1 Introduction

1.1 CONCORD-3 will update world-wide surveillance of cancer survival to the most recent year possible. This document provides a detailed description of the data that each registry is asked to provide. It has been developed from the data specification used for CONCORD-2.[1]

1.2 Data for CONCORD-3 will be sent to the Cancer Survival Group at the London School of Hygiene and Tropical Medicine (LSHTM). Quality control and survival analyses will be performed at LSHTM. We may receive more than 4,000 data files. **This annex sets out the data structure required for us to manage these files efficiently.**

1.3 We define **15 index sites** - oesophagus, stomach, colon, rectum, liver, pancreas, lung, melanoma of the skin, breast (women), cervix, ovary, prostate and brain, plus lymphoma and leukaemia.

1.4 For simplicity, we will use the word "**cancer**" to refer to all primary malignant neoplasms, including the haematological malignancies.

1.5 We define **index cancers** (see page 14) as those that:

- occur at an **index site**
- were diagnosed in persons **normally resident** in the territory covered by the registry, and who are thus included in the cancer incidence rates routinely reported by the registry
- were diagnosed during the **calendar period** covered by the registry's data submission

Data submission

1.6 You are invited to submit data on **all 15 index cancers**, but that is not a requirement. Some registries only register selected cancers (e.g. breast, colorectal; childhood cancers).

1.7 We will focus on estimating survival for patients diagnosed with an **index cancer** during the 15-year period **1 January 2000 to 31 December 2014,** or part of that period. You are invited to contribute data for **all 15 years**, but that is not a requirement. Some registries only began operation after 2000. Other registries may not yet have complete incidence and follow-up data for patients diagnosed as recently as 2014.

1.8 When identifying the data you plan to submit, please ensure that (a) the *incidence data* are considered to be complete for all the calendar years that you submit and (b) the *follow-up* of all patients for their vital status is also considered to be complete, at least up to 31 December of the last year of incidence, and preferably a later year. **We can accept data for more recent periods**, if your data are complete for 2015 or a later year. Some examples follow:

- incidence data 2000-2012, follow-up to 31 December 2012
- incidence data 2000-2012, follow-up to 31 December 2013
- incidence data 2005-2013, follow-up to 31 December 2014

1.9 Some participating **cancer registries** will cover the entire national population; others will only cover part of a country (state, province, region, etc.).

1.10 Most survival analyses will be for **adults** (aged 15-99 years), but we will also examine survival from brain tumours and haematological malignancies in **children** (0-14 years).

1.11 With the exception of brain tumours, survival analyses will include only ***invasive* primary malignancies (behaviour code 3).** However, please submit **all tumour records for each index cancer**, including benign (behaviour code 0), uncertain (1) or *in situ* (2), for example *in situ* cancers of the breast or cervix. Data on tumour behaviour will enable comparison of the intensity of diagnostic activity between participating registries.

1.12 During the period 2000-2014, most registries will have used ICD-O-3[2] for coding tumour site, morphology and behaviour, in preference to ICD-9,[3] ICD-10[4] or ICD-O-2.[5] Some registries have recently begun using the first revision of ICD-O-3, published in 2013.[6] The CONCORD Working Group agreed to use ICD-O-3 (Cork, Ireland, 2012). If your data are not coded to ICD-O-3 or its first revision, please discuss this with us **before submitting your data**.

1.13 **All cancer data files must have the same structure:**

- All data files will be checked for adherence to protocol, as the first step of quality control. Tables of protocol adherence will be sent to you shortly after data submission. Data files that do not meet the protocol cannot be used. If you are in doubt about how to construct your data files, please discuss this with us **before submitting your data**.
- **Every tumour record must have the same structure.** Please include all **core variables** and all **optional variables** in every record. For example, the variables on **stage at diagnosis** (variables 24-39) and **the first course of treatment** (variables 40-51) are optional. Please do not leave any variables blank, or empty. Instead, use the appropriate "missing value" (page 37), as follows:
  - *You do not collect a particular data item*. For example, you do not collect data on region (variable 7). Use the missing value for region (99999) in **all tumour records**.
  - *No data are available for a given variable in a particular tumour record*. For example, a tumour record contains no data for sex (variable 6). Use the missing value for sex (9) in that tumour record. Do not assign an imputed value.
  - *You decide not to supply a variable*. For example, you collect data on stage at diagnosis, but you decide not to provide data on stage. Use the missing value (page 37) for all stage variables (variables 24-39) in **all tumour records**.
- If it is routine practice in your registry to substitute an imputed value for a missing value (e.g. the month of the year), and some of the variables you submit contain imputed values, **please tell us**: we will ask you for a description of the imputation procedures.
- If tumour records in your database include a special code ("flag") to indicate when a missing value has been imputed, please discuss this with us **before submitting your data**. We will ask you for a description of how each flag has been generated.
- If you have modified a standard coding scheme (such as ICD-O-3) by adding special codes for local use in your registry, **please recode your data** to the standard form before submission. If you have any doubts about the appropriate conversion, please discuss this with us **before submitting your data**.
- Data files should be submitted using the **CONCORD File Transmission Utility (Annex 3)**. This is a safe, quick and convenient method that meets all data security requirements. It is free of charge for all participating cancer registries.

2 Variable names and short descriptions

2.1 The sequence of variables in each cancer record is given below. Details of the content and coding of each variable are given in Section 3.

Core variables

Name	Short description
VAR1	Country
VAR2	Registry
VAR3	Person code
VAR4	Tumour code
VAR5	IARC check flag *
VAR6	Sex
VAR7	Region *
VAR8	Race/ethnicity *
VAR9	Day of birth
VAR10	Month of birth
VAR11	Year of birth
VAR12	Day of diagnosis
VAR13	Month of diagnosis
VAR14	Year of diagnosis
VAR15	Last known vital status
VAR16	Day of last known vital status
VAR17	Month of last known vital status
VAR18	Year of last known vital status
VAR19	Basis of diagnosis
VAR20	Topography
VAR21	Morphology
VAR22	Behaviour
VAR23	Grade **

Optional variables *

Name	Short description
Stage at diagnosis ***	
VAR24	SEER Summary Stage 2000
VAR25	Pathological T
VAR26	Pathological N
VAR27	Pathological M
VAR28	Clinical T
VAR29	Clinical N
VAR30	Clinical M
VAR31	Condensed T
VAR32	Condensed N
VAR33	Condensed M
VAR34	Dukes' stage
VAR35	FIGO stage
VAR36	Ann Arbor stage **
VAR37	Tumour size
VAR38	No. of lymph nodes examined
VAR39	No. of lymph nodes involved
First course of treatment **	
VAR40	Cancer-directed surgery
VAR41	Day of surgery
VAR42	Month of surgery
VAR43	Year of surgery
VAR44	Radiotherapy
VAR45	Day of radiotherapy
VAR46	Month of radiotherapy
VAR47	Year of radiotherapy
VAR48	Systemic therapy
VAR49	Day of systemic therapy
VAR50	Month of systemic therapy
VAR51	Year of systemic therapy

* If your registry does not collect these data, please see paragraph 1.13
** New variable(s) in CONCORD-3
*** Variables for stage at diagnosis are renumbered from those used in CONCORD-2

2.2 Abbreviations

AJCC	American Joint Committee on Cancer
FIGO	Fédération Internationale de Gynécologie et d'Obstétrique
IARC	International Agency for Research on Cancer
ICCC	International Classification of Childhood Cancer
ICD[-O]	International Classification of Diseases [for Oncology]
LSHTM	London School of Hygiene & Tropical Medicine
SEER	Surveillance, Epidemiology and End Results programme
TNM	Tumour Nodes Metastasis

3 DESCRIPTION OF VARIABLES

Variable 1 **Country** **Core variable**

Numeric variable, four digits.

We will send you the code to be used for your country to help you prepare your data.

This 4-digit code must be included as variable 1 in **all tumour records**.

Variable 2 **Registry** **Core variable**

Numeric variable; one to three digits (range 1-950).

We will send you the code to be used for your registry to help you prepare your data.

The code for your registry must be included as variable 2 in **all tumour records**.

Together with the country code (variable 1), this variable will be used to link your data files with the relevant life tables during survival analysis.

Variable 3 **Person code** **Core variable**

Numeric variable, up to a maximum of 15 digits, ***or***
Alphanumeric variable, up to a maximum of 15 characters.

This is a unique code that can be used in your **cancer registry** to refer to each registered cancer patient.

The **person code** can be any unique string of characters, but ***not*** the person's name, national identity number, social security number or any similarly recognisable code.

The **person code** must be included in each tumour record, to enable you to check the record in the event that we identify possible errors during quality control.

The same **person code** must be included in any other tumour records supplied for the same person.

Together with the **tumour code** (variable 4), this variable provides a unique identification of each tumour included in the study, for the purposes of quality control, but without compromising patient confidentiality.

Note:
If your registry does not routinely use a **person code**, you will need to create a unique code for each person to be included in your data files. The code will be used to identify patients with more than one **index cancer**. Also, if we identify errors or inconsistencies in a tumour record for a particular person during quality control, you will be able to use the person code to check each tumour record for that person in your registry.

If you have any doubts about the appropriate procedure to create a person code, please discuss this with us **before submitting your data**.

Variable 4 **Tumour code** **Core variable**

Numeric variable, up to a maximum of ten digits, ***or***
Alphanumeric variable, up to a maximum of ten characters.

This is the code used in your **cancer registry** to refer to each registered tumour.

Together with the **person code** (variable 3), this variable will enable persons with more than one **index cancer** to be identified.

For example, if you submit data for all patients diagnosed during 2000-2014, a patient with an invasive primary cancer of the breast diagnosed in 2000, followed by a new invasive primary cancer of the colon diagnosed in 2005, will be included in the survival analyses for each of those cancers.

Variable 5 **IARC CHECK flag** **Core variable**

Numeric variable, one digit.

We will use this variable to avoid asking you to check tumour records that you have already checked with the International Agency for Research on Cancer's IARC CHECK program.

Please use the code 9 in ***all tumour records***, if:

- you ***do not use*** IARC CHECK
- you ***do use*** IARC CHECK, but you decide not to provide this variable

Code **Meaning**

1 = Tumour record ***has not been checked*** with IARC CHECK

This tumour record ***has been checked*** with IARC CHECK

2 = No error(s) or warning(s)
3 = Error(s) and/or warning(s) have been corrected
4 = No change was made because the registry confirmed that the original record was correct

9 = This variable will not be provided

Variable 6 **Sex** **Core variable**

Numeric variable, one digit.

Code **Meaning**

1 = Male
2 = Female
9 = Sex is ambiguous, or sex was not known

Please do not exclude records from your data if the sex of the patient is unknown.

Variable 7 **Region** **Core variable**

Numeric variable, up to five digits.

It may be possible to estimate survival for geographic areas within the territory of your registry. If your registry has national coverage, such analyses could be for regions (e.g. provinces, states, etc.) within your country. Alternatively, if your registry covers a province or state, such analyses could be for smaller regions (e.g. counties) within your territory.

Please use the code 99999 for this variable in ***all tumour records***, if:

- you ***do not collect*** data for separate areas of the territory covered by your registry
- you ***do collect*** regional data, but you decide not to provide this variable

If you would like us to provide survival estimates by region (province, state, county, etc.) within your registry territory, you will need to include a suitable geographic code in **all tumour records**.

The codes for geographic region will be different for each registry that supplies this variable. You will also need to tell us which region (province, state, county, etc.) corresponds to each code.

As an example, the counties within some US states are a geographic variable of interest:

Code		Meaning
21001	=	Kentucky, Adair
21003	=	Kentucky, Allen
21005	=	Kentucky, Anderson
21007	=	Kentucky, Ballard
21009	=	Kentucky, Barren
21011	=	Kentucky, Bath
21...	=	Kentucky, ...
99999	=	Region not known, or you will not supply this variable

Note:
We will also need to construct appropriate life tables for each geographic region (province, state, county, etc.) for which you wish to obtain separate survival estimates: see **Life tables (Annex 2)**.

Variable 8 **Race/ethnicity** **Core variable**

Numeric variable, one or two digits.

It may be possible to estimate survival separately for each race/ethnicity within a population. Cancer registries in some countries collect information on race and/or ethnicity (Australia, Israel, Malaysia, New Zealand, Singapore, UK, USA) or nationality (Kuwait).

By contrast, most European registries **do not** record information on race or ethnicity. In some countries, it is illegal to do so.

Please use the code 99 for this variable in ***all tumour records***, if:

- you ***do not collect*** data on race or ethnicity
- you ***do collect*** data on race or ethnicity, but you decide not to provide this variable

If you would like us to provide survival estimates by race or ethnicity, you will need to include a suitable code for race/ethnicity in **all tumour records**.

The categories for race/ethnicity will be different for each registry that supplies this variable. You will also need to tell us which race or ethnic group corresponds to each code.

As an example, the codes usually used for race/ethnicity in the USA are:

Code		Meaning
1	=	White, Hispanic
2	=	White, Non-Hispanic
3	=	White, Hispanic status unknown
4	=	Black, Hispanic
5	=	Black, Non-Hispanic
6	=	Black, Hispanic status unknown
7	=	Asian or Pacific Islander, Hispanic
8	=	Asian or Pacific Islander, Non-Hispanic
9	=	Asian or Pacific Islander, Hispanic status unknown
10	=	American Indian/Alaska Native, Hispanic
11	=	American Indian/Alaska Native, Non-Hispanic
12	=	American Indian/Alaska Native, Hispanic status unknown
13	=	Other, unspecified or unknown race, Hispanic
14	=	Other, unspecified or unknown race, Non-Hispanic
15	=	Other, unspecified or unknown race, Hispanic status unknown
99	=	Unknown or missing, ***or*** variable not supplied

Note: If you would like us to provide survival analyses by race or ethnicity, we will need to construct life tables for each racial or ethnic group: see Life tables (Annex 2).

If we cannot construct robust life tables for each race or ethnic group, the scope for estimation of net survival by race or ethnic group may be limited.

Variables 9-11 Date of birth ***Core variables***

A full and accurate date of ***birth*** (day, month and year) is important, because it is used to calculate the exact age at diagnosis. This is used to determine the age group (at diagnosis) into which patients are assigned for age-specific survival estimates. It is also used to calculate the exact age at death, and thus to select the appropriate background death rate from the life table in estimating net survival. It is also the basis for age-standardised survival.

Most registries record the full date of birth, but registries face legal, ethical or regulatory problems in providing the full date of birth to external researchers. Some registries only record part of the date.

We have published a peer-reviewed article setting out why full dates are important, based on empirical evidence and sensitivity analyses with a large national data set.[7] The article also shows the difficulties that arise in quality control when full dates cannot be obtained. It also shows the biases that arise in the estimation and comparison of survival. The article is accessible with your password on the CONCORD web-site.

The Cancer Survival Group at LSHTM maintains **statutory approval (Annex 4)** and **ethical approval (Annex 5)** from the relevant bodies in the UK to receive and analyse individual tumour records with full dates of birth, diagnosis and death for the CONCORD study.

If you cannot include full dates of birth, diagnosis and death, please discuss this with us **before submitting your data**. We may be able to help you obtain ethical approval, or to find an alternative solution.

Imputation of dates

Please do not impute the missing components of any dates. We will do this, if necessary, in the same way for all data sets. If missing components of some dates have *already* been imputed in your data, **we will ask you to tell us** the rules you use to impute the day and/or the month of any dates

If you routinely add a "flag" to tumour records to show when the day and/or the month of any date has been imputed, please discuss this with us **before submitting your data**.

Variable 9 Day of birth **Core variable**

Numeric variable, one or two digits.

1-31 = The day of birth
99 = The day of birth of this patient is not known

Variable 10 Month of birth **Core variable**

Numeric variable, one or two digits.

1-12 = The month of birth
99 = The month of birth of this patient is not known

Variable 11 Year of birth **Core variable**

Numeric variable, four digits.

YYYY = The year of birth, from 1900 (person diagnosed in 2000, aged 99) to the present
9999 = The year of birth of this patient is not known

Variables 12-14 Date of diagnosis ***Core variables***

The date of diagnosis should be the date used by the registry for cancer incidence.

A full and accurate **date of diagnosis** (day, month, year) is important, because it is the starting point for the duration of survival. A few cancer registries only record the month and year of diagnosis. Other registries only began to record the *full* date of diagnosis at some point since 2000.

Some registries routinely capture more than one possible date of diagnosis (e.g. date of admission, date of biopsy, date of surgery, etc.). When you submit your data for CONCORD, **you will need to submit the questionnaire (Annex 6)** on coding practices in your registry. This includes information about any rules that you use to select the date of diagnosis from two or more possible dates.

Variable 12 Day of diagnosis **Core variable**

Numeric variable, one or two digits.

1-31 = The day of the date of diagnosis
99 = The day of the date of diagnosis of this patient is not known

Note: please see comments above (page 9) about the imputation of dates.

Variable 13 Month of diagnosis **Core variable**

Numeric variable, one or two digits.

1-12 = The month of the date of diagnosis
99 = The month of the date of diagnosis of this patient is not known

Note: please see comments above (page 9) about the imputation of dates.

Variable 14 Year of diagnosis **Core variable**

Numeric variable, four digits.

YYYY = The year of diagnosis, from 2000 onwards
Missing values are not allowed

Variable 15 Last known vital status **Core variable**

Numeric variable, one digit.

This variable encodes the patient's **last known vital status**, to the extent that it is known to the cancer registry. The ***date*** of the patient's **last known vital status** is recorded in variables 16-18.

Code	Meaning
1	Alive
2	Dead
3	Lost to follow-up
9	Vital status is not known

Information about vital status is conventionally captured using either **'active'** or **'passive'** procedures, which we discuss below. Some registries use both. When you submit your data for CONCORD, **you will need to submit the questionnaire (Annex 6)** on routine practices in your registry. If you have any doubts about which procedure is used for follow-up in your registry, please contact us **before submitting your data**.

'Active' follow-up
Active follow-up refers to the situation in which the registry actively seeks information about the vital status of each cancer patient on a regular basis, e.g. from the patient's doctor, or hospital, or even home visits.

If your registry uses this approach, you should use code "3" for patients whose vital status (alive or dead) could not be ascertained at the last vital status check: these patients are lost to follow-up. The last *date at which they were known to be alive* should be given in variables 16-18.

Code "3" should be used for patients known to have emigrated, since they are also lost to follow-up: the *date of emigration* should be given in variables 16-18.

'Passive' follow-up
Passive follow-up refers to the situation in which the registry routinely receives information from one or more reliable sources on the vital status of *all registered patients*. These sources vary widely between registries, but may include social security or health insurance files, or a regional or national index of persons who have died. The information may be derived in various ways, such as by computer linkage with the registry database, manual scanning of the death index, or supply of details about all deaths in the registry's territory.

For international survival comparisons, the key features of passive follow-up are that:

- The registry uses this approach for updating its own data for survival analysis, and
- The registry's procedures reliably identify ***all deaths of registered cancer patients, not just the deaths for which cancer is mentioned on the death certificate***, and
- The registry can reliably assume that registered cancer patients are alive, unless information about a patient's death has been received from one or more of these sources.

If your registry uses passive follow-up, patients who are *not known to be dead* would normally be assumed to be alive on the date of the most recent linkage between the registry and a death index or other vital status records. The vital status of those patients should be coded as "1" (alive).

However, if some patients cannot be traced by any passive follow-up procedure, their vital status may remain undetermined: it should then be coded as "9" (unknown).

When you submit your data, we will ask you to tell us *the last date when you performed linkage* or other follow-up to determine the vital status of your patients (**the "freeze" date**).

Variables 16-18 Date of the patient's last known vital status ***Core variables***

This is the most recent date for which the patient's **last known vital status** (variable 15) was available.

The **date of last known vital status** should be coded as:

- the date of death, if the patient is dead (variable 15 is coded as "2")
- missing (99,99,9999), if the patient is known to be dead, but the date of death is not known
- the date of emigration, if the patient has emigrated (variable 15 is coded as "3")
- the date of loss to follow-up, if the patient has been lost to follow-up (variable 15 is coded as "3")

If the patient is considered to be alive, but not emigrated or lost to follow-up, the **date of last known vital status** should be one of the following:

- 31 December of the last year for which follow-up of all patients is believed to be complete, ***or***
- the date on which the registry last checked that patient's vital status, e.g. contact with the patient's doctor or a home visit (registries that perform active follow-up), ***or***
- the date of the most recent linkage with a death index ("freeze" date; registries that perform passive follow-up)

Variable 16 Day of last known vital status **Core variable**

Numeric variable, one or two digits.

1-31 = The day of the date of last known vital status
99 = The day of this date is not known

Note: please see comments above (page 9) about the imputation of dates.

Variable 17 Month of last known vital status **Core variable**

Numeric variable, one or two digits.

1-12 = The month of the date of last known vital status
99 = The month of this date is not known

Note: please see comments above (page 9) about the imputation of dates.

Variable 18 Year of last known vital status **Core variable**

Numeric variable, four digits.

YYYY = The year of the date of last known vital status, from 2000 onwards
9999 = The year of this date is not known

Variable 19 Basis of diagnosis **Core variable**

Numeric variable, one digit.

This variable indicates the degree of certainty with which a diagnosis of cancer has been established.

The distinction between a diagnosis based on pathological examination of cells or tissue (microscopically verified) and a diagnosis based on other investigations, such as clinical examination or imaging, is important for both cancer incidence and survival. However, the categories for the basis of diagnosis required for survival analysis differ slightly from the categories conventionally used for incidence ***(see note below)***.

Code Meaning

Not microscopically verified

1 = Clinical diagnosis ***only***
2 = Clinical investigation: endoscopy (without biopsy) or imaging (e.g. X-ray, ultrasound, scintigraphy, computed tomography (CT) or magnetic resonance imaging (MRI))
3 = Clinical diagnosis, not otherwise specified (i.e. it is not known if code "1" or "2" applies)

Microscopically verified

4 = Cytologically confirmed (e.g. smear; blood film; aspirate of bone marrow or ascites)
5 = Histologically confirmed (tissue diagnosis from biopsy or surgical specimen)
6 = Microscopically verified, not otherwise specified (i.e. not known if code "4" or "5" applies)

Evidence of cancer does not include the date of diagnosis

7 = Death-certificate-only registration (DCO) ***(see note below)***
8 = Autopsy only - malignancy detected only at autopsy ***(see note below)***

No information

9 = Unknown

Note:
Cancers registered solely on the basis of a death certificate (code 7) or detected only at autopsy (code 8) can usually be **included in incidence statistics** for the year in which they are registered.

For DCO and autopsy-detected cancers, however, the true date of diagnosis – and thus the duration of survival – are unknown. Therefore, they are normally ***excluded from survival analyses***. Some cancer registries do not register DCOs or autopsy-detected cancers.

If your cancer registry ***did*** register DCO or autopsy-only cancers during the calendar period covered by your data submission, **you should include those cancers in the data you submit for this study**, to enable comparative quality control.

Variable 20 **Topography** **Core variable**

Alphanumeric variable, four characters.

Please select records for submission with the tumour site (topography) coded to the International Classification of Diseases for Oncology (ICD-O-3[2]; topography codes are the same in the first revision of ICD-O-3[6]). **Note:** Melanoma and the lymphomas and leukaemias are the exception: please select records for these malignancies with the ICD-O-3 morphology code.

Please provide the full 4-character ICD-O-3 topography code ***without the decimal point (".")***. Thus, liver cancer will be C220, and prostate cancer will be C619. With this modification, the anatomic site of the **index cancers** will be coded as:

Oesophagus:	C150-C155; C158-C159
Stomach:	C160-C166; C168-C169
Colon:	C180-C189; C199 ***Note: includes*** rectosigmoid junction, C199
Rectum:	C209; C210-C212; C218 ***Note: includes*** anal canal (C211) and anorectal junction (C218) ***Note: excludes*** skin of anus and perianal skin, C445
Liver:	C220-C221 ***Note: includes*** intrahepatic bile duct, C221
Pancreas:	C250-C254; C257-C259
Lung:	C340-C343; C348-C349 ***Note: excludes*** trachea, C339
Melanoma of skin:	**Please select melanomas with the morphology code**, not the topography code. Do not change the topography code in your data.
Breast:	C500-C506; C508-C509 ***Note: excludes*** skin of breast, C445
Cervix uteri:	C530-C531; C538-C539
Ovary:	C480-C482; C569; C570-C574; C577-C579 ***Note: includes*** peritoneum and retroperitoneum (C480-C482), where high-grade serous cancers originating from the fallopian tube (C570) are often detected ***Note: includes*** other and unspecified female genital organs, C577-C579
Prostate:	C619
Brain (adults and children):	C710-C719 ***Note:*** please submit records for children (0-14 years) and adults (15-99 years) ***in two separate files***. We will estimate survival separately for children and adults.
Lymphomas and leukaemias (adults and children):	**Please select lymphomas and leukaemias with the morphology code**, not the topography code. Do not change the topography code in your data.

Variable 21 Morphology **Core variable**

Numeric variable, four digits.

Tumour morphology should be coded to the third edition of the International Classification of Diseases for Oncology (ICD-O-3),[2] or the first revision of ICD-O-3.[6] The first revision of ICD-O-3 contains many changes to the morphology codes, particularly for leukaemias, lymphomas, and tumours of the digestive tract and central nervous system.

For microscopically confirmed tumours, the range of morphology codes in ICD-O-3 (as updated by the first revision) is now **8000-9992**.

For tumours *without* microscopic verification, you should use:

9999 This is ***not*** a valid ICD-O-3 code: but we ask you to use it here to mean that you do not have morphology data for tumours without microscopic verification.

Note: however, the code 9999 **will not be valid** for melanomas, leukaemias or lymphomas (see below). These tumours are ***defined by their morphology***, so they must have a morphology code in the range 8720-8790 (melanoma) or 9590-9992 (lymphomas and leukaemias).

MELANOMA: please select tumour records for submission with ICD-O-3 morphology codes in the range 8720-8790.

We will select melanomas of the skin with ICD-O-3 topography codes (C440-C449), together with skin of the labia majora (C510), vulva (C519), penis (C609) and scrotum (C632). This will be more efficient than asking you to submit data for all skin tumours; in many registries, most tumours at these sites will be basal cell carcinomas or squamous cell carcinomas.

LEUKAEMIAS and LYMPHOMAS: please select tumour records for submission with ICD-O-3 morphology codes in the range 9590-9992.

Note: The range of morphology codes **9590-9992** is the same for children and adults. Please submit records for all haematopoietic malignancies in this code range ***in two separate files***, one for children (0-14 years) and one for adults (15-99 years). We will estimate survival separately for children and adults.

Childhood leukaemias and lymphomas will be grouped on the basis of the third revision of the International Classification of Childhood Cancers[8] (ICCC-3). The ICCC-3 groupings are based on ICD-O-3 morphology codes.

Adult leukaemias and lymphomas will be grouped on the basis on the categories established by a consensus of haematologists, pathologists and epidemiologists in the HAEMACARE Working Group.[9-11] The HAEMACARE manual for coding haematological malignancies is available in English[12] and Spanish.[13] The HAEMACARE groups are also based on ICD-O-3 morphology codes.

Variable 22 Behaviour **Core variable**

Numeric variable, one digit.

Survival analyses will only include invasive, primary, malignant neoplasms (behaviour code 3). The exception is for brain tumours, where benign tumours (behaviour code 0) will be included.

We will also report the **distribution of tumour behaviour** for each cancer. This will enable comparison of the intensity of diagnostic activity for solid tumours between participating countries or regions, e.g. the proportion of women with breast or cervical cancer who were registered with *in situ* carcinoma.

Please do not select tumours for submission on the basis of tumour behaviour.

If your registry collects data on tumours that are benign (behaviour code 0), of uncertain behaviour (1) or *in situ* (2), such as *in situ* carcinoma of the cervix, ***please include all these records*** in your data files.

Tumour behaviour should be coded to the third edition of the International Classification of Diseases for Oncology (ICD-O-3).[2] The coding of tumour behaviour has been the same in all editions of ICD-O.

Code		Meaning
0	=	Benign
1	=	Uncertain whether benign or malignant
2	=	Carcinoma *in situ*
3	=	Malignant, primary site
6	=	Malignant, metastatic site ***(see note below)***
9	=	Malignant, uncertain whether primary or metastatic site ***(see note below)***

Note:
Behaviour codes 6 and 9 are included in ICD-O-3, but they are not usually used by cancer registries.[2] We show them here only for completeness.

If your registry ***does*** use behaviour codes 6 and 9, please include them in your data files; please do not recode them before data submission. Instead, ***please provide us with a description*** of how the codes have been used in your data.

Variable 23 Grade **Core variable**

Numeric variable, one digit.

Histological grade (or differentiation) is a major prognostic factor for several cancers. It is only applicable to malignant tumours. It should reflect the highest differentiation code recorded in the diagnostic statement or pathological report, i.e. the one with the most adverse prognostic significance (Rule G in ICD-O-3[6]).

If you do not collect data on histological grade or differentiation, please use the code 9 for this variable in ***all tumour records***.

Code		Meaning
1	=	Grade I - Well differentiated, ***or*** Differentiated, NOS
2	=	Grade II - Moderately differentiated, ***or*** Moderately well differentiated, ***or*** Intermediate differentiation
3	=	Grade III - Poorly differentiated
4	=	Grade IV - Undifferentiated, ***or*** Anaplastic
9	=	Grade or differentiation not determined, ***or*** not stated, ***or*** not applicable***, or*** No pathology was performed

Immunophenotype designation for leukaemias and lymphomas only (see note below)

5	=	T-cell
6	=	B-cell, ***or*** pre-B, ***or*** B-precursor
7	=	Null cell, ***or*** "Non T-non B"
8	=	NK (natural killer) cell
9	=	Cell type not determined, ***or*** not stated, ***or*** not applicable

Note adapted from ICD-O-3,[2] (p31), and ICD-O-3 first revision[6] (p22):

In ICD-O-3, the cell lineage of haematopoietic malignancies is implicit in the four-digit morphology code, so the additional codes (5-8) for grade or differentiation are not strictly necessary.

However, some registries may use the additional code to identify cases in which the diagnosis is specifically supported by immunophenotypic data. For those registries, the immunophenotype code (codes 5-8) can be provided instead of other diagnostic terms for grade or differentiation, such as "well differentiated" (code 1) or "grade III" (code 3).

STAGE OF DISEASE AT DIAGNOSIS

Optional variables

Provision of data on stage at diagnosis (variables 24-39) is *optional*.

Please use the codes for missing values (see page 37) for ***all the variables*** on stage at diagnosis ***in all tumour records*** if:

- you ***do not collect*** data on tumour stage***, or***
- you ***do collect*** data on tumour stage, but you decide not to provide ***any*** of the stage variables

"Tumour stage" describes how far the cancer has spread at the time of diagnosis. It is a key determinant of survival.

Knowledge of the stage at diagnosis of cancer patients is increasingly important for the interpretation of international survival comparisons.[14-22]

Among the registries that collect data on stage, data of satisfactory quality are often available for many of the **index cancers** included in CONCORD-3, at least for more recent years. Where possible, we will perform analyses of survival by stage at diagnosis.

Many different coding schemes are used to categorise tumour stage in cancer registries around the world.[23] We will try to obtain data on **at least one widely used categorisation of stage** at diagnosis for each tumour:

* Data on TNM stage must be coded to the **7th edition**.[24]

Variable 24 SEER Summary Stage 2000 **Optional**

Numeric variable, one digit.

SEER Summary Stage 2000 is a simple categorisation of stage, developed by the US National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) programme. The North American Association of Central Cancer Registries uses SEER Summary Stage 2000[25] (http://seer.cancer.gov/tools/ssm/). We borrow text from the introduction here. It has been in use in the US and Canada since 1 January 2001.

"Summary stage" is the most basic way of categorising how far a cancer has spread from its point of origin. Summary staging uses all the information available in the medical record. It is a **combination of the most precise clinical and pathological evidence for the extent of disease**. Many population-based cancer registries report summary stage for their registered cases, because the staging categories are sufficiently broad to enable measurement of progress in cancer control.

We expect that North American registries will supply SEER Summary Stage 2000 coded directly for cases diagnosed 2001-2003, but derived from Collaborative Stage for cases diagnosed in 2004 and later (http://seer.cancer.gov/tools/collabstaging). If your registry plans to supply SEER Summary Stage 2000 coded in any other way, ***we ask you to inform us*** of the procedures you have used. The comparability of these staging schemes over time is addressed on the following SEER web-page:
http://seer.cancer.gov/seerstat/variables/seer/yr1973_2009/lrd_stage/index.html

Regional spread of disease is divided into several categories, according to the method of spread of the cancer:

Code		Meaning
0	=	*In situ*
1	=	Localised only
2	=	Regional spread by direct extension ***only***
3	=	Regional lymph nodes involved ***only***
4	=	Regional spread by ***both*** direct extension ***and*** lymph node involvement
5	=	Regional, NOS (not otherwise specified) – use this code if there is regional spread of the cancer, but ***the route of spread is not known***
7	=	Distant site(s) or lymph node(s) are involved
9	=	Unknown if there is extension or metastasis (unstaged, unknown or unspecified), ***or*** This is a ***death-certificate-only*** case, ***or*** This is an ***autopsy-only*** case

TNM stage (variables 25-30) ***Optional variables***

The Tumour-Nodes-Metastasis (TNM) classification of stage at diagnosis uses a combination of clinical and pathological evidence, like SEER Summary Stage 2000.

As decided by the CONCORD Working Group (Cork, Ireland, 2012), we will use the **7th edition of TNM**,[24] published by UICC. This is identical to the classification published by the American Joint Committee on Cancer in 2009.[26] For most of the **index cancers**, the rules for coding the stage from the clinical data changed between the sixth[27] and seventh[24] editions, so if your stage data are coded to earlier editions than TNM-7, please contact us **before submitting your data.**

The three components of TNM are tumour size (T); the status of regional lymph nodes, i.e. the extent of lymph node invasion by tumour (N), and whether there is metastasis (spread of disease to an organ or organs distant from the organ of origin) (M).

TNM stage data may be based on pathological evidence ("p") or clinical evidence ("c").

If you do not know whether your TNM data are pathological or clinical, please code the data as ***pathological*** TNM (variables 25-27), and use code 9 for the ***clinical*** TNM variables (28-30).

Variable 25 Pathological T **Optional**

Numeric variable, one digit.

This variable encodes information on the physical size or extent of the tumour.

For most **index cancers** (i.e., excluding brain tumours, lymphomas and leukaemias), up to 4 sub-categories (a, b, c, d) exist for each of the stage categories pT1, pT2, pT3 and pT4. These sub-categories should be coded in the same way as the parent category: for example, pT1a should be coded to "1", in the same way as pT1.

For **cervical cancer**, the additional sub-categories pT1a1, pT1a2, pT1b1 and pT1b2 should be coded to "1", in the same way as pT1. Similarly, the additional sub-categories pT2a1 and pT2a2 should be coded to "2", in the same way as pT2.

The following codes will be used:

Code		Meaning
0	=	pT0 – no histological evidence of primary tumour
1	=	pT1 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pT1a, pT1b and pT1c* *Use this code also for sub-categories pT1a1, pT1a2, pT1b1 and pT1b2* ***(cervix)***
2	=	pT2 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pT2a, pT2b and pT2c* *Use this code also for sub-categories pT2a1 and pT2a2* ***(cervix)***
3	=	pT3 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pT3a, pT3b and pT3c*
4	=	pT4 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pT4a, pT4b, pT4c and pT4d*
8	=	is – *in situ* carcinoma
9	=	pTX – unknown: the primary tumour cannot be assessed histologically

Variable 26 Pathological N **Optional**

Numeric variable, one digit.

This variable encodes the extent of involvement of regional lymph nodes with tumour.

For cancers of the stomach, colon, rectum and breast, and for melanoma, up to 3 subcategories of pN1, pN2 and pN3 also exist (a, b and c). These should be coded in the same way as the parent category: for example, pN2b should be coded to "2", in the same way as pN2.

The following codes will be used:

Code		Meaning
0	=	pN0 – no regional lymph nodes involved with tumour, histologically
1	=	pN1 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pN1a, pN1b and pN1c* ***(colon, rectum, breast)*** *Use this code also for pN1mi (micrometastasis)* ***(breast)*** *Use this code also for sub-categories pN1a and pN1b* ***(melanoma)***
2	=	pN2 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pN2a and pN2b* ***(colon, rectum, breast)*** *Use this code also for sub-categories pN2a, pN2b and pN2c* ***(melanoma)***
3	=	pN3 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories pN3a and pN3b* ***(stomach)*** *Use this code also for sub-categories pN3a, pN3b and pN3c* ***(breast)***
9	=	pNX – unknown: the regional lymph nodes cannot be assessed histologically

Variable 27 Pathological M **Optional**

Numeric variable, one digit.

This variable encodes information on the presence or absence of distant metastases.

For cancers of the colon, rectum, lung and prostate, and for melanoma, subcategories of pM1 also exist (a, b and c). These should be coded to "1", in the same way as for pM1.

The following codes will be used:

Code Meaning

1 = pM1 – Distant metastases have been microscopically confirmed
Use this code also for sub-categories pM1a and pM1b ***(colon, rectum, lung)***
Use this code also for sub-categories pM1a, pM1b and pM1c ***(prostate, melanoma)***

9 = Unknown

Note: this is not a valid TNM code (see below): we use it here only to show that no data were available on pathological M status for this tumour.

The code "MX" was used in earlier editions of TNM to indicate that the metastatic status of the tumour was unknown. However, clinical assessment of metastasis can be based on physical examination alone, so pMX is no longer considered an appropriate code.

The codes pM0 and pMX are ***not valid*** in the 7th edition of TNM.[24]

Variable 28-30 Clinical TNM stage ***Optional variables***

Clinical data on tumour stage may be available from clinical examination, or from imaging of the tumour (X-ray, computed tomography [CT], magnetic resonance imaging [MRI], ultrasound, etc.).

If no surgical or invasive diagnostic procedure has been performed, clinical data may be the only available data on tumour stage.

Variable 28 Clinical T **Optional**

Numeric variable, one digit.

This variable encodes information on the physical size or extent of the tumour.

For most of the **index cancers** (excluding brain tumours, lymphomas and leukaemias), up to 4 sub-categories (a, b, c, d) exist for each of the stage categories cT1, cT2, cT3 and cT4. These sub-categories should be coded in the same way as the parent category: for example, cT1a should be coded to "1", in the same way as cT1.

For **cervical cancer**, the additional sub-categories cT1a1, cT1a2, cT1b1 and cT1b2 should all be coded to "1", in the same way as cT1. Similarly, the additional sub-categories cT2a1 and cT2a2 should both be coded to "2", in the same way as cT2.

The following codes will be used:

Code		Meaning
0	=	cT0 – no evidence of primary tumour
1	=	cT1 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cT1a, cT1b and cT1c* *Use this code also for sub-categories cT1a1, cT1a2, cT1b1 and cT1b2* ***(cervix)***
2	=	cT2 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cT2a, cT2b and cT2c* *Use this code also for sub-categories cT2a1 and cT2a2* ***(cervix)***
3	=	cT3 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cT3a, cT3b and cT3c*
4	=	cT4 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cT4a, cT4b, cT4c and cT4d*
8	=	is – *in situ* carcinoma
9	=	cTX – unknown: the primary tumour cannot be assessed

Variable 29 Clinical N **Optional**

Numeric variable, one digit.

This variable encodes information on the involvement of regional lymph nodes with tumour.

For cancers of the stomach, colon, rectum and breast, and for melanoma, up to 3 subcategories of cN1, cN2 and cN3 also exist (a, b and c). These should be coded in the same way as the parent category: for example, cN2b should be coded to "2", in the same way as cN2.

The following codes will be used:

Code		Meaning
0	=	cN0 – no regional lymph nodes involved with tumour
1	=	cN1 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cN1a, cN1b and cN1c **(colon, rectum, breast)*** *Use this code also for sub-categories cN1a and cN1b **(melanoma)***
2	=	cN2 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cN2a and cN2b **(colon, rectum, breast)*** *Use this code also for sub-categories cN2a, cN2b and cN2c **(melanoma)***
3	=	cN3 – the content of this category varies with the cancer (see TNM-7 manual[24]) *Use this code also for sub-categories cN3a and cN3b **(stomach)*** *Use this code also for sub-categories cN3a, cN3b and cN3c **(breast)***
9	=	cNX – unknown: the regional lymph nodes cannot be assessed

Variable 30 Clinical M **Optional**

Numeric variable, one digit.

This variable encodes information on the presence or absence of distant metastases.

For cancers of the colon, rectum, lung and prostate, and for melanoma, sub-categories of cM1 also exist (a, b and c). These sub-categories should be coded to "1", in the same way as for cM1.

The following codes will be used:

Code		Meaning
0	=	cM0 – No metastases ***(see note 1 below)***
1	=	cM1 – Metastases ***(see note 2 below)*** *Use this code also for sub-categories cM1a and cM1b* ***(colon, rectum, lung)*** *Use this code also for sub-categories cM1a, cM1b and cM1c* ***(prostate, melanoma)***
9	=	This is ***not*** a valid TNM-7 code: we ask you to use it here only if you are not providing data on TNM stage.

Note 1:
If the clinician ***does not record the presence of metastases***, it is assumed under TNM-7[24] that no metastases are present (cM0). You should code these cases to "0".

Note 2:
The code "MX" was used in earlier editions of TNM to indicate that the metastatic status of the tumour was unknown. However, assessment of metastasis can be based on clinical examination or imaging alone, so cMX is no longer considered an appropriate code.

The code cMX is ***not valid*** in the 7th edition of TNM.[24]

Variables 31-33 Condensed TNM ***Optional variables***

The condensed TNM scheme for recording tumour stage was developed by the European Network of Cancer Registries[28] for tumour records in which the individual values of T and/or N and/or M are not explicitly recorded. Condensed TNM is based on the TNM 6th edition.[27]

Please use the code 9 for variables 31-33 in ***all tumour records***:

- if your registry ***does not use*** condensed TNM
- if your registry ***does use*** condensed TNM, but you decide not to provide these variables

Variable 31 Condensed T **Optional**

Numeric variable, one digit.

Code		Meaning
1	=	L - Localised disease ***Use this code for:*** T1 cancers of the ovary T1 and T2 cancers of the oesophagus, stomach, colon, rectum, liver, pancreas, lung, cervix and prostate T1, T2 and T3 cancers of the breast, and melanoma
2	=	A - Advanced disease ***Use this code for:*** T2 and T3 cancers of the ovary T3 and T4 cancers of the oesophagus, stomach, colon, rectum, liver, pancreas, lung, cervix and prostate T4 cancers of the breast, and melanoma
9	=	X – Cannot be assessed: no information on tumour size category

Variable 32 Condensed N **Optional**

Numeric variable, one digit.

Code		Meaning
1	=	N0 – No regional lymph node invasion by tumour
2	=	N+ – Regional lymph nodes invaded by tumour
9	=	NX – Cannot be assessed: no information on nodal status

Variable 33 Condensed M **Optional**

Numeric variable, one digit.

This code is based on the best available information - clinical, instrumental or pathological. Clinical signs and findings are sufficient to justify classifying a tumour as having metastasised (M+), even without *pathological* confirmation of metastatic deposits.

Code		Meaning
1	=	M0 – No distant metastasis
2	=	M+ – Distant metastases present
9	=	MX – Cannot be assessed: no information on whether metastases are present

Variable 34 Dukes' stage **Optional**

Numeric variable, one digit.

Dukes' stage[29] is a specialised classification of tumour stage for cancers of the ***colon and rectum only***. For **all other index cancers**, please use the code 9 for this variable in every tumour record.

Dukes' stage should ***only*** be reported if TNM stage data (variables 25-30) are not available. The TNM classification is preferable, because it is more detailed.

Dukes' stage was modified[30] to include a category for metastasis (group D), and sub-categories for direct extension in groups B and C. Modified Dukes' stage is no longer recommended for clinical use, but it is still widely used. If your data are classified with Dukes' stage, use the codes below:

Code		Meaning
1	=	Dukes' stage A - this is equivalent to T1, N0, M0; ***or*** T2, N0, M0
2	=	Dukes' stage B - this is equivalent to T3, N0, M0; ***or*** T4, N0, M0
3	=	Dukes' stage C - this is equivalent to T(any), N1, M0; ***or*** T(any), N2, M0
4	=	Dukes' stage D - this is equivalent to T(any), N(any), M1
9	=	Dukes' stage missing: no information on Dukes' stage

Variable 35 FIGO stage **Optional**

Numeric variable, one digit.

FIGO stage[31] is a specialised classification of tumour stage for ***cervical, ovarian*** and other gynaecological cancers. For **all other index cancers**, please use the code 9 for this variable in every tumour record.

FIGO stage should ***only*** be reported if TNM stage data (variables 25-30) are not available. The TNM classification is preferable, because it is more detailed.

FIGO stage provides five broad categories, which ***differ between cervix and ovary (see below):***

Stage 0	Carcinoma *in situ* (common in cervical cancer)
Stage I	Confined to the organ of origin
Stage II	Invasion of surrounding organs or tissue
Stage III	Spread to distant nodes or tissue within the pelvis
Stage IV	Distant metastasis(es)

Cancer of the cervix (C530, C531, C538, C539)

Code Meaning

0 = FIGO Stage 0 – carcinoma *in situ*

1 = FIGO Stage I – Tumour confined to cervix (extension to corpus uteri should be disregarded)
Use this code also for sub-categories IA, IA1, IA2, IB, IB1 and IB2

2 = FIGO Stage II – Tumour invades beyond uterus but not to pelvic wall or lower third of vagina
Use this code also for sub-categories IIA, IIA1, IIA2 and IIB

3 = FIGO Stage III – Tumour extends to pelvic wall or lower third of vagina, or causes hydronephrosis
Use this code also for sub-categories IIIA and IIIB

4 = FIGO Stage IVA – Tumour invades mucosa of the bladder or rectum, or extends beyond true pelvis

5 = FIGO Stage IVB – Distant metastasis

9 = FIGO Stage unknown

Cancer of the ovary (C569) or Fallopian tube (C570)

Code Meaning

1 = FIGO Stage I – Tumour limited to one or both ovaries or fallopian tubes
Use this code also for sub-categories IA, IB and IC

2 = FIGO Stage II – Tumour involves one or both ovaries or fallopian tubes, with pelvic extension
Use this code also for sub-categories IIA, IIB and IIC

3 = FIGO Stage III – Tumour involves one or both ovaries or fallopian tubes with microscopically confirmed peritoneal metastasis outside the pelvis, and/or regional lymph node metastasis
Use this code also for sub-categories IIIA, IIIB and IIIC

4 = FIGO Stage IV – Distant metastasis outside the peritoneal cavity

9 = FIGO Stage unknown

Variable 36 Ann Arbor stage **Optional**

Numeric variable, one digit.

Ann Arbor stage[32] is a specialised classification of stage for **lymphomas**. For **all other index cancers**, please use the code 9 for this variable in every tumour record.

For lymphomas, only Ann Arbor stage should be reported. We recommend that you use the modified version of the Ann Arbor staging system, shown in the TNM 7th edition.[24]

If you use any other version of the Ann Arbor classification, please contact us **before submitting your data**.

Ann Arbor stage provides four broad categories:

Stage I Involvement of a single lymph node region, ***or***

Localised involvement of a single extra-lymphatic organ or site

Stage II involvement of two or more lymph node regions **on the same side of the diaphragm**, ***or***

Localised involvement of a single extra-lymphatic organ or site and its regional lymph node(s), with or without involvement of other lymph node regions on the same side of the diaphragm

Stage III Involvement of lymph node regions **on both sides of the diaphragm**, which may also be accompanied by localised involvement of an associated extra-lymphatic organ, or by involvement of the spleen, or both

Stage IV Disseminated (multifocal) involvement of one or more extra-lymphatic organs, with or without associated lymph node involvement, ***or***

Isolated extra-lymphatic organ involvement with distant (non-regional) nodal involvement

Several subcategories of each stage exist, depending on symptoms (A, B) or organ involvement (E, S, E+S, for stages I-III). These should be coded in the same way as the parent category: for example, stage IIIE+S should be coded to "3", in the same way as stage III.

In accordance with TNM-7, please code ***both clinical and pathological Ann Arbor stage*** with the codes shown below:

Code Meaning

1 = Ann Arbor Stage I
This code should also be used for sub-categories IA, IB and IE

2 = Ann Arbor Stage II
This code should also be used for sub-categories IIA, IIB and IIE

3 = Ann Arbor Stage III
This code should also be used for sub-categories IIIA, IIIB, IIIE, IIIS, IIIE+S (etc.)

4 = Ann Arbor Stage IV
This code should also be used for sub-categories IVA and IVB

9 = Ann Arbor Stage unknown

Variable 37 **Tumour size** **Optional**

Numeric variable, from one to three digits.

Tumour size (maximum tumour diameter) should be reported in **millimetres**, as an integer.

Tumour size is only applicable to solid tumours. For the ***lymphomas and leukaemias***, please use the code 999 in every tumour record.

For **breast cancer**, tumour size should be based on histological examination, if available. For **lung cancer**, tumour size may be available by imaging.

It is difficult to be prescriptive about the maximum physical dimensions of a tumour. We will accept values in the range 1 - 300mm (1mm – 30cm). For example, a tumour with a maximum diameter of 35mm (3.5cm) would be coded as "35". Zero is ***not*** a valid tumour dimension. Use the code 999 if tumour size is not available.

Code		Meaning
1-300	=	Maximum tumour diameter, **in millimetres**
999	=	Not known, ***or***
		Not applicable (***lymphoma, leukaemia***)

Variable 38 **Number of lymph nodes examined** **Optional**

Numeric variable, one or two digits.

Report the exact ***number of lymph nodes examined***, as recorded in the pathological report: valid range 0-98.

Code		Meaning
0-98	=	Number of lymph nodes **examined**
99	=	The number of lymph nodes **examined** is unknown, ***or***
		No pathological examination was done, ***or***
		Not applicable (***lymphoma, leukaemia***)

Variable 39 **Number of lymph nodes involved** **Optional**

Numeric variable, one or two digits.

Report the exact ***number of involved lymph nodes (lymph nodes containing tumour cells)***, as recorded in the pathological report: valid range 0-98.

Code		Meaning
0-98	=	Number of **involved** lymph nodes (lymph nodes containing tumour cells)
99	=	The number of **involved** lymph nodes is unknown, ***or***
		No pathological examination was done, ***or***
		Not applicable (***lymphoma, leukaemia***)

INITIAL COURSE OF TREATMENT

Optional variables

Provision of data on the initial course of treatment (variables 40-51) is *optional*.

Treatment of cancer usually involves a combination of surgery, radiotherapy, chemotherapy, hormones and other systemic therapies, often given over several years.

Population-based cancer registries cannot record the full details of all treatments for all patients, although some registries link their data to more detailed clinical audit data. Many registries record whether a particular type of treatment was given, and the date it was given. Such data should enable international comparison of the distribution of treatment modalities for each cancer, and the interval between diagnosis and first treatment, by age and calendar period. If data on stage are available, stage-specific survival may be examined together with the proportion of patients who received each type of treatment, to help interpretation of international survival comparisons.

In a study of this scale, it is not feasible to capture the details of each treatment, e.g. radiotherapy fractionation, chemotherapy drugs and doses, or the surgical procedure(s) performed. None of the classifications of surgical procedures is sufficiently widespread for use in world-wide comparisons.

We will therefore use binary (yes/no) variables.

The data should be for the ***first course of treatment***, i.e. treatment performed within six months of a cancer diagnosis.

Variable 40 Cancer-directed surgery

Optional

Numeric variable, one digit.

If you decide not to provide this variable, please use the code 9 in ***all tumour records***.

The date of the ***first*** cancer-directed surgical procedure will be coded in variables 41-43.

This variable is intended to capture evidence on whether ***any surgical procedure(s)*** were performed to treat or manage the patient's cancer. Cancer-directed surgery includes any major or minor procedure **done with therapeutic intent**, such as laparotomy, thoracotomy, craniotomy and "keyhole" surgery. Removal of a suspicious lesion during a diagnostic examination may also have therapeutic intent, if pathology later confirms the lesion was malignant.

The ***first therapeutic surgical procedure*** may be of curative or palliative intent, depending on the stage of disease at diagnosis.

You should ***include:***

- Excision biopsy (e.g. ***colorectal cancer, melanoma***).
- Cone biopsy for ***cervical cancer***.
- Large loop excision of the transformation zone (LLETZ; also known as loop diathermy or loop biopsy) for ***cervical cancer***.
- Insertion of a stoma, or a stent, to relieve obstructive symptoms (e.g. ***colon, oesophagus***).

It should ***not include*** a procedure performed **only for diagnostic purposes**, such as needle biopsy, fine needle aspiration, brush biopsy, bone marrow biopsy or cytological smear.

Code		Meaning
1	=	Cancer-directed surgery ***was performed***
2	=	Cancer-directed surgery ***was not performed***
9	=	Not known if cancer-directed surgery was performed

Variables 41-43 Date of first cancer-directed surgery ***Optional variables***

This is the date on which the ***first*** cancer-directed surgical procedure was performed.

If you decide not to provide these variables, please code the date as missing (99,99,9999) in ***all tumour records***.

Variable 41 Day of first cancer-directed surgery **Optional**

Numeric variable, one or two digits.

1-31 = The day of the date of the first cancer-directed surgical procedure
99 = The day of this date is not known

Variable 42 Month of first cancer-directed surgery **Optional**

Numeric variable, one or two digits.

1-12 = The month of the date of the first cancer-directed surgical procedure
99 = The month of this date is not known

Variable 43 Year of first cancer-directed surgery **Optional**

Numeric variable, four digits.

YYYY = The year of the date of the first cancer-directed surgical procedure, from 2000 onwards
9999 = The year of this date is not known

Variable 44 Radiotherapy **Optional**

Numeric variable, one digit.

If you decide not to provide this variable, please use the code 9 in ***all tumour records***.

The date of the ***first*** radiotherapy procedure will be coded in variables 45-47.

This variable is intended to capture evidence on whether ***any form of radiation*** was given to treat or manage the patient's cancer. This includes external beam radiation from any source, brachytherapy (local implantation of radioisotopes), or systemic delivery of radioisotopes via the bloodstream.

This variable should ***not include*** any form of diagnostic imaging.

Radiotherapy may be pre-operative (neo-adjuvant), intra-operative, or post-operative (adjuvant), depending on the site and stage of the disease.

The ***first radiotherapy procedure*** may be of curative or palliative intent, depending on the stage of disease at diagnosis.

In some countries, the personnel and equipment required to deliver radiotherapy effectively are very scarce, or unavailable.[33]

Details of radiation dose, fractionation, radiation fields, techniques or regimens cannot be captured in studies of this scale.

We will therefore use a simple binary (yes/no) variable.

Code		Meaning
1	=	Radiotherapy ***was given***
2	=	Radiotherapy ***was not given***
9	=	Not known if radiotherapy was given

Variables 45-47 Date of radiotherapy ***Optional variables***

This is the date on which the ***first*** therapeutic radiotherapy procedure was performed. This would normally be within six months of a cancer diagnosis.

Radiotherapy may be pre-operative (neo-adjuvant), intra-operative, or post-operative (adjuvant), depending on the site and stage of the disease.

Radiotherapy may also be given without surgery, whether for curative or palliative purposes.

If you decide not to provide these variables, please code the date as missing (99,99,9999) in ***all tumour records***.

Variable 45 Day of the first radiotherapy procedure **Optional**

Numeric variable, one or two digits.

1-31 = the day of the date of the first radiotherapy procedure
99 = the day of this date is not known

Variable 46 Month of the first radiotherapy procedure **Optional**

Numeric variable, one or two digits.

1-12 = the month of the date of the first radiotherapy procedure
99 = the month of this date is not known

Variable 47 Year of the first radiotherapy procedure **Optional**

Numeric variable, four digits.

YYYY = the year of the date of the first radiotherapy procedure, from 2000 onwards
9999 = the year of this date is not known

Variable 48 Systemic therapy **Optional**

Numeric variable, one digit.

If you decide not to provide this variable, please use the code 9 in ***all tumour records***.

The date of the ***first*** use of systemic therapy will be coded in variables 49-51.

This variable is intended to capture evidence on whether ***any form of systemic therapy*** was given to treat or manage the patient's cancer. This includes treatment with cytotoxic chemotherapy, angiogenesis inhibitors, hormonal treatments and immunotherapy.

For solid tumours, chemotherapy may be given pre-operatively (neo-adjuvant chemotherapy) to reduce tumour size, or post-operatively (adjuvant chemotherapy) to treat residual disease or to prevent recurrence, depending on the site and stage of the disease.

For leukaemias, chemotherapy or some form of systemic therapy will usually be the main component of treatment, but in some countries, access to these forms of treatment may be limited or unavailable.[34,35]

The ***first systemic therapy*** may be of curative or palliative intent, depending on the stage of disease at diagnosis.

Systemic therapy may be given orally, or via an intravenous, intrathecal or intraperitoneal route. Details of drug regimen, dose and duration cannot be captured in studies of this scale.

We will therefore use a simple, binary (yes/no) variable.

Code		Meaning
1	=	Systemic therapy ***was given***
2	=	Systemic therapy ***was not given***
9	=	Not known if systemic therapy was given

Variables 49-51 Date of first systemic therapy ***Optional variables***

This is the date on which the first course of systemic therapy was started. This would normally be within six months of a cancer diagnosis.

Systemic therapy may be pre-operative (neo-adjuvant) or post-operative (adjuvant), depending on the site and stage of the disease.

Systemic therapy may also be given without surgery, whether for curative or palliative purposes.

If you decide not to provide these variables, please code the date as missing (99,99,9999) in ***all tumour records***.

Variable 49 Day of the first systemic therapy **Optional**

Numeric variable, one or two digits.

1-31 = the day of the date of the first systemic therapy
99 = the day of this date is not known

Variable 50 Month of the first systemic therapy **Optional**

Numeric variable, one or two digits.

1-12 = the month of the date of the first systemic therapy
99 = the month of this date is not known

Variable 51 Year of the first systemic therapy **Optional**

Numeric variable, four digits.

YYYY = the year of the date of the first systemic therapy, from 2000 onwards
9999 = the year of this date is not known

4 Valid values for each variable

Name of variable	Short description	No. of digits or characters	Valid values (or *range* of valid values)	Value to be used when valid data are missing
VAR1	Country	4	Use the value provided *	Not allowed
VAR2	Registry	1, 2 or 3	Use the value provided *	Not allowed
VAR3	Person code	Up to 15	Numeric or alphanumeric	Not allowed
VAR4	Tumour code	Up to 10	Numeric or alphanumeric	Not allowed
VAR5	IARC CHECK flag[1]	1	1,2,3,4	9
VAR6	Sex	1	1,2	9
VAR7	Region[1,2]	Up to 5	Numeric (see page 7)	99999
VAR8	Race/ethnicity[1,2]	1 or 2	Numeric (see page 8)	99
VAR9	Day of birth	1 or 2	1-31	99
VAR10	Month of birth	1 or 2	1-12	99
VAR11	Year of birth	4	1900 - latest year	9999
VAR12	Day of diagnosis	1 or 2	1-31	99
VAR13	Month of diagnosis	1 or 2	1-12	99
VAR14	Year of diagnosis	4	2000 - latest year	Not allowed
VAR15	Last known vital status	1	1,2,3	9
VAR16	Day of last known vital status	1 or 2	1-31	99
VAR17	Month of last known vital status	1 or 2	1-12	99
VAR18	Year of last known vital status	4	2000 - latest year	9999
VAR19	Basis of diagnosis	1	1,2,3,4,5,6,7,8	9
VAR20	Topography	4	Alphanumeric (see page 14)	Not allowed
VAR21	Morphology	4	8000-9992	9999
VAR22	Behaviour	1	0,1,2,3,6,9	Not allowed
VAR23	Grade	1	0,1,2,3,4,5,6,7,8	9
	Stage at diagnosis[1]			
VAR24	SEER Summary Stage 2000	1	0,1,2,3,4,5,7	9
VAR25	Pathological T	1	0,1,2,3,4,8	9
VAR26	Pathological N	1	0,1,2,3	9
VAR27	Pathological M	1	1	9
VAR28	Clinical T	1	0,1,2,3,4,8	9
VAR29	Clinical N	1	0,1,2,3	9
VAR30	Clinical M	1	0,1	9
VAR31	Condensed T	1	1,2	9
VAR32	Condensed N	1	1,2	9
VAR33	Condensed M	1	1,2	9
VAR34	Dukes' stage[3]	1	1,2,3,4	9
VAR35	FIGO stage[4]	1	0,1,2,3,4,5	9
VAR36	Ann Arbor stage[5]	1	1,2,3,4	9
VAR37	Tumour size (mm)	1, 2 or 3	1-300	999
VAR38	No. of lymph nodes examined	1 or 2	0-98	99
VAR39	No. of lymph nodes involved	1 or 2	0-98	99

Valid values for each variable (continued)

Name of variable	Short description	No. of digits or characters	Valid values (or *range* of valid values)	Value to be used when valid data are missing
	First course of treatment[1]			
VAR40	Cancer-directed surgery	1	1,2	9
VAR41	Day of first surgery	1 or 2	1-31	99
VAR42	Month of first surgery	1 or 2	1-12	99
VAR43	Year of first surgery	4	2000 - latest year	9999
VAR44	Radiotherapy	1	1,2	9
VAR45	Day of first radiotherapy	1 or 2	1-31	99
VAR46	Month of first radiotherapy	1 or 2	1-12	99
VAR47	Year of first radiotherapy	4	2000 - latest year	9999
VAR48	Systemic therapy	1	1,2	9
VAR49	Day of first systemic therapy	1 or 2	1-31	99
VAR50	Month of first systemic therapy	1 or 2	1-12	99
VAR51	Year of first systemic therapy	4	2000 - latest year	9999

***** We will send you the code to use for this variable; it should be used ***in all tumour records***

[1] If you ***do not wish*** to provide data for these variables, use the "missing value" (last column) in ***all tumour records***

[2] If you ***do wish*** to provide data for this variable, please contact us first, to agree the codes that you will use

[3] Valid values only for **colon** and **rectal cancer**; for all other cancers, please use the code 9 in ***all tumour records***

[4] Valid values only for **cervical** and **ovarian cancer**; for all other cancers, please use the code 9 in ***all tumour records***

[5] Valid values only for **lymphomas**; for all other malignancies, please use the code 9 in ***all tumour records***

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