Intelligent ecosystem to improve the governance, the sharing, and the re-use of health data for rare cancers

Deliverable 3.1

FHIR Implementation Guide

29 February 2024

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Revision History

Revision	Date of Issue	Author(s)	Brief Description of Change
1.0	2024-02-29	G. Cangioli, R. Gazzarata (HL7)	First release
	2024-03-11	E. Martinelli (INT)	Revision by Coordinator
2.0	2024-03-12	G. Cangioli, R. Gazzarata (HL7)	Revised after internal peer-review by UDEU
		E. Martinelli (INT)	Final review and submission in EU portal

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Addressees of this document

This document is addressed to the whole IDEA4RC Consortium. It is an official deliverable for the project and shall be delivered at the European Commission and appointed experts.

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Abbreviations and definitions

Abbreviation	Definition
API	Application programming interface
EEHRxF	European Electronic Health Record exchange Format
EHR	Electronic Health Record
EUROCAN	European network for Rare adult solid Cancer
FAIR	Findable, Accessible, Interoperable and Reusable
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Leven Seven
IG	Implementation Guide
FSH	FHIR shorthand files

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1 EXECUTIVE SUMMARY

FHIR (Fast Healthcare Interoperability Resources) is a next generation standards framework created by HL7 to exchange healthcare information electronically and create working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR solutions, as the name suggests, are built from a set of modular components called "Resources". Thanks to their very flexible structure, FHIR resources can be easily used in any healthcare domain, but to build working interoperability solutions, they must be adapted to the specific context of use by defining an Implementation Guide (IG).

This document presents the activities performed for the creation of the IDEA4RC FHIR IG developed during the first 18 month of IDEA4RC project and the resulting FHIR IG. Precondition for the implementation of the "FHIR capsule", the set of technical tools to enable holders of rare cancer data resources, coming from multiple sites, repositories, and services, across EU countries, to wrap and efficiently map them as sets of FHIR resources, to share them granularly, seamlessly, and selectively through FHIR APIs (Application Programming Interfaces).

The IDEA4RC FHIR IG was developed following a co-creation approach involving EURACAN (European network for Rare adult solid Cancer) referees, the other WPs and main stakeholders, and by using computable specifications to enable the automatic validation and considering the main European and international initiatives as for example OSIRIS[1].
The latest version of the IDEA4RC FHIR IG is available at https://build.fhir.org/ig/hl7-eu/idea4rc/

[1] https://www.e-cancer.fr/Professionnels-de-la-recherche/Recherche-translationnelle/OSIRIS-projet-national-sur-le-partage-des-donnees

2 METHODOLOGY

WP3 adopts an **adaptive, iterative**, and **incremental** approach, allowing working on the FHIR implementation guide without requiring WP2 completing the definition of all the functional requirements (model).

This implies the publication of intermediate products based on the requirements known at that time. Products have been, and are being, progressively refined through a continuous improvement process involving other WPs. The adoption of tools permitting the sharing of the in-progress specifications, along with a formal versioning management of the in-development material, makes the in-progress results available for consultation in real-time while working on them.

To achieve the described results, a tight internal and external cooperation has been established. Activities have been coordinated with WP2 and the other interested WPs through regular coordination meetings and with cross-WPs and tasks participation.

As known, there are several possible methodologies. (OMG UML, DCIM / ISO 13972:2022, FHIR Logical Models, etc) and tools - more or less formal - that can be used to capture and formalize information needs. For the purpose of this project, it has been chosen to

- keep as possible distinct the conceptual, the logical and implementable levels; and
- reuse what was already available and used by the different categories of stakeholders engaged in IDEA4RC. E.g., data sheet for the conceptual level, FHIR logical model for the computable representation in the FHIR IG.

Figure 1 summarises the overall process followed:

1. Information needs are captured by WP2 in the form of a common data model
2. The proposed model is formalized in the FHIR IG in the form of FHIR Logical Models to facilitate the information needs tracking to the implementable specifications.
3. WP3 together with WP2 analyses the model for determining the best representation with HL7 FHIR resources. During this phase clarifications about the model are requested, leading sometime to a refinement of the model itself. The link between the logical and the implementable models are formalized as FHIR ConceptMap.

4. Based on the mapping identified in step 3, FHIR resources are profiled using terminology assets included.

This process is realized by continuous iterations to refine the used artefacts.

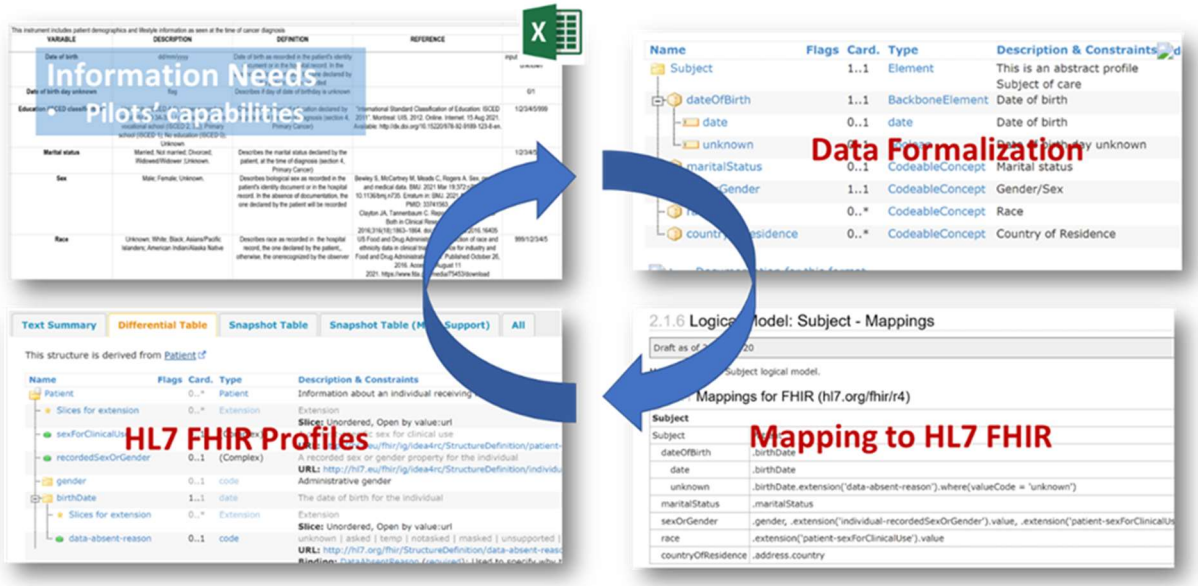

Figure 1 – Overview of the methodology.

Technically, the model produced by WP2 in collaboration with other Work Packages [See https://docs.google.com/spreadsheets/d/1Vw1Dr2K4oG__cDQTutGaJhZvGUvQTLwc4qWreP6qMSs/edit#gid=1851293965] has been exported as an excel file[2].

This excel, after some manual refinements, has been used for generating FHIR shorthand (FSH) scripts (for information on FSH, please see Chapter 3).

FSH files finally utilized for generating the actual FHIR logical models included in the guide.

[2] The material used (scripts for conversion, diagram, etc.) is available in https://github.com/unai-zulaika/IDEA4RC-Datamodel-tools

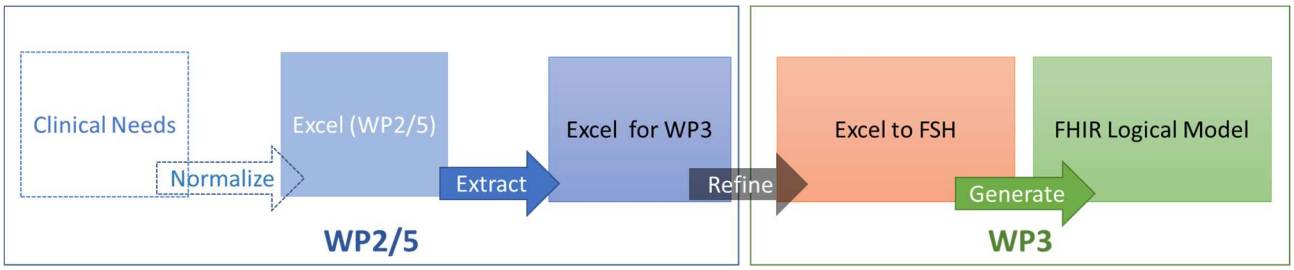

Figure 2 – Process followed for generating the FHIR Logical Models.

To keep track of the data elements foreseen for Sarcoma, for Head and Neck cancer or for both, a new feature recently introduced in HL7 FHIR has been adopted: the obligations (see https://build.fhir.org/obligations.html).

Obligation provides a mean to distinguish in a model the structural constraints (e.g., cardinality, invariant, vocabulary bindings,...) from the functional constraints on these data elements.

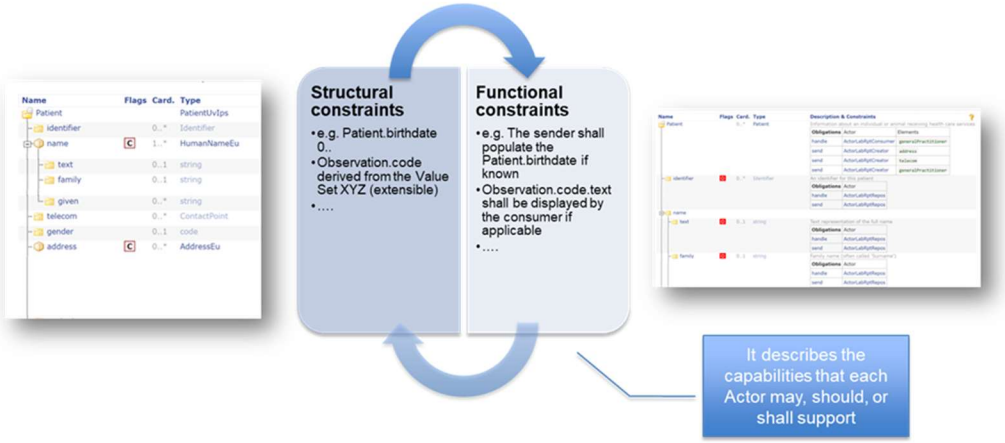

Figure 3 – HL7 FHIR Obligations

The following figure shows how obligations are used in the Patient model (https://build.fhir.org/ig/hl7-eu/idea4rc/StructureDefinition-Subject.html) to highlights the elements expected for both types of cancer and those used only for the Sarcoma.

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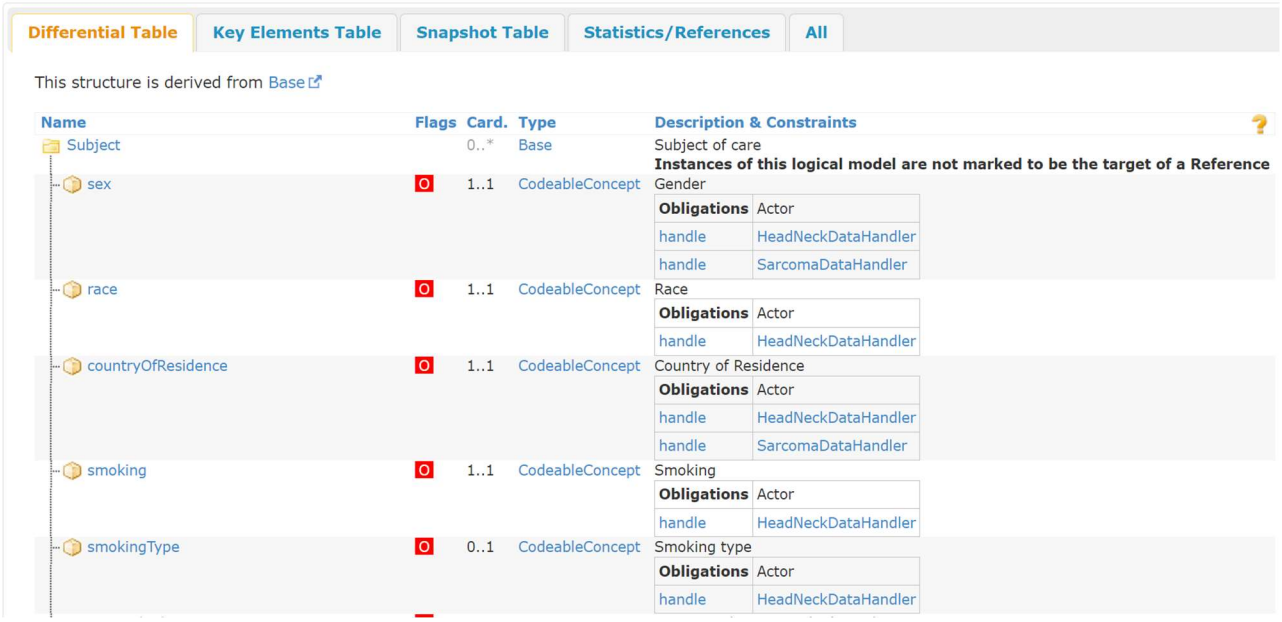

Figure 4 – Use of HL7 FHIR Obligations in the IDEA4RC FHIR IG

Another key element of the methodology applied is the formalization of the conceptual/logical to implementable model forward mapping.

This has been realized by means of the HL7 FHIR ConceptMap resource, a type of FHIR resources initially designed for terminology concept-to-concept mapping, but applicable also for model concepts mapping.

The use of this resource allows to decouple the mapping from the source and target models and to specify the kind of relationship among concepts, not achievable for example by using the map element of the FHIR StructureDefinition. An example is provided in the following figure.

Group 1 Mapping from Subject of care to Patient: IDEA4RC

Source Code	Relationship	Target Code	Comment
Subject.sex (Gender)	is equivalent to	Patient.gender	For the time being assumed to be the administrative gender
Subject.race (Race)	is equivalent to	Patient.extension:race.value[x]	
Subject.countryOfResidence (Country of Residence)	is equivalent to		
Subject.smoking (Smoking)	(not mapped)		
Subject.smokingType (Smoking type)	(not mapped)		
Subject.cigSmokedPerDay (Cigarettes/cigars smoked per day)	(not mapped)		

Group 2 Mapping from Subject of care to Observation: Tobacco use

Source Code	Relationship	Target Code
Subject.smoking (Smoking)	is equivalent to	Observation.component:smokingStatus.value[x]:valueCodeableConcept
Subject.smokingType (Smoking type)	is equivalent to	Observation.component:tobaccoProduct.value[x]:valueCodeableConcept
Subject.cigSmokedPerDay (Cigarettes/cigars smoked per day)	is equivalent to	Observation.component:numberPerDay.value[x]:valueQuantity
Subject.yearsAsSmoker (Number of years as a smoker)	is equivalent to	Observation.component:yearsAsSmokervalue[x]:valueQuantity

Figure 5 – Use of HL7 FHIR ConceptMap in the IDEA4RC FHIR IG

Finally, this guide has been developed by taking in account several European and international initiatives including, but limited to:

- the FHIR4FAIR IG project, aimed to provide guidance on how HL7 FHIR can be used for supporting FAIR (Findable, Accessible, Interoperable and Reusable) health data implementation and assessment to enable a cooperative usage of the HL7 FHIR and FAIR paradigms.
- the X-eHealth project, aimed at promoting a faster and sustainable EU digital transformation by defining a uniform interoperable data-sharing format framework, the Electronic Health Record exchange Format (EHRxF)
- the FAIR4Health project, aimed to facilitate and encourage the EU health research community to FAIRify, share and reuse their datasets derived from publicly funded research initiatives
- The EU Funded PancareSurPass project FHIR IG, used for collecting cancer treatment data for producing Cancer Survivorship Passport documents
- the mCODE (short for Minimal Common Oncology Data Elements), an US initiative intended to increase interoperability by assembling a core set of structured data elements for oncology EHRs.

3 THE FHIR IMPLEMENTATION GUIDE

A FHIR Implementation Guide "is a set of rules about how FHIR resources are used (or should be used) to solve a particular problem, with associated documentation to support and clarify the usage. Classically, FHIR implementation guides are published on the web after they are generated using the FHIR Implementation Guide Publisher."

A FHIR implementation guide provides a human readable specification and a set of computable conformance resources that can be used, for example, for the instance validation. (See Figure 6).

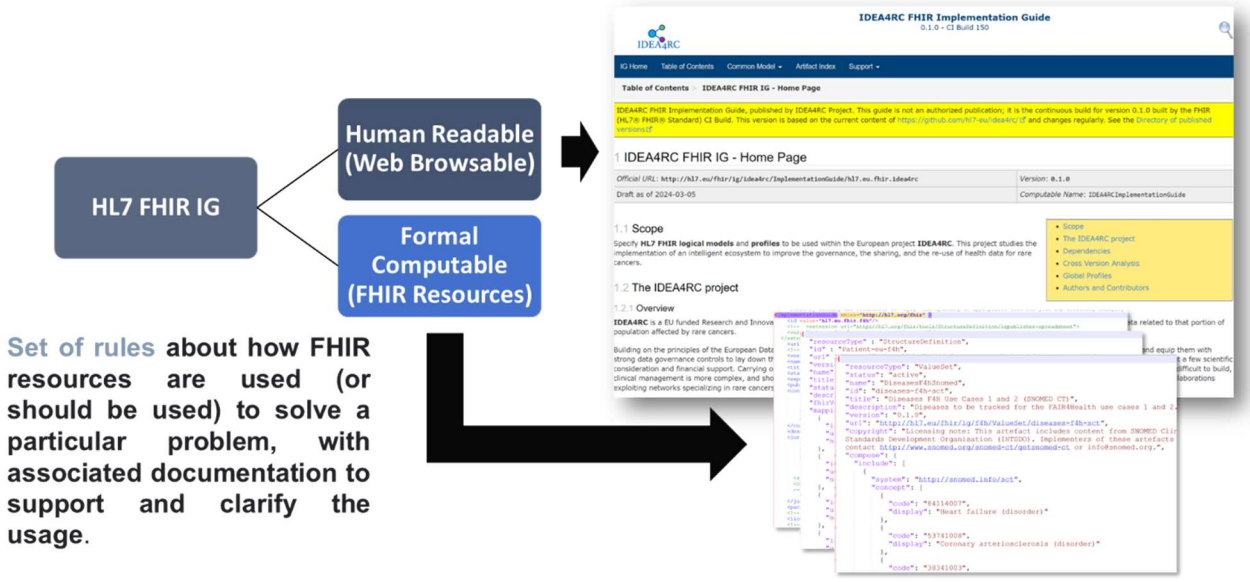

Figure 6 – A FHIR IG

3.1 The tool-stack

An overview of the tool stack used to develop and manage a FHIR IG is provided in Figure 7.

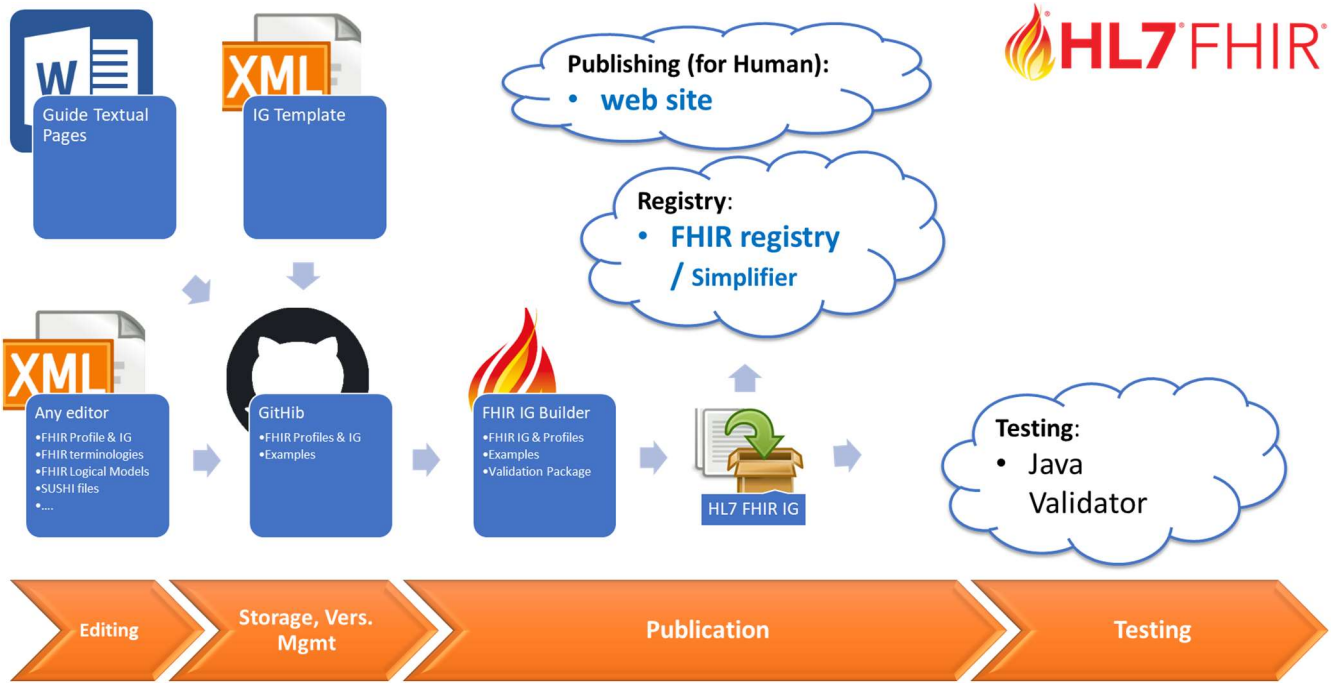

Figure 7 - The FHIR IG toolstack

The first step for the creation of a FHIR IG is the initialization in GitHub of a dedicated building environment collecting all the input artefacts needed to generate the FHIR IG. The GitHub repository is also used for the versioning management of files.

IDEA4RC GITHUB REPOSITORY: HTTPS://GITHUB.COM/HL7-EU/IDEA4RC

Different kinds of inputs files are used for the implementation of a FHIR IG: there are word, markdown or (x)html documents for the guide pages, jscripts, xhtml files for the IG templates, jpeg or png for logos or images, FHIR XML or JSON files for or FHIR shorthand files (FSH) FHIR profiles, logical models, terminologies and examples, and so on. FSH is a domain-specific language for defining FHIR artifacts, created in response to the need in the FHIR community for scalable, fast, user-friendly tools for IG creation and maintenance. Conceived in September 2019 with the first version of the specification released in March 2020, FSH has been rapidly adopted by the FHIR community. Several significant tools for processing FSH have been developed, including SUSHI, a reference implementation and *de facto* standard compiler for transforming FSH into FHIR artifacts.

Different editors can be used for the creation of the input files, but all the source files are stored in the GitHub repository and automatically processed by the FHIR Implementation Guide Publisher (Figure 8).

HL7 FHIR IG PUBLISHER: HTTPS://CONFLUENCE.HL7.ORG/DISPLAY/FHIR/IG+PUBLISHER+DOCUMENTATION

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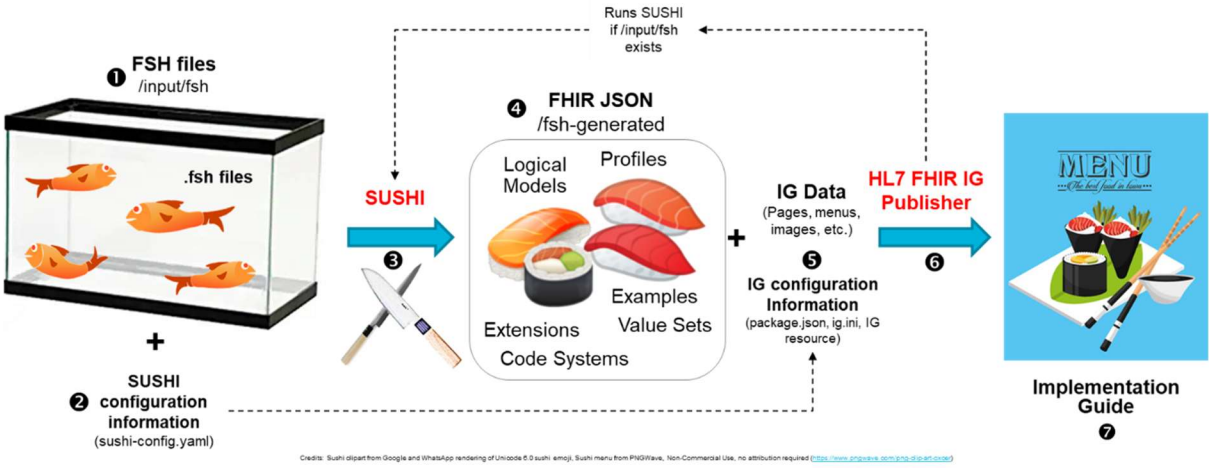

Figure 8 - The process of publication of a FHIR IG

The generated FHIR human readable IG and the computable FHIR package are then published in a public site.

IDEA4RC FHIR IG URL:

HTTPS://BUILD.FHIR.ORG/IG/HL7-EU/IDEA4RC/

The generated package can be used for validating the FHIR instances for example by using the HL7 FHIR java validator or other testing tools.

HL7 FHIR JAVA VALIDATOR: HTTPS://CONFLUENCE.HL7.ORG/DISPLAY/FHIR/USING+THE+FHIR+VALIDATOR

3.2 The IDEA4RC FHIR IG

The IDEA4RC FHIR IG aims to specify HL7 FHIR logical models and profiles to be used within the European project IDEA4RC for the implementation of an intelligent ecosystem to improve the governance, the sharing, and the re-use of health data for rare cancers.

The IDEA4RC FHIR IG provides a human readable representation as browsable web site (Figure 9) and a list of artifacts (https://build.fhir.org/ig/hl7-eu/idea4rc/artifacts.html) including:

- Logical model
- Model mapping
- Resource Profiles
- Obligations
- Extension Definitions
- Terminologies

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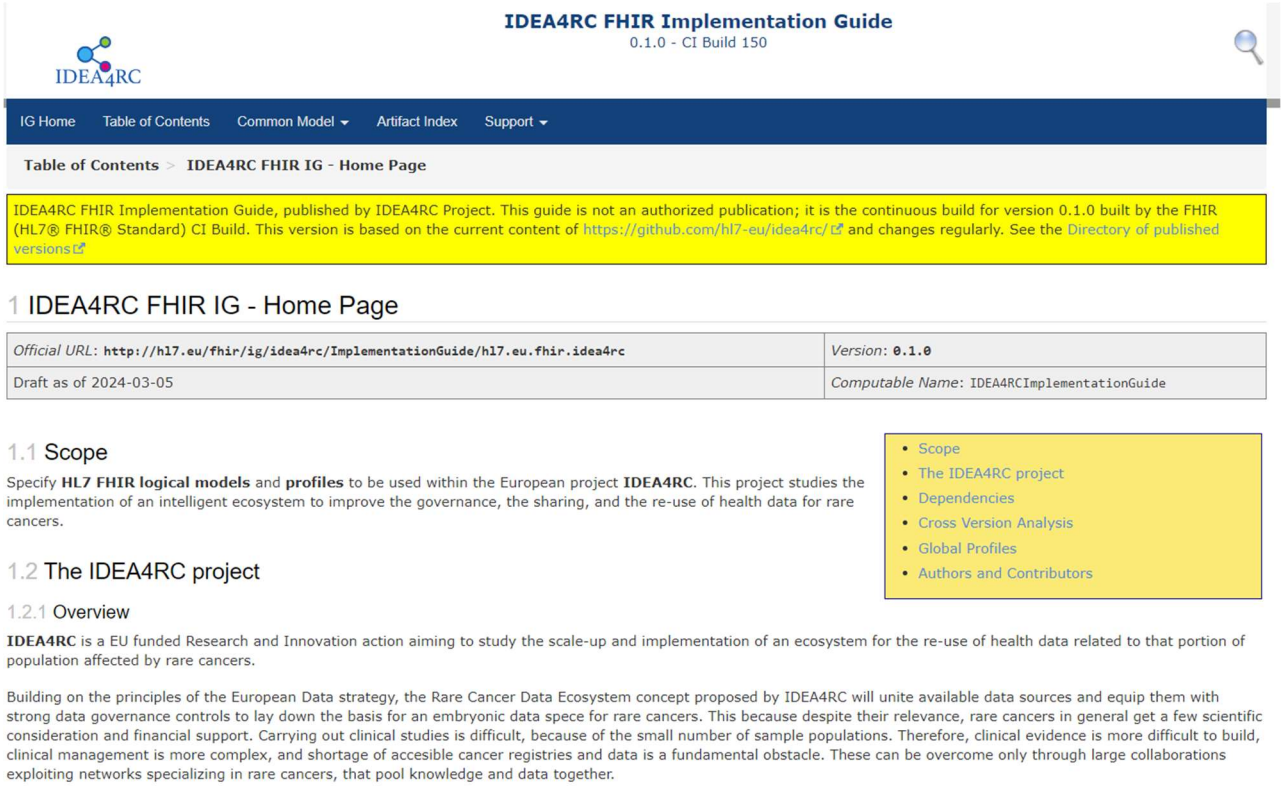

Figure 9 - The IDEA4RC FHIR IG Home Page

The navigation in the IDEA4RC FHIR IG started with the Home Page (Figure 9), reporting the scope of the IG, and IDEA4RC project overview, objectives and FHIR IG dependencies with the other FHIR IGs implemented outside the project by HL7 Int, HL7 Europe or international initiatives. Then the human user can have an overview of the agreed IDEA4RC data model in the IDEA4RC Model Overview page (Figure 10).

For each entity of the IDEA4RC data model (Figure 10) a corresponding HL7 FHIR Logical model has been specified (see e.g. Figure 12). The complete list of the models is available in the Artefacts Summary page (Figure 11), section IDEA4RC Common Models.
As previously mentioned, these FHIR logical models were the inputs of the activities of task T3.1 for the design and the implementation of the corresponding FHIR profiles (Figure 13).

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2 IDEA4RC Model Overview

2.1 IDEA4RC Overview

IDEA4RC aims at developing an IT infrastructure to facilitate the sharing and re-use of health data among clinical centers to promote research on rare cancers and improve patients' access to high quality care. Our challenge is building a new tool to overcome interoperability issues and make it easier to comply with privacy regulations. To achive this result a common data model has been agreed.

Contents:
- IDEA4RC Overview
- Model Overview

An overview of this model is provided hereafter; a detailed ERD is instead shown in the IDEA4RC Detailed ERD Model page.

The IDEA4RC model has been then formalized as HL7 FHIR Logical Models, listed in the IDEA4RC Logical Models page.

2.2 Model Overview

The following diagram provide a high level description of the IDEA4RC MODEL

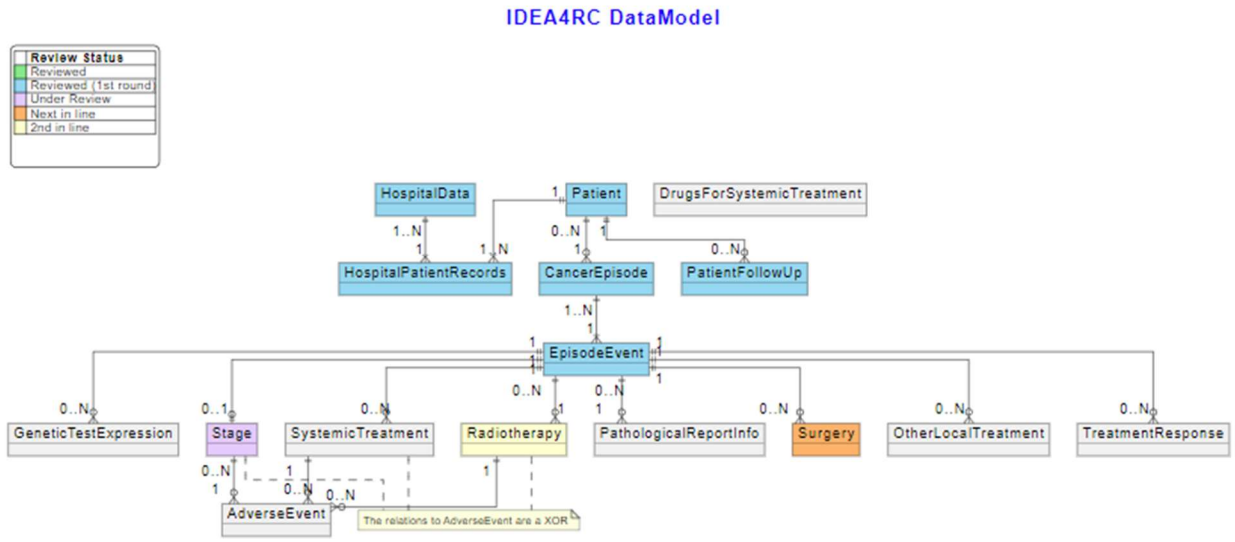


Figure 10 - The IDEA4RC Model Overview page in the FHIR IG

6 Artifacts Summary

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

6.0.1 IDEA4RC Common Models

Logical models representing the IDEA4RC Common Models

Adverse Event	IDEA4RC Adverse Event common model
Cancer Episode	IDEA4RC Cancer Episode common model
Episode Event	IDEA4RC Episode Event common model
Genetic Test Expression	IDEA4RC Genetic Test Expression common model
Hospital Patient Records	IDEA4RC Hospital Patient Records common model. This includes also the HospitalData model.
Patient	IDEA4RC Patient common model
Patient Follow-Up	IDEA4RC Patient Follow Up common model
Radiotherapy	IDEA4RC Radiotherapy common model
Stage	IDEA4RC Stage common model
Surgery	IDEA4RC Surgery common model
Systemic Treatment	IDEA4RC Systemic Treatment common model
Treatment Response	IDEA4RC Treatment Response common model

Figure 11 – The list of logical models representing the IDEA4RC Common Models available from the Artifacts page.

6.2.1 Logical Model: Cancer Episode

Official URL: http://hl7.eu/fhir/ig/idea4rc/StructureDefinition/CancerEpisode	*Version*: 0.1.0
Draft as of 2024-03-05	*Computable Name*: CancerEpisodeI4rc

Cancer Episode Maturity Level: 0 Draft

Usage:

- Use this Logical Model Profile: Episode Event

6.2.1.1 Formal Views of Profile Content

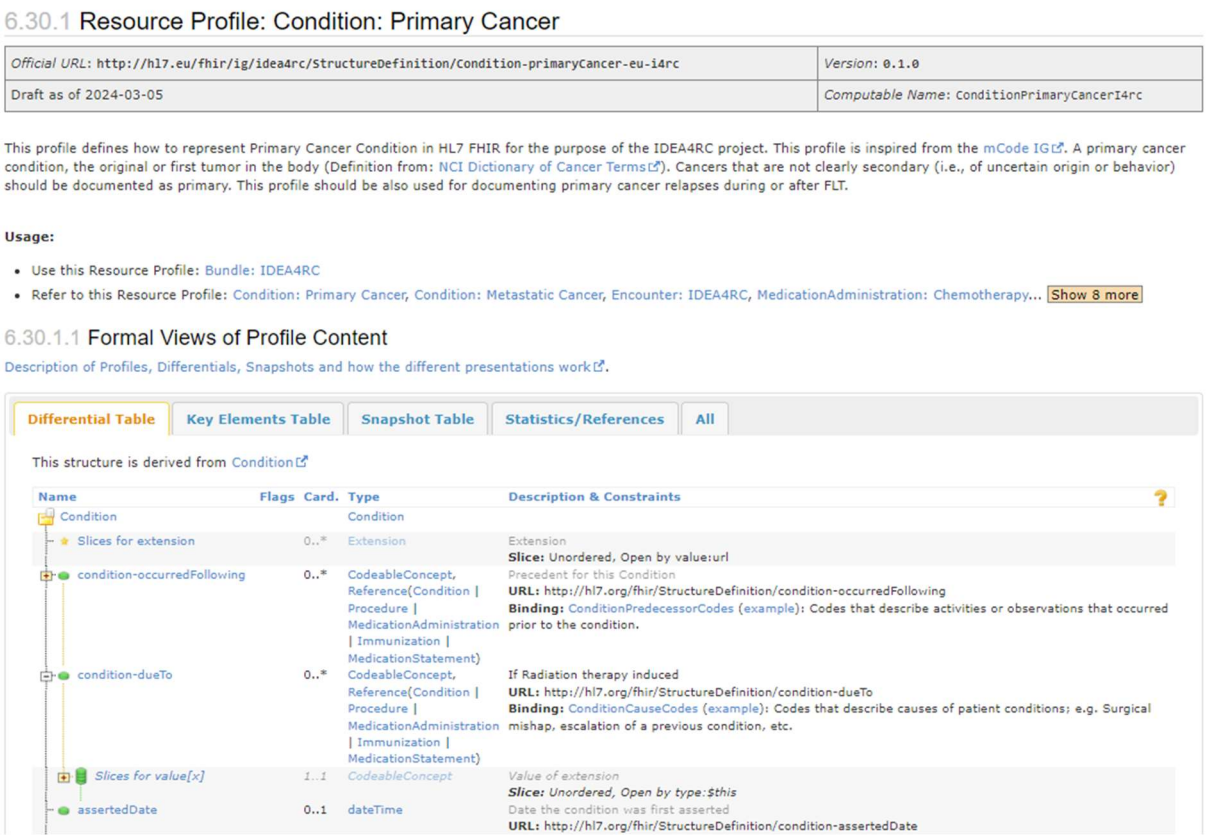
Description of Profiles, Differentials, Snapshots and how the different presentations work.

Differential Table | Key Elements Table | Snapshot Table | Statistics/References | All

This structure is derived from Base

Name	Flags	Card.	Type	Description & Constraints
CancerEpisode		0..*	Base	Cancer Episode **Instances of this logical model are not marked to be the target of a Reference**
patient	O	1..1	Subject	Patient **Obligations** Actor handle HeadNeckDataHandler handle SarcomaDataHandler
dateOfDiagnosis	O	1..1	date	Date of diagnosis (biopsy or surgical piece) **Obligations** Actor handle HeadNeckDataHandler handle SarcomaDataHandler
typeOfBiopsy	O	1..1	CodeableConcept	Type of biopsy **Obligations** Actor handle SarcomaDataHandler
biopsyDoneBy	O	1..1	CodeableConcept	Biopsy done by **Obligations** Actor handle HeadNeckDataHandler

Figure 12 – An example of FHIR logical model profile: the Cancer Episode



6.30.1 Resource Profile: Condition: Primary Cancer

Official URL: http://hl7.eu/fhir/ig/idea4rc/StructureDefinition/Condition-primaryCancer-eu-i4rc	*Version*: 0.1.0
Draft as of 2024-03-05	*Computable Name*: ConditionPrimaryCancerI4rc

This profile defines how to represent Primary Cancer Condition in HL7 FHIR for the purpose of the IDEA4RC project. This profile is inspired from the mCode IG. A primary cancer condition, the original or first tumor in the body (Definition from: NCI Dictionary of Cancer Terms). Cancers that are not clearly secondary (i.e., of uncertain origin or behavior) should be documented as primary. This profile should be also used for documenting primary cancer relapses during or after FLT.

Usage:

- Use this Resource Profile: Bundle: IDEA4RC
- Refer to this Resource Profile: Condition: Primary Cancer, Condition: Metastatic Cancer, Encounter: IDEA4RC, MedicationAdministration: Chemotherapy... Show 8 more

6.30.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

Differential Table | Key Elements Table | Snapshot Table | Statistics/References | All

This structure is derived from Condition

Name	Flags	Card.	Type	Description & Constraints
Condition			Condition	
Slices for extension		0..*	Extension	Extension **Slice:** Unordered, Open by value:url
condition-occurredFollowing		0..*	CodeableConcept, Reference(Condition | Procedure | MedicationAdministration | Immunization | MedicationStatement)	Precedent for this Condition **URL:** http://hl7.org/fhir/StructureDefinition/condition-occurredFollowing **Binding:** ConditionPredecessorCodes (example): Codes that describe activities or observations that occurred prior to the condition.
condition-dueTo		0..*	CodeableConcept, Reference(Condition | Procedure | MedicationAdministration | Immunization | MedicationStatement)	If Radiation therapy induced **URL:** http://hl7.org/fhir/StructureDefinition/condition-dueTo **Binding:** ConditionCauseCodes (example): Codes that describe causes of patient conditions; e.g. Surgical mishap, escalation of a previous condition, etc.
Slices for value[x]		*1..1*	*CodeableConcept*	*Value of extension* ***Slice:** Unordered, Open by type:$this*
assertedDate		0..1	dateTime	Date the condition was first asserted **URL:** http://hl7.org/fhir/StructureDefinition/condition-assertedDate

Figure 13 – An example of Resource Profile: the Condition: Primary Cancer

Since there is not usually a one to one correspondence between logical models and FHIR profiles, nor between their elements, the way these model elements are mapped into the FHIR profiles has been formalized as HL7 FHIR ConceptMap (Figure 14).

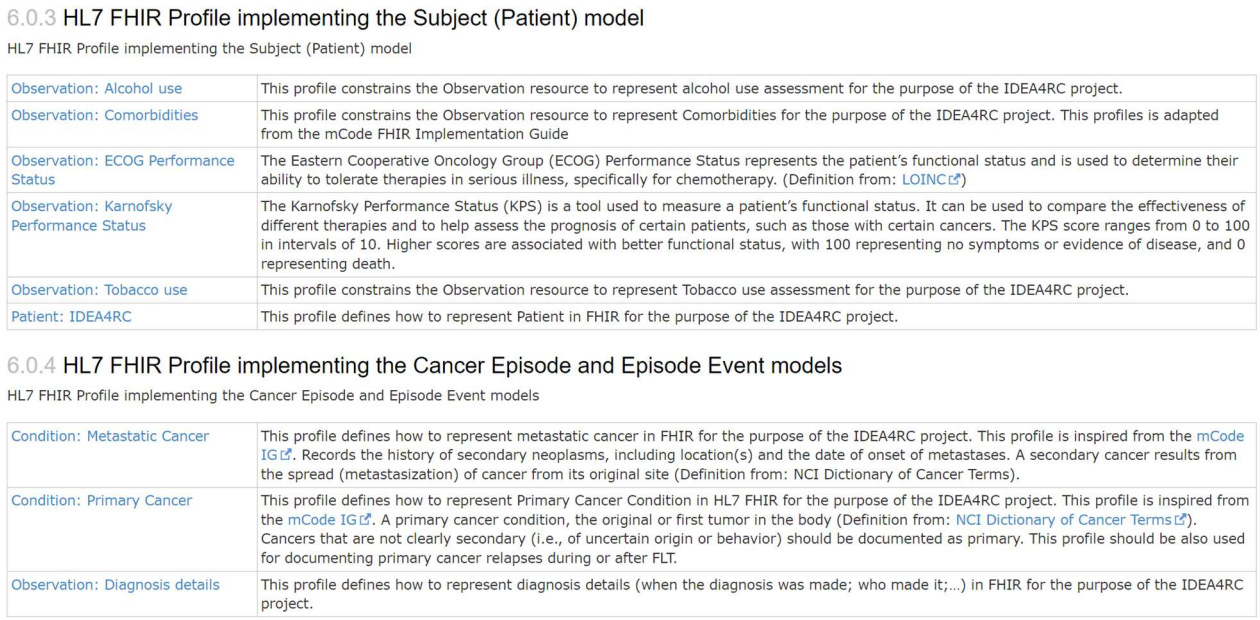
Group 1 Mapping from Cancer Episode to Condition: Primary Cancer

Source Code	Relationship	Target Code	Comment
CancerEpisode.patient (Patient)	is equivalent to	Condition.subject	
CancerEpisode.dateOfDiagnosis (Date of diagnosis (biopsy or surgical piece))	is related to	Condition.onsetDateTime	If the onsetAge is not used
CancerEpisode.dateOfDiagnosis (Date of diagnosis (biopsy or surgical piece))	is related to	Condition.evidence:diagnosisDetails.detail	see details in group2
CancerEpisode.typeOfBiopsy (Type of biopsy)	is related to	Condition.evidence:diagnosisDetails.detail	see details in group2
CancerEpisode.biopsyDoneBy (Biopsy done by)	is related to	Condition.evidence:diagnosisDetails.detail	see details in group2
CancerEpisode.ageAtDiagnosis (Age at diagnosis)	is equal to	Condition.onsetAge	Applicable only if onSetDateTime is not used otherwise is a calculated value from birthdate and onSetDateTime
CancerEpisode.radiotherapyInducedSarcoma (Radiotherapy induced sarcoma)	is equivalent to	Condition.extension:condition-dueTo	true' when extension:condition-dueTo.valueCodeableConcept = $sct#108290001 'Radiation oncology AND/OR radiotherapy'
CancerEpisode.grading (Grading)	is related to	Condition.stage.summary	
CancerEpisode.hnClassification (Classification for Head and Neck tumors)	is related to	Condition.code	At this stage represented as condition.code. Evaluate if it represents a morphology/hystology classification. This comment applies to all the inlcuded elements.
CancerEpisode.hnClassification.histologySquamous (Histology Squamous)	is related to	Condition.code	

Figure 14 – An example of ConceptMap: Cancer Episode to Primary Cancer profile

The list of the Model Maps is available in the "IDEA4RC Common Models Maps" section (https://build.fhir.org/ig/hl7-eu/idea4rc/artifacts.html#2) of the Artefacts Summary page.

Moreover, to facilitate the users' consultation the specified profiles have been grouped in the artefacts index page per referred model entity. The following figure shows for example the list of the profiles specified for implementing the subject/patient and the cancer episode entities.



6.0.3 HL7 FHIR Profile implementing the Subject (Patient) model

HL7 FHIR Profile implementing the Subject (Patient) model

Observation: Alcohol use	This profile constrains the Observation resource to represent alcohol use assessment for the purpose of the IDEA4RC project.
Observation: Comorbidities	This profile constrains the Observation resource to represent Comorbidities for the purpose of the IDEA4RC project. This profiles is adapted from the mCode FHIR Implementation Guide
Observation: ECOG Performance Status	The Eastern Cooperative Oncology Group (ECOG) Performance Status represents the patient's functional status and is used to determine their ability to tolerate therapies in serious illness, specifically for chemotherapy. (Definition from: LOINC)
Observation: Karnofsky Performance Status	The Karnofsky Performance Status (KPS) is a tool used to measure a patient's functional status. It can be used to compare the effectiveness of different therapies and to help assess the prognosis of certain patients, such as those with certain cancers. The KPS score ranges from 0 to 100 in intervals of 10. Higher scores are associated with better functional status, with 100 representing no symptoms or evidence of disease, and 0 representing death.
Observation: Tobacco use	This profile constrains the Observation resource to represent Tobacco use assessment for the purpose of the IDEA4RC project.
Patient: IDEA4RC	This profile defines how to represent Patient in FHIR for the purpose of the IDEA4RC project.

6.0.4 HL7 FHIR Profile implementing the Cancer Episode and Episode Event models

HL7 FHIR Profile implementing the Cancer Episode and Episode Event models

Condition: Metastatic Cancer	This profile defines how to represent metastatic cancer in FHIR for the purpose of the IDEA4RC project. This profile is inspired from the mCode IG. Records the history of secondary neoplasms, including location(s) and the date of onset of metastases. A secondary cancer results from the spread (metastasization) of cancer from its original site (Definition from: NCI Dictionary of Cancer Terms).
Condition: Primary Cancer	This profile defines how to represent Primary Cancer Condition in HL7 FHIR for the purpose of the IDEA4RC project. This profile is inspired from the mCode IG. A primary cancer condition, the original or first tumor in the body (Definition from: NCI Dictionary of Cancer Terms). Cancers that are not clearly secondary (i.e., of uncertain origin or behavior) should be documented as primary. This profile should be also used for documenting primary cancer relapses during or after FLT.
Observation: Diagnosis details	This profile defines how to represent diagnosis details (when the diagnosis was made; who made it;...) in FHIR for the purpose of the IDEA4RC project.

Figure 15 - FHIR profiles grouped per implemented model entity.

Finally, Figure 14 shows how these kinds of artefacts – included in the guide – are related each other.

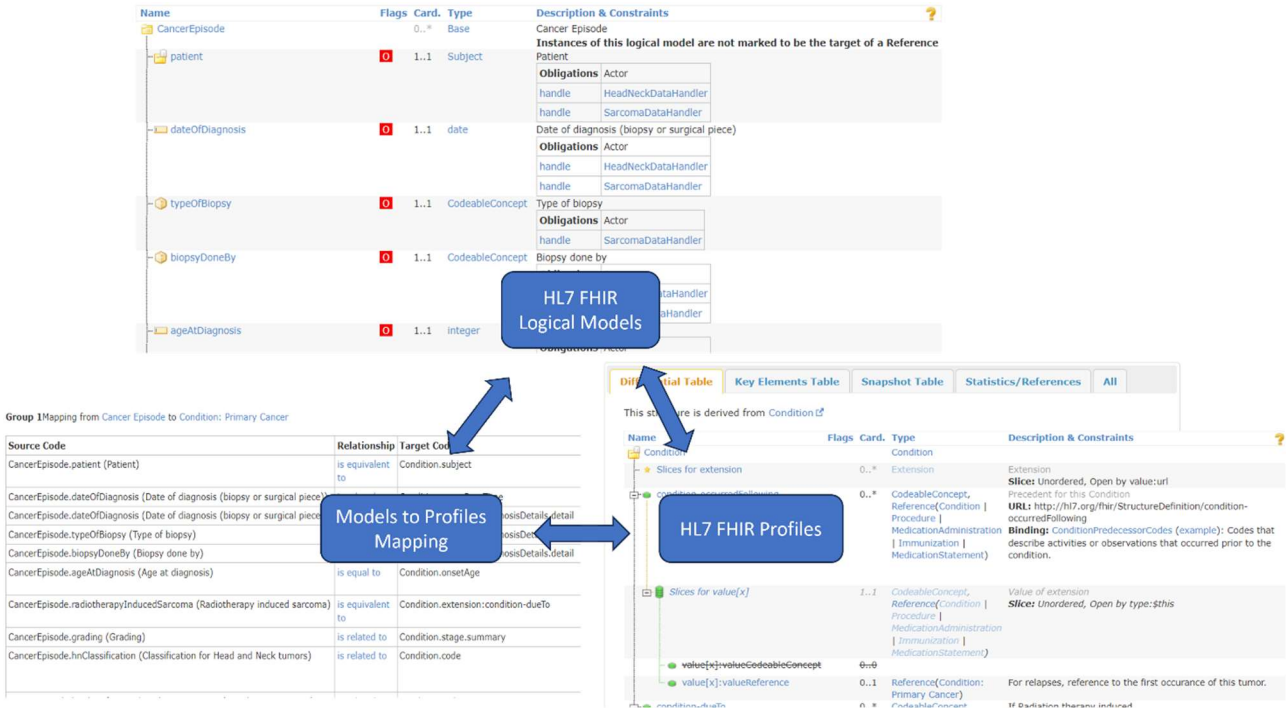


Figure 16 – Relationships among Logical Models, Concept Maps and FHIR profiles

For each artefact, a set of descriptive pages are provided, the information provided changes depending on the artefact.

For each profile two views are provided the Differential and the Snapshot (see Figure 17):

- A profile differential includes only the details of things that have changed in the profile (constraints or extensions): only the differences.
- A profile snapshot includes the details of all the data elements in both the base resource and the profile: fully calculated from of the structure

The differential view is useful for human readers to quickly understand what has been changed respect to the specialized resource / profiles.

Another important and useful capability of FHIR profiling is slicing, "where multiple sets of constraints for a specific use case can be defined for a resource element or a complex element group (slicing can be used with repeating, type choice or non-repeating elements)". Most of the slices specified in this guide are *open* (i.e. *slicing.rules* is not *closed*), which means that it is

possible for resource instances with elements that do not match any of the defined slices to still be conformant with the profile as long as they satisfy the remaining profile constraints.

Finally, all the computable files corresponding to all the IDEA4RC FHIR artefacts (profiles, conceptMap, ect..) are available at https://build.fhir.org/ig/hl7-eu/idea4rc/downloads.html to support the implementation and the validation of the resources compliant to the IDEA4RC FHIR IG.

More details about how to read FHIR resources and profiles can be found in the FHIR standard documentation at https://build.fhir.org/ig/FHIR/ig-guidance/

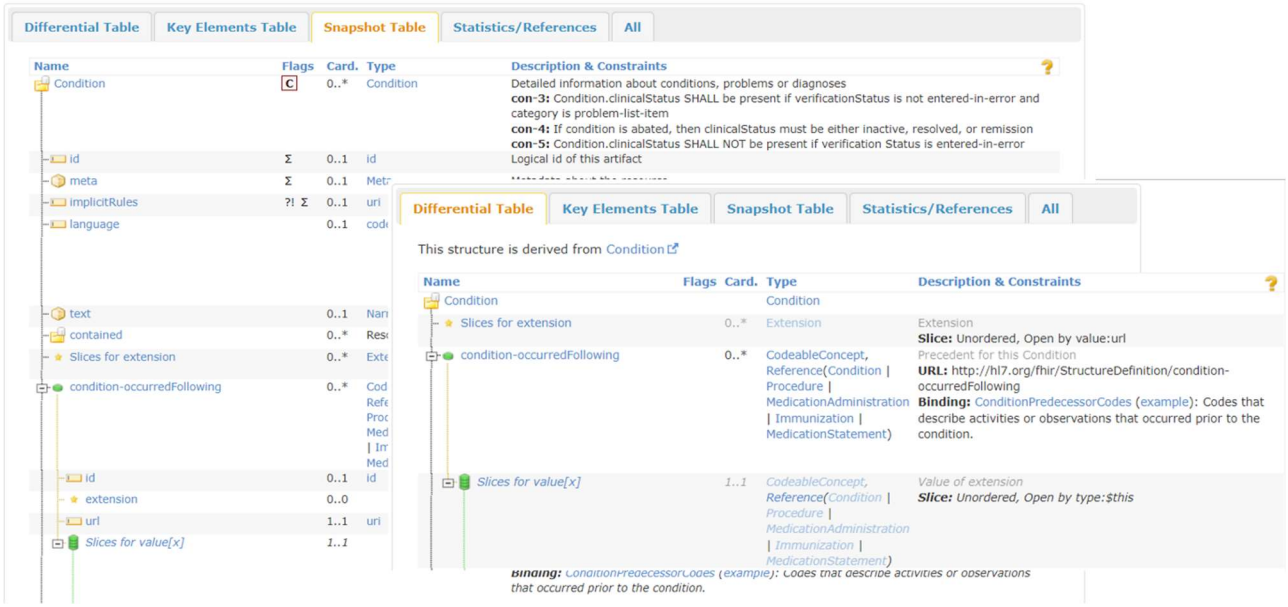


Figure 17 – Example of differential and snapshot view

The last important aspect to highlight is that IDEA4RC HL7 FHIR IG profiles have been designed inspiring from existing HL7 FHIR IGs developed by international initiatives. A formal derivation from these IGs has not been often possible due to terminology constraints not applicable for our project. This is the case of the minimal Common Oncology Data Elements (mCODE) Implementation Guide (available at https://hl7.org/fhir/us/mcode/STU3/), that was created by a US initiative intended to increase interoperability by assembling a core set of structured data elements for oncology EHRs. For example, the IDEA4RC FHIR profile "Observation:

Comorbidities" adopts some extension defined in mCODE FHIR IG, while the IDEA4RC FHIR profiles "Condition: Metastatic Cancer" and "Condition: Primary Cancer" were inspired from this IG.

For details about the most updated specified IDEA4RC FHIR IG please refer to the build.fhir.org IDEA4RC project environment https://build.fhir.org/ig/hl7-eu/idea4rc/ .

Released versions will be published in http://hl7.eu/fhir/ig/idea4rc.

4 CONCLUSIONS AND FUTURE WORK

In this document, the methodology adopted for realizing the IDEA4RC FHIR IG has been described; as well a description of the content developed during these first 18 months of the IDEA4RC project.

At the present, a complete first version of the implementation guide is available at **https://build.fhir.org/ig/hl7-eu/idea4rc**

This guide includes:

- the full representation of the IDEA4RC common model as HL7 FHIR Logical Models
- the formalization of how the IDEA4RC common model is mapped into the HL7 FHIR resources
- the implementable FHIR profiles used to realize the model.

A continuous improvement process has been established to refine the IDAE4RC FHIR IG based on the feedback received by the implementers and the improvements applied on the model.

This refinement work will continue up to the end of the project, when a final version of the guide will be released at the IG canonical url: **https:/hl7.eu/ig/hl7-eu/idea4rc.**

The IDEA4RC model and FHIR IG will be used as input in the proposed activity of harmonization and standardization for an European Cancer Common Data Model and FHIR IG supported by the IDEA4RC Task 10.3 and documented in the IDEA4RC deliverable D10.3.