Privacy Notice for the European Registry for Patients with Mechanical Circulatory Support (EUROMACS)

EUROMACS is part of the Quality Improvement Programme, run by the European Association for Cardio-Thoracic Surgery (EACTS).It maintains a register with the purpose of research on the outcomes of patients implanted with a ventricular assist device (VAD) and also the patients with cardiac failure who have received a total artificial heart (TAH).

The purpose of EUROMACS is to collect and evaluate the data of patients with mechanical circulatory support systems, with the aim of optimising the treatment of patients with a Ventricular Assist Device (VAD).

VAD implantation has been available as a standard treatment for the last 20 years and is now available as a standard treatment in cardiac centres worldwide. Each of these centres treats a certain number of patients and has information on these patients only. By pooling the data from many centres in a single Registry, it is possible to make much more reliable studies of the treatment. Its possibilities, limitations and risks can be much better analysed.

Data Controller: EACTS, EACTS House, Madeira Walk, Windsor, SL4 1EU, UK
Data Protection Officer: Cori Mackin – Cori.Mackin@Eacts.co.uk

Data Processor 1: EACTS, EACTS House, Madeira Walk, Windsor, SL4 1EU, UK
Data Protection Officer 1: Cori Mackin – Cori.Mackin@Eacts.co.uk

Data Processor 2: Dendrite Clinical Systems Ltd., the Hub, Station Road, Henley-on-Thames, Oxfordshire, RG9 2BA, UK
Data Protection Officer 2: Neal McCann – neal.mccann@e-dendrite.com

Data Processor 3: University Hospitals Birmingham NHS Foundation Trust – Birmingham, B15 1JD
Data Protection Officer 3: Berit Reglar – berit.reglar@uhb.nhs.uk

For clinical matters, please contact your hospitals clinical team.

If you would like to discuss anything else relating to EUROMACS, please contact:
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Lawful Basis:

The lawful basis for data processing under Article 6 and 7, for this project is consent and necessity for the purposes of the legitimate interests pursued by the controller or by a third party as listed in:

Article 6(1) (a): the data subject has given consent to the processing of his or her personal data for one or more specific purposes

Article 6(1) (f): processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Article 7(1): Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.

Article 7(2): If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.

Article 7(3): The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.

Article 7(4): When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

As per Article 9, special category data collected includes: ethnic group and health. The condition applicable, as listed in:

Article 9(2) (a): the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject.

Article 9(2) (j): processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with

Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

According to Article 4(11), 'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

In order to send out the consent form and collect patient information the study needs to access personal data. This privacy notice explains what personal data we are processing and why.

According to Article 8, the conditions applicable to child's consent in relation to information security services are:

1. Where point (a) of Article 6(1) applies, in relation to the offer of information society services directly to a child, the processing of the personal data of a child shall be lawful where the child is at least 16 years old. Where the child is below the age of 16 years, such processing shall be lawful only if and to the extent that consent is given or authorised by the holder of parental responsibility over the child.

Member States may provide by law for a lower age for those purposes provided that such lower age is not below 13 years.

2. The controller shall make reasonable efforts to verify in such cases that consent is given or authorised by the holder of parental responsibility over the child, taking into consideration available technology.

3. Paragraph 1 shall not affect the general contract law of Member States such as the rules on the validity, formation or effect of a contract in relation to a child.

How we collect information about participants:

Participation in the study will be kept confidential. Ethical and legal practice will be followed and all information about you will be handled in confidence.

Hospitals and Cardiac centres around Europe can voluntarily contribute data to EUROMACS registry in adherence to the EU General Data Protection Regulation (GDPR). Participating hospitals are required to obtain consent from patients in order to collect and record their clinical and treatment data into a database specifically holding EUROMACS data.

What personal data will be collected and how will it be used:

The Registry aims to collect information about clinical outcomes in patients who receive VAD implants. Data collected will include special category data, more specifically:

- Demographic and clinical assessment data at baseline and follow-up (every 6 months until the patient has reached one of the end points i.e. deceased, weaned or transplant.)
- Date of discharge/death
- Quality of life (EQ5D)
- Details on implanted devices
- End point

https://www.uab.edu/medicine/intermacs/intermacs-documents – link to INTERMACS Data Dictionary Doc

Identifiable data about patient treatment will be collected and entered electronically at hospital the patient was seen at/recruited at. The data will then be sent securely to a database designed for this specific purpose, which will be established by the database provider Dendrite. Each participating hospital will be able to access the data about its own patients and will be able to record periodic follow ups. Data from the Registry will be transferred for analysis and reporting to EACTS and UHB.

AT EACTS and UHB NHSFT, all patient information will be stored on password protected computers and will only be accessible to the named individuals on the team who will be carrying out analysis of your data. When the results of the study are reported, individuals who have taken part will not be identified in any way. All data processing will take place in line with the requirements of the data protection legislation.

Only authorised researchers from the authorised studies approved by the EUROMACS Committee under EACTS will be able to access the aggregated data relevant for the topic of the study.

We share your personal data with 3rd party processors and controllers we have retained to perform various services on our behalf and in relation to the purposes set forth in this Privacy Policy. These 3rd parties are contractually required to act only on our instructions and to maintain an appropriate level of data protection and data security. Service providers are not authorised by us to use the data provided by us for their own purposes or to disclose the data to third parties except as necessary to perform services or functions for EACTS or to comply with legal requirements. For example, service providers are not authorized by EACTS to use the data we share with them for their own marketing purposes.

What are my rights as the patient?
The hospital's and/or the patient's participation in the Registry is entirely voluntary and is independent of a patient's treatment.

If your hospital is participating in the Registry, they will ensure that any data communication (transferral of patient data from the hospital to the Registry) shall only take place providing that you have been sufficiently informed by the doctor and that you have consented in writing to making use of these data. If you agree to participate, you will be asked to sign a declaration of consent, in the form of a Patient Consent Form. Your hospital is responsible for obtaining such consent from you.

We also ask your permission to collect data up until your VAD system is removed (e.g. for heart transplantation or if your heart recovers).

How can participants opt out of the Registry?

Participants who decide not to participate in the Registry are free to decline or withdraw at any time, without giving a reason. Participants have the right to erasure, also known as the right to be forgotten.

Participants can withdraw their consent by contacting their local hospital.