

Founding Charter



QUIP ADULT CARDIAC DATABASE (ACD):

1 INTRODUCTION

- 1.1 This Charter is an agreement between the European Association for Cardio-Thoracic Surgery ("EACTS") and the various Cardio-Thoracic Surgery Centres and surgeons listed in Appendix 1 ("the Participators"). It outlines the purpose, the principles and the rules governing the QUIP Adult Cardiac Database ("ACD").
- 1.2 Any Cardio-Thoracic Surgery Centre or surgeon by submitting the registration form becomes a party to this Charter and agrees to comply with these rules.

2 AIMS

- 2.1 The ACD collects data allowing users to examine the outcomes of surgical procedures carried out in participating countries.
- 2.2 Participators will be able to compare their outcomes with the collective data shared by colleagues internationally.
- 2.3 The detailed risk stratification of specific patients will enable doctors to advise patients with more confidence about the risks involved in various procedures for patients sharing their characteristics and history.
- 2.4 Restricted access to the database will be made available to researchers in order to advance the art and science of cardiac surgery.
- 2.5 Other access to the ACD may be made available by the EACTS Council on such terms as it may see fit.
- 2.6 The fields of data held on the ACD may be varied from time to time by the Council of EACTS.
- 2.7 The Council of EACTS shall have power to delegate day to day control to the ACD Committee ("the Committee") which is to be chaired by the ACD Director ("the Director").

3 DATA PROTECTION

- 3.1 No patient identifiable personal data is intended to be held on the ACD. Where it appears that data may enable a patient to be identified, the Committee will take steps to prevent this happening.
- 3.2 No surgeon identifiable personal data is intended to be held on the ACD. However it may occasionally be possible for surgeons to be identifiable from the surrounding data or other information available to users of the service, or as a result of an order being made by a court of law, and accordingly their surgical outcomes to be known. Surgeons who permit their data to be placed on the ACD consent to this possibility, and Participators must ensure that information submitted relates only to surgeons who have been informed of and agree to this risk.
- 3.3 Under exceptional circumstances, the contents of the ACD may be disclosed where this is required by law.
- 3.4 Where data supplied to the ACD raises a cause for concern about the outcomes at a specific centre, the Director will write to the relevant Medical Director of the Centre concerned advising them of this concern.
- 3.5 Notwithstanding the intention that the ACD will not hold personal data, EACTS undertakes to ensure that appropriate technical and organisational measures are in place against unauthorised or unlawful processing of the data supplied to the ACD and against accidental loss or destruction of, or damage to, such data held or processed by it and that it has taken, or will take at all material times steps to ensure the reliability of any of its staff and/or contractors who will have access to the data supplied to the ACD.
- 3.6 The security policy governing the use of this information is set out at Appendix 2.

4 ACCESS

- 4.1 Users are able to see the collective ACD providing details of outcomes for patients with numerous characteristics undergoing every procedure that is entered on the ACD.
- 4.2 More detailed access to the ACD for research purposes will be permitted at the discretion of the Committee.
- 4.3 The Committee may also provide reports containing their own data to Participators on request.
- 4.4 The ACD has been created and developed for non-commercial purposes. The Committee shall be empowered to make charges to researchers and others to whom access is granted.

5 OWNERSHIP

- 5.1 The collective pooled data about outcomes shall be the property of EACTS.
- 5.2 The Participators shall be entitled to discontinue submitting data to the ACD at any time. Any data already submitted will remain in the ACD.

6 PUBLICATIONS AND OTHER USE OF DATA

- 6.1 The Participators have a right to publish for comparative purposes the collective data available on the ACD.
- 6.2 Any further information obtained from the ACD may only be published with the written permission of the Director.

7 PRINCIPLES OF OPERATION

- 7.1 Any Individual Cardio-Thoracic Surgery Centre or surgeon wishing to participate must fill in the ACD registration form and they will become a Participator when their registration is accepted by the Committee.
- 7.2 The Participators are responsible for:
 - 7.2.1 Providing accurate, complete and truthful information;
 - 7.2.2 Ensuring that participation in the ACD complies with any applicable local laws and internal procedures;
 - 7.2.3 Advising the Committee of any change in circumstances affecting its participation or the reliability and completeness of the data that it is supplying.
- 7.3 EACTS reserves the right to refuse registration of the Participator and may terminate participation at any time or make continued participation conditional upon such terms as it may impose.

8 DATA VALIDATION

- 8.1 The reliability of the submitted data is a vital element of the operation of the ACD.
- 8.2 Data may be inserted into the ACD by the registered Participators only.
- 8.3 Data is submitted using the fields supplied by the Committee.
- 8.4 Participators undertake to ensure that the inserted data is accurate, complete and robust. They undertake to
 - 8.4.1 Crosscheck data against other local sources of data, such as operative logs or administrative data to ensure that case ascertainment is complete;
 - 8.4.2 Utilise local independent sources of mortality to ensure that mortality returns are accurate;
 - 8.4.3 Monitor data accuracy to ensure that risk factors are reliably recorded.
- 8.5 EACTS is not obliged to verify whether the input data fulfils these requirements. However,
 - 8.5.1 the Committee reserve the right to remove data from the ACD or take such other steps as may seem appropriate if it suspects that data is not robust or for any other reason.
 - 8.5.2 The Committee shall have an unfettered right to such steps as it considers necessary to audit the data inserted by any Participator.
- 8.6 Participators are responsible for ensuring that only properly authorized persons submit data to the ACD.
- 8.7 EACTS shall not be responsible for any inaccuracies and shall be indemnified by Participators in respect of any harm caused to any person in any way as a result of inaccurate data being supplied or information being supplied without the required consent.
- 8.8 The Committee shall have an unfettered right to remove any data from the ACD without being required to give any reason.

9 SUPERVISING AUTHORITIES

- 9.1 The EACTS Council is EACTS official body responsible for strategic decisions regarding the ACD. In particular, the EACTS Council:
 - 9.1.1 Approves the Charter and any changes to the Charter;
 - 9.1.2 Decides on the location of the ACD;
 - 9.1.3 Defines the scope of the data collected in the ACD;
 - 9.1.4 Decides which data shall be publicly available.
 - 9.1.5 Approves any changes to the Security Policy contained in Appendix 2.
- 9.2 The EACTS Council is empowered to delegate any of its functions except 9.1.1 to the Committee. The Director and the Committee shall be appointed and dismissed by the EACTS Council.
- 9.3 The Director is responsible for day-to-day operation maintenance and development of the ACD and data analysis. In particular, The Director:
 - 9.3.1 Determines any issues concerning the verification of the data provided by a Participator;
 - 9.3.2 Gives consent to the publication of information and reports contained in the ACD;
 - 9.3.3 Monitors the Participators' actions to ensure compliance with the Charter;
 - 9.3.4 Appoints a member of the Committee to act as the ACD Coordinator ("the Coordinator").

- 9.4 The Coordinator is responsible for the creation, development, maintenance and upgrade of the software allowing the Participators to submit data to the ACD. In particular, the Coordinator is responsible for:
 - 9.4.1 Data collection activities, data optimization and data protection
 - 9.4.2 Assisting Participators and providing technical support
 - 9.4.3 Technical organization of the process of verification of data

10 MISCELLANEOUS

- 10.1 The Charter is subject to the laws of England.
- 10.2 Any disputes arising from, or in connection with this Charter shall be settled by EACTS Council.

APPENDIX 1

CARDIO-THORACIC SURGERY CENTRES AND SURGEONS

Separate document completed by EACTS staff and stored securely at EACTS House, Windsor, UK.

Any Cardio-Thoracic Surgery Centre or surgeon by submitting the registration form becomes a party to this Charter and will be added to Appendix 1.

APPENDIX 2

SECURITY POLICY

Between the Database Provider contracted by EACTS (Database Provider") and the European Association for Cardio-Thoracic Surgery, EACTS House, Madeira Walk, Windsor, SL4 1EU, UK ("EACTS").

The Database Provider will allow users to upload data via a secure upload facility, which can be accessed using a standard Internet Explorer web browser without the need to install additional software or perform any complex system configurations.

It is agreed that this Agreement shall be governed by and construed in accordance with the laws of the United Kingdom. In the event that any provision shall be held to unlawful or otherwise ineffective, the remaining provisions shall remain in full force and effect. Any and all legal transactions must be transacted or brought in the courts in England, United Kingdom.

DATA PROCESSING

1. SCOPE AND RESPONSIBILITY

- 1.1 To the extent that Personal Data are entered into the Database, EACTS will be Data Controller and the Database Provider may act as "Data Processor". EACTS is solely responsible for complying with all statutory requirements relating to data protection, in particular regarding the transmission of Personal Data to the Database and the processing of such Personal Data by the Database Provider.
- 1.2 The Database Provider undertakes to respect the aims principles and objectives of the EACTS QUIP Adult Database Charter "the Charter" to assist EACTS to discharge its obligations under that Charter.
- 1.3 The obligations imposed under the Charter and this Security Policy will continue after the termination of the contractual relationship between EACTS and the Database Provider.

2. OBLIGATIONS OF THE DATABASE PROVIDER AS DATA PROCESSOR

- 2.1 The Database Provider will be registered under UK law in accordance with the United Kingdom Data Protection Act 1998 ("the Act"). The Database Provider is required to maintain the registration during the term of the contract and is required to abide by terms of the Act and any successor thereto.
- 2.2 The Database Provider will Process Personal Data in accordance with the Agreement and only in accordance with EACTS' instructions. The Database Provider may not use the Personal Data for any purpose other than to provide the services stipulated in this agreement in accordance with EACTS' instructions. "Processing" or "Process" means any operation or set of operations which is performed upon the Personal Data, including storage, modification, transfer, restricting access, or deletion.
- 2.3 The Database will solely be operated on the Database Provider's secure hosted servers located in the United Kingdom.
- 2.4 The Database Provider will take the required technical and organisational measures required by the Act to protect Personal Data entered into the Database against unauthorised Processing and unauthorised or accidental loss or destruction, damage, alteration, or disclosure.
- 2.5 The Database Provider's staff are not allowed to collect, process or use Personal Data without sufficient authorisation.
- 2.6 The Database Provider will inform EACTS immediately of any breach of security measures that impact the security of Personal Data (which are part of the Database), or any processing of Personal Data in violation of the agreement.
- 2.7 The Database Provider will enable EACTS to review, and upon request in accordance with the directions of EACTS will correct, delete or block any Personal Data which are part of the Database.
- 2.8 The Database Provider shall at all times provide EACTS with up to date information about the specific technical and organizational measures taken by the Database Provider and any subcontractor to protect Personal Data.

QUIP Adult Cardiac Database Charter, version 1.2, 13-10-2017

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3. TECHNICAL AND ORGANISATIONAL MEASURES

The Database Provider shall take appropriate technical and organisational measures, to:

- 3.1 prevent unauthorised access to Personal Data Processing systems;
- 3.2 prevent the Database being used without authorisation of EACTS;
- 3.3 ensure that persons entitled to use the Database gain access only to such Personal Data as they are entitled to access in accordance with their access rights, and that, in the course of processing or use and after storage, Personal Data cannot be read, copied, modified or deleted without authorisation;
- 3.4 ensure that Personal Data successfully entered into the Database cannot be read, copied, modified or deleted without authorisation of EACTS;
- 3.5 ensure the establishment of an audit trail to document whether and by whom Personal Data has been entered, modified, or removed;
- 3.6 take appropriate steps to ensure that Personal Data
 - 3.6.1 is processed solely in accordance with the instructions of EACTS;
 - 3.6.2 is protected against accidental destruction or loss;
 - 3.6.3 collected for different purposes is processed separately. Any Personal Data transmitted to the Database will be separated from the content of other Participators so that the access rights of each Participator will be limited to the data stored by that Participator.

4. AUDITS, DOCUMENTATION

The Database Provider will, on a regular basis and immediately on request, enable EACTS to verify the implementation of, and compliance with, the technical and organizational measures stipulated in Section 3. In order to allow EACTS to establish documentation in accordance with Section 11(2)5 of the Act, the Database Provider shall at all times provide EACTS with up to date documentation of the specific technical and organizational measures taken by the Database Provider and any subcontractor to protect Personal Data.

5. ENQUIRIES FROM DATA SUBJECTS TO EACTS OR THE DATABASE PROVIDER

Where EACTS is obliged to provide information to an individual about the collection, processing or use of its Personal Data, the Database Provider will provide the required assistance to EACTS so EACTS may make the information available.

6. SUBCONTRACTING

The Database Provider will not subcontract the performance of any of its obligations under this agreement without the prior express consent in writing of the EACTS. The obligations upon the Database Provider will be imposed upon any subcontractor.