Hospital logo and name

***You can insert the hospital's own log here and update the document with the data for your organisation***

*Here you can insert the hospital logo*

# ARTORIA - R (pAtients pResenting wiTh cOngenital heaRt dIseAse -Register)

## Patient information

**Programme Director at** *Hospital Name*

Prof..... Tel:+.....

**Responsible doctors by** *hospital name*

Dr..... Tel: +.....

Dr..... Tel: +.....

**Sponsor organisation**

ARTORIA - R (pAtients pResenting wiTh cOngenital heaRt dIseAse -Register),
University Heart and Vascular Centre Hamburg, Martinistr. 52, 20251 Hamburg
Germany

**Dear patient,**

Your attending doctors have determined that you are suffering from a serious disease of the heart muscle that can no longer be treated with medication. The doctors at the hospital where you are being treated have therefore recommended that you register for a transplant of the heart or the heart and a combined organ.

Your doctor has discussed the surgical procedure with you in detail and offered you to participate in the ARTORIA registry. On the following pages we inform you about the aims, the procedure for submitting information to the registry and possible risks of participation. Please

read this information carefully. You will then have the opportunity to discuss your questions with a doctor.

**How is participation in the register organised?**

Participation in the register is completely voluntary and independent of your treatment. If you decide not to participate, this will not affect the treatment you receive at .....Name of hospital..... If you agree to participate, please sign the consent form at the end. You can stop participating in the register or withdraw your consent at any time without giving any reason. This would not be to your disadvantage in any way.

If you decide to end your participation in the registry, please inform your attending physician immediately (telephone numbers can be found on page 1).

The .....Name of the Hospital..... reserves the right to exclude your data from the register at any time and without giving reasons, even if we consider such participation to be in your best interests. If you cease to participate, we will not submit any further personal data to the register and will delete or anonymise the data already collected, although we may continue to submit anonymous data where permitted by law.

**What is a register?**

A registry is a collection of data (information) about patients suffering from a certain disease (e.g. a tumour registry) or undergoing a certain treatment, in your case the treatment of heart failure with the aim of a heart transplant (see above).

**What is the purpose of the ARTORIA register?**

Thanks to improved therapy in childhood, many patients with congenital heart defects reach adulthood and are referred to as adults with congenital heart defects (EMAH). However, EMAH often develop heart failure (HF) as a result of initial palliative surgery or complex anatomy and subsequently require advanced HF therapy. EMAH are usually excluded from trials evaluating heart failure therapies and, in this context, more data on heart failure treatment in EMAH are needed to improve the management of EMAH who have HF.

The Registry for Patients with Congenital Heart Failure (ARTORIA-R) will collect data from people with EMAH who have been evaluated or are on the list for transplantation of a heart or heart and combined organ internationally, currently including countries from Europe, the United Kingdom, the United States and the Asia-Pacific region.

The data is entered into the electronic database REDCap (Research Electronic Data Capture). REDCap is a secure web application for creating and managing online surveys and databases

that can be accessed by the investigators participating in the registry. All variables in the registry reflect key components that are important for listing patients or assessing current HF treatment.

ARTORIA-R will provide valid information on the current management and outcomes of adults with congenital heart defects suffering from advanced heart failure as currently treated worldwide, thus providing data in those topics where randomised trials are difficult to design and conduct due to the lack of relevant numbers of EMAH or the exclusion of EMAH from heart failure research.

The most important questions about the management of heart failure in EMAH could be answered by the database, as EMAH with advanced heart failure are still very rare compared to non-EMAH patients. Some of the questions are:

- Improve the staging criteria for EMAH. These variables, which were originally developed for non-EMAH patients and do not take into account young age and the absence of cardiovascular risk factors
- Use of ventricular assist devices in patients on the transplant waiting list, which is often an option for non-EMAH patients
- Influence of heart failure drug treatment during the time on the waiting list

All of these issues are important to improve heart failure therapy, but data are often lacking because EMAH are underrepresented in heart failure research or are not included in randomised trials.

**What are the alternatives?**

Your treatment is completely independent of whether you participate in the registry. If you decide not to participate, you will receive the same treatment as any other patient with the same disease.

**What does participation mean for me?**

If you decide to participate, please sign the attached consent form. If you participate, certain data routinely collected by you and by healthcare professionals such as your cardiologist and cardiac surgeon before, during and after your surgery (e.g. your height, weight, length of stay in the ICU, your clinical condition after surgery and later, and various blood test results) will be collected and stored in encrypted form and pseudonymised to de-identify them (ie, the recipients of this data cannot easily identify to whom the data belong without using additional information stored separately from the data). The data is then sent in pseudonymised form to a database in Germany (Universitäres Herz- und Gefäßzentrum Hamburg, Klinik für Kardiologie). The data to be collected and stored by the registry is almost exclusively

information that is routinely collected during your treatment. No special examinations are carried out for the registry, and your participation has no influence on the treatment you receive. Follow-up examinations take place at the usual intervals at the treating clinic .....Name of hospital.... will take place. Your data will be stored for 30 years from the time of initial registration and will then be completely anonymised so that no one can identify the data as yours from that point on.

Participation in the register also implies that employees of the data-holding body (such as data administrators or statisticians) access your data entered into the register for the purpose of register operation. These persons are obliged to maintain confidentiality. The purpose of their access is to operate the register, to verify the accuracy of data submitted to the register and to select data for research purposes.

The staff of .....Name of hospital... may also access your data for the purposes for which they are authorised to use the data about you that they hold on site at the ...name of hospital.... store.

**How long does it take to join the register?**

We ask for your consent to collect data until you withdraw your consent. Otherwise, the data we collect will be retained for 30 years from the date of initial registration and then anonymised.

**Can I benefit from participating?**

The purpose of the registry, simply put, is to increase our knowledge of this form of ACHD disease spectrum and its therapy in advanced heart failure so that the treatment of patients can be further improved. The knowledge that can be gained by analysing the data from the registry can influence the treatment we offer to patients in general. So you could personally benefit from the new findings.

**Which centres contribute to the register?**

The registry is multicentre, i.e. in addition to the .... Name of the hospital... various heart centres in Europe and worldwide participate in the registry. The study coordinator of the registry at the Clinic for Cardiology of the University Heart and Vascular Centre Hamburg in Germany is:

Christoph Sinning, MD
Senior physician, specialist for internal medicine/cardiology
Additional designation adults with congenital heart defects (EMAH)
Clinic for Cardiology

University Heart and Vascular Centre Hamburg
Martinistraße 52, 20246
Hamburg, Germany

**Who has access to the stored data?**

The registry organisation (see page 1) collects and controls the data and acts as the data controller within the meaning of the Data Protection Act. It may commission service providers to provide services on its behalf, such as data hosting services.

In principle, any person or institution contributing data to the registry and interested in a specific question regarding the treatment of advanced heart failure in the cohort of EMAH listed or evaluated for heart or heart and combined organ transplantation may apply to the registry for permission to analyse the data in anonymised form. A special committee of doctors and scientists appointed by the registry organisation will decide on permission, but only anonymised data will be made available for these purposes.
The staff of ...name of hospital.... can also view your data from the register for the purposes for which they use the other data they have available about you.

**What risks are associated with participation for me?**

We do not assume that your participation in the register is associated with any risks. The potential risk of data misuse is minimised by strict compliance with the legal requirements on data protection, in particular the EU General Data Protection Regulation (GDPR, EU 2016/679).

**Are there any costs or do I get paid?**

There are no additional costs for you or the hospital beyond the normal costs of treatment. You will not receive any remuneration for your participation.

**Who can answer my questions?**

Your attending physician and/or the physicians named on page 1 will be happy to answer any questions you may have about the registry and your participation at any time.

**Will I be protected by the insurance?**

Participation in the registry has no direct impact on your individual care and does not require additional insurance. Decisions about your treatment will continue to be made by your doctors and will be covered by the usual insurance arrangements that apply to such treatment. It was not necessary for us to obtain special patient insurance for this study. The study doctor is

covered by the general liability insurance of ...Name of hospital.... for all claims that could arise from negligent behaviour. For health damage that could be related to participation in the study, the ....Name of the hospital... is liable. is liable within the framework of the legal provisions. We ask you to report any health impairments and deteriorations in health to your attending physician without delay (telephone numbers on page 1).

**How is data protection guaranteed?**

The personal data about your health and illness that is collected for the register when you agree to participate will be processed as follows:

**Your personal data (name, complete date of birth and address) will be recorded by the doctor on your consent form, but will not be passed on to the registry. This consent form with the unencrypted personal data will be kept by the doctor in your hospital. A copy of the form will be kept in your medical record.**

**When you participate, certain data that is collected (e.g. your height, weight, length of stay in the ICU, your clinical condition after surgery and later during your participation in the Registry, and various blood test results) is collected and stored in encrypted form and pseudonymised to de-identify it (i.e. the recipients of this data cannot readily identify to whom the data belongs without using additional, separately stored information). The data collected for the register are pseudonymised, stored electronically in this form and forwarded to the register.**

**The data of the register of ... Name of the hospital ... may be combined with data from other participating institutions. The study organisation may provide anonymised datasets to researchers and institutions or other third parties contributing data to the registry for further scientific studies.**
**Our academic and industrial cooperation partners include institutions and companies from countries of the European Union, the European Economic Area or other countries where the European Commission has determined an adequate level of data protection. As this is a long-term research project, the cooperation partners may change.**

**The electronic key needed to match the pseudonymised data with your personal information is stored on a computer at the ...Name of hospital... Study Centre, separate from the other data, and can only be accessed by the ...Name of hospital... Staff working directly on the project.**

**The results obtained from the register may be published, but no personal data will ever be disclosed.**

**After 30 years from the date of the first registration, the data in the register will be completely anonymised. This means that the data can no longer be matched with your personal details, even if the electronic key is released.**

**You can revoke your consent to data processing at any time. In this case, no new data will be collected and the already stored personal information and the corresponding electronic key will be deleted or anonymised, provided that there are no legal retention obligations to the contrary.**

**You have the right to request information about the data stored about you. You also have the right to have any errors in your personal data corrected. Please contact your attending physician (see page 1) if you would like to receive a copy of the information submitted to the register.**

**You also have the right to lodge a complaint with the competent data protection supervisory authority in your country: .....**

**By signing the consent form, you consent to the use and disclosure of your medical information in the manner described in this document.**

**Other issues that were discussed:**

If you wish to participate in the register, please sign the consent form and date it yourself.

Hospital logo and name

# ARTORIA - R (pAtients pResenting wiTh cOngenital heaRt dIseAse -Register)

## Patient consent

**Programme Director at** *Hospital Name*

Prof..... Tel:+.....

**Responsible doctors by** *hospital name*

Dr..... Tel: +.....

Dr..... Tel: +.....

**Sponsor organisation**

ARTORIA - R (pAtients pResenting wiTh cOngenital heaRt dIseAse -Register),
University Heart and Vascular Centre Hamburg, Martinistr. 52, 20251 Hamburg
Germany

**(Insert patient sticker here)**

I declare that Dr. _____ has informed me orally and in writing about the nature, significance, consequences and risks of participating in the ARTORIA registry. I had the opportunity to discuss my questions about this with the doctor. I have understood the patient information (version 1.1 of 10 August 2023) and have received a copy of the information sheet and this consent form.

I am willing to participate in the ARTORIA register.

I am aware that I can revoke my consent at any time and order that my data may no longer be processed, without giving reasons and without adverse consequences for me.

I agree that the project manager or one of the attending physicians may contact my other physicians regarding the register and release them from medical confidentiality in this respect.

**I consent to my personal information and health data being processed by the ...name of hospital..... to the extent necessary for the register.**

**I consent to my health data being collected, pseudonymised, stored and passed on to the registry and authorise my attending physician to pass on this data and to check the personal data stored.**

**Furthermore, I authorise representatives of the study organisation to randomly check the stored data, including my personal data, for accuracy. With my signature, I declare my consent to these checks of my medical records.**

**I agree that the Registry may make my data available for disclosure by ...Name of hospital..... for the same purposes in anonymised form.**

**I have been informed that the data obtained from the register will be evaluated by doctors/scientists in order to investigate various questions related to my disease and treatment. I have been informed that the results of these evaluations may be published, but only in completely anonymised form.**

I have received a copy of the patient information and consent form for my records.

....Place...., Date _____

_____

Signature of the patient

I declare that I have informed the participant named above about the nature, significance, consequences and risks of participating in the ARTORIA Registry. I have given him/her a copy of the information sheet, this consent form and the privacy notice of the registry.

....Place..., date _____

_____

Signature of the informing doctor