Nationale Krebsregistrierungsstelle
Organe national d'enregistrement du cancer
Servizio nazionale di registrazione dei tumori
National Agency for Cancer Registration

Kinderkrebsregister
Registre du cancer de l'enfant
Registro dei tumori pediatrici
Childhood Cancer Registry

NATIONAL CANCER DATA DICTIONARY

V 1.1

Part B2

SUPPLEMENTARY VARIABLES

Children

Adolescents

15.10.2019

CONTENTS

SUPPLEMENTARY DATA

Supplementary data will be collected for all neoplasms diagnosed in children and adolescents

This includes all reportable neoplasms as described in the document “A_Data Dictionary of Basic Variables”.

PATIENT DATA

MEDICAL CONDITIONS

Predispositions, prior diseases & comorbidities

Inherited predispositions*

Variable number: **9.1**

Item length: 2

Item format: Number

Definition

The data item records the patient's inherited medical conditions.

Rationale

Pre-existing medical conditions may increase the risk of developing particular types of cancer.

Code	Label	Description /clinical Manifestation
1	Familial ovarian cancer	BRCA1/2 mutations; ICD10 Z80.4
2	Familial prostate cancer	ICD10 Z80.4
3	Hereditary breast and ovarian cancer syndrome (HBOC)	BRCA1/2 mutations; ICD10 Z80
4	Hereditary breast cancer	BRCA1/2 mutations; ICD10 Z80.3
5	Li-Fraumeni syndrome	TP53 mutation; ICD10 D48.9
6	Nijmegen breakage syndrome	Microcephaly, other malformations; mutations NBS1 gene; incr. risk for breast and other cancer; ICD10 Q87.8
7	Saethre-Chotzen syndrome	Craniosynostosis, other malformations; TWIST1; ICD10 Q87.0
8	Familial adenomatous polyposis	Hundreds to thousands of adenomas in the rectum and colon; mutation in the APC gene; ICD10 D12.6
9	Juvenile gastrointestinal polyposis	Hamartomatous polyps in the gastrointestinal tract; ICD10 D12.6
10	Peutz-Jeghers syndrome	Hamartomatous polyps, mucocutaneous pigmentation in the gastrointestinal tract; ICD10 Q85.8
11	Hyperplastic polyposis syndrome	Pancolonic multiple hyperplastic serrated polyps; ICD10 D12.6
12	Hereditary mixed polyposis syndrome	Higher numbers of polyps at younger ages. risk for colon cancer; ICD10 D12.6
13	Familial or hereditary nonpolyposis colorectal cancer (HNPCC)	DNA mismatch repair (MMR) genes mutation. ICD10 C18.9
14	McCune-Albright syndrome	Fibrous dysplasia, café au lait, mutation GNAS gene; ICD10 Q78.1
15	Bannayan-Riley-Ruvalcaba syndrome	PTEN mutation; ICD10 Q87.8
16	Cowden syndrome	Multiple hamartomas; PTEN mutation; ICD10 Q85.8
17	Bloom syndrome	BLM mutation; ICD10 Q82.2

National usage

*The variable is to be submitted to the NACR (National Agency for Cancer Registration) via the responsible cantonal cancer registry.

References

>Familial ovarian cancer, Familial prostate cancer, Hereditary breast and ovarian cancer syndrome, Hereditary breast cancer, Li-Fraumeni syndrome: Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology.
>Nijmegen breakage syndrome: Int J Cancer. 2008 Feb 15;122(4):802-6. Nijmegen Breakage Syndrome mutations and risk of breast cancer. Bogdanova N(1), Feshchenko S, Schürmann P, Waltes R, Wieland B, Hillemanns P, Rogov YI, Dammann O, Bremer M, Karstens JH, Sohn C, Varon R, Dörk T.
>Saethre-Chotzen syndrome breast cancer: Genes Chromosomes Cancer. 2007 Jul;46(7):656-60. Women with Saethre-Chotzen syndrome are at increased risk of breast cancer. Sahlin P(1), Windh P, Lauritzen C, Emanuelsson M, Grönberg H, Stenman G.
>Familial adenomatous polyposis colon : Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
>Juvenile gastrointestinal polyposis colon cancer : Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
>Peutz-Jeghers syndrome: Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
>Hyperplastic polyposis syndrome : Evidenced-based Guideline for Colorectal Cancer, long version 1.0, AWMF registration number: 021-007OL, http://leitlinienprogrammonkologie.de/Leitlinien.7.0.html
>Hereditary mixed polyposis syndrome: Evidenced-based Guideline for Colorectal Cancer, long version 1.0, AWMF registration number: 021-007OL, http://leitlinienprogrammonkologie.de/Leitlinien.7.0.html
>Familial nonpolyposis colorectal cancer : Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
>McCune-Albright syndrome: Increased Risk of Breast Cancer at a Young Age in Women with Fibrous Dysplasia. Majoor BC, Boyce AM, Bovée JV, Smit VT, Collins MT, Cleton-Jansen AM, Dekkers OM, Hamdy NA, Dijkstra PS, Appelman-Dijkstra NM. J Bone Miner Res. 2018 Jan;33(1):84-90. doi: 10.1002/jbmr.3286. Epub 2017 Sep 20. PMID:28856726
>Bannayan-Riley-Ruvalcaba syndrome: Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
>Cowden syndrome: Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
>Bloom syndrome: Hereditary Cancer Predisposition Syndromes, J Clin Oncol 23:276-292. 2005 by American Society of Clinical Oncology
> https://icd.who.int/dev11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f264268169

Notes

>Multiple predispositions may be registered for each diagnosis.
>This variable from the adult supplementary dataset will also be used for any cases of colorectal (ICD10 C18-C20), breast (ICD10 C50) and prostate (ICD10 C61) cancer in children and adolescents in order to analyse these malignancies across all age groups.

Type of medical condition

Variable number: **9.2**

Item length: 1

Item format: Number

Definition

The data item identifies medical conditions which predispose to the development of cancer, are relevant to treatment decisions or possible late effects of cancer therapy.

Rationale

The information is used to adjust outcome statistics when evaluating patient survival and other outcomes

Code	Label	Description
1	Predisposition	Condition present at birth that predisposes to the development of cancer. Predispositions may be inherited syndromes (e.g. neurofibromatosis), or first present in the child who later developed cancer (e.g. Trisomy 21).
2	Prior disease	Non-inherited condition that predisposes to the development of cancer, or is relevant to treatment decisions or possible late effects. Prior diseases may be infections (e.g. HIV), hearing loss diagnosed before any ototoxic chemotherapy or a previous benign neoplasm.
3	Comorbidity	Comorbidities: diseases present at the time of the cancer diagnosis that may affect patient treatment and/or survival.

National usage

The variable is not to be submitted to the NACR.

References (not exhaustive selection)

Eeles RA, Easton DF Ponder BAJ et al. (Eds) Genetic predisposition to cancer,2nd Edition (2003) CRC Press London ISBN 9780429102936 https://doi.org/10.1201/b13271

Godley LA and Shimamura A. (2017). Genetic predisposition to hematologic malignancies: management and surveillance. Blood 2017 130:424-432; doi: https://doi.org/10.1182/blood-2017-02-735290

Jongmans MC, Loeffen JL, Waanders E, et al. (2016) Recognition of genetic predisposition in pediatric cancer patients: An easy-to-use selection tool. Eur J Med Genet. 2016 Mar;59(3):116-25. doi: 10.1016/j.ejmg.2016.01.008. Epub 2016 Jan 26. Review.

Postema FAM, Hopman SMJ, Hennekam RC, Merks JHM. Consequences of diagnosing a tumor predisposition syndrome in children with cancer: A literature review. Pediatr Blood Cancer. 2018 Jan;65(1). doi: 10.1002/pbc.26718. Epub 2017 Aug 22.

Saletta F, Dalla Pozza L, Byrne JA.Genetic causes of cancer predisposition in children and adolescents. Transl Pediatr. 2015 Apr;4 (2):67-75. doi: 10.3978/j.issn.2224-4336.2015.04.08.

Medical condition ICD version

Variable number: **9.3**

Item length: 2

Item format: Number

Definition

This data item records the version of the International Classification of diseases published by the World Health Organization (WHO) used to code the diagnosis.

Rationale

The International Classification of diseases (ICD) forms traditionally the basis for most types of cancer reporting. It is regularly updated to include the progress in medical knowledge.

Code	Label	Description
10	ICD-10 WHO	English WHO version; or the official (SFSO) translation of the WHO version into German (ICD-10-GM), French and Italian.
11	ICD-11 WHO	

National usage

The variable is not to be submitted to the NACR.

References

>www.who.int/classifications/icd/en [last accessed: 27.12.2018].
>www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/nomenklaturen/medkk/instrumente-medizinische-kodierung [last accessed: 29.12.2018].

Notes

>The German modification of ICD-10 (ICD-10-GM) is used in Switzerland. ICD-10-GM is based on ICD-10 (WHO) and is issued by the “Deutschen Institut für Medizinische Dokumentation und Information” (DIMDI). DIMDI issues yearly updates, which are implemented in Switzerland every two years.

Medical condition ICD code

Variable number: **9.4**
Item length: 255
Item format: Text

Definition

Predispositions, prior diseases or comorbidities, which can be classified using ICD-10. Disease code of the International Classification of diseases published by the World Health Organization (WHO. The item is entered without a decimal point.

Rationale

The information is used to adjust outcome statistics when evaluating patient survival and other outcomes

Code examples#	Label
Q850	Neurofibromatosis (non-malignant); von Recklinghausen disease
Q909	Down syndrome, unspecified; Trisomy 21 NOS
Z806	Family history of leukaemia
B210	HIV disease resulting in Kaposi sarcoma
D225	Melanocytic naevi of trunk
H900	Conductive hearing loss, bilateral
E102	Type 1 diabetes mellitus with renal complications

#: only examples are shown to reduce table size

National usage

The variable is not to be submitted to the NACR.

References

> https://icd.who.int/browse10/2016/en [last accessed: 27.12.2018].
>www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/nomenklaturen/medkk/instrumente-medizinische-kodierung [last accessed: 29.12.2018].

Notes

>The German modification of ICD-10 (ICD-10-GM) is used in Switzerland. ICD-10-GM is based on ICD-10 (WHO) and is issued by the "Deutschen Institut für Medizinische Dokumentation und Information" (DIMDI). DIMDI issues yearly updates, which are implemented in Switzerland every two years.

>Predispositions can have an ICD code and/or an OMIM code. Therefore, both coding systems are necessary to record all reported predispositions.

Medical condition OMIM® code

Variable number: **9.5**
Item length: 7
Item format: Alphanumeric

Definition:
Online Mendelian Inheritance in Man® (OMIM®) code for the inherited condition or gene present that results in a predisposition to develop cancer.

Rationale
The OMIM® database contains information on all known Mendelian disorders and over 15,000 genes and is updated daily. Any reported inherited cancer predisposing condition/gene can be recorded using the appropriate code.

Code examples#	Label	Description
#180200	RB1	Hereditary (familial) retinoblastoma
#194072	WAGR	Wilms tumour, aniridia, genitourinary anomalies and mental retardation syndrome
*600185	BRCA2	BRCA2 gene
#162200	NF1	Neurofibromatosis Type I, von Recklinghausen disease
162260	NF3	Neurofibromatosis Type III

#: only examples are shown to reduce table size

National usage
The variable is not to be submitted to the NACR.

References
www.omim.org
Feurstein S, Drazer MW & Godley LA. (2016) Genetic predisposition to leukemia and other hematologic malignancies. Seminars in Oncology 43 (2016) 598-608

Notes
>Predispositions can have an ICD code and/or an OMIM® code. Therefore, both coding systems are necessary to record all reported predispositions.

Late effects

Late effect date of diagnosis

Variable number: **9.6.1**
Item length: 10
Item format: Date

Definition
This data item records the date when a late effect of cancer treatment was first diagnosed.

Rationale
Late effects of cancer treatment can occur immediately (e.g. after CNS surgery) or be diagnosed after a period of time (e.g. ototoxic hearing loss after cisplatin treatment)

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Late effect date accuracy

Variable number: **9.6.2**
Item length: 1
Item format: Number

Definition
The data item indicates the accuracy of the date when the late effect was diagnosed

Rationale
The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Late effect ICD version

Variable number: **9.7**

Item length: 2

Item format: Number

Definition

This data item records the version of the International Classification of diseases published by the World Health Organization (WHO) used to code the diagnosis.

Rationale

The International Classification of diseases (ICD) forms traditionally the basis for most types of cancer reporting. It is regularly updated to include the progress in medical knowledge.

Code	Label	Description
10	ICD-10 WHO	English WHO version; or the official (SFSO) translation of the WHO version into German (ICD-10-GM), French and Italian.
11	ICD-11 WHO	

National usage

The variable is not to be submitted to the NACR.

References

>www.who.int/classifications/icd/en [last accessed: 27.12.2018].
>www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/nomenklaturen/medkk/instrumente-medizinische-kodierung [last accessed: 29.12.2018].

Notes

>The German modification of ICD-10 (ICD-10-GM) is used in Switzerland. ICD-10-GM is based on ICD-10 (WHO) and is issued by the "Deutschen Institut für Medizinische Dokumentation und Information" (DIMDI). DIMDI issues yearly updates, which are implemented in Switzerland every two years.

Late effect ICD code

Variable number: **9.8**

Item length: 4

Item format: Alphanumeric

Definition

Disease code of the International Classification of diseases published by the World Health Organization (WHO. The item is entered without a decimal point.

Rationale

This item allows the identification and reporting of medical conditions that appeared after, or as a result of cancer treatment.

Code examples#	Label
E231	Drug-induced hypopituitarism
H910	Ototoxic hearing loss
M965	Post-radiation scoliosis

#: only examples are shown to reduce table size

National usage

The variable is not to be submitted to the NACR.

References

> https://icd.who.int/browse10/2016/en [last accessed: 27.12.2018].
>www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/nomenklaturen/medkk/instrumente-medizinische-kodierung [last accessed: 29.12.2018].

Notes

>The German modification of ICD-10 (ICD-10-GM) is used in Switzerland. ICD-10-GM is based on ICD-10 (WHO) and is issued by the "Deutschen Institut für Medizinische Dokumentation und Information" (DIMDI). DIMDI issues yearly updates, which are implemented in Switzerland every two years.

DIAGNOSIS

Tumour related prognostic information: Childhood and adolescent cancers

- In children and adolescent cancers, molecular markers, karyotype and/or methylation patterns will be recorded in the same manner as the tumour related prognostic information for cancers of the breast, prostate etc. in the basic dataset.

Molecular or cytogenetic marker(s) tested

Variable number: **5.7.1**
Item length: 128
Item format: Alphanumeric

Definition
Molecular genetics, methylation status or cytogenetics test result in a text format.

Rationale
Changes from the normal karyotype, methylation status and/or changes in specific genes associated with cancer can affect the disease prognosis. Newer ICD-O morphology codes can be used to classify cancers with known molecular changes, diagnosed in years where these codes were not yet available.

Code Examples*	Description
Karyotype	Karyotype of malignant cells
NMYC	NMYC oncogene
CMYC	CMYC oncogene
NTRK	Neurotrophic tyrosine kinase receptor gene
BRAF V600E	BRAF gene with val600-to-glu mutation
BRCA2	BRCA2 gene
9877/3	Acute myeloid leukaemia with mutated NPM1
9912/3	Acute myeloid leukaemia with BRC-ABL1

#: only examples are shown to reduce table size

National usage
The variable is not to be submitted to the NACR.

References
Dupain C, Harttrampf AC, Urbinati G, et al. (2017)Relevance of fusion genes in pediatric cancers : Toward precision medicine..Mol Ther Nucleic Acids. 2017 Mar 17; 6:315-326. doi: 10.1016/j.omtn.2017.01.005. Epub 2017 Feb 9..

Arber DA, Orazi A, Hasserjian R, et al. (2016) The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia Blood,127:2391-2405; doi: https://doi.org/10.1182/blood-2016-03-643544

Notes
>The combined molecular genetics test results can be used to assess prognosis over many years of registration, including time periods where specific ICD-O morphology codes were not yet available.

Molecular or cytogenetic marker(s) test result

Variable number: **5.7.2**
Item length: 2
Item format: Number

Definition
Molecular genetics, methylation status or cytogenetics test result in a code format to identify changes in gene(s) and/or karyotype which are important for cancer prognosis.

Rationale
The codes record the specific gene changes identified in the malignant cells. The changes can positively or negatively affect the cancer prognosis, and/or which treatment is given.

Code	Label
0	Negative
1	Positive
2	Mutation / mutated
3	Amplified / overexpressed
4	Loss / deletion
5	Fusion / translocation
6	Break apart
7	Hypodiploid
8	Wild type / normal / diploid
9	Hyperdiploid
10	Triploid
11	Tetraploid
12	Hypomethylated
13	Hypermethylated
14	Inactivated
15	Activated
16	Copy number variant
17	Good prognosis
18	Intermediate prognosis
19	Poor prognosis
20	No prognostic value
21	New molecular ICD-O code

National usage
The variable is not to be submitted to the NACR.

Notes
The combined molecular genetics test results can be used to assess prognosis over many years, including time periods where specific ICD-O morphology codes were not yet available.

TREATMENT

First treatment complex/ Further treatments

- In children and adolescents, all treatments will be recorded. The first treatment complex is part of the basic dataset and will be submitted to the NACR via the responsible cantonal cancer registry. Subsequent treatments will not be submitted to the NACR.
- Variables 7.1 -7.6 (inclusive) are from the basic dataset.

Basis of (first) treatment complex decision(s)

Variable number: **7.1**

Item length: 1

Item format: Number

Definition

This data item records the basis of treatment decision(s) for the entire first treatment complex, and subsequent treatments. In most cases the first treatment decision is discussed and agreed in multidisciplinary tumour boards. A tumour board is an interdisciplinary medical committee that develops an individual treatment plan for patients with a malignant disease.

Rationale

The information serves to evaluate the treatment quality.

Code	Label	Description
1	Tumour board	An interdisciplinary medical committee.
2	Other (not specified)	Not a tumour board.
9	Unknown	The basis of treatment decision is unknown.

National usage

The variable is to be submitted to the NACR for the first treatment complex only.

References

Notes

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Date of (first) treatment complex decision

Variable number: **7.2.1**

Item length: 10

Item format: Date

Definition

This data item records the date when the treatment decision was made. To be recorded for the first treatment complex, and for any additional treatment decisions.

Rationale

This information is used to evaluate treatment quality.

Code examples#	Description
01.01.2005	For single digit day or month, record with a leading 0
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

#: only examples are shown to reduce table size

National usage

The variable is to be submitted to the NACR for the first treatment complex only with day set to unknown (i.e. 15). In addition, the accompanying age in days is to be submitted to the NACR.

References

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Notes

> If the treatment decisions were made in more than one tumourboard, the date of the first tumourboard is recorded.

Accuracy for date of (1st) treatment complex decision

Variable number: **7.2.2**

Item length: 1

Item format: Number

Definition

The data item indicates the accuracy of the date when the treatment decision was made.

Rationale

The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage

The variable is to be submitted to the NACR for the first treatment complex decision only..

References

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Notes

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(First) treatment goal(s)

Variable number: **7.3**

Item length: 1

Item format: Number

Definition

The data item records the goal for the first treatment complex and any additional treatments.

Rationale

Quality assessment of treatment patterns depends on the goal of the first treatment complex.

Code	Label	Description
1	Curative	A treatment approach with the aim to remove the tumour, rid the body of wandering cancer cells, and prevent a recurrence.
2	Palliative	The purpose of palliative treatment is to relieve the symptoms and to improve quality of life in cases, when curative treatment is impossible
9	Unknown	

National usage

The variable is to be submitted to the NACR for the first treatment complex only.

References

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Notes

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CHOP Treatment Code

Variable number: **7.4**
Item length: 8 (max)
Item format: Alphanumeric

Definition
The data item records the CHOP code, or NACR-assigned CHOP-like code for treatments where no CHOP code exists, for each treatment. CHOP is the Swiss classification of surgical operations and other diagnostic and treatment procedures and interventions.

Rationale
This information is readily available at the sources (clinics, physicians) in standardized and updated form. Treatment indicators at the system level will be compared with evidence-based guidelines.

Code examples#	Label	Description
85.21	Local excision of a lesion on the breast	CHOP procedure code used by Swiss treatment institutions.
85.45.00	Radical mastectomy, not otherwise specified	CHOP procedure code used by Swiss treatment institutions.
…	…	
99.2R.01	Hormontherapy, NOS	CHOP-like code created for cancer registration use only.
998	No treatments planned	CHOP-like code created for cancer registration use only.
…	…	
999	Unknown	No information in patients records.

#: only examples are shown to reduce table size

National usage
The variable is to be submitted to the NACR for the first treatment complex only.

References

Notes
>CHOP codes include specific codes for autologous and allogenic stem cell transplants, and different forms of radiotherapy

Start date of treatment

Variable number: **7.5.1**
Item length: 10
Item format: Date

Definition
The data item records the dates when each treatment of the first treatment complex (or later treatments in children and adolescents) has been started.

Rationale
This information is used to evaluate treatment quality. It is important to measure the delay between diagnosis and treatment, as well as the time intervals between treatments, and between treatment and recurrence.

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is to be submitted to the NACR for the first treatment complex only with day set to unknown (i.e. 15).

References
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Notes

Accuracy for start date of treatment

Variable number: **7.5.2**
Item length: 1
Item format: Number

Definition
Indicates the accuracy of the date(s) when each treatment has started.

Rationale
The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage
The variable is to be submitted to the NACR for the first treatment complex only.

References
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Notes

Treatment institution

Variable number: **7.6**
Item length: 255
Item format: Text

Definition

The data item records the name and address of the responsible person and institution submitting treatment information to the cancer registry.

Rationale

This information allows providing quality feedback to those institutions requesting it. It also allows regional and national statistical reports on the relative contribution of different types of institutions treating cancer patients.

National usage
The variable is not to be submitted to the NACR.

References

->Medical practices: GLN (Global Location Number) www.refdata.ch/de/weitere-leistungen/swiss-rx-login
>Hospitals: official hospital lists www.bag.admin.ch/bag/de/home/zahlen-und-statistiken/zahlen-fakten-zu-spitaelern/spital-suchen

Notes

>Addresses will be taken from uniform national lists of health service providers.
>Metadata for the institution responsible for treatment will also be registered to facilitate the exchange of information.
>The cancer registries define, and update on a regular basis, the official address of all responsible persons and hospital units submitting cancer information.
>Multiple persons or institutions may be registered per diagnosis.

Other standard chemotherapy or systemic therapy

Standard drug combinations

Variable number: **11.1**
Item length: 32
Item format: Alphanumeric (dropdown)

Definition
This item identifies standard chemotherapy combinations, which are not part of a clinical trial

Rationale
Chemotherapy combinations can be used to identify patients at risk of suffering treatment related late effects (e.g. hearing loss after cisplatin), and to compare survival.

Code examples#	Description
BEACOPP	Bleomycin, Etoposide, Doxorubicin (Adriamycin), Cyclophosphamide, Vincristin (Oncovin), Procarbazine, Prednisolone
R-CVP	Rituximab (Mabthera), Cyclophosphamide, Vincristine, Prednisolone
VIDE	Vincristine, Ifosfamide, Doxorubicin, Etoposide

#: only examples are shown to reduce table size

National usage
The variable is not to be submitted to the NACR.

References
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Notes

ATC code(s)

Variable number: **11.2**
Item length: 7
Item format: Alphanumeric

Definition
ATC code(s) for the drugs of interest used in cancer treatment (chemotherapy, immunotherapy, targeted, hormonal or other systemic therapy)

Rationale
This standardised code for cancer treatment drugs can be used to identify patients who received drugs with potentially harmful side effects (e.g. cisplatin)

Code examples#	Generic name
L01XA02	Carboplatin
L01XC02	Rituximab
L01XE01	Imatinib

#: only examples are shown to reduce table size

National usage
The variable is not to be submitted to the NACR.

References
- www.whocc.no/atc_ddd_index

Carmen Martos, Emanuele Crocetti (Coordinator), Otto Visser, Brian Rous, Francesco Giusti and the Cancer Data Quality Checks Working Group, A proposal on cancer data quality checks: one common procedure for European cancer registries – version 1.1, EUR 29089 EN, Publications Office of the European Union, Luxembourg, 2018,

Notes
ATC codes may be entered individually for single drugs or generated automatically from the standard drug combination selected in the previous variable

1st treatment complex end date

Variable number: **11.3.1**
Item length: 10
Item format: Date

Definition
The end date of all treatments which together comprise the first treatment complex.

Rationale
This date will be used to distinguish between treatments which are part of the first treatment complex and later treatments (e.g. after a relapse)

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is not to be submitted to the NACR.

References
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Notes

Accuracy for end date of 1st treatment complex

Variable number: **11.3.2**
Item length: 1
Item format: Number

Definition
The data item indicates the accuracy of the date when the 1st treatment complex ended

Rationale
The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Treatment end date

Variable number: **11.4.1**
Item length: 10
Item format: Date

Definition
The end date of all treatments for this case, including after all relapses, progressions or transformations

Rationale
Can be used in survival analyses, or to calculate the length of time a patient spends in remission.

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Accuracy of treatment end date

Variable number: **11.4.2**
Item length: 1
Item format: Number

Definition
The data item indicates the accuracy of the date when all treatments ended

Rationale
The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Study participation

Study patient

Variable number: **12.1**
Item length: 1
Item format: Number

Definition
This data item differentiates between patients who are enrolled in trials, treated according to standard therapy protocols, and those who are not.

Rationale
Therapy outcome and patient survival can vary according to the use or non-use of standard treatment protocols.

Code	Description
0=missing	No information, default
1=SP: study patient according to protocol	Patient officially enrolled in a clinical trial protocol and receiving highly standardized treatment and follow-up
2=NA: non-study patient according to protocol	Patient not enrolled in a trial, but following the same standard treatment protocol.
3=NO: non-study patient not according to protocol	Patient not enrolled in a trial protocol and not following a standard treatment protocol.
9=unknown	Unclear if patient is treated according to a standard protocol or not

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Type of study

Variable number: **12.2**
Item length: 1
Item format: Number

Definition
This item identifies the study protocol type, not all are randomised studies

Rationale
This variable is part of the identifying characteristics of study protocols followed in Switzerland

Code	Description
0	No information, default
1	1=Clinical/Therapeutic
2	2=Research project chapter 2
3	3=Research project chapter 3
4	4=Registry
5	5=Biological
6	6=CH only Clinical (old)
9	9=Unknown what kind of study

National usage
The variable is not to be submitted to the NACR.

References
-www.spog.ch

Notes

Study protocol

Variable number: **12.3**
Item length: 64
Item format: Alphanumeric (dropdown)

Definition
Official name of study protocol, as published by the study organisers, or in the SPOG list of study protocols

Rationale
This variable can be used in analyses of survival and other outcomes, in groups of patients with the same disease but who are treated according to different study protocols

Code examples#
AIEOP-BFM ALL 2009
I-HIT-MED Register
SPOG 2015 FN Definition

#: only examples are shown to reduce table size

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Regimen

Variable number: **12.4**

Item length: 32

Item format: Dropdown Text

Definition

This data item identifies exactly which treatment arm and/or chemotherapeutic drugs are used, and to which treatment arm a patient has been randomised or assigned.

Rationale

Different therapy arms and regimens contain different treatment modalities, and are used to treat different risk groups

Code examples#	Description
SR R1	Standard risk, good responders (R1)
HR R2	High risk , poor responders (R2)
A	Treatment arm A

#: only examples are shown to reduce table size

National usage

The variable is not to be submitted to the NACR.

References

-

Notes

Protocol modified

Variable number: **12.5**
Item length: 1
Item format: Number

Definition
This item identifies departures from standard pre-defined treatment protocols

Rationale
Treatment protocols can be modified in the event of a drug allergy, or adverse events e.g. by substituting one drug for another, or by reducing the standard drug dose.

Code	Label
0	No, treatment protocol was not modified
1	Yes, treatment was not given exactly according to the protocol

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Date patient left study

Variable number: **12.6.1**
Item length: 10
Item format: Date

Definition
This item shows if a patient left a study before finishing all planned treatments

Rationale
There may be differences in survival or response if a patient did not receive the full planned course of treatment.

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Study leaving date accuracy

Variable number: **12.6.2**

Item length: 1

Item format: Number

Definition

The data item indicates the accuracy of the date when the patient left the study early

Rationale

The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage

The variable is not to be submitted to the NACR.

References

-

Notes

REMISSION STATUS AND FOLLOW UP

Date of remission status or clinical follow-up

Variable number: **13.1.1**
Item length: 10
Item format: Date

Definition
The date at which remission status was ascertained, after some or all treatment, or the date of routine clinical follow-up.

Rationale
This can be used to calculate time to remission, or the percentage of patients reaching complete remission in different disease groups. This can be used to follow the course of disease in individual patients.

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Accuracy of date of remission status/clinical follow up

Variable number: **13.1.2**
Item length: 1
Item format: Number

Definition
The accuracy of the remission status date

Rationale
The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Remission status

Variable number: **13.2**
Item length: 1
Item format: Number

Definition
The remission status reached on the specified date of assessment or routine clinical follow-up

Rationale
This can be used to calculate the percentage of patients reaching complete remission in different disease groups or after different therapies, and follow the course of disease in individual patients.

Code	Label
1	1=Complete remission / in remission
2	2=Partial remission
3	3=Stable disease (evidence of disease, otherwise well) needs no treatment
4	4=Favourable response (retinoblastoma)
5	5=Progressive disease
6	6=Relapse/in treatment for relapse
9	9=Unknown

National usage
The variable is not to be submitted to the NACR.

References
-

Notes
NB A patient can have several clinical follow-ups while in treatment for relapse, or with slow tumour progression without an urgent need for treatment. Therefore this is not identical to the variable defining the date of relapse or progression.

Disease specific remission status

Disease specific remission status will be collected for leukaemia, lymphoma and multiple myeloma only

Date of complete remission assessment

Variable number: **14.1.1**
Item length: 10
Item format: Date

Definition
Date of complete remission assessment for specific diseases

Rationale
This variable is used to measure treatment success at defined timepoints and assign the correct treatment risk group

Code examples	Description
01.01.2005	For single digit day or month, record with a leading 0.
15.01.2005	Exact day unknown: set day as 15th of the respective month.
30.06.2005	Exact day and month unknown: set date as 30th of June of the respective year.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes
To be used for leukaemias, lymphomas and multiple myelomas only

Accuracy of date of complete remission status assessment

Variable number: **14.1.2**
Item length: 1
Item format: Number

Definition
The accuracy of the complete remission status date

Rationale
The data item is used to identify groups of patients where ages or time periods are not known with certainty (e.g. for sensitivity analyses).

Code	Label	Description
0	Exact date	All date components are known.
1	Day uncertain	The day in date is imputed.
2	Day/Month uncertain	The day and month in date are imputed.
3	Estimated date	All date components are imputed.

National usage
The variable is not to be submitted to the NACR.

References
-

Notes

Type of complete remission

Variable number: **14.2**
Item length: 1
Item format: Number

Definition
The assessment of remission status either by microscopic examination of representative bone marrow and cerebrospinal fluid (morphological remission) or by the used of flow cytometry or polymerase chain reaction on bone marrow samples to detect minimal residual disease (MRD)

Rationale
Detection of minimal residual disease (MRD) is the most sensitive method to evaluate treatment response and one of the strongest predictors of outcome in childhood acute lymphoblastic leukemia (ALL). In the past morphological remission was used to evaluate treatment response.

Code examples	
1	1-morphological remission
2	2-MRD (minimal residual disease)

National usage
The variable is not to be submitted to the NACR.

References
-van der Velden VH, Hochhaus A, Cazzaniga et al. (2003) Detection of minimal residual disease in hematologic malignancies by real-time quantitative PCR: principles, approaches, and laboratory aspects. Leukemia 17, 1013-1034

-Dworzak MN, Froschl G, Printz D et al. (2002)Prognostic significance and modalities of flow cytometric minimal residual disease detection in childhood acute lymphoblastic leukemia. Blood 99, 1952-1958.

- AIEOP-BFM ALL 2009 Study protocol EudraCT Number: 2007-004270-43

Notes
To be used for leukaemias, lymphomas and multiple myelomas only. Morphological remission is assessed at day 33 in lymphoid leukaemias and at the start of subsequent treatment elements. MRD is assessed at day 33 and week 12 and at later dates for high risk (HR) patients.

Result

Variable number: **14.3**
Item length: 1
Item format: Number

Definition
The result of the complete remission assessment

Rationale

Code	Label
1	1-positive / not in complete morphological remission /MRD positive
2	2-slow early responder/MRD weakly positive
3	3-negative / in complete morphological remission / MRD negative
4	4-unclear / cannot be assessed
9	9-unknown

National usage
The variable is not to be submitted to the NACR.

References

--van der Velden VH, Hochhaus A, Cazzaniga et al. (2003) Detection of minimal residual disease in hematologic malignancies by real-time quantitative PCR: principles, approaches, and laboratory aspects. Leukemia 17, 1013-1034

-Dworzak MN, Froschl G, Printz D et al. (2002)Prognostic significance and modalities of flow cytometric minimal residual disease detection in childhood acute lymphoblastic leukemia. Blood 99, 1952-1958.

- AIEOP-BFM ALL 2009 Study protocol EudraCT Number: 2007-004270-43

-Flohr T, Schrauder A, Cazzaniga G, et al.(2008) Minimal residual disease-directed risk stratification using real-time quantitative PCR analysis of immunoglobulin and T-cell receptor gene rearrangements in the international multicenter trial AIEOP-BFM ALL 2000 for childhood acute lymphoblastic leukemia. Leukemia. 22(4):771-82.

Notes
MRD at day 33 and week 12 is used for ALL risk group assessment, and to decide on treatment, it is more important for risk group classification than morphological remission ,

APPENDIX

Changes made between version 1.0 and 1.1

Page 20 Variable 5.7.1 Molecular or cytogenetic marker(s) tested

Change from code to text format

OMIM Code dropped. Code examples changed to reflect new rationale

Old version

Code Examples*	**Description**	**OMIM Code (where applicable)**
Karyotype	Karyotype of malignant cells	
Methylation	Methylation status of cancer cells	
BRAF	BRAF oncogene	*164757
SHH	Sonic hedgehog gene	*600725
BCR/ABL	Breakpoint cluster region including BCR/ABL fusion gene	*151410
NMYC	NMYC oncogene	*164840
BRCA2	BRCA2 gene	*600185
ETV6/RUNX1	ETV6/RUNX1 fusion gene (TEL/AML1)	*600618

Page 21 Variable 5.7.2 Molecular or cytogenetic marker(s) test result

Code list extended from 15 to 22 choices to better encompass the possible test results

Old version

Code	**Label**
0	Negative/inactivated
1	Positive/activated
2	Mutation/mutated
3	Amplified/overexpressed
4	Loss
5	Fusion/translocation
6	Break apart
7	Hypodiploid
8	Wild type / normal/ diploid
9	Hyperdiploid
10	Triploid
11	Tetraploid
12	Hypomethylated
13	Hypermethylated
99	Unknown

Page 23 Title page for First treatment complex

Deleted: “Only treatments which were administered will be registered.”

Page 27 (First) treatment goal(s)

Note “Planned but not applied treatments are not registered.” deleted.

Page 28 Variable 7.4 CHOP Treatment Code

Code example 99.9R.00 (Watchful waiting) replaced with code example 998 (No treatments planned).

Note: “Treatments which were planned but not carried out are not to be recorded” deleted.

END