

**Lay summary of the EUROlinkCAT Work package 3 protocol for submission for ethics approval**

***Who are we?***

EUROlinkCAT is a project funded by the European Union Horizon 2020 research and innovation programme. It will last for five years (2017-2021) and will bring together different sources of information about the lives of children born with congenital anomalies (also known as birth defects).

***What is known and what is unknown?***

We know that children born with a severe congenital anomaly have a shorter life expectancy compared to other children. Continuing improvements in health care services and treatments during pregnancy and early life improve their chance of living longer but little is known about the survival in children with specific congenital conditions and about the factors that increase survival.

***What are we trying to do?***

This part of the EUROlinkCAT project will analyse the survival of children with a range of different congenital anomalies during their first 10 years of life. We want to find out whether there are differences between different European regions. We will also examine particular factors - for example, if the anomaly was diagnosed before birth or not - that may contribute to these children’s survival. For those children who do not survive to 10 years of age, we will investigate the causes of death.

***How are we going to do this?***

To answer these questions, 21 participating European registries of congenital anomalies\* that are part of the European Surveillance of Congenital Anomalies (EUROCAT), will link their data on children with congenital anomalies to their region’s mortality data. They will use a unique identifier to make sure that the information on mortality refers to a child recorded in their registry. As the registries will access identifiable data for this data linkage, appropriate ethics approval will be sought.

***What do we need to do next?***

We have proposed a detailed research protocol that each registry will use for their ethics application, in which we described our study’s aim and objectives, what data the registries will need to obtain, the details of the linkage procedure and data quality checking, and the analyses that the registers will do. We have also described the procedures for the safe handling, storage and destruction of the data at the end of the project to ensure that no information on individual children will be released. The registries will now seek approval to link the mortality data with their registry data. When this approval is granted, the registries can go ahead with the data linkage which will provide linked data for the analysis.

***What useful information do we expect to obtain as a result of this project?***

This study will provide information for parents of children born with these conditions, families, health professionals and policy makers on the survival up to 10 years old, whether there are any inequalities in survival and whether certain factors, such as geographical location, influence this survival.