

EACTS CONGENITAL DATABASE POLICY

1. INTRODUCTION

The following policy (the “**Policy**”) outlines the purpose and the principles of use of the EACTS Congenital Database. The EACTS Congenital Database is operated by the European Association of the Cardio-Thoracic Surgery (“**EACTS**”) established under the laws of England, with its seat in London, 3 Park Street, Windsor, Berkshire SL4 1LU, the United Kingdom.

Any Cardio-Thoracic Surgery Center (“**CTS Center**”), by submitting the registration form or logging on to the EACTS Congenital Database, acknowledges the Policy and agrees to follow it.

2. AIMS

- (i) The aim of the EACTS Congenital Database is to collect data allowing comparing the outcomes, the performances, and the manner in which congenital heart surgical procedures are carried out across the globe. In this way, the EACTS Congenital Database shall enable risk stratification and help defining optimal surgical treatment for certain subsets of patients exposed to incremental mortality and morbidity risk factors.
- (ii) The ultimate goal of the EACTS Congenital Database is to improve early and late survival rates as well as the quality of life of surgically treated patients with congenital heart disease across the globe.
- (iii) The EACTS Congenital Database does not serve to rank CTS Centers or surgeons, and does not participate in malpractice investigations or conformity checking of CTS Centers and surgeons. To this end, the data contained therein remains anonymous and does not enable identification of either CTS centers, or surgeons, or patients.
- (iv) The EACTS Congenital Database was created and developed for non-commercial purposes.

3. HISTORY

In 1992, the European Congenital Heart Surgeons Association (“**ECHSA**”) established the European Congenital Heart Defects Database (ECHDD) for academic purposes as a database of congenital heart surgical procedures.

In 1999, at the Congenital Business Meeting held during the annual meeting of the EACTS in Glasgow, Scotland, it was decided that the ECHDD would become a part of EACTS ECSUR project and it was renamed to **EACTS Congenital Database**. Since then, EACTS Congenital Database is sponsored mainly by EACTS, while ECHSA continues to provide a financial support.

In 2006, the EACTS Council and ECHSA decided to adopt a policy providing for detailed rules of operating and use of the EACTS Congenital Database and protection of data contained therein. On 16-11-2007 adopted this Policy.

4. ACCESS

Access to the EACTS Congenital Database is free of charge and available via the Internet page <http://www.eactscongenitaldb.org> (the “**EACTS Congenital Database Internet Page**”). It

enables access to the aggregated data organized in the form of reports; the input data submitted by the CTS Centers remains anonymous in accordance with the principles set out in Section 5. The following types of access can be distinguished:

(i) Public access

Certain aggregated data is publicly available in the form of basic reports generated via the EACTS Congenital Database. Such reports are available without the need for registration of the CTS Center. The scope of the publicly available data is defined by the EACTS Council.

(ii) Access of CTS Centers

Any registered CTS Center has access to all kinds of reports generated via the EACTS Congenital Database containing all aggregated data submitted by the CTS Centers.

5. ANONYMITY OF THE DATA

(i) The data regarding congenital heart surgical procedures performed by surgeons from Europe and around the world contained in the EACTS Congenital Database is collected, stored, analyzed, and presented in an anonymous manner.

(ii) The EACTS Congenital Database does not enable disclosure of the identity of the surgeon who performed a procedure, the name of the patient, or the identity of the CTS Center that submitted the data.

(iii) Subject to the CTS Center's fulfillment of the obligations under this Policy, EACTS shall make all reasonable efforts to safeguard the full anonymity of the data in the EACTS Congenital Database and to ensure that the data is not traceable to the name of the CTS Center that submitted data.

(iv) Save for the circumstances described in Sections 5(v) and (vi), the name of the CTS Center that submitted data may not be decoded by any institution, person or entity, including EACTS.

(v) In order to ensure technical functionality of the EACTS Congenital Database and enable verification of the data as referred to in Section 8, the EACTS Congenital Database Coordinator, or his duly authorized representative (any of them or collectively referred to as “**EACTS Congenital Database Staff**”), have access to information as to which CTS Center submitted the data.

(vi) Under exceptional circumstances, the name of the CTS Center that submitted data may be disclosed to the governmental authorities or courts of the competent jurisdiction, and only in accordance with the applicable laws.

6. PUBLICATIONS AND OTHER USE OF DATA

(i) The CTS Centers have a right to publish for scientific purposes the publicly available basic reports, referred to in Section 4(i).

(ii) Any further information obtained from the EACTS Congenital Database, in particular the reports available only to the registered the CTS Centers in accordance with Section 4(ii), may be used by CTS Centers solely for internal purposes. Any publishing of such reports

in whatever form, either in electronic form or printed form, in whole or in part, requires prior written consent of the EACTS Congenital Database Director.

- (iii) Any publication of the reports or other information as set out in Section 6(i) and (ii) requires reference to the EACTS Congenital Database as the source of publication.
- (iv) EACTS and ECHSA are authorized to use the information and reports available via the EACTS Congenital Database for scientific purposes, provided that such use guarantees full anonymity of the data. In particular, neither the EACTS nor ECHSA shall use the data to rank the CTS Centers in any way.
- (v) In the event of any publication made pursuant to Section 6(iv) the publishing party shall acknowledge the other party authorized to make such publication in the publication, i.e. EACTS shall acknowledge ECHSA and ECHSA shall acknowledge EACTS.

7. PRINCIPLES OF OPERATION

7.1 REGISTRATION

- (i) Any CTS Center interested in registration must fill in the registration form available on the EACTS Congenital Database Internet Page, and submit it to EACTS through a secure connection.
- (ii) EACTS has the right to verify the information provided in the registration form. The verification is carried out by reviewing publicly available information, in particular by looking for data about the CTS Center in the Internet, and checking the publications record and other relevant scientific activities of the head of the department and/or the registering person.
- (iii) The CTS Center is responsible for:
 - providing accurate, complete and truthful information on the registration form;
 - ensuring that the registration in the EACTS Congenital Database complies with any applicable local laws and internal procedures;
 - ensuring that the person conducting the registering holds authorization to act on behalf of the CTS Center, and, if necessary, on behalf of any larger healthcare establishment that the CTS Center may be organizational unit of.

EACTS has the right to refuse registration of the CTS Center if, in its opinion, any of the requirements set out in this Section 7.1(iv) is not fulfilled.

- (iv) EACTS waives all responsibility for any damage caused by persons who registered with the EACTS Congenital Database on behalf of the CTS Center without the proper authorization for such registration.
- (v) A CTS Center that has successfully completed the registration process becomes full participant and user of the EACTS Congenital Database in accordance with this Policy.
- (vi) CTS Centers are obliged to inform EACTS without undue delay of any subsequent change of any information provided in the registration form during the registration process.

- (vii) A list of the registered CTS Centers is displayed on the EACTS Congenital Database Internet Page, however without a possibility of linking a particular CTS Center with any data contained in the EACTS Congenital Database.

7.2 DATA INPUT

- (i) Data may be inserted into EACTS Congenital Database by the registered CTS Centers only.
- (ii) Data is submitted using the International Pediatric and Congenital Cardiac Code (available at www.ipccc.net) in the version of the International Congenital Heart Surgery Nomenclature and Database Project of the European Association for Cardio-Thoracic Surgery and the Society of Thoracic Surgeons.
- (iii) The CTS Center is obligated to ensure that the inserted data is accurate, complete and truthful. EACTS is not obliged to verify whether the input data fulfills these requirements. However, EACTS has the right to remove the data from the EACTS Congenital Database if it suspects, or is informed, that the data is not accurate, complete or truthful.
- (iv) CTS Centers are responsible for ensuring that only properly authorized persons submit data to the EACTS Congenital Database. EACTS waives all responsibility for any damage caused by persons who inserted data to the EACTS Congenital Database on behalf of the CTS Center without a proper authorization.
- (v) After the registration, a CTS Center receives, free of charge, access to the software for data collection. The software may be installed provided that the user's PC conforms to the requirements set out on the EACTS Congenital Database Internet Page.
- (vi) The data submitted by the CTS Center is uploaded to a secure web page. The data is sent as a xml file that does not contain the names of doctors or patients, or any other personal data that would allow the identification of any natural person. Before the data is ultimately transmitted to the EACTS Congenital Database, the CTS Center has an opportunity to verify the file.
- (vii) Once the computer program operated by the EACTS Congenital Database has checked the correctness of the submitted data, the data is computed by the server and inserted into the EACTS Congenital Database.
- (viii) In the event that the CTS Center's involvement in the EACTS Congenital Database is terminated, the data inserted by such a CTS Center will remain in the EACTS Congenital Database unless otherwise decided by the EACTS Congenital Database Director.

7.3 CTS CENTER ID AND USER ACCOUNT

- (i) Once the registration of the CTS Center has been successfully completed, the CTS Centers will be assigned a unique identification number ("**CTS Center ID**").
- (ii) In addition to the CTS Center ID, a CTS Center will be assigned a requested number of accounts, one for each person authorized to input data into the EACTS Congenital Database ("**User**"), each secured with a unique password. The User is a person named by the CTS Center as the person authorized to log in to the EACTS Congenital Database on behalf of the CTS Center.

- (iii) It is the CTS Center's responsibility to ensure that only authorized persons within CTS Center, on a need-to-know basis, know the Center ID, and the User's account or passwords.
- (iv) The CTS Center is obligated to immediately inform the EACTS Database Coordinator of any changes regarding persons authorized as Users in order to enable EACTS Database Coordinator to change the password of that User or otherwise disable the account. The EACTS Database Coordinator shall without undue delay respond to the CTS Center's request to change the password or otherwise disable the User's account.
- (v) The CTS Center shall impose an obligation on its employees and contractors who are authorized as Users to keep the CTS Center ID and the User's account and its password strictly confidential. The confidentiality obligation should also ensure the secrecy of such information after the termination of the employment or any other relevant relationship between the CTS Center and the User .
- (vi) EACTS shall act with due diligence to ensure strict confidentiality of the CTS Center ID or the User's account. EACTS shall not be liable for unauthorized disclosure of such information by persons who are not under EACTS' direct control or supervision.

8. DATA VERIFICATION

- (i) The EACTS considers the verification of the accuracy of submitted data as a vital element of the operation of EACTS Congenital Database.
- (ii) Verification is provided free of charge by EACTS and the CTS Center covers only the travel and accommodation expenses incurred by the EACTS Congenital Database Staff conducting the verification.
- (iii) Verification is aimed at assessing whether the data contained in the EACTS Congenital Database is accurate. Verification of the data at source is one of the instruments necessary to ensure the quality and reliability of the EACTS Congenital Database.
- (iv) Verification is performed either at the request of the CTS Center or on the basis of the decision the EACTS Congenital Database Director.
- (v) The verification process is based on an interview conducted by EACTS Congenital Database Staff with an appointed representative of the CTS Center. During the verification process, the CTS Center ensures the availability of an appointed representative of the CTS Center at the CTS Center's premises for the purpose of an interview.
- (vi) In the verification process, a "back-to-back" method is used: the EACTS Congenital Database Staff asks for certain anonymous information, while the appointed CTS Center's representative provides such anonymous information by accessing medical documentation and source data available at the CTS Center (whether anonymous or non-anonymous). At any time, the EACTS Congenital Database Staff does not have access to non-anonymous data of patients or any other non-anonymous information resources available at the CTS Center. In particular, the verification does not enable the EACTS Congenital Database Staff to identify a patient who has undergone surgery or the surgeon who performed the surgery. Only an authorized representative of the CTS Center may have access to non-anonymous information.

- (vii) The CTS Center is responsible for ensuring that the use of medical documentation or other source data available at the CTS Center in the verification process is made within the local statutory limits and in accordance with any internal procedures of the CTS Center.
- (viii) The EACTS Congenital Database Staff performing the verification process act on behalf of EACTS and they cannot be regarded as contractors of the CTS Center, even if the verification is conducted on request of the CTS Center.
- (ix) Once the verification process is successfully completed, EACTS provides the CTS Center with a certificate and report containing an assessment of accuracy of the data submitted in the EACTS Congenital Database by the CTS Center.
- (x) The EACTS Congenital Database Director publishes on the EACTS Congenital Database Internet Page a list of the verified CTS Centers, confirming in this way that the EACTS performed the verification process. The list does not contain any information as to the assessment of accuracy of the data submitted by the CTS Center.
- (xi) Since the EACTS Congenital Database Staff does not have direct access to the medical documentation or other source data of the CTS Center, the ultimate responsibility for the accuracy, completeness and truthfulness of the data remains with the CTS Center and the reservations contained in Section 13(iii) remain unaffected.

9. SUPERVISING AUTHORITIES

9.1 EACTS COUNCIL

The EACTS Council is EACTS official body responsible for strategic decisions regarding the EACTS Congenital Database. In particular, the EACTS Council:

- approves the Policy and any changes to the Policy;
- decides on the location of the EACTS Congenital Database;
- defines the scope of the data collected in the EACTS Congenital Database;
- decides which data shall be publicly available in the form of basic reports, as provided for in Section 4(i);
- appoints and dismisses the EACTS Congenital Database Director.

9.2 EACTS CONGENITAL HEART DISEASES COMMITTEE

The EACTS Congenital Heart Diseases Committee is EACTS official body responsible for all congenital heart disease activities, including maintenance of the EACTS Congenital Database. In particular, the EACTS Congenital Heart Diseases Committee:

- adopts proposals for the decisions of the EACTS Council as provided for in Section 9.1.

9.3 EACTS CONGENITAL DATABASE DIRECTOR

- (i) The EACTS Congenital Database Director is responsible for day-to-day operation, maintenance and development of the EACTS Congenital Database and data analysis. In particular, The EACTS Congenital Database Director:
- decides on the verification of the data provided by a CTS Center, in accordance with Section 8.4;
 - gives consent to the publication of information and reports contained in the EACTS Congenital Database, as provided for in Section 6(ii);
 - decides on the removal of data from the EACTS Congenital Database;
 - monitors the CTS Centers' actions to ensure compliance with the Policy, in accordance with Section 12;
 - appoints and dismisses the EACTS Congenital Database Coordinator.
- (ii) The EACTS Congenital Database Director is appointed and dismissed by the EACTS Council.
- (iii) The EACTS Congenital Database Director reports to the EACTS Congenital Heart Diseases Committee.
- (iv) The EACTS Congenital Database Director has no access to the CTS Center Database referred to in Section 10(ii).

9.4 EACTS CONGENITAL DATABASE COORDINATOR

- (i) The EACTS Congenital Database Coordinator is responsible for the creation, development, maintenance and upgrade of the software allowing the CTS Centers to submit the data to the EACTS Congenital Database. In particular, the EACTS Congenital Database Coordinator is responsible for:
- data collection activities, data optimization and data protection;
 - assisting CTS Centers and providing technical support to the CTS Centers. For this purpose, the Coordinator keeps the CTS Centers Database referred to in Section 10(ii);
 - technical organization of the process of verification of data according to the rules set out in Section 9.
- (ii) The EACTS Congenital Database Coordinator is appointed and dismissed by the EACTS Congenital Database Director. EACTS Congenital Database Coordinator should be a physician and possess appropriate qualifications and experience as to ensure proper operation of the EACTS Congenital Database.
- (iii) The EACTS Congenital Database Coordinator reports to the EACTS Congenital Database Director.

10. PERSONAL DATA

- (i) The EACTS Congenital Database does not contain any personal data.

- (ii) For the purpose of registration and communication with CTS Centers, and verification of the data provided, a database of CTS Centers is established (the “**CTS Center Database**”).
- (iii) The CTS Center Database contains data provided by a CTS Center in the registration form and contains some personal data. It is maintained in printed form as well as in a computer system.
- (iv) The CTS Center Database is kept by the EACTS Congenital Database Coordinator on behalf of the EACTS. No other person than EACTS has access to the CTS Center Database.
- (v) Personal data contained in the CTS Center Database is protected in accordance with the laws applicable to the data controller and data processor.

11. FINANCING

- (i) EACTS Congenital Database is sponsored by EACTS and receives additional financial support from ECHSA.
- (ii) By the end of each financial year, the EACTS Congenital Database Director presents to the EACTS Congenital Heart Disease Committee proposed budget for next year. The budget proposal is negotiated until adopted by the EACTS Council. By the end of each financial year the EACTS Congenital Database Director reports on the realization of the budget to the EACTS Congenital Heart Diseases Committee.
- (iii) Without prejudice to Section 8(ii), the EACTS Congenital Database cannot receive any other financial resources or other forms of sponsorship than those received from EACTS and ECHSA. In particular, direct financing of the EACTS Congenital Database by CTS Centers, other healthcare establishments, industry or media is prohibited.

12. SANCTIONS FOR BREACH OF THE POLICY

- (i) The EACTS Congenital Database Director monitors the use of the EACTS Congenital Database and reports to EACTS Congenital Heart Diseases Committee, to ensure compliance with the Policy.
- (ii) In the event of non-compliance with the Policy, the EACTS Congenital Database Director or the EACTS Congenital Heart Diseases Committee may request to cure the breach, setting the deadline for such a cure.
- (iii) In the event of a serious breach of the Policy, the EACTS Congenital Database Director or the EACTS Congenital Heart Diseases Committee may suspend or terminate participation of a CTS Center in the EACTS Congenital Database project.
- (iv) The following shall in particular be considered a serious breach:
 - breach of the obligations to provide accurate, complete and truthful information and data, as set out in Sections 7.1 and 7.2;
 - breach of the confidentiality obligations, as set out in Section 7.3;
 - breach of the publication principles, as set out in Section 6.

13. MISCELLANEOUS

- (i) The Policy is subject to the laws of Poland.
- (ii) Any disputes arising from, or in connection with, this Policy shall be settled by the court having jurisdiction over the seat of EACTS.
- (iii) EACTS shall not be liable for any damage, loss, or claim that may arise from an act, omission, or misconduct of any person who remains beyond control or supervision of EACTS..
- (iv) EACTS shall make reasonable efforts to ensure the accuracy of the EACTS Congenital Database or the EACTS Congenital Database Internet Page, but accuracy cannot be guaranteed and EACTS makes no warranties or representations in this respect. The EACTS Congenital Database or the EACTS Congenital Database Internet Page's content is provided "as is" and without warranties of any kind, either express or implied. To the fullest extent permissible pursuant to Polish law, EACTS disclaims all warranties, express or implied, and waives any liability for the accuracy of the data and reports produced on the basis of this data.
- (v) EACTS has in place reasonable technical and organizational security measures to ensure the proper operation of the EACTS Congenital Database or the EACTS Congenital Database Internet Page, and to ensure an uninterrupted use of this Web Site. However, absolute security cannot be guaranteed on the Internet, and the EACTS Congenital Database or the EACTS Congenital Database Internet Page might be vulnerable to attack by programs that contain viruses, "Trojan horses", or worms, or other attacks designed to interrupt, destroy or limit their functionality, the integrity of the information contained therein, or the security of transmission, or to deny access. EACTS is not responsible for interruptions or improper operation of the EACTS Congenital Database or the EACTS Congenital Database Internet Page caused by circumstances beyond EACTS' control.

Version approved on 16-11-2007