

## Privacy Notice for Clinical Trial Participants in the EU

This privacy notice is for data subjects participating in clinical trials in the EU.

Eupraxia Pharmaceuticals Inc. (“**Eupraxia**”) is committed to protecting the privacy and security of Personal Data it processes for the purpose of conducting clinical trials. This Privacy Notice explains how we do this.

Eupraxia is subject to Canada’s federal privacy legislation - the Personal Information Protection and Electronic Documents Act (“**PIPEDA**”) – which applies when personal information is transferred between provinces and across international borders. However, when we collect and use Personal Data or monitor behavior or responses of data subjects who live in the European Union (“**EU**”) Eupraxia is also subject to the General Data Protection Regulation (“**GDPR**”).

Clinical trials in the EU are also regulated by the Clinical Trials Directive 2001/20/EC and the Clinical Trials Regulation 536/2014/EU, which have specific requirements about informed consent for taking part. Eupraxia complies with these regulations and with any applicable laws in the country where the clinical trial is performed.

### Eupraxia and Clinical Trial Data

Eupraxia does not directly collect and use Personal Data from Clinical Trial Participants taking part in our clinical trials. However, we are responsible for its collection and use by the Contract Research Organizations (“**CROs**”) and service providers (“**third parties**”) that conduct the trial on our behalf. Eupraxia only ever receives Pseudonymized Data from those third parties. This means Eupraxia cannot identify you personally.

During the clinical trial consent process, doctors enrolling Clinical Trial Participants into the study provide information about the trial, explain how Personal Data will be managed and protected and share a link to this Privacy Notice.

### Data Subjects in the EU

If you are a Clinical Trial Participant in the EU and would like more information about the specific trial in which you enrolled or you have questions about the processing of your Personal Data, please contact the doctor that enrolled you in the trial.

### Data Protection Officer

Eupraxia's Data Protection Officer is responsible for overseeing our privacy management program and compliance with the EU data protection law.

Katie Groulx, Data Protection Officer

Eupraxia Pharmaceuticals Inc.

201-2067 Cadboro Bay Road, Victoria, British Columbia, Canada V8R 5G4

Phone: 1-250-590-7290

[privacy@eupraxiapharma.com](mailto:privacy@eupraxiapharma.com)

### **Member Representative in the EU**

DataRep

Lautruphøj 1 – 3

Ballerup

2750

Denmark

Email: [datarequest@datarep.com](mailto:datarequest@datarep.com) (use "Eupraxia" in the subject line)

Webform: [www.datarep.com/data-request](http://www.datarep.com/data-request)

### **Controller Information**

Eupraxia Pharmaceuticals Inc.

201-2067 Cadboro Bay Road, Victoria, British Columbia, Canada V8R 5G4

[privacy@eupraxiapharma.com](mailto:privacy@eupraxiapharma.com)

### **Scope**

This Privacy Notice applies to Personal Data of Clinical Trial Participants in Eupraxia clinical trials. Personal Data can be in any format, including electronic and paper, and processed by categories of third-party organizations and data recipients as described below.

## Definitions

**“Clinical Trial Participant”** means an individual participating in a clinical trial in the EU and providing personal information to third parties Eupraxia has contracted with to conduct the trial. Clinical Trial Participant has the same meaning as “Data Subject” under Article 4 of the GDPR.

**“Personal Data”** means any information relating to an identified or identifiable natural person (**‘Data Subject’**) in the EU; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

**“Pseudonymized Data”** means Personal Data that has been de-identified and can no longer be attributed to a specific individual without the use of additional information. Personal Data will be considered pseudonymized provided that this additional information is kept separately and is subject to technical and organizational measures to ensure that the Personal Data are not attributed to an individual. Eupraxia will treat Pseudonymized Data with the same care and high standards as Personal Data.

**“Clinical Trial Data”** is the data processed for clinical trial purposes. It includes Pseudonymized Data received from third parties as well as new data generated by Eupraxia and third parties based on data collected for the clinical trial. These new data may not relate to an identified or identifiable natural person.

**“Processing”** means any operations or set of operations performed on Personal Data. It includes the collection, use and disclosure of Personal Data as defined in Canada’s Personal Information Protection and Electronic Documents Act (**“PIPEDA”**).

## Categories of Personal Data Processed

### Personal details

- Clinical Trial Subject identifier (a unique ID number attributable to you)
- Location data – country, investigator site
- Personal details – year of birth, age in years, sex

## Special categories of data

- Health data
  - Physical details – height, weight, Body Mass Index (BMI)
  - Childbearing status
  - Physical and mental health data, including medical and surgical histories, medication usage, physical examinations, health assessments (e.g., blood pressure, heart function, x-rays, magnetic resonance images (MRIs)), laboratory testing results from blood, urine and other tissues, and opinions of your disease state or general health
  - Psychological details – e.g., quality of life questionnaires
- Data revealing racial or ethnic origin

## What Your Personal Data is Used For

Eupraxia processes data collected from Clinical Trial Participants for the purpose of scientific research into the effects of medical treatment and for safety and reliability purposes.

## Legal Basis for Processing Personal Data

### Clinical Trial Data for Research Purposes:

Data processing related to research activities in the context of the clinical trial are carried out on the legal basis of:

- legitimate interests pursued by Eupraxia - GDPR Article 6(1)(f) and
- scientific purposes (for special categories of Personal Data) - GDPR Article 9(2)(j).

Eupraxia has a legitimate interest in processing Personal Data for scientific and statistical purposes related to the clinical trial and will ensure appropriate protections are in place.

### Clinical Trial Data for Reliability and Safety Purposes:

Data processing expressly provided by GDPR and relevant national provisions and which are related to the protection of health while setting standards of quality and safety for medicinal products by generating reliable and robust data will be based on:

- Eupraxia's legal obligation - GDPR Article 6(1)(c) and
- a public interest in the area of public health - GDPR Article 9(2)(i).

This includes processing records respecting adverse events.

### **Automated Processing**

During the course of the Clinical Trial, Eupraxia will not make decisions about Data Subjects based solely on automated processing.

### **Categories of Third Parties and Data Recipients**

Eupraxia works with CROs and third-parties to run our clinical trials. These include:

- Contract Research Organizations
- Statistical Research Analysts
- Clinical Advisors
- Safety monitoring board or safety review committee
- Technical providers of hosting and software services

Eupraxia's CROs and third-parties are required by law and contractual agreements to:

- Keep your Personal Data confidential and secure; and
- Only use your Personal Data in accordance with Eupraxia's instructions.

The list of third parties that Eupraxia uses for each clinical trial is available upon request from the Data Protection Officer.

### **Clinical Trial Data Transmitted to Third Countries**

Eupraxia is located in Canada. For the purposes of the Clinical Trial only, Clinical Trial Data from data subjects in the EU will be processed in the EU, Canada, and the US.

The European Commission has confirmed that Canada's federal privacy law, PIPEDA, ensures an adequate level of protection (GDPR Article 45). Eupraxia is compliant with PIPEDA. This means that transfers of Personal Data between Canada and the EU do not require any specific authorization.

Some of the CROs and third parties who process data on Eupraxia's behalf are located in the US. The European Commission has not confirmed that US Privacy laws ensure an adequate level of protection. Eupraxia requires that our data processors in the US provide appropriate safeguards to protect your Personal Data and maintain your rights by following GDPR and/or Eupraxia's privacy policy.

- Clinical Trial Data is pseudonymized before it is transferred out of the EU.
- We will ensure that there are adequate measures and specific guarantees in place to protect Personal Data.

## **Retention**

Eupraxia will retain Clinical Trial Data and will instruct third parties to retain Personal Data or Clinical Trial Data, depending on their role in the study, subject to applicable legislation.

- In Canada the retention period for clinical trial data is 25 years under Canadian Food and Drug Regulations.
- The EU requires that data be retained for at least 15 years after the trial is completed or discontinued.

## **Your Rights**

If you are a Data Subject in the EU and wish to exercise your rights related to your Personal Data, Eupraxia will provide support to exercise those rights.

We may not be able to comply with a direct request when Eupraxia is not able to identify you. This would occur where Eupraxia has received Pseudonymized Data or where Personal Data have been destroyed or erased in accordance with our record retention obligations and practices.

Your rights related to the clinical trial are described in the Informed Consent Form that you received when enrolling in the clinical trial.

Depending on the legal basis for processing the Clinical Trial Data under the GDPR, rights related to the Personal Data of Clinical Trial Participants in the EU may include:

- Access to your Personal Data
- Right to rectification where Personal Data are incorrect or incomplete
- Right to restrict/suspend further processing of Personal Data
- Right to complain to a [supervisory authority](#)

Please contact the doctor that enrolled you in the clinical trial if you would like to exercise your rights related to your Personal Data collected for clinical trial purposes. The doctor's contact details are on the clinical trial Informed Consent Form.

## **Security Measures**

Eupraxia has taken appropriate technical and organizational security measures to protect Clinical Trial Data against unintentional or unlawful destruction, loss, alteration, unauthorized disclosure, unauthorized access, and any other unlawful or unauthorized forms of processing under applicable law.

Measures include controlling physical access to the data, as well as the relevant access, input, disclosure, security of availability, and its separation from other data.

We also consider the protection of Clinical Trial Data when developing or selecting the hardware, software and procedures in line with the principle of data protection through technology and privacy by design.

## **Questions and Complaints**

If contacting Eupraxia about any data privacy issue by email, please do not include any personal information (other than your contact information) in either the subject line or the content of your message.

You may contact our Data Protection Officer with questions or complaints regarding this Privacy Notice and Eupraxia's processing of Clinical Trial Data:

Katie Groulx, Data Protection Officer

Eupraxia Pharmaceuticals Inc.

201-2067 Cadboro Bay Road, Victoria, British Columbia, Canada V8R 5G4

Phone: 1-250-590-7290

[privacy@eupraxiapharma.com](mailto:privacy@eupraxiapharma.com)

Eupraxia will reply within 30 calendar days of receipt and will attempt to resolve any complaint in accordance with this Privacy Notice.

You may also lodge a complaint with the Data Protection Supervisory Authority in your country of residence. The relevant EU supervisory authority name and contact details can be found here:

[https://edpb.europa.eu/about-edpb/about-edpb/members\\_en](https://edpb.europa.eu/about-edpb/about-edpb/members_en)