

Information on the processing of personal data for Safety Reporting

Pursuant to the applicable legislation on the protection of personal data, Recordati Rare Diseases SARL, a company of the Recordati Group ("**Recordati**", or the "**Data Controller**" or "**we**", "**us**") has drawn up this document (the "**Privacy Notice**") to describe how it processes personal data in the context of safety reporting.

This Privacy Notice applies the processing of personal data pertaining to:

- individuals, including healthcare professionals and caregivers, who report adverse events or special case scenarios (such as exposure during pregnancy, breastfeeding, overdose, lack of efficacy); and
- individuals to whom such adverse events or special case scenarios refer.

(hereinafter, jointly referred to as "**Data Subjects**" or "**you**").

1. Data Controller and Data Protection Officer

The data controller is Recordati Rare Diseases SARL, with registered office in Tour HEKLA 52 Avenue du Général de Gaulle, 92800 Puteaux – France, a company of the Recordati Group.

The Data Protection Officer of the Recordati Group can be contacted for any privacy issue arising or in connection with the processing of personal data at the following email address: groupDPO@recordati.com.

2. Types of data processed

The following personal data will be processed (hereinafter "**Personal Data**"):

- i) identification data (name, surname, initials);
- ii) demographic data (gender, country, date of birth, age group, personal identification number assigned to the patient, description of physical features of the body, if relevant);
- iii) contact details (e-mail, telephone number, address);
- iv) information about health (relevant elements of medical history and concurrent conditions, concomitant/co-suspect medication, clinical test results, samples and tissues, sample number and visit number, data related to clinical trials);
- v) if a healthcare professional contacts us, information about their profession, affiliated institution, professional experience, and qualifications.
- vi) if a patient's relative or caregiver contacts us, information about their relationship to the patient;
- vii) if a business partner, such as a pharmacy or wholesale supplier, contacts us, we may collect information about their profession, including the name and surname, company affiliation, and professional title or role; and
- viii) any other personal data voluntarily provided by the Data Subject.

3. Purpose of processing and legal basis

Your Personal Data will be processed for the following purposes. For each purpose, the corresponding legal basis is also indicated:

#	Purpose of processing	Legal basis	Personal Data processed
1.	Safety Reporting: to manage suspected adverse event or special case scenarios (such as exposure during pregnancy, breastfeeding, overdose, lack of efficacy) reports spontaneously submitted through Recordati's	Compliance with legal obligations applicable to us in the context of safety reporting and vigilance activities. Reasons of public interest in the public health care sector, by way of guarantee of high quality and	All Personal Data of paragraph 2 above

	communication channels.	safety parameters in medicinal products and medical devices.	
2.	Internal and Regulatory Authorities Reporting: in case of adverse events, special case scenarios, to share your enquiry with the relevant internal function within Recordati and to report the data to regulatory authorities.	Compliance with legal obligations applicable to us in the context of safety reporting and vigilance activities; Reasons of public interest in the public health care sector, by way of guarantee of high quality and safety parameters in medicinal products and medical devices.	All Personal Data of paragraph 2 above, depending on the content of the enquiry or report shared from time to time

The provision of your Personal Data for the purposes mentioned above is mandatory; in failure, we will not be able to manage your enquiry and/or provide you with a reply or comply with the provisions of the applicable legislation.

4. Processing methods and storage period

The processing will be based on the principles of lawfulness, fairness, transparency, proportionality and minimization and will be carried out using suitable tools to guarantee security and confidentiality through the use of procedures that avoid the risk of loss, unauthorized access, illicit use and dissemination of Personal Data.

Personal Data processed for the purpose described in par. 3.1 above will be kept for the time necessary to comply with safety reporting and vigilance obligations and, in any case, for no longer than 70 years after the product or medical device to which the suspected adverse event or special case scenarios refer has been withdrawn from the market. Where possible, relevant Personal Data will be processed in pseudonymized form.

Personal Data processed for the purpose described in par. 3.2 above will be kept for the time necessary to comply with the applicable regulatory obligations and follow up to regulatory authorities' requests.

5. Communication and transfer of Personal Data

Your Personal Data may be accessed by Recordati employees and collaborators, specifically designated as persons authorised to process it, where necessary for the pursuit of the purposes described above.

Your Personal Data may also be communicated or made accessible to consultants and third-party suppliers of technical or organizational services, functional to the purposes described above, in their capacity as our data processors, specifically designated and instructed on the basis of a specific contract.

Your Personal Data may also be accessed by authorities or other public bodies by virtue of legal provisions or secondary or EU legislation, in their capacity as independent data controllers, for their respective institutional purposes.

Personal Data may also be transferred outside the European Economic Area¹ to countries which do not benefit from an adequacy decision by the European Commission. Such transfers will take place in compliance with the conditions set out in current legislation, in accordance with the Standard Contractual Clauses (SCCs) adopted by the European Commission.

A copy of the SCCs or further information about these safeguards can be obtained by contacting us at groupDPO@recordati.com.

¹ The European Economic Area (EEA) consists of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Republic of Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

6. Rights of the Data Subject

The Data Controller informs you that you can exercise, at any time, the following rights by contacting the Data Controller or the DPO at the addresses indicated above:

- a) the "right of access" to your Personal Data and, in particular, to obtain confirmation of the existence or otherwise of Personal Data concerning you;
- b) the "right to rectification", i.e. the right to request the rectification of inaccurate data or the completion of incomplete data;
- c) the "right to erasure", i.e. the right to request the erasure, the transformation into anonymous form of data processed in violation of the law, including those whose retention is not necessary in relation to the purposes for which the Personal Data were collected or subsequently processed;
- d) the "right to restriction of processing", i.e. the right to obtain from the Data Controller the restriction of processing in certain cases provided for pursuant to the privacy legislation;
- e) the "right to data portability", i.e. the right to receive (or to transmit directly to another data controller) Personal Data in a structured, commonly used and machine-readable format;
- f) the "right to object", i.e. the right to object, in whole or in part:
 - to the processing of Personal Data carried out by the data controller for its own legitimate interest;
 - to the processing of Personal Data carried out by the data controller for marketing or profiling purposes.

The exercise of the above rights is not subject to any formal constraint and is free of charge. The Data Controller may ask you to verify your identity before taking further action following your request to exercise the rights referred to above.

You may also lodge a complaint with the competent Supervisory Authority (in particular in the Member State of your habitual residence, place of work or place of the alleged violation), if you are of the opinion that your Personal Data are being processed in such a way as to result in violations of privacy legislation. You may also contact the Supervisory Authority if the exercise of your rights is subject to delay, limitation or exclusion by the Data Controller.

You may also contact the relevant supervisory authority if the exercise of your rights is subject to delay, limitation or exclusion by the data controller.

In order to facilitate the exercise of the right to lodge a complaint, please find below the name and contact details of the supervisory authority of France:

- website: <https://www.cnil.fr/fr>;
- contacts: <https://www.cnil.fr/fr/saisir-la-cnil/nous-contacter>.

The name and contact details of the supervisory authorities of the European Union are available at the following link: [Our Members | European Data Protection Board \(europa.eu\)](#).

7. Changes to this Privacy Notice

This Privacy Notice is valid from the date of effectiveness provided below. However, the Privacy Notice may subsequently be updated or integrated, from time to time, also as consequence of possible subsequent amendments and/or integrations of the applicable laws. Changes will be notified in advance and Data Subjects will be able to consult the constantly updated version of this Privacy Notice on Recordati's website.

Date: 13.01.2026