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Specification of the information architecture and data modeling based on FAIR principles

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DEM	Demonstrator, pilot, prototype	
DEC	Websites, patent fillings, videos etc.	
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Dissemination Level		
PU	Public	**X**
CO	Confidential (Consortium members including the Commission Services)	
CI	Classified Information (Commission Decision 2015/444/EC)	

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1.Versions History

Version	Date	Author	Comments
0.8	10-2-2023	R. Cornet	
0.9	15-2-2023	R. Cornet	Version for review
1.0	22-2-2023	R. Cornet	Final version after review

2. Executive Summary

The FAIR Principles provide 15 high-level recommendations to make data Findable, Accessible, Interoperable, and Reusable. However, they do not specify how to realize this. This means that making data FAIR is a non-trivial endeavor.

The CAPABLE Platform provides the functionalities to support patients and clinicians in monitoring and where possible improving well-being of the patients after cancer treatment.

This system encompasses patient data and decision support guidelines, which the implemented information architecture intends to make maximally FAIR.

This is realized by means of the following components:

- A register of globally unique, persistent, resolvable Unique Resource Identifiers
- A FAIR Data Point that complies with the FAIR Data Point Specification
- Data Catalog Vocabulary (DCAT) to represent metadata
- HL7 FHIR to access data
- A licensing policy

The information architecture contributes to fulfilling these project objectives:

- To specify an information architecture that enables data and meta-data to be FAIR;
- To specify functionalities that enable readability of (meta-)data by humans and machines;
- To specify computer-interpretable guidelines.

The implemented architecture provides a solid and standardized foundation for FAIR data, in which the metadata can be expanded over time to adhere to current and future practices, and in which other data can be included if relevant.

3.Introduction

The CAPABLE consortium is committed to delivering data management, integration, modeling, and access by application of state-of-the-art technologies, including terminologies such as SNOMED CT, modeling standards such as OMOP-CDM (Observational Medical Outcomes Partnership - Common Data Model), and messaging standards such as HL7 FHIR (for Health Level 7 – Fast Healthcare Interoperability Resources). In addition, this will be realized in line with the FAIR Principles, in order to make the data Findability, Accessibility, Interoperability and Reusability, while taking into account openness as well as privacy and security concerns.

The above is realized in an information architecture, that contributes to fulfilling these project objectives:

- To specify an information architecture that enables data and meta-data to be FAIR;
- To specify functionalities that enable readability of (meta-)data by humans and machines;
- To specify computer-interpretable guidelines.

Recommendations and requirements for such an information architecture have been described in D3.2. These are used as starting point for the realization of the architecture and are described in Chapter 4.

A high-level description of the architecture is provided in Chapter 5.

Chapter 6 assesses the adherence of the architecture to the requirements, substantiated by clarifications and links to its implementation.

Chapter 7 assesses the adherence of the architecture to the recommendations.

4.Requirements & Recommendations

Requirements and recommendations for the FAIR infrastructure were described in D3.2 - Data-related Functionality to Realize a FAIR Infrastructure [1].

We reflect on these to assess the extent to which they are fulfilled in Chapters 6 and 7.

The Requirements and recommendations are shown in Table 1 and Table 2.

FAIR Principles	**Required functionality to fulfil the principle**
To be Findable:	Searchable (third-party) repository, e.g.: ➢ FairDataPoint ➢ FigShare ➢ Zenodo (See section 7)
F1. (meta)data are assigned a globally unique and persistent identifier	No specific functionality
F2. data are described with rich metadata (defined by R1 below)	No specific functionality
F3. metadata clearly and explicitly include the identifier of the data it describes	No specific functionality
F4. (meta)data are registered or indexed in a searchable resource	Search-functions provided by (third-party) repository

To be Accessible:	Service with standardized communication protocol, such as HL7 FHIR, (based on REST) or SPARQL.
A1. (meta)data are retrievable by their identifier using a standardized communications protocol	Query functionality
A1.1 the protocol is open, free, and universally implementable	Adopt standard protocol
A1.2 the protocol allows for an authentication and authorization procedure, where necessary	Protocol provides A&A
A2. metadata are accessible, even when the data are no longer available	No specific functionality
To be Interoperable:	Interoperability of service is established through criteria specified under Accessibility (standard protocol) and Reusability (community standards)
I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.	No specific functionality
I2. (meta)data use vocabularies that follow FAIR principles	No specific functionality
I3. (meta)data include qualified references to other (meta)data	No specific functionality
To be Reusable:	Provide guidance on usage and provenance
R1. (meta)data are richly described with a plurality of accurate and relevant attributes	No specific functionality
R1.1. (meta)data are released with a clear and accessible data usage license	To be selected in Deliverable 3.3
R1.2. (meta)data are associated with detailed provenance	Provenance functions based on data model and vocabularies (Section 6.1)
R1.3. (meta)data meet domain-relevant community standards	Adherence to data models and vocabularies (See sections 4 and 5.4)

Table 1. The FAIR Guiding Principles, accompanied by requirements regarding functionality of a FAIR infrastructure. From [1].

Recommendation	Related FAIR principles
1. Create a CAPABLE FAIR Data Point (FDP), e.g., according to the implementation provided at [2] or the Python implementation at [3]. Using that implementation contributes to F4, as the FDP will be registered at the FDP home [4].	F4, A1, A1.1, A2, I1
2. For metadata, use globally unique persistent identifiers taking into account the 10 lessons described in [5].	F1
3. Populate the CAPABLE FDP with sufficiently rich metadata, including a description of the dataset based on the Data Catalog Vocabulary (DCAT) [6] or its Application Profile for data portals in Europe (DCAT-AP) [7].	F2, F3
4. Metadata in the CAPABLE FDP adopts established vocabularies used in the legal, research, and medical domain.	I2, I3, R1.3
5. Provide license and provenance information, using Data Use Ontology [8], Provenance Data Model [9], and Provenance Ontology [10].	R1, R1.1, R1.2
6. Provide access to data using HL7 FHIR.	A1, A1.1, A1.2
7. Model data provided by the HL7 FHIR server as much as possible using established vocabularies used in the medical domain. Representation of resources using Turtle syntax can be considered, especially if mappings between resource types (and their attributes) and other ontologies are established.	I2, I3, R1.3
8. The CAPABLE FDP provides reference to the HL7 FHIR server.	F3, R1

Table 2. Recommendations. From [1].

5.FAIR Information Architecture

The CAPABLE Platform and data in it are made **Findable** via the FAIR Data Point, which provides metadata about the platform, including the URL of the HL7 FHIR endpoint, and further descriptions of resources within the CAPABLE Platform. A description of information model, represented as HL7 FHIR resources, is provided via a dedicated service, Simplifier, which is also linked to the FAIR Data Point.

Accessibility of the data in the CAPABLE Platform is handled via the FHIR basic authentication mechanism. Metadata in the FAIR Data Point and in Simplifier are available without access restrictions.

The data in the CAPABLE Platform is made maximally **Interoperable** by the use of OMOP CDM (internal representation) and HL7 FHIR (external communication) as information models, and the use of terminologies such as SNOMED CT to provide a structured and standardized representation of patient information captured in the model.

Reusability of the data in the CAPABLE Platform is established by means of the metadata by which it is described in the FAIR Data Point.

Figure 1 depicts the FAIR information architecture.

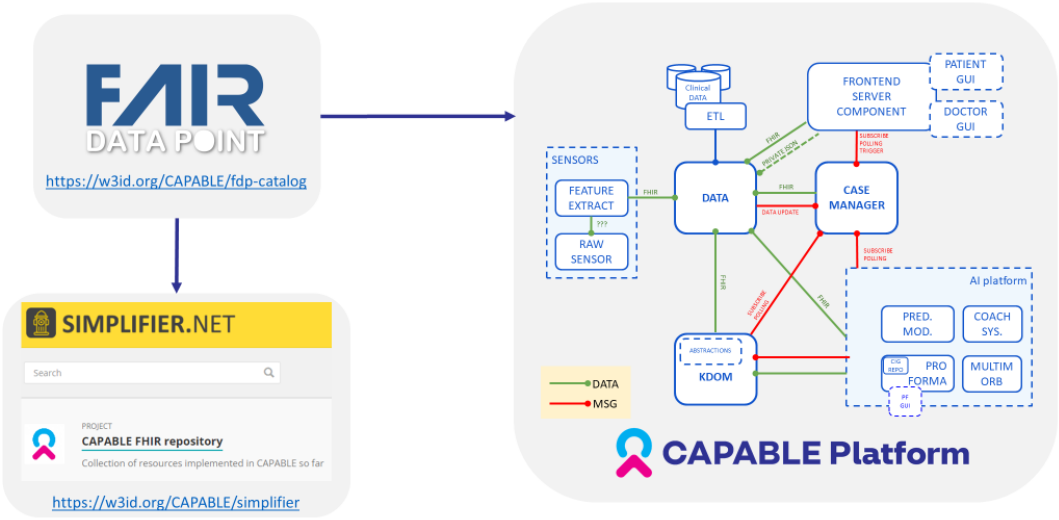


Figure 1. High-level overview of the FAIR information architecture.

6. Adherence to Requirements

6.1. Findability

To be Findable, a FAIR Data Point has been established, that forms the entry point to all CAPABLE resources. The FAIR Data Point is available at https://w3id.org/CAPABLE/fdp-catalog. This provides a Data Catalog (DCAT)-compliant catalog of CAPABLE-resources.

F1. (meta)data are assigned a globally unique and persistent identifier

Globally unique, persistent, resolvable identifiers (GUPRIs) can be defined using the CAPABLE identifier registry available under https://github.com/perma-id/w3id.org. This registry provides identifiers starting with https://w3id.org/CAPABLE/ which redirect to the actual location of the identified resource.

Persistent URI	Resource
https://w3id.org/CAPABLE/	https://capable-project.eu/
https://w3id.org/CAPABLE/zenodo	https://zenodo.org/communities/capable/
https://w3id.org/CAPABLE/ontologies/SATO	https://raw.githubusercontent.com/Capable-project/sato-ontology/main/SATO.owl

Table 3. Examples of persistent identifiers

Table 3 provides examples of current resources for which persistent identifiers exist. On the one hand, these are "convenience" identifiers, such as the one for Zenodo, providing an identifier that can be easily remembered. On the other hand, these are identifiers which are crucial for machine-processing, such as the one for the SATO ontology. Within this ontology, the classes and properties are defined using the same identifier. For example, is contains a concept with this identifier:

https://w3id.org/CAPABLE/ontologies/SATO#assessment_result

The persistent identifier for the SATO ontology, preceding the anchor character "#" ensures that the definition for this concept can be retrieved.

F2. data are described with rich metadata

The FAIR Data Point provides a set of basic metadata schemas that are shown in Figure 2.

These can be extended to represent other metadata. While currently there are few community standards, when they emerge, they can be easily incorporated into the FAIR Data Point.

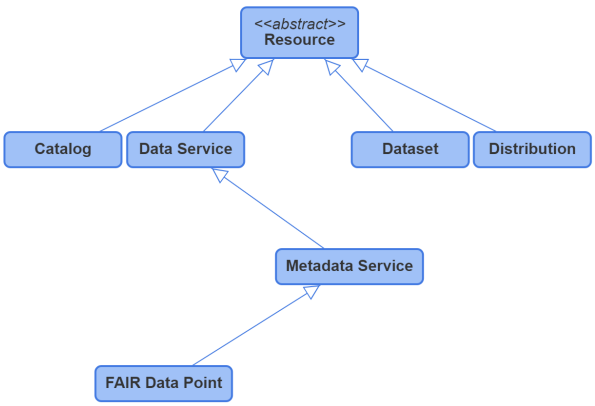


Figure 2. Metadata schemas in the FAIR Data Point

One exception is the description of the resources made available through the HL7 FHIR endpoint. These resources are provided via https://w3id.org/CAPABLE/simplifier for human processing and https://w3id.org/CAPABLE/simplifier-api for machine-processing via a FHIR Application Programming Interface (API).

F3. metadata clearly and explicitly include the identifier of the data it describes

The use of DCAT in the FAIR Data Point ensured explicit reference to the resource being described.

F4. (meta)data are registered or indexed in a searchable resource

The FAIR Data Point is a searchable resource, providing both human- and machine-readability.

Resolving the identifier https://w3id.org/CAPABLE/fdp-catalog in a web browser will provide a graphical way of interacting with the data and metadata. Resolving the same identifier automatically will provide machine-processible RDF (Resource Descriptor Framework) data in Turtle syntax.

As mentioned under F2, metadata describing the resources in the FHIR endpoint is provided via a FHIR API.

6.2. Accessibility

To be Accessible, services with standardized communication protocols are required.

A1. (meta)data are retrievable by their identifier using a standardized communications protocol

For the data, this is established using an HL7 FHIR API. Metadata on FHIR resources is also provided via an HL7 FHIR API, all other metadata are provided via the FAIR Data Point either via the web interface or as RDF data. Metadata can also be accessed by directly running a SPARQL query on the FAIR Data Point.

We show these access options in figures below.

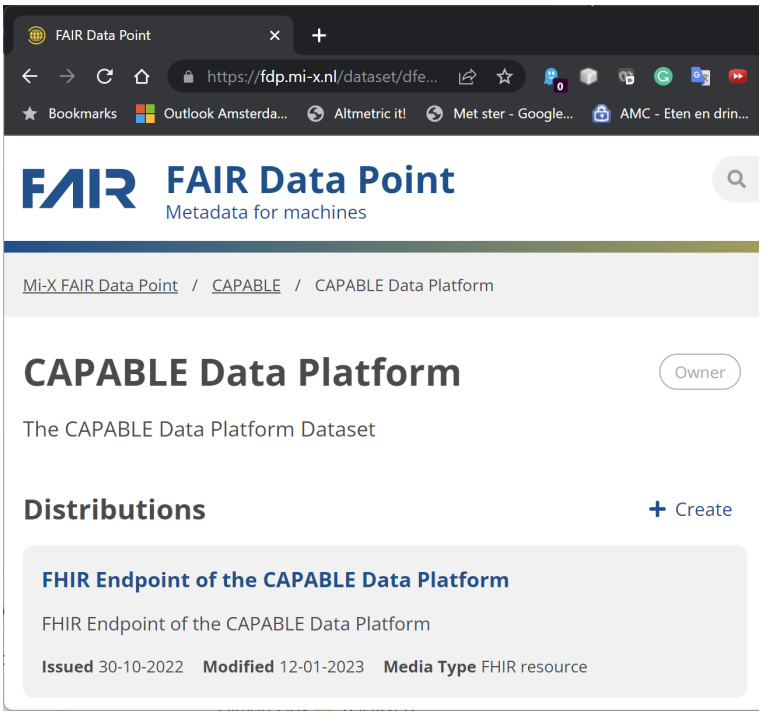


Figure 3. Web interface for the CAPABLE Data Platform metadata on the FAIR Data Point

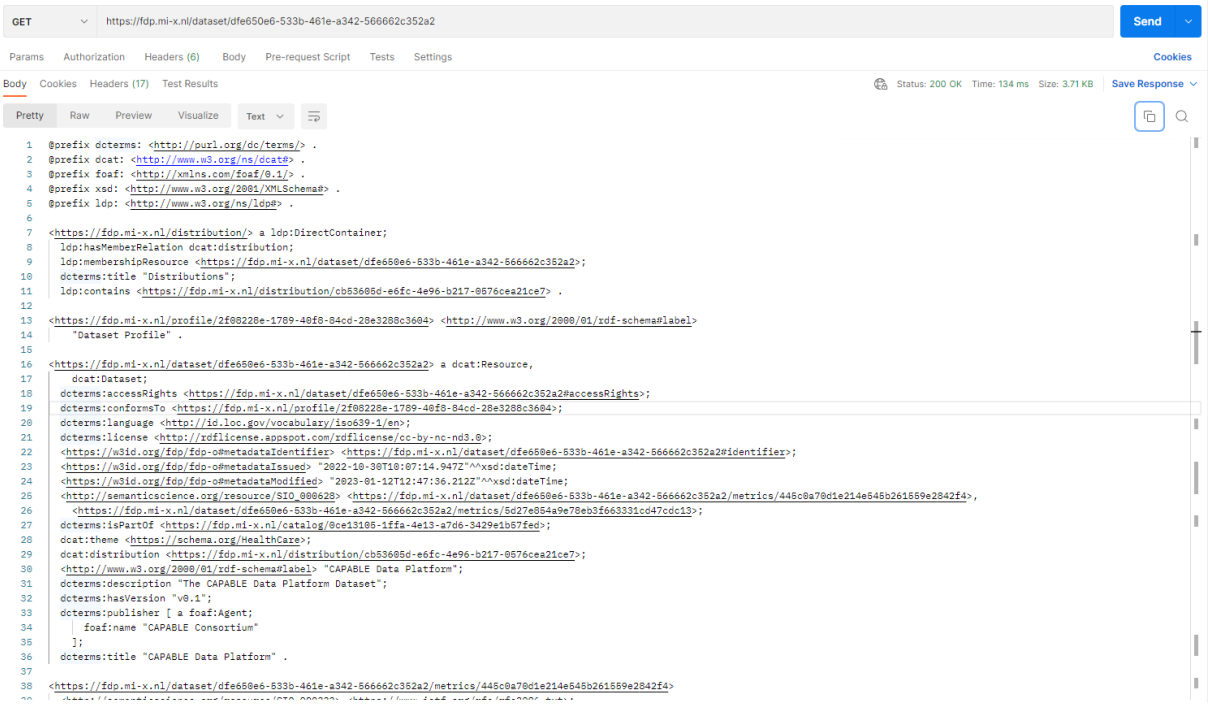
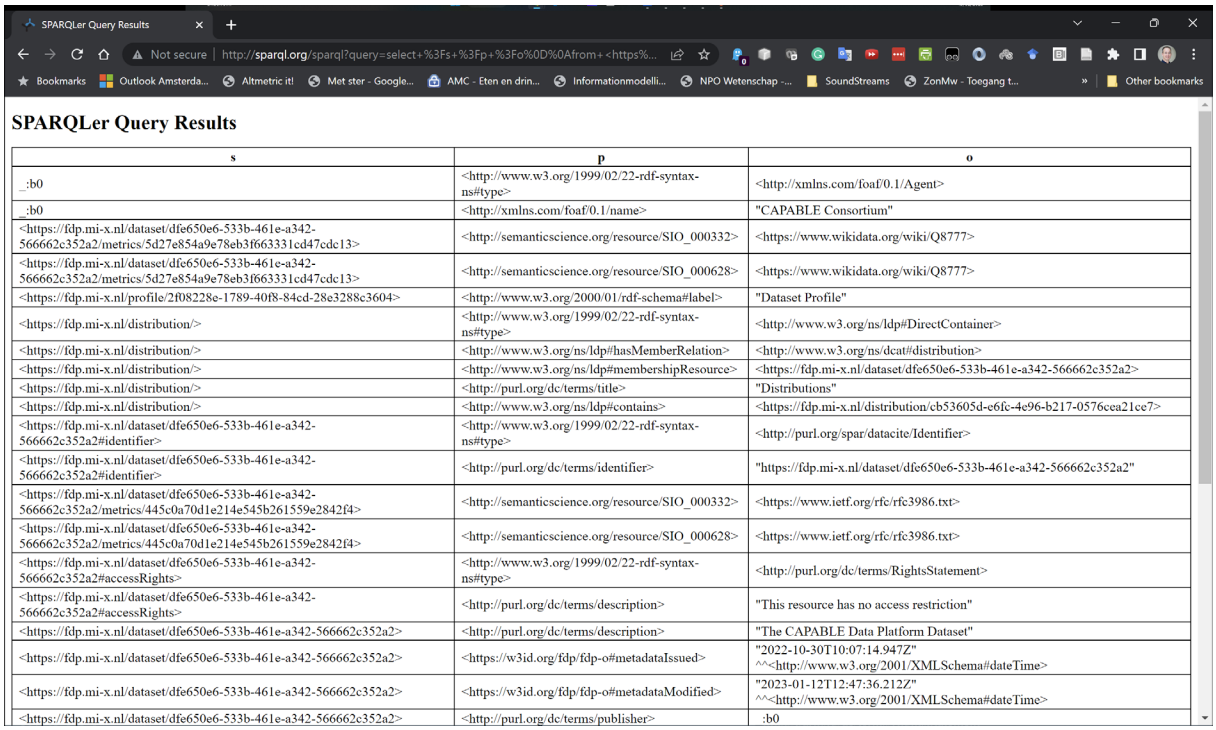


Figure 4. RDF in Turtle format as machine-processable response from the FAIR Data Point

Apart from returning HyperText Mark-up Language (HTML) for human processing and RDF for machine-processing, the FAIR Data Point also enables use of SPARQL Protocol And RDF Query Language (SPARQL). A SPARQL query retrieving all triples from the above dataset would be:

```
select ?s ?p ?o
from <https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2>
where { ?s ?p ?o }
```

The result of running this query in a SPARQL client, e.g., http://sparql.org/sparql.html, is shown in Figure 5.



SPARQLer Query Results

s	p	o
_:b0	<http://www.w3.org/1999/02/22-rdf-syntax-ns#type>	<http://xmlns.com/foaf/0.1/Agent>
_:b0	<http://xmlns.com/foaf/0.1/name>	"CAPABLE Consortium"
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2/metrics/5d27e854a9e78eb3f663331cd47cdc13>	<http://semanticscience.org/resource/SIO_000332>	<https://www.wikidata.org/wiki/Q8777>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2/metrics/5d27e854a9e78eb3f663331cd47cdc13>	<http://semanticscience.org/resource/SIO_000628>	<https://www.wikidata.org/wiki/Q8777>
<https://fdp.mi-x.nl/profile/2f08228e-1789-40f8-84cd-28e3288c3604>	<http://www.w3.org/2000/01/rdf-schema#label>	"Dataset Profile"
<https://fdp.mi-x.nl/distribution/>	<http://www.w3.org/1999/02/22-rdf-syntax-ns#type>	<http://www.w3.org/ns/ldp#DirectContainer>
<https://fdp.mi-x.nl/distribution/>	<http://www.w3.org/ns/ldp#hasMemberRelation>	<http://www.w3.org/ns/dcat#distribution>
<https://fdp.mi-x.nl/distribution/>	<http://www.w3.org/ns/ldp#membershipResource>	<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2>
<https://fdp.mi-x.nl/distribution/>	<http://purl.org/dc/terms/title>	"Distributions"
<https://fdp.mi-x.nl/distribution/>	<http://www.w3.org/ns/ldp#contains>	<https://fdp.mi-x.nl/distribution/cb53605d-e6fc-4e96-b217-0576cea21ce7>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2#identifier>	<http://www.w3.org/1999/02/22-rdf-syntax-ns#type>	<http://purl.org/spar/datacite/Identifier>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2#identifier>	<http://purl.org/dc/terms/identifier>	"https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2"
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2/metrics/445c0a70d1e214e545b261559e2842f4>	<http://semanticscience.org/resource/SIO_000332>	<https://www.ietf.org/rfc/rfc3986.txt>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2/metrics/445c0a70d1e214e545b261559e2842f4>	<http://semanticscience.org/resource/SIO_000628>	<https://www.ietf.org/rfc/rfc3986.txt>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2#accessRights>	<http://www.w3.org/1999/02/22-rdf-syntax-ns#type>	<http://purl.org/dc/terms/RightsStatement>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2#accessRights>	<http://purl.org/dc/terms/description>	"This resource has no access restriction"
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2>	<http://purl.org/dc/terms/description>	"The CAPABLE Data Platform Dataset"
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2>	<https://w3id.org/fdp/fdp-o#metadataIssued>	"2022-10-30T10:07:14.947Z" ^^<http://www.w3.org/2001/XMLSchema#dateTime>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2>	<https://w3id.org/fdp/fdp-o#metadataModified>	"2023-01-12T12:47:36.212Z" ^^<http://www.w3.org/2001/XMLSchema#dateTime>
<https://fdp.mi-x.nl/dataset/dfe650e6-533b-461e-a342-566662c352a2>	<http://purl.org/dc/terms/publisher>	:b0

Figure 5. Response from the FAIR Data Point on the SPARQL query

A1.1 the protocol is open, free, and universally implementable

The protocols used include HL7 FHIR and SPARQL.

SPARQL is a generic query language, independent of the healthare domain.

Conversely, HL7 FHIR is a healthcare-specific protocol. However, implementing the RESTful (Representational State Transfer) architectural style, it follows generic API principles.

A1.2 the protocol allows for an authentication and authorization procedure, where necessary

While metadata are open, the data provided via the FHIR server are not. HL7 FHIR does implement authentication and authorization. The CAPABLE FHIR server implements Basic authentication, in which a username and password are sent in the request header. User-based authorization is dealt with by the server-side implementation.

A2. metadata are accessible, even when the data are no longer available

By strictly setting aside the metadata in a FAIR Data Point and via the Simplifier API, metadata will be available, independent from the availability of the data. The use of persistent identifier enables relocation of the metadata to other servers or domains, as updating the redirection as described under F1 is sufficient to establish continued access with the same identifiers.

6.3. Interoperability

To be Interoperable the CAPABLE Platform needs to adhere to modeling and terminology standards that are accepted by the community.

I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation

Data are represented as HL7 FHIR Resources, which are broadly applicable in the healthcare domain. These resources are commonly rendered as JSON (JavaScript Object Notation) or XML (eXtensible Markup Language). Representation of FHIR Resources using RDF is under investigation in the community, and not yet implemented in the CAPABLE Platform.

I2. (meta)data use vocabularies that follow FAIR principles

Data are represented using vocabularies from the Observational Health Data Sciences and Informatics (OHDSI) Vocabularies Repository, called ATHENA. ATHENA consists of some 100 biomedical vocabularies, many of which are broadly accepted and available in languages such as RDF Schema or the Web Ontology Language OWL.

Metadata rely on the use of semantic web vocabularies, which are also represented using RDF Schema or OWL.

I3. (meta)data include qualified references to other (meta)data

Data, represented as FHIR Resources, provides qualified references based on the specifications of the resources. As the common representation of FHIR Resources is based on JSON, not all references are based on globally unique, persistent identifiers. However, the Turtle representation of the Resource structure does provide such identifiers. This is shown in Figure 6.

Turtle Template

```
@prefix fhir: <http://hl7.org/fhir/> .

[ a fhir:Patient;
  fhir:nodeRole fhir:treeRoot; # if this is the parser root

  # from Resource: .id, .meta, .implicitRules, and .language
  # from DomainResource: .text, .contained, .extension, and .modifierExtension
  fhir:Patient.identifier [ Identifier ], ... ; # 0..* An identifier for this patient
  fhir:Patient.active [ boolean ]; # 0..1 Whether this patient's record is in active use
  fhir:Patient.name [ HumanName ], ... ; # 0..* A name associated with the patient
  fhir:Patient.telecom [ ContactPoint ], ... ; # 0..* A contact detail for the individual
  fhir:Patient.gender [ code ]; # 0..1 male | female | other | unknown
  fhir:Patient.birthDate [ date ]; # 0..1 The date of birth for the individual
  # Patient.deceased[x] : 0..1 Indicates if the individual is deceased or not. One of these 2
    fhir:Patient.deceasedBoolean [ boolean ]
    fhir:Patient.deceasedDateTime [ dateTime ]
  fhir:Patient.address [ Address ], ... ; # 0..* An address for the individual
  fhir:Patient.maritalStatus [ CodeableConcept ]; # 0..1 Marital (civil) status of a patient
  # Patient.multipleBirth[x] : 0..1 Whether patient is part of a multiple birth. One of these 2
    fhir:Patient.multipleBirthBoolean [ boolean ]
    fhir:Patient.multipleBirthInteger [ integer ]
  fhir:Patient.photo [ Attachment ], ... ; # 0..* Image of the patient
  fhir:Patient.contact [ # 0..* A contact party (e.g. guardian, partner, friend) for the patient
    fhir:Patient.contact.relationship [ CodeableConcept ], ... ; # 0..* The kind of relationship
    fhir:Patient.contact.name [ HumanName ]; # 0..1 A name associated with the contact person
    fhir:Patient.contact.telecom [ ContactPoint ], ... ; # 0..* A contact detail for the person
    fhir:Patient.contact.address [ Address ]; # 0..1 Address for the contact person
    fhir:Patient.contact.gender [ code ]; # 0..1 male | female | other | unknown
    fhir:Patient.contact.organization [ Reference(Organization) ]; # 0..1 Organization that is a
ssociated with the contact
    fhir:Patient.contact.period [ Period ]; # 0..1 The period during which this contact person o
r organization is valid to be contacted relating to this patient
  ], ...;
  fhir:Patient.communication [ # 0..* A language which may be used to communicate with the patie
nt about his or her health
    fhir:Patient.communication.language [ CodeableConcept ]; # 1..1 The language which can be us
ed to communicate with the patient about his or her health
    fhir:Patient.communication.preferred [ boolean ]; # 0..1 Language preference indicator
  ], ...;
  fhir:Patient.generalPractitioner [ Reference(Organization|Practitioner|PractitionerRole) ], ..
. ; # 0..* Patient's nominated primary care provider
  fhir:Patient.managingOrganization [ Reference(Organization) ]; # 0..1 Organization that is the
custodian of the patient record
  fhir:Patient.link [ # 0..* Link to another patient resource that concerns the same actual pers
on
    fhir:Patient.link.other [ Reference(Patient|RelatedPerson) ]; # 1..1 The other patient or re
lated person resource that the link refers to
    fhir:Patient.link.type [ code ]; # 1..1 replaced-by | replaces | refer | seealso
  ], ...;
]
```

Figure 6. Structure definition of the Patient Resource, represented in Turtle. From [11].

6.4. Reusability

To be Reusable, the FAIR architecture needs to provide guidance on usage and provenance

R1. (meta)data are richly described with a plurality of accurate and relevant attributes

While the FAIR Data Point caters for such description, there is no broad agreement on schemas and vocabularies to represent such information. This is ongoing research within the community, the results of which can be adopted within the FAIR Data Point, given its extensible nature.

R1.1. (meta)data are released with a clear and accessible data usage license

Data are released with as permissive license as possible, under the condition that this doesn't infringe on the privacy of any subjects to which the data pertain or relate.

Metadata are released with permissive Creative Common licenses as much as possible, unless other sources are reused that imply restrictions.

R1.2. (meta)data are associated with detailed provenance

While PROV-DM [12] and PROV-O [10] provide a schema and ontology for representing provenance, agreement on what provenance information to provide is to be reached within the community. This can and will be implemented in the FAIR Data Point once such agreement is established.

R1.3. (meta)data meet domain-relevant community standards

Metadata being based on generic semantic web standards, and data being represented using healthcare-specific standards, this requirement is fulfilled. Monitoring developments and changes in the community, including versioning of standards, will be needed to continue to meet this requirement.

7.Adherence to Recommendations

In this chapter, adherence to the recommendations summarized in Chapter 4 is assessed.

1. Create a CAPABLE FAIR Data Point
   This recommendation is implemented, see https://w3id.org/CAPABLE/fdp-catalog
2. For metadata, use globally unique persistent identifiers
   This recommendation is implemented, using the mechanism provided by https://github.com/perma-id/w3id.org
3. Populate the CAPABLE FDP with sufficiently rich metadata
   This is partially implemented, due to the lack of agreement in the community on schemas and ontologies. This is an area of attention
4. Metadata in the CAPABLE FDP adopts established vocabularies used in the legal, research, and medical domain
   This is adhered to, and adherence will be monitored when more metadata is added.
5. Provide license and provenance information
   This is partially implemented, as desired licensing needs to be determined, agreed on, and aligned with any licenses of (meta)data being reused.
6. Provide access to data using HL7 FHIR
   Access to data is implemented based on HL7 FHIR. Access depends on authentication and authorization.
7. Model data provided by the HL7 FHIR server as much as possible using established vocabularies used in the medical domain
   This is adhered to by adopting established vocabularies from the ATHENA repository.
8. The CAPABLE FDP provides reference to the HL7 FHIR server
   This is implemented using DCAT, in which the CAPABLE Platform Dataset provides a Distribution which has an access link to the HL7 FHIR endpoint.

8.Glossary

API	Application Programming Interface
DCAT	Data Catalog
FAIR	Findable, Accessible, Interoperable, Reusable
FDP	FAIR Data Point
FHIR	Fast Healthcare Interoperability Resources
GUPRI	Globally Unique Persistent Resolvable Identifier
HL7	Health Level 7
HTML	HyperText Mark-up Language
JSON	JavaScript Object Notation
OHDSI	Observational Health Data Sciences and Informatics
OMOP-CDM	Observational Medical Outcomes Partnership - Common Data Model
OWL	Web Ontology Language
RDF	Resource Descriptor Framework
REST	Representational State Transfer
SPARQL	SPARQL Protocol And RDF Query Language
XML	eXtensible Markup Language

9. References

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