

Interoperability of the CRC Cohort dataset: openEHR mapping and OMOP vocabularies integration

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Revision history

Revisions	Authors	Reviewers	Main changes
V2 - 24th May 2023	Cecilia Mascia	Giovanni	Update of the document to the current
	(CRS4)	Delussu,	version of the template (Semantic
		Francesca	version 38.1.0, containing the update of
		Frexia (CRS4)	the following archetypes:
			CLUSTER.specimen.v1 (the
			updated version of the
			archetype only differs for added translations)
			 CLUSTER.timing nondaily.v1
			(the updated version of the
			archetype only differs for added translations)
			EVALUATION.specimen_summar
			y.v1 (the added archetype is a
			new version respect to the
			previous, but differs in data
			elements not included in the
			CRC template)
V1 - 10th January	Cecilia Mascia	Giovanni	Update of the document to the current
2023	(CRS4)	Delussu,	version of the model (Semantic
2023	(CN34)	Francesca	version 27.0.1) with a new "Sample"
		Frexia (CRS4)	section.
		TTEXIA (CN34)	Section.
V0 - 04th Aug 2022	Cecilia		First version: description of the first
	Mascia,		version of the mapping at the end of the
	Francesca		EOSC-Life WP1 Demonstrator
	Frexia (CRS4)		"Cloudification of BBMRI-ERIC CRC-
			Cohort and its Digital Pathology Imaging"
			(APPID 1228)



Context

This document describes the semantic model, expressed in openEHR format¹, for the clinical data included in the Colorectal Cancer Cohort (CRC-Cohort) dataset included among the available collections in the BBMRI-ERIC Directory². The CRC-Cohort is a collection of clinical data and digital high-resolution digital pathology images pertaining to tumor cases. The collection has been assembled from a number of participating biobanks and other partners through the ADOPT BBMRI-ERIC project(H2020-INFRADEV-3-2015)³.

The modelling has been started within the EOSC-Life WP1 Demonstrator "Cloudification of BBMRI-ERIC CRC-Cohort and its Digital Pathology Imaging" (APPID 1228), which had among its objectives the improvement of the interoperability and reusability of the CRC-Cohort dataset.

Mapping

Method

This section reports the mapping between the XSD model of the CRC cohort dataset and the new openEHR model (<u>CRC cohort rev</u> template, semantic version: 27.0.1) specifically designed to accommodate these data⁴. After a preliminary selection of possibly relevant archetypes from the openEHR Clinical Knowledge Manager (CKM)⁵, the different attributes of each element of the source model – i.e. meaning, datatype, cardinality, allowed values, etc. – have been analysed in order to find a proper correspondence with archetypes' nodes. Archetypes were then assembled to form the template. The structure of the template can be seen at this link.

When defined, mapping descriptors are embedded in the template for each node and for each assumable value in the form of key-value pairs that could be processed automatically during conversion as "annotations" (see Listing 1).

Listing 1 - Template annotation

¹ https://www.openehr.org/

² https://www.bbmri-eric.eu/scientific-collaboration/colorectal-cancer-cohort/

³ https://www.bbmri-eric.eu/scientific-collaboration/adopt-bbmri-eric/

⁴ https://github.com/crs4/crc_cohort_modelling/releases/tag/v27.0.1

⁵ https://ckm.openehr.org/ckm/



To support semantic interoperability, we leverage on the openEHR possibility to bind external terminologies to data nodes and values. Therefore, model and data instances are further enriched by associating concepts from the OMOP⁶ standard vocabulary (available via <u>ATHENA</u>, the OHDSI vocabularies repository). These mappings of the assumable values exist both in the template and the final data instance. In fact, at the template level, it is possible to restrict the possible values for a node to a predefined list, where OMOP concept IDs can be added (in the example, "Female", "Male" and "Other") and used afterwards in the data instance (see Table 1). In this way, it is possible to query the CDR via AQL (Archetype Query Language) to ask, for instance, "records where the biological sex is equal to 8532 (Female)" (see Listing 2).

openEHR template	openEHR data instance
<pre>[]</pre>	<pre>[] "crc_cohort/biological_sex code": "8532", "crc_cohort/biological_sex value": "Female", "crc_cohort/biological_sex terminology": "OMOP_standard_vocabulary", []</pre>
<pre>code="OMOP_standard_vocabulary::8507"> <items id="text">Male</items> </pre>	
<term_definitions code="OMOP_standard_vocabulary::9177"> <items id="text">Other</items> []</term_definitions 	

Table 1

```
select
    a/uid/value -- composition uid
from EHR e
contains COMPOSITION a
contains EVALUATION a_a[openEHR-EHR-EVALUATION.gender.v1]
where a_a/data[at0002]/items[at0022]/value/defining_code/code_string='8532' -- female
```

Listing 2 - Query example

⁶ https://www.ohdsi.org/data-standardization/the-common-data-model/



Results

This section provides documentation of the mapping of each element of the CRC-Cohort data model and XSD to the openEHR template, showing the main attributes for each match.

Diagnostic exam

Dataelement_88_1 - DIAG_COLONOSCOPY

Colonoscopy - Diagnostic exam. In case of rectal cancer, use rectoscopy also qualifies to answer TRUE here.

4.49 Dataelement_88_1 - DIAG_COLONOSCOPY		
XSD label	Dataelement_88_1	
Data model label	DIAG_COLONOSCOPY	
Level in data model	REQUIRED	
XSD name	Colonoscopy	
XSD type	xs:string	
List of permitted values in XSD	"Colonoscopy diagnostic exam- Unknown" "Colonoscopy diagnostic exam- Not done" "Colonoscopy diagnostic exam - Negative" "Colonoscopy diagnostic exam - Positive"	
Type in data model	LIST_OF_VALUES [Negative; Positive; Not done; Unknown]	
openEHR mapping		
Parent archetype id	openEHR-EHR-ACTION.procedure.v1	
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)	
Node id	at0048	
Node label	Colonoscopy	
Data type	TEXT - Limited to list: 'Negative'; 'Positive'; 'Not done'; 'Unknown'	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Diagnostic examinations']/items[openEHR-EHR-ACTION.procedure.v1, 'Colonoscopy']/description[at0001]/items[at0048, 'Colonoscopy']	



Dataelement_31_3 - DIAG_CT_DONE

Diagnostic exam CT. This value shall be TRUE only if they were done within the context of the primary diagnosis.

4.16 Dataelement_31_3 - DIAG_CT_DONE		
XSD label	Dataelement_31_3	
Data model label	DIAG_CT_DONE	
Level in data model	REQUIRED	
XSD name	СТ	
XSD type	xs:string	
List of permitted	"CT - Unknown" "CT - Done, data not available" "CT - Done, data	
values in XSD	available" "CT- Not done"	
Type in data model	LIST_OF_VALUES [Done, data available; Done, data not available; Not	
Type III data IIIodei	done; Unknown]	
openEHR mapping		
Parent archetype id	openEHR-EHR-ACTION.procedure.v1	
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)	
Node id	at0048	
Node label	СТ	
Data type	TEXT - Limited to list: 'Done, data available', 'Done, data not	
Data type	available', 'Not done', 'Unknown'	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Diagnostic	
	examinations']/items[openEHR-EHR-ACTION.procedure.v1,	
	'CT']/description[at0001]/items[at0048, 'CT']	



Dataelement_61_5 - DIAG_LIVER_IMAGING_DONE

Liver imaging diagnostic exam. This value shall be TRUE only if they were done within the context of the primary diagnosis.

4.33 Dataelement_61_5 - DIAG_LIVER_IMAGING_DONE		
XSD label	Dataelement_61_5	
Data model label	DIAG_LIVER_IMAGING_DONE	
Level in data model	REQUIRED	
XSD name	Liver imaging	
XSD type	xs:string	
List of permitted values in XSD	"Liver imaging - Unknown Not done" "Liver imaging - Done, data available" "Liver imaging - Done, data not available" "Liver imaging - Unknown"	
Type in data model	LIST_OF_VALUES [Done, data available; Done, data not available; Not * done; Unknown]	
openEHR mapping		
Parent archetype id	openEHR-EHR-ACTION.procedure.v1	
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)	
Node id	at0048	
Node label	Liver imaging	
Data type	TEXT - Limited to list: 'Done, data available', 'Done, data not available', 'Not done', 'Unknown'	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Diagnostic examinations']/items[openEHR-EHR-ACTION.procedure.v1, 'Liver imaging']/description[at0001]/items[at0048, 'Liver imaging']	



Dataelement_63_4 - DIAG_X_DONE

Lung imaging diagnostic exam. If CT or MRI or PET scan is available, this should be also considered one of the "Done" options. This value shall be TRUE only if they were done within the context of the primary diagnosis.

4.34 Dataelement_63_4 - DIAG_X_DONE		
XSD label	Dataelement_63_4	
Data model label	DIAG_X_DONE	
Level in data model	REQUIRED	
XSD name	Lung imaging	
XSD type	xs:string	
List of permitted	"Lung imaging - Not done" "Lung imaging - Done, data available"	
values in XSD	"Lung imaging - Done, data not available" "Lung imaging - Unknown"	
Type in data model	LIST_OF_VALUES [Done, data available; Done, data not available; Not	
Type III data IIIodei	* done; Unknown]	
openEHR mapping		
Parent archetype id	openEHR-EHR-ACTION.procedure.v1	
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)	
Node id	at0048	
Node label	Lung imaging	
Data type	TEXT - Limited to list: 'Done, data available', 'Done, data not	
Data type	available', 'Not done', 'Unknown'	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Diagnostic	
	examinations']/items[openEHR-EHR-ACTION.procedure.v1, 'Lung	
	imaging']/description[at0001]/items[at0048, 'Lung imaging']	



Dataelement_30_3 - DIAG_MRI_DONE

MRI diagnostic exam. This value shall be TRUE only if they were done within the context of the primary diagnosis.

4.15 Dataelement_30_3 - DIAG_MRI_DONE		
XSD label	Dataelement_30_3	
Data model label	DIAG_MRI_DONE	
Level in data model	REQUIRED	
XSD name	MRI	
XSD type	xs:string	
List of permitted	"MRI - Unknown" "MRI - Done, data not available" "MRI - Done, data	
values in XSD	available" "MRI - Not done"	
Type in data model	LIST_OF_VALUES [Done, data available; Done, data not available; Not	
Type III data IIIodei	done; Unknown]	
openEHR mapping		
Parent archetype id	openEHR-EHR-ACTION.procedure.v1	
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)	
Node id	at0048	
Node label	MRI	
Data type	TEXT - Limited to list: 'Done, data available', 'Done, data not	
Data type	available', 'Not done', 'Unknown'	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Diagnostic	
	examinations']/items[openEHR-EHR-ACTION.procedure.v1,	
	'MRI']/description[at0001]/items[at0048, 'MRI']	



Histopathology

Dataelement_57_3 - DIGITAL_IMAGING_AVAILABILITY

Do you have high-resolution digital imaging (corresponding to magnification 40x) from histopathology? Only scans of the surgical material should be considered here.

4.29 Dataelement_57_3 - DIGITAL_IMAGING_AVAILABILITY		
XSD label	Dataelement_57_3	
Data model label	DIGITAL_IMAGING_AVAILABILITY	
Level in data model	OPTIONAL	
XSD name	Availability digital imaging	
XSD type	xs:string	
List of permitted values in XSD	"No" "Can be generated" "Readily available"	
Type in data model	LIST_OF_VALUES [Can be generated; No; Readily available]	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.multimedia_source.v0	
(Container archetype)	(openEHR-EHR-CLUSTER.specimen.v1)	
Node id	at0005	
Node label	Availability digital imaging	
Data type	TEXT - Limited to list: 'Can be generated', 'No', 'Readily available'	
Occurrences	Optional	
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- OBSERVATION.laboratory_test_result.v1]/data[at0001]/events[at000 2]/data[at0003]/items[openEHR-EHR- CLUSTER.anatomical_pathology_exam.v0, 'Anatomical pathology examination']/items[at0005]/items[openEHR-EHR- CLUSTER.media_file.v1]/items[at0007, 'Availability digital imaging']	



Dataelement_58_2 - DIGITAL_IMAGING_INVASION_FRONT_AVAILABILITY

Do you have high-resolution digital imaging (corresponding to magnification 40x) containing invasion front from the histopatology?

4.30 Dataelement_5	3_2 - DIGITAL_IMAGING_INVASION_FRONT_AVAILABILITY	
XSD label	Dataelement_58_2	
Data model label	DIGITAL_IMAGING_INVASION_FRONT_AVAILABILITY	
Level in data model	OPTIONAL	
XSD name	Availability invasion front digital imaging	
XSD type	xs:string	
List of permitted values in XSD	"Invasion front not included" "Readily available" "Can be generated" "No"	
Type in data model	LIST_OF_VALUES [Can be generated; Invasion front not included; No; * Readily available]	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.multimedia_source.v0	
(Container archetype)	(openEHR-EHR-CLUSTER.anatomical_pathology_exam.v0)	
Node id	at0005	
Node label	Availability invasion front digital imaging	
Data type	TEXT - Limited to list: 'Can be generated', 'Invasion front non included', 'No', 'Readily available'	
Occurrences	Optional	
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- OBSERVATION.laboratory_test_result.v1]/data[at0001]/events[at000 2]/data[at0003]/items[openEHR-EHR- CLUSTER.anatomical_pathology_exam.v0, 'Invasion front']/items[at0005]/items[openEHR-EHR-CLUSTER.media_file.v1, 'Digital imaging invasion front']/items[at0007, 'Availability invasion front digital imaging']	



Dataelement_82_1 - BIOLOGICAL_MATERIAL_FROM_RECURRENCE_AVAILABLE

Biological material from recurrence available

4.45 Dataelement_82_1 - BIOLOGICAL_MATERIAL_FROM_RECURRENCE_AVAILABLE	
XSD label	Dataelement_82_1
Data model label	BIOLOGICAL_MATERIAL_FROM_RECURRENCE_AVAILABLE
Level in data model	OPTIONAL
XSD name	Biological material from recurrence available
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	YES_NO [] ((true false yes no f t))
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.anatomical_pathology_exam.v0
(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
Node id	at0006
Node label	Biological material from recurrence available
Data type	BOOLEAN
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.result_details.v0,

Notes:

- The possible choices in the original dataset should be normalised to the allowed values in the template (TRUE or FALSE) during the conversion.



Dataelement_68_2 - HIST_METASTASIS

Histopathology part - Localization of metastasis. Multiple metastases can be added, each with its own location. This is intended for primary diagnosis only.

4.36 Dataelement_6	8_2 - HIST_METASTASIS
XSD label	Dataelement_68_2
Data model label	HIST_METASTASIS
Level in data model	REQUIRED
XSD name	Localization of metastasis
XSD type	Not defined.
List of permitted values in XSD	"Localization of metastasis - None" "Localization of metastasis - Pulmonary" "Localization of metastasis - Osseous" "Localization of metastasis - Hepatic" "Localization of metastasis - Brain" "Localization of metastasis - Lymph nodes" "Localization of metastasis - Bone marrow" "Localization of metastasis - Pleura" "Localization of metastasis - Peritoneum" "Localization of metastasis - Adrenals" "Localization of metastasis - Skin" "Localization of metastasis - Others"
Type in data model	LIST_OF_VALUES [Adrenals; Bone marrow; Brain; Hepatic; Lymph nodes; * None; Osseous; Peritoneum; Pleura; Pulmonary; Skin; Others]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.anatomical_location.v1
(Container archetype)	(openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)
Node id	at0001
Node label	Localization of metastasis
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 4051774 - Adrenals; 4029619 - Bone marrow; 4133034 - Brain; 45880117 - Hepatic; 45881859 - Lymph Nodes; 45878582 - None; 45880118 - Osseous45880116 - Peritoneum; 45882504 - Pleura; 45881858 - Lung; 45881860 - Skin; 45878394 - Others
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR-EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[at0263]/items[openEHR-EHR- CLUSTER.anatomical_location.v1]/items[at0001, 'Localization of metastasis']



Dataelement_92_1 - HIST_LOCALIZATION

4.53 Dataelement_92_1 - HIST_LOCALIZATION	
XSD label	Dataelement_92_1
Data model label	HIST_LOCALIZATION
Level in data model	REQUIRED
XSD name	Localization of primary tumor
XSD type	xs:string
List of permitted values in XSD	"Localization of primary tumor - C20" "Localization of primary tumor - C19" "Localization of primary tumor - C18.7" "Localization of primary tumor - C18.6" "Localization of primary tumor - C18.5" "Localization of primary tumor - C18.4" "Localization of primary tumor - C18.3" "Localization of primary tumor - C18.2" "Localization of primary tumor - C18.1" "Localization of primary tumor - C18.0"
Type in data model	LIST_OF_VALUES [C 18.0 - Caecum; C 18.1 - Appendix; C 18.2 - Ascending * colon; C 18.3 - Hepatic flexure; C 18.4 - Transverse colon; C * 18.5 - Splenic flexure; C 18.6 - Descending colon; C 18.7 - * Sigmoid colon; C 19 - Rectosigmoid junction; C 20 - Rectum]
openEHR mapping	
Parent archetype id	openEHR-EHR-EVALUATION.problem_diagnosis.v1
(Container archetype)	(openEHR-EHR-SECTION.result_details.v0)
Node id	at0012
Node label	Localization of primary tumor
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 432837 - C 18.0 - Caecum 433143 - C 18.1 - Appendix 4247719 - C 18.2 - Ascending colon 438979 - C 18.3 - Hepatic flexure 432257 - C 18.4 - Transverse colon 437798 - C 18.5 - Splenic flexure 441800 - C 18.6 - Descending colon 436635 - C 18.7 - Sigmoid colon 438699 - C 19 - Rectosigmoid junction 74582 - C 20 - Rectum
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[at0012, 'Localization of primary tumor']



Dataelement_91_1 - HIST_MORPHOLOGY

Histopathology Part - Morphology. This is a mandatory part of histopathological diagno- sis, therefore it should be available. If really not available, "Other" may be used, but it is a sign of insufficient data detail

4.52 Dataelement_91_1 - HIST_MORPHOLOGY	
XSD label	Dataelement_91_1
Data model label	HIST_MORPHOLOGY
Level in data model	REQUIRED
XSD name	Morphology
XSD type	xs:string
List of permitted values in XSD	"Signet ring cell carcinoma" "Cribriform comedo-type adenocarcinoma" "Adenocarcinoma" "Mucinous carcinoma" "Medullary carcinoma" "Signet-ring cell carcinoma" "Medullary carcinoma" "High-grade neuroendocrine carcinoma" "Large cell neuroendocrine carcinoma" "Squamous cell carcinoma" "Adeonsquamous carcinoma" "Micropapillary carcinoma" "Serrated adenocarcinoma" "Spindle cell carcinoma" "Mixed adenoneuroendocrine carcinoma" "Undifferentiated carcinoma" "Other"
Type in data model	LIST_OF_VALUES [Adenocarcinoma; Adeonsquamous carcinoma; High-grade * neuroendocrine carcinoma; Large cell neuroendocrine carcinoma; * Medullary carcinoma; Micropapillary carcinoma; Mixed * adenoneuroendocrine carcinoma; Mucinous carcinoma; Serrated * adenocarcinoma; Signet-ring cell carcinoma; small cell * neuroendocrine carcinoma; Spindle cell carcinoma; Squamous cell * carcinoma; Undifferentiated carcinoma; Other]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0
(Container archetype)	(openEHR-EHR-EVALUATION.problem diagnosis.v1)
Node id	at0033
Node label	Morphology
Data type	CODED TEXT - Limited to list with codes from OMOP vocabulary: 42530737 - Adenocarcinoma 45877054 - Adenosquamous carcinoma NS_777787 - High-grade neuroendocrine carcinoma 21498829 - Large cell neuroendocrine carcinoma 42530704 - Medullary carcinoma 42531058 - Micropapillary carcinoma



	21499071 - Mixed adenoneuroendocrine carcinoma 45877325 - Mucinous adenocarcinoma 42531033 - Serrated adenocarcinoma 45877053 - Signet ring cell carcinoma 21498439 - Small cell neuroendocrine carcinoma 42530773 - Spindle cell carcinoma, NOS 45883774 - Squamous cell carcinoma 45877326 - Undifferentiated carcinoma 45878142 - Other
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[at0033, 'Morphology']



Histopathology - TNM

Dataelement_75_1 - TNM_DISTANT_METASTASIS

TNM - Distant metastasis. It shall be interpreted as pTN - for tumor samples and biopsies, as the TN should come from the sample or biopsy. M may come from imaging (hence it may come from cTNM clinical assessment).

4.41 Dataelement_7	5_1 - TNM_DISTANT_METASTASIS
XSD label	Dataelement_75_1
Data model label	TNM_DISTANT_METASTASIS
Level in data model	REQUIRED
XSD name	Distant metastasis
XSD type	xs:string
List of permitted values in XSD	"Distant metastasis - MX" "Distant metastasis - M1c" "Distant metastasis - M0" "Distant metastasis - M1" "Distant metastasis - M1a" "Distant metastasis - M1b"
Type in data model	LIST_OF_VALUES [M0; M1; M1a; M1b; M1c; MX]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.tnm-pathological.v1
(Container archetype)	(openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)
Node id	at0005.1
Node label	Distant metastasis
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 45878650 - M0, 45876322 - M1, 45882500 - M1a, 45881618 - M1b, 45878386 - M1c, 45876323 - MX
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0,



Dataelement_71_1 - TNM_PRIMARY_TUMOR

TNM Primary Tumor. It shall be interpreted as pTN - for tumor samples and biopsies, as the TN should come from the sample or biopsy. M may come from imaging (hence it may come from cTNM clinical assessment).

4.39 Dataelement_7	L_1 - TNM_PRIMARY_TUMOR
XSD label	Dataelement_71_1
Data model label	TNM_PRIMARY_TUMOR
Level in data model	REQUIRED
XSD name	Primary Tumor
XSD type	xs:string
List of permitted values in XSD	"Primary Tumor - T4" "Primary Tumor - T4b" "Primary Tumor - T4a" "Primary Tumor - T3" "Primary Tumor - T2" "Primary Tumor - T1" "Primary Tumor - Tis" "Primary Tumor - T0" "Primary Tumor - TX"
Type in data model	LIST_OF_VALUES [T0; T1; T2; T3; T4; T4a; T4b; Tis; TX]
openEHR mapping	
Parent archetype id (Container archetype)	openEHR-EHR-CLUSTER.tnm-pathological.v1 (openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)
Node id	at0003.1
Node label	Primary tumour
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 4218531 - T0, 4207195 - T1, 4217143 - T2, 4234703 - T3, 4266213 - T4, 40482367 - T4a, 40483194 - T4b, 4225738 - Tis, 4182266 - TX
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[openEHR-EHR-CLUSTER.tnm-pathological.v1]/items[at0003.1, 'Primary tumour']



Dataelement_77_1 - TNM_REGIONAL_LYMPH_NODES

TNM - Regional lymph nodes. It shall be interpreted as pTN - for tumor samples and biopsies, as the TN should come from the sample or biopsy. M may come from imaging (hence it may come from cTNM clinical assessment).

4.42 Dataelement_7	7_1 - TNM_REGIONAL_LYMPH_NODES
XSD label	Dataelement_77_1
Data model label	TNM_REGIONAL_LYMPH_NODES
Level in data model	REQUIRED
XSD name	Regional lymph nodes
XSD type	xs:string
List of permitted values in XSD	"Regional lymph nodes - N3" "Regional lymph nodes - NX" "Regional lymph nodes - N0" "Regional lymph nodes - N1" "Regional lymph nodes - N1a" "Regional lymph nodes - N1b" "Regional lymph nodes - N1c" "Regional lymph nodes - N2" "Regional lymph nodes - N2a" "Regional lymph nodes - N2b"
Type in data model	LIST_OF_VALUES [N0; N1; N1a; N1b; N1c; N2; N2a; N2b; N3; NX]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.tnm-pathological.v1
(Container archetype)	(openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)
Node id	at0004.1
Node label	Regional lymph nodes
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 45881617 - N0; 45881613 - N1; 45880982 - N1a; 45881615 - N1b; 46237062 - N1c; 45881614 - N2; 45882498 - N2a; 45880111 - N2b; 45882499 - N3; 45884289 - NX
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[openEHR-EHR-CLUSTER.tnm-pathological.v1]/items[at0004.1, 'Regional lymph nodes']

Histopathology - UICC staging



Dataelement_70_2 - UICC_STAGE

UICC Stage. The stages list is based on 8th edition, and backwards compatible with earlier editions.

4.38 Dataelement_7	0_2 - UICC_STAGE
XSD label	Dataelement_70_2
Data model label	UICC_STAGE
Level in data model	REQUIRED
XSD name	Stage
XSD type	xs:string
List of permitted values in XSD	"Stage - IV" "Stage - III" "Stage - II" "Stage - IVC" "Stage - IIC" "Stage - IVB" "Stage - IVA" "Stage - IIIC" "Stage - IIIB" "Stage - IIIA" "Stage - IIB" "Stage - II A" "Stage - I" "Stage - O"
Type in data model	LIST_OF_VALUES [0; I; II; II A; IIB; IIC; III; IIIA; IIIB; IIIC; IV; IVA; IVB; IVC]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.tnm-pathological.v1
(Container archetype)	(openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)
Node id	at0031.1
Node label	Stage
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 45884284 - Stage - 0; 45880980 - Stage - I; 45880979 - Stage - II; 45876316 - Stage - II A; 45882497 - Stage - IIB; 45878382 - Stage - IIC; 45878643 - Stage - III; 45880978 - Stage - IIIA; 45884285 - Stage - IIIB; 45881608 - Stage - IIIC; 45880109 - Stage - IV; 45880108 - Stage - IVA; 45876315 - Stage - IVB; 45876314 - Stage - IVC.
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[openEHR-EHR-CLUSTER.tnm-pathological.v1]/items[at0031.1, 'Stage']



Dataelement_73_3 - UICC_VERSION

The version of the UICC system under which the staging was done

4.40 Dataelement_73	4.40 Dataelement_73_3 - UICC_VERSION	
XSD label	Dataelement_73_3	
Data model label	UICC_VERSION	
Level in data model	REQUIRED	
XSD name	UICC version	
XSD type	xs:string	
List of permitted	"8th edition" "Not known" "7th edition" "6th edition" "5th edition"	
values in XSD	"4th edition or earlier"	
	LIST_OF_VALUES [4th. ed (used before 1998); 5th. ed (used 1998-	
Type in data model	2002);	
Type III data IIIodei	* 6th. ed (used 2003-2009); 7th ed. (used 2010-2017); 8th ed. (
	* used since 2017); Not known]	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.tnm-pathological.v1	
(Container archetype)	(openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)	
Node id	at0032	
Node label	UICC version	
	TEXT - Limited to list: '4th. ed (used before 1998)', '5th. ed (used	
Data type	1998-2002)', '6th. ed (used 2003-2009)', '7th ed. (used 2010- 2017)',	
	'8th ed. (used since 2017)', 'Not known'	
Occurrences	11 (Mandatory)	
	/content[openEHR-EHR-SECTION.result_details.v0,	
	'Histopathology']/items[at0002]/items[openEHR-EHR-	
Path	EVALUATION.problem_diagnosis.v1, 'Cancer	
	diagnosis']/data[at0001]/items[openEHR-EHR-	
	CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it	
	ems[openEHR-EHR-CLUSTER.tnm-pathological.v1]/items[at0032,	
	'UICC version']	
	-	



Histopathology - WHO classification

Dataelement_83_1 - WHO_GRADE

Grade. For Sweden "medium high" shall map to G3, and "low medium" shall map to G2. This has to be documented in the provenance information

4.46 Dataelement_83	3_1 - WHO_GRADE
XSD label	Dataelement_83_1
Data model label	WHO_GRADE
Level in data model	REQUIRED
XSD name	Grade
XSD type	xs:string
List of permitted values in XSD	"WHO Grading - Grade - G1" "WHO Grading - Grade - G2" "WHO Grading - Grade - G4" "WHO Grading - Grade - GX"
Type in data model	LIST_OF_VALUES [G1; G2; G3; G4; GX]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.tnm-pathological.v1
(Container archetype)	(openEHR-EHR-CLUSTER.synoptic_details_colorectal_carcinoma.v0)
Node id	at0006
Node label	Grade
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 36769915 -G1 36769543 -G2 36769033 -G3 36769351 -G4 36770136 -GX
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR- EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[openEHR-EHR-CLUSTER.tnm-pathological.v1]/items[at0006, 'Grade']



Dataelement_53_3 - WHO_GRADE_VERSION

The version of the WHO classification system used.

4.25 Dataelement_53_3 - WHO_GRADE_VERSION	
XSD label	Dataelement_53_3
Data model label	WHO_GRADE_VERSION
Level in data model	REQUIRED
XSD name	WHO version
XSD type	xs:string
List of permitted values in XSD	"Not known" "1st edition" "2nd edition" "3rd edition" "4th edition"
Type in data model	LIST_OF_VALUES [1st ed. (1979-1990); 2nd ed. (1991-2000); 3rd ed. *
Type iii data modei	(2001-2010); 4th ed. (used since 2011); Edition not known]
openEHR mapping	
Parent archetype id	$open \hbox{\it EHR-CLUSTER}. synoptic_details_colorectal_carcinoma.v0$
(Container archetype)	(openEHR-EHR-EVALUATION.problem_diagnosis.v1)
Node id	at0271
Node label	WHO version
Data type	TEXT - Limited to list: '1st ed. (1979-1990)', '2nd ed. (1991- 2000)', '3rd ed. (2001-2010)', '4th ed. (used since 2011)', 'Edition not known'
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Histopathology']/items[at0002]/items[openEHR-EHR-EVALUATION.problem_diagnosis.v1, 'Cancer diagnosis']/data[at0001]/items[openEHR-EHR- CLUSTER.synoptic_details_colorectal_carcinoma.v0]/items[at0001]/it ems[at0269]/items[at0271, 'WHO version']



Molecular markers

Dataelement_87_1 - BRAF_PIC3CA_HER_MUTATION_STATUS

BRAF, PIC3CA, HER2 mutation status. If only 1 or 2 of the three mutation analyses have been done, the "Partial information available" value shall be selected

4.48 Dataelement_8	7_1 - BRAF_PIC3CA_HER_MUTATION_STATUS
XSD label	Dataelement_87_1
Data model label	BRAF_PIC3CA_HER_MUTATION_STATUS
Level in data model	OPTIONAL
XSD name	BRAF, PIC3CA, HER2 mutation status
XSD type	xs:string
List of permitted values in XSD	"BRAF, PIC3CA, HER2 mutation status - Partial information available" "BRAF, PIC3CA, HER2 mutation status - not mutated" "BRAF, PIC3CA, HER2 mutation status - mutated" "BRAF, PIC3CA, HER2 mutation status - not done"
Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Partial information available; * Not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-OBSERVATION.laboratory_test_result.v1
(Container archetype)	(openEHR-EHR-SECTION.result_details.v0)
Node id	at0057
Node label	BRAF, PIC3CA, HER2 mutation status
Data type	TEXT - Limited to list 'Mutated'; 'Not mutated'; 'Partial information available'; 'Not done'
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'Oncogenic mutations test']/data[at0001]/events[at0002]/data[at0003]/items[at0057, 'BRAF, PIC3CA, HER2 mutation status']



Dataelement_14_3 - MM_MICROSAT_INSTABILITY

Microsatellites analysed BAT26, D17S250, D5S346, BAT40, D2S123 and BAT25. Image cytometry does not qualify for comparability reasons.

4.5 Dataelement_14_3 - MM_MICROSAT_INSTABILITY	
XSD label	Dataelement_14_3
Data model label	MM_MICROSAT_INSTABILITY
Level in data model	REQUIRED
XSD name	Microsatellite instability
XSD type	xs:string
List of permitted	"YES" "NO" "NOT DONE"
values in XSD	_
Type in data model	LIST_OF_VALUES [no; yes; not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-OBSERVATION.laboratory_test_result.v1
(Container archetype)	(openEHR-EHR-SECTION.result_details.v0)
Node id	at0057
Node label	Microsatellite instability
Data type	TEXT - Limited to list: 'Yes', 'No', 'Not done'
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'Microsatellites instability analysis']/data[at0001]/events[at0002]/data[at0003]/items[at0057, 'Microsatellite instability']



Dataelement_15_2 - MM_MISMATCH_REPAIR_GE

Mismatch repair gene expression – IHC array for different genes (common for 3). Expression of MLH1, MSH2, PMS2 and MSH6.

4.6 Dataelement_15	_2 - MM_MISMATCH_REPAIR_GE
XSD label	Dataelement_15_2
Data model label	MM_MISMATCH_REPAIR_GE
Level in data model	REQUIRED
XSD name	Mismatch repair gene expression
XSD type	xs:string
List of permitted values in XSD	"LOSS_OF_EXPRESSION" "EXPRESSION" "NOT_DONE"
Type in data model	LIST_OF_VALUES [expression; loss of expression; not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-OBSERVATION.laboratory_test_result.v1 (openEHR-
(Container archetype)	EHR-SECTION.result_details.v0)
Node id	at0057
Node label	Mismatch repair gene expression
Data type	TEXT - Limited to list: 'Expression', Loss of expression', 'Not done'
Occurrences	11 (Mandatory)
	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular
	markers']/items[at0002]/items[openEHR-EHR-
Path	OBSERVATION.laboratory_test_result.v1, 'Mismatch repair gene
	analysis']/data[at0001]/events[at0002]/data[at0003]/items[at0057,
	'Mismatch repair gene expression']



Dataelement_16_3 - MM_RISK_SITUATION_HNPCC

Risk situation (only HNPCC), Amsterdam criteria.

4.7 Dataelement_16	3 - MM_RISK_SITUATION_HNPCC
XSD label	Dataelement_16_3
Data model label	MM_RISK_SITUATION_HNPCC
Level in data model	OPTIONAL
XSD name	Risk situation (only HNPCC)
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	YES_NO [] ((true false yes no f t))
openEHR mapping	
Parent archetype id	openEHR-EHR-EVALUATION.health_risk.v1
(Container archetype)	(openEHR-EHR-SECTION.result_details.v0)
Node id	at0003
Node label	Risk situation (only HNPCC)
Data type	TEXT - Limited to list: 'TRUE', 'FALSE'
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-EVALUATION.health_risk.v1]/data[at0001]/items[at0003, 'Risk situation (only HNPCC)']

Notes:

- The information about the criteria used is stored in another node of the template, the 'Assessment method', which is filled with the default value 'Amsterdam criteria'.
- The possible choices of the original dataset should be normalised to the allowed values in the template (TRUE or FALSE) during the conversion.



Molecular markers - KRAS mutation status

Notes:

At the moment, there is not a perfect correspondence between the allowed values for the fields in this section. Given that the chosen archetype allows to express the presence/absence of a variant, we adopted the following mapping: Not mutated \rightarrow Absent; Mutated \rightarrow Present; Not done \rightarrow Indeterminate

Dataelement_25_3 - MM_KRAS_MUTATION_NRAS_EX4

NRAS exon 4 (codons 117 or 146) mutation status

4.13 Dataelement_2	5_3 - MM_KRAS_MUTATION_NRAS_EX4
XSD label	Dataelement_25_3
Data model label	MM_KRAS_MUTATION_NRAS_EX4
Level in data model	REQUIRED
XSD name	NRAS exon 4 (codons 117 or 146)
XSD type	xs:string
List of permitted values in XSD	"Not mutated" "Mutated" "Not done"
Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.genetic_variant_presence.v0
(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
Node id	at0002
Node label	NRAS exon 4 (codons 117 or 146)
Data type	CODED TEXT: > Present [The target variant is present.] — [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] — [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] — [LOINC(2.65)::LA11884-6]
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'KRAS mutation status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-EHR-CLUSTER.genetic_variant_presence.v0, 'NRAS exon 4 (codons 117 or 146)']/items[at0002, 'NRAS exon 4 (codons 117 or 146)']



Dataelement_24_4 - MM_KRAS_MUTATION_NRAS_EX3

NRAS exon 3 (codons 59 or 61) mutation status

4.12 Dataelement_2	4_4 - MM_KRAS_MUTATION_NRAS_EX3
XSD label	Dataelement_24_4
Data model label	MM_KRAS_MUTATION_NRAS_EX3
Level in data model	REQUIRED
XSD name	NRAS exon 3 (codons 59 or 61)
XSD type	xs:string
List of permitted values in XSD	"Not mutated" "Mutated" "Not done"
Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.genetic_variant_presence.v0
(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
Node id	at0002
Node label	NRAS exon 3 (codons 59 or 61)
Data type	CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6]
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'KRAS mutation status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-EHR-CLUSTER.genetic_variant_presence.v0, 'NRAS exon 3 (codons 59 or 61)']/items[at0002, 'NRAS exon 3 (codons 59 or 61)']



Dataelement_23_5 - MM_KRAS_MUTATION_NRAS_EX2

NRAS exon 2 (codons 12 or 13) mutation status

Data model label Dataelement_23_5	4.11 Dataelement_23	3_5 - MM_KRAS_MUTATION_NRAS_EX2
Level in data model REQUIRED XSD name NRAS exon 2 (codons 12 or 13) XSD type xs:string List of permitted values in XSD "Not mutated" "Mutated" "Not done" Type in data model LIST_OF_VALUES [Mutated; Not mutated; Not done] Parent archetype id (container archetype) (openEHR-EHR-CLUSTER.genetic_variant_presence.v0 (openEHR-EHR-OBSERVATION.laboratory_test_result.v1) Node id at0002 Node label NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-	XSD label	Dataelement_23_5
XSD name XSD type List of permitted values in XSD Type in data model LIST_OF_VALUES [Mutated; Not mutated; Not done] OpenEHR mapping Parent archetype id (Container archetype) Node id NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-	Data model label	MM_KRAS_MUTATION_NRAS_EX2
XSD type	Level in data model	REQUIRED
List of permitted values in XSD Type in data model LIST_OF_VALUES [Mutated; Not mutated; Not done] openEHR mapping Parent archetype id (Container archetype) Node id NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-EHR-Section]	XSD name	NRAS exon 2 (codons 12 or 13)
<pre>values in XSD Type in data model LIST_OF_VALUES [Mutated; Not mutated; Not done] openEHR mapping Parent archetype id (Container archetype) Node id NRAS exon 2 (codons 12 or 13) CODED TEXT:</pre>	XSD type	xs:string
openEHR mapping Parent archetype id (Container archetype) openEHR-EHR-CLUSTER.genetic_variant_presence.v0 (openEHR-EHR-OBSERVATION.laboratory_test_result.v1) Node id at0002 Node label NRAS exon 2 (codons 12 or 13) CODED TEXT:	-	"Not mutated" "Mutated" "Not done"
Parent archetype id (Container archetype) Node id Node label NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-	Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Not done]
Parent archetype id (Container archetype) Node id Node label NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-EHR-		
(Container archetype) (openEHR-EHR-OBSERVATION.laboratory_test_result.v1) Node id at0002 Node label NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-	openEHR mapping	
Node id at0002 Node label NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-	Parent archetype id	openEHR-EHR-CLUSTER.genetic_variant_presence.v0
Node label NRAS exon 2 (codons 12 or 13) CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-	(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-	Node id	at0002
> Present [The target variant is present.]	Node label	NRAS exon 2 (codons 12 or 13)
[LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-		
[LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-	Data type	[LOINC(2.65)::LA9633-4]
> Indeterminate [The result is indeterminate.]		> Absent [The target variant is absent.]
[LOINC(2.65)::LA11884-6] Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-		[LOINC(2.65)::LA9634-2]
Occurrences 11 (Mandatory) /content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-		> Indeterminate [The result is indeterminate.]
/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-		[LOINC(2.65)::LA11884-6]
markers']/items[at0002]/items[openEHR-EHR-	Occurrences	11 (Mandatory)
status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-	Path	markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'KRAS mutation status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-EHR-CLUSTER.genetic_variant_presence.v0, 'NRAS exon 2 (codons 12)



Dataelement_22_4 - MM_KRAS_MUTATION_KRAS_EX4

KRAS exon 4 (codons 117 or 146)

4.10 Dataelement_2	2_4 - MM_KRAS_MUTATION_KRAS_EX4
XSD label	Dataelement_22_4
Data model label	MM_KRAS_MUTATION_KRAS_EX4
Level in data model	REQUIRED
XSD name	KRAS exon 4 (codons 117 or 146) mutation status
XSD type	xs:string
List of permitted values in XSD	"Not mutated" "Mutated" "Not done"
Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.genetic_variant_presence.v0
(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
Node id	at0002
Node label	KRAS exon 4 (codons 117 or 146)
Data type	CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6]
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'KRAS mutation status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-EHR-CLUSTER.genetic_variant_presence.v0, 'KRAS exon 4 (codons 117 or 146)']/items[at0002, 'KRAS exon 4 (codons 117 or 146)']



Dataelement_21_5 - MM_KRAS_MUTATION_KRAS_EX3

KRAS exon 3 (codons 59 or 61) mutation status

4.9 Dataelement_21	_5 - MM_KRAS_MUTATION_KRAS_EX3
XSD label	Dataelement_21_5
Data model label	MM_KRAS_MUTATION_KRAS_EX3
Level in data model	REQUIRED
XSD name	KRAS exon 3 (codons 59 or 61)
XSD type	xs:string
List of permitted values in XSD	"Not mutated" "Mutated" "Not done"
Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.genetic_variant_presence.v0
(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
Node id	at0002
Node label	KRAS exon 3 (codons 59 or 61)
Data type	CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6]
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'KRAS mutation status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-EHR-CLUSTER.genetic_variant_presence.v0, 'KRAS exon 3 (codons 59 or 61)']/items[at0002, 'KRAS exon 3 (codons 59 or 61)']



Dataelement_20_3 - MM_KRAS_MUTATION_KRAS_EX2

KRAS exon 2 (codons 12 or 13) mutation status

4.8 Dataelement_20	_3 - MM_KRAS_MUTATION_KRAS_EX2
XSD label	Dataelement_20_3
Data model label	MM_KRAS_MUTATION_KRAS_EX2
Level in data model	REQUIRED
XSD name	KRAS exon 2 (codons 12 or 13)
XSD type	xs:string
List of permitted values in XSD	"Not mutated" "Mutated" "Not done"
Type in data model	LIST_OF_VALUES [Mutated; Not mutated; Not done]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.genetic_variant_presence.v0
(Container archetype)	(openEHR-EHR-OBSERVATION.laboratory_test_result.v1)
Node id	at0002
Node label	KRAS exon 2 (codons 12 or 13)
Data type	CODED TEXT: > Present [The target variant is present.] [LOINC(2.65)::LA9633-4] > Absent [The target variant is absent.] [LOINC(2.65)::LA9634-2] > Indeterminate [The result is indeterminate.] [LOINC(2.65)::LA11884-6]
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.result_details.v0, 'Molecular markers']/items[at0002]/items[openEHR-EHR-OBSERVATION.laboratory_test_result.v1, 'KRAS mutation status']/data[at0001]/events[at0002]/data[at0003]/items[openEHR-EHR-CLUSTER.genetic_variant_presence.v0, 'KRAS exon 2 (codons 12 or 13)']/items[at0002, 'KRAS exon 2 (codons 12 or 13)']

Patient Data



Patient Pseudonyms

A pseudonym for the patient. The pseudonym has to be generated in compliance with the CRC-Cohort Data Protection Policy requirements.

Patient Pseudonyms	
XSD label	
Data model label	PATIENT_ID
Level in data model	REQUIRED
XSD name	Patient pseudonym
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	TEXT [] ()
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.case_identification.v0 (openEHR-EHR-
(Container archetype)	COMPOSITION.report.v1)
Node id	at0001
Node label	Patient pseudonym
Data type	TEXT
Occurrences	11 (Mandatory)
Path	/context/other_context[at0001]/items[openEHR-EHR-CLUSTER.case_identification.v0]/items[at0001, 'Patient pseudonym']



${\tt Dataelement_3_1-AGE_AT_PRIMARY_DIAGNOSIS}$

Age at initial histopathological diagnosis (biopsy or surgical specimen of the primary tumor) rounded to years.

4.21 Dataelement_3_1 - AGE_AT_PRIMARY_DIAGNOSIS	
XSD label	Dataelement_3_1
Data model label	AGE_AT_PRIMARY_DIAGNOSIS
Level in data model	REQUIRED
XSD name	Age at diagnosis (rounded to years)
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [a] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-EVALUATION.problem_diagnosis.v1)
Node id	at0009
Node label	Age at diagnosis
Data type	DURATION [years] (0<=x<=1000)
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.demographics_rcp.v1, 'Patient data']/items[openEHR-EHR-EVALUATION.problem_diagnosis.v1, 'Primary diagnosis']/data[at0001]/items[openEHR-EHR-CLUSTER.timing_nondaily.v1, 'Diagnosis timing']/items[at0006, 'Primary diagnosis']/items[at0009, 'Age at diagnosis']



Dataelement_85_1 - SEX

Biological sex of the person, defined by chromosomes.

4.47 Dataelement_85_1 - SEX	
XSD label	Dataelement_85_1
Data model label	SEX
Level in data model	REQUIRED
XSD name	Biological sex
XSD type	xs:string
List of permitted values in XSD	"other" "female" "male"
Type in data model	LIST_OF_VALUES [female; male; other]
openEHR mapping	
Parent archetype id	openEHR-EHR-EVALUATION.gender.v1
(Container archetype)	(openEHR-EHR-SECTION.demographics_rcp.v1)
Node id	at0019
Node label	Biological sex
	TEXT - Limited to list with codes from OMOP vocabulary:
Data type	8532 - FEMALE
Data type	8507 - MALE
	NS_852 - OTHER
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.demographics_rcp.v1, 'Patient
	data']/items[openEHR-EHR-
	EVALUATION.gender.v1]/data[at0002]/items[at0019, 'Biological sex']

Notes:

- It was not possible to identify a precise match to describe the patient's sex based on the chromosomes. Therefore, this element is mapped with the node "Sex assigned at birth", defined as "The sex of an individual determined by anatomical characteristics observed and registered at birth."



Dataelement_51_3 - DATE_DIAGNOSIS

Date at which colon cancer was diagnosed for the first time. Histopathological diagnosis by biopsy or surgery qualifies as primary diagnosis

4.24 Dataelement_51_3 - DATE_DIAGNOSIS	
XSD label	Dataelement_51_3
Data model label	DATE_DIAGNOSIS
Level in data model	OPTIONAL
XSD name	Date of diagnosis
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	DATE [] (ISO_8601_WITH_DAYS)
openEHR mapping	
Parent archetype id	openEHR-EHR-EVALUATION.problem_diagnosis.v1
(Container archetype)	(openEHR-EHR-SECTION.demographics_rcp.v1)
Node id	at0003
Node label	Date of diagnosis
Data type	DATE TIME
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.demographics_rcp.v1, 'Patient data']/items[openEHR-EHR-EVALUATION.problem_diagnosis.v1, 'Primary diagnosis']/data[at0001]/items[at0003, 'Date of diagnosis']



${\tt Dataelement_2_2-CLINICAL_STUDY_PARTICIPANT}$

Participation in clinical study

4.14 Dataelement_2_2 - CLINICAL_STUDY_PARTICIPANT	
XSD label	Dataelement_2_2
Data model label	CLINICAL_STUDY_PARTICIPANT
Level in data model	OPTIONAL
XSD name	Participation in clinical study
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	YES_NO [] ((true false yes no f t))
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.case_identification.v0
(Container archetype)	(openEHR-EHR-COMPOSITION.report.v1)
Node id	at0006
Node label	Participation in clinical study
Data type	TEXT - Limited to list: 'TRUE', 'FALSE'
Occurrences	Optional
Path	/context/other_context[at0001]/items[openEHR-EHR-CLUSTER.case_identification.v0]/items[at0006, 'Participation in clinical study']



Dataelement_4_3 - TIME_OF_RECURRENCE_RELATIVE

Weeks between primary diagnosis and diagnosed recurrence. If only months is available, conversion is weeks := months * 4. Any re-occurrence of cancer, be it a local re-occurrence, a lymph node metastasis, or a distant metastasis

4.23 Dataelement_4_3 - TIME_OF_RECURRENCE_RELATIVE		
XSD label	Dataelement_4_3	
Data model label	TIME_OF_RECURRENCE_RELATIVE	
Level in data model	OPTIONAL	
XSD name	Time of recurrence (metastasis diagnosis)	
XSD type	xs:string	
List of permitted values in XSD	Not defined.	
Type in data model	NATURAL_NUMBER [week] (0<=x)	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1	
(Container archetype)	(openEHR-EHR-EVALUATION.problem_diagnosis.v1)	
Node id	at0009	
Node label	Time of recurrence	
Data type	DURATION [weeks] (0<=x<=1000)	
Occurrences	Optional	
Path	/content[openEHR-EHR-SECTION.demographics_rcp.v1, 'Patient data']/items[openEHR-EHR-EVALUATION.problem_diagnosis.v1, 'Metastasis diagnosis']/data[at0001]/items[openEHR-EHR-CLUSTER.timing_nondaily.v1, 'Metastasis diagnosis']/items[at0006, 'Metastasis diagnosis']/items[at0009, 'Time of recurrence']	



Pharmacotherapy

Dataelement_11_2 - PHARMACOTHERAPY_END_RELATIVE

End of the drug intake in weeks since initial diagnosis.

4.2 Dataelement_11_2 - PHARMACOTHERAPY_END_RELATIVE	
XSD label	Dataelement_11_2
Data model label	PHARMACOTHERAPY_END_RELATIVE
Level in data model	REQUIRED
XSD name	Date of end of pharmacotherapy
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [week] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-ACTION.medication.v1)
Node id	at0009
Node label	Date of end of pharmacotherapy
Data type	DURATION [weeks] (0<=x<=1000)
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Pharmacotherapy']/items[openEHR-EHR- ACTION.medication.v1]/description[at0017]/items[openEHR-EHR- CLUSTER.timing_nondaily.v1, 'Pharmacotherapy end']/items[at0006, 'End of pharmacotherapy']/items[at0009, 'Date of end of pharmacotherapy']



Dataelement_10_2 - PHARMACOTHERAPY_START_RELATIVE

Start of the drug intake in weeks since initial diagnosis.

4.1 Dataelement_10	_2 - PHARMACOTHERAPY_START_RELATIVE
XSD label	Dataelement_10_2
Data model label	PHARMACOTHERAPY_START_RELATIVE
Level in data model	REQUIRED
XSD name	Date of start of pharmacotherapy
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [week] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-ACTION.medication.v1)
Node id	at0009
Node label	Date of start of pharmacotherapy
Data type	DURATION [weeks] (0<=x<=1000)
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1,



Dataelement_59_5 - PHARMACOTHERAPY_SCHEME

Scheme of pharmacotherapy. If the therapy was terminated or changed (e.g., dosage reduced), "Other" shall be selected.

4.31 Dataelement_5	9_5 - PHARMACOTHERAPY_SCHEME
XSD label	Dataelement_59_5
Data model label	PHARMACOTHERAPY_SCHEME
Level in data model	REQUIRED
XSD name	Scheme of pharmacotherapy
XSD type	xs:string
	"Other"
	"Scheme of pharmacotherapy - 5-FU 325-350 mg/m2 + LV 20
	mg/m2i.v. bolus, day1-5, weeks 1 and 5"
	"Scheme of pharmacotherapy - 5-FU 400 mg/m2 + 100 mg i.v. bolus,
	d1,2, 11,12,21,22"
	"Scheme of pharmacotherapy - 5-FU 225 mg/m2 i.v. continuous
	infusion, 5 days per week"
	"Scheme of pharmacotherapy - 5-FU 1000 mg/m2 i.v. continuous
List of permitted	infusion, day 1-5, weeks 1 and 5"
values in XSD	"Scheme of pharmacotherapy - Capecitabine 800-825 mg/m2 bid po,
	day 1 -5, together with radiation or continuously untill end of
	radiation"
	"Scheme of pharmacotherapy - UFT (300-340mg/m2/day) and LV
	(22.5-90 mg /day) po continuously, 5(-7) days per week, together with radiotherapy"
	"Scheme of pharmacotherapy - Only preoperatively (no standard): 5-
	FU 250 mg/m2 i.v. continuous infusion on days 1-13 nad 22-35 and
	oxaliplatin 50mg/m2 i.v. day 1,8,22 and 29"
	LIST_OF_VALUES [5-FU 1000 mg/m2 i.v. continuous infusion, day 1-
	5,* weeks 1 and 5; 5-FU 225 mg/m2 i.v. continuous infusion, 5 days
	per week; 5-FU 325-350 mg/m2 + LV 20 mg/m2i.v. bolus, day1-5,
	weeks 1 and 5; 5-FU 400 mg/m2 + 100 mg i.v. bolus, d 1,2,
	11,12,21,22; Capecitabine 800-825 mg/m2 bid po, day 1-5, together
Type in data model	with radiation or continuously until end of radiation; Only
	preoperatively (no standard): 5-FU 250 mg/m2 i.v. continuous
	infusion on days 1-13 nad 22-35 and oxaliplatin 50mg/ m2 i.v. day
	1,8,22 and 29; UFT (300-340mg/m2/day) and LV (22.5 -90 mg/day) po
	continuously, 5(-7) days per week, together with radiotherapy; Other]



openEHR mapping	
Parent archetype id	openEHR-EHR-ACTION.medication.v1
(Container archetype)	(openEHR-EHR-SECTION.adhoc.v1)
Node id	at0020
Node label	Scheme of pharmacotherapy
Data type	TEXT - Limited to list: '5-FU 1000 mg/m2 i.v. continuous infusion, day 1-5, weeks 1 and 5', '5-FU 225 mg/m2 i.v. continuous infusion, 5 days per week', '5-FU 325-350 mg/m2 + LV 20 mg/m2i.v. bolus, day1-5, weeks 1 and 5', '5-FU 400 mg/m2 + 100 mg i.v. bolus, d 1,2, 11,12,21,22', 'Capecitabine 800-825 mg/m2 bid po, day 1-5, together ith radiation or continuously untill end of radiation', 'Only preoperatively (no standard): 5-FU 250 mg/m2 i.v. continuous infusion on days 1- 13 nad 22-35 and oxaliplatin 50mg/m2 i.v. day 1,8,22 and 29', 'UFT (300-340mg/m2/day) and LV (22.5-90 mg/day) po continuously, 5(-7) days per week, together with radiotherapy', 'Other'
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Pharmacotherapy']/items[openEHR-EHR- ACTION.medication.v1]/description[at0017]/items[at0020, 'Scheme of pharmacotherapy']



Dataelement_81_3 - PHARMACOTHERAPY_SCHEME_DESCRIPTION

Other pharmacotherapy scheme. When Other option is selected for pharmacotherapy scheme, the plain text description shall be provided.

4.44 Dataelement_81_3 - PHARMACOTHERAPY_SCHEME_DESCRIPTION	
XSD label	Dataelement_81_3
Data model label	PHARMACOTHERAPY_SCHEME_DESCRIPTION
Level in data model	if(PHARMACOTHERAPY_SCHEME==Other){REQUIRED}else{OPTIONAL}
XSD name	Other pharmacotherapy scheme
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	TEXT [] ()
openEHR mapping	
Parent archetype id	openEHR-EHR-ACTION.medication.v1
(Container archetype)	(openEHR-EHR-SECTION.adhoc.v1)
Node id	at0156
Node label	Other pharmacotherapy scheme
Data type	TEXT
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Pharmacotherapy']/items[openEHR-EHR- ACTION.medication.v1]/description[at0017]/items[at0156, 'Other pharmacotherapy scheme']



Radiation therapy

Dataelement_13_2 - RADIATION_THERAPY_END_RELATIVE

End of the radiation therapy in weeks since initial diagnosis.

4.4 Dataelement_13_2 - RADIATION_THERAPY_END_RELATIVE	
XSD label	Dataelement_13_2
Data model label	RADIATION_THERAPY_END_RELATIVE
Level in data model	REQUIRED
XSD name	Date of end of radiation therapy
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [week] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-ACTION.procedure.v1)
Node id	at0009
Node label	Date of end of radiation therapy
Data type	DURATION [weeks] (0<=x<=600)
Occurrences	11 (Mandatory)
	/content[openEHR-EHR-SECTION.adhoc.v1,
	'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Radiation
	therapy']/items[openEHR-EHR-ACTION.procedure.v1, 'Radiation
Path	therapy']/description[at0001]/items[openEHR-EHR-
	CLUSTER.timing_nondaily.v1, 'Radiation therapy end']/items[at0006,
	'End of radiation therapy']/items[at0009, 'Date of end of radiation
	therapy']



Dataelement_12_4 - RADIATION_THERAPY_START_RELATIVE

Start of the radiation therapy in weeks since initial diagnosis. For combined therapies, they should be entered as separate therapies.

4.3 Dataelement_12	_4 - RADIATION_THERAPY_START_RELATIVE
XSD label	Dataelement_12_4
Data model label	RADIATION_THERAPY_START_RELATIVE
Level in data model	REQUIRED
XSD name	Date of start of radiation therapy
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [week] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-ACTION.procedure.v1)
Node id	at0009
Node label	Date of start of radiation therapy
Data type	DURATION [weeks] (0<=x<=600)
Occurrences	11 (Mandatory)
	/content[openEHR-EHR-SECTION.adhoc.v1,
	'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Radiation
	therapy']/items[openEHR-EHR-ACTION.procedure.v1, 'Radiation
Path	therapy']/description[at0001]/items[openEHR-EHR-
	CLUSTER.timing_nondaily.v1, 'Radiation therapy start']/items[at0006,
	'Start of radiation therapy']/items[at0009, 'Date of start of radiation
	therapy']



Response to therapy

${\tt Dataelement_34_1-THERAPY_RESPONSE_TIMESTAMP_RELATIVE}$

Date response was obtained in weeks since initial diagnosis.

4.18 Dataelement_34_1 - THERAPY_RESPONSE_TIMESTAMP_RELATIVE	
XSD label	Dataelement_34_1
Data model label	THERAPY_RESPONSE_TIMESTAMP_RELATIVE
Level in data model	REQUIRED
XSD name	Date response was obtained in weeks since initial diagnosis
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [week] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-EVALUATION.clinical_synopsis.v1)
Node id	at0009
Node label	Time of therapy response
Data type	DURATION [weeks] (0<=x<=1300)
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Response to therapy']/items[openEHR-EHR- EVALUATION.clinical_synopsis.v1]/protocol[at0003]/items[openEHR- EHR-CLUSTER.timing_nondaily.v1, 'Response timing']/items[at0006, 'Therapy response timestamp']/items[at0009, 'Time of therapy response']



Dataelement_33_1 - THERAPY_RESPONSE

Response to therapy - Specific response

4.17 Dataelement_3	3_1 - THERAPY_RESPONSE
XSD label	Dataelement_33_1
Data model label	THERAPY_RESPONSE
Level in data model	REQUIRED
XSD name	Specific response
XSD type	xs:string
List of permitted values in XSD	"Specific response - Complete response" "Specific response - Partial response" "Specific response - Stable disease" "Specific response - Progressive disease"
Type in data model	LIST_OF_VALUES [Complete response; Partial response; Progressive disease; Stable disease]
openEHR mapping	
Parent archetype id	openEHR-EHR-EVALUATION.clinical_synopsis.v1
(Container archetype)	(openEHR-EHR-SECTION.adhoc.v1)
Node id	at0002
Node label	Specific response
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 36309727 - Complete response 36309453 - Partial response 36308003 - Progressive disease 36309215 - Stable disease
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1,



Sample

Dataelement_54_2 - SAMPLE_MATERIAL_TYPE

Type of specimen

4.26 Dataelement_54	1_2 - SAMPLE_MATERIAL_TYPE
XSD label	Dataelement_54_2
Data model label	SAMPLE_MATERIAL_TYPE
Level in data model	REQUIRED
XSD name	Material type
XSD type	xs:string
List of permitted values in XSD	"Other" "Healthy colon tissue" "Tumor"
Type in data model	LIST_OF_VALUES [Healthy colon tissue; Tumor tissue; Other]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.specimen.v1
(Container archetype)	(openEHR-EHR-EVALUATION.specimen_summary.v1)
Node id	at0029.1
Node label	Material Type
	TEXT - Limited to list with codes from OMOP vocabulary:
Data type	4122248 - Tumor tissue sample
Data type	4134449 - Tissue specimen from colon
	NS_4163599 - Other specimen type
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Sample']/items[openEHR-EHR-EVALUATION.specimen_summary.v1]/data[at0001]/items[openEHR-EHR-CLUSTER.specimen.v1]/items[at0029, 'Material type']



Dataelement_55_2 - SAMPLE_PRESERVATION_MODE

The preservation mode for the specimen

4.27 Dataelement_5	5_2 - SAMPLE_PRESERVATION_MODE
XSD label	Dataelement_55_2
Data model label	SAMPLE_PRESERVATION_MODE
Level in data model	REQUIRED
XSD name	Preservation mode
XSD type	xs:string
List of permitted values in XSD	"Other" "Cryopreservation" "FFPE"
Type in data model	LIST_OF_VALUES [Cryopreservation; FFPE; Other]
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.specimen_preparation.v0
(Container archetype)	(openEHR-EHR-CLUSTER.specimen.v1)
Node id	at0079.1
Node label	Preservation mode
Data type	TEXT - Limited to list: 'Cryopreservation', 'FFPE', Other''
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Sample']/items[openEHR-EHR-EVALUATION.specimen_summary.v1]/data[at0001]/items[openEHR-EHR-CLUSTER.specimen.v1]/items[at0079, 'Preservation mode']



Dataelement_56_2 - SAMPLE_ID

An identifier, unique within the biobank

4.28 Dataelement_56_2 - SAMPLE_ID	
XSD label	Dataelement_56_2
Data model label	SAMPLE_ID
Level in data model	REQUIRED
XSD name	Sample ID
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	TEXT [] ()
openEHR mapping	
Parent archetype id	openEHR-EHR-EVALUATION.specimen_summary.v1
(Container archetype)	(openEHR-EHR-SECTION.adhoc.v1)
Node id	at0002.1
Node label	Sample ID
Data type	IDENTIFIER
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Sample']/items[openEHR-EHR-EVALUATION.specimen_summary.v1]/data[at0001]/items[at0002, 'Sample ID']



Dataelement_89_3 - YEAR_OF_SAMPLE_COLLECTION

Calender year in which the sample was collected.

4.50 Dataelement_89_3 - YEAR_OF_SAMPLE_COLLECTION	
XSD label	Dataelement_89_3
Data model label	YEAR_OF_SAMPLE_COLLECTION
Level in data model	REQUIRED
XSD name	Year of sample collection
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [years] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.specimen.v1
(Container archetype)	(openEHR-EHR-EVALUATION.specimen_summary.v1)
Node id	at0015.1
Node label	Year of sample collection
Data type	DATE TIME
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Sample']/items[openEHR-EHR-EVALUATION.specimen_summary.v1]/data[at0001]/items[openEHR-EHR-CLUSTER.specimen.v1]/items[at0015, 'Year of sample collection']

Note:

The DATE TIME datatype of the template node requires a complete date, so even if it is possible to record just a year (e.g., 2021), the resulting data will be:

```
"year_of_sample_collection": [
"2021-01-01T00:00Z"
]
```

Surgery



Dataelement_93_1 - SURGERY_LOCATION

Location of the tumor

4.54 Dataelement_9	3_1 - SURGERY_LOCATION
XSD label	Dataelement_93_1
Data model label	SURGERY_LOCATION
Level in data model	REQUIRED
XSD name	Location of the tumor
XSD type	xs:string
List of permitted values in XSD	"Location of tumor - C18.0"; "Location of tumor - C18.1"; "Location of tumor - C18.2"; "Location of tumor - C18.3"; "Location of tumor - C18.4"; "Location of tumor - C18.5"; "Location of tumor - C18.6"; "Location of tumor - C18.7"; "Location of tumor - C19"; "Location of tumor - C20.9"
Type in data model	LIST_OF_VALUES [C 18.0 - Cecum; C 18.1 - Appendix; C 18.2 - Ascending (right); C 18.3 - Hepatic flexure; C 18.4 - Transverse colon; C 18.5 - Splenic flexure; C 18.6 - Descending (left); C 18.7 - Sigmoid; C 19 - Rectosigmoid; C 19.9 - Rectosigmoid*; C 20 - Rectum; C 20.9 - Rectum*]
openEHR mapping	
Parent archetype id	openEHR-EHR-ACTION.procedure.v1
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)
Node id	at0063
Node label	Location of the tumor
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 432837 - C 18.0 - Caecum; 433143 - C 18.1 - Appendix; 4247719 - C 18.2 - Ascending colon; 438979 - C 18.3 - Hepatic flexure; 432257 - C 18.4 - Transverse colon; 437798 - C 18.5 - Splenic flexure; 441800 - C 18.6 - Descending colon; 436635 - C 18.7 - Sigmoid colon; 438699 - C 19 - Rectosigmoid junction; 74582 - C 20 - Rectum
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1,

<u>Note</u>: *The codes C19.9 and C20.0 from ICD-O-3 are included in, and thus mapped to, the C19 and C20 codes from ICD-10.

Dataelement_67_1 - SURGERY_TYPE_OTHER

Surgery type, if not present on the list



4.35 Dataelement_67_1 - SURGERY_TYPE_OTHER	
XSD label	Dataelement_67_1
Data model label	SURGERY_TYPE_OTHER
Level in data model	OPTIONAL
XSD name	Other surgery type
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	TEXT [] ()
openEHR mapping	
Parent archetype id	openEHR-EHR-ACTION.procedure.v1
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)
Node id	at0049
Node label	Other surgery type
Data type	TEXT
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Surgery']/items[openEHR-EHR-ACTION.procedure.v1, 'Surgery']/description[at0001]/items[at0049, 'Other surgery type']



Dataelement_9_2 - SURGERY_RADICALITY

Whether the surgery removed the entire tumor.

4.55 Dataelement_9	4.55 Dataelement_9_2 - SURGERY_RADICALITY	
XSD label	Dataelement_9_2	
Data model label	SURGERY_RADICALITY	
Level in data model	REQUIRED	
XSD name	Surgery radicality	
XSD type	xs:string	
List of permitted values in XSD	"R2" "R1" "R0" "RX"	
Type in data model	LIST_OF_VALUES [R0; R1; R2; RX]	
openEHR mapping		
Parent archetype id	openEHR-EHR-ACTION.procedure.v1	
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)	
Node id	at0048	
Node label	Surgery radicality	
	TEXT - Limited to list with codes from OMOP vocabulary:	
	4121182 - RO	
Data type	4175704 - R1	
	4081832 - R2	
	4123024 - RX	
Occurrences	11 (Mandatory)	
	/content[openEHR-EHR-SECTION.adhoc.v1,	
Path	'Surgery']/items[openEHR-EHR-ACTION.procedure.v1,	
	'Surgery']/description[at0001]/items[at0048, 'Surgery radicality']	



Dataelement_49_1 - SURGERY_TYPE

Surgery type

4.22 Dataelement_4	9_1 - SURGERY_TYPE
XSD label	Dataelement_49_1
Data model label	SURGERY_TYPE
Level in data model	REQUIRED
XSD name	Surgery type
XSD type	xs:string
List of permitted values in XSD	"Other" "Endo-rectal tumor resection" "Abdomino-perineal resection" "Anterior resection of rectum" "Low anteroir colon resection" "Pan-procto colectomy" "Total colectomy" "Sigmoid colectomy" "Transverse colectomy" "Left hemicolectomy" "Right hemicolectomy"
Type in data model	LIST_OF_VALUES [Abdomino-perineal resection; Anterior resection of rectum; Endo-rectal tumor resection; Left hemicolectomy; Low anteroir colon resection; Pan-procto colectomy; Right hemicolectomy; Sigmoid colectomy; Total colectomy; Transverse colectomy; Other]
openEHR mapping	
Parent archetype id	openEHR-EHR-ACTION.procedure.v1
(Container archetype)	(openEHR-EHR-SECTION.procedures_rcp.v1)
Node id	at0002
Node label	Surgery type
Data type	TEXT - Limited to list with codes from OMOP vocabulary: 4144721 - Abdomino-perineal resection, 4166855 - Anterior resection of rectum, NS_XX1 - Endo-rectal tumor resection, 4219780 - Left hemicolectomy, NS_XX2 - Low anterior colon resection, 44807810 - Pan-procto colectomy, 4233412 - Right hemicolectomy, 4225427 - Sigmoid colectomy, 4096461 - Total colectomy, 4097958 - Transverse colectomy, 36308041 - Other
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Surgery']/items[openEHR-EHR-ACTION.procedure.v1, 'Surgery']/description[at0001]/items[at0002, 'Surgery type']



Dataelement_8_3 - SURGERY_START_RELATIVE

Time difference between initial diagnosis and surgery. Weeks between initial diagno- sis and date of surgery. Pre-operatively treated cases (neoadjuvant therapy) are welcome, but there needs to be surgery later on anyway, to have also sufficient amount of biological material.

4.51 Dataelement_8_3 - SURGERY_START_RELATIVE	
XSD label	Dataelement_8_3
Data model label	SURGERY_START_RELATIVE
Level in data model	REQUIRED
XSD name	Time difference between initial diagnosis and surgery
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [week] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-ACTION.procedure.v1)
Node id	at0009
Node label	Surgery start relative
Data type	DURATION [weeks] (0<=x<=600)
Occurrences	11 (Mandatory)
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Surgery']/items[openEHR-EHR-ACTION.procedure.v1, 'Surgery']/description[at0001]/items[openEHR-EHR- CLUSTER.timing_nondaily.v1, 'Surgery timing']/items[at0006, 'Surgery']/items[at0009, 'Surgery start relative']



Targeted therapy

Dataelement_36_1 - TARGETED_THERAPY_END_RELATIVE

Targeted therapy - Date of end (weeks since initial diagnosis).

4.20 Dataelement_3	5_1 - TARGETED_THERAPY_END_RELATIVE
XSD label	Dataelement_36_1
Data model label	TARGETED_THERAPY_END_RELATIVE
Level in data model	OPTIONAL
XSD name	Date of end of targeted therapy
XSD type	xs:string
List of permitted values in XSD	Not defined.
Type in data model	NATURAL_NUMBER [] (0<=x)
openEHR mapping	
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1
(Container archetype)	(openEHR-EHR-ACTION.procedure.v1)
Node id	at0009
Node label	Date of end of targeted therapy
Data type	DURATION [weeks] (0<=x<=600)
Occurrences	Optional
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Targeted therapy']/items[openEHR-EHR-ACTION.procedure.v1, 'Targeted therapy']/description[at0001]/items[openEHR-EHR- CLUSTER.timing_nondaily.v1, 'Targeted therapy end']/items[at0006, 'End of targeted therapy']/items[at0009, 'Date of end of targeted therapy']



Dataelement_35_3 - TARGETED_THERAPY_START_RELATIVE

Targeted therapy - Date of start (weeks since initial diagnosis).

4.19 Dataelement_35_3 - TARGETED_THERAPY_START_RELATIVE		
XSD label	Dataelement_35_3	
Data model label	TARGETED_THERAPY_START_RELATIVE	
Level in data model	REQUIRED	
XSD name	Date of start of targeted therapy	
XSD type	xs:string	
List of permitted values in XSD	Not defined.	
Type in data model	NATURAL_NUMBER [] (0<=x)	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1	
(Container archetype)	(openEHR-EHR-ACTION.procedure.v1)	
Node id	at0009	
Node label	Date of start of targeted therapy	
Data type	DURATION [weeks] (0<=x<=600)	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1,	
	'Therapies']/items[openEHR-EHR-SECTION.adhoc.v1, 'Targeted	
	therapy']/items[openEHR-EHR-ACTION.procedure.v1, 'Targeted	
	therapy']/description[at0001]/items[openEHR-EHR-	
	CLUSTER.timing_nondaily.v1, 'Targeted therapy start']/items[at0006,	
	'Start of targeted therapy']/items[at0009, 'Date of start of targeted	
	therapy']	



Vital status and survival information

Dataelement_7_2 - OVERALL_SURVIVAL_STATUS

Weeks after first colon cancer therapy started for the given person. If the data is collected at the source in months only, the conversion should be weeks := months*4

4.43 Dataelement_7_2 - OVERALL_SURVIVAL_STATUS		
XSD label	Dataelement_7_2	
Data model label	OVERALL_SURVIVAL_STATUS	
Level in data model	REQUIRED	
XSD name	Overall survival status	
XSD type	xs:string	
List of permitted values in XSD	Not defined.	
Type in data model	NATURAL_NUMBER [week] (0<=x)	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1	
(Container archetype)	(openEHR-EHR-EVALUATION.clinical_synopsis.v1)	
Node id	at0009	
Node label	Overall survival status	
Data type	DURATION [weeks] (0<=x<=3000)	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Vital status and survival information']/items[openEHR-EHR-EVALUATION.clinical_synopsis.v1, 'Vital status and survival information']/protocol[at0003]/items[openEHR-EHR-CLUSTER.timing_nondaily.v1, 'Vital status timing']/items[at0006, 'Overall survival status']	



Dataelement_5_2 - VITAL_STATUS

Vital status

4.32 Dataelement_5_2 - VITAL_STATUS		
XSD label	Dataelement_5_2	
Data model label	VITAL_STATUS	
Level in data model	REQUIRED	
XSD name	Vital status	
XSD type	xs:string	
List of permitted	"ALIVE" "DEATH_COLON_CANCER" "DEATH_OTHER"	
values in XSD	"DEATH_UNKNOWN_REASON" "UNKNOWN"	
Type in data model	LIST_OF_VALUES [death due to colon cancer; death due to other	
	reasons; death for unknown reasons; person is still alive; unknown]	
openEHR mapping		
Parent archetype id	openEHR-EHR-EVALUATION.clinical_synopsis.v1	
(Container archetype)	(openEHR-EHR-SECTION.adhoc.v1)	
Node id	at0002	
Node label	Vital status	
Data type	TEXT - Limited to list: 'death due to colon cancer', 'death due to other reasons', 'death for unknown reasons', 'person is still alive', 'unknown'	
Occurrences	11 (Mandatory)	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Vital status and survival information']/items[openEHR-EHR-EVALUATION.clinical_synopsis.v1, 'Vital status and survival information']/data[at0001]/items[at0002, 'Vital status']	



Dataelement_6_3 - VITAL_STATUS_TIMESTAMP

Timestamp of last update of vital status

4.37 Dataelement_6_3 - VITAL_STATUS_TIMESTAMP		
XSD label	Dataelement_6_3	
Data model label	VITAL_STATUS_TIMESTAMP	
Level in data model	if(VITAL_STATUS!=UNKNOWN){REQUIRED}else{OPTIONAL}	
XSD name	Timestamp of last update of vital status	
XSD type	xs:string	
List of permitted values in XSD	Not defined.	
Type in data model	DATE [](ISO_8601_WITH_DAYS)	
openEHR mapping		
Parent archetype id	openEHR-EHR-CLUSTER.timing_nondaily.v1	
(Container archetype)	(openEHR-EHR-EVALUATION.clinical_synopsis.v1)	
Node id	at0001	
Node label	Timestamp of last update of vital status	
Data type	DATE	
Occurrences	Optional	
Path	/content[openEHR-EHR-SECTION.adhoc.v1, 'Vital status and survival information']/items[openEHR-EHR-EVALUATION.clinical_synopsis.v1, 'Vital status and survival information']/protocol[at0003]/items[openEHR-EHR-CLUSTER.timing_nondaily.v1, 'Vital status timing']/items[at0001, 'Timestamp of last update of vital status']	