

# European Venous Registry

## Privacy Notice for patients

This Privacy Notice explains how the European Venous Registry (EVeR) (“we”) processes patients' personal data, which has been previously collected with their consent through a patient consent form.

At EVeR, we take great care in processing personal data in compliance with the EU General Data Protection Regulation (hereinafter “GDPR”) and those of the GDPR. We only collect and use the information necessary to achieve the purposes described below. Your data will be treated in accordance with this Privacy Notice at all times.

### **Why this privacy notice?**

We would like to inform you how your personal data is collected and processed within the registry. We assure you that your personal data is protected and managed in compliance with the legislation in force and, in particular, in accordance with the GDPR.

### **Background**

The data is collected for the creation of the registry EVeR. This registry will be used to perform quality assurance regarding the performance of various medical devices and treatments and prognosis of patients with deep venous disease, allowing the outcomes of venous interventions to be evaluated and the hospitals involved and all patients who received those treatments to be contacted for a follow-up examination. The registry therefore facilitates improved patient protection. For more information, please visit the registry website: [www.esvs.org/ever-venous-registry](http://www.esvs.org/ever-venous-registry).

Participation in the registry is voluntary and subject to strict data protection and confidentiality guidelines, ensuring that your information is securely stored and only used for authorized purposes.

### **Who is responsible for processing the data?**

The EVeR registry is supervised by the European Society for Vascular Surgery – ESVS Charity (ESVS), as data controller, and operated by medical centres and Dendrite Clinical Systems, a trusted provider of clinical registries. ESVS is committed to advancing vascular health through research and education, supported by the contributions of over 3,000 members globally.

ESVS is located at 18 Saxon Way, SO51 5PT Romsey, United Kingdom. ESVS's Data Protection Officer (DPO) can be contacted at [ever.patientprivacy@mydata-trust.info](mailto:ever.patientprivacy@mydata-trust.info).

As ESVS is not based in the EU, they have appointed ESVS France S.A.S.U. as Data Protection Representative in the EU, who can be contacted at 275 boulevard Albert 1er, 33130 Bègles, France.

### **What Data Does EVeR Collect?**

Medical centre is permitted to centrally archive all relevant medical data. This includes data from admission, surgery/treatment, rehabilitation, and follow-up examinations (pre-operative, procedural, 3-month follow-up and annual follow-ups) documented by various medical departments. If you agree, some information may be collected electronically by using Dendrite access. Your IP address and your phone number may be available to the technical support of Dendrite strictly for service setup and maintenance.

Depending on the country of your residence, the legal basis for processing your personal data by EVeR may vary. In some cases, the processing is permitted because EVeR has a legitimate interest in conducting scientific research. In other cases, it is based on your explicit consent, which you provided by completing the informed consent form with your physician. Additionally, in certain countries, EVeR may be legally obligated to process your data for scientific research in accordance with the 'Code of Conduct Regulating the Processing of Personal Data in Clinical Trials and Other Clinical Research and Pharmacovigilance Activities' (CoC), as endorsed by Farmaindustria.

In addition to medical data collected during your admission, treatment, and follow-up, Patient-Reported Outcome Measures (PROMs) will also be collected. PROMs are standardized questionnaires that patients complete to assess their health status, symptoms, and quality of life from their own perspective. These measures help evaluate treatment effectiveness, monitor recovery, and improve overall patient care.

PROMs may be collected:

- During follow-up visits with your physician.
- Electronically (ePROMs) via text message or email, allowing you to complete the assessments remotely using a smartphone, tablet, or computer. You will receive instructions and reminders for completing these surveys at specific time points during your follow-up.

If you prefer not to receive ePROMs electronically, you may opt out by notifying your physician or contacting the EVeR registry.

## **What Are The Purpose of Data Collection**

The information collected through EVeR aims to:

- Evaluate the performance of medical devices and treatments for venous diseases.
- Assess treatment outcomes for patients with deep venous disease.
- Monitor and improve clinical care and treatment options across different centers and regions.
- Facilitate follow-up studies and quality improvement initiatives to enhance patient care.
- Collect patient-reported outcomes to assess the impact of treatments on patients' daily lives, symptoms, and overall well-being.
- Use PROMs to enhance patient-centered care by integrating patient perspectives into clinical decision-making.

## **How is EVeR Registry Data Processed And Secured?**

Your data will be securely transferred by your healthcare provider to Dendrite via secure networks and stored in accordance with European and national data protection laws, including GDPR. Only authorized personnel involved in your care and the registry administration will have access to your personal information, which will be pseudonymized or anonymized when used for research.

## **What Security Measures Does ESVS Take To Protect Your Personal Data?**

EVeR registry will take appropriate technical and organisational security measures to protect your personal data in compliance with applicable data protection and privacy laws, which includes protection against accidental or unlawful destruction, loss, alteration, unauthorised access to, or disclosure of your personal data.

Dendrite, the carefully selected service provider hosting the EVeR registry, is required to implement robust measures in compliance with applicable laws to ensure the confidentiality and security of your personal data. Dendrite will process your information strictly in line with a data processing agreement established with us, adhering to the highest industry standards for secure data storage and protection.

## **Who Has Access to Your Data?**

Access to your data is limited to:

- Your medical centre and treating physicians.

- Regulatory bodies and authorities, e.g. in respect of clinical trials guidelines;
- Our trusted service providers that supply goods and/or services to us, such as legal counsel, auditors and IT service suppliers;
- Other trusted parties pursuant to a court order, to protect the interests of EVer/ESVS, or where otherwise required by law or legal process;
- Actual or prospective purchasers of EVer/ESVS businesses in the event of a sale, merger or acquisition;
- Other medical centres and device manufacturers may access aggregated or pseudonymized data for research or quality control purposes, following approval.

Sharing your personal data as described above may involve transferring it to other countries, including countries outside of the EU/EEA, such as USA, UK, Türkiye etc. whose data protection and privacy laws may not be equivalent to, or as protective as, those that exist in your country of residence. Any transfers of Personal Data to ESVS group affiliates, vendors or suppliers outside the EEA will be done in compliance with the international data transfer restrictions that apply under EU data protection laws, including, where appropriate, through the use of appropriate safeguards (e.g. EU model contracts clauses for data transfers).

You can receive a copy of the appropriate safeguards by contacting EVer's DPO at the contact details provided above (in the section entitled "who is responsible for processing the data?").

### **How Long Will Your Data Be Retained?**

Where you have given consent to the processing of your personal data, the data will be retained for at least 20 years, ensuring long-term study of outcomes and continuous quality improvements in the treatment of venous diseases.

### **What Are Your Rights?**

Per GDPR, you have the following rights in relation to your personal data:

- Right of access;
- Right to rectification;
- Right to restriction of processing; and
- Right to erasure.

Please, note that these rights are not absolute and will be subject to a case-by-case analysis by EVeR registry's data protection officer (DPO).

### **How to exercise my data rights?**

If you have shared your data with the EVeR registry and wish to exercise your data rights (if applicable in your country)—such as viewing the data held on the registry, withdrawing from it, opting out of receiving electronic PROMs or requesting that your data no longer be included—you have several options:

- Notify your treating physician
- Complete a data rights request form at this link <https://ever.e-dendrite.com/sar.html>
- Contact the Data Protection Officer (DPO) – Reach out to the DPO using the contact information provided below to submit your request.

Your decision will not impact the care you receive, and your data will be removed from the registry as requested.

### **Contact Information**

For any questions or concerns regarding your data, you can contact EVeR registry's DPO at [ever.patientprivacy@mydata-trust.info](mailto:ever.patientprivacy@mydata-trust.info) or your local data protection authority. You can find the contact information of your local DPA [here](#).

### **Changes to this Privacy Notice**

*This Privacy Notice is effective from **25\_Jan\_2025**. We reserve the right to change this notice at any time (for example, to comply with changes in laws or regulations; our practices, procedures and organisational structures; requirements imposed or recommended by supervisory authorities; or otherwise). Changes to this notice shall be applicable on the effective date of implementation. We will communicate any changes to you, where we are required to do so.*