wide range of test management tools: |
| | a) Tools that help organize and run interoperability events involving large numbers of participants, such as the Swiss Projectathon or assessment sessions of a community where a large number of tests are performed. |
| Test management tools | The tools in this group will typically manage test scenarios for peer-to-peer tests and may also support test planning and setup of the Swiss Projectathon. They may also support the configuration process for all participating communication partners (e.g. IP addresses, ports, codes to be used, message types, other tools such as simulators and validators). In order to trigger actual test runs, the software ideally selects the communication partners from the pool of existing systems based on a number of criteria, including their communication capabilities and test instances required to reach the system's certification goals for the event (e.g. to run each test case with a certain number of distinct test partners). Such tools may also support other functionalities such as authoring of test cases and reporting of interim and final test results to the test managers and test partners. |

7/57

² https://www.antilope-project.eu/front/index.html

| Test tool category | Description |
|---------------------------|---|
| | b) Execution frameworks that facilitate the selection of individual tests and the collection of test results, including evidence of tests performed such as pass/fail verdicts with corresponding traces. Example: Gazelle Management Tool (https://gazelle.ihe.net/content/gazelle-user-guides or https://gazelle.ihe.net/EU-CAT/home.seam) |
| | A conformance tester is an automated tool that is capable of checking the behavior of the system under test. The tester takes the role of the communication partner, provides stimuli to the system under test, collects the responses and evaluates whether the order, timing and/or content of messages sent by the system under test conforms to the requirements of a given standard and integration profile. Advanced testers may take the roles of all entities that are communicating with the system under test. |
| Conformance testers | In some situations, a conformance tester is used to validate the structure and/or content of a document used in eHealth systems. |
| | The extent to which the conformance tester tools test the requirements in the integration profile varies and depends on the test plan defined in the CTS. Advanced conformance testing tools would check most or all important requirements. |
| | Depending on the level of precision in reporting discovered problems, conformance tester tools can provide valuable assistance in the rapid discovery and resolution of interoperability problems. |
| | Example: Gazelle EVS Client (https://gazelle.ihe.net/EVSClient/home.seam) |
| | A simulator, or stub, is a tool acting as a connection partner to the system that needs to be tested. In most cases, a simulator stimulates the system under test (SUT) in order to |
| | trigger a certain behavior. The kind of stimulation depends on the type of partner to be tested. For a system on a network, the stimulation would occur by sending network messages. For other systems, this could mean feeding data into specific directories, simulating user input or any other input. |
| Simulators/stubs | A simulator itself does not assess the behavior of the tested entity. However, a simulator may have integrated capability to collect the trace of the exchange that could then be evaluated manually or by other means. |
| | Simulator tools are useful for pre-testing before interoperability events or as a replacement for needed communication partners that are not available in an event. |
| | For eHealth interoperability, testing general purpose tools may not be sufficient, and specific sophisticated simulators may be required. |
| | Example: Gazelle Patient Manager (https://gazelle.ihe.net/PatientManager/home.seam) |
| Software libraries | Software libraries may be used to build both eHealth systems and eHealth testing tools. An example is a library that supports encoding and decoding of HL7 messages. Such a library can be and is used to build a system that follows an IHE integration profile, but it can also be used to build testing tools that can be used for testing the same integration profile. While, strictly speaking, such libraries are not testing tools as such, the ability to share code development efforts may contribute significantly to the improvement of interoperability of eHealth systems. |
| Test data generators | A test data generator accelerates test data preparation by providing valid input data to be used in testing. The best results are achieved if a data generator can be used in such a way as to efficiently generate data that respects the constraints set by an integration profile being tested. |
| | Example: Gazelle Demographic Data Server (https://gazelle.ihe.net/DDS/home.seam) |
| Reference implementations | A reference implementation is, generally speaking, an implementation of a specification (standard or integration profile) to be used as a definitive interpretation for that specification. Other testing tool categories (libraries, conformance testers and others) may also represent reference implementations. |

| Test tool category | Description |
|--------------------|--|
| Support tools | During testing and debugging, various support tools may be useful. While they do not test anything themselves, they may provide the means of collecting the information that is needed to progress with testing. Examples include viewers that present the information in an understandable format, proxies that facilitate reliable and uniform collection of traces and many others. Example: Gazelle Security Suite (https://gazelle.ihe.net/gss/home.seam) |
| Network sniffers | Network sniffers are also known as network analysers or protocol analysers. A sniffer is capable of decoding and analysing communication protocol messages inside the data packages. This can be done transparently to an ongoing communication, as required by non-destructive protocol testing. Network sniffers must be able to decode all relevant communication protocols (TCP/IP, HL7, DICOM, etc.) in order to prepare message validation or other tasks. Sniffers are not only used in eHealth but are applicable to any domain that uses network messaging to exchange information. Example: Gazelle Proxy (https://gazelle.ihe.net/proxy/home.seam) |

5. SIA actors and responsibilities

The following paragraph provides the technical and operational requirements as well as the rules for the actors to comply with during SIA.

Responsibilities these actors may have during other parts of the certification process are beyond the scope of this document.

- FOPH: The Federal Office of Public Health holds the role of scheme owner. With technical experts (for example from eHealth Suisse, IHE Services or a selected test laboratory), the FOPH specifies this SIAS to cover all the requirements and criteria for assessing the community's conformity with the Swiss interoperability specifications. In the context of a SIA, the FOPH is responsible for providing the CTS.
- Community and reference community: The community provides access for patients and health professionals to the electronic patient record. The community must be certified by a certification body. In the context of an SIA, the community is responsible for following the technical certification process led by the test laboratory and submits its SIA results to the certification body.
- Test laboratory: The test laboratory, mandated by the FOPH, performs the SIA and evaluates the community's EPR platform for compliance with technical requirements as described in section 6.4 of this document. In the context of an SIA, the test laboratory is responsible for the following tasks:
 - The test laboratory receives the Certification Test System (CTS) from the FOPH as a virtual machine/SaaS, which includes the necessary testing environment for performing the SIA.
 - The test laboratory performs the SIA with the community following this SIAS and according to overarching requirements (e.g. ISO/IEC 17025).
 - When the SIA is completed, the test laboratory provides the test report to the community and the certification body.
- Certification body: The certification body reviews the technical and organisational requirements of the EPRO-FDHA in the community. During the SIA the certification body has no active role. After the SIA is completed, the certification body has, on request, access to all test related data produced during the SIA. The certification body decides in which category (verification procedure, ordinary renewal or extraordinary renewal) the certification process shall apply to the community when adaptations are reported.

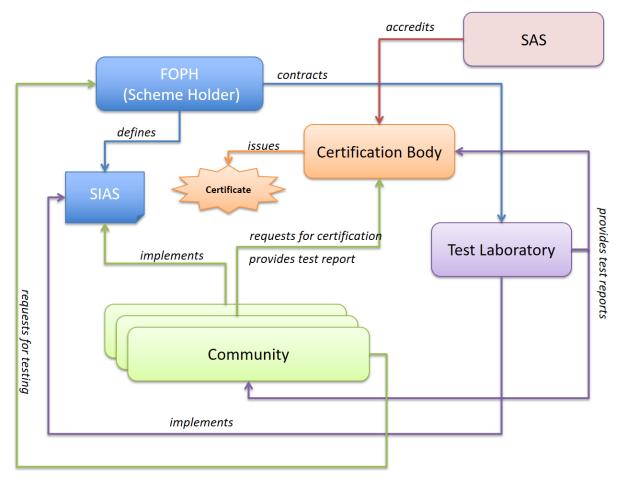


Figure 1: Actors, roles and certification workflow

6. Requirements

Requirements are statements of necessary conditions the actors need to comply with.

The requirements are being stated as

- SHALL: required or mandatory;
- SHALL NOT: prohibited;
- SHOULD: preferred, best practice or recommendation;
- MAY: acceptable or permitted.

These statements are compliant with RFC 2119.

6.1 Requirements for the FOPH

[R01] The FOPH SHALL approve the CTS validation report that is provided by the test laboratory after installation and before the first use of each major version of the CTS.

6.2 Requirements for the certification body

[RA1] The certification body decides if the adaptations³ that are reported by the community shall be examined in the context of the verification procedure, ordinary renewal or extraordinary renewal of the certification (art. 36, para. 2, ODEP). If necessary, the FOPH or the test laboratory MAY support the certification body for the evaluation of the category as defined in [RA2].

[RA2] Three categories of influence on the certification are defined:

- Adaptions to be audited during renewal of the certification: This category includes those topics/changes whose implementation by the communities is not considered urgent, as there is little or no risk to the Swiss EPR if they are not implemented. The transition period for implementation corresponds to the validity of the certification.
- Adaptions to be audited during the annual audit: This category includes those topics/changes
 whose implementation by the communities is not considered particularly urgent. A maximum
 implementation period of one year is accepted.
- 3. Adaptions to be audited during an extraordinary renewal of the certification: This category includes topics/changes whose implementation by the communities is considered particularly urgent. Failure to implement the change entails the risk that the interoperability of the community systems is no longer given and/or a data protection and data security risk exists. It is therefore mandatory that the communities implement and certify the change as soon as possible.

6.3 Requirements for test laboratories

[RB1] The test laboratory SHALL provide a guideline on how to prepare for the SIA to the communities.

[RB2] The test laboratory SHALL approve the list of SUTs provided by the community (see [RC1]) that are included in the EPR platform and that SHALL be assessed and this before registering the SUTs at the SIA. This approval also includes any documented deviations from EPRO-FDHA, annex 2, chapter 2.9, if applicable. (see chapter 3 *Scope of the SIA*)

[RB3] The test laboratory SHALL accurately and clearly report the results of each test or series of tests carried out in accordance with any specific instructions in the test scripts. The two execution test reports SHALL at least fulfil the ISO/IEC 17025 report requirements.

[RB4] In addition to the requirements listed in [RB3], the execution test reports SHALL – where relevant for the interpretation of the test results – include information about deviations from, additions to or exclusions from the test methods, and information on specific test conditions, any opinions or interpretations.

[RB5] When all the registered SUTs of the community EPR platform have completed their assessments, the test laboratory SHALL provide to the community all the execution test reports (detailed and summary execution test reports) of the SUTs that are included in the EPR platform.

[RB6] The test laboratory SHALL use the CTS provided by the FOPH. In case of provision as SaaS, the FOPH SHALL provide access credentials to the platform.

[RB7] The validation report of the major version of the CTS and its configuration SHALL be sent to the FOPH, which will authorise the test laboratory to perform the SIA.

Note: The test laboratory receives the CTS on its premises or accesses the CTS directly in the cloud using its credentials. The test laboratory configures the CTS according to its own procedures

³ Substantial technical or organizational adaptations are for example, but are not limited to, new or updated procedures which are audited during the certification process, IT infrastructure adaptations that ensure data exchanges between communities or the update of the authentication procedure by the software editors providing the identification means.

and controls the conformity of the CTS using, for example, reference test data before starting any test session. The test laboratory issues a validation report on the CTS conformity.

[RB8] The SIA MAY be conducted online. In this case, the test laboratory SHALL define operational rules and procedures for running the SIA. The operational rules and procedures that impact the EPR platform SHALL be clearly provided and explained to the community during the preparation of the SIA.

[RB9] The test laboratory SHALL NOT disclose the status of the community or the results of the SIA without the community's prior written approval (which MAY be given by email).

[RB10] The test laboratory SHALL operate under the Federal Act on Data Protection (FADP).

6.4 Requirements for the communities and reference communities

Note: The document "Technical guidelines for SIA testing" provides information on the SIA testing process. It describes the SIA process, the main testing activities and technical requirements. Furthermore, it provides the list of actors and components needed to implement a reference EPR platform. The document "Technical guidelines for SIA testing" can be requested from the FOPH.

6.4.1 Context reminder

A reference community or a community manages the EPR platform accessible by patients and healthcare professionals. The EPR platform is an aggregation of components or SUTs that collaborate in order to provide all the services for the EPR and where the set of integration profiles as defined in EPRO-FDHA, annex 2, chapter 2.9, is distributed among all the SUTs constitutive of the EPR platform.

[RC1] When a community registers for a SIA, the community SHALL provide an exhaustive list of SUTs and the needed information (see [RD5]) to the test laboratory and, if relevant, a documentation of any deviation from the required transactions as defined in EPRO-FDHA, annex 2, chapter 2.9. (see chapter 3 *Scope of the SIA*).

[RC2] When the list of SUTs is approved, the community SHALL register the EPR platform to the test laboratory for the assessment of their EPR platform SUTs and will provide their SUT characteristics (name, version, integration profile/actor/option) no later than three weeks before the start of the SIA testing.

[RC3] The list of SUTs that contribute to the integrity of the EPR platform SHALL NOT change at any time during the SIA. Its integrity SHALL be attested to when requested by the test laboratory.

[RC4] The community SHALL provide to the test laboratory all the information and documentation needed to successfully perform the SIA with a community or a reference community.

[RC5] When the conformity assessment is completed, the community SHALL send **all** the detailed reports of their EPR platform SUTs to the certification body as part of the documents needed for issuing the certification.

[RC6] The community MAY appeal the findings documented in a test execution report only if the community failed testing and believes in good faith that the test laboratory reported an incorrect decision about the compliance of the EPR platform based upon how it was evaluated during the SIA, due to a perceived bias or error and that, as a result, the test execution report does not accurately reflect the conformity of the EPR platform with the requirements listed in section 6.4.3. Both parties SHALL agree that neither of them will make any public statements or disclosures about the community's appeal during or after the appeal except as required by law. The appeal will be processed by the test laboratory under its ISO/IEC 17025 accreditation.

6.4.2 Preparation before the assessment

[RD1] The community SHALL select a set of integration profiles in the list of integration profile/actor pairs presented in section 6.4.3 for **each** of the SUTs of their EPR platform.

[RD2] During preparation, the community MAY be supported by the test laboratory only for the SIA scope and its context to successfully perform the SIA.

[RD3] For more efficiency and to reduce cost, the community SHOULD participate in one of the Swiss Projectathons and SHOULD test the SUTs of their EPR platform.

Note 1: The Projectathon supports operators and implementers in improving their products and facilitating the adoption of the testing tools they will use during the SIA.

Note 2: The community has to prepare themselves by means of the reference EPR platform.

[RD4] The community SHALL nominate a project leader who will interface with the test laboratory during the SIA and during preparation of the SIA.

Note: The test laboratory MAY request other human resources such as SUT operators with relevant skills and experiences.

[RD5] All the needed information about the SUTs – such as name(s) of the vendors(s), names of the SUTs, versions of the SUTs, names of the SUT operators, name and address of the community, contact names, previous execution test reports – SHALL be provided to the test laboratory.

6.4.3 Test plan

This section describes the technical criteria for certification called *test plan*. This test plan is defined based on the integration profiles and test methods, e.g. test cases and test tools, embedded in the CTS.

The next sub-section provides the list of profiles, actors and transactions as well as the reference specifications and a reference to a sub-section with a description of the related test cases. To perform test cases, the Certification Test System (CTS) is used as a reference test system. The CTS includes a set of test tools as described in the annex 7.1.

6.4.3.1 IHE Integration Profiles

| Integration Profile | Nat- Ext. | Actors | Transactions | Reference Specifications | Test cases |
|---|-----------|---|--|---|--------------------|
| ATNA Audit Trail and Node Authentication Basic security through a) functional access controls, b) defined security audit logging and c) secure network communications | Yes | Secure Application Audit Repository | Authenticate Node [ITI-19] Record Audit Event [ITI 20] | IHE IT Infrastructure Technical Framework Vol 1 – Section 9; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download Amendment 1 to Annex 5 of the EPDV-EDI Revision 01-06-2023 XSD Schemas 23-06-2021 | Section 6.4.4.1 |
| CT Consistent Time Synchronizes system clocks and time stamps of computers in a network (median error less than 1 second) | Yes | Time Client | Maintain Time [ITI-1] | IHE IT Infrastructure Technical Framework Vol 1 – Section 7; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download | Section 6.4.4.2 |

⁴ Please note that ITI-TF Rev.19 has been archived by IHE. To consult the ITI specifications, you should download this zip file only once.

| HPD Health Provider Directory Supports discovery and management of healthcare provider information, both individual and organizational, in a directory structure | Yes | Provider Information Directory Provider Information Consumer HPD Healthcare Provider Directory | Provider Information Query [ITI-58] Provider Information Feed [ITI-59] Provider Information Delta Download (CH:PIDD) | IHE IT Infrastructure Technical Framework Supplement • Healthcare Provider Directory; Revision 1.8 (2020-08-28) Central Services Interface Documentation • Revision-1.0.41 (2023-07-10) Amendment 1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | Section 6.4.4.3 |
|--|-----|--|--|---|--------------------|
| PDQv3 Patient Demographics Query HL7 V3 Queries for patient identity from a central patient information server leveraging HL7 version 3 | Yes | Patient De- mographics Sup- plier Patient De- mographics Con- sumer | Patient Demographics Query HL7 V3 [ITI-47] | IHE IT Infrastructure Technical Framework • Vol 1 – Section 24; Revision 19.0 (2022-06-17) • Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download Amendment 1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | Section 6.4.4.4 |
| PIXv3 Patient Identifier Cross-Referencing HL7 V3 Queries for the patient identify Cross-References between hospitals, sites, Health Information exchange networks etc. leveraging HL7 version 3 | Yes | Patient Identifier Cross-Reference Manager Patient Identifier Cross-Reference Consumer Patient Identity Source | Patient Identity Feed HL7 V3 [ITI-44] PIXV3 Query [ITI-45] | IHE IT Infrastructure Technical Framework • Vol 1 – Section 23; Revision 19.0 (2022-06-17) • Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download Amendment 1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | Section 6.4.4.5 |
| SVS Sharing Value Set Distributes centrally-managed common, uniform no- menclatures | No | Value Set Consumer MDI Metadata Index Service | Retrieve Value Set [ITI-48] | IHE IT Infrastructure Technical Framework Vol 1 – Section 21; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) | Section 6.4.4.6 |

| XCA Cross Community Access Supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/ enterprises that have agreed to work together. | No | Initiating Gateway (no Option) Responding Gateway (No option) | Cross Gateway Query [ITI-38] Cross Gateway Retrieve [ITI-39] | Download Central Services Interface Documentation Revision-1.0.41 (2023-06-01) IHE IT Infrastructure Technical Framework Vol 1 – Section 18; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download | Section 6.4.4.7 |
|---|-----|---|--|---|---------------------|
| XCA-I Cross Community Access for Imaging Extends XCA to share images, diagnostic reports and related information across communities | No | Initiating Gateway (Imaging) (no Option) Responding Gateway (Imaging) (No option) | Cross Gateway Retrieve Image Document Set [RAD-75] | IHE Radiology Technical Framework Vol 1 – Section 18; Revision 17 (2018-07-27) Vol 3 – Revision 17 (2018-07-27) | Section 6.4.4.8 |
| XCPD Cross-Community Patient Discovery Locates communities with electronic health records for a patient and translates patient identifiers across communities | Yes | Initiating Gateway (no Option) Responding Gateway (No option) | Cross Gateway Patient Discovery [ITI-55] | IHE IT Infrastructure Technical Framework Vol 1 – Section 27; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download Amendment 1 to Annex 5 of the EPDV-EDI Revision 01-06-2023 | Section 6.4.4.9 |
| XDS Cross-Enterprise Document Sharing Shares and discovers electronic health record documents between healthcare enterprises, physician offices, clinics, acute care inpatient facilities and personal health records | Yes | Document Consumer Document Registry Document Source Document Repository | Registry Stored Query [ITI-18] | IHE IT Infrastructure Technical Framework Vol 1 – Section 10; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download | Section 6.4.4.10 |

| | | | | Amendment 1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | |
|--|-----|---|---|--|---------------------------------|
| XDS Metadata Update Provides support for updating metadata used in the profiles XDS and XDR. | No | Document Registry Document Administrator | Update Document set (ITI-57) | IHE IT Infrastructure Technical Framework • Technical Framework Supplement (TI) Revision 1.13 (2022-06-17) Amendment 1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | Section 6.4.4.10 |
| XDS-I Cross-enterprise Document Sharing for Imaging Extends XDS to share images, diagnostic reports and related information across a group of care sites | No | Imaging Document Consumer Imaging Document Source | Provide and Register Imaging Document Set – MTOM/XOP [RAD-68] Retrieve Imaging Document Set [RAD-69] | IHE Radiology Technical Framework Vol 1 – Section 18; Revision 17 (2018-07-27) Vol 3; Revision 20.0 (2022-03-10) Amendment 1 to Annex 5 of the EPDV-EDI Revision 01-06-2023 | Section 6.4.4.116.4 .4.11 |
| XDM Cross-Enterprise Document Media Interchange Transfers documents and metadata using CDs, USB memory or email attachments | No | Portable Media Creator Portable Media Importer | Distribute Document Set on Media [ITI-32] | IHE IT Infrastructure Technical Framework Vol 1 – Section 16; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Download | Section 6.4.4.12 |
| XUA Cross-Enterprise User Assertion Communicates claims about the identity of an authenticated principal (user, application, system,) across enterprise boundaries - federated identity | Yes | X-Service User X-Service Provider | Authenticate User Get X-User Assertion Provide X-User Assertion [ITI-40] | IHE IT Infrastructure Technical Framework Vol 1 – Section 13; Revision 19.0 (2022-06-17) Vol 2 ITI TF-2; Revision 19.0 (2022-06-17) Amendment 1 to Annex 5 of the EPDV-EDI Revision 01-06-2023 | Section 6.4.4.13 |

| RMU Restricted Metadata Update | Yes | Update Initiator Update Responder | Restricted Update Document Set [ITI-92) | IHE IT Infrastructure Technical Framework Supplement Restricted Metadata Update | Section 6.4.4.14 |
|---|-----|---------------------------------------|---|--|------------------|
| Provides a mechanism for changing Document | | | | Revision 1.3 (2021-07-02) | |
| Sharing Metadata both within and across community boundaries in a controlled manner | | | | Amendment 1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | |

6.4.3.2 National Integration Profiles

| Integration Profile | National Extension | Actors and Options | Transactions | Reference Specifications | Test Cases |
|--|-----------------------------|---|--|---|---------------------|
| CH: ADR Authorization Decision request Defines new functionalities for XDS-based communities concerning the enforcement of access policies. They are applied to the clinical data by an XDS Document registry, as well as to the access policies themselves, which are stored in a Policy Repository | New actors and transactions | Authorization Decision Provider Authorization Decision Consumer | Authorization Decision Request (CH:ADR) | Amendment 2.1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 XSD Schemas • 26-11-2021 | Section 6.4.4.15 |
| CH: PPQ Privacy Policy Query Defines new functionalities for XDS-based communities concerning the management of access policies in terms of updating or modifying policies as well as querying policies from and adding policies to a Policy Repository by a Policy Source and Policy Consumer | New actors and transactions | Policy RepositoryPolicy SourcePolicy Consumer | Privacy Policy Feed [CH:PPQ-1] Privacy Policy Retrieve [CH:PPQ-2] | Amendment 2.1 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 XSD Schemas • 26-11-2021 | Section 6.4.4.16 |
| CH:ATC Audit Trail Consumption Defines the audit trail consumption requirements a community has to provide for a patient's audit trail | Yes | Patient Audit Consumer Patient Audit Repository | Retrieve ATNA Audit Event [ITI-81] | Amendment 2.2 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 | Section 6.4.4.17 |
| CH:CPI Community Portal Index | Yes | CPI Consumer CPI Provider | Community Information Query [CH:CIQ] | Amendment 2.3 to Annex 5 of the EPDV-EDI • Revision 01-06-2023 Central Services Interface Documentation | Section 6.4.4.18 |

| Index containing all information about certified (reference-) communities and their endpoints according to the Federal Act on the Electronic Patient Record (EPRA) | | | Community Information Delta Download [CH:CIDD] | Revision-1.0.41 (2023-07-10) XSD Schemas Revision 23-06-2021 | |
|--|-----|--|--|--|---------------------|
| CH:EMED Exchange format eMedication | Yes | CH- EMED_CONTENT_ CONSUMER | • N/A | Annex 4 of the EPD-EDI • 2023-06-01 (DE) • 2023-06-01 (FR) | Section 6.4.4.20 |
| CH:VACD Exchange format eVaccination | Yes | CH- VACD_CONTENT_ CREATOR CH- VACD_CONTENT_ CONSUMER | • N/A | Annex 4 of the EPD-EDI • 2023-06-01 (DE) • 2023-06-01 (FR) | Section 6.4.4.21 |

6.4.3.3 Other Interfaces: UPI

Standard interfaces to the Unique Person Identification (UPI) register of the Central Compensation Office (ZAS)

| Profile | National Extension | Actors and Options | Interfaces | Reference Specifications | Test Cases |
|--|-----------------------|------------------------|---|--|------------------|
| UPI Unique Person Identification Index maintained by the Central Compensation Office (ZAS) that implements administrative identification of physical persons and the identification management | | UPI_Service UPI Client | eCH-0213 UPI / SPID announcements: This interface covers all SPID-based announcements that record information in the UPI. This standard also describes the common types of the three interfaces (eCH-0213-commons). The communication is based on a request addressed to the UPI and the response of the latter. | eCH-0213 Schnittstellenstandard Meldungen UPI/SPID • Version 1.0 (2017-09-13) | Section 6.4.4.19 |
| | | UPI_Service UPI Client | eCH-0214 | eCH-0214 Abfragen UPI/SPID | |

| UPI_Service UPI Client | UPI / SPID request: thisinterface covers all UPI requests concern- ing SPIDs. This is a read only in- terface. The communication is based on a request and a re- sponse from UPI. eCH-0215 Broadcast Mutations UPI / SPID: this interface describes the broad- cast (distribution) of the mutations of people with SPID that the UPI | Version 2.0 (2018-12-03) eCH-0215 Broadcast Mutationen UPI/SPID Version 2.0 (2018-12-03) |
|------------------------|--|---|
| | sends to all the customers who subscribed. | |

6.4.4 Test cases description and related tools

The following tables provide for each integration profile, the related test cases, a short test case description and the test case version. Above each table, there is a link to a PDF document with a detailed description of all test cases for the corresponding profile.

6.4.4.1 ATNA – Audit trail and Node Authentication

Detailed test case description for ATNA

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|------------------------------|--|--|
| 12564 | ATNA_SA-SN_ITI19_Error_Cases | Verify Secure Application or Secure Node acting as Server are able to reject invalid TLS handshakes | Version: 1.1 Last modified: 03/01/2020 16:07:20 |
| 12562 | ATNA_SA-SN_ITI-20 | Verify a Secure Application or a Secure Node is able to send an Audit Message with the Syslog protocol to the Syslog Collector simulator | Version: 1.0 Last modified: 11/09/2019 12:50:06 |
| 13534 | ATNA_SA-SN_Questionnaire | ATNA Secure Application or Secure Node completes the ATNA Questionnaire to provides information on secured elements of the system. | Version: 1.1 Last modified: 13/09/2023 8:51:34 |

6.4.4.2 CT - Consistent Time

Detailed test case description for CT

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|-----------------------|---|--|
| 13432 | CHCT_TIME-CLIENT_ITI1 | Synchronize a system with a public NTP server on Swiss time | Version: 1.0 Last modified: 30/08/2019 14:59:45 |

6.4.4.3 HPD – Health Provider Directory

Detailed test case description for HPD

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|-----------------------------|--|--|
| 13293 | CHHPD_PROV_INFO_CONS_ITI-58 | Provider Info Consumer ITI-58 HPD query request on HPD Simulator Provider Info Directory message validation using EVSClient. | Version: 1.0 Last modified: 04/09/2019 17:09:47 |
| 13295 | CHHPD_PROV_INFO_DIR_ITI-58 | Provider Info Consumer ITI-58 HPD query request on HPD Simulator Provider Info Directory message validation using EVSClient. | Version: 1.0 Last modified: 07/04/2022 18:13:37 |
| 13297 | CHHPD_PROV_INFO_DIR_ITI-59 | An ITI-59 Provider Information Feed initiated from HPD Simulator to your system. HPD query response message validation using EVSClient | Version: 1.0 Last modified: 04/09/2019 10:54:21 |
| 13291 | CHHPD_PROV_INFO_SRC_ITI-59 | HPD Provider Info Feed message from Provider Info Source, sent on HPD Simulator Provider Info Directory, validated using EVSClient | Version: 1.0 Last modified: 03/09/2019 11:31:37 |

6.4.4.4 PDQv3 – Patient identifier Cross-Referencing HL7v3

Detailed test case description for PDQv3

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|-------------------------|--|--|
| 13203 | CHPDQv3_PDC_ITI-47 | This test evaluates the capability of the system acting as a CH:PDQV3 Patient Demographics Consumer actor to send a valid query (ITI-47) to the PatientManager tool acting as a CH:PDQV3 Patient Demographics Supplier | Version: 1.1 Last modified: 04/12/2019 14:07:56 |
| 13206 | CHPDQv3_PDS_ITI-47_1 | This test checks the ability of your system acting as a CH:PDQV3 Patient Demographic Supplier to answer to an exact match query (ITI-47) in a single domain | Version: 1.0 Last modified: 03/09/2019 15:52:54 |
| 13207 | CHPDQv3_PDS_ITI-47_2 | Test test checks the ability of your system acting as CH:PDQV3 Patient Demographic Supplier to answer to a query (ITI-47) in a single domain | Version: 1.0 Last modified: 03/09/2019 16:06:16 |
| 13201 | CHPIX_CHPDQ_SERVER_CONF | This is a preliminary test for CH:PDQv3 suppliers and CH:PIXV3 managers. The goal is to populate the system under test with a well-known set of patient data. | Version: 1.0 Last modified: 17/06/2019 16:59:58 |

6.4.4.5 PIXv3 – Patient Identifier Cross Referencing HL7v3

Detailed test case description for PIXv3

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|-------------------------|---|--|
| 13201 | CHPIX_CHPDQ_SERVER_CONF | This is a preliminary test for CH:PDQv3 suppliers and CH:PIXV3 managers. The goal is to populate the system under test with a well-known set of patient data. | Version: 1.0 Last modified: 17/06/2019 16:59:58 |
| 13210 | CHPIXV3_CONS_ITI-45 | This test checks the ability of the CH:PIXV3 Patient Identifier Cross-Reference Consumer actor to query for patient identifiers (ITI-45). | Version: 1.1 Last modified: 07/04/2022 08:46:32 |
| 13213 | CHPIXV3_MGR_CONF | The purposes of this test are first to demonstrate that your system acting as CH:PIXV3 Patient Identifier Cross-Reference Manager can be configured to access feeds from specific patient identity source systems and then to actually configure your system to access feeds from the testing tool. | Version: 1.1 Last modified: 21/06/22 10:47:09 |
| 13212 | CHPIXV3_MGR_ITI-44 | This test checks the ability of the CH:PIXV3 Patient Identifier Cross-Reference Manager to integrate the messages exchanged in the context of the Patient Identity Feed HL7v3 (ITI-44) transaction: add record, revise record and resolve duplicates. | Version: 1.1 Last modified: 07/04/2022 13:43:15 |
| 13214 | CHPIXV3_MGR_ITI-45_1 | This test checks that your CH:PIXV3 Patient Identifier Cross-Reference manager correctly answers to PIXV3 queries (ITI-45) when both the query patient identifier and the requested domain are known. | Version: 1.0 Last modified: 03/09/2019 15:06:51 |
| 13216 | CHPIXV3_MGR_ITI-45_3 | This test verifies the ability of the CH:PIXV3 Patient Identifier Cross reference manager actor to handle the error case of the PIXV3 Query (ITI-45) where no identifier exists for the queried patient in any of the domains sent in DataSource.value | Version: 1.0 Last modified: 03/09/2019 15:07:41 |
| 13217 | CHPIXV3_MGR_ITI-45_4 | This test verifies the ability of the CH:PIXV3 Patient Identifier Cross reference manager actor to handle the error case of the PIXV3 Query (ITI-45) where the system under test does not know the patient identifier enclosed in the query. | Version: 1.0 Last modified: 03/09/2019 15:08:06 |

| 13218 | CHPIXV3_MGR_ITI-45_5 | This test verifies the ability of the CH:PIXV3 Patient Identifier Cross reference manager actor to handle the error case of the PIXV3 Query (ITI-45) when it does not recognize one or more of the Patient Identification Domains for which an identifier has been requested. | Version: 1.0 Last modified: 03/09/2019 15:09:09 |
|-------|----------------------|---|--|
| 13219 | CHPIXV3_MGR_ITI-45_6 | This test checks that your SUT correctly answers to PIXV3 queries when it knows multiple identifiers within at least one of the requested domains | Version: 1.0 Last modified: 04/09/2019 10:33:58 |
| 13208 | CHPIXV3_SRC_ITI-44 | This test verifies the ability of the CH:PIXV3 Patient Identity Source actor to issue conform messages for the Patient Identity Feed HL7V3 (ITI-44) transaction: add record, revise record and resolve duplicates operations. | Version: 1.1 Last modified: 06/09/2021 16:20:55 |

6.4.4.6 SVS – Sharing Value Set

Detailed test case description for SVS

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|---------------------------|--|--|
| 13276 | SVS_VALUE_SET_CONS_ITI-48 | Value Set Consumer SUT ITI-48 Retrieve Value Set Request with Value Set Repository simulator | Version: 1.0 Last modified: 03/09/2019 15:40:19 |
| 13274 | SVS_VALUE_SET_REPO_CONF | SVS Repository is loaded with value sets (codes) for the test session | Version: 1.1 Last modified: 24/09/2019 12:39:33 |
| 13282 | SVS_VALUE_SET_REPO_ITI_48 | Value Set Repository SUT responds to ITI-48 Retrieve Value Set Request from Value Set Consumer simulator | Version: 1.0 Last modified: 03/09/2019 15:30:04 |

6.4.4.7 XCA – Initiating Gateway Actor

Detailed test case description for XCA

| Test Case Permanent ID | Test Case Name | Test Case description | Version and reference |
|---------------------------|------------------------------|---|--|
| 13460 | CHXCA_INIT-GW_ITI-38 | This test is to verify the SUT capacity to query the metadatas of documents through an ITI-38 transaction to a XCA Responding Gateway. | Version: 1.3 Last modified: 14/11/2023 8:43:27 |
| 13461 | CHXCA_INIT-GW_ITI-39 | This test is to verify the SUT capacity to retrieve documents through an ITI-39 transaction to a XCA Responding Gateway. | Version: 1.4 Last modified: 14/11/2023 8:44:36 |
| 13449 | CHXCA_RESP_GW_ITI-38 | This test is to verify the SUT capacity to provide the metadatas of documents through an ITI-38 transaction from a XCA Initiating Gateway. | Version: 1.2 Last modified: 14/11/2023 8:48:37 |
| 13447 | CHXCA_RESP_GW_ITI-38_INVALID | This test is to verify the SUT capacity to provide the correct error messages in response to a flawed ITI-38 transaction formulated by an XCA Initiating Gateway. | Version: 1.1 Last modified: 14/11/2023 8:49:37 |
| 13446 | CHXCA_RESP_GW_ITI-39 | This test is to verify the SUT capacity to provide documents through an ITI-39 transaction in response to a XCA Initiating Gateway. | Version: 1.3 Last modified: 14/11/2023 8:50:30 |
| 13448 | CHXCA_RESP_GW_ITI-39_INVALID | This test is to verify the SUT capacity to send the correct error messages in response to a flawed ITI-39 transaction through a XCA initiating gateway | Version: 1.3 Last modified: 14/11/2023 8:51:46 |
| 13445 | XCA_INIT_GW_CONF | Description of the data and configuration needed for the tests of the XCA Initiating Gateway actor | Version: 1.2 Last modified: 11/02/2020 10:17:27 |

6.4.4.8 XCA-I - Cross Community Access for Imaging

Detailed test case description for XCA-I

| Test Case Permanent ID | Test Case Name | Test Case description | Version and reference |
|---------------------------|-------------------------------|--|---|
| 13488 | CHXCA-I_INIT_GW_RAD-69_RAD-75 | This test will verify the ability of the SUT to answer an RAD-69 query from a Document Consumer, as well as sending a document set the request (RAD-75) to a Responding Gateway simulator. | Version: 1.2 Last modified: 7/12/2023 16:06:47 |
| 13487 | CHXCA-I_RESP_GW_RAD-69_RAD-75 | This test is to provide the data necessary to execute the XCA-I RAD-69 and RAD-75 transactions for Initiating Gateway testing. | Version: 1.2 Last modified: 7/12/2023 16:05:52 |

6.4.4.9 XCPD - Cross Community Patient Discovery

Detailed test case description for XCPD

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|-----------------------|--|--|
| 13245 | CHXCPD_INIT-GW_ITI-55 | This test evaluates the capability of the CH:XCPD Initiating Gatewey to send a valid Cross-Community Patient Discovery (ITI-55) query. | Version: 1.0 Last modified: 04/09/2019 11:56:21 |
| 13244 | CHXCPD_RESP-GW_CONF | This is a test to configure the system under test acting as a CH:XCPD Responding Gateway before the other tests are executed. | Version: 1.0 Last modified: 17/06/2019 16:36:22 |
| 13246 | CHXCPD_RESP-GW_ITI-55 | This test verifies the ability of the system under test acting as a CH:XCPD Responding Gateway to handle Cross-Community Patient Discovery queries (ITI-55) for which it owns matching patients. | Version: 1.0 Last modified: 04/09/2019 09:46:05 |

6.4.4.10 XDS - Cross-Enterprise Document Sharing and Metadata Update

Detailed test case description for XDS

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|------------------------|-------------------------|---|--|
| 13437 | CHXDS.b_DOC_CONS_CONF | Description of the registry and repository content used for testing. | Version: 1.1 Last modified: 03/01/2020 16:08:39 |
| 13438 | CHXDS.b_DOC_CONS_ITI-18 | This test verifies the SUT's ability to request a document metadatas through an ITI-18 transaction against a simulated XDS document registry (with the support of XUA). | Version: 1.2 Last modified: 14/11/2023 8:58:01 |
| 13463 | CHXDS.b_DOC_CONS_ITI-43 | This test is to verify the SUT capacity to request a document through an ITI-43 transaction with a XDS document repository. | Version: 1.2 Last modified: 14/11/2023 9:01:26 |
| 13519 | CHXDS.b_DOC_REG_CONF | Configuration and data feed for the XDS Document Registry. | Version: 1.1 Last modified: 03/01/2020 16:05:11 |
| 13436 | CHXDS.b_DOC_REG_ITI-18 | This test is to verify the SUT capacity to provide document metadatas through an ITI-18 transaction with a XDS document consumer. | Version: 1.2 Last modified: 14/11/2023 9:06:17 |
| 13435 | CHXDS.b_DOC_REG_ITI-42 | This test is to verify the SUT capacity to register a document metadatas through an ITI-42 transaction with a XDS document repository. | Version: 1.2 Last modified: 14/11/2023 9:08:14 |
| 13316 | CHXDS.b_DOC_REG_ITI-57 | Document Registry SUT receives update document metadata from Document Administrator Simulator. | Version: 1.2 Last modified: 14/11/2023 9:10:55 |

| 13440 | CHXDS.b_DOC_REPO_CONF | This test targets at setting up the context for the XDS.b Document Repository actor. | Version: 1.2 Last modified: 06/02/2020 16:46:36 |
|-------|------------------------------|--|---|
| 13443 | CHXDS.b_DOC_REPO_ITI41_ITI42 | This test verifies the capacity of a system to receive and accept a document in a Provide and Register (ITI-41) transaction. It includes metadata forwarding (ITI-42). | Version: 1.2 Last modified: 14/11/2023 9:22:46 |
| 13444 | CHXDS.b_DOC_REPO_ITI43 | This test verifies the capacity of a system to respond to a retrieve request in a Retrieve Document (ITI-43) transaction. | Version: 1.2 Last modified: 14/11/2023 9:25:28 |
| 13433 | CHXDS.b_DOC_SRC_ITI-41 | This test is to verify the SUT capacity to register a document and its metadata through an ITI-41 transaction with a XDS document repository. | Version: 1.2 Last modified: 14/11/2023 9:29:13 |
| 13318 | XDS.b_DOC_ADMIN_ITI-57 | ITI-57 Update Document Set for Document Administrator from a Document Administrator SUT to a simulated Document Registry | Version: 1.2 Last modified: 14/11/2023 8:55:51 |

6.4.4.11 XDS-I - Cross-Enterprise Document Sharing for Imaging

Detailed test case description for XDS-I

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|---------------------------|---|---|
| 13476 | CHXDS-I.b_DOC_CONS_RAD-69 | This test is to verify the SUT capacity to request an image document through a RAD-69 transaction with a XDS-I document source simulator. | Version: 1.2 Last modified: 13/11/2023 11:23:44 |
| 13475 | CHXDS-I.b_DOC_SRC_RAD-68 | This test is to verify the SUT capacity to register a DICOM KOS through a RAD-68 transaction with a XDS document repository. | Version: 1.2 Last modified: 13/11/2023 11:18:11 |
| 13477 | CHXDS-I.b_DOC_SRC_RAD-69 | This test is to verify the SUT capacity to provide an image document requested through a RAD-69 transaction initiated by a XDS-I Document Consumer simulator. | Version: 1.2 Last modified: 14/11/2023 9:31:51 |

6.4.4.12 XDM - Cross Enterprise Document Media Interchange

Detailed test case description for XDM

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|---------------------------|---|--|
| 13284 | XDM_PMC_Create_Media | Portable Media Creator creates CD-R and/or USB | Version: 1.1 Last modified: 14/11/2023 11:46:20 |
| 13285 | XDM_PMC_Validate_ZIP | NIST tool validates XDM Zip file generated by Portable Media Creator | Version:1.0 Last modified: 08/10/2020 11:53:17 |
| 13515 | XDM_PMI_Import_Error_case | Portable Media Creator and Importer exchange content on XDM media (CD-R or USB). Content is taken from gazelle samples so no PMC needed for this test. Content contains errors that shall be reported by the SUT. | Version: 1.0 Last modified: 11/02/2020 16:04:22 |
| 13288 | XDM_PMI_Import_Media | Portable Media Creator and Importer exchange content on XDM media (CD-R or USB). Content is taken from gazelle samples so no PMC needed for this test | Version: 1.0 Last modified: 11/02/2020 16:04:48 |

6.4.4.13 XUA - Cross Enterprise User Assertion

Detailed test case description for XUA

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|--------------------------------------|--|--|
| 13366 | CHXUA_X-ASSERT-PROV_ASS | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is an Assistant. | Version: 1.2 Last modified: 6/12/2023 9:46:18 |
| 13364 | CHXUA_X-ASSERT-PROV_DADM | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is a Document Administrator. | Version: 1.1 Last modified: 6/12/2023 9:47:30 |
| 13362 | CHXUA_X-ASSERT-PROV_HCP | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is an Healthcare Professional. | Version: 1.1 Last modified: 6/12/2023 9:48:04 |
| 13442 | CHXUA_X-ASSERT- PROV_INVALID_CASE | Simulated X-Service User sending an invalid requests for an assertion to an X-Assertion Provider | Version: 1.1 Last modified: 14/11/2023 10:33:06 |
| 13360 | CHXUA_X-ASSERT-PROV_PADM | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is a Policy Administrator. | Version: 1.1 Last modified: 6/12/2023 9:48:40 |
| 13358 | CHXUA_X-ASSERT-PROV_PAT | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is a Patient. | Version : 1.1 Last modified: 6/12/2023 9:49:18 |
| 13356 | CHXUA_X-ASSERT-PROV_REP | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is a Representative. | Version: 1.1 Last modified: 6/12/2023 9:49:56 |
| 13354 | CHXUA_X-ASSERT-PROV_TCU | This test checks the conformance of the assertion issued by the X Assertion Provider when the Authenticate User is a Technical User. | Version: 1.1 Last modified: 6/12/2023 9:50:29 |

| CHXUA_X_SERV_USR_AUTH_USR | Verify X-Service User is able to initiate and run a valid CH:XUA Authenticate User transaction with the simulated User Authentication Provider using the artifact binding. | Version: 1.0 Last modified: 16/09/2019 11:58:06 |
|--------------------------------|--|---|
| CHXUA_X-SERV-USR_GXUA_ASS | X-Service User requests an assertion to a simulated X-Assertion Provider for an Assistant. | Version: 1.1 Last modified: 14/11/2023 10:45:23 |
| CHXUA_X-SERV- USR_GXUA_DADM | X-Service User requests an assertion to a simulated X-Assertion Provider for a Document Administrator. | Version: 1.1 Last modified: 14/11/2023 11:05:16 |
| CHXUA_X-SERV-USR_GXUA_HCP | X-Service User requests an assertion to a simulated X-Assertion Provider for an Healthcare Provider. | Version: 1.1 Last modified: 14/11/2023 11:06:57 |
| CHXUA_X-SERV- USR_GXUA_PADM | X-Service User requests an assertion to a simulated X-Assertion Provider for a Policy Administrator. | Version: 1.1 Last modified: 14/11/2023 11:07:58 |
| CHXUA_X-SERV-USR_GXUA_PAT | X-Service User requests an assertion to a simulated X-Assertion Provider for a Patient. | Version: 1.1 Last modified: 14/11/2023 11:09:33 |
| CHXUA_X-SERV-USR_GXUA_REP | X-Service User requests an assertion to a simulated X-Assertion Provider for a Representative. | Version: 1.1 Last modified: 14/11/2023 11:10:15 |
| CHXUA_X-SERV-USR_GXUA_TCU | X-Service User requests an assertion to a simulated X-Assertion Provider for a Technical User. | Version: 1.1 Last modified: 14/11/2023 11:11:02 |
| XUA_X-SERVICE-PROV_ITI-40 | This test is used to synthesis the testing of the XUA X-Service- Provider actor. | Version: 1.2 Last modified: 05/05/2020 17:31:34 |
| XUA_X-SERVICE-USER_ITI-40 | This test is used to synthesis the testing of the XUA X-Service-User actor. | Version: 1.0 Last modified: 12/09/2019 17:59:34 |
| | CHXUA_X-SERV-USR_GXUA_ASS CHXUA_X-SERV- USR_GXUA_DADM CHXUA_X-SERV-USR_GXUA_HCP CHXUA_X-SERV- USR_GXUA_PADM CHXUA_X-SERV-USR_GXUA_PAT CHXUA_X-SERV-USR_GXUA_REP CHXUA_X-SERV-USR_GXUA_TCU XUA_X-SERVICE-PROV_ITI-40 | Authenticate User transaction with the simulated User Authentication Provider using the artifact binding. CHXUA_X-SERV-USR_GXUA_ASS X-Service User requests an assertion to a simulated X-Assertion Provider for an Assistant. CHXUA_X-SERV-USR_GXUA_DADM X-Service User requests an assertion to a simulated X-Assertion Provider for a Document Administrator. CHXUA_X-SERV-USR_GXUA_HCP X-Service User requests an assertion to a simulated X-Assertion Provider for an Healthcare Provider. CHXUA_X-SERV-USR_GXUA_PADM X-Service User requests an assertion to a simulated X-Assertion Provider for a Policy Administrator. CHXUA_X-SERV-USR_GXUA_PAT X-Service User requests an assertion to a simulated X-Assertion Provider for a Patient. CHXUA_X-SERV-USR_GXUA_REP X-Service User requests an assertion to a simulated X-Assertion Provider for a Representative. CHXUA_X-SERV-USR_GXUA_TCU X-Service User requests an assertion to a simulated X-Assertion Provider for a Technical User. XUA_X-SERV-USR_GXUA_TCU This test is used to synthesis the testing of the XUA X-Service-Provider actor. XUA_X-SERVICE-USER_ITI-40 This test is used to synthesis the testing of the XUA X-Service-Provider actor. |

6.4.4.14 RMU - Restricted Metadata Update

Detailed test case description for RMU

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|------------------------|--|--|
| 13332 | RMU_UPDATE_INIT_ITI-92 | The Initiator prepares and issues an update to DocumentEntry metadata objects via Restricted Update Document (ITI-92) transaction with the Responder as a simulator. | Version: 1.3 Last modified: 13/11/2023 11:36:53 |
| 13330 | RMU_UPDATE_RESP_ITI-92 | The Responder accepts requests for updates to DocumentEntry metadata objects send by a simulated Update Initiator. | Version: 1.4 Last modified: 5/12/2023 11:21:26 |

6.4.4.15 CH:ADR - Authorization Decision Request

Detailed test case description for CH:ADR

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|---------------------------|-------------------------------------|--|--|
| 13147 | CHADR_due_to_ATC_for_Provider | Authorization Decision Provider | Version: 1.2 Last modified: 13/11/2023 15:04:59 |
| 13148 | CHADR_due_to_ATC_for_Provider_Error | Authorization Decision Provider Error case | Version: 1.2 Last modified : 30/06/23 11:06:42 |
| 12899 | CHADR_due_to_PPQ_for_Provider | Authorization Decision Provider | Version: 1.2 Last modified: 13/11/2023 15:10:30 |
| 12927 | CHADR_due_to_PPQ_for_Provider_Error | Authorization Decision Provider Error case | Version: 1.2 Last modified: 13/11/2023 15:12:47 |
| 12894 | CHADR_due_to_XDS_for_Provider | A simulator sends ADR AuthorizatoonDecisionrequests due to XDS requests to an ADR Provider SUT | Version: 1.2 Last modified: 13/11/2023 15:15:16 |
| 12929 | CHADR_due_to_XDS_for_Provider_Error | Authorization Decision Provider | Version: 1.2 Last modified: 13/11/2023 15:16:53 |
| 13522 | CHADR_FOR_CONSUMER | This test is used to synthesize the testing of the ADR Authorization Decision Consumer actor. | Version: 1.1 Last modified: 30/06/2023 11:15:13 |

6.4.4.16 CH:PPQ - Privacy Policy Query

Detailed test case description for CH:PPQ

| Test Case Permanent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|------------------------|------------------------------|---|--|
| 13380 | CHPPQ_POLICY_CONS_PPQ2 | Policy Consumer executes a valid PPQ-2 XACML Policy query to a simulated Policy Repository | Version: 1.2 Last modified: 13/11/2023 15:47:10 |
| 13368 | CHPPQ_POLICY_REPO_PPQ-1_ADD | System acting as PPQ Repository must respond to a simulated PPQ request aiming at adding a policy in the repository. | Version: 1.2 Last modified: 13/11/2023 15:50:24 |
| 13370 | CHPPQ_POLICY_REPO_PPQ-1_DEL1 | System acting as PPQ Repository must respond to valid and invalid PPQ requests aiming at deleting a policy in the repository. | Version: 1.2 Last modified: 13/11/2023 15:51:26 |
| 13382 | CHPPQ_POLICY_REPO_PPQ-1_UPD | PPQ Repository must respond to a valid simulated PPQ UpdatePolicy Request. | Version: 1.2 Last modified: 13/11/2023 15:52:29 |
| 13386 | CHPPQ_POLICY_REPO_PPQ-2 | PPQ Repository must respond to a valid simulated PPQ XACMLPolicy Request | Version: 1.2 Last modified: 13/11/2023 15:54:06 |
| 13374 | CHPPQ_POLICY_SRC_PPQ-1_ADD | Policy Source requests to add new Policy in a simulated PPQ repository | Version: 1.2 Last modified: 13/11/2023 15:55:03 |
| 13376 | CHPPQ_POLICY_SRC_PPQ-1_DEL | Policy Source Delete Policy requests to a simulated PPQ repository a valid PPQ-1 Delete Policy query | Version: 1.2 Last modified: 13/11/2023 15:56:40 |
| 13378 | CHPPQ_POLICY_SRC_PPQ-1_UPD | Policy Source Policy requests to a simulated PPQ repository a valid UpdatePolicy request | Version: 1.2 Last modified: 13/11/2023 15:57:39 |
| 13520 | PPQ_REPO_CONF | Configuration and data feed for the PPQ Repository | Version: 1.0 Last modified: 12/09/2019 17:12:37 |

6.4.4.17 CH:ATC - Authorization Request

Detailed test case description for CH:ATC

| Test Case Permnent ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|--------------------------|---------------------------------|---|--|
| 13221 | CHATC_ARR_CONF | Configuration and data feed for the ATC Patient Audit Record Repository. | Version: 1.0 Last modified: 08/09/2019 16:04:20 |
| 13678 | CHATC_ARR_ITI81_ErrorCases | Patient Audit Record Repository must handle correctly authorization enforcement and various error situations of ITI-81 according to CH:ATC profile. | Version: 1.1 Last modified: 28/06/2022 14:14:38 |
| 13224 | CHATC_ARR_ITI81_NormalCases | The purpose of this test case is to make sure your Patient Audit Record Repository is able to answer to the Search operation on AuditEvent resources using the search parameters as defined in CH:ATC profile | Version: 1.3 Last modified: 6/12/2023 15:19:35 |
| 13226 | CHATC_PAT_AUDIT_CONS_ITI81 | This is a no-peer test run against a simulator of the ATC Audit Record Repository actor. We are checking that the Patient Audit Consumer is able to query using the required parameter and evaluate its capability to use the optional parameter. This test also checks that the system sends the IUA assertion in the HTTP header. | Version: 1.3 Last modified: 8/12/2023 15:37:01 |
| 13228 | CHATC_PAT_AUDIT_CONS_Transla te | Verify that a Patient Portal is able to translate Audit Events with codes into German, French or Italian | Version: 1.1 Last modified: 13/11/2023 10:38:56 |

6.4.4.18 CH:CPI - Community Portal Index

Detailed test case description for CH:CPI

| Test Case ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|--------------|-------------------------|---|--|
| 13642 | CHCPI_CONSUMER_CHCIDD_1 | CPI consumer as SUT must query CPI provider | Version: 2.0 Last modified: 04/04/2022 13:09:34 |
| 13643 | CHCPI_CONSUMER_CHCIQ_1 | CH-CPI consumer as SUT must query CH-CPI provider | Version: 2.0 Last modified: 04/04/2022 13:09:44 |

6.4.4.19 UPI – Unique Person Identification

Detailed test case description for UPI

| Test Case ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|--------------|---|---|--|
| 13644 | CH:UPI_eCH0213_SPID_CANCEL | UPI client send an eCH0213 request to cancel the SPID for a patient | Version: 2.1 Last modified: 14/11/2023 8:25:11 |
| 13645 | CH:UPI_eCH0213_SPID_CREATION | UPI client send an eCH0213 request to create an SPID for a patient | Version: 2.1 Last modified: 14/11/2023 8:27:00 |
| 13646 | CH:UPI_eCH0213_SPID_INACTIVATE | Verify the inactivation of a SPID for a patient | Version: 2.1 Last modified: 14/11/2023 8:28:35 |
| 13647 | CH:UPI_eCH0214_FROM_DEMOGRAPHICS | UPI client send an eCH0214 request for a patient attributes using his demographics. | Version: 2.2 Last modified: 14/11/2023 8:29:54 |
| 13648 | CH:UPI_eCH0214_FROM_NAVS | UPI client send an eCH0214 request for a patient demographics using his NAVS. | Version: 2.1 Last modified: 14/11/2023 8:31:27 |
| 13649 | CH:UPI_eCH0214_FROM_SPID | UPI client send an eCH0214 request for a patient demographics using his SPID. | Version: 2.1 Last modified: 14/11/2023 8:32:35 |
| 13650 | CH:UPI_eCH0215_RECEIVE_A_BROADCAST _MUTATION | UPI client receive an eCH0215 broadcast mutation and modifiy its patients. | Version: 1.0 Last modified: 30/05/2022 16:26:35 |

6.4.4.20 EMED – Medication Exchange Format

Detailed test case description for EMED

| Test Case ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|--------------|---------------------------------|--|----------------------------------|
| 13731 | CH-EMED_Import_Doc_PDF_Med_Card | CH-EMED Import Medication Card document PDF rep- | Version: 1.0 |
| | | resentation | Last modified: 21/06/23 17:05:50 |

6.4.4.21 VACD – eVaccination Exchange Format

Detailed test case description for VACD

| Test Case ID | Test Case Name | Test Case description | Test Case and Test Data Version |
|--------------|----------------------------------|--|--|
| 13719 | CH-VACD_Aggregated_Doc_add_dose | The Content Creator has to demonstrate that it can aggregate Immunization Administration documents in one result document. | Version: 1.0 Last modified: 14/11/23 14:24:10 |
| 13720 | CH-VACD_Aggregated_Doc_allergy | The Content Creator has to demonstrate that it can aggregate Immunization Administration documents in one result document. | Version: 1.1 Last modified: 14/11/23 14:24:27 |
| 13721 | CH-VACD_Aggregated_Doc_foreign | The Content Creator has to demonstrate that it can aggregate Immunization Administration documents in one result document. | Version: 1.1 Last modified: 14/11/23 14:24:46 |
| 13722 | CH-VACD_Aggregated_Doc_Val_Vacci | The Content Creator has to demonstrate that it can aggregate Immunization Administration documents in one result document. | Version: 1.1 Last modified: 14/11/23 14:25:01 |
| 13723 | CH-VACD_Create_Immunization | The Content Creator has to demonstrate that it can create a valid Immunization Administration document from its system. | Version: 1.2 Last modified: 13/11/23 14:18:12 |
| 13726 | CH-VACD_Create_Vac_Record_doc | The Content Creator has to demonstrate that it can create a valid Vaccination Record document from its system. | Version: 1.2 Last modified: 13/11/23 14:17:23 |
| 13727 | CH-VACD_Import_Data_Immu_Admin | The Content Consumer has to demonstrate that it can extract data elements. Optionally, the Content Consumer can show the extract data in a document by using a stylesheet. | Version: 1.1 Last modified: 13/11/23 13:59:01 |
| 13730 | CH-VACD_Import_Data_Vac_Rec_Doc | The Content Consumer has to demonstrate that it can extract data elements. Optionally, the Content Consumer can show the extract data in a document by using a stylesheet. | Version: 1.0 Last modified: 21/06/23 17:03:51 |

7. Annexes

7.1 Certification Test System and Test Tools

| Test management Test management tool 6.10.5 NONE | Tool name | Antilope D3.1 classification | installed version | Tested profile |
|--|--------------------------------|-------------------------------|----------------------|----------------|
| EVSClient | Gazelle Test Management | Test management tool | 6.10.5 | NONE |
| CH:ATC R3 | Proxy | Proxy | 5.0.7 | NONE |
| CH:ATC R4 | EVSClient | Interoperability validator | 6.4.1 | CH:ADR |
| CH:EMED CH:PPQ CH:UPI CH:VACD CH:UPI CH:VACD CH:XUA CH:PIX CH:PDQ CH:XUA CH:PIX CH:PDQ CH:XCPD CH:XDS CH:XDDS CH: | | | | CH:ATC R3 |
| CH:PPQ | | | | CH:ATC R4 |
| CH:UPI | | | | CH:EMED |
| CH:VACD CH:XUA CH:PIX CH:PDQ CH:XCPD CH:XDS CH:XDS CH:XCA SVS CH:XCA CH:XCB CH:XDS CH:XDD CH | | | | CH:PPQ |
| CH:XUA CH:PIX CH:PDQ CH:XCPD CH:HPD CH:XDS CH:XDS CH:XCA SVS | | | | CH:UPI |
| CH:PIX | | | | CH:VACD |
| CH:PDQ | | | | CH:XUA |
| CH:XCPD | | | | CH:PIX |
| CH:HPD | | | | CH:PDQ |
| CH:XDS | | | | CH:XCPD |
| CH:XCA SVS SVS Gazelle Webservice Tester Conformance tester 1.7.4 CH:PPQ CH:XCA CH:XCA CH:XCA CH:XCA CH:XCA CH:XDS CH:XDS CH:ADR CH:RMU CH:SVS CH:XUA CH:ATC XDS Testing (NIST XDS Toolkit) Conformance tester 7.6.0 CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XCA CH:XDS CH:XCA CH:XDS CH:XCA CH:XDS CH:XCA CH:XDS CH:XCPD CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:HPD |
| SVS | | | | CH:XDS |
| Gazelle Webservice Tester Conformance tester 1.7.4 CH:PPQ CH:XCA CH:XCA-I CH:XDS-I.b CH:XDS-I.b CH:XDS CH:ADR CH:RMU CH:RMU CH:SVS CH:XUA CH:ATC CH:ATC XDS Testing (NIST XDS Toolkit) Conformance tester 7.6.0 CH:XDS CH:XDS CH:XDS-I.b | | | | CH:XCA |
| CH:XCA | | | | SVS |
| CH:XCA-I CH:XDS-I.b CH:XDS CH:XDS CH:ADR CH:RMU CH:SVS CH:XUA CH:XUA CH:XUA CH:XUA CH:XUA CH:XDS CH:X | Gazelle Webservice Tester | Conformance tester | 1.7.4 | CH:PPQ |
| CH:XDS-1.b CH:XDS | | | | CH:XCA |
| CH:XDS CH:ADR CH:RMU CH:SVS CH:XUA CH:ATC XDS Testing (NIST XDS Toolkit) Conformance tester T.6.0 CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS CH:XDS-I.b XDStar Client Simulator/stub, interoperability validator CH:XDS CH:XCA CH:XDS CH:XCPD CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:XCA-I |
| $\begin{array}{c} \text{CH:ADR} \\ \text{CH:RMU} \\ \text{CH:SVS} \\ \text{CH:XUA} \\ \text{CH:ATC} \\ \\ \text{XDS Testing (NIST XDS Toolkit)} \\ \text{COnformance tester} \\ \text{COnformance tester} \\ \text{CH:XDS} \\ \text{CH:XDS} \\ \text{CH:XDS-I.b} \\ \\ \text{CH:XDS-I.b} \\ \text{CH:XDS-I.b} \\ \\ \text{CH:XDS} \\ \text{CH:XDS} \\ \text{CH:XDS} \\ \text{CH:XDS} \\ \text{CH:XDS} \\ \text{CH:XDS} \\ \text{CH:XCPD} \\ \text{CH:RMU} \\ \\ \text{Patient Manager} \\ \text{Simulator/stub} \\ \text{Simulator/stub} \\ \text{9.16.6} \\ \text{CH:PDQ} \\ \text{CH:PIX} \\ \end{array}$ | | | | CH:XDS-I.b |
| $\begin{array}{c} \text{CH:RMU} \\ \text{CH:SVS} \\ \text{CH:XUA} \\ \\ \text{CH:ATC} \\ \\ \text{XDS Testing (NIST XDS Toolkit)} \\ \text{Conformance tester} \\ \text{Conformance tester} \\ \text{CH:XDS} \\ \\ \text{CH:XDS-I.b} \\$ | | | | CH:XDS |
| CH:SVS CH:XUA CH:ATC XDS Testing (NIST XDS Toolkit) Conformance tester 7.6.0 CH:XDS CH:XDS CH:XDS-I.b CH:XDS-I.b XDStar Client Simulator/stub, interoperability validator Validator CH:XDS CH:XCA CH:XDS CH:XCPD CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:ADR |
| CH:XUA CH:ATC XDS Testing (NIST XDS Toolkit) Conformance tester 7.6.0 CH:XDS CH:XDS CH:XDS-1.b CH:XDS-1.b CH:XDS | | | | CH:RMU |
| XDS Testing (NIST XDS Toolkit) Conformance tester 7.6.0 CH:XDS CH:XDS CH:XDS-I.b XDStar Client Simulator/stub, interoperability validator CH:XDS CH:XDS CH:XCA CH:XDS CH:XCPD CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:SVS |
| XDS Testing (NIST XDS Toolkit) Conformance tester 7.6.0 CH:XDS CH:XDS-I.b XDStar Client Simulator/stub, interoperability validator CH:XDS CH:XCA CH:XDS CH:XDS CH:XCPD CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:XUA |
| XDStar Client Simulator/stub, interoperability validator CH:XDS-I.b CH:XCA CH:XDS CH:XCPD CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:ATC |
| XDStar Client Simulator/stub, interoperability validator CH:XDS CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | XDS Testing (NIST XDS Toolkit) | Conformance tester | 7.6.0 | CH:XDS |
| validator CH:XDS CH:XCPD CH:RMU Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:XDS-I.b |
| Patient Manager Simulator/stub 9.16.6 CH:XCPD CH:RMU 9.16.6 CH:PDQ CH:PIX | XDStar Client | | 2.5.13 | CH:XCA |
| Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | validator | | CH:XDS |
| Patient Manager Simulator/stub 9.16.6 CH:PDQ CH:PIX | | | | CH:XCPD |
| CH:PIX | | | | CH:RMU |
| | Patient Manager | Simulator/stub | 9.16.6 | CH:PDQ |
| CH-VCDD | | | | CH:PIX |
| GII.ACPD | | | | CH:XCPD |
| HPD Simulator Simulator/stub 2.4.5 CH:CPI | HPD Simulator | Simulator/stub | 2.4.5 | CH:CPI |
| CH:HPD | | | | CH:HPD |
| SVS Simulator Support tools, Simulator/stub 2.3.4 SVS | SVS Simulator | Support tools, Simulator/stub | 2.3.4 | |
| Authentication Simulator Simulator/stub 0.1.2 CH:XUA | | · · · | | |

| Gazelle Security Suite | Support tool, Simulator/stub, in- | 6.3.3 | CH:ATNA |
|-------------------------------------|-----------------------------------|-------|----------|
| | teroperability validator | | CH:XUA |
| EPR Assertion Provider Simulator | Simulator/stub | 1.3.0 | CH:XUA |
| EPR Get X User Assertion Validator | Validator (in EVS Client) | 1.1.2 | CH:XUA |
| Gazelle STS | Simulator/stub | 1.3.1 | CH:XUA |
| EPR ADR Simulator | Simulator/stub | 1.3.7 | CH:ADR |
| EPR PPQ Simulator | Simulator/stub | 1.3.7 | CH:PPQ |
| Metadata Update Responders | Simulator/stub | 1.3.1 | CH:RMU |
| (EPR RMU Simulator) | | | CH:XDSMU |
| EPR XDSMU Simulator | Simulator/stub | 1.2.0 | CH:RMU |
| | | | CH:XDSMU |
| ATC Patient Audit Record Repository | Simulator/stub | 2.0.1 | CH:ATC |
| XDS XCA Simulator | Simulator/stub | 1.0.3 | CH:XCA |
| | | | CH:XDS |
| Assertion Manager | Support tools | 4.2.5 | NONE |
| Demographic Data Server | Test data generator | 4.3.4 | NONE |
| Gazelle HL7 Validator | Interoperability validator | 3.8.3 | CH:PIX |
| | | | CH:XCPD |
| | | | CH:PDQ |
| Schematron Validator | Interoperability validator | 2.5.2 | CH:ADR |
| | | | CH:ATNA |
| | | | CH:PPQ |
| | | | CH:UPI |
| | | | CH:XUA |
| Gazelle FHIR Validator (R4) | Interoperability validator | 4.1.7 | CH:ATC |
| | | | CH:EMED |
| | | | CH:VACD |
| Matchbox | Interoperability validator | 3.3.3 | CH:ATC |
| | | | CH:EMED |
| | | | CH:VACD |
| UPI EPR-SPID Manager | Simulator/stub | 1.0.1 | CH:UPI |
| UPI EPR-SPID Responder | Simulator/stub | 1.0.1 | CH:UPI |
| | | | |

7.2 Execution test report summary (sample)

See following page.

[LOGO TEST LABORATORY] [LOGO Community]

Swiss Interoperability Conformity Assessment

Execution Test Report Summary

The [product and version] of the [Company] documented in this report is a component of the EPR platform of the community [Name, address] This product and version was tested according to the requirements developed in the Swiss Interoperability Conformity Assessment Scheme (SIAS) to demonstrate conformance with the specifications described in annex 2 section [XX] section [XX], annex 3 section [YY] and annex 5 section [ZZ] of the ordinance of FDHO; RS 816.111.

It demonstrates that the product is capable to contribute to the EPR platform of the community, according to normative specifications defined in EPRO-FDHO.

Testing consisted of observed demonstrations in a controlled environment under normal operating conditions and using approved test tools used by the ISO/IEC 17025 accredited test laboratory. Test efforts also included review of test tool results, self-attestation materials and, where applicable, interoperability testing files and audit logs. Testing was constrained by the requirements as specified in the latest version of the SIAS at the time of testing. Any exceptions to these requirements are noted within the execution test reports when applicable.

Report ID:

Test Session: [Dates]

Community: [Name] [Address]

Number of the component: [X]

Total Number of components tested for the community: [Z]

Company Name

Product Name

Version

[Name of the test laboratory] [N°Accreditation] [Report ID]/

Integration Profiles/Actors Tested for Conformity Assessment

The [name of test laboratory] determined that

[product pame] [version] provided for conformity assessment by

[company name] located at [address]

successfully demonstrated compliance to the integration profile(s)/actor(s) pairs required for the Swiss Conformity Assessment described in the SIAS [Date].

The system under test was made available for test on [Date]. Tests were executed from [Date] to [Date], [on-line] [on the premises of the test laboratory at [Address]].

| Integration Profile | Actors and options | Reference Specifications | Test Results |
|---|------------------------------|---|----------------------|
| IHE Integration Profiles | | | |
| IHE RMU Restricted Metadata Update Document Metadata Update | Name of the actor No options | IHE IT Infrastructure Technical Framework Supplement Restricted Metadata Update; Revision 1.0 (2018-05-23) Amendment 1 to Annex 5 of the EPDV-EDI Revision 15-07-2019 | Passed |
| IHE Integration Profiles w | ith ext <mark>ens</mark> ion | | |
| CH: ATNA Audit Trail and Node Authentication | No options | IHE IT Infrastructure Technical Framework • Vol 1 – Section 9; | Passed with comments |
| CH Profiles | | | |
| CH: ADR Authorization Decision request | No options | Amendment 2.1 to Annex 5 of the EPDV-EDI • Revision 15-07- 2019 XSD Schemas • Revision 15-07- 2019 | Passed |

[Name of the test laboratory] [N°Accreditation][Report ID]/

Additional Software required for testing

The following additional software/options were required by [Company Name] to assist in demonstrating compliance with the associated conformance requirements by providing the specified functionality:

| Software Products and Developer | Associated files/Actors | Integration | Pro- | Functio | nality Provided |
|---------------------------------|-------------------------|-------------|------|---------|-----------------|
| None | - | | | - | |

[Name of the test laboratory] [N°Accreditation][Report ID]/

Report Summary

[Name of the test laboratory] [N°Accreditation][Report ID]/

[Test Laboratory Name] an accredited ISO/IEC 17025 under contract [Reference] with FOPH has reviewed and confirms that [Product] [Version] successfully passed the test scripts identified in this report through attestation, observed demonstration, review of audit logs, and interoperability file validations. Testing was conducted using SIAS requirements testing processes based on ISO/IEC 17025. All tests results documented in this report including the mentioned exceptions, are considered formal test results. This test result summary is authorized by

| Test laboratory Representative | Function/Title |
|--|--|
| ,, | |
| | |
| | |
| Signature and Date | Information on the Accreditation Body |
| Signature and Date | (logo, other) |
| A detailed test report is kept by [Test Labora available upon requests to the [Company National Company Nati | tory], the [Community Name] and the certification body and ame]. |
| Please visit https:// for the most curren | nt vers <mark>ion</mark> of the SIAS |
| | |
| | |
| | |
| About [Test laboratory] | |
| Information on [Test Laboratory], | |
| Name of the contact | |
| Address | |
| Copyright | |
| | |

Appendix A – Testing Comments

This appendix documents or references any exceptions identified during the SIA.

| Integration Profile | Actors and options | Test Case Comments | Test Tools |
|--------------------------|--------------------|--------------------|---------------|
| IHE Integration Profiles | | | |
| IHE CT | Time Client | | No test tools |
| Consistent Time | No option | | |

Additional software required for testing with exceptions:

| Software Products and Developer | Associated files/Actors | Integration | Pro- | Functionality Provided |
|---------------------------------|-------------------------|-------------|------|------------------------|
| None | - | | | - |

[Name of the test laboratory] [N°Accreditation][Report ID]/

7.3 Detailed test report (Template example)

See following page.

TEST EVENT - DATE

[COMPANY]

Test Laboratory

| Contact | |
|---------------|--|
| Email address | |

Tested Organization

| Contact Name | |
|---------------|--|
| Address | |
| Email address | |

Tested System(s)

| Name of the test session | | | | | | | |
|--|---------|--|-------|--|--|--|--|
| Product Name | Version | | Owner | | | | |
| | | | | | | | |
| This test session was held from dd/mm/yyyy to dd/mm/yyyy | | | | | | | |

Report identification

This report has been generated on dd/mm/yyyy with identifier [name of test session].[COMPANY.Id].

Disclaimer

This report summarizes the outcome of the testing performed by [COMPANY] during the [TEST SESSION], it includes information about success and failure and should only be used internally. This report does not certify the capabilities of any commercial product offered by [COMPANY].

System: [SUT] (Version)

Results per Integration Profile/Actor/Option

| Results per integration profile/actor/option | | | | | | | |
|--|-------|----------------|-------|-------------------|--|--|--|
| Integration Profile | Actor | Option | Type* | Result | | | |
| | | (None, option) | (T,S) | (Pass, Failed) | | | |
| | | | | | | | |
| | | | | | | | |
| * T: Thorough/S: Supportive | | | | | | | |

Test instances summary

| Test instances summary | | | | | | | |
|------------------------|---|-----------|--------|--------|--------------------|--|--|
| Tests | | Performed | Passed | Failed | Partially verified | | |
| [nn] | 7 | [nn] | [nn] | [nn] | [nn] | | |

Tests: Number of individual test cases run during the session.

Performed: Total number of test instances performed (This count does not take into account the aborted, still running and not verified test instances)

This report shall not be reproduced, except in full, without the written permission of the FOPH.

8. Changelog

Version 0.8.2

- Transactions for UPI added (section 6.4.3.3 and 6.4.4.19)
- List of test tools added (section 7.1)
- Changelog added (section 8)
- Minor changes and corrections

Edition 1.0

- Links to legislative texts updated (section 2.1)
- Responsibilities of certification body and test lab modified (section 5, 6)
- Links to specifications updated (section 6.4.3.1, 6.4.3.2, 6.4.3.3)
- Links to test case PDF per profile added (section 6.4.4)
- List of certification test system and test tools updated (section 7.1)

Edition 1.1

- Link to amendment 2.3. appendix 5 of EPRO-FDHA updated to edition 3 of amendment 2.3. appendix 5 of EPRO-FDHA. (New endpoint for RMU was added.) (section 2.1)
- Links to XSD Schemas updated (section 6.4.3.2)
- Tables with test case descriptions updated and aligned to CTS 1.1 (section 6.4.4). Changes apply to:
 - o 6.4.4.1 ATNA Audit trail and Node Authentication
 - 0 0

- HPD Health Provider Directory
- o 6.4.4.6 SVS Sharing Value Set
- 0

- XDS Cross-Enterprise Document Sharing
- 0

- o XDS-I Cross-Enterprise Document Sharing for Imaging
- 0

- o CH:PPQ Privacy Policy Query
- Table with test tools updated (section 7.1)
- Minor changes and corrections

Edition 1.2

- A more detailed definition was added to chapter 3 *Scope of the SIA*. Plus some depending changes were made in chapters 6.3 and 6.4.1.
- Tables with test case descriptions updated and aligned to CTS 1.2 (section 6.4.4). Changes apply to:
 - o 6.4.4.1 ATNA Audit trail and Node Authentication
 - o 6.3.4.4 PDQv3 Patient Identifier Cross-Referencing HL7v3
 - o 6.4.4.6 SVS Sharing Value Set
 - 0 0

- o XCA Initiating Gateway Actor
- 0 0

- XDS Cross-Enterprise Document Sharing
- 0 0

- O XDS-I Cross-Enterprise Document Sharing for Imaging
- o 6.3.4.14 XUA CrossEnterprise User Assertion
- o 6.3.4.16 RMU Restricted Metadata Update
- \circ 0 CH:ADR Authorization Decision Request

0

- o CH:PPQ Privacy Policy Query
- Table with test tools updated (section 7.1)
- Minor changes and corrections

Edition 1.3

- Updating of references to legal texts and specifications to the state of legislation as of 15.04.2020 (chapters 2.1, 6.4.3.1, 6.4.3.2)
- Removal of transaction ITI-46 from chapter 6.4.3.1
- Table with test case descriptions for PIXv3 updated (chapter 6.4.4.5)
- Minor changes and corrections

Edition 1.4

- Table with test case descriptions for PIXv3 updated (chapter 6.4.4.5)
- Table with test case descriptions for XUA updated (chapter 0)
- Table with test case descriptions for CH:CPI updated (chapter 6.4.4.18)

Edition 1.5

- Updating of references to legal texts that were updated in April, 2021
- Additional paragraph in the chapter 2, scope of the SIA on the technical guidelines for SIA testing
- Requirements for the certification body in chapter 6.2 updated
- Requirements for the communities and reference communities in chapter 6.4 updated
- Tables 6.4.4.10 XDS Cross-Enterprise Document Sharing and 6.4.4.12 XDS Metadata Update merged
- Table with test case description for ATNA updated (chapter 6.4.4.1)
- Table with test case description for HPD updated (chapter 6.4.4.3)
- Table with test case description for PIXv3 updated (chapter 6.4.4.5)
- Table with test case description for XCA updated chapter 6.4.4.7)
- Table with test case description for XDS updated (chapter 6.4.4.10)
- Table with test case description for XDM updated (chapter 6.4.4.12)
- Table with test case description for XUA updated (chapter 6.4.4.13)
- Table with test case description for RMU updated (chapter 6.4.4.15)
- Table with test case description for CH:ATC updated (chapter 6.4.4.18)
- Table with test case description for CH:UPI updated (chapter 6.4.4.20)
- Certification Test System and Test Tools in Annex 7.1 updated

Edition 1.5.1

- 6.4.3.1 IHE Integration Profiles and Chapter 6.4.3.2 National Integration Profiles: Links to specifications in column Reference Specifications were updated.
- Certification Test System and Test Tools in Annex 7.1 updated based on new CTS version 1.5
- Correction of typos

Edition 1.6

- Table with test case description for CH:CPI updated (chapter 6.4.4.19)
- Table with test case description for CH:UPI updated (chapter 6.4.4.20)
- List of test tools updated with UPI simulator and new version of HPD simulator (section 7.1)

Edition 1.6.1

- Updated versions and dates of test cases modified by patch 20220630 (section 6.4.4)
- Update of the Proxy version modified by patch 20220630 (section 7.1)

Edition 1.8

- Update of the Legislative text part (section 2.1).
- Add the eVaccination and eMedication reference documents.
- Update the test cases' version and last modified date. Update the links to access the updated test cases.
- Add the eVaccination and eMedication test cases.
- Update the Certification Test System and Test tools part with the new tools versions.
- Section 6.4.3
 - Update of the test plan with new IHE & CH reference documents.
 - Adaptation to ITI-TF Rev. 19 download process (Archived by IHE)
 - Removed XDS-SD profile
- Section 6.4.4
 - Update of the test cases version and last modified date.
 - Update of the links to access the updated test cases.
- Section 7.1
 - Update of the Certification Test System and Test tools part with the new tools versions.