British Isles Network of Congenital Anomaly Registers

BINOCAR Standard Operating Procedure for Reporting using Standardised Methods

Instructions for the Registration and Surveillance of Congenital Anomalies in England and Wales

Authors:

Anna Springett (BINOCAR Hub)
Elizabeth Draper (EMSYCAR)

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1.1	30 January 2015	First version put together by AS, ED and the BINOCAR Management Committee

Contents

Standard reporting information

This document outlines the standard definitions used by BINOCAR for data collection, coding, analysis and reporting. These are based on EUROCAT definition to facilitate international comparisons.

Term	Definition
Age-standardised ratio	A comparison of the number of observed cases in a population with the number of expected cases if the age distribution were the same as a standard population.
Birth prevalence	The total number of cases of congenital anomaly (live births, stillbirths, late miscarriages and terminations of pregnancy for fetal anomaly) compared to the total number of births (live births and stillbirths).
Births/total births	Live births and stillbirths.
Case	A baby/fetus with one or more congenital anomalies.
Congenital anomaly	Any defect present at delivery, probably originating before birth, and includes structural, chromosomal, genetic and biochemical defects and malformations.
Infant mortality rate	The number of deaths of babies less than one year of age per 1,000 live births.
Isolated congenital anomaly	One anomaly or multiple anomalies within the same body system.
Late miscarriage	Late fetal deaths from 20-23 completed weeks of gestation.
Multiple congenital anomalies	Two or more unrelated structural anomalies .
Neonatal death	Death of a live born baby occurring before 28 completed days after birth. Early = 0-6 completed days; Late = 7-27 completed days.
Prenatal detection rate	The number of cases with a specified congenital anomaly diagnosed prenatally divided by all cases with a specified congenital anomaly. Presented as a percentage of all cases.
Prenatal diagnosis	A diagnosis made in a live fetus at any gestation before delivery.
Prenatal screening	Tests for identifying fetuses who may be at higher risk of certain congenital anomalies (e.g. Down syndrome). Those women whose pregnancies have been identified at higher risk may opt for a diagnostic test such as chorionic villus sampling (CVS) or amniocentesis.
Sequences	Pattern of multiple anomalies derived from a single known or presumed prior anomaly, insult or mechanical factor.
Severe congenital heart defects (CHD)	This is the definition EUROCAT uses and includes the following congenital heart defects: • Common arterial truncus • Transposition of great vessels • Single ventricle • Atrioventricular septal defect • Tetralogy of Fallot • Triscuspid atresia and stenosis • Ebstein's anomaly • Pulmonary valve atresia • Aortic valve atresia/stenosis • Hypoplastic left heart • Hypoplastic right heart • Coarctation of aorta • Total anomalous pulmonary venous return
Stillbirths	Fetal deaths from 24 completed weeks of gestation. The baby is born showing no signs of life.

Termination of pregnancy with fetal anomaly	Term used to describe the deliberate ending of a pregnancy with the intention that the fetus will not survive and which is carried out when the fetus is diagnosed prenatally as having a major congenital anomaly.

Incidence and birth prevalence

Incidence is the total number of 'new' cases of disease occurring in a population in a specified time period, whereas prevalence is the total number of 'all' cases in a population at one point in time. As congenital anomaly registers report the number of babies with anomalies born during a calendar year, one might anticipate that incidence rates would be reported. However, conventionally, as in this report, congenital anomaly registers report prevalence estimates. This is because it is not possible to ascertain all 'new' cases of any particular anomaly, as a proportion of pregnancies affected with an anomaly will miscarry spontaneously before being diagnosed. There are no available population estimates of the total number of pregnancies at risk of being affected by an anomaly due to miscarriages and terminations of pregnancy. As such, congenital anomaly registers report prevalence estimates per 10,000 total births (live and stillbirths). By convention these are referred to as birth prevalence estimates even though the pregnancy may not result in a 'birth' because of late miscarriage or termination of pregnancy for fetal anomaly.

Calculation of birth prevalence and their 95% confidence intervals

$$\text{Birth prevalence} = \frac{\text{Number of cases (live births + stillbirths + late miscarriages + TOPFAs)}}{\text{Number of births (live births+stillbirths)}} \text{x } 10{,}000$$

$$\text{Lower 95\% confidence limit} = \frac{\left(\frac{1.96}{2} - \sqrt{\text{number of cases} + 0.02}\right)^2}{\text{number of births}} \text{x } 10{,}000$$

$$\text{Upper 95\% confidence limit} = \frac{\left(\frac{1.96}{2} + \sqrt{\text{number of cases} + 0.96}\right)^2}{\text{number of births}} \text{x } 10{,}000$$

The confidence intervals are calculated using the Poisson distribution.[1]

Geography of registers

The geography of a register is currently assigned using postcode at delivery converted to local authority. The coverage of each register in 2014 is provided in the following table.

[1] Bégaud B, Martin K, Abouelfath A, Tubert-Bitter P, Moore N, Moride Y. Any easy to use method to approximate Poisson confidence limits. European Journal of Epidemiology (2005) 20: 213-216.

Register	Coverage	
CARIS (Wales)	All of Wales	
CAROBB (Oxfordshire, Berkshire & Buckinghamshire)	**Local Authorities:** Aylesbury Vale Bracknell Forest Cherwell Chiltern Milton Keynes Oxford Reading Slough	 South Bucks South Oxfordshire Vale of White Horse West Berkshire Windsor & Maidenhead Wokingham Wycombe
EMSYCAR (East Midlands & South Yorkshire)	**Strategic Health Authority:** East Midlands **Local Authorities:** Barnsley Doncaster Rotherham Sheffield North East Lincolnshire North Lincolnshire	
NorCAS (Northern England)	**Strategic Health Authority:** North East **Local Authorities:** Allerdale Carlisle Copeland Eden	
SWCAR (South West England)	**Local Authorities:** Bath and North East Somerset Bristol, City of Cheltenham Cornwall Cotswold East Devon Exeter Forest of Dean Gloucester Isles of Scilly Mendip Mid Devon North Devon North Somerset Plymouth	 Sedgemoor South Gloucestershire South Hams South Somerset Stroud Swindon Taunton Deane Teignbridge Tewkesbury Torbay Torridge West Devon West Somerset Parts of Wiltshire
WANDA (Wessex)	**Local Authorities:** Basingstoke and Deane Bournemouth Christchurch East Dorset Eastleigh Fareham Gosport Havant Isle of Wight New Forest North Dorset Poole	 Portsmouth Purbeck Southampton Test Valley West Dorset Weymouth and Portland Winchester Parts of East Hampshire Parts of Hart Parts of West Berkshire Parts of Wiltshire

Coding of variables

The variables that are sent to EUROCAT should be coded according to EUROCAT's Guide 1.4 Section 2.2.1 (please see appendix A). Please also see BINOCAR SOP – Coding, classification, inclusion and exclusion for more information.

The extra variables that are sent to the BINOCAR Hub should be coded according to the BINOCAR SOP - Extra BINOCAR Variables.

The other variables that are used within the register and not transfer out should be coded according to a local SOP.

Regional/national/international reporting

The data presented in regional and national reports needs to be identical to the data presented by EUROCAT on their website. If the data doesn't match then there needs to be a clear explanation of the reason for the difference.

See BINOCAR SOP - Small Numbers for information on the disclosure control required for regional reporting.

Only cases with confirmed congenital anomalies are included in regional and national reports, cases with suspected anomalies where further investigation is being carried out are not included. The timing of reporting is important as reporting too early would mean fewer confirmed cases and therefore a lower prevalence.

Prevalence data

Birth prevalence data is presented on the EUROCAT website using the following criteria:

- One or multiple registers (presented individually or combined)
- One or multiple anomalies (including or excluding chromosomal anomalies)
- One or multiple years (presented individually or combined)
- Number of cases, population, prevalence and/or proportions
- Table (excel) or graph (PDF).

The link from the BINOCAR website allows for the selection of data from the BINOCAR registers separately:
http://www.binocar.org/Data/Prevalence

The EUROCAT website can be used to select data from all EUROCAT registers:
http://www.eurocat-network.eu/accessprevalencedata/prevalencetables

Prenatal data

Prenatal detection data can be accessed from the EUROCAT website using one or more of the following criteria:

- One of a list of selected anomalies
- Graph or table
- Overall data or by outcome, maternal age, indication or gestation (where appropriate)

The data for Down, Patau and Edwards syndrome are from the National Down Syndrome Cytogenetic Register (NDSCR) covering all of England and Wales and not from the individual registers. All other anomalies show data from the regional registers separately.

Go to the EUROCAT website to view these data:
http://www.eurocat-network.eu/prenatalscreeninganddiagnosis/prenataldetection(pd)rates

Appendix A – Coding of EUROCAT variables

Summary of variables (core variables are shaded blue) (Issued April 2013)

Variable Number	Variable Name	Variable heading
Baby and Mother – Variables 1 to 18		
1	CENTRE	Centre Number
2	NUMLOC	Local ID
3	BIRTH_DATE	Date of Birth
4	SEX	Sex
5**	NBRBABY	Number of babies/fetuses delivered
6	SP_TWIN	Specify twin type of birth, like or unlike, zygosity
7	NBRMALF	Number of malformed in multiple set
8	TYPE	Type of Birth
9	CIVREG	Civil registration status
10	WEIGHT	Birth weight
11	GESTLENGTH	Length of gestation in completed weeks
12	SURVIVAL	Survival beyond one week of age
13	DEATH_DATE	Date of death
14	DATEMO	Date of birth of mother
15	AGEMO	Age of mother at delivery
16*	BMI	Maternal Body Mass Index
17	RESIDMO	Mother's residence code
18	TOTPREG	Total number of previous pregnancies
Diagnosis – Variables 19 to 57		
19**	WHENDISC	When discovered
20	CONDISC	Condition at discovery
21	AGEDISC	If prenatally diagnosed, gestational age at discovery
22**	FIRSTPRE	First positive prenatal test
23	SP_FIRSTPRE	Specify first prenatal test in text if coded 7 ("other test positive")
24	KARYO	Karyotype of infant/fetus
25	SP_KARYO	Specify karyotype
26*	GENTEST	Genetic Test
27*	SP_GENTEST	Specify genetic test
28	PM	Post mortem examination
29**	SURGERY	First surgery for malformation performed or planned
30	SYNDROME	Syndrome
31	SP_SYNDROME	Specify Syndrome
32	MALFO1	Malformation
33	SP_MALFO1	Specify malformation
34	MALFO2	As MALFO1
35	SP_MALFO2	Specify malformation
36	MALFO3	As MALFO1
37	SP_MALFO3	Specify malformation
38	MALFO4	As MALFO1
39	SP_MALFO4	Specify malformation
40	MALFO5	As MALFO1

41	SP_MALFO5	Specify malformation
42	MALFO6	As MALFO1
43	SP_MALFO6	Specify malformation
44	MALFO7	As MALFO1
45	SP_MALFO7	Specify malformation
46	MALFO8	As MALFO1
47	SP_MALFO8	Specify malformation
48*	PRESYN	Prenatal diagnosis for syndrome
49*	PREMAL1	Prenatal diagnosis for malformation
50*	PREMAL2	As PREMAL1
51*	PREMAL3	As PREMAL1
52*	PREMAL4	As PREMAL1
53*	PREMAL5	As PREMAL1
54*	PREMAL6	As PREMAL1
55*	PREMAL7	As PREMAL1
56*	PREMAL8	As PREMAL1
57#	OMIM	OMIM code / Type of Mendelian Inheritance
Exposure – Variables 58 to 78		
58**	ASSCONCEPT	Assisted conception
59##	OCCUPMO	Mother's occupation at time of conception
60	ILLBEF1	Illness before pregnancy 1
61	ILLBEF2	Illness before pregnancy 2
62*	MATDIAB	Maternal Pregestational Diabetes
63*	HbA1c	Glycated haemoglobin value
64	ILLDUR1	Illness during pregnancy
65	ILLDUR2	Illness during pregnancy 2
66*	FOLIC_G14	Folic acid supplementation
67*	FIRSTTRI	First trimester medication
68	DRUGS1	Drugs
69	SP_DRUGS1	Specify drug exposures
70	DRUGS2	As for DRUGS1
71	SP_DRUGS2	Specify drug exposures
72	DRUGS3	As for DRUGS1
73	SP_DRUGS3	Specify drug exposures
74	DRUGS4	As for DRUGS1
75	SP_DRUGS4	Specify drug exposures
76	DRUGS5	As for DRUGS1
77	SP_DRUGS5	Specify drug exposures
78	EXTRA_DRUGS	Extra drugs
Family History – Variables 79 to 90		
79	CONSANG	Consanguinity
80	SP_CONSANG	Specify text information on consanguinity
81	SIBANOM	Siblings with anomalies
82	SP_SIBANOM	Specify type of anomaly and describe the malformation
83	PREVSIB	Previous malformed sibs notified to EUROCAT
84	SIB1	Local ID number notified to the Central Registry
85	SIB2	As SIB1
86	SIB3	As SIB1
87	MOANOM	Mother's family with anomalies
88	SP_MOANOM	Specify type of anomaly and describe the malformation

89	FAANOM	Father's family with anomalies
90	SP_FAANOM	Specify type of anomaly and describe the malformation
Socio-demographic – Variables 91 to 94		
91	MATEDU	Maternal education
92	SOCM	Socioeconomic status of mother
93	SOCF	Socioeconomic status of father
94	MIGRANT	Migrant status
General Comments – Variable 95		
95	GENREM	General additional comments

* New variable In Guide 1.4
** Variable compatible with Guide 1.3, but coding has been extended/modified
# Variable name change only
Guide 1.4 use ISCO-08 classifications

Coding Instructions (issued March 2013)

Baby and Mother (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
1	CENTRE	CENTRE NUMBER	Code allocated by Central Registry
2	NUMLOC	LOCAL ID Each case has a unique identification. This number is a maximum of 11 characters long, consisting of numbers, letters or both. ID numbers should not repeat themselves in different years.	Up to 11 digits
3	BIRTH_DATE	DATE OF BIRTH Please enter dates as a numeric string, not in date format (eg. do not use 28/02/89 or 28-02-89, instead use 280289).	Day, month, year 99 = Not known for day and month DO NOT TRANSMIT RECORDS IF YEAR OF BIRTH IS NOT KNOWN
4	SEX	SEX Indicate chromosomal sex, if known, in case of ambiguous genitalia and code malformations in variables 32-47. Indicate indeterminate sex in case of ambiguous genitalia with unknown or abnormal sex chromosome complement. If sex could not be determined at autopsy due to maceration or other problems, indicate as "not known".	1 = Male 2 = Female 3 = Indeterminate 9 = Not known

Baby and Mother (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
5	NBRBABY	NUMBER OF BABIES/FETUSES DELIVERED Fill out a separate form for each malformed baby/fetus in a multiple set. Only one form to be completed for conjoined twins (Siamese). The code is "2" for a conjoined twin, unless another baby was delivered at the same time (code "3"). Conjoined twins have a specific ICD/BPA code, to be coded under "syndrome" (variable 30). Give full description of type of conjoined twinning in syndrome text field (variables 31). Any other anomalies are coded in variables 32-47. Notes. If code 8 is used, please specify in variable sp_twin the gestational age at which last known to be a multiple pregnancy and/or first known to be a singleton. The purpose of this coding system is to allow us to distinguish malformed cases which would have civil registration as singleton births from malformed cases which would have civil registration as multiple births. Please specify the sex and outcome (live, still) of the malformed/non-malformed co-twin and zygosity.	1 = Singleton 2 = Twins 3 = Triplets 4 = Quadruplets 5 = Quintuplets 6 = Sextuplets or more 7 = Multiple birth, number of babies not known 8 = Singleton at time of delivery/termination, but known to have been a multiple pregnancy at an earlier stage in pregnancy 9 = Not known
6	SP_TWIN	SPECIFY TWIN TYPE OF BIRTH (malformed and non-malformed), like or unlike sex, zygosity	Free text
7	NBRMALF	NUMBER OF MALFORMED IN MULTIPLE SET To be completed for multiple delivery only. Remember to give local ID of co-twin in SIB1 field (variable 84) if more than one malformed.	1 = One 2 = Two 3 = Three 4 = Four 5 = Five 6 = Six or more 9 = Not known

Baby and Mother (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
8	TYPE	TYPE OF BIRTH Birth with type of birth not known should be transmitted to EUROCAT, but will be excluded from routine EUROCAT analysis. EUROCAT includes all live births, fetal deaths with gestational age (GA) ≥20 weeks and terminations of pregnancy (at any gestational age) after prenatal diagnosis of malformation. Fetal deaths with GA < 20 weeks (code = 3) may be reported to EUROCAT but will not be included in prevalence data. The distinction between stillbirth and spontaneous abortion should follow the definitions in use in your country (to be specified in your Registry Description). There is usually a lower gestational age limit or birthweight limit for stillbirths. This varies from country to country. Below this limit fetal deaths are called spontaneous abortions. Terminations of pregnancy refer to cases where prenatal diagnosis was made of malformation in a live fetus and the pregnancy was then terminated. If the fetus died spontaneously in utero either before or after prenatal diagnosis of malformation then it should be coded as spontaneous abortion or stillbirth, not as termination of pregnancy. If a termination was performed for other reasons than malformation, the case should not be transmitted to Central Registry. This means that early terminations where there was no suspicion of malformation before termination should be excluded from the case files. Stillbirths or perinatal deaths resulting from termination of pregnancy following prenatal diagnosis must be coded as terminations (value = 4), irrespective of civil registration status. For a non-natural fetal reduction in a multiple pregnancy where one fetus is malformed, code 4 (in that case gestlength = gestational age at reduction; date of birth = date of reduction; and code carefully all multiple birth variables).	1 = Live birth 2 = Stillbirth 3 = Spontaneous abortion 4 = TOPFA 9 = Not known

Baby and Mother (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
9	CIVREG	CIVIL REGISTRATION STATUS Livebirths and stillbirths are civilly registered leading to either a birth or stillbirth certificate and appear in official birth statistics for your region. Code here whether this case fulfilled the conditions for live or stillbirth registration in your country.	1 = Livebirth 2 = Stillbirth 3 = No civil registration 9 = Not known
10	WEIGHT	BIRTH WEIGHT Give weight in grams.	9999 = Not known (Do not use 99 or 999 for "Not Known" as this will be considered the birth weight).
11	GESTLENGTH	LENGTH OF GESTATION IN COMPLETED WEEKS Give best estimate based on last menstrual period (LMP) and/or ultrasound determination. If the case is the result of fetal reduction give GA at fetocide.	99 = Not known
12	SURVIVAL	SURVIVAL BEYOND ONE WEEK OF AGE Yes = Child known to be alive after one week. No = Child known to have died before or during first week (including stillbirths and abortions). Alive at discharge <1 week refers to cases that are alive at discharge from maternity units before one week of age. Please specify in your Registry Description the day when discharge from maternity units usually takes place. If survival at one week is unknown, but survival at discharge from maternity unit less than one week is known, use the latter. The definition of first week of life varies between countries. Follow your country's perinatal mortality definition and specify this in your Registry Description. Not known = Not known if child has died during first week.	1 = Yes 2 = No 3 = Alive at discharge <1 week 9 = Not known

Baby and Mother (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
13	DEATH_DATE	DATE OF DEATH **For live births only.** Please enter dates as a numeric string, not in date format (eg. do not use 28/02/89 or 28-02-89, instead use 280289).	Day, month, year 99= Died, not known day or month 44 =Died, not known year (Do not use 99 for "not known" year of death, as this will be read as died in 1999, day and month not known.) 222222= Known to be alive at 1 year 333333= Not known if alive or dead at 1 year
14	DATEMO	DATE OF BIRTH OF MOTHER Give as much information as is known eg. Feb 1963 = 990263, 1963 = 999963. Please enter dates as a numeric string, not in date format (eg. do not use 28/02/89 or 28-02-89, instead use 280289). This variable can be used to calculate maternal age at Expected Date of Delivery for preterm deliveries and terminations.	Day, month, year 99 = Not known day or month 44 = Not known year
15	AGEMO	AGE OF THE MOTHER AT DELIVERY In completed years at the time of delivery. If only the year of birth is available, assume that the mother was born on 30 June.	99 = Not known
16	BMI	MATERNAL BODY MASS INDEX Enter BMI (2 digits). The EDMP will also allow entry of maternal height (in centimetres) and weight (in kilograms) and calculate BMI automatically. Values measured at first antenatal visit are preferred, but pre-pregnancy self-reported values may be given. If mother known to be obese, enter code for obesity E660 in maternal illness before pregnancy (variable 60) Whilst BMI is a new variable in Guide 1.4 (for case born from 2013 onwards) if any registry has this information for previous cases, EUROCAT is interested in collecting this information from 2005 onwards	2 digits Expected range 15 – 50 97 = exact BMI NK but <30 98 = exact BMI NK but >=30 99 = Not known
17	RESIDMO	MOTHER'S RESIDENCE CODE Use local code for locality of residence at time of delivery.	Local code (up to 10 digits)

Baby and Mother (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
18	TOTPREG	TOTAL NUMBER OF PREVIOUS PREGNANCIES NOTE – The current reported pregnancy is NOT included. Include all previous abortions whether spontaneous or induced. Multiple pregnancies count as 1 in the total	00 = None 01 = One 02 = Two 03 = Three etc 20 = Twenty or more 99 = Not known

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
19	WHENDISC	WHEN DISCOVERED When the baby was first suspected of having a congenital anomaly. For prenatal diagnosis: when a major congenital anomaly was first suspected (EXCLUDING soft markers except if nuchal translucency indicates a very high risk followed by confirmation of diagnosis at delivery/termination). If prenatal diagnosis is made when fetus is dead code 1 (for stillbirths) or 7 (for spontaneous abortions). For live births: when first suspicion of an anomaly was at death OR at post mortem, when discovered is age at death (eg. At birth, < 1 week, 1-4 weeks etc). For stillbirths: when first suspicion of an anomaly was at birth OR at post mortem, when discovered is at birth (eg. Code = 1). All cases MUST have been confirmed as having a congenital anomaly. Please also complete variables 12 “SURVIVAL”, 13 “DEATH-DATE”, 20 “CONDISC” and 28 “PM”.	1 = At birth 2 = Less than 1 week 3 = 1-4 weeks 4 = 1-12 months 5 = Over 12 months 6 = Prenatal diagnosis in live fetus 7 = At abortion (spontaneous) 9 = Not known 10 = Postnatal diagnosis, age not known
20	CONDISC	CONDITION AT DISCOVERY Condition of fetus or baby when malformation was first suspected.	1 = Alive 2 = Dead 9 = Not known
21	AGEDISC	IF PRENATALLY DIAGNOSED, GESTATIONAL AGE AT DISCOVERY IN COMPLETED WEEKS GA as defined in variable gestlength. Gestational age at which the fetus was first suspected to be malformed (EXCLUDING soft markers). Indicate time of examination rather than time when result known. If no prenatal diagnosis please leave blank.	99 = Not known

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
22	FIRSTPRE	FIRST POSITIVE PRENATAL TEST This refers to the first prenatal test whether screening procedure or diagnostic test which indicated a possible congenital anomaly or need for further tests. For code 7 = other specified test, give information in text field (variable 23). If test performed and result negative, then the "When discovered" variable cannot be coded 6 (prenatal diagnosis). This field is to record what DID happen, not any possible plans or intentions. Ultrasound < 14 weeks means only ultrasound performed which may include a nuchal measurement. The serum/combined screening must involve a biochemical test	1 = Ultrasound at GA < 14 weeks 2 = Ultrasound at GA 14-21 weeks 3 = Ultrasound at GA ≥ 22 weeks 4 = Ultrasound GA not known 5 = Serum/combined screening 6 = CVS or amniocentesis 7 = Other test positive 8 = Test(s) performed, result negative 9 = Not known 10 = No test performed 11 =Fetal karyotype on maternal blood
23	SP_FIRSTPRE	SPECIFY "OTHER" FIRST PRENATAL TEST If FIRSTPRE = 7, specify which positive prenatal test	Free text
24	KARYO	KARYOTYPE OF INFANT/FETUS Specify result in variable 25. Array results count as a karyotype test If performed and results known, please specify (according to Paris nomenclature). "Probe test performed" refers to FISH, PCR, or other analyses restricted to specific chromosomal anomalies. "Failed" refers to a technical failure where a repeat examination could not be done and the karyotype is therefore unknown.	1 = Performed, result known 2 = Performed, results not known 3 = Not performed 4 = Probe test performed 8 = Failed 9 = Not known
25	SP_KARYO	SPECIFY KARYOTYPE	Free text
26	GENTEST	GENETIC TEST For syndromes and single gene disorders, a genetic test may have confirmed the clinical diagnosis either prenatally or postnatally. Please complete for these cases. Karyotype should still be completed as per variable 24 & 25 Whilst GENETIC TEST is a new variable in Guide 1.4 (for cases born from 2013 onwards) if any registry has this information for previous cases, EUROCAT is interested in collecting this information from 2005 onwards	1 = Yes, diagnosis confirmed by genetic test 2 = No, diagnosis not confirmed by genetic test 3 = Not Performed 9 = Not known
27	SP_GENTEST	SPECIFY TYPE OF GENETIC TEST	Free text

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
28	PM	POST MORTEM EXAMINATION If performed record the malformation(s) discovered in the "malformation" section in the form. If other findings record in the "comments" space (variable 95). "Results known" means that the autopsy record has been reviewed by the registry. "Results not known" means that the autopsy record was not available to the registry. "Macerated fetus" means that although a post mortem was performed, maceration of the fetus prevented a full protocol from being followed.	1 = Performed, results known 2 = Performed, results not known 3 = Not performed 4 = Macerated fetus 9 = Not known
29	SURGERY	FIRST SURGICAL PROCEDURE FOR MALFORMATION (PERFORMED OR EXPECTED) **Complete for all livebirths** **(and fetal deaths, only if there was prenatal surgery)** The variable surgery does not include insertions of catheters. Performed (or expected) means that this case has already, or will at the appropriate age, have surgery for one or more of the listed malformations. "No surgery required" means that this case does not have a severe enough malformation, or that the malformation is not correctable by surgery. "Too severe for surgery" means that there has been an active decision to withhold surgery due to low chances of survival or very poor prognosis.	1 = Performed (or expected) in the first year of life 2 = Performed (or expected) after the first year of life 3 = Prenatal surgery 4 = No surgery required 5 = Too severe for surgery 6 = Died before surgery 9 = Not known

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
30	SYNDROME	SYNDROME OR ASSOCIATION Refer to EUROCAT Guide on syndromes. Give name of syndrome or association in text variable 31. All the anomalies observed by the local clinician should be coded in the remaining boxes for malformations.If not a recognised syndrome or association, leave blank. When 2 syndromes are present in the same subject, code the more important one in the syndrome variables 30 and 31, and include the other one in variables 32 and 33 MALF01. Ensure karyotype information is given in variables 24 and 25, and that autopsy and medical genetics reports have been reviewed, where appropriate. In case of conjoined twins, give full description in syndrome text variable 31. Local registries are advised to keep photographs and x-ray images of all syndrome cases, as the diagnosis is predominantly established on the basis of specific facial dysmorphism.	ICD 10 First 4 digits are ICD10 5th digit = BPA supplement or leave blank
31	SP-SYNDROME	SPECIFY SYNDROME Please specify availability of photographs and x-ray images of syndrome case.	
32	MALFO1	MALFORMATION A baby/fetus with ONLY minor anomalies (see exclusion list, chapter 7) should not be transmitted to Central Registry. When a major anomaly is present, code both major and minor anomalies. Up to 8 malformations can be coded – if more than 8 are present, specify additional anomalies in the text variable for the 8th anomaly (text variable 47 SP_MALFO8). Include in the 8 specified codes the most important ones, or those tabulated in EUROCAT Reports. Give written description of the malformations available in malformation text variables 33, 35, 37, 39, 41, 43, 45 and 47.	ICD 10 First 4 digits are ICD 5th digit = BPA classification OR leave blank
33	SP_MALFO1	SPECIFY MALFORMATION	Free text
34	MALFO2	AS MALFO1	As MALF01
35	SP_MALFO2	SPECIFY MALFORMATION	Free text
36	MALFO3	AS MALFO1	As MALF01
37	SP_MALFO3	SPECIFY MALFORMATION	Free text

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
38	MALFO4	AS MALFO1	As MALF01
39	SP_MALFO4	SPECIFY MALFORMATION	Free text
40	MALFO5	AS MALFO1	As MALF01
41	SP_MALFO5	SPECIFY MALFORMATION	Free text
42	MALFO6	AS MALFO1	As MALF01
43	SP_MALFO6	SPECIFY MALFORMATION	Free text
44	MALFO7	AS MALFO1	As MALF01
45	SP_MALFO7	SPECIFY MALFORMATION	Free text
46	MALFO8	AS MALFO1	As MALF01
47	SP_MALFO8	SPECIFY MALFORMATION	Free text

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
48	PRESYN	PRENATAL DIAGNOSIS FOR SYNDROME When each anomaly was first diagnosed. This basis for this variable is to record whether the prenatal findings strongly suggest the postnatal diagnosis. This variable is not designed for fetal medicine specialists to assess the accuracy of their prenatal diagnosis. Thus the finding of a significant heart anomaly prenatal is considered to be prenatally detected, even if the *exact* anomaly was not correctly diagnosed. 'Yes, prenatally diagnosed', should be used when the prenatal finding is nearly 100% predictive of the congenital anomaly. 'Partially' means that the prenatal finding is consistent with the postnatal anomaly but has a lesser predictive value, being suggestive of more than one type of anomaly, an example here would be increased nuchal translucency. The examples below are to illustrate this principle and ensure consistency of coding. Queries about individual cases can be send to Central registry	1 = Yes, this anomaly was diagnosed prenatally 2 = No, this anomaly was diagnosed postnatally 3 = This anomaly partially prenatally diagnosed 9 =Not known

Prenatal Finding	**Postnatal Finding**	**Prenatal/Postnatal/ Partial**
Double bubble	Duodenal atresia/stenosis	Prenatal
High risk screening (no amnio)	T21	Partial
Ventriculomegaly	Agenesis corpus callosum	Partial
Ventriculomegaly	Neuronal migration anomalies	Partial
Ventriculomegaly	Hydrocephalus	Prenatal
Significant heart anomaly	*Any* significant heart anomaly	Prenatal
Heart abnormality	22q11 del	Partial
Cleft lip	Cleft lip and palate	Partial
IUGR	Skeletal displasia	Postnatal
Anhydramnios	Renal agenesis	Partial
Micrognathia	Pierre Robin/cleft palate	Prenatal
Severe skeletal dysplasia	Specific skeletal dysplasia eg thanatophoric/achondrogenesis	Prenatal
Echogenic bowel	CF	Partial
Absent stomach bubble	Oesophageal atresia	Partial

Diagnosis (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
49	PREMAL1	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
50	PREMAL2	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
51	PREMAL3	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
52	PREMAL4	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
53	PREMAL5	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
54	PREMAL6	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
55	PREMAL7	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
56	PREMAL8	PRENATAL DIAGNOSIS FOR MALFORMATION AS PRESYN	AS PRESYN
57	OMIM	OMIM / TYPE OF MENDELIAN INHERITANCE To be coded by medical geneticist or after advice from medical geneticist. This code is to be used for cases with single gene origin only – Refer to EUROCAT Syndrome Guide. The first digit may be filled in without the rest of the code if the full OMIM code is not known. Full codes can be found on the OMIM website http://www.ncbi.nlm.nih.gov/omim/	

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
58	ASSCONCEPT	ASSISTED CONCEPTION IVF = In vitro fertilization GIFT = Gamete intra fallopian transfer ICSI = Intracytoplasmic sperm injection	0 = No 1 = Induced ovulation only 2 = Artificial insemination 3 = IVF 4 = GIFT 5 = ICSI 6 = Egg donation 8 = Other 9 = Not known 10 = Assisted conception, type unknown

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
59	OCCUPMO	MOTHER'S OCCUPATION AT TIME OF CONCEPTION Code main occupation at time of conception (or earliest known time in first trimester). Note that the main purpose of the variable relates to potential teratogenic occupational exposures in early pregnancy. Be as precise as possible. Code according to 2008 (ISCO-08) Classification for birth with birth dates from 2013. Code according to the 1988 International Standard Classification of Occupations (ISCO-88) for births with birth dates up to 2012. Links for ISCO classifications: http://www.ilo.org/public/english/bureau/stat/isco/isco08/index.htm Available in many languages. The 4 digit codes give the necessary specificity. They are grouped into the following main groups: 0 = Armed Forces (NB – do not preface you codes with zero UNLESS it is an armed forces occupation. All database systems must accept a leading zero and not drop it). 1 = Managers 2 = Professionals 3 = Technicians and Associate Professionals 4 = Clerical Support Workers 5 = Service and Sales Workers 6 = Skilled agricultural, forestry and fishery workers 7 = Craft and related trades workers 8 = Plant and machine operators, and assemblers 9 = Elementary occupations EUROCAT Supplement: 9991 = Employed (including self-employed), but occupation unknown 9995 = Housewife 9996 = Student 9997 = Unemployed 9999 = Not known whether employed or not	**4 digit** code 9999 = Not known (do NOT use 9, 99 or 999 for not known)

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
60	ILLBEF1	ILLNESS BEFORE PREGNANCY 1 Record any illness whether chronic or acute with onset before pregnancy and that may affect fetal development (eg. childhood cancer, metabolic disease). Code according to ICD10. The codes mentioned below are only examples. Any additional details may be entered in the general comments section (variable 95). Do not insert the decimal point in the code (e.g. Code E05.0 as E050) Abridged list: Hyperthyroidism E050 - E059 Hypothyroidism E000 - E039 Diabetes Type 1 E100 - E109 Diabetes Type 2 E110 - E119 Obesity E660 - E669 If maternal BMI ≥ 30 give code for obesity Anorexia /eating disorder F500-F509 Epilepsy G400 - G409 Asthma J450 - J459 Chronic alcoholism F102 Drug addict F112 - F122 - F132 - F142 F152 - F192	ICD 10 0 = No illness 1 = Yes, but no information available 9 = Not known
61	ILLBEF2	ILLNESS BEFORE PREGNANCY 2 AS FOR ILLBEF1	

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
62	MATDIAB	MATERNAL **PRE**GESTATIONAL DIABETES This variable is specifically for **pre**gestational diabetes. Gestational diabetes is dealt with under the 'illness during pregnancy' variable (variable 64) Type 1 diabetes: characterized by hyperglycemia due to an absolute deficiency of the insulin hormone produced by the pancreas An HbA1c of 48mmol/mol is recommended as the cut-off point for diagnosing diabetes. Type 2 diabetes: characterized by hyperglycemia due to a defect in insulin secretion An HbA1c of 48mmol/mol is recommended as the cut-off point for diagnosing diabetes. *Maturity Onset Diabetes in the Young (MODY) displays an autosomal dominant pattern of inheritance An HbA1c of 48mmol/mol is recommended as the cut-off point for diagnosing diabetes. Impaired Glucose Intolerance is a state of higher than normal blood (or plasma) glucose concentration, but less than the diagnostic cut-off for diabetes. Diagnosed before pregnancy. Diagnosed by fasting plasma glucose from 6.1 – 6.9 mmol/L (WHO criteria) http://www.who.int/diabetes/publications/en/	1= Yes, type 1 diabetes (IDDM) 2= Yes, type 2 diabetes (NIDDM) 3 = Yes, type MODY* (all types) 4 = Yes, type not known 5 = No, but impaired glucose intolerance 6 = No pregestational diabetes 9 = Not known

Exposure (core variables shaded blue)

<table>
<tr><th>Variable Number</th><th>Variable Name</th><th>Explanation and Instructions</th><th>Code</th></tr>
<tr><td>63</td><td>HbA1c</td><td>GLYCATED HAEMOGLOBIN (HbA1c) VALUE
Give the first HbA1c value measured in the first trimester (in mmol/mol units)

Normal values for non-diabetic individuals <48mmol/mol

<table>
<tr><td>%</td><td>4.0</td><td>4.1</td><td>4.2</td><td>4.3</td><td>4.4</td><td>4.5</td><td>4.6</td><td>4.7</td><td>4.8</td><td>4.9</td></tr>
<tr><td>mmol/mol</td><td>20</td><td>21</td><td>22</td><td>23</td><td>25</td><td>26</td><td>27</td><td>28</td><td>29</td><td>30</td></tr>
<tr><td>%</td><td>5.0</td><td>5.1</td><td>5.2</td><td>5.3</td><td>5.4</td><td>5.5</td><td>5.6</td><td>5.7</td><td>5.8</td><td>5.9</td></tr>
<tr><td>mmol/mol</td><td>31</td><td>32</td><td>33</td><td>34</td><td>36</td><td>37</td><td>38</td><td>39</td><td>40</td><td>41</td></tr>
<tr><td>%</td><td>6.0</td><td>6.1</td><td>6.2</td><td>6.3</td><td>6.4</td><td>6.5</td><td>6.6</td><td>6.7</td><td>6.8</td><td>6.9</td></tr>
<tr><td>mmol/mol</td><td>42</td><td>43</td><td>44</td><td>45</td><td>46</td><td>48</td><td>49</td><td>50</td><td>51</td><td>52</td></tr>
<tr><td>%</td><td>7.0</td><td>7.1</td><td>7.2</td><td>7.3</td><td>7.4</td><td>7.5</td><td>7.6</td><td>7.7</td><td>7.8</td><td>7.9</td></tr>
<tr><td>mmol/mol</td><td>53</td><td>54</td><td>55</td><td>56</td><td>57</td><td>58</td><td>60</td><td>61</td><td>62</td><td>63</td></tr>
<tr><td>%</td><td>8.0</td><td>8.1</td><td>8.2</td><td>8.3</td><td>8.4</td><td>8.5</td><td>8.6</td><td>8.7</td><td>8.8</td><td>8.9</td></tr>
<tr><td>mmol/mol</td><td>64</td><td>65</td><td>66</td><td>67</td><td>68</td><td>69</td><td>70</td><td>72</td><td>73</td><td>74</td></tr>
<tr><td>%</td><td>9.0</td><td>9.1</td><td>9.2</td><td>9.3</td><td>9.4</td><td>9.5</td><td>9.6</td><td>9.7</td><td>9.8</td><td>9.9</td></tr>
<tr><td>mmol/mol</td><td>75</td><td>76</td><td>77</td><td>78</td><td>79</td><td>80</td><td>81</td><td>83</td><td>84</td><td>85</td></tr>
<tr><td>%</td><td>10.0</td><td>10.1</td><td>10.2</td><td>10.3</td><td>10.4</td><td>10.5</td><td>10.6</td><td>10.7</td><td>10.8</td><td>10.9</td></tr>
<tr><td>mmol/mol</td><td>86</td><td>87</td><td>88</td><td>89</td><td>90</td><td>91</td><td>92</td><td>93</td><td>95</td><td>96</td></tr>
<tr><td>%</td><td>11.0</td><td>11.1</td><td>11.2</td><td>11.3</td><td>11.4</td><td>11.5</td><td>11.6</td><td>11.7</td><td>11.8</td><td>11.9</td></tr>
<tr><td>mmol/mol</td><td>97</td><td>98</td><td>99</td><td>100</td><td>101</td><td>102</td><td>103</td><td>104</td><td>105</td><td>107</td></tr>
<tr><td>%</td><td>12.0</td><td>12.1</td><td>12.2</td><td>12.3</td><td>12.4</td><td>12.5</td><td>12.6</td><td>12.7</td><td>12.8</td><td>12.9</td></tr>
<tr><td>mmol/mol</td><td>108</td><td>109</td><td>110</td><td>111</td><td>112</td><td>113</td><td>114</td><td>115</td><td>116</td><td>117</td></tr>
<tr><td>%</td><td>13.0</td><td>13.1</td><td>13.2</td><td>13.3</td><td>13.4</td><td>13.5</td><td>13.6</td><td>13.7</td><td>13.8</td><td>13.9</td></tr>
<tr><td>mmol/mol</td><td>119</td><td>120</td><td>121</td><td>122</td><td>123</td><td>124</td><td>125</td><td>126</td><td>127</td><td>128</td></tr>
</table>
</td><td>999 = Not known

3 digits</td></tr>
</table>

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
64	ILLDUR1	ILLNESS DURING PREGNANCY Record illnesses with chronic or acute onset during the first 20 weeks of pregnancy including asymptomatic maternal infections. For gestational diabetes include at any point in pregnancy (Any additional details may be entered in the general comments section, variable 95). For maternal infections, use chapters A and B of the ICD 10 coding (4 digits). Fetal infections and associated malformations should be coded under syndrome and malformation 1-8 code (variable 30-47). Do not insert the decimal point in the code (eg. Code B34.1 as B341) Coxsackie's B341 Cytomegalic Inclusion Diseases B250 - B259 Gestational Diabetes O244 – O249 Herpes Simplex B000 - B009 HIV (AIDS) B200 - B249 Influenza J100 - J119 Listeria A320 - A329 Mumps B260 - B269 Rubella B060 - B069 Syphillis A530 - A539 Toxoplasmosis B580 - B589 Varicella (Chicken Pox) B010 - B019 Viral Hepatitis B190 - B199 Drug poisoning T360-T509	ICD 10 0 = No 1 = Yes, but no information available 9 = Not known
65	ILLDUR2	ILLNESS DURING PREGNANCY AS FOR ILLDUR1	
66	FOLIC_G14	FOLIC ACID SUPPLEMENTATION Recommend to your local maternity hospitals or midwives to collect these data. Folic acid supplementations include folic acid only tablets, a multivitamin preparation which contains folic acid or contraceptive pills which contain folic acid. If the folic acid dose is high, please add the code B03BB01 in the drugs variable	1 = Folic acid taken pre and post-conceptionally 2 = Folic acid taken only post-conceptionally 3 = Folic acid not taken 4 = Folic acid taken, timing unknown 9 = Not know if folic acid taken

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
67	FIRSTTRI	<u>FIRST TRIMESTER MEDICATION</u> "Yes" means that the data sources clearly state that medication was taken in the first trimester. "No" means that the data sources clearly state that no medication was taken in the first trimester. "Undetermined" means that the usual data sources were consulted, but • it was not clearly stated that medication was either taken or not taken • the information regarding medication use was illegible • Type of medication is unknown "Medication taken but timing unknown" means that the usual data sources stated that medication was taken but the timing of use was not stated for **some**or **all**of the medications. Use this option also for cases in which the data sources clearly state that certain medication was taken in the first trimester, but for other medication the timing was unknown. Use SP_DRUGS fields to explain for each recorded medication whether it was taken in the first trimester, or if timing was unknown. "Not Known" means that the usual data sources were not found. Only fill in DRUGS1-5 and EXTRADRUGS if you have coded FIRSTTRI = 1 (Yes medication taken) or = 4 (Medication taken, but timing unknown). If you have coded FIRSTTRI = 2 (no medication taken), FIRSTTRI = 3 (undetermined) or FIRSTTRI = 9 (unknown), there shouldn't be any ATC codes in any of the DRUGS variables • Include any medication that was taken by the mother during the first trimester of pregnancy (from the 1st day of the last menstrual period up to the 12th week of gestation). Medication with long elimination half time and taken before conception should be included (eg. Acitretin, Etretinate, etc.). • Use of folic acid (either as folic acid only tablets or a multivitamin preparation which contains folic acid) should be registered in the folic acid variable • Do not include usual vitamins and mineral supplementation, but include unusual intakes of vitamins or minerals (eg. Vitamin A mega doses). • Only medications taken at physiologic doses should be included.	1 = Yes, medication taken in first trimester 2 = No medication taken in first trimester 3 = Undetermined 4 = Medication taken, but timing unknown 9 = Not Known

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
		Whilst FIRSTTRI is a new variable in Guide 1.4 (for cases born from 2013 onwards) if any registry has this information for previous cases, EUROCAT is interested in collecting this information from 2005 onwards	
68	DRUGS1	DRUGS – 7 DIGIT MAXIMUM Record any drug taken by the mother during the first trimester of pregnancy (from the 1st day of last menstrual period up to the 12th week of gestation). Drugs with long elimination half time and taken before conception should also be recorded (eg. Acitretin, etretinate etc). If it is not known in which trimester the drug was taken, and this information cannot be obtained, code it but write in the space for comments that it is not sure whether the drug was taken in the first trimester. Use ATC-coding and use as many digits as possible (from 3 to 7). Website http://www.whocc.no/atcddd/. Do not record usual vitamins and mineral supplementation, but record unusual intakes of vitamins or minerals (eg. Vitamin A mega doses). The ATC coding system does not have a code for alternative drugs or herbs. If these are used, give the main code Z. ATC example: N03A: antiepileptic drug N03AF01: carbamazepine Details of the dosage and timing should be given in text variable 69. Do not forget to mention in the appropriate section (disease during or before pregnancy) the indication for drug use. Only drugs take at physiologic doses to be recorded. If a drug overdose or self-poisoning, this MUST be explained in the drug description.	
69	SP_DRUGS1	SPECIFY DRUG EXPOSURES	Free text
70	DRUGS2	AS FOR DRUGS1 Please give details in text variable 71 SP_DRUGS2.	As for DRUGS1
71	SP_DRUGS2	SPECIFY DRUG EXPOSURES	Free text
72	DRUGS3	AS FOR DRUGS1 Please give details in text variable 73 SP_DRUGS3.	As for DRUGS1
73	SP_DRUGS3	SPECIFY DRUG EXPOSURES	Free text
74	DRUGS4	AS FOR DRUGS1 Please give details in text variable 75 SP_DRUGS3.	
75	SP_DRUGS4	SPECIFY DRUG EXPOSURES	

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
76	DRUGS5	AS FOR DRUGS1 Please give details in text variable 77 SP_DRUGS3.	
77	SP_DRUGS5	SPECIFY DRUG EXPOSURES	

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
78	EXTRA_DRUGS	EXTRA DRUGS This field is only to be used if drug fields 1-5 have already been filled. Record any drug taken by the mother during the first trimester of pregnancy (from the 1st day of last menstrual period up to the 12th week of gestation). Drugs with long elimination half time and taken before conception should also be recorded (eg. Acitretin, etretinate etc). If it is not known in which trimester the drug was taken, and this information cannot be obtained, code it but write in the space for comments that it is not sure whether the drug was taken in the first trimester. Use ATC-coding and use as many digits as possible (from 3 to 7). Website http://www.whocc.no/atcddd/. Do not record usual vitamins and mineral supplementation, but record unusual intakes of vitamins or minerals (eg. Vitamin A mega doses). The ATC coding system does not have a code for alternative drugs or herbs. If these are used, give the main code Z. ATC example: N03A: antiepileptic drug N03AF01: carbamazepine Details on the dosage and timing should be given in the drug description. Do not forget to mention in the appropriate section (disease during or before pregnancy) the indication for drug use. Only drugs taken at physiologic doses to be recorded. If a drug overdose or self-poisoning, this MUST be explained in the drug description. If importing data from a local program, enter the ATC code and text description in the following format: <ATC code | text description> If more than one extra drug is to be imported for a single case, the enter the ATC codes in the extra drugs field as follows: <ATC code | text description><ATC code | text description>	

Exposure (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
		For example a case with valproate and lamotrigine exposure is entered in the extra_drugs field as: <N03AG01 | Valproate><N03AX09 | Lamotrigine> (See chapter 2.4 of EDMP User Guide for further guidance)	

Family History (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
79	CONSANG	CONSANGUINITY Restrictive definition of consanguinity: where the parents of the malformed case have one or more ancestors in common no more remote than a great-grandparent (=second cousins)	0 = Not related or relationship more distant than second cousin 1 = Relationship of second cousin or closer 9 = Not known
80	SP_CONSANG	SPECIFY TEXT INFORMATION ON CONSANGUINITY	Free text
81	SIBANOM	SIBS WITH ANOMALIES If the sibling (including twin) was notified to EUROCAT fill in variables 83-86 below. Make sure that the local identification numbers given correspond to those in the central database; otherwise give more information in text here. If previous siblings were not notified to EUROCAT specify in text SP_SIBANOM the year of birth and malformations of each sibling. If one sibling has both the same anomaly and a different anomaly, code under “same”. If one sibling has the same anomaly and another sibling has a different anomaly, code under “same and other” Always give details in text variable 82 SP_SIBANOM	1 = Same 2 = Other 3 = Same and other 4 = No 9 = Not known
82	SP_SIBANOM	SPECIFY TYPE OF ANOMALY OF SIBLINGS	Free text
83	PREVSIB	PREVIOUS MALFORMED SIBLINGS NOTIFIED TO EUROCAT If yes, give the local ID number in variables SIB1, SIB2 or SIB3 (variables 84-86). Include malformed co-twins or siblings from the same pregnancy, irrespective of birth order within multiple set. Exclude, conjoined twin.	1 = Yes 2 = No 9 = Not known

Family History (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
84	SIB1	SIB LOCAL ID NUMBER NOTIFIED TO THE CENTRAL REGISTRY Enter here also the code numbers of co-twins or siblings from the same pregnancy, irrespective of birth order within multiple sets. Leave blank if no previous siblings notified to EUROCAT.	Local ID
85	SIB2	AS SIB1	Local ID
86	SIB3	AS SIB1	Local ID
87	MOANOM	MOTHER'S FAMILY WITH ANOMALIES Include mother herself as well as mother's family. Specify type of anomaly in written text and relation to the infant. If the aetiology is known, "same" means the same aetiology, even if the spectrum of malformations present is slightly different. If the aetiology is unknown or multifactorial, "same" is a matter of judgment by a qualified coder, but full specification of the anomaly should be given, whether other or the same. "Same and other" refers to two different relatives. If a relative has both the same and another anomaly, code "same". Restrict the family to first, second and third degree relatives (mother, father, siblings, grandparents, aunt, uncles, half-siblings, first cousins). Always give details in text variable 88 SP_MOANOM.	1 = Same 2 = Other 3 = Same and other 4 = No 9 = Not known
88	SP_MOANOM	SPECIFY TYPE OF ANOMALY AND DESCRIBE THE MALFORMATION	Free text
89	FAANOM	FATHER'S FAMILY WITH ANOMALIES As MOANOM Please give details in text variable 90 SP_FAANOM	As MOANOM
90	SP_FAANOM	SPECIFY TYPE OF ANOMALY AND DESCRIBE THE MALFORMATION	Free text

Family History (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
91	MATEDU	MATERNAL EDUCATION Refer to International Standard Classification of Education 1997 for more information and Kunst et al (2001). Assign according to the highest level of education completed (or for full-time students, level in progress). Elementary and lower secondary refers to the period of compulsory education, usually to age 15/16. Upper secondary refers to the last two school or college years (usually to age 18) preparing students for tertiary education or the workforce. Tertiary refers to Bachelor's degree (English), Diploma (German), License (French) or equivalent, and to higher degrees (eg. doctorates), or to other forms of higher education.	1 = Elementary and lower secondary 2 = Upper secondary 3 = Tertiary 9 = Not known
92	SOCM	SOCIOECONOMIC STATUS OF MOTHER Current or last occupation. Upper non-manual – professionals, administrators and managers eg. doctor, architect, lawyer, banker, manager, teacher, nurse, performer. Lower non-manual – routine non-manual eg. Book-keeper, salesman, receptionist, secretary, computer operator, clerk, waiter. Skilled manual – cook, butcher, carpenter. Unskilled manual – semi and unskilled manual eg. factory worker, driver, agricultural worker, porter. Self employed/artisan – owner or shop, restaurant or hotel, independent artisan. Farmer – eg. self-employed farmer or fisherman. If code 8 ("other/student"), please specify in text in space for general comments (variable 95). For further information see Kunst et al (2001)*	1 = Upper non-manual 2 = Lower non-manual 3 = Skilled manual 4 = Unskilled manual 5 – Self employed/artisan 6 = Farmer 8 = Other/Student 9 = Not known
93	SOCF	SOCIOECONOMIC STATUS OF FATHER As SOCM	0 = Single mother, no father recorded 1 = Upper non-manual 2 = Lower non-manual 3 = Skilled manual 4 = Unskilled manual 5 – Self employed/artisan 6 = Farmer 8 = Other/Student 9 = Not known

Family History (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
94	MIGRANT	MIGRANT STATUS This variable is included to allow assessment of the extent to which services such as prenatal screening are reaching migrants. It does not ask for ethnicity. If code 4, give text details in the general comments section (variable 95).	1 = Mother migrated from outside EU during pregnancy 2 = Mother migrated from outside EU during adult life (from age 18) 3 = Mother not a migrant as defined in 1 or 2 4 = Other (specify in text) 9 = Not known

Footnote: * Kunst AE, Bos V, Mackenbach JP and the EU Working Group on Socio-economic Inequality in Health, "Monitoring Socio-Economic Inequalities in Health in the European Union: Guidelines and Illustrations", A Report to the Health Monitoring Programme of the European Commission.

General Comments (core variables shaded blue)

Variable Number	Variable Name	Explanation and Instructions	Code
95	GENREM	GENERAL ADDITIONAL COMMENTS	Free text