

## **EuSOS: Operational Guidelines for Secondary Studies.**

### **Coordinator**

Each secondary study has to name a responsible coordinator. This person is the primary contact, responsible for the conduction of the study and the contact to the EuSOS steering committee.

By agreeing to be a coordinator of a EuSOS secondary study the individual agrees to develop the draft manuscript within a reasonable time of receiving the data from the EuSOS steering committee. A reasonable timeframe for this response would be within a period of four weeks. Failure to deliver on this may precipitate removal of the individual from further participation in the study

### **Research proposals.**

Each coordinator must submit a brief research proposal so that the EuSOS steering committee can assess the validity of the proposal. This proposal needs to include:

- A hypothesis
- Detailed inclusion/ exclusion criteria for cohort building (if it is different from the original cohort)
- The statistical analysis needed. This is a dynamic process and some information can already be derived from the primary EuSOS univariate analysis. Further information can then be requested when needed.
- Dummy tables, and where applicable graphs, indicating what summary data and comparisons will be presented

### **Data handling**

Data handling and processing will be done by the EuSOS steering committee. No raw data will be sent out to investigators, only aggregated or analysed data.

Individual country analyses will not be performed unless there is an exceptional reason for doing so.

### **Order of processing**

Secondary studies will be prioritized by the EuSOS steering committee. Secondary studies from outside of the steering committee will be processed in the order of arrival, however the steering committee reserve the right to re-order the priorities if necessary.

### **Ownership of the data**

The ownership of pooled data remains with the EuSOS steering committee. Authors of secondary studies are allowed to use the data for their accepted study, but they do not gain ownership of these data or analyses.

## **Publication**

As soon as the secondary study is ready for publication it has to be submitted back to the EuSOS steering committee chair. Publication of any data without the approval of the chair is not allowable.

Publication in this context includes not only original papers in scientific journals but also any other form of written or orally given presentations.

Citation.

Each sub-study must cite the EuSOS primary manuscript published in the Lancet.

## **Authorship**

Each paper will be published on behalf of the EuSOS study group. Only persons contributing specifically to the sub-study in question will be named authors of these papers. For this reason each manuscript submitted to the EuSOS steering committee for approval prior to publication must state the contributions of each author. It is expected that members of the EuSOS steering committee will participate in each secondary study.