

ANTIEPILEPTIC DRUGS AND PREGNANCY REGISTRY

(EURAP)

DATA MANAGEMENT MANUAL

(Case Record Form)

International concerted Action on the Teratogenesis of Anti-epileptic Drugs

## Data management manual

### Risk Factor Questionnaire

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  - Questionnaire
  
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  - Specific guidelines
  - Questionnaire
  
- C Follow-up at 24 - 28 weeks of pregnancy (includes 2nd trimester)
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- D Follow-up at birth (3rd trimester and neonatal period)
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  - Questionnaire
  
- E Follow-up at one year of age
  - Specific guidelines
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## Sub-form A: Registration (to be completed as early as possible)

### *Specific guidelines* (codes' names refer to data dictionary)

- For all forms the following is applicable:
  - If the question was not ascertained, fill in 8, 88, 888 or 8888, depending on the available space.
  - If answer is unknown, fill in 9, 99, 999, 9999. This applies for all questions on all forms of this questionnaire.
  - Dates should be provided in the form: ddmmyyyy. If any of the parts in a date is unknown, leave it empty; if the entire date is unknown enter 0.
- If a twin is expected, also fill in two forms. If a triplet is expected fill in three forms, etc

Pregn_num	The pregnancy number should be numbered consecutively by each centre individually. Always fill in leading zero's wherever applicable.																																																								
Date_A	Date of reporting form A and all subsequent dates should be provided in the format: ddmmyyyy.																																																								
Date_first	Date of first notification of pregnancy to investigator (and the assignment of the identification number of pregnancy).																																																								
Country	<p>The identification number of a country is a unique code, which is assigned by the data collection centre (DCC) and exists of two digits. Fill in with leading zero when necessary. The country codes are listed below and range from 01 to 99.</p> <table> <tr> <td>01 = Austria</td> <td>14 = Italy</td> <td>27 = Sweden</td> <td>40 = Jordan</td> </tr> <tr> <td>02 = Belgium</td> <td>15 = Latvia</td> <td>28 = Switzerland</td> <td>41 = Chile</td> </tr> <tr> <td>03 = Croatia</td> <td>16 = Lithuania</td> <td>29 = Turkey</td> <td>42 = Scotland</td> </tr> <tr> <td>04 = Czech Republic</td> <td>17 = Luxembourg</td> <td>30 = United Kingdom</td> <td>43 = Ecuador</td> </tr> <tr> <td>05 = Denmark</td> <td>18 = Netherlands</td> <td>31 = Ukraine</td> <td>44 = Hong Kong</td> </tr> <tr> <td>06 = Estonia</td> <td>19 = Norway</td> <td>32 = Georgia</td> <td>45 = Albania</td> </tr> <tr> <td>07 = Finland</td> <td>20 = Poland</td> <td>33 = Israel</td> <td>46 = Philippine</td> </tr> <tr> <td>08 = France</td> <td>21 = Portugal</td> <td>34 = Australia</td> <td>47 = Usa</td> </tr> <tr> <td>09 = Germany</td> <td>22 = Romania</td> <td>35 = Yugoslavia</td> <td>48 = China</td> </tr> <tr> <td>10 = Greece</td> <td>23 = Russia</td> <td>36 = India</td> <td>49 = Brazil</td> </tr> <tr> <td>11 = Hungary</td> <td>24 = Slovakia</td> <td>37 = Japan</td> <td>50 = Malta</td> </tr> <tr> <td>12 = Iceland</td> <td>25 = Slovenia</td> <td>38 = Macedonia</td> <td>51 = Honduras</td> </tr> <tr> <td>13 = Ireland</td> <td>26 = Spain</td> <td>39 = Argentina</td> <td>52 = Uruguay</td> </tr> <tr> <td>53 = Egypt</td> <td>54 = Guatemala</td> <td>55 = Taiwan</td> <td></td> </tr> </table>	01 = Austria	14 = Italy	27 = Sweden	40 = Jordan	02 = Belgium	15 = Latvia	28 = Switzerland	41 = Chile	03 = Croatia	16 = Lithuania	29 = Turkey	42 = Scotland	04 = Czech Republic	17 = Luxembourg	30 = United Kingdom	43 = Ecuador	05 = Denmark	18 = Netherlands	31 = Ukraine	44 = Hong Kong	06 = Estonia	19 = Norway	32 = Georgia	45 = Albania	07 = Finland	20 = Poland	33 = Israel	46 = Philippine	08 = France	21 = Portugal	34 = Australia	47 = Usa	09 = Germany	22 = Romania	35 = Yugoslavia	48 = China	10 = Greece	23 = Russia	36 = India	49 = Brazil	11 = Hungary	24 = Slovakia	37 = Japan	50 = Malta	12 = Iceland	25 = Slovenia	38 = Macedonia	51 = Honduras	13 = Ireland	26 = Spain	39 = Argentina	52 = Uruguay	53 = Egypt	54 = Guatemala	55 = Taiwan	
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Centre	The identification number of each study centre in a country is only unique for the country itself and is assigned by the national coordinator. The number exists of two digits ranging from 01 to as many centres that participate.																																																								
Rep_phys	The name of the reporting physician should be written in full, in order to be able to contact the physician personally in case of questions or lack of clarity.																																																								
Fam_name	<p>The first three letters of the family name (maiden name) should be encoded on the form. Some examples of coding are:</p> <table> <tr> <td>Sharp</td> <td>---&gt; SHA</td> <td>Ängström</td> <td>---&gt; AEN</td> </tr> <tr> <td>van Dijk</td> <td>---&gt; DIJ</td> <td>Östergaard</td> <td>---&gt; OES</td> </tr> <tr> <td>Æspergaard</td> <td>---&gt; AES</td> <td>Østergaard</td> <td>---&gt; OES</td> </tr> <tr> <td>Ålberg</td> <td>---&gt; AAL</td> <td>etc...</td> <td></td> </tr> </table> <p>(If the family name has only 2 letters, enter 3 as third character. For example: family name is WU ----- &gt; enter WU3)</p>	Sharp	---> SHA	Ängström	---> AEN	van Dijk	---> DIJ	Östergaard	---> OES	Æspergaard	---> AES	Østergaard	---> OES	Ålberg	---> AAL	etc...																																									
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fir_name	The first 3 letters of the first name should be coded on the form in the same way as the family name. (If the first name has only 2 letters, enter 3 as third character. For example: first name is WU ----- > enter WU3)
Soc_moth/ soc_fath	The educational level should be based on the education followed and finished.
eth_moth	The ethnic background of the mother should be based on appearance and birthplace.
Xray	Ionising radiation exposure before pregnancy, including X-rays, therapeutic and professional exposure should be coded. If answer to ionising radiation exposure is yes, please specify type of radiation in full and if possible frequencies, time period or age in the comment field.
gravida	The number of this pregnancy be coded, including all stillbirths, neonatal deaths, miscarriages, premature deliveries, induced abortions due to any indications (maternal indication, foetal malformations).
parity	The number of previous deliveries should be coded, including stillbirths, neonatal deaths, and premature deliveries .
malform_sp	If previously malformed children were born, specify the birth date of each child and its malformation as precisely as possible.
fetal_sp	Specify date of induced abortion and the malformation(s) on the basis of which the induced abortion was performed.
epilepsy	The type of maternal epilepsy should be coded. Only one answer is allowed.
ILAE	If an epilepsy syndrome is known, please specify in full, according to the ILAE classification for epilepsy syndromes.
malf_fam	Specify in whom of the first-degree relatives congenital malformations occur. More than one family member could be involved. Therefore 3 fields are available to specify. Please fill in all fields (note that this field refers only to proband's close family, and not to patient's. Therefore, here you should enter only proband's father, proband's mother and proband's siblings if they have any malformation).
epil_fam	Specify in whom of the family members epilepsy occurs. Epilepsy could occur in more than one family member. Therefore 3 fields are available to specify. Please fill in all fields (note that this field refers only to proband's close family, and not to patient's. Therefore, here you should enter only proband's father and proband's siblings if they have epilepsy).

**Sub-form B:** Follow-up at the end of 1st trimester *Specific guidelines* (codes' names refer to data dictionary)

Xray	Ionising radiation exposure during 1st trimester, including X-rays, therapeutic and professional exposure should be coded. If answer to ionising radiation exposure is yes, please specify type of radiation in full and if possible frequencies, time period or age in the comment field.
suppl_fa	Please include folic acid content also in multivitamin tablets.
fert_ass	Specify whether pregnancy occurred through assisted fertilisation.
dose1_tr1	Specify the total daily dose in milligrams. If not in same unit, convert into milligrams before filling in. This applies for all subsequent dosage questions.
peak1_tr1	Specify the highest dose per administration per day in milligrams.

**Sub-form C: Follow-up at the end of 2nd trimester** *Specific guidelines* (Codes' names refer to data dictionary)

AED_tr2	When a woman does not use AED during 2nd trimester, skip questions "sort1_tr2" through "gift_tr2".
sort1_tr2	Generic name of AED used during 2nd trimester of pregnancy in full. Fill in only if changed respect to 1st trimester.
dose1_tr2	Total daily dose of AED in mg in 2nd trimester. Fill in only if changed respect to 1st trimester.
date_us	If more than one ultrasound performed, enter the most significant or, if normal, the first.

**Sub-form D: Follow-up at birth (Includes 3rd trimester and neonatal period)**

*Specific guidelines* (Codes' names refer to data dictionary)

NB: To be completed within three months after birth.

AED_tr3	When a woman does not use AED during 3rd trimester, skip questions "sort1_tr3" through "gift1_tr3".
sort1_tr3	Generic name AED used during 3rd trimester of pregnancy in full. Fill in only if changed respect to 2nd trimester.
dose1_tr3	Total daily dose of AED in mg in 3rd trimester. Fill in only if changed respect to 2nd trimester.
peri_death	Intrauterine death after 27th week or death within 7 days from birth.

## Sub-form A: Registration (to be completed as early as possible)

*Questionnaire* (codes' names refer to data dictionary)

Pregn_num	Number of pregnancy of the centre (5 digits)	
Date_I	Date of reporting form A (ddmmyyyy)	
date_first	Date of notification of pregnancy to investigator (and assignement of identification number; ddmmyyyy)	
LMP	First day of last menstruation (ddmmyyyy)	
country	Identification number country	
Centre	Identification number centre	
rep_phys	Reporting physician	
reas_AED	Is epilepsy reason for prescribing AED? 0 = no 1 = yes	
reasAED_sp	If previous question is 0, specify other reason	
gender_p	Father has epilepsy? 0 = no 1 = yes 8 = not ascertained 9 = unknown	
fam_name	Family name (first 3 letters)	
fir_name	First name (first 3 letters)	
bir_moth	Birth date mother (ddmmyyyy)	
soc_moth	Eductional level mother 1 = tertiary 2 = secondary 3 = primary 4 = illiteracy 8 = not ascertained 9 = unknown	
eth_moth	Ethnic background of the mother 1 = Caucasian 2 = North African 3 = Negro 4 = Asiatic 5 = Aborigenal 6 = Pacific Islands 7 = Mixed 8 = other 88 = not ascertained 99 = unknown	
soc_fath	Eductional level father (see soc_moth)	
Xray	Ionising radiation exposure 3 months before pregnancy 0 = no 1 = yes (enter specification in comment field) 8 = not ascertained 9 = unknown	

Gravida	Number of this pregnancy 01 = first pregnancy 02 = second pregnancy 03 = third pregnancy etc.... 88 = not ascertained 99 = unknown	
Parity	Number of previous deliveries 00 = none 01 = once 02 = twice etc.... 88 = not ascertained 99 = unknown	
Stillborn	Number of stillborn offspring (see parity)	
Death	Number of neonatal deaths (see parity)	
Normal	Number of not malformed offspring (or with chromosomal abnormalities) (see parity)	
Malformed	Number of malformed offspring (see parity)	
malform_sp	Specify malformations or chromosomal abnormalities	
Abortion	Number of spontaneous abortions	
maternal_a	Number of induced abortions not due to foetal malformations (or due to chromosomal abnormalities)	
fetal_a	Number of induced abortion due to foetal malformation	
fetal_sp	Specify malformations or chromosomal abnormalities	
Epilepsy	Type of maternal epilepsy 1 = generalised 2 = localisation related 3 = undetermined 8 = not ascertained 9 = unknown	
Etiology	Aetiology of epilepsy 1 = idiopathic 2 = symptomatic 3 = cryptogenic 8 = not ascertained 9 = unknown	
ILAE	Epilepsy syndrome	
malf_fam	Proband's family history of congenital malformations 00 = none 01 = proband's mother (enter specification in comment field) 02 = proband's father (enter specification in comment field) 03 = proband's sister 04 = proband's brother 05 = proband's sibling 06 = proband's twin 88 = not ascertained 99 = unknown	1.
		2.
		3.

treatPrevPreg	Was patient on AED in previous pregnancies? Complete only in case of abnormal outcome 1 = yes (with same AED treatment) 2 = yes (with different AED treatment) 3 = no 8 = not ascertained 9 = unknown	
epil_fam	Proband's family history of epilepsy 00 = none 02 = proband's father (enter specification in comment field) 03 = proband's sister 04 = proband's brother 88 = not ascertained 99 = unknown	1. <hr/> 2. <hr/> 3.
commentsA	Comments	

## Sub-form B: Follow-up at the end of 1st trimester

*Questionnaire* (codes' names refer to data dictionary)

Pregn_num	Number of pregnancy of the centre (5 digits)	
date_B	Date of reporting sub-form B (ddmmyyyy)	
country	Identification number country	
Centre	Identification number centre	
Spont_ab	Spontaneous abortion 0 = no 1 = yes 8 = not ascertained 9 = unknown	
Spont_abdate	Spontaneous or induced abortion date (ddmmyyyy)	
term_pregn	Induced termination of pregnancy 0 = no 1 = foetal abnormality (enter specification in "Specify results" field) 2 = maternal medical 3 = maternal social 4 = other (enter specification in comment field) 8 = not ascertained 9 = unknown	
Chrom/malf	Post mortem examination 0 = not performed 1 = chromosome abnormalities 2 = malformations 3 = chromosome abnormalities and malformations 4 = no abnormalities 5 = other abnormalities 8 = not ascertained 9 = unknown	
Specresult	Specify results (post mortem examination)	
Aterm	Calculated term date (ddmmyyyy)	
OAC_preg	Oral contraceptive use during pregnancy 0 = no 1 = yes 8 = not ascertained 9 = unknown	
fert_ass	Assisted fertilisation 0 = no 1 = si 8 = not ascertained 9 = unknown	

smoke_tr1	Cigarette smoking in 1st trimester 0 = no 1 = 1-10/day 2 = 11-20/day 3 = >20/day 8 = not ascertained 9 = unknown	
alcoh_tr1	Alcohol intake in 1st trimester 0 = no 1 = <1 drinks/day 2 = <3 drinks/day 3 = 3-6 drinks/day 4 = >6 drinks/day 8 = not ascertained 9 = unknown	
Xray_tr1	Ionising radiation exposure in 1st trimester 0 = no 1 = yes (enter specification in comment field) 8 = not ascertained 9 = unknown	
othdis_tr1	Specify other maternal diseases (including relevant infections) in 1st trimester of pregnancy	
suppl_fa	Folic acid use; dose in $\mu\text{g}$ (Please include folic acid content also in multivitamin tablets) 0000 = none 0100 = 100 $\mu\text{g}$ = 0,1 mg 0400 = 400 $\mu\text{g}$ = 0,4 mg 0500 = 500 $\mu\text{g}$ = 0,5 mg 1000 = 1000 $\mu\text{g}$ = 1,0 mg 4000 = 4000 $\mu\text{g}$ = 4,0 mg 5000 = 5000 $\mu\text{g}$ = 5,0 mg etc. 7777 = dose unknown 8888 = not ascertained 9999 = unknown	
start_fa	Start date of folic acid use (ddmmyyyy)	
end_fa	End date of folic acid use (ddmmyyyy)	
AED_tr1	AED use in 1st trimester 0 = no 1 = yes 8 = not ascertained 9 = unknown	
sort1_tr1	Generic name in full of AED used in 1st trimester	1. 2. 3. 4. 5.

dose1_tr1	Total daily dose of AED in mg in 1st trimester	1. 2. 3. 4. 5.
peak1_tr1	Largest single dose of AED in mg per day	1. 2. 3. 4. 5.
gift1_tr1	Number of administrations per day of AED in 1st trimester	1. 2. 3. 4. 5.
star1_tr1	Start date of AED (ddmmyyyy)	1. 2. 3. 4. 5.
end1_tr1	End date of AED (ddmmyyyy)	1. 2. 3. 4. 5.
AEDmodtr1	Was AED dosage changed in 1st trimester? 0 = no 1 = yes 8 = not ascertained 9 = unknown	
Othmed_tr1	Specify other drugs used in 1st trimester	
GTCS_tr1	Frequency of generalised tonic-clonic seizures in 1st trimester 0 = none 1 = < 1/month 2 = monthly 3 = weekly 4 = > weekly 5 = daily 6 = other 8 = not ascertained 9 = unknown	
OTH_tr1	Frequency of other seizures in 1st trimester (see GTCS_tr1)	
Statustr1	Status epilepticus in 1st trimester 0 = no 1 = non-convulsive 2 = convulsive 8 = not ascertained 9 = unknown	
commentsB	Comments	

## Sub-form C: Follow-up at the end of 2nd trimester

*Questionnaire* (codes' names refer to data dictionary)

Pregn_num	Number of pregnancy of the centre (5 digits)	
date_C	Date of completion of sub-form C (ddmmyyyy)	
country	Identification number country	
Centre	Identification number centre	
Stil_birth	Still birth 0 = no 1 = yes 8 = not ascertained 9 = unknown	
Stil_birthdate	Induced termination date or still birth date (ddmmyyyy)	
term_pregn	Induced termination of pregnancy 0 = no 1 = foetal abnormality (enter specification in "Specify results" field) 2 = maternal medical 3 = maternal social 4 = other (enter specification in comment field) 8 = not ascertained 9 = unknown	
Chrom/malf	Post mortem examination 0 = not performed 1 = chromosome abnormalities 2 = malformations 3 = chromosome abnormalities and malformations 4 = no abnormalities 5 = other abnormalities 8 = not ascertained 9 = unknown	
Specresult	Specify results (post mortem examination)	
smoke_tr2	Cigarette smoking in 2nd trimester 0 = no 1 = 1-10/day 2 = 11-20/day 3 = >20/day 8 = not ascertained 9 = unknown	
alcoh_tr2	Alcohol intake in 2nd trimester 0 = no 1 = <1 drinks/day 2 = <3 drinks/day 3 = 3-6 drinks/day 4 = >6 drinks/day 8 = not ascertained 9 = unknown	

othdis_tr2	Specify other maternal diseases (including relevant infections) in 2nd trimester	
AED_tr2	AED use in 2nd trimester 0 = no 1 = yes 8 = not ascertained 9 = unknown	
sort1_tr2	Generic name AED in full used in 2nd trimester. Fill in only if changed respect to 1st trimester.	1. 2. 3. 4. 5.
dose1_tr2	Total daily dose of AED in mg in 2nd trimester. Fill in only if changed respect to 1st trimester.	1. 2. 3. 4. 5.
gift1_tr2	Number of administrations per day of AED in 2nd trimester. Fill in only if changed respect to 1st trimester.	1. 2. 3. 4. 5.
star1_tr2	Start date of AED (ddmmyyyy)	1. 2. 3. 4. 5.
end1_tr2	End date of AED (ddmmyyyy)	1. 2. 3. 4. 5.
AEDmodtr2	Was AED dosage changed in 2nd trimester? 0 = no 1 = yes 8 = not ascertained 9 = unknown	
othmed_tr2	Specify other drugs used in 2nd trimester	
GTCS_tr2	Frequency of generalised tonic-clonic seizures in 2nd trimester 0 = none 1 = < 1/month 2 = monthly 3 = weekly 4 = > weekly 5 = daily 6 = other 8 = not ascertained 9 = unknown	

OTH_tr2	Frequency of other seizures in 2nd trimester (see GTCS_tr2)	
Statustr2	Status epilepticus in the 2nd trimester 0 = no 1 = non-convulsive 2 = convulsive 8 = not ascertained 9 = unknown	
struct_us	Malformation directed ultrasound performed 0 = not performed 1 = yes normal 2 = yes malformation (enter specification in the "Specify results" field) 3 = yes, abnormalities other than malformation (enter specification in the "Specify results" field) 8 = not ascertained 9 = unknown	
date_us	Date of malformation directed ultrasound (ddmmyyyy)	
result_us	Specify result of ultrasound	
sampl_cv	Chorionic villus sampling performed 0 = not performed 1 = yes, normal 2 = yes, chromosome abnormalities 8 = not ascertained 9 = unknown	
Amniocentesis	Amniocentesis 0 = not performed 1 = yes, normal 2 = yes, chromosome abnormalities 8 = not ascertained 9 = unknown	
AFP_amn	Result amniocentesis-AFP in $\mu\text{g/ml}$ 0 = not performed 1 = normal, but results unknown 2 = abnormal, but results unknown ..... 8 = not ascertained 9 = unknown	
Karyo_amn	Result of examination of chorionic villus sampling or amniotic cells, including karyotype	
AFP_ser	Result maternal serum-AFP in $\mu\text{g/ml}$ 0 = not performed 1 = normal, but results unknown 2 = abnormal, but results unknown ..... 8 = not ascertained 9 = unknown	

obst_compl	Obstetric complications 0 = no 1 = yes (enter specification in comment field) 8 = not ascertained 9 = unknown	
commentsC	Comments	

### Sub-form D: Follow-up at birth (including still births)

(Includes 3rd trimester and neonatal period)

*Questionnaire* (codes' names refer to data dictionary) NB: To be completed within three months after birth.

Pregn_num	Number of pregnancy of the centre (5 digits)	
date_D	Date of reporting form D (ddmmyyyy)	
country	Identification number country	
Centre	Identification number centre	
smoke_tr3	Cigarette smoking in 3rd trimester 0 = no 1 = 1-10/day 2 = 11-20/day 3 = >20/day 8 = not ascertained 9 = unknown	
alcoh_tr3	Alcohol intake in 3rd trimester 0 = no 1 = <1 drinks/day 2 = <3 drinks/day 3 = 3-6 drinks/day 4 = >6 drinks/day 8 = not ascertained 9 = unknown	
othdis_tr3	Specify other maternal disease (including relevant infections) in 3rd trimester	
AED_tr3	AED use in 3rd trimester 0 = no 1 = yes 8 = not ascertained 9 = unknown	
sort1_tr3	Generic name AED in full used in 3rd trimester. Fill in only if changed respect to 2nd trimester.	1. 2. 3. 4. 5.
dose1_tr3	Total daily dose of AED in mg in 3rd trimester. Fill in only if changed respect to 2nd trimester.	1. 2. 3. 4. 5.
gift1_tr3	Number of administrations per day of AED in 3rd trimester. Fill in only if changed respect to 2nd trimester.	1. 2. 3. 4. 5.

star1_tr3	Start date of AED (ddmmyyyy)	1. 2. 3. 4. 5.
end1_tr3	End date of AED (ddmmyyyy)	1. 2. 3. 4. 5.
AEDmodtr3	Was AED dosage changed in 3rd trimester? 0 = no 1 = yes 8 = not ascertained 9 = unknown	
Othmed_tr3	Specify other drugs used in 3rd trimester	
GTCS_tr3	Frequency of generalised tonic-clonic seizures in 3rd trimester 0 = none 1 = < 1/month 2 = monthly 3 = weekly 4 = > weekly 5 = daily 6 = other 8 = not ascertained 9 = unknown	
OTH_tr3	Frequency of other seizures in 3rd trimester (see GTCS_tr3)	
Statustr3	Status epilepticus in the 3rd trimester 0 = no 1 = non -convulsive 2 = convulsive 8 = not ascertained 9 = unknown	
obst_compl	Obstetric complications 0 = no 1 = yes (enter specification in comment field) 8 = not ascertained 9 = unknown	
birth_pr	Birth date of proband (child out of this pregnancy) (ddmmyyyy)	
sexe_pr	Sex of proband 1 = male 2 = female 8 = not ascertained 9 = unknown	

place_pr	Place of birth of proband 1 = hospital 2 = home 3 = other (enter specification in comment field) 8 = not ascertained 9 = unknown	
deliv_pr	Delivery of proband 1 = non-instrumental 2 = induced delivery 3 = caesarean section 4 = vacuum extraction 5 = extraction by forceps 6 = other (enter specification in comment field) 8 = not ascertained 9 = unknown	
singl_mult	Single or multiple birth (for multiple births, fill in one form for each child) 1 = single 2 = first of twin 3 = second of twin 4 = first of triplets 5 = second of triplets 6 = third of triplets 8 = not ascertained 9 = unknown	
GTCS_del	Seizures during delivery (including status epilepticus) 0 = no 1 = convulsive seizures 2 = other seizures 3 = convulsive status 4 = non-convulsive status 8 = not ascertained 9 = unknown	
apgar1-pr	Apgar score proband at 1 minute 88 = not ascertained 99 = unknown	
apgar5_pr	Apgar score proband at 5 minute 88 = not ascertained 99 = unknown	
weight_pr	Weight of proband at birth in grams 8888 = not ascertained 9999 = unknown	
length_pr	Length of proband at birth in cm's 88 = not ascertained 99 = unknown	
OFC_pr	Occipital-frontal head circumference of proband at birth in cm's 88 = not ascertained 99 = unknown	

peri_death	Perinatal death of proband 0 = no 1 = yes 8 = not ascertained 9 = unknown	
time_death	If yes, specify date (ddmmyyyy)	
caus_death	If yes, specify cause perinatal death proband	
malf_prob	Congenital malformations 0 = no 1 = yes malformation 2 = yes chromosome abnormalities 3 = yes chromosome abnormalities and malformation 8 = not ascertained 9 = unknown	
malf_spec	If congenital malformations yes, specify in detail (include date at diagnosis)	
commentsD	Comments	

## Sub-form E: Follow-up at the age of one year

Pregn_num	Number of pregnancy of the centre (5 digits)	
date_E	Date of reporting form E (ddmmyyy)	
country	Identification number country	
Centre	Identification number centre	
Meth_asc	Method of ascertainment 1 = telephone interview 2 = doctor visit 3 = other (enter specification in comment field)	
Death_first	Death during first year of life 0 = no 1 = yes	
Spec_cause	If yes, specify cause	
Cong_malf	Congenital malformations detected postnatally 0 = no 1 = yes malformation 2 = yes chromosome abnormalities 3 = yes chromosome abnormalities and malformation 8 = not ascertained 9 = unknown	
Spec_det	If yes, specify characteristics in details	
Spec_age	Specify age in months at detection of malformation	
Hosp_adm	Hospital admission during first year of life 0 = no 1 = yes 8 = not ascertained 9 = unknown	
Reas_hosp	If yes, specify the number of hospitalizations and the reasons	
commentsE	Comments	