



## Source Data Verification Protocol

The data verification procedure at the site is planned in steps as follows:

1. 100% of patients data of the year ..... are supplied to the Database
2. The Centers performing verification need to validate their data in the data collection software according to the instructions from data upload summary, to make sure that all operations have a status = valid.
3. The Database Coordinator sends to the site the documents, that consist of:
  - List of patients ID of the year .....
  - Form claiming the completeness of patients list and the mortality rate. This form needs to be undersigned by a hospital authority (e.g. Medical Director).
  - the form of data verification at the site containing the list of items that will be verified.
4. Person locally responsible for the verification indicates the source of information at the site, different to the local copy of the database or related to the database (patients' files, hospital computerized system etc.).
5. The Database Coordinator visits the site and checks on the reliability of the data undergoing verification according to the form provided.
6. After verification is completed the person locally responsible undersigns all forms.

The hospital mortality will be defined as "at 30 days" or within the same hospitalization.

Bohdan Maruszewski, MD PhD  
Professor of Cardiothoracic Surgery

ECHSA Congenital Database Director