### Introduction

The goal of this Implementation Guide is to develop best practices for implementing the [FAIR principles](https://doi.org/10.1038/sdata.2016.18) when HL7 FHIR resources are used to represent the data. In doing this, two main situations should be considered:

1. **Native HL7 FHIR solution aiming at being FAIR.**
2. **Non-native HL7 FHIR solution where health data is FAIRified by using HL7 FHIR.**This may be further classified considering (a) pure HL7 FHIR based solutions or (b) hybrid solutions (i.e., a combination of HL7 FHIR and non-FHIR solutions)

In the first case, i.e., a native HL7 FHIR solution, it is reasonable to assume by design that the HL7 FHIR resources are "the" FAIR data objects, (for a definition of a FAIR data object see section 4.1 of the EC publication [Turning FAIR into reality](https://ec.europa.eu/info/publications/turning-fair-reality_en) ) with all the consequences that this assumption implies in term of data and metadata representation.

This page summarizes some best practices for implementing the FAIR principles for the cases where this assumption can be considered true.

Throughout the FAIR principles referred to in this guide, the phrase ‘(meta)data’ means that the principle should be applied to both metadata and data.

### Native HL7 FHIR solution

#### Findability

##### F1: (Meta)data are assigned a globally unique and persistent identifier

The first and arguably most important FAIR principle is [F1](https://www.go-fair.org/fair-principles/f1-meta-data-assigned-globally-unique-persistent-identifiers/): "(Meta)data are assigned a globally unique and persistent identifier" (adapted from [GO-FAIR F1 principle](https://www.go-fair.org/fair-principles/f1-meta-data-assigned-globally-unique-persistent-identifiers/)). In practice, often another property of such identifiers is added, namely machine resolvability, to enable retrieval of metadata and data by machines.

When medical data is exposed as HL7 FHIR Resources, then automatically, per the base [Resource](https://www.hl7.org/fhir/resource.html) type, the resource will have a resource [id](https://www.hl7.org/fhir/resource-definitions.html#Resource.id) (named in HL7 FHIR as the "logical" id in opposition to the business identifiers), that "Once assigned, this value never changes": this identifier is persistent per its specification. When combined with the URL prefix of the HL7 FHIR server, a globally unique and also machine resolvable identifier can be constructed (this is the so called 'location URL').

Example: are two GUPRIs (Globally Unique, Persistent and Resolvable Identifiers) for synthetic Patient records from public HL7 FHIR test servers: <http://test.fhir.org/r4/Patient/10> and <https://server.fire.ly/Patient/3591a18b-3eeb-4551-9688-22794aaf9911>. Both identifiers resolve to a description of the resource or the resource itself. **However**, if the URL at which the HL7 FHIR resource server is hosted changes, or if resources are copied to a different server, all the identifiers thus constructed would change as well.

The page [FHIR identifiers and FAIR principles on IDs](https://confluence.hl7.org/display/SOA/FHIR+identifiers+and+FAIR+principles+on+IDs) provides an overview on how HL7 FHIR resources can be identified and under which conditions these identifiers fulfill the FAIR principles on IDs:

Since these identifiers are not mutually exclusive, it is always desirable that - as appropriate - more identifiers (business identifiers, canonical url) are used, so that, depending on the context of use and the kind of resource shared, the most proper identifier is selected. For example, it might advisable that any resource describing metadata at the study level would be also identifiable through permanent identifier as for example DOIs (example <https://doi.org/10.5281/zenodo.4474373>); this will consolidate the persistency and facilitate the search and the access of these objects beyond HL7 FHIR. While the registration of DOIs for any created and shared HL7 FHIR resource might be too costly.

**Summary recommendation**: Establish adequate organizational and technical solutions to assure that the end point where resources are published is 'always' resolvable. Assign, as appropriate, also other identifiers (business identifiers, canonical url). Determine based on a cost/effectiveness evaluation what are the resources for which it is worth to register identifiers on a public permanent registry (e.g.  [https://doi.org/](https://doi.org/10.5281/zenodo.4474373)). Use both reference and identifier elements in the Reference data type. Promote the specification of HL7 FHIR profiles enforcing these choices.

##### F2: Data are described with rich metadata (a plurality of accurate and relevant attributes, defined by R1)

The rationale behind this principle is that someone should be able to find data based on the information provided by their metadata, even without the data’s identifier (adapted from [GO-FAIR F2 principle](https://www.go-fair.org/fair-principles/f2-data-described-rich-metadata/)). HL7 FHIR provides different means to fulfill this scope either considering ['intrinsic'](https://www.go-fair.org/fair-principles/f2-data-described-rich-metadata/) , as well as ‘[contextual](https://www.go-fair.org/fair-principles/f2-data-described-rich-metadata/)’ metadata.

All HL7 FHIR Resources have a [Meta](https://www.hl7.org/fhir/resource-definitions.html#Resource.meta) element which includes some intrinsic resource metadata as for example versionId, lastUpdated, source, profile, security labels and tags . They are technical in nature and apart from profile do not really address the context of the data provided in the resource. The Meta field is not mandatory, but it is advised to at least populate the versionId and lastUpdated fields. Moreover, each resource is a collection of elements describing the data and the context in which this data has been generated and exists (metadata) and that can be used for searches. There are finally particular HL7 FHIR resources, as Citation, Library, Provenance and others, that can be used to capture specific metadata information.

The adoption of HL7 FHIR can therefore enable the documentation of 'rich' metadata, but the conformance with HL7 FHIR is not a necessarily a sufficient condition for fulfilling this requirement.

In fact, in order to satisfy the 'richness' criterium, the use case is important - because whether metadata is 'rich' enough would really depend on what users would need to search on in terms of metadata fields to find the resources.

The capability of the used resources to capture the expected information is a pre-condition for enabling the data search via HL7 FHIR APIs, that needs to be supported by the HL7 FHIR server used. In fact not all the HL7 FHIR resource elements are by default searchable and  it is not required that a HL7 FHIR server support all the 'standard' search parameters.

Therefore, depending on the use case, implementers should identify what are the minimal, recommended and suggested intrinsic and contextual metadata that should be returned to describe the data and what is the subset of these elements for which HL7 FHIR searches should be performed.

To do that, implementers should look for specific HL7 FHIR Implementation Guides (IG) that cover the Resource types and the use case of interest; and/or define HL7 FHIR IGs that apply in their usage context. These IGs should contain HL7 FHIR profiles for the used resources and capability statements describing what a HL7 FHIR server should offer to satisfy this findability principle in that use case.

**Summary recommendation**: Communities should define what rich metadata are sufficient to describe the data and which should be used for HL7 FHIR searches. This should be formalized with appropriate HL7 FHIR conformance resources in HL7 FHIR implementation guides.

##### F3: Metadata clearly and explicitly include the identifier of the data they describe

This simple and obvious principle is of critical importance to FAIR. The metadata and the dataset they describe are usually separate resources (adapted from [GO-FAIR F3 principle](https://www.go-fair.org/fair-principles/f3-metadata-clearly-explicitly-include-identifier-data-describe/)). The association between a metadata resource description and the dataset should be made explicit by mentioning a dataset’s globally unique and persistent identifier in the metadata.

The F3 principle can be interpreted differently depending on how metadata information are implemented in HL7 FHIR, but it is in general possible to satisfy this requirement. When metadata is represented by a HL7 FHIR resource distinct from those recording data (e.g. a Citation resource pointing to the used data) the mechanism typically used by HL7 FHIR to assure this link is through either the Reference datatype or canonical urls. The Reference data type supports either (a) the direct reference to the HL7 FHIR resource with absolute or relative url based on the resource logical ID; and (b) the reference to its business identifier.

In the cases when metadata information are recorded in the same HL7 FHIR resource of the data they describe, data are uniquely identified within the resource either by their path ( e.g. Evidence.statistic.modelCharacteristic.value) or by their identifiers (e.g. Questionnaire.item.linkId).

All the adopted identifiers (see F1 recommendations) should always be included in any resource record that holds data for the resource in question. Since this is usually done in HL7 FHIR by referring other HL7 FHIR resources, both references (reference and identifier) should be provided.

**Summary recommendation**: When applicable include in the references both the resource and the business identifier. The metadata description should always be semantically coherent and machine resolvable even when the the resource data itself is no longer available, for a variety of potential reasons.

##### F4: (Meta)data are registered or indexed in a searchable resource

Identifiers and rich metadata descriptions alone will not ensure ‘findability’ on the internet. Perfectly good data resources may go unused simply because no one knows they exist. If the availability of a digital resource such as a dataset, service or repository is not known, then nobody (and no machine) can discover it (adapted from [GO-FAIR F4 principle](https://www.go-fair.org/fair-principles/f4-metadata-registered-indexed-searchable-resource/)).

In order to adhere to this F4 principle, the HL7 FHIR [search framework](https://www.hl7.org/fhir/search.html) can be used. The extent of data and metadata that have to be registered or indexed would however depend on what users would need to search to find the resources.

Most HL7 FHIR servers implement one or more search parameters, so by publishing resources into such a HL7 FHIR server may be sufficient to fulfill the FAIR principle F4 but this might not be enough.

Therefore, it would make sense to look for specific HL7 FHIR Conformance resources and/or Implementation Guides that describe the metadata and data elements that shall or should be provided to a HL7 FHIR server for the use case in question and registered or indexed by that server.

HL7 FHIR CapabilityStatement, SearchParameter, StructureDefiniton , possibly documented within a Implementation Guide should be used to document this.

**Summary recommendation**: Each community should define what are the relevant metadata and data that have to be registered or indexed by a HL7 FHIR server for each supported resource to fulfil this principle; formalizing them with HL7 FHIR conformance resources and implementation guides.

#### Accessibility

##### A1: Metadata and data are retrievable by each of their identifiers using a standardised communication protocol

FHIR is described as a 'RESTful' specification based on common industry level use of the term REST, in this RESTful framework, transactions are performed directly on the server resource using an HTTP request/response.

**Summary recommendation**: This principle is covered by virtue of using HL7 FHIR RESTful API

##### A1.1: The protocol is open, free and universally implementable

Both HL7 FHIR RESTful API and the http protocols  are open, free and universally implementable.

There are different definitions of what an 'open standard' is, but also considering openness of access; of the process and of the rights of use, HL7 FHIR fulfills all of them. It is released under Creative Commons "No Rights Reserved" ([CC0](http://creativecommons.org/publicdomain/zero/1.0/)) licence and it is globally implemented.

**Summary recommendation**: This principle is covered by virtue of using HL7 FHIR RESTful API

##### A1.2: The protocol allows for an authentication and authorisation, where necessary

It often makes sense to request users to create a user account for a repository. This allows authentication of the owner (or contributor) of each dataset, and to potentially set user-specific rights. This can also affect the choice of the repository that is suitable to share data and associate metadata.

HL7 FHIR is not 'per se' a security protocol, nor does it define any security related functionality; however it defines exchange protocols and content models (<https://www.hl7.org/fhir/exchange-module.html>) that can be used with various open security protocols such asHMAC authentication (<https://en.wikipedia.org/wiki/HMAC>), HTTPS (<https://en.wikipedia.org/wiki/HTTPS>) (see e.g. <https://hl7.org/fhir/security.html#http> for Communications Security in HL7 FHIR)

**Summary recommendation**:  Each community should declare what are the security standards there are adopted in their context.

##### A2: Metadata should be accessible even when the data is no longer available

This principle is important because there can be many reasons why data are no longer available whereas the associated metadata should be a permanent record to describe the data. Future reuse of available data requires separately identified metadata and it also crucial to enable future reproducibility of new data for more science.

The practical application of this A2 FAIR principle to data and metadata from the clinical sciences and specifically should consider the following aspects.

* Some clinical data elements may serve as metadata for other data elements. If all data elements have identifiers compliant with FAIR principle, A1 being global, unique, persistent and resolvable by machine (GUPRI) it should be possible to comply with this FAIR principle, A2.
* Clinical data and associated metadata can be stored on multiple HL7 FHIR servers.
* To maintain FAIR compliance, it is critical to manage and maintain the persistency aspect of GUPRIs (independently on HL7 FHIR) for all data and metadata elements.

In the HL7 FHIR space this requirement is fulfilled as far as metadata and data can be represented with distinct resources (see also [Metadata and data page](metadata.html)) and the used identifiers comply with FAIR principle, F1.

**Summary recommendations:** follow F1 recommendations.

#### Interoperability

##### I1: Metadata and data use a formal, accessible, shared, and broadly applicable language for knowledge representation

There are different ways to interpret 'language knowledge representation', for example the capability to:

* have a machine readable physical representation, e.g. JSON
* represent and formalize healthcare models and data;
* share clinical knowledge artifacts;
* provide an expression logic
* strive for semantic computable interoperability (i.e. semantic interoperability between machines)

HL7 FHIR supports XML, JSON and RDF machine readable physical representations. It provides in general a formal (FHIR Infrastructure, the core framework on which HL7 FHIR depend, is a Normative part of HL7 FHIR); accessible and shared (the HL7 FHIR standard is public, accessible and usable by everyone) and broadly applicable language: HL7 FHIR is widely used in the Healthcare for covering a wide range of domains and use cases (from genetic to administrative data for representing healthcare related models and data). The HL7 FHIR Clinical Reasoning module provides "resources and operations to enable the representation, distribution, and evaluation of clinical knowledge artifacts such as clinical decision support rules, quality measures, public health indicators, order sets, clinical protocols, and evidence summaries.". It enables finally the representation of logic using languages such as HL7 FHIRPath and Clinical Quality Language (CQL).

FHIR resources can be used together with other knowledge representation approaches, including SNOMED CT Compositional Grammar

Thus, if we are looking to the first four aspects this principle is covered by virtue of using HL7 FHIR resources to represent metadata and data.

Concerning instead the last point, the compliance with HL7 FHIR, even if it is a strong enabler, may not be sufficient for the semantic computable interoperability. For example a vocabulary used by the sender or an extension defined in a specific context might not be understood by the receiver. To strive for semantic computable interoperability communities are invited to agree on context specific HL7 FHIR Implementation Guides, relying as possible on existing ones.

**Summary recommendation**: Even though in general this principle is covered by virtue of using HL7 FHIR, to strive to semantic computable interoperability communities should agreed on common vocabularies, profiles and other conformance resources that applies for their context of use.

##### I2: Metadata and data use vocabularies that follow the FAIR principles

HL7 FHIR provides a formal way to bind codeable elements with vocabularies (intended as terminologies), but with very few exceptions, it doesn't impose the usage of any of them.

HL7 FHIR includes terminology resources and API that may facilitate the fulfillment of some 'technical' FAIR principles as the unique, global persistent identification of vocabulary metadata and data (e.g. by using the canonical URL).

To satisfy this principle HL7 FHIR implementers should make an assessment of the FAIRness of the terminologies to be used and  enforce the adoption of the FAIR-compliant vocabularies.

**Summary recommendation**:  HL7 FHIR implementers should select FAIR-compliant vocabularies, preferably managed through HL7 FHIR  terminology services.

This choice should be formalized through  community specified HL7 FHIR Implementation Guide, including appropriate conformance and terminology resources.

**For future consideration:** realize a catalog of FAIR-compliant vocabularies.

##### I3: Metadata and data include qualified references to other metadata and data

A qualified reference is intended as a cross-reference that explains its intent.

HL7 FHIR technically supports different kinds of references among HL7 FHIR resources and also to non-FHIR objects.

This capability of HL7 FHIR doesn't guarantee however "per se" that as many meaningful links between metadata and data resources are used to enrich the contextual knowledge about the data (that is the goal).

Thus, if on one hand this principle is technically satisfied by HL7 FHIR, HL7 FHIR implementers should determine what are the links among resources that are needed to provide a sufficient contextual knowledge for the scope of their community.

**Summary recommendation**:  HL7 FHIR implementers should determine what are the qualified references to other resources that are needed to provide a sufficient contextual knowledge for the scope of their community. This should be formalized through a community HL7 FHIR Implementation Guide.

#### Reusability

##### R1: Metadata and data are richly described with a plurality of accurate and relevant attributes

This principle is related the F2, but while F2 focuses on metadata that allows its discovery, R1 focuses on the context under which the data were generated as well as they should been used.

General considerations made for F2 about HL7 FHIR apply also for R1, HL7 FHIR is therefore an enabling factor, but the conformance with HL7 FHIR is not necessarily a sufficient condition for fulfilling this requirement.

The fact data and metadata are 'richly described' depends on the context of use; therefore, depending on the use case, implementers should identify what are the minimal, recommended and suggested intrinsic and contextual information that should be returned to describe the data and make them actually USEFUL in a particular context.

To do that implementers should look for specific HL7 FHIR Implementation Guides (IG) that cover the Resource types and the use case of interest; and/or define HL7 FHIR IGs that apply in their usage context.

**Summary recommendation:** Communities should define which rich metadata are sufficient to describe data to make them useful in their context. This should be formalized with appropriate HL7 FHIR conformance resources in HL7 FHIR implementation guides.

##### R1.1: Metadata and data are released with a clear and accessible data usage license

HL7 FHIR provides different means to specify the license and the conditions under which data can be used. For example, a resource may convey specific security metadata by using the security labels, enabling policy fragments to accompany the resource data; the Citation resource offers a copyright element to covey human readable copyright information at different level of granularity (Citation , abstract, cited artefacts); the Consent resource can be used to record choices which permits or denies identified recipient(s) or recipient role(s) to perform one or more actions within a given policy context, for specific purposes and periods of time.

The solution to be adopted may change depending on the type of data and the context of use.

The adoption of HL7 FHIR is not however a sufficient condition for fulfilling this requirement, implementers should therefore define how this requirement is supposed to be met.

**Summary recommendation:** Published HL7 FHIR resources have to include clear references to the usage license. Communities should specify in community HL7 FHIR implementation guide how - for each kind of data - this is realized in their context.

##### R1.2: Metadata and data are associated with detailed provenance

This principle focuses on specific type of contextual data as where the data came from, how they have been processed; if it has been published before; who need to be cited and/or acknowledged....

Most of this information may be captured in HL7 FHIR by using the Provence resource enabling the recording of data sources and of the actions applied on them at different level of granularity.

Other kinds of resources, e.g. the Citation, could be used for capturing instead publication related infos.

As for some other principles, HL7 FHIR can technically support the data FAIRness, but it is not a sufficient condition for fulfilling this requirement; that depends also on the capability of the organization to capture and record this information.

**Summary recommendation:** Implementers are encouraged to use the Provenance resource to improve description the data context. Communities should specify in community HL7 FHIR implementation guide how this requirement is realized in their context.

##### R1.3: Metadata and data meet domain-relevant community standards

HL7 FHIR is a globally recognized standard in the health domain, that can be used to represent human and machine-readable metadata and data information.  
It defines also formal profiling mechanisms to specify community agreed rules.

There are several published HL7 FHIR Implementation Guides describing how HL7 FHIR should be used for specific scopes.

Beyond this, there might be implementation independent standards (e.g. clinical guidelines) a community wish to refer to.

Implementers are therefore suggested to look for existing HL7 FHIR implementation guides or define new ones to cover appropriately the community expectations.

**Summary recommendation:** Even though HL7 FHIR can be considered it self a 'domain-relevant community standard' , implementers are strongly suggested to identify and if needed specify appropriate  HL7 FHIR Implementation Guides covering the community expectations in terms of models, vocabularies and so on for their context of use.