

Swiss OncoData Infrastructure (SODI) Core Dataset

Version: **March 2026**

Purpose of this document

This document specifies the Swiss OncoData Infrastructure (SODI) Core Dataset, i.e., the minimum standardized set of variables collected in the SCI SODI standard eCRF. It provides definitions, formats/units, and permissible values, and references applicable external standards (SPHN, NICER). Additional variables may be captured for project-specific requirements, provided they do not conflict with the core dataset definitions.

References:

SPHN Dataset	Release 2026_1
NICER	National Cancer Data Dictionary V1.5, Part A

Category	Question	Definition
Registration and Eligibility	Informed consent	Patient informed consent (date, type, status, date of withdrawal)
Demographics and Background information	Year of birth	Year of birth of the individual
Demographics and Background information	Sex	The genetic sex of the individual
Demographics and Background information	Height (cm)	The body height of the individual
Demographics and Background information	Smoking status	The smoking status of the individual at registration
Demographics and Background information	History of atopy	Indicator of atopy in patient's history
Demographics and Background information	Autoimmune disorders	Autoimmune disorders of the patient including specification.
Follow-up / Patient status	Date of Follow-up	Date of follow-up assessment.
Follow-up / Patient status	Survival status	Individuals survival status
Follow-up / Patient status	Date last known alive or last contact	Date of last known alive or last contact in case of a survival status is alive or lost to follow-up.
Follow-up / Patient status	Date of death and reason	Date of death of the individual including reason
Oncological diagnoses	ICD-10 code/term	Code/term of the oncological diagnosis acc. to ICD-10.
Oncological diagnoses	Date of initial diagnosis	Initial date of oncological diagnosis.
Oncological diagnoses	Topography	Topography of the current oncological diagnosis acc. to ICD-O-3.
Oncological diagnoses	Morphology	Morphology of the current oncological diagnosis acc. to ICD-O-3.
Oncological diagnoses	cTNM	Clinical TNM result acc. to TNM classification (incl. date and y-prefix)
Oncological diagnoses	pTNM	Pathological TNM result acc. to TNM classification (incl. date and y-prefix)
Oncological diagnoses	Tumor stage	Initial tumor stage of the current oncological diagnosis (incl. date)
Oncological diagnoses	Histopathological Grade (ICD-O / WHO classification)	Initial histopathological grade of the current oncological diagnosis acc. to ICD-O / WHO classification (incl. date).
Oncological diagnoses	Metastasis	In case of metastasis: location of metastasis.
Comorbidities	ICD-10 code/term	Code/term of significant non-oncological comorbidity acc. to ICD-10.
Comorbidities	Date of initial diagnosis	Initial date of comorbidity.
Drug therapies	ATC code/term	ATC code/term of the anti-cancer drug therapy according to WHO ATC catalog.
Drug therapies	Clinical trial	Indicator if this drug therapy is part of a clinical trial.
Drug therapies	Treatment start date	Start date of the current anti-cancer drug therapy.
Drug therapies	Treatment stop date	Stop date of the current anti-cancer drug therapy.
Drug therapies	Planned single dose	Planned absolute single dose of the current anti-cancer drug therapy.
Drug therapies	Dose reduction	Was there any dose reduction during this drug therapy?
Drug therapies	Dose reduction reason	Reason for the dose reduction during this drug therapy.
Drug therapies	Dose reduction overall reduction	Overall reduction in case of a dose reduction during this drug therapy.
Drug therapies	Reason to stop drug	Main reason why the current anti-cancer drug therapy has been stopped.
Drug therapies	Indication	Indication of the current anti-cancer drug therapy (neoadjuvant, adjuvant or advanced (non-neoadjuvant and non-adjuvant)).
Radiotherapies	Procedure	Procedure of the current radiotherapy.
Radiotherapies	Target body site	Target body site of the current radiotherapy.
Radiotherapies	Radiotherapy Start date	Start date of the current radiotherapy.
Radiotherapies	Radiotherapy Stop date	Stop date of the current radiotherapy.
Radiotherapies	Radiotherapy total dose	Total dose of current radiotherapy (incl. unit)

Category	Question	Definition
Radiotherapies	Radiotherapy acc. to plan	Was this radiotherapy performed according to the initial plan?
Radiotherapies	Radiostherapy not acc. to plan reason	Reason why this therapy was not performed according to the initial plan.
Radiotherapies	Indication	Indication of the current anti-cancer drug therapy (neoadjuvant, adjuvant or advanced (non-neoadjuvant and non-adjuvant)).
Surgeries	CHOP code/name	Code/name of the surgery - level 3 of the CHOP catalog.
Surgeries	Surgery Date	Date of the current surgery.
Surgeries	Resection margin	Resection margin of the current surgery acc. to pathology report.
Other therapies	Other therapy	Type of other anti-cancer therapy in this treatment line (except drug therapy, radiotherapy and surgery).
Other therapies	Other therapy start date	Start date of current other therapy.
Other therapies	Other therapy stop date	Stop date of current other therapy.
Other therapies	Indication	Indication of the current anti-cancer drug therapy (neoadjuvant, adjuvant or advanced (non-neoadjuvant and non-adjuvant)).
Tumor assessments	Response	Response of the current tumor assessment.
Tumor assessments	Assessment date	Date of the tumor assessment.
Tumor assessments	Method of assessment	Method of the tumor assessment
Tumor assessments	Dissociated response	Clinical relevant dissociated response
Tumor assessments	Type of progression	Type of progression at current tumor assessment.
Tumor assessments	Metastasis	In case of metastatic progression: location of metastasis
Tumor assessments	Evaluation	Indicator if current PD was evaluated clinically and/or radiological by the clinician.
Physical Examinations: ECOG - Performance status	ECOG performance status	Result of the ECOG performance status (incl. date). Collected at least at time of each tumor assessment.
Physical Examinations: Body weight	Body weight BR (kg)	The body weight of the individual (incl. date). Collected at least at time of each tumor assessment.
Laboratory	Test	Laboratory test name (acc. to list of tests and if measured). Collected at least at time of each tumor assessment.
Laboratory	Result	Result of the laboratory test (incl. unit).
Laboratory	Collection date	Collection date of the sample for the current laboratory test.
Tumor marker	Test	Tumor marker name (acc. to list of tests and if measured).
Tumor marker	Result	Tumor marker result (incl. unit)
Tumor marker	Collection date	Collection date of the sample for the current tumor marker.
Immunohistochemistry / FISH	PD-L1	PD-L1 (incl. date, antibody, CPS)
Immunohistochemistry / FISH	Test	Non-genomic biomarker test name (acc. to list of tests and if measured).
Immunohistochemistry / FISH	Result	Result of the non-genomic biomarker test.
Immunohistochemistry / FISH	FISH amplifications - CNV	CNV in case of FISH amplification (ratio)
Immunohistochemistry / FISH	Collection date	Date of the non-genomic biomarker assessment.
Genomic testing / NGS	Specimen collection date	Date when the specimen was collected.
Genomic testing / NGS	NGS report date	Date of the NGS/pathology report
Genomic testing / NGS	Gene panel test name	Name of the gene panel test (NGS test kit)
Genomic testing / NGS	Specimen type	Specimen type used for the test
Genomic testing / NGS	Primary tumor or metastasis tested	Primary tumor or metastasis tested?
Genomic testing / NGS	Metastasis sample location	If sample is from metastasis, location of the metastasis.
Genomic testing / NGS	Pathology assessment of tumor cells	Percentage of pathologically assess tumor cells.

Category	Question	Definition
Genomic testing / NGS	ctDNA fraction	If specimen type is plasma, the ctDNA fraction.
Genomic testing / NGS	MSAF	Maximum somatic allele frequency (MSAF)
Genomic testing / NGS	MSI	Molecular microsatellite status
Genomic testing / NGS	TMB	Tumor mutational burden (TMB)
Genomic testing / NGS	HRD status	Homologous Recombination Deficiency (HRD) status
Genomic testing / NGS	GIS status	Genomic Instability Score (GIS) status
Genomic testing / NGS	BRCA status	BRCA status
Genomic testing / NGS	Gene	Name of the gene acc. to OncoKB
Genomic testing / NGS	Alteration	Name of the gene alteration acc. to OncoKB
Genomic testing / NGS	VAF	Variant Allele Frequency (VAF)
Genomic testing / NGS	CNV	Essential Copy Number Variations (CNV)
Genomic testing / NGS	CNV result	Essential CNV number of gene copies ((high-level amplification: > 8; deep deletion: 0)
Genomic testing / NGS	Rearrangements	Essential predictive Rearrangements/Fusions
Adverse events	CTCAE term	Adverse event CTCAE SOC/Term
Adverse events	CTCAE grade	Adverse event CTCAE Grade
Adverse events	AE Start date	Start date of Adverse event
Adverse events	AE Stop date	Stop date of Adverse event

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
0.0	10	Encounter	general	upn	UPN (Unique Patient Number)	Text	RWD_nnnnnn	11	Unique SODI patient identifier	Subject Pseudo Identifier	
0.0	20	Encounter	general	usn	USN (Unique Site Number)	Text	nnnn	4	Unique SCI site identifier	Data Provider	
1.0	10	Registration and Eligibility	mnpp0001_er	regdat	SODI registration date	Date			Date when the patient was registered in SODI	Healthcare Encounter	
1.1	10	Registration and Eligibility	emnpp0001_subic	icdat	Informed consent date	Date			Date on which the consent was signed	Consent	
1.1	20	Registration and Eligibility	emnpp0001_subic	ictype	Informed consent type	Drop-down	General consent (5); expandable		The type of consent that has been used to ask the individual for consent	Consent	
1.1	30	Registration and Eligibility	emnpp0001_subic	icstat	Informed consent status	Drop-down	Active (1); Withdrawn (3)		Status of the consent	Consent	
1.1	40	Registration and Eligibility	emnpp0001_subic	icendat	Informed consent withdrawal date	Date			Date on which the consent was refused or withdrawn	Consent	
2.0	10	Demographics and Background information	mnpp0001_dm	brthyr	Year of birth	Date			Year of birth of the individual	Birth Date	1.3.1
2.0	20	Demographics and Background information	mnpp0001_dm	sex	Sex	Drop-down	Female (1); Male (2); Other (99)		The genetic sex of the individual	Administrative Sex	1.2
2.0	30	Demographics and Background information	mnpp0001_dm	lborres_hgt	Height (cm)	Number 3,0		cm	The body height of the individual	Body Height	
2.0	40	Demographics and Background information	mnpp0001_dm	smoke	Smoking status	Drop-down	Non-smoker (1); Smoker (2); Ex-smoker (3); Unknown (88)		The smoking status of the individual at registration	Tobacco Exposure	
2.0	50	Demographics and Background information	mnpp0001_dm	atopyn	History of atopy	Drop-down	Yes (1); No (0); Unknown (88)		Indicator of atopy in patient's history	Problem Condition / Excluded disorder	
2.0	60	Demographics and Background information	mnpp0001_dm	aimyn	Autoimmune disorders	Drop-down	Yes (1); No (0); Unknown (88)		Indicator if the individual has any autoimmune disorders	Problem Condition / Excluded disorder	
2.0	70	Demographics and Background information	mnpp0001_dm	aimspc	Autoimmune disorders specify	Text		80	Specification of autoimmune disorders	Problem Condition / Excluded disorder	
3.0	10	Follow-up / Patient status	mnpp0001_fu	fudat	Date of Follow-up	Date (incomplete)			Date of follow-up assessment.	Follow Up	1.14.1
3.0	20	Follow-up / Patient status	mnpp0001_fu	fuss	Survival status	Drop-down	Alive (1); Lost to follow-up (2); Dead (3)		Individuals survival status	Vital Status	1.13
3.0	30	Follow-up / Patient status	mnpp0001_fu	fussdat	Date last known alive or last contact	Date (incomplete)			Date of last known alive or last contact in case of a survival status is alive or lost to follow-up.	Vital Status	
3.0	40	Follow-up / Patient status	mnpp0001_fu	fudthdat	Date of death	Date (incomplete)			Date of death of the individual	Death Date	
3.0	50	Follow-up / Patient status	mnpp0001_fu	fudthr	Death reason	Drop-down	Cancer (1); Secondary malignancy (2); Unknown (88); Other (99)		Main reason of death of the individual	Death	(1.15)
4.0	10	Genomic testing / NGS	mnpp0001_gt	gtcoldat	Specimen collection date	Date			Date when the specimen was collected.	Tumor specimen	
4.0	20	Genomic testing / NGS	mnpp0001_gt	gtrepmat	NGS report date	Checked Date (dd.mm.yyyy)			Date of the NGS/pathology report	Lab Test Event	
4.0	30	Genomic testing / NGS	mnpp0001_gt	testkit	Gene panel test name	Text	Lookup table: paneltests2		Name of the gene panel test (NGS test kit)	Gene Panel	
4.0	40	Genomic testing / NGS	mnpp0001_gt	testkitoth	Gene panel test name other	Text 100			Other Name of the gene panel test (NGS test kit)	Gene Panel	
4.0	50	Genomic testing / NGS	mnpp0001_gt	spec	Specimen type	Popup (Label Group)	Tissue (1); Cytology (2); Plasma (3); Germline (4); Unknown (88)		Specimen type used for the test	Tumor specimen	
4.0	60	Genomic testing / NGS	mnpp0001_gt	pathtype	Primary tumor or metastasis tested	Popup (Label Group)	Primary tumor (1); Metastasis (2); Unknown (88)		Primary tumor or metastasis tested?	Tumor specimen	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
4.0	70	Genomic testing / NGS	mnpp0001_gt	pathloc	Metastasis sample location	Popup (Label Group)	Adrenals (1); Bone marrow (2); Brain (3); Hepatic (4); Lymph nodes (5); Osseous (6); Omentum (11); Peritoneum (7); Pleura (8); Pulmonary (9); Skin (10); Other (99); Unknown (88)		If sample is from metastasis, location of the metastasis.	Tumor specimen	
4.0	80	Genomic testing / NGS	mnpp0001_gt	tcells	Pathology assessment of tumor cells	Numeric 2,0		%	Percentage of pathologically assess tumor cells.	Tumor specimen	
4.0	90	Genomic testing / NGS	mnpp0001_gt	ctdna	ctDNA fraction	Numeric 3,1		%	If specimen type is plasma, the ctDNA fraction.	Tumor specimen	
4.0	100	Genomic testing / NGS	mnpp0001_gt	msaf	MSAF	Numeric 3,1		%	Maximum somatic allele frequency (MSAF)	Molecular Test Result	
4.0	110	Genomic testing / NGS	mnpp0001_gt	msi	MSI	Popup (Label Group)	MS - stable (1); MS - instable (2); N/A (66)		Molecular microsatellite status	Molecular Test Result	
4.0	120	Genomic testing / NGS	mnpp0001_gt	tmb	TMB	Numeric 3,0		mutations/m b	Tumor mutational burden (TMB)	Molecular Test Result	
4.0	130	Genomic testing / NGS	mnpp0001_gt	hrd	HRD status	Popup (Label Group)	Positive (1); Negative (0); N/A (66)		Homologous Recombination Deficiency (HRD) status	Molecular Test Result	
4.0	140	Genomic testing / NGS	mnpp0001_gt	gis	GIS status	Popup (Label Group)	Positive (1); Negative (0); N/A (66)		Genomic Instability Score (GIS) status	Molecular Test Result	
4.0	150	Genomic testing / NGS	mnpp0001_gt	brca	BRCA status	Popup (Label Group)	Mutation (1); Wildtype (0); N/A (66)		BRCA status	Molecular Test Result	
4.0	160	Genomic testing / NGS	mnpp0001_gt	brcatt	BRCA test type	Popup (Label Group)	Somatic (1); Germline (2); Unknown (88)		Test type of BRCA status	Molecular Test Result	
4.1	10	Genomic testing / NGS	emnpp0001_subgt	gene	Gene	Catalog			Name of the gene acc. to OncoKB	Gene	
4.1	20	Genomic testing / NGS	emnpp0001_subgt	alterat	Alteration	Catalog			Name of the gene alteration acc. to OncoKB	Variant Descriptor	
4.1	30	Genomic testing / NGS	emnpp0001_subgt	geneoth	Gene/alteration other	Text 100			Other Name of the gene alteration	Variant Descriptor	
4.1	40	Genomic testing / NGS	emnpp0001_subgt	vaf	VAF	Numeric 3,0		%	Variant Allele Frequency (VAF)	Variant Descriptor	
4.2	10	Genomic testing / NGS	emnpp0001_subcnv	cnv	CNV	Text	Lookup table: cnvs		Essential Copy Number Variations (CNV)	Copy Number Variation	
4.2	20	Genomic testing / NGS	emnpp0001_subcnv	cnvoth	CNV other	Text 20			Other Essential Copy Number Variations (CNV)	Copy Number Variation	
4.2	30	Genomic testing / NGS	emnpp0001_subcnv	cnvorres	CNV result	Numeric 3,2		gene copies	Essential CNV number of gene copies ((high-level amplification: > 8; deep deletion: 0)	Copy Number Variation	
4.3	10	Genomic testing / NGS	emnpp0001_subrea	rea	Rearrangements	Text	Lookup table: rearrange		Essential predictive Rearrangements/Fusions	Gene Fusion	
4.3	20	Genomic testing / NGS	emnpp0001_subrea	reaoth	Rearrangements other	Text 20			Other Essential predictive Rearrangements/Fusions	Gene Fusion	
101.0	10	Oncological diagnoses	emnpp0001_subdg	icd_catc	ICD-10 Category	Catalog	ICD-10		Category code of the oncological diagnosis acc. to ICD-10.	Oncology Diagnosis	3.3
101.0	20	Oncological diagnoses	emnpp0001_subdg	icd_catt	ICD-10 Category term	Catalog	ICD-10		Category term of the oncological diagnosis acc. to ICD-10.	Oncology Diagnosis	3.3
101.0	30	Oncological diagnoses	emnpp0001_subdg	icd_lv4c	ICD-10 Code	Catalog	ICD-10		Code of the oncological diagnosis acc. to ICD-10.	Oncology Diagnosis	3.3
101.0	40	Oncological diagnoses	emnpp0001_subdg	icd_lv4t	ICD-10 Term	Catalog	ICD-10		Term of the oncological diagnosis acc. to ICD-10.	Oncology Diagnosis	3.3
101.0	50	Oncological diagnoses	emnpp0001_subdg	dgstdat	Date of initial diagnosis	Date (dd.mm.yyyy)			Initial date of oncological diagnosis.	Oncology Diagnosis	2.3.1

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101.0	60	Oncological diagnoses	emnpp0001_subdg	icdo_tc	ICD-O-3 Topography Code	Catalog	ICD-O-3		Topography code of the current oncological diagnosis acc. to ICD-O-3.	Oncology Diagnosis	3.4
101.0	70	Oncological diagnoses	emnpp0001_subdg	icdo_tt	ICD-O-3 Topography Term	Catalog	ICD-O-3		Topography term of the current oncological diagnosis acc. to ICD-O-3.	Oncology Diagnosis	3.4
101.0	80	Oncological diagnoses	emnpp0001_subdg	icdo_mc	ICD-O-3 Morphology Code	Catalog	ICD-O-3		Morphology code of the current oncological diagnosis acc. to ICD-O-3.	Oncology Diagnosis	3.5
101.0	90	Oncological diagnoses	emnpp0001_subdg	icdo_mt	ICD-O-3 Morphology Term	Catalog	ICD-O-3		Morphology term of the current oncological diagnosis acc. to ICD-O-3.	Oncology Diagnosis	3.5
101.0	100	Oncological diagnoses	emnpp0001_subdg	tnmct	cTNM cT	Popup (Label Group)	TX (1); T0 (2); Tis (3); Ta (4); T1 (5); T1a (6); T1a1 (7); T1a2 (8); T1b (9); T1b1 (10); T1b2 (11); T1c (12); T2 (13); T2a (14); T2a1 (15); T2a2 (16); T2b (17); T2c (18); T3 (19); T3a (20); T3b (21); T3c (22); T3c1 (23); T3c2 (24); T4 (25); T4a (26); T4b (27);		Clinical T result acc. to TNM classification.	TNM Classification	4.3
101.0	110	Oncological diagnoses	emnpp0001_subdg	tnmcn	cTNM cN	Popup (Label Group)	NX (1); N0 (2); N1 (3); N1a (4); N1b (5); N1c (6); N2 (7); N2a (8); N2b (9); N2c (10); N3 (11); N3a (12); N3b (13); N3c (14)		Clinical N result acc. to TNM classification.	TNM Classification	4.4
101.0	120	Oncological diagnoses	emnpp0001_subdg	tnmcm	cTNM cM	Popup (Label Group)	MX (1); M0 (2); M1 (3); M1a (4); M1b (5); M1c (6)		Clinical M result acc. to TNM classification.	TNM Classification	4.5
101.0	130	Oncological diagnoses	emnpp0001_subdg	tnmcdat	cTNM date	Date (dd.mm.yyyy)			Date of clinical TNM.	TNM Classification	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
101.0	140	Oncological diagnoses	emnpp0001_subdg	tnmpt	pTNM pT	Popup (Label Group)	TX (1); T0 (2); Tis (3); Ta (4); T1 (5); T1a (6); T1a1 (7); T1a2 (8); T1b (9); T1b1 (10); T1b2 (11); T1c (12); T2 (13); T2a (14); T2a1 (15); T2a2 (16); T2b (17); T2c (18); T3 (19); T3a (20); T3b (21); T3c (22); T3c1 (23); T3c2 (24); T4 (25); T4a (26); T4b (27);		Pathological T result acc. to TNM classification.	TNM Classification	4.8
101.0	150	Oncological diagnoses	emnpp0001_subdg	tnmpn	pTNM pN	Popup (Label Group)	NX (1); N0 (2); N1 (3); N1a (4); N1b (5); N1c (6); N2 (7); N2a (8); N2b (9); N2c (10); N3 (11); N3a (12); N3b (13); N3c (14)		Pathological N result acc. to TNM classification.	TNM Classification	4.1
101.0	160	Oncological diagnoses	emnpp0001_subdg	tnmpm	pTNM pM	Popup (Label Group)	MX (1); M0 (2); M1 (3); M1a (4); M1b (5); M1c (6)		Pathological M result acc. to TNM classification.	TNM Classification	4.13
101.0	170	Oncological diagnoses	emnpp0001_subdg	tnmpdat	pTNM date	Date (dd.mm.yyyy)			Date of pathological TNM.	TNM Classification	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
101.0	180	Oncological diagnoses	emnpp0001_subdg	uicc	Tumor stage UICC	Popup (Label Group)	Stage 0 (1); Stage 0is (2); Stage 0a (3); Stage I (4); Stage IA (5); Stage IA1 (6); Stage IA2 (7); Stage IA3 (8); Stage IB (9); Stage IC (22); Stage IE (23); Stage II (10); Stage IIA (11); Stage IIB (12); Stage IIC (13); Stage IIE (24); Stage III (14); Stage IIIA (15); Stage IIIB (16); Stage IIIC (17); Stage IV (18); Stage IVA (19); Stage IVB (20); Stage IVC (21); N/A (66); Unknown (88)		Tumor stage of the current oncological diagnosis acc. to UICC.	Tumor Stage Assessment / Tumor Stage Assessment Result	4.17
101.0	190	Oncological diagnoses	emnpp0001_subdg	stagedat	Tumor stage date	Date (dd.mm.yyyy)			Date of the tumor stage assessment.	Tumor Stage Assessment Event	
101.0	200	Oncological diagnoses	emnpp0001_subdg	tnmgrade	Histopathological Grade (ICD-O / WHO classification)	Popup (Label Group)	GX (1); GB (2); G1 (3); G2 (4); G3 (5); G4 (6); T-cell (7); B-cell (8); Null cell (9); NK cell (10); N/A (66); Unknown (88)		Histopathological grade of the current oncological diagnosis acc. to ICD-O / WHO classification.	Tumor Stage Assessment / Tumor Stage Assessment Result	3.7
101.0	210	Oncological diagnoses	emnpp0001_subdg	gradedat	Histopathological Grade date	Date (dd.mm.yyyy)			Date of the histopathological grade of the current oncological diagnosis.	Tumor Stage Assessment Event	
101.0	220	Oncological diagnoses	emnpp0001_subdg	mloc_pul	Metastasis Pulmonary	Checkbox			Location of metastasis - Pulmonary	Metastasis Presence	4.42
101.0	230	Oncological diagnoses	emnpp0001_subdg	mloc_oss	Metastasis Osseous	Checkbox			Location of metastasis - Osseous	Metastasis Presence	4.42
101.0	240	Oncological diagnoses	emnpp0001_subdg	mloc_hep	Metastasis Hepatic	Checkbox			Location of metastasis - Hepatic	Metastasis Presence	4.42
101.0	250	Oncological diagnoses	emnpp0001_subdg	mloc_bra	Metastasis Brain	Checkbox			Location of metastasis - Brain	Metastasis Presence	4.42
101.0	260	Oncological diagnoses	emnpp0001_subdg	mloc_lym	Metastasis Lymph nodes	Checkbox			Location of metastasis - Lymph nodes	Metastasis Presence	4.42
101.0	270	Oncological diagnoses	emnpp0001_subdg	mloc_mar	Metastasis Bone marrow	Checkbox			Location of metastasis - Bone marrow	Metastasis Presence	4.42
101.0	280	Oncological diagnoses	emnpp0001_subdg	mloc_ple	Metastasis Pleura	Checkbox			Location of metastasis - Pleura	Metastasis Presence	4.42
101.0	290	Oncological diagnoses	emnpp0001_subdg	mloc_per	Metastasis Peritoneum	Checkbox			Location of metastasis - Peritoneum	Metastasis Presence	4.42
101.0	300	Oncological diagnoses	emnpp0001_subdg	mloc_adr	Metastasis Adrenals	Checkbox			Location of metastasis - Adrenals	Metastasis Presence	4.42
101.0	310	Oncological diagnoses	emnpp0001_subdg	mloc_ski	Metastasis Skin	Checkbox			Location of metastasis - Skin	Metastasis Presence	4.42

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
101.0	320	Oncological diagnoses	emnpp0001_subdg	mloc_ome	Metastasis Omentum	Checkbox			Location of metastasis - Omentum	Metastasis Presence	4.42
101.0	330	Oncological diagnoses	emnpp0001_subdg	mloc_oth	Metastasis Others	Checkbox			Location of metastasis - Others	Metastasis Presence	4.42
101.0	340	Oncological diagnoses	emnpp0001_subdg	mloc_unk	Metastasis Unknown	Checkbox			Indicator if location of metastasis is unknown.	Metastasis Presence	4.42
102.1	10	Comorbidities	emnpp0001_subcdiag	icd_catc	ICD-10 Category	Catalog	ICD-10		Category code of the comorbidity acc. to ICD-10.	Problem Condition	
102.1	20	Comorbidities	emnpp0001_subcdiag	icd_catt	ICD-10 Category term	Catalog	ICD-10		Category term of the comorbidity acc. to ICD-10.	Problem Condition	
102.1	30	Comorbidities	emnpp0001_subcdiag	icd_lv4c	ICD-10 Code	Catalog	ICD-10		Code of the comorbidity acc. to ICD-10.	Problem Condition	
102.1	40	Comorbidities	emnpp0001_subcdiag	icd_lv4t	ICD-10 Term	Catalog	ICD-10		Term of the comorbidity acc. to ICD-10.	Problem Condition	
102.1	50	Comorbidities	emnpp0001_subcdiag	dgstdat	Date of initial diagnosis	Date (dd.mm.yyyy)			Initial date of comorbidity.	Problem Condition	
103.1	10	ECOG - Performance status	emnpp0001_subecog	psorres	ECOG performance status	Popup (Label Group)	0 (0); 1 (1); 2 (2); 3 (3); 4 (4); 5 (5); Not done (77)		Result of the ECOG performance status.	Assessment	
103.1	20	ECOG - Performance status	emnpp0001_subecog	psdat	ECOG Assessment date	Checked Date (dd.mm.yyyy)			Date of assessment of the current ECOG performance status assessment.	Assessment Event	
104.1	10	Laboratory	emnpp0001_sublb	lbtest	Laboratory test name	Popup (Label Group)	Albumin (1); ALT (2); AST (3); Bilirubin total (4); Creatinine serum (5); CRP (6); D-dimer (23); Eosinophils abs (7); Eosinophils % (8); Ferritin (22); Glucose blood (9); Hemoglobin (10); IL-6 (24); LDH (107); Leukocytes (11); Lymphocytes abs (12); Lymphocytes % (13); Monocytes abs (14); Monocytes % (15); Neutrophils abs (16); Neutrophils % (17); NTproBNP (26); Potassium (18); Sodium (19); Thrombocytes (20); Troponin (25); TSH (21); Not done (77)		Laboratory test name (acc. to list of tests and if measured).	Lab Test	
104.1	20	Laboratory	emnpp0001_sublb	lborreso	Result operator	Popup (Label Group)	< (1); > (2)		Operator/prefix of the result of the laboratory test.	Lab Result	
104.1	30	Laboratory	emnpp0001_sublb	lborres	Result	Number 5,3			Result of the laboratory test.	Lab Result	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
104.1	40	Laboratory	emnpp0001_sublb	lborresu	Unit	Popup (Label Group)	% (1); 10E3/uL (2); 10E9/L (3); g/dL (12); g/L (4); mg/L (5); mmol/L (6); mU/L (7); ng/L (10); ng/mL (14); pg/mL (13); U/L (8); ug/L (11); umol/L (9)		Unit of the laboratory test result.	Lab Result	
104.1	50	Laboratory	emnpp0001_sublb	lbdatt	Collection date	Checked Date (dd.mm.yyyy)			Collection date of the sample for the current laboratory test.	Lab Test Event	
105.1	10	Tumor marker	emnpp0001_subtm	lbttest	Tumor marker test name	Popup (Label Group)	AFP (101); beta-hCG (102); CA125 (103); CA15-3 (104); CA19-9 (105); CEA (106); Inhibin A (111); Inhibin B (112); LDH (107); NSE (108); PSA (109); S100 (110); Not done (77)		Tumor marker name (acc. to list of tests and if measured).	Lab Test	
105.1	20	Tumor marker	emnpp0001_subtm	lborreso	Result operator	Popup (Label Group)	< (1); > (2)		Operator/prefix of the result of the test.	Lab Result	
105.1	30	Tumor marker	emnpp0001_subtm	lborres	Result	Number 5,3			Tumor marker result	Lab Result	
105.1	40	Tumor marker	emnpp0001_subtm	lborresu	Unit	Popup (Label Group)	kU/L (13); ng/L (16); ng/mL (14); U/L (8); U/mL (10); ug/L (11)		Unit of the the tumor marker result.	Lab Result	
105.1	50	Tumor marker	emnpp0001_subtm	lbdatt	Collection date	Date (dd.mm.yyyy)			Collection date of the sample for the current tumor marker.	Lab Test Event	
106.0	10	Immunohistochemistry / FISH	mnpp0001_pt	pdl1ab	PD-L1 Antibody	Popup (Label Group)	28-8 (rabbit) (1); 22C3 (mouse) (2); SP142 (rabbit) (3); SP263 (rabbit) (4); 73-10 (5); Other (99); Unknown (88); Not done (77)		Used diagnostic PD-L1 antibody	Molecular Test	
106.0	20	Immunohistochemistry / FISH	mnpp0001_pt	pdl1tc	PD-L1 Scale: tumor cells	Popup (Label Group)	0-1% (1); ≥1%-<5% (2); ≥5%-<10% (3); ≥10%-<25% (4); ≥25%-<50% (5); ≥50%-<75% (6); ≥75% (7); Not available (66)		Result for PD-L1 positive tumor cells	Molecular Test Result	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
106.0	30	Immunohistochemistry / FISH	mnpp0001_pt	pdl1ic	PD-L1 Scale: immune cells	Popup (Label Group)	0-1% (1); >=1%-<5% (2); >=5%-<10% (3); >=10%-<25% (4); >=25%-<50% (5); >=50%-<75% (6); >=75% (7); Not available (66)		Result for PD-L1 positive immune cells	Molecular Test Result	
106.0	40	Immunohistochemistry / FISH	mnpp0001_pt	pdl1cpso	PD-L1 CPS operator	Popup (Label Group)	< (1); > (2)		Operator/prefix of the result of the PD-L1 CPS result.	Molecular Test Result	
106.0	50	Immunohistochemistry / FISH	mnpp0001_pt	pdl1cps	PD-L1 CPS	Number 3,0			Result PD-L1 CPS	Molecular Test Result	
106.0	60	Immunohistochemistry / FISH	mnpp0001_pt	pdl1dat	PD-L1 date	Date (dd.mm.yyyy)			Date of PD-L1 assessment.	Lab Test Event	
106.1	70	Immunohistochemistry / FISH	emnpp0001_submm	lbtest	Non-genomic biomarker test name	Popup (Label Group)	Immunohistochemistry - ALK (205); Immunohistochemistry - Androgen receptor (%) (209); Immunohistochemistry - AR-V7 (%) (208); Immunohistochemistry - EGFR (%) (210); Immunohistochemistry - Estrogen (%) (214); Immunohistochemistry - FOLR1 (%) (228); Immunohistochemistry - HER2 (211); Immunohistochemistry - MLH1 (201); Immunohistochemistry - MSH2 (202); Immunohistochemistry - MSH6 (203); Immunohistochemistry - pan-TRK (207); Immunohistochemistry - PMS2 (204); Immunohistochemistry - Progesterone (%) (213); Immunohistochemistry - PTEN (% loss) (212); Immunohistochemistry - ROS1 (206); FISH-Rearrangements - ALK (%) (215); FISH-Rearrangements - FGFR2 (%) (221); FISH-Rearrangements - FGFR3 (%) (222); FISH-Rearrangements - NTRK1 (%) (218); FISH-Rearrangements - NTRK2 (%) (219); FISH-Rearrangements - NTRK3 (%) (220); FISH-Rearrangements - RET (%) (217); FISH-Rearrangements - ROS1 (%) (216); FISH-Amplifications - AR (ratio) (227); FISH-Amplifications - FGFR1 (ratio) (225); FISH-Amplifications - FGFR2 (ratio) (226); FISH-Amplifications - HER2 (ratio) (223); FISH-Amplifications - MET (ratio) (224)		Non-genomic biomarker test name (acc. to list of tests and if measured).	Molecular Test	
106.1	80	Immunohistochemistry / FISH	emnpp0001_submm	folr1_testt	FOLR1 Test type	Popup (Label Group)	VENTANA FOLR1 (FOLR1-2.1) RxDx Assay (1); Biocare Medical Clone 26B3.F2 Antibody (2); Leica BN3.2 Clone Antibody (3); Other laboratory developed test (4); Unknown (88)		Type of FOLR1 test	Molecular Test	
106.1	90	Immunohistochemistry / FISH	emnpp0001_submm	folr1_testtoth	FOLR1 Test type other	Text 40			Other type of FOLR1 test	Molecular Test	
106.1	100	Immunohistochemistry / FISH	emnpp0001_submm	lbint	FOLR1 intensity	Popup (Label Group)	0 (0); 1+ (1); 2+ (2); 3+ (3); N/A (66)		Intensity of FOLR1 test	Molecular Test Result	
106.1	110	Immunohistochemistry / FISH	emnpp0001_submm	lborres	Result	Popup (Label Group)	Negative (0); Positive (1); Equivocal (2); Not done (77)		Alphanumeric result of the non-genomic biomarker test.	Molecular Test Result	
106.1	120	Immunohistochemistry / FISH	emnpp0001_submm	lborresn	Result numeric	Number 3,2			Numeric result of the non-genomic biomarker test.	Molecular Test Result	
106.1	130	Immunohistochemistry / FISH	emnpp0001_submm	lbcnv	FISH amplifications - CNV	Number 2,0			CNV in case of FISH amplification (ratio)	Molecular Test Result	
106.1	140	Immunohistochemistry / FISH	emnpp0001_submm	lbdatt	Collection date	Checked Date (dd.mm.yyyy)			Date of the non-genomic biomarker assessment.	Lab Test Event	
107.1	10	Drug therapies	emnpp0001_exdrug	atc_psubc	ATC Pharmacological subgroup	Catalog	WHO ATC		Pharmacological subgroup of the anti-cancer drug therapy according to WHO ATC catalog.	Substance / Systemic Cancer Therapy	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
107.1	20	Drug therapies	emnpp0001_exdrug	atc_psubt	ATC Pharmacological subgroup term	Catalog	WHO ATC		ATC code of the pharmacological subgroup of the anti-cancer drug therapy according to WHO ATC catalog.	Substance / Systemic Cancer Therapy	
107.1	30	Drug therapies	emnpp0001_exdrug	atc_csubc	ATC Chemical subgroup	Catalog	WHO ATC		Chemical subgroup of the anti-cancer drug therapy according to WHO ATC catalog.	Substance / Systemic Cancer Therapy	
107.1	40	Drug therapies	emnpp0001_exdrug	atc_csubt	ATC Chemical subgroup term	Catalog	WHO ATC		ATC code of the chemical subgroup of the anti-cancer drug therapy according to WHO ATC catalog.	Substance / Systemic Cancer Therapy	
107.1	50	Drug therapies	emnpp0001_exdrug	atc_subc	ATC Chemical substance	Catalog	WHO ATC		Chemical substance of the anti-cancer drug therapy according to WHO ATC catalog.	Substance / Systemic Cancer Therapy	
107.1	60	Drug therapies	emnpp0001_exdrug	atc_subt	ATC Chemical substance term	Catalog	WHO ATC		ATC code of the chemical substance of the anti-cancer drug therapy according to WHO ATC catalog.	Substance / Systemic Cancer Therapy	
107.1	70	Drug therapies	emnpp0001_exdrug	extern	Drug name other	Textarea 3,60			Name of the anti-cancer drug therapy in case it's not available in the WHO ATC catalog or regimen name if the current drug therapy is part of a combination therapy (additional information).	Substance / Systemic Cancer Therapy	
107.1	80	Drug therapies	emnpp0001_exdrug	reldiag	Related oncological diagnosis	Textarea 3,80 (Reference-item)	Reference to icd_lvl4t		Reference to the related oncological diagnoses (ATC term)	Oncology Diagnosis	
107.1	90	Drug therapies	emnpp0001_exdrug	ctril	Clinical trial	Popup (Label Group)	Yes (1); No (0); Unknown (88)		Indicator if this drug therapy is part of a clinical trial.	Clinical Trial Study	
107.1	100	Drug therapies	emnpp0001_exdrug	exsttat	Treatment start date	Date (dd.mm.yyyy)			Start date of the current anti-cancer drug therapy.	Systemic Cancer Therapy	7.5.1 (1st treatment)
107.1	110	Drug therapies	emnpp0001_exdrug	exendat	Treatment stop date	Date (dd.mm.yyyy)			Stop date of the current anti-cancer drug therapy.	Systemic Cancer Therapy	
107.1	120	Drug therapies	emnpp0001_exdrug	exdos	Planned single dose	Number 4,2			Planned absolute single dose of the current anti-cancer drug therapy.	Drug administration event	
107.1	130	Drug therapies	emnpp0001_exdrug	exdosu	Planned single dose unit	Textfield 8			Unit of the absolute single dose of the current anti-cancer drug therapy.	Drug administration event	
107.1	140	Drug therapies	emnpp0001_exdrug	exdosr	Dose reduction	Popup (Label Group)	Yes (1); No (0); Unknown (88)		Was there any dose reduction during this drug therapy?	Drug Prescription	
107.1	150	Drug therapies	emnpp0001_exdrug	exdosrr	Dose reduction reason	Popup (Label Group)	Due to toxicity (1); Doctor's decision (2); Patient's decision (3); Patient forgot (4); Administrative reasons (5); Unknown (88)		Reason for the dose reduction during this drug therapy.	Drug Prescription	
107.1	160	Drug therapies	emnpp0001_exdrug	exdosrp	Dose reduction overall reduction	Popup (Label Group)	1-10% (1); 11-20% (2); 21-30% (3); 31-40% (4); 41-50% (5); 51-60% (6); 61-70% (7); >70% (8); Unknown (88)		Overall reduction in case of a dose reduction during this drug therapy.	Drug Prescription	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
107.1	170	Drug therapies	emnpp0001_exdrug	extreas	Reason to stop drug	Popup (Label Group)	Toxicity (1); Costs (2); Disease progression (3); End of planned therapy (4); No noticeable improvement (5); Cytogenetic resistance (6); Comorbidity (7); Patient choice (8); Death (9); Lost to follow-up (10); Secondary malignancy (11); Unknown (88); Other (99)		Main reason why the current anti-cancer drug therapy has been stopped.	Drug Administration Event	
107.1	180	Drug therapies	emnpp0001_exdrug	exindic2	Indication	Popup (Label Group)	Neoadjuvant (1); Adjuvant (2); Advanced (3); N/A (66); Unknown (88)		Indication of the current anti-cancer drug therapy (neoadjuvant, adjuvant or advanced (non-neoadjuvant and non-adjuvant)).	Systemic Cancer Therapy	
108.1	10	Radiotherapies	emnpp0001_exrt	exproc	Radiotherapy procedure	Popup (Label Group)	External radiotherapy (photons, protons or electrons) (1); Radiosurgery (CyberKnife-GammaKnife) (2); Stereotactic radiotherapy (3); Brachytherapy (4); Systemic radionuclide therapy (5); Intraoperative radiotherapy (6); Radiotherapy with hyperthermia (7); Unknown (88); Other (99)		Procedure of the current radiotherapy.	Radiotherapy Procedure	
108.1	20	Radiotherapies	emnpp0001_exrt	exloc	Target body site	Popup (Label Group)	Acetabulum (1); Anal canal (2); Axilla right (radiotherapy) (3); Brain (4); Cervical (5); Femur (6); Head (7); Humerus (8); Liver (33); Lung (9); Lymph node abdominal (10); Lymph node inguinal (11); Lymph node mediastinal + supraclavicular (12); Lymph node supraclavicular (13); Mamma (14); Mediastinum (15); Mesentery (16); Musculus gluteus maximus (17); Nose (18); Oesophagus (37); Oral cavity (19); Os sacrum + Humerus (20); Osseous (21); Paravertebral (22); Pelvis (23); Pharynx (24); Popliteal fossa (25); Prostate (34); Spine (26); Stomach (35); Sulcus bicipitalis medialis (27); Suprarenal gland (28); Testis (36); Thorax (29); Urinary bladder (30); Vagina (21);		Target body site of the current radiotherapy.	Radiotherapy Procedure	
108.1	30	Radiotherapies	emnpp0001_exrt	reldiag	Related oncological diagnosis	Textarea 3,80 (Reference-item)	Reference to icd_lv4t		Reference to the related oncological diagnoses (ATC term)	Oncology Diagnosis	
108.1	40	Radiotherapies	emnpp0001_exrt	exsttat	Radiotherapy Start date	Date (dd.mm.yyyy)			Start date of the current radiotherapy.	Radiotherapy Procedure	7.5.1 (1st treatment)
108.1	50	Radiotherapies	emnpp0001_exrt	exendat	Radiotherapy Stop date	Date (dd.mm.yyyy)			Stop date of the current radiotherapy.	Radiotherapy Procedure	
108.1	60	Radiotherapies	emnpp0001_exrt	exdos	Radiotherapy total dose	Number 4,1			Total dose of current radiotherapy.	Radiotherapy Procedure	
108.1	70	Radiotherapies	emnpp0001_exrt	exdosu	Radiotherapy total dose unit	Popup (Label Group)	Gy (1); MBq (2); Other (99)		Until of the total dose of current radiotherapy.	Radiotherapy Procedure	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
108.1	80	Radiotherapies	emnpp0001_exrt	explan	Radiotherapy acc. to plan	Popup (Label Group)	Yes (1); No (0); Unknown (88)		Was this radiotherapy performed according to the initial plan?	Radiotherapy Procedure	
108.1	90	Radiotherapies	emnpp0001_exrt	explanr	Radiostherapy not acc. to plan reason	Popup (Label Group)	Due to toxicity (1); Doctor's decision (2); Patient's decision (3); Patient missed therapy (4); Aministrative reasons (5); Unknown (88)		Reason why this therapy was not performed according to the initial plan.	Radiotherapy Procedure	
108.1	100	Radiotherapies	emnpp0001_exrt	exindic2	Indication	Popup (Label Group)	Neoadjuvant (1); Adjuvant (2); Advanced (3); N/A (66); Unknown (88)		Indication of the current anti-cancer drug therapy (neoadjuvant, adjuvant or advanced (non-neoadjuvant and non-adjuvant)).	Radiotherapy Procedure	
109.1	10	Surgeries	emnpp0001_exsurg	chop_lvl2c	CHOP Level 2	Catalog	CHOP 2020		Code of the surgery - level 2 of the CHOP catalog.	Oncology Surgery	7.4 (1st treatment)
109.1	20	Surgeries	emnpp0001_exsurg	chop_lvl2t	CHOP Level 2 term	Catalog	CHOP 2020		Name of the surgery - level 2 of the CHOP catalog.	Oncology Surgery	
109.1	30	Surgeries	emnpp0001_exsurg	chop_lvl3c	CHOP Level 3	Catalog	CHOP 2020		Code of the surgery - level 3 of the CHOP catalog.	Oncology Surgery	7.4 (1st treatment)
109.1	40	Surgeries	emnpp0001_exsurg	chop_lvl3t	CHOP Level 3 term	Catalog	CHOP 2020		Name of the surgery - level 3 of the CHOP catalog.	Oncology Surgery	
109.1	50	Surgeries	emnpp0001_exsurg	reldiag	Related oncological diagnosis	Textarea 3,80 (Reference-item)	Reference to icd_lvl4t		Reference to the related oncological diagnoses (ATC term)	Oncology Diagnosis	
109.1	60	Surgeries	emnpp0001_exsurg	exstdat	Surgery Date	Date (dd.mm.yyyy)			Date of the current surgery.	Oncology Surgery	7.5.1 (1st treatment)
109.1	70	Surgeries	emnpp0001_exsurg	exres	Resection margin	Popup (Label Group)	RX (1); R0 (2); R1 (3); R2 (4); N/A (66); Unknown (88)		Resection margin of the current surgery acc. to pathology report.	Pathology Tumor Assessment Event, Pathology Tumor Assessment, Assessment Result	(6.1)
110.1	10	Other therapies	emnpp0001_exoth	extern	Other therapy	Popup (Label Group)	Cellular therapy (6); High intensity focused ultrasound (HIFU) (3); Hyperthermia (5); Irreversible electroporation (NanoKnife) (2); Radiofrequency ablation (RFA) (1); Other (99)		Type of other anti-cancer therapy in this treatment line (except drug therapy, radiotherapy and surgery).	Medical Procedure	
110.1	20	Other therapies	emnpp0001_exoth	reldiag	Related oncological diagnosis	Textarea 3,80 (Reference-item)	Reference to icd_lvl4t		Reference to the related oncological diagnoses (ATC term)	Medical Procedure	
110.1	30	Other therapies	emnpp0001_exoth	exstdat	Other therapy start date	Date (dd.mm.yyyy)			Start date of current other therapy.	Medical Procedure	7.5.1 (1st treatment)
110.1	40	Other therapies	emnpp0001_exoth	exendat	Other therapy stop date	Date (dd.mm.yyyy)			Stop date of current other therapy.	Medical Procedure	
110.1	50	Other therapies	emnpp0001_exoth	exindic2	Indication	Popup (Label Group)	Neoadjuvant (1); Adjuvant (2); Advanced (3); N/A (66); Unknown (88)		Indication of the current anti-cancer drug therapy (neoadjuvant, adjuvant or advanced (non-neoadjuvant and non-adjuvant)).	Medical Procedure	
111.1	10	Tumor assessments	emnpp0001_tr	respdat	Assessment date	Date (dd.mm.yyyy)			Date of the tumor assessment.	Oncology Disease Assessment Event	8.2.1
111.1	20	Tumor assessments	emnpp0001_tr	resp	Response	Popup (Label Group)	CR - Complete response (1); PR - Partial response (2); SD - Stable disease (3); PD - Progressive disease (4); NE - Not evaluable (5); Non PD, non CR (6); N/A (66); Unknown (88)		Response of the current tumor assessment.	Oncological Disease Assessment Result	(8.1)
111.1	30	Tumor assessments	emnpp0001_tr	respmeth_mri	Method of assessment - MRI	Checkbox			Method of the tumor assessment - MRI.	Oncology Disease Assessment Event	

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111.1	40	Tumor assessments	emnpp0001_tr	respmeth_ct	Method of assessment - CT	Checkbox			Method of the tumor assessment - CT.	Radiological Oncology Disease Assessment	
111.1	50	Tumor assessments	emnpp0001_tr	respmeth_petct	Method of assessment - PET CT	Checkbox			Method of the tumor assessment - PET CT.	Radiological Oncology Disease Assessment	
111.1	60	Tumor assessments	emnpp0001_tr	respmeth_petmri	Method of assessment - PET MRI	Checkbox			Method of the tumor assessment - PET MRI.	Radiological Oncology Disease Assessment	
111.1	70	Tumor assessments	emnpp0001_tr	respmeth_xray	Method of assessment - X-ray	Checkbox			Method of the tumor assessment - X-ray.	Radiological Oncology Disease Assessment	
111.1	80	Tumor assessments	emnpp0001_tr	respmeth_us	Method of assessment - Ultrasound	Checkbox			Method of the tumor assessment - Ultrasound.	Radiological Oncology Disease Assessment	
111.1	90	Tumor assessments	emnpp0001_tr	respmeth_bc	Method of assessment - Biochemical	Checkbox			Method of the tumor assessment - Biochemical.	Biochemical Oncology Disease Assessment	
111.1	100	Tumor assessments	emnpp0001_tr	respmeth_clin	Method of assessment - Clinical	Checkbox			Method of the tumor assessment - Clinical.	Clinical Oncology Disease Assessment	
111.1	110	Tumor assessments	emnpp0001_tr	respmeth_oth	Method of assessment - Other	Checkbox			Method of the tumor assessment - Other.	Oncology Disease Assessment	
111.1	120	Tumor assessments	emnpp0001_tr	respdiss	Dissociated response	Popup (Label Group)	Yes (1); No (0); Unknown (88)		Clinical relevant dissociated response	Oncology Disease Assessment Result	
111.1	130	Tumor assessments	emnpp0001_tr	pd	Type of progression	Popup (Label Group)	Local (1); Regional (2); Metastatic (3); Biochemical (4); Unknown (88); Other (99)		Type of progression at current tumor assessment.	Metastasis Presence	
111.1	140	Tumor assessments	emnpp0001_tr	mloc_pul	Metastasis Pulmonary	Checkbox			Location of new or progressive metastases - Pulmonary	Metastasis Presence	8.6
111.1	150	Tumor assessments	emnpp0001_tr	mloc_oss	Metastasis Osseous	Checkbox			Location of new or progressive metastases - Osseous	Metastasis Presence	8.6
111.1	160	Tumor assessments	emnpp0001_tr	mloc_hep	Metastasis Hepatic	Checkbox			Location of new or progressive metastases - Hepatic	Metastasis Presence	8.6
111.1	170	Tumor assessments	emnpp0001_tr	mloc_bra	Metastasis Brain	Checkbox			Location of new or progressive metastases - Brain	Metastasis Presence	8.6
111.1	180	Tumor assessments	emnpp0001_tr	mloc_lym	Metastasis Lymph nodes	Checkbox			Location of new or progressive metastases - Lymph nodes	Metastasis Presence	8.6
111.1	190	Tumor assessments	emnpp0001_tr	mloc_mar	Metastasis Bone marrow	Checkbox			Location of new or progressive metastases - Bone marrow	Metastasis Presence	8.6
111.1	200	Tumor assessments	emnpp0001_tr	mloc_ple	Metastasis Pleura	Checkbox			Location of new or progressive metastases - Pleura	Metastasis Presence	8.6
111.1	210	Tumor assessments	emnpp0001_tr	mloc_per	Metastasis Peritoneum	Checkbox			Location of new or progressive metastases - Peritoneum	Metastasis Presence	8.6
111.1	220	Tumor assessments	emnpp0001_tr	mloc_adr	Metastasis Adrenals	Checkbox			Location of new or progressive metastases - Adrenals	Metastasis Presence	8.6
111.1	230	Tumor assessments	emnpp0001_tr	mloc_ski	Metastasis Skin	Checkbox			Location of new or progressive metastases - Skin	Metastasis Presence	8.6
111.1	240	Tumor assessments	emnpp0001_tr	mloc_ome	Metastasis Omentum	Checkbox			Location of new or progressive metastases - Omentum	Metastasis Presence	8.6
111.1	250	Tumor assessments	emnpp0001_tr	mloc_oth	Metastasis Others	Checkbox			Location of new or progressive metastases - Others	Metastasis Presence	8.6
111.1	260	Tumor assessments	emnpp0001_tr	mloc_unk	Metastasis Unknown	Checkbox			Indicator if location of metastasis is unknown.	Metastasis Presence	8.6
111.1	270	Tumor assessments	emnpp0001_tr	mloc_na	Metastasis NA	Checkbox			Indicator if no new or progressive metastases are available.	Metastasis Presence	

Form ID	Item ID	Form name	Table name	Variable name	Variable description	Data type	Options (separated by semicolon)	Unit / format	Definition	Ref. SPHN (Concept)	Ref. NICER
111.1	280	Tumor assessments	emnpp0001_tr	pdevclin	Evaluation - clinical evaluation	Checkbox			Indicator if current PD was evaluated clinically by the clinician.	Clinical Oncology Disease Assessment	
111.1	290	Tumor assessments	emnpp0001_tr	pdevrad	Evaluation - radiological evaluation	Checkbox			Indicator if current PD was evaluated radiologically by the clinician.	Radiological Oncology Disease Assessment	
112.1	10	Body weight	emnpp0001_subwgt	lborres_wgt	Body weight BR (kg)	Number 3,1		kg	The body weight of the individual.	Body Weight	
112.1	20	Body weight	emnpp0001_subwgt	lbdatt_wgt	Body weight BR collection date	Checked Date (dd.mm.yyyy)			The date of the body weight measurement.	Body Weight	
113.1	10	Adverse events	emnpp0001_ae	aesoc	CTCAE SOC	Catalog			Adverse event CTCAE System Organ Class	Adverse Event	
113.1	20	Adverse events	emnpp0001_ae	aeterm	CTCAE term	Catalog			Adverse event CTCAE Term	Adverse Event	
113.1	30	Adverse events	emnpp0001_ae	aegrade	CTCAE grade	Catalog			Adverse event CTCAE Grade	Adverse Event	
113.1	40	Adverse events	emnpp0001_ae	aeoth	AE term other	Text 80			Adverse event Term other	Adverse Event	
113.1	50	Adverse events	emnpp0001_ae	aestdat	AE start date	Date (incomplete)			Start date of Adverse event	Adverse Event	
113.1	60	Adverse events	emnpp0001_ae	aeendat	AE stop date	Date (incomplete)			Stop date of Adverse event	Adverse Event	