# Conformity Framework Proposal for EHDS

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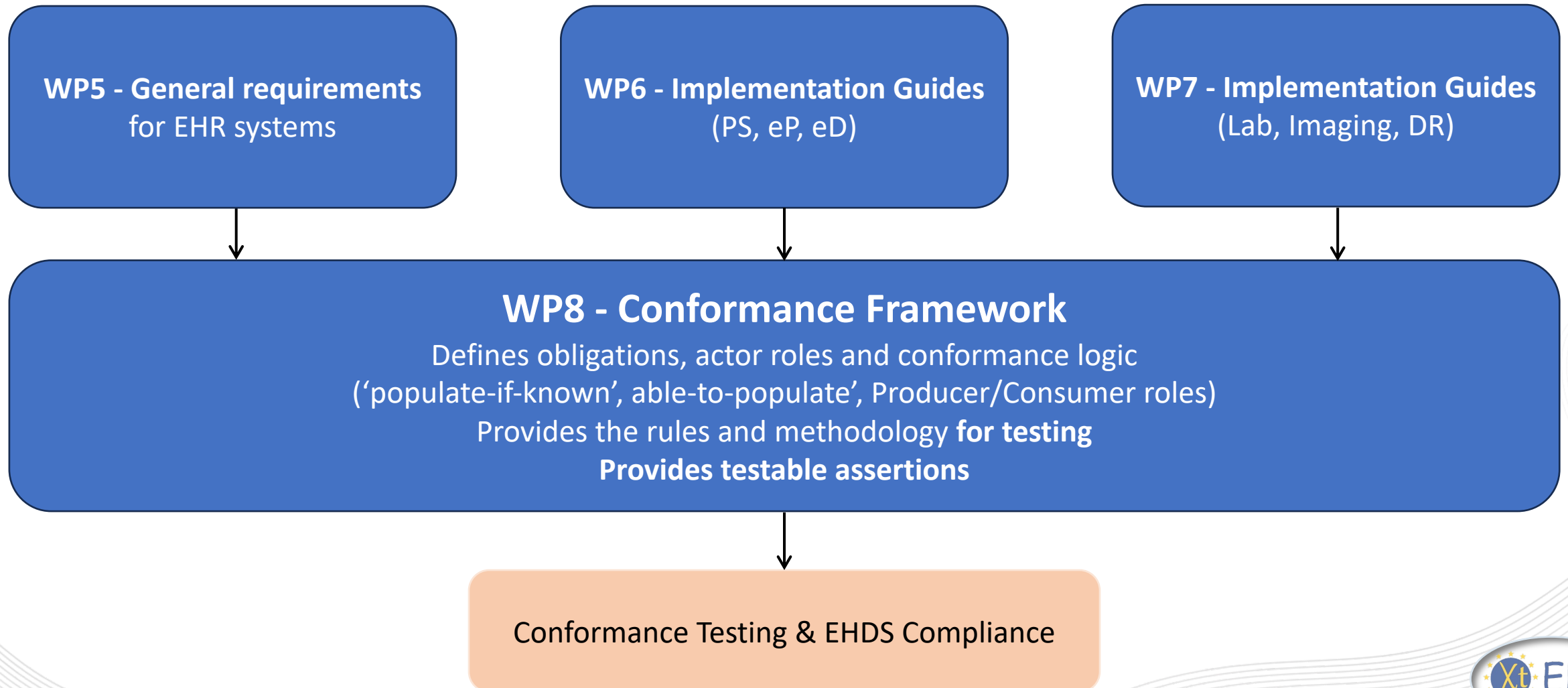
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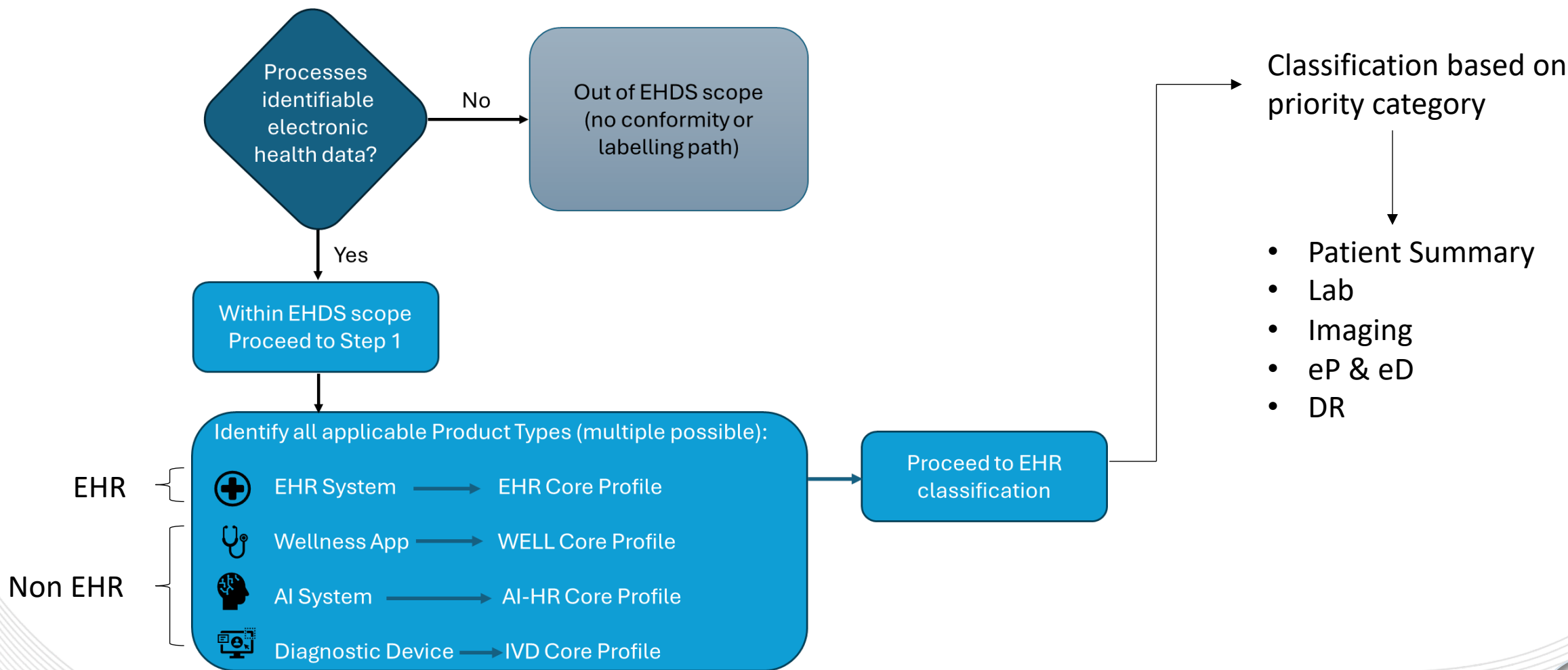
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# Relation between WP8 Conformance Framework and WP6-WP7 Implementation Guides

**WP5 - General requirements**
for EHR systems

**WP6 - Implementation Guides**
(PS, eP, eD)

**WP7 - Implementation Guides**
(Lab, Imaging, DR)

**WP8 - Conformance Framework**
Defines obligations, actor roles and conformance logic
('populate-if-known', able-to-populate', Producer/Consumer roles)
Provides the rules and methodology **for testing**
**Provides testable assertions**

Conformance Testing & EHDS Compliance

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# Determining Product Types and Core Profiles

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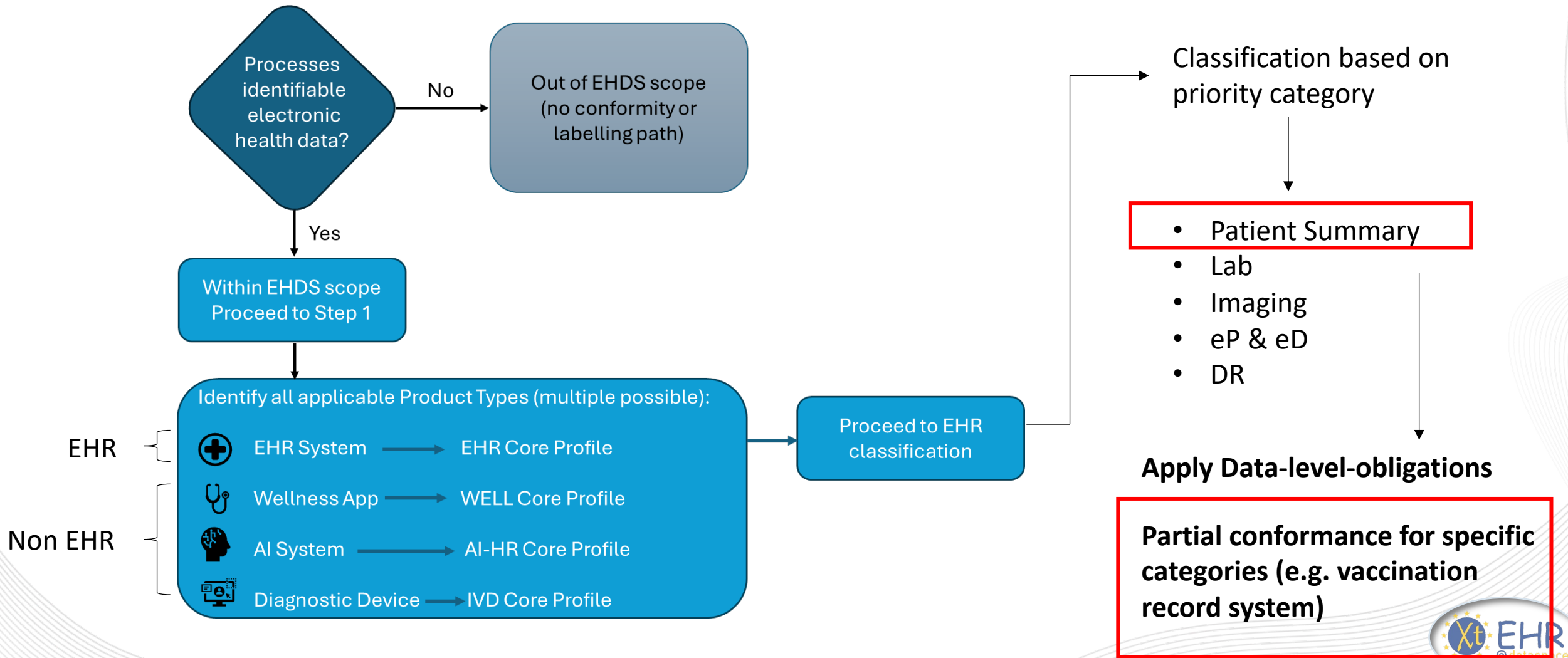
# Mapping of EHR Classification Dimensions to Interoperability Profiles

| Priority Category | Intended Use | Actor Role | Resulting Interoperability Profile | Description |
|---|---|---|---|---|
| Patient Summary | Healthcare Provider (HP) | Producer | EHR–PS–HP–Producer | System used by a healthcare provider to generate and share structured patient summaries. |
| Patient Summary | HP | Consumer | EHR–PS–HP–Consumer | System used by a healthcare provider to view or import patient summaries received from other providers. |
| Patient Summary | Patient | Producer | EHR–PS–Patient–Producer | Patient application enabling citizens to contribute or validate data in their patient summary. |
| Patient Summary | Patient | Consumer | EHR–PS–Patient–Consumer | Patient portal allowing citizens to access and review their patient summary. |

# Origins of the Xt-EHR Conformity Framework:
## *From HL7 CDA to EHDS Alignment*

- The obligation model is **not new**—it is based on long-standing HL7 conformance principles.

- Originates from HL7 CDA's structured conformance rules and later formalised in **FHIR's obligation codes**.

- Xt-EHR simply **adapts and aligns** this proven approach to the EHDS regulatory context.

- The model is **standard-agnostic** and works for any EEHRxF-compliant format (FHIR, DICOM, CDA).

- Builds on internationally recognised practice rather than creating a new or proprietary method.

- Ensures continuity with existing interoperability ecosystems already used in Europe.

# Conformance Stages (Tiers) in Xt-EHR

- **Tier 1 – Core Conformance**
    - Mandatory baseline for EHDS certification
    - Includes all SHALL-level obligations
    - Ensures safe, structured, and interoperable data exchange across borders
    - Represents the minimum level required for legal and functional compliance
- **Tier 2 – Extended Conformance**
    - Optional, value-adding capabilities
    - Includes SHOULD-level and recommended obligations
    - Supports enhanced interoperability, completeness, and advanced data uses
    - Allows manufacturers to go beyond the minimum without increasing regulatory burden

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- Allows a **progressive, implementable pathway** for systems with different levels of maturity
- Avoids over-burdening smaller systems while guaranteeing a harmonised Core
- Aligns with **EEHRxF's staged adoption logic** and HL7 conformance practices
- Provides clarity for certification (D8.2) and consistent expectations across Member States

# Conformance Stages (Tiers) in Xt-EHR

| Name | Card. | Type | Description & Constraints | Filter: |
|------|-------|------|--------------------------|---------|
| EHDSHumanName | 0..* | Base | Human name model **Instances of this logical model can be the target of a Reference** | |
| use | 0..1 | CodeableConcept | Use **Binding Description:** (preferred): hl7:Name Use | |
| text | 0..1 | string | Text | |
| family | 0..* | string | Family | |
| given | 0..* | string | Given | |
| prefix | 0..* | string | Prefix | |
| suffix | 0..* | string | Suffix | |

Tier 1 (Mandatory)

Tier 2 (Optional)

# Functional Roles (Actors) – Producer

**Producer:** A system or application that **generates or makes available structured health data** conformant with the EEHRxF logical models (e.g. implemented in FHIR, DICOM, or equivalent interoperable standards).
It is responsible for **populating relevant data elements** according to the "able-to-populate" and "populate-if-known" obligations, and for associating appropriate metadata (e.g. authorship, provenance, status) before making the data available to downstream consumers.

**Consumer:** A system or application that **receives, processes, or displays structured health data** conformant with the EEHRxF logical models (e.g. implemented in FHIR, DICOM, or equivalent interoperable standards).
It is responsible for **ingesting, validating, and maintaining the meaning and context** of the received data and associated metadata (e.g. provenance, authorship, status) in accordance with the applicable "process" obligations, ensuring semantic integrity and correct presentation to end users or other systems.

# Examples of Producers

- **Hospital EHR system** – Generates and exports patient discharge summaries (FHIR Composition, DocumentReference resources).

- **Radiology Information System (RIS)** – Creates FHIR ImagingStudy and DiagnosticReport resources for imaging results.

- **Laboratory Information System (LIS)** – Produces Observation and Specimen resources with test results.

- **General Practitioner's clinical application** – Emits Condition, MedicationStatement, and AllergyIntolerance resources.

# Examples of Consumers

- **Receiving hospital EHR system** – Imports a cross-border patient summary (Composition) for continuity of care.

- **Specialist clinical workstation** – Displays imaging results (ImagingStudy, DiagnosticReport) received from another facility.

- **Pharmacy dispensing system** – Reads ePrescription resources to prepare dispensation.

- **Electronic Health Record Access Service** app – Displays patient-accessible data (Observation, MedicationRequest, etc.).

# Actors
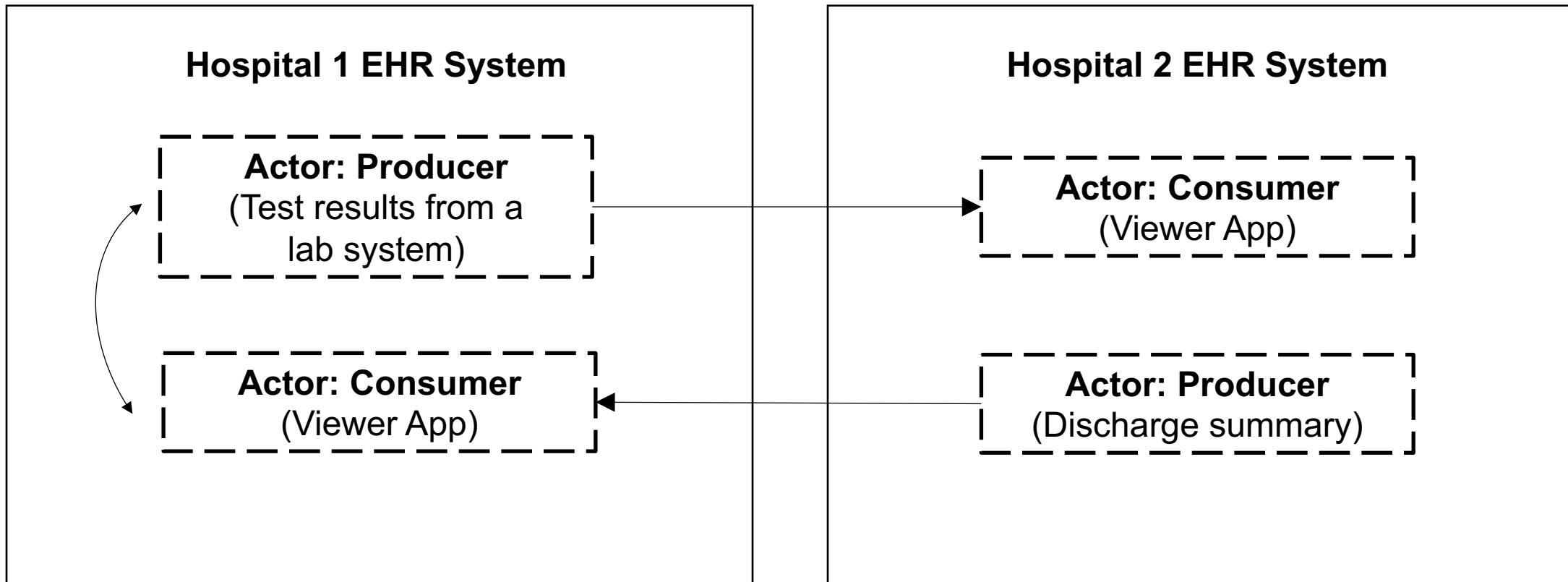
# Strength of Obligations

**SHALL** … an absolute requirement; there are no valid exceptions.

**SHOULD** … a recommendation; implementors MAY depart only if they fully understand and accept the consequences.
*If there is no value to populate, **omitting that element does not break conformance**—you only get a warning if you regularly omit it when the precondition is met.*

**MAY*** … purely optional; implementors are free to support it or not, with no conformance impact.

*\*May can be omitted with one statement that if there is no obligation the it is "MAY"*

# Obligations

**Producer Obligations**
populate
populate-if-known
able-to-populate
in-narrative
exclude-narrative
user-input
explain
persist

**Exchanger Obligations**
no-alter
alter

**Consumer Obligations**
no-error
reject-invalid
accept-invalid
handle
display
process
print
ignore

# Obligations

**Producer Obligations**
populate
populate-if-known
able-to-populate
in-narrative
exclude-narrative
user-input
explain
persist

~~Exchanger Obligations~~
~~no-alter~~
~~alter~~

**Consumer Obligations**
no-error
reject-invalid
accept-invalid
handle
display
process
print
ignore

https://build.fhir.org/ig/HL7/fhir-extensions/CodeSystem-obligation.html

# Obligations

**populate-if-known**

Conformant applications producing resources SHALL/SHOULD correctly populate this element if they know a value for the element, but it is acceptable if the system is unable to ever know a value for the element. Notes: 'Knowing' an element means that a value for the element is available in memory, persistent store, or is otherwise available within the system claiming conformance.

# Populate if known

**Name → Populate if known (Should)**

# Populate if known

**Name → Populate if known (Should)**

| Name | Flags | Card. |
|------|-------|-------|
| 📁 EHDSPatient | | 0..* |
| ⬡ personalIdentifier | | 1..* |
| 🔒 name | | 0..* |
| ▦ dateOfBirth | | 0..1 |
| ⬡ administrativeGender | | 0..1 |
| 🔒 address | | 0..* |
| 🔒 telecom | | 0..* |
| ⬡ maritalStatus | | 0..1 |
| ⬡ citizenship | | 0..* |
| ⬡ communicationLanguage | | 0..* |

**Producer**

Yes

Anna Müller

SQL    FHIR Data store    etc

```
{
  "personalIdentifier": [
    {
      "system":
"http://hospital.example.org/mrn",
      "value": "998877"
    }
  ],
  "name": [
    {
      "use": "official",
      "family": "Müller",
      "given": ["Anna"]
    }
  ]
}
```

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# Populate if known

**Name → Populate if known (Should)**



| Name | Flags | Card. |
|---|---|---|
| 📁 EHDSPatient | | 0..* |
| 🔵 personalIdentifier | | 1..* |
| 🔒 name | | 0..* |
| ▭ dateOfBirth | | 0..1 |
| 🔵 administrativeGender | | 0..1 |
| 🔒 address | | 0..* |
| 🔒 telecom | | 0..* |
| 🔵 maritalStatus | | 0..1 |
| 🔵 citizenship | | 0..* |
| 🔵 communicationLanguage | | 0..* |

**Producer**

Yes

Anna Müller

SQL      FHIR Data store      etc

{
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    {
      "system": "http://hospital.example.org/mrn",
      "value": "998877"
    }
  ]
}

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| Name | Flags | Card. |
|------|-------|-------|
| 📁 EHDSPatient | | 0..* |
| 🔲 personalIdentifier | | 1..* |
| 🔲 name | 🔒 | 0..* |
| 🔲 dateOfBirth | | 0..1 |
| 🔲 administrativeGender | | 0..1 |
| 🔲 address | 🔒 | 0..* |
| 🔲 telecom | 🔒 | 0..* |
| 🔲 maritalStatus | | 0..1 |
| 🔲 citizenship | | 0..* |
| 🔲 communicationLanguage | | 0..* |

**Producer**

No

SQL

FHIR Data store

etc

{
  "personalIdentifier": [
    {
      "system": "http://hospital.example.org/mrn",
      "value": "998877"
    }
  ]
}

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**Name → Populate if known (Shall)**

| Name | Flags | Card. |
|------|-------|-------|
| 📁 EHDSPatient | | 0..* |
| 🔵 personalIdentifier | | 1..* |
| 🔒 name | | 0..* |
| ▭ dateOfBirth | | 0..1 |
| 🔵 administrativeGender | | 0..1 |
| 🔒 address | | 0..* |
| 🔒 telecom | | 0..* |
| 🔵 maritalStatus | | 0..1 |
| 🔵 citizenship | | 0..* |
| 🔵 communicationLanguage | | 0..* |

**Producer**

Yes

Anna Müller

SQL

FHIR Data store

etc

{
  "personalIdentifier": [
    {
      "system": "http://hospital.example.org/mrn",
      "value": "998877"
    }
  ]
}

❌

# Populate if known

**Name → Populate if known (Shall)**

| Name | Flags | Card. |
|---|---|---|
| 📁 EHDSPatient | | 0..* |
| 🔲 personalIdentifier | | 1..* |
| 🔒 name | | 0..* |
| ▭ dateOfBirth | | 0..1 |
| 🔲 administrativeGender | | 0..1 |
| 🔒 address | | 0..* |
| 🔒 telecom | | 0..* |
| 🔲 maritalStatus | | 0..1 |
| 🔲 citizenship | | 0..* |
| 🔲 communicationLanguage | | 0..* |

**Producer**

No

SQL    FHIR Data store    etc

{
  "personalIdentifier": [
    {
      "system": "http://hospital.example.org/mrn",
      "value": "998877"
    }
  ]
}

✓

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# Able to populate

**able-to-populate**

Conformant applications producing resource instances SHALL/SHOULD/MAY be able to correctly populate this element. Notes: Typically, this means that an application needs to demonstrate during some conformance testing process that there are some conditions under which it populates the element with a correct value. (i.e. not a data-absent-reason or equivalent.) This obligation does not impose expectations on the circumstances in which the element will be sent, only that it can be in at least some situations.

# Able to populate

**Name → Able to populate (Should)**



**Producer**

```
"name": [
  {
    "use": "official",
    "family": "Müller",
    "given": ["Anna"]
  }
]
```

# Able to populate

**Name → Able to populate (Should)**



**Producer**

Provide a brief justification
e.g. "Not applicable in our clinical workflow"
or "Pending future UI enhancement"

# Able to populate

**Name → Able to populate (Shall)**



**Producer**

```
"name": [
  {
    "use": "official",
    "family": "Müller",
    "given": ["Anna"]
  }
]
```
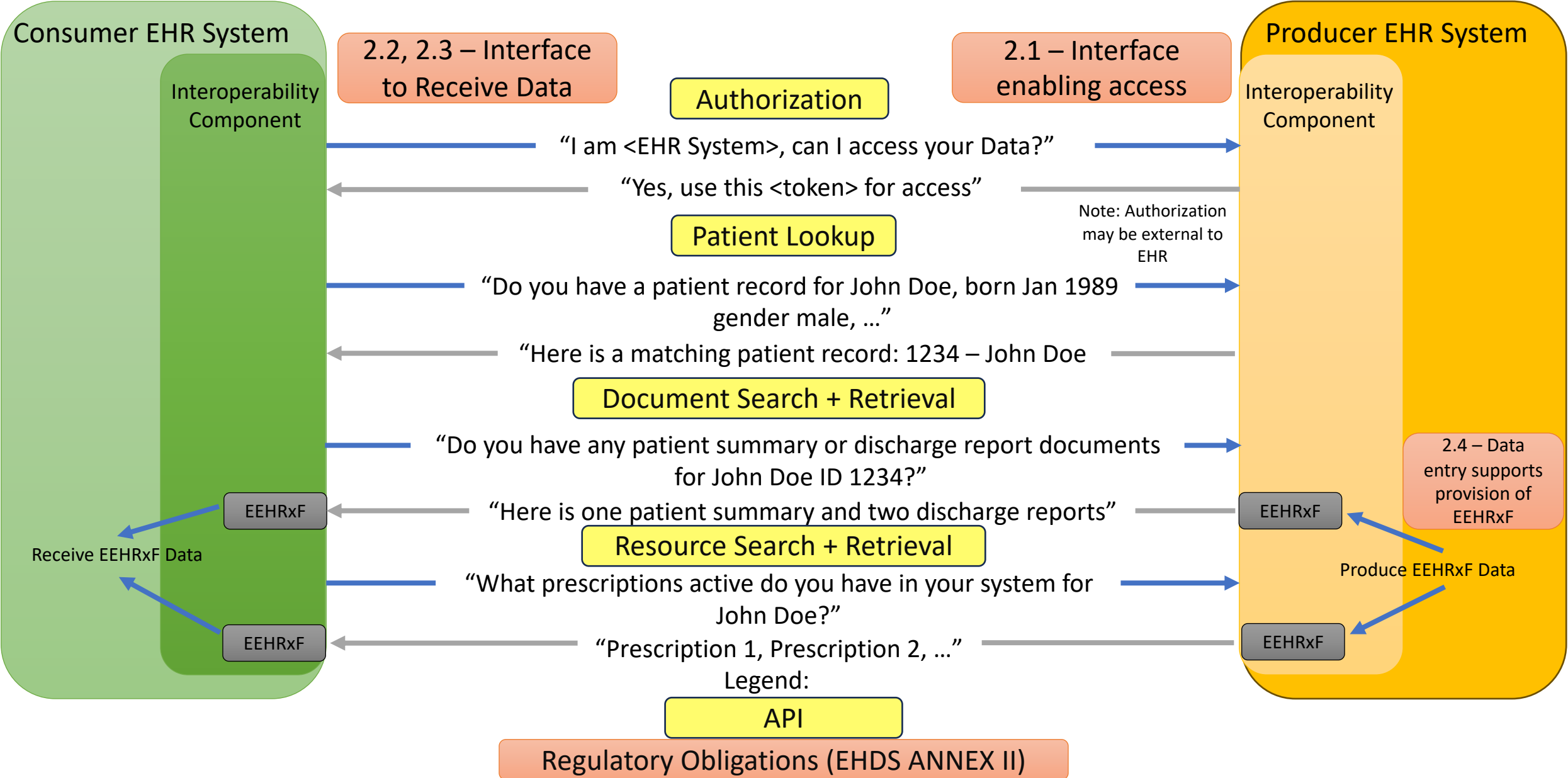
# Able to populate

**Name → Able to populate (Shall)**

# Examples of Interoperability Profiles for EHR Dataset

| Element | Element Description | Cardinality | Binding Description | Binding strength | Producer | Consumer | Conformance Stage |
|---|---|---|---|---|---|---|---|
| last update | Date/time when the resource or document was last updated. | 1..1 | | | **Able to populate (shall)** | **Display (shall)** | Tier 1 |
| status | Status of the resource or document. e.g. draft/final. If the state is draft the document cannot be shared externally, can be used only for internally (for example in the same organisation) | 1..1 | Propose: https://hl7.org /fhir/R5/value set- composition- status.html | Preferred | **Able to populate (shall)** | **Display (shall)** | Tier 1 |
| status reason (choose only one from the following) | Reason for the current status. Used when a resource is amended, corrected, voided, or withdrawn. | 0..1 | | | **Able to populate (shall)** | **Display (shall)** | Tier 1 |

LHIR
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Interoperability Component Exchange

Consumer EHR System

Producer EHR System

2.2, 2.3 – Interface to Receive Data

2.1 – Interface enabling access

Interoperability Component

Interoperability Component

**Authorization**

"I am <EHR System>, can I access your Data?"

"Yes, use this <token> for access"

Note: Authorization may be external to EHR

**Patient Lookup**

"Do you have a patient record for John Doe, born Jan 1989 gender male, …"

"Here is a matching patient record: 1234 – John Doe

**Document Search + Retrieval**

"Do you have any patient summary or discharge report documents for John Doe ID 1234?"

2.4 – Data entry supports provision of EEHRxF

"Here is one patient summary and two discharge reports"

EEHRxF

EEHRxF

**Resource Search + Retrieval**

Produce EEHRxF Data

"What prescriptions active do you have in your system for John Doe?"

Receive EEHRxF Data

"Prescription 1, Prescription 2, …"

EEHRxF

EEHRxF

Legend:

**API**

Regulatory Obligations (EHDS ANNEX II)

# Testable Assertions for System Authorization

| Requirement ID | Normative part | Suggestion for testable implementation (Example) |
|---|---|---|
| **api-producer-authDiscovery** | The EHR system Interoperability Component SHALL enable discovery of its authorization server information to enable a consumer to retrieve authorization. It MAY be handled via machine-discoverable metadata or coordinated out of band. | The EHR system Interoperability component acting as a producer **SHALL create a SignedServiceMetadata XML document that complies with the OASIS Service Metadata Publishing specifications and push it to the SMP registry.** |
| **api-producer-authProvideToken** | The EHR system Interoperability Component SHALL support issuing authorization tokens to consumer EHR systems using the consumer's registered identity credentials and scopes of access. | The EHR system Interoperability component acting as a producer **SHALL support the IHE IUA profile as an AuthorizationTon Server with the SAML Token option to issue authorization tokens to consuming EHR systems.** |
| **api-consumer-authObtainToken** | The EHR system Interoperability Component SHALL obtain an authorization token from the producer's designated authorization server. | The EHR system Interoperability Component acting as a consumer **SHALL support the import of the SignedServiceMetadata XML document from the SMP registry.** |
| **api-producer-authRequireToken** | The EHR system Interoperability Component SHALL require a valid authorization token from the Consumer EHR on Interoperability Component exchange. | The EHR system Interoperability Component acting as a producer **SHALL support the IHE IUA profile as a Resource server with the SAML token option to require a valid authorization token from the Consumer.** |
| **api-consumer-authPresentToken** | The EHR system Interoperability Component SHALL present a valid token to the Producer EHR on Interoperability Component Exchange. | The EHR system Interoperability component acting as a consumer **SHALL support the IHE IUA profile as an Authorization Client to obtain a SAML token and incorporate it in its requests to the producer.** |

# Testable Assertions for Patient Match

| Requirement ID | Normative part | Suggestion for testable implementation (Example) |
|---|---|---|
| **api-producer-patient** | The EHR system Interoperability Component SHALL offer a patient lookup API sufficient for a consumer to unambiguously identify the patient electronic health record in the producer system given patient identification data (demographics or other forms of patient identity) as search parameters. | The EHR system interoperability component acting as producer **SHALL support the IHE PDQm profile as a Patient Demographics Supplier actor to offer a way for consumer to unambiguously identify the patient.** |
| **api-consumer-patient** | The EHR system Interoperability Component SHALL support an external patient lookup query API in order to unambiguously identify the patient electronic health record in an external system (such as a producer EHR system), using the consumer system's available patient identification data (demographics or other forms of patient identity) | The EHR system interoperability component acting as consumer **SHALL support the IHE PDQm profile as a Patient Demographics Consumer actor with the Patient search option to unambiguously identify the patient at the producer.** |