Participant Information Sheet

Study Title: European Venous Registry (EVeR)

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Dear Patient,

If you have been diagnosed with a deep venous condition, your treatment and recovery are important to us. The European Venous Registry (EVeR) is a secure database that collects real-world medical data to improve treatment, safety, and outcomes for future patients. By joining, you can help shape better care for people with venous disease.

EVeR Registry Overview

The EVeR Registry is managed under the supervision of the European Society for Vascular Surgery (ESVS). Data collection and analysis are facilitated by Dendrite, a trusted clinical registry provider.

- ESVS: Our mission is to improve vascular health for the public benefit. We are proud to have over 3,000 members from all over the world. Members are medical specialists involved in the care and treatment of patients suffering from vascular disease. (For more information, please visit www. esvs.org)
- Dendrite: A trusted clinical registry provider and partner for the leading clinical societies/associations, government departments of health, research institutions, patient organisations and healthcare providers. Dendrite has set up multiple venous registries for both US and UK professional organisations and societies.

The registry's purpose is to:

- Assess the quality and outcomes of venous treatments and interventions.
- Improve patient safety and care delivery by analyzing treatment data and devices.
- Inform research and clinical decisions with high-quality aggregated data.

The registry is supported by both medical institutions and industry sponsors, primarily device manufacturers. Their involvement is crucial in funding the registry's development and ensuring high-quality data collection to improve patient care.

- Medical Institutions: These include hospitals, academic research centers, and specialist vascular clinics that contribute patient data to the registry. They play a key role in providing real-world clinical insights and ensuring the accuracy of the collected information.
- Device Manufacturers: The majority of industry sponsors are medical device companies that develop and manufacture technologies used in venous treatments, such as stents, catheters, and other interventional tools. Their financial support helps sustain the registry, but they do not influence its scientific content or operations.

Is this a non-profit study?

Yes, the European Venous Registry project is a non-profit study.

Device manufacturers provide financial support to the non-profit ESVS Charity to help develop and run the registry. However, the ESVS itself does not operate for profit, and all funding is

solely used to support the registry's development and research. Additionally, the study remains completely independent from commercial influence, as the ESVS and deep venous treatment specialists are solely responsible for its content.

Why Am I Invited to Join?

You are invited to participate in the European Venous Registry (EVeR) project because you have been diagnosed with acute or chronic lower limb deep venous disease, confirmed through imaging. This includes:

- Deep venous disease affecting the iliac and/or common femoral veins, with or without extension to the inferior vena cava (IVC).
- A new, imaging-confirmed diagnosis involving the IVC only.

Your participation will help improve the understanding and treatment of deep venous disease, benefiting future patients and advancing medical research.

What am I being asked to do?

If you choose to participate in the EVeR Registry, you are agreeing to allow your treating physician to record relevant medical information about your diagnosis, treatment, and follow-up care in a secure database.

What you will do:

- Allow your treating physician to securely record details of your condition and treatment by signing a consent form.
- Continue receiving your usual care no extra tests, procedures, or visits.

What will NOT happen:

- No changes will be made to your treatment plan.
- No experimental treatments will be given.
- No commercial company will contact you or access your personal data that could identify you.

Will I receive any reimbursement for participating?

No, participants will not receive reimbursement for taking part in this study. Participation is entirely voluntary, and there are no direct financial costs or expenses expected for participants. The purpose of the study is to contribute to medical research and improve healthcare for future patients, rather than to provide compensation for involvement.

What data is collected?

With your explicit consent, the hospital can register all relevant medical data on your treatment.

Personal data: Your hospital ID, year of birth, and gender will be collected by your hospital to securely identify your records. These details will be held along with your medical data to ensure accurate record-keeping and data integrity.

Medical data: Information about your diagnosis, treatment, and follow-up visits, including data related to any procedures, rehabilitation, or outcomes.

Who has access to my data?

In addition to the hospital collecting your data, Dendrite (in the United Kingdom) as the service provider, and ESVS (France) as the registry owner will have access to your personal data solely to fulfil the registry purposes outlined above.

Other medical centres may request access to data stored by Dendrite from EVeR for research purposes. If approved, these medical centres will only receive access to pseudonymised data. Additionally, device manufacturers may request access to data stored by Dendrite from EVeR for quality assurance purposes, regulatory submissions, and health economic authority submission. If approved, they will only receive access to pseudonymised data of their own devices, and aggregated data of others.

Only authorized personnel have access to your pseudonymized medical data. These include:

- Your treating physician and approved hospital staff involved in your care and responsible for data entry.
- Researchers and registry administrators who analyze data to improve treatments and healthcare outcomes.
- Regulatory bodies and ethics committees if required, to ensure compliance with data protection and ethical standards.

What is Pseudonymization?

Your data will be pseudonymised before it is stored in the EVeR registry. This means that your personal identifiers, such as your name and date of birth, will be replaced with a unique code. This process helps protect your privacy by ensuring that your medical data cannot be directly linked to you without additional information, which is kept separately and securely.

How is your data secured?

Your data is encrypted during transfer and securely stored in compliance with data protection laws, including GDPR. All personnel with access to your data are trained in confidentiality and data protection protocols. The registry provider follows industry best practices for information security and implements physical and procedural safeguards to protect your data. Additionally, the provider mandates annual data protection training for its staff, ensuring they fully understand the importance of maintaining patient confidentiality.

Why is Consent required?

Your consent is needed to allow your treating physician to register your data in the EVeR registry. Without your consent, your personal data will not be transferred, processed, or evaluated within the registry.

Participation is entirely voluntary, and if you choose to withdraw your consent at any time, the EVeR registry will immediately stop processing your data.

Your decision to give or withhold consent will not affect your current or future care in any way. Your treatment and medical care will remain unchanged, regardless of whether you choose to participate in the registry.

Are There Any Risks to Participating?

Participating in the EVeR registry involves minimal risk, as it is an observational study that collects information about standard treatments related to your diagnosis, treatment, and follow-up care. The registry does not influence or alter your treatment in any way. However, there are a few potential risks to consider:

- Privacy and Data Security Risks: While your personal information is protected through strict data security measures and pseudonymization (removing identifying details and replacing them with a unique code), there is always a small risk of data breaches. In the unlikely event of a breach, appropriate steps will be taken to protect your information and notify you if necessary.
- Data Sharing Outside the EU: During this study, pseudonymised and aggregated data will be shared with study centres outside of the EU, which may not be subject to the same data protection regulations as those in the EU under the General Data Protection Regulation (GDPR). Not all these countries provide an equally high level of data protection, and there is a possible risk that your GDPR-guaranteed rights may not be enforceable in those regions. However, all participating study sites are required to protect your data according to strict ethical and security standards. Your name and identity will never be shared outside of your treating hospital. By participating in this study, you agree that your data may be shared with study centres outside the EU.

- Potential for Re-contact**:** As part of the study, your treating physician or the research team may re-contact you for follow-up assessments. This is to gather additional information about your health status and treatment outcomes over time. If you agree to follow-up contact, you will be informed about the purpose and frequency of these communications. You are free to decline follow-up participation at any time, without any impact on your current or future medical care.

What are my rights and how can I exercise them?

To exercise your legal rights regarding the protection of your personal data, please contact our Data Protection Officer at EVeR.patientprivacy@mydatatrust.info

Under data protection laws, you have the right to:

1. Access to your personal data
2. Rectification of your personal data
3. Erasure of your personal data
4. Restriction of processing of your personal data
5. Portability of your personal data
6. Objection to the processing of your personal data (including objection to profiling)
7. Objection to automated decision making (including profiling)

How Can I Withdraw from the Study?

Your participation in the EVeR registry is entirely voluntary, and you have the right to withdraw at any time without affecting your current or future medical care.

If you decide to withdraw, you can do so by:

- Contacting your treating physician at your hospital.
- Emailing EVeR.patientprivacy@mydatatrust.info.

Once you withdraw, your data will no longer be collected or processed in the study. However, please note that the withdrawal of your consent does not affect the lawfulness of any previous data processing that took place before your withdrawal.

If you wish to exercise your rights regarding your data, you can contact the appointed study contact person (details below). If we are unable to fulfill your request, we will provide a clear explanation of the reasons.

What If There Is a Problem?

If you experience any issues related to your participation in the EVeR registry, or if you believe there has been a breach of your personal data, you have the right to raise your concerns. Your data is handled with strict confidentiality, but in the rare case of a breach, appropriate measures will be taken to address the issue and protect your rights.

If you have any concerns or complaints, you can contact:

Patient Advice and Liaison Service (PALS) which offer confidential advice, support, and information on health-related matters. They provide a point of contact for patients, their families, and their careers. You can find your nearest PALS office by:

- Visiting the NHS website: NHS.UK
- Asking your physician or hospital
- Calling NHS 111 for assistance

Alternatively, you can also contact the Data Protection Officer with email address below for further assistance regarding data privacy and security.

Who Can I Contact for More Information or to Report a Concern?

If you have any questions or would like to discuss the study in more detail, please contact:

- **For Study Information**

  Prof. Robert Hinchliffe - Principal Investigator

  Department of Vascular Surgery, University of Bristol, Southmead Hospital

  Email: robert.hinchliffe@bristol.ac.uk

- **For Complaints or Data Protection Concerns:** If you have a complaint or concern about your participation or how your data is being handled, please contact:

  1. **University of Bristol Data Protection Officer**

     Henry Stuart - Information Governance Manager

     University Secretary's Office

     Address: Beacon House, Queen's Road, BA2 5QA

     Email: henry.stuart@bristol.ac.uk

     Telephone: +44 (0)117 394 1824

  2. **European Society for Vascular Surgery (ESVS) Data Protection Officer**

     MyData-TRUST

     Address: Boulevard Initialis, 7, 7000 Mons, Belgium

     Email: ever.dpo@mydata-trust.info

- **General Inquiries about the EVeR Registry or ESVS Charity**

  The European Society for Vascular Surgery (ESVS)

  Phone: +33 (0)6 31 01 94 66

  Email: info@esvs.org