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| **EUROlinkCAT Data Request Form** |

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| --- | --- |
| 1 | **Title of the project** |
|  |
| 2 | **Full name of researcher(s)** (Lead Investigator first, then include anyone who will have access to the data or a role in the project) |
|  |
| 3 | **Current position(s) held** (of named researchers above) |
|  |
| 4 | **Address and Contact Details of Lead Investigator** (Lead Investigator - please attach a brief CV with your application giving your name, address, qualifications, current position, most recent publications and most recent research projects) |
| **Work address** |
|  |
| **Telephone**  |
|  |
| **Email** |
|  |
| 5 | **Proposed study start date (DD/MM/YYYY)** |
|  |
| **Proposed study completion date (DD/MM/YYYY)** |
|  |
| 6 | **Summary of the study** (please attach a full research protocol where available) |
| **Background:****Aim:** |
| 7 | **Methods** (please outline the design of the study, population and definition of main outcome measures) |
| **Statistical Methods:** |
| 8 | **How do you intend to publish your research?** |
|  |  |
| 9 | **Data required** (see section on data selection tables, pages 4-11) |
| (a) **In Table 1**, please specify registries(b) **In Table 2**, please specify anomalies(c) **In Table 3**, please specify risk factors of interest(d) **In Table 4**, please specify data tablesPlease see the following DOI links, which contain detailed information about the variables in EUROlinkCAT:Work Package 3 Survival Common Data Model: <https://www.eurolinkcat.eu/loadFile.aspx?filename=EUROlinkCAT%20Common%20Data%20Model%20-%20Survival.pdf> Work Package 4 Morbidity Common Data Model: <https://www.eurolinkcat.eu/loadFile.aspx?filename=EUROlinkCAT%20WP4%20CDM%2018thNov2020(2).pdf>  |

**Terms and Conditions for use of EUROlinkCAT data**

* Data released from the Central Results Repository (CRR) based at Ulster University is to be used only for the research study outlined in Section 7. Any significant deviation from the research protocol must be agreed by the EUROlinkCAT Management Committee.
* Data released from the CRR must be treated as confidential.
* Data released from the CRR must not be divulged to a third party.
* Data released from the CRR must be stored on a secure network, accessed only via a computer which is password protected and restricted to named personnel.
* On completion of the analysis the Lead Investigator’s institution must archive the dataset for a maximum of 10 years from the release date of the data.
* After a maximum of 10 years from the release date of the data, the data must be returned to the Ulster University and destroyed/removed from users’ systems.

**By signing below, you are agreeing to abide by the Terms and Conditions for use of EUROlinkCAT data. Once signed and once you have checked the applicant checklist below, please email the completed EUROlinkCAT Data Request Form to:**

**Dr Maria Loane:** ma.loane@ulster.ac.uk

EUROlinkCAT Central Results RepositoryFaculty of Life and Health Sciences, Ulster University

Tel. +44 (0) 2890 366 480

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| --- |
| **Signature** (either insert your e-signature or print, sign and scan this document) |
|  |
| **Full name of signatory** |
|  |
| **Date (DD/MM/YYYY)** |
|  |
|  |
| **Applicant Checklist** | Mark with an X once complete |
| Supplied research protocol (where applicable) |  |
| Supplied brief CV of lead investigator |  |
| Data request tables completed |  |
| Signed form, thus accepting terms and conditions |  |

**Data available in EUROlinkCAT**

Below is a list of all analyses that are available in the EUROlinkCAT Central Results Repository (CRR).

Please note:

* Not all tables are available for all anomalies or for all registries or for all risk factors.
* Data sets were created and analysed separately for the different work packages. Care must be taken when selecting data from several work packages as there may be differences in the numbers of children in the cohorts.

**Abbreviations used in tables below**

|  |  |
| --- | --- |
| CA | Congenital Anomaly |
| CDH | Congenital diaphragmatic hernia |
| Cox PH | Cox’s Proportional Hazards RatioThe proportional hazards ratios are given for comparing the survival in groups according to risk factors derived from fitting cox’s proportional hazards models |
| Gestage | Gestational age at birth |
| HR hospitalisation | Hazard Rate. The proportional hazards ratios are given for comparing the risk of hospital admission in children with CA compared to reference children using Cox’s proportional hazards models  |
| ICU | Intensive Care Unit |
| IRR LOS | Incidence Rate Ratio. The IRR is calculated comparing the risk of a child with a CA being in hospital for a day compared to a reference child. Similar to the hazards ratios for being admitted to hospital, but takes into account the number of days in hospital by fitting negative binomial regression models |
| KM Survival | Kaplan Meier SurvivalThese tables provide the estimated proportion of children surviving at each age (1-week, 1 month, 3 months, 6 months, 9 months, 1 year and every year to 9 years for common anomalies – fewer time points for rare anomalies). The survival estimates are derived from Kaplan Meier models |
| KM Hosp | Kaplan Meier estimates of the proportions of children admitted to hospital during specified age periods. Kaplan Meier models are used to account for censoring occurring in the data for ages > 1 year |
| LOS | Length of Stay |
| PD | Prenatal Diagnosis of 4 anomalies only: spina bifida, transposition of great arteries (TGA), congenital diaphragmatic hernia (CDH) or gastroschisis |
| TGA | Transposition of great arteries |

**Table 1: List of EUROCAT Registries providing data to the EUROlinkCAT CRR**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **EUROCAT Registry Number** | **Country** | **Registry name** | **Small number suppression**  | **Availability of Data** | **Requested (X to select)** |
| **Mortality Data** | **Morbidity Hospital Stays** | **Surgery Data** | **Prenatal Diagnosis Data** | **Prescription Data** | **Morbidity Data for Reference Children** |
| 3 | Denmark | Odense | A | Yes | Yes | Yes | Yes | Yes | Yes |  |
| 5 | France | Paris | No | Yes |  |  |  |  |  |  |
| 8 | Italy | Tuscany | No | Yes | Yes | Yes | Yes | Yes | Yes |  |
| 13 | Netherlands | North Netherlands | B | Yes | Yes |  |  | Antibiotics only | Yes |  |
| 18 | Italy | Emilia Romagna | No | Yes | Yes | Yes | Yes | Yes | Yes |  |
| 21 | Croatia | Zagreb | No | Yes |  |  |  |  |  |  |
| 23 | Malta | Malta | No | Yes |  |  |  |  |  |  |
| 29 | Belgium | Antwerp | B | Yes |  |  |  |  |  |  |
| 33 | Germany | Saxony Anhalt | No | Yes |  |  |  |  |  |  |
| 38 | Finland | Finland | No | Yes | Yes | Yes | Yes | Yes | Yes |  |
| 57 | United Kingdom | Wales  | C | Yes | Yes | Yes | Yes | Yes | Yes |  |
| 59 | Norway | Norway | No | Yes |  |  |  |  |  |  |
| 62 | Ukraine | OMNI-Net | No | Yes |  |  |  |  |  |  |
| 68 | United Kingdom | PHE/Thames Valley | C | Yes | Yes | Yes | Yes | Yes |  |  |
| 70 | United Kingdom | PHE/Wessex | C | Yes | Yes | Yes | Yes | Yes |  |  |
| 72 | United Kingdom | PHE/East Midlands & South Yorkshire | C | Yes | Yes | Yes | Yes | Yes |  |  |
| 86 | Spain | Valencia Region | No | Yes | Yes | Yes | Yes | Yes | Yes |  |

A: Small number suppression is applied before data is released to researchers, but some EUROlinkCAT personnel can analyse original data

B: Small number suppression is applied

C: Small number suppression must be applied by researchers prior to any publication

|  |  |
| --- | --- |
|  | Data not available |

**Table 2: Anomalies in EUROlinkCAT**

|  |  |  |
| --- | --- | --- |
| **Anomaly Name** | **EUROlinkCAT Code** | **Requested (X to select)** |
| Reference Children | con |  |
| All anomalies | al1 |  |
| Anencephaly | al4 |  |
| Encephalocele | al5 |  |
| Spina Bifida | al6 |  |
| Hydrocephalus | al7 |  |
| Severe microcephaly | al8 |  |
| Arhinencephaly / holoprosencephaly | al9 |  |
| Anophthalmos / microphthalmos | al11 |  |
| Anophthalmos | al12 |  |
| Congenital cataract | al13 |  |
| Congenital glaucoma | al14 |  |
| Anotia | al16 |  |
| Cleft lip with or without cleft palate | al102 |  |
| Cleft palate | al103 |  |
| ALL Congenital Heart Defects (CHD) | al17 |  |
| Severe CHD | al97 |  |
| Common arterial truncus | al18 |  |
| Transposition of great vessels | al19 |  |
| Single ventricle | al20 |  |
| Ventricular septal defect (VSD)  | al21 |  |
| Atrial septal defect (ASD) | al22 |  |
| Atrioventricular septal defect (AVSD) | al23 |  |
| Tetralogy of Fallot | al24 |  |
| Tricuspid atresia and stenosis | al25 |  |
| Ebstein’s anomaly | al26 |  |
| Pulmonary valve stenosis | al27 |  |
| Pulmonary valve atresia | al28 |  |
| Aortic valve atresia/stenosis | al29 |  |
| Hypoplastic left heart | al30 |  |
| Hypoplastic right heart | al31 |  |
| Coarctation of aorta | al32 |  |
| Total anomalous pulmonary venous return | al33 |  |
| Patent Ductus Arteriosus (PDA) as only Congenital Heart Defect (CHD) in term infants (>=37 weeks) | al100 |  |
| Double outlet right ventricle | al109 |  |
| Mitral valve anomalies | al110 |  |
| Aortic atresia / interrupted aortic arch | al111 |  |
| VATER/VACTERL | al112 |  |
| VSD (excluding severe CHD) | al21\_excl\_al97 |  |
| ASD (excluding severe CHD) | al22\_excl\_al97 |  |
| Choanal atresia | al35 |  |
| Cystic adenomatous malformation of lung | al36 |  |
| Gastrointestinal subgroups combined | al41-al48,al50,al51,aud3 |  |
| Oesophageal atresia with or without tracheo-oesophageal fistula | al41 |  |
| Duodenal atresia or stenosis | al42 |  |
| Atresia or stenosis of other parts of small intestine | al43 |  |
| Ano-rectal atresia and stenosis | al44 |  |
| Hirschsprung’s disease | al45 |  |
| Atresia of bile ducts | al46 |  |
| Annular pancreas | al47 |  |
| Diaphragmatic hernia | al48 |  |
| Gastroschisis | al50 |  |
| Omphalocele | al51 |  |
| Bilateral renal agenesis | al53 |  |
| Multicystic renal dysplasia | al54 |  |
| Congenital hydronephrosis | al55 |  |
| Bladder exstrophy | al56 |  |
| Posterior urethral valve including Prune Belly | al57 |  |
| Hypospadias | al59 |  |
| Indeterminate sex | al60 |  |
| Limb reduction defects | al62 |  |
| Club foot – talipes equinovarus | al66 |  |
| Hip dislocation and / or dysplasia | al67 |  |
| Polydactyly | al68 |  |
| Syndactyly | al69 |  |
| Craniosynostosis | al75 |  |
| Situs inversus | al79 |  |
| Chromosomal | al88 |  |
| Down syndrome | al89 |  |
| Down syndrome without CHD | al891 |  |
| Down syndrome with CHD | al892 |  |
| Down syndrome with CHD and gastrointestinal anomaly | ds2 |  |
| Down syndrome with any CHD, but not gastrointestinal anomalies | ds3 |  |
| Down syndrome with any gastrointestinal anomaly, but not CHD | ds4 |  |
| Down syndrome without CHD or gastrointestinal anomaly | ds5 |  |
| Patau syndrome/tri 13 | al90 |  |
| Edward syndrome/tri 18 | al91 |  |
| Turner syndrome | al92 |  |
| Klinefelter syndrome | al93 |  |
| Anomalies of corpus callosum | aud1 |  |
| Anomalies of intestinal fixation | aud3 |  |
| Unilateral renal agenesis | aud4 |  |
| Accessory kidney | aud5 |  |
| Bladder exstrophy | aud6 |  |
| Epispadia | aud7 |  |
| Posterior urethral valves | aud8 |  |
| Prune Belly | aud9 |  |
| Arthrogryposis multiplex congenita | aud10 |  |
| Williams syndrome | aud12 |  |
| Di George syndrome | aud14 |  |
| Goldenhar syndrome | aud15 |  |
| Cornelia de Lange syndrome | aud16 |  |
| Noonan syndrome | aud17 |  |
| Prader-Willi | aud18 |  |
| Beckwith Wiedemann syndrome | aud20 |  |
| Williams syndrome | aud21 |  |
| Angelman syndrome | aud22 |  |
| Wolff-Hirschhorn syndrome | aud23 |  |
| Cri-du chat syndrome | aud24 |  |
| Karyotype XXX | aud25 |  |
| Pierre-Robin sequence | aud27 |  |

**Table 3: Risk Factors of Interest – limited to only certain more frequent anomalies**

|  |  |
| --- | --- |
| **Risk Factor** | **Requested (X to select)** |
| Isolated anomaly or multiple |  |
| Singleton or multiple birth |  |
| Birth Cohort (1995-1999,2000-2004,2005-2009,2010-2014) |  |
| Maternal Age |  |
| Gestational Age |  |
| Birth weight |  |
| Socio-economic measures (vary by registry) |  |
| Prenatal diagnosis or not of spina bifida, transposition of great arteries (TGA), congenital diaphragmatic hernia (CDH) or gastroschisis |  |

**Table 4: List of data tables available from EUROlinkCAT CRR**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Work Package** | **Description Work Package** | **Spreadsheet ID** | **Spreadsheet Description** | **Table ID** | **Table Description** | **Requested (X to select)** |
| WP3 | Mortality / Survival | WP3\_LINK | Information on linkage of EUROCAT data to Mortality data  | 1A | Linkage strength by year |  |
| 1A2 | Linkage by risk factors |  |
| 2 | Linkage by survival |  |
| 3 | Accuracy variables by year |  |
| 4A | Cause of death by cohort <1 year |  |
| 4B | Cause of death by cohort 1-9 years |  |
| WP3                        | Analysis of Mortality Data       | 1 | Births, Deaths |  |
| 2 | Deaths Prenatal Diagnosis |  |
| 3 | Deaths by Individual birth years |  |
| 4A | Cause of death< 1 year |  |
| 4B | Cause of death1-9 years |  |
| 4C | Correct ICD code on death certificate |  |
| 5A | KM Survival isolated |  |
| 5B | KM Survival structural |  |
| 5C | KM Survival multiple |  |
| 5D | KM Survival Down syndrome only |  |
| 5E | KM Survival Rare anomalies |  |
| 5F | KM Survival isolated by birth cohort |  |
| 5G | KM Survival structural by birth cohort |  |
| 5H | KM Survival multiple by birth cohort |  |
| 5I | KM Survival Down syndrome by birth cohort |  |
| 6A | Cox PH risk factors prenatal survival to 1 year |  |
| 6B | Cox PH risk factors < 1 year isolated |  |
| 6C | Cox PH risk factors < 1 year structural |  |
| 6D | Cox PH risk factors < 1 year multiple |  |
| 6E | Cox PH risk factors < 1 year Down syndrome only |  |
| 6F | Cox PH risk factors 1-9 years isolated |  |
| 6G | Cox PH risk factors 1-9 years structural |  |
| 6H | Cox PH risk factors 1-9 years multiple |  |
| 6I | Cox PH risk factors 1-9 years Down syndrome only |  |
| WP4 | Morbidity | WP4\_LINKAGE | Linkage Information EUROCAT / Reference to Hospital data | 1 | Matching confidence |  |
| 2 | Matching by risk factor |  |
| 3 | Matching by mortality |  |
| 4 | Accuracy risk factor |  |
| WP4\_LOS | Information on length of hospital stays | 0 | No. Deaths |  |
| 1 | No. children,days exp,days hosp |  |
| 2 | KM hosp and Median Stays |  |
| 3 | KM hosp > 10 days |  |
| 4C\_1 | HR hospitalisation |  |
| 4C\_2 | IRR days hosp |  |
| WP4\_LOSRF | Information on length of hospital stays according to risk factors | 0 | No. Deaths |  |
| 1 | No. children,days exp,days hosp |  |
| 2 | KM hosp and Median Stays by Cohort,Gest,Sing,Sex,SES |  |
| 3 | HR hosp by Cohort,Gest,Sing,Sex,SES |  |
| 4 | IRR LOS by Cohort,Gest,Sing,Sex,SES |  |
| 5A | IRR & HR by RF adj model |  |
| 5B | IRR & HR by RF adj model |  |
| 6 | HR hosp > 10 days by Cohort,Gest,Sing,Sex,SES |  |
| 7A | HR diagnoses by Cohort,Gest,Sing,Sex,SES |  |
| 7B | HR diagnoses by Cohort,Gest,Sing,Sex,SES |  |
| WP4\_PD | Information on spina bifida, TGA, CDH or gastroschisis comparing pre and postnatal diagnoses | 1 | PD counts alive and gest age |  |
| 1b | PD gestage deaths |  |
| 2R | PD KM hosp |  |
| 3R | PD KM hosp |  |
| 4\_1 | PD: HR hospitalisation |  |
| 4\_2 | PD: IRR days hosp |  |
| 5A | KM hosp > 10 days |  |
| 5B | KM hosp > 21 days |  |
| 6 | PD: Surgery counts |  |
| WP4\_PRESC | Information on prescriptions | TOTAL | Prescriptions : Asthmatic |  |
| TOTAL | Prescriptions: Cardiac |  |
| TOTAL | Prescriptions: Diabetic |  |
| TOTAL | Prescriptions: Epileptic |  |
| TOTAL | Prescriptions: Infections |  |
| WP4\_SANDD |  | 5A | Counts of surgeries |  |
| 5B | Age at surgery |  |
| 6 | Counts ICU |  |
| 8 | Counts Ventilation |  |
| 9A | Diagnoses all anomalies |  |
| 9BC | Diagnoses by anomaly |  |
| WP4\_SS | 10A | Cardiac deaths after surgery |  |
| 10B | Gastrointestinal deaths and surgery |  |
| 5C | Risk of specific surgeries |  |
| 5D | Counts and ages of specific surgeries |  |
| 5E | Numbers surgeries (Analysis of any surgery by CA subgroup) |  |
| 5F | Age at surgery (Analysis of any surgery by CA, median age and median number of surgeries) |  |