

## PRIVACY NOTICE FOR PATIENTS/PARTICIPANTS IN RESEARCH STUDIES

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This privacy notice describes how **Servier Laboratories Ltd** and **Servier Research and Development Ltd** ("Servier", "we" or "us"), whose registered offices are located at Sefton House, Sefton Park, Bells Hill, Stoke Poges, Slough, SL2 4JS, United Kingdom, collect and process personal information about you, how we use and protect this information, and your rights in relation to this information.

Personal information is information, or a combination of pieces of information that could reasonably allow you to be identified.

This privacy notice applies to all personal information collected or processed about you in relation to:

- Management of research studies activities,
- Management of pharmacovigilance activities; or
- Management of medical information delivery.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#).

You will have been provided with a participant information sheet and informed consent form before agreeing to take part in a research study and that document will include details of how your personal information for the research study will be managed.

**When providing us with personal information relating to another person, you must ensure that you have provided them with the information set out in this privacy notice and have obtained their consent where necessary.**

## **1. PERSONAL INFORMATION WE USE**

Your research doctor will collect personal information about you from a variety of sources in accordance with our instructions, including information collected from you directly (e.g. during your study visit) and indirectly from other sources, described below.

### **1.1 Personal information we collect directly from you**

The categories of personal information collected directly from you vary with each research study, but will usually include:

- (a) personal details (e.g. name, date/year of birth, sex)
- (b) contact details (e.g. phone number, email address, postal address, mobile number)
- (c) special categories of personal information (see below)

### **1.2 Personal Information collected from other sources**

Your research doctor will also collect personal information about you indirectly from other sources, such as your medical records, other doctors and/or your personal or professional legal representatives, if applicable.

The categories of personal information collected about you from these other sources are

- (a) personal details (e.g. name, date/year of birth, sex)
- (b) contact details (e.g. phone number, email address, postal address, mobile number)
- (c) special categories of personal information (see below)

### **1.3 Other information collected about you**

If any other personal information will be collected about you the reason why will be explained to you by your research doctor and in your patient information sheet and informed consent form.

### **1.4 Special categories of personal data**

Some of the categories of information collected are special categories of personal data (also known as sensitive personal information). In particular, personal information that relates to your health, such as your medical history and reports on medical diagnoses, injuries and treatment.

Special categories of personal information will vary per research study, but your research doctor will collect and process, at minimum, the following personal information that you provide directly to the research doctor or that is collected by your research doctor from other sources:

- (a) Your height and weight and general health (such as blood pressure)

- (b) Information about your medical history and past treatments, relevant to the research study
- (c) The results of laboratory tests and investigations, relevant to the research study; and
- (d) Any other information, relevant to the research study

## **2. HOW WE USE YOUR PERSONAL INFORMATION AND THE BASIS ON WHICH WE USE IT**

We use your personal information for the following purposes:

- (a) comply with legal obligation to which we are subject regarding research studies to cooperate with regulators and law enforcement bodies;
- (b) comply with our legal obligation on pharmacovigilance and contact you if we need further details from you about your report;
- (c) Management of research studies and medical information delivery;

We must have a legal basis to process your personal information. In most cases the legal basis will be one of the following:

- (a) to comply with our regulatory and legal obligations as described above; and
- (b) exercise our legal rights where it is necessary to do so, for example to detect, prevent and respond to fraud claims, intellectual property infringement claims or violations of law;
- (b) legitimate interest in using information relating to your health and care for research studies as a sponsor of the research study, when you agree to take part in a research study. This means that we will use your data, collected in the course of a research study, in the ways needed to conduct and analyse the research study. When we process personal information to meet our legitimate interests, we put in place robust safeguards to ensure that your privacy is protected and to ensure that our legitimate interests are not overridden by your interests or fundamental rights and freedoms. For more information regarding this process, please contact us using the details in section below.

## **3. YOUR RIGHTS OVER YOUR PERSONAL INFORMATION**

You have certain rights regarding your personal information, subject to certain exceptions in accordance with applicable law. These include the following rights to:

- access your personal information. There may be some exceptions, for instance in the event of a manifestly unfounded or excessive request, or if the exercise of this right affect a legal

investigation or the right of freedom of another data subject, which means you may not always receive all the information we process about you;

- rectify any inaccurate information we hold about you;
- erase your personal information except in certain circumstances for example if it is necessary for us to process your personal information to comply with a legal obligation (as described in section 2 above) or for the establishment, exercise or defence of a legal claim;
- restrict our use of your personal information in certain circumstances;
- object to our use of your personal information in certain circumstances where we use your personal for our legitimate interests (as described in section 2 above). If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible and anonymized the data; and
- receive your personal information in a usable electronic format and transmit it to a third party (right to data portability);
- lodge a complaint with your data protection authority (the Information Commissioner's Office in the UK: <https://ico.org.uk/global/contact-us/> or call on 0303 123 1113)

If you would like to discuss or exercise your rights, please contact your research doctor using the contact details in your patient information sheet and informed consent form or Servier directly.

We encourage you to contact your research doctor to update or correct your information if it changes or if the personal information held about you is inaccurate.

We will contact you if we need additional information from you in order to honour your requests.

#### **4. INFORMATION SHARING**

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#).

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in

research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Your personal data processed by Servier will only be accessible to a limited number of recipients on a need to know basis or where required by law. Thus, the main categories of recipients will be Servier's authorized employees and departments acting within their scope of activities, including but not limited to:

- Clinical Operations Department;
- Medical Affairs Department;
- Pharmacovigilance Department;
- Research and Biopharmacy Department;
- Methodology and Valorisation of Data Department;
- Information Technology Department, where necessary.

We will share your personal information with third parties under the following circumstances:

- **Service providers and business partners.** We may share your personal information with our service providers and business partners (e.g. hosting providers, contractual research organizations, travel agencies, hotels, air carriers) who may need access to your personal information in order to provide their services.
- **Servier group companies.** Servier Laboratories Ltd and Servier Research and Development Ltd are ultimately owned by Les Laboratoires Servier, so we work closely with other businesses and companies that fall under the Servier Group. We may share certain information with Les Laboratoires Servier and other Servier Group companies. Information on the global presence of the Servier group can be found here: <https://servier.com/en/company/global-presence/>.
- **Law enforcement agencies, courts, regulators, government authorities or other third party.** We will share your personal information with these parties where we believe this is necessary to comply with a legal or regulatory obligation or to support a legal or criminal investigation or otherwise to protect our rights or the rights of any third party.
- **Asset purchasers.** We may share your personal information with any third party that purchases, or to which we transfer, all or substantially all of our assets and business. Should such a sale or transfer occur, we will use reasonable efforts to try to ensure that the entity to which we transfer your personal information uses it in a manner that is consistent with this privacy notice.

Note that we may be required by law to collect certain personal information about you. Failure to provide this information may prevent or delay the fulfilment of these obligations. We will inform you at the time your information is collected whether certain data is compulsory and the consequences of the failure to provide such data.

Because we operate as part of a global business, the recipients referred to above may be located outside the jurisdiction in which you are located (or in which we provide the services). See the section on "International Data Transfer" below for more information.

## **5. INFORMATION SECURITY AND STORAGE**

We implement technical and organisational measures to ensure a level of security appropriate to the risk to the personal information we process. These measures are aimed at ensuring the ongoing integrity and confidentiality of personal information. We evaluate these measures on a regular basis to ensure the security of the processing.

We will keep your personal information for as long as you are a participant in the research study. Once the research study has come to an end, we will retain your personal information for a period of time that enables us to:

- Comply with record retention requirements under the law
- Defend or bring any existing or potential legal claims
- Deal with any complaints regarding the services

We will delete your personal information when it is no longer required for these purposes. If there is any information that we are unable, for technical reasons, to delete entirely from our systems, we will put in place appropriate measures to prevent any further processing or use of the data.

More specifically:

- Personal data collected for research studies activities are kept in the information systems of the data controller, participating centre or healthcare professional taking part in the research until the study product is marketed or until the final research report or until 2 years following the publication of the research results. They are then archived in paper or electronic form for a period in accordance with applicable laws and regulations;
- Personal data collected for pharmacovigilance activities are kept for 10 years after the relevant marketing authorisation has ceased to exist, then data are deleted or archived in an anonymised form, unless otherwise provided by mandatory local regulations;
- Personal data collected for medical information management are kept for 3 years after the request.

We will delete your personal information when it is no longer required for these purposes. If there is any information that we are unable, for technical reasons, to delete entirely from our systems, we will put in place appropriate measures to prevent any further processing or use of the data.

## **6. INTERNATIONAL DATA TRANSFER**

Given the global nature of the Servier Group, we may transfer personal information including sensitive personal information to other entities of the Servier Group based outside the UK to appropriately deal with your enquiry. A list of Servier Group entities and where they are based is available here: <https://servier.com/en/company/global-presence/>.

In addition to Servier Group entities overseas, your personal information may be transferred to, stored, and processed by an international organisation or a third party located in a country that is not regarded as ensuring an adequate level of protection for personal information under **Data Protection Law applicable in UK**, including but not limited to the retained EU law version of the General Data Protection Regulation ((EU) 2016/679), as it forms part of the law of England and Wales, Scotland, and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018; the Data Protection Act; and the Privacy and Electronic Communications Regulations 2003 as amended or by the Information Commissioner's Office in the UK.

We have put in place appropriate safeguards (such as contractual commitments and standard contractual clauses) in accordance with applicable legal requirements to ensure that your data is adequately protected. For more information on the appropriate safeguards in place, please contact us at the details below.

## 7. CONTACT US

**Servier Laboratories Ltd or Servier Research and Development Ltd** is the controller responsible for the personal information we collect and process by your research doctor.

If you have questions or concerns regarding the way in which your personal information has been used, please contact your research doctor using the contact details provided in your patient information sheet and informed consent form.

Our Data Protection Relay can be contacted at: [DataPrivacy-UK@servier.com](mailto:DataPrivacy-UK@servier.com) or by Telephone: 01753 666409 and Post: Compliance Department, Servier Laboratories Ltd, Sefton House, Sefton Park, Bells Hill, Stoke Poges, Buckinghamshire SL2 4JS

Servier and your research doctor are committed to working with you to obtain a fair resolution of any complaint or concern about privacy. If, however, you believe that we have not been able to assist with your complaint or concern, you have the right to make a complaint to the data protection authority of the UK (the Information Commissioner's Office in the UK: <https://ico.org.uk/global/contact-us/> or call on 0303 123 1113) or your local data protection authority if you are based outside the UK.

## 8. CHANGES TO THE POLICY

You may request a copy of this privacy notice from us using the contact details set out above. We may modify or update this privacy notice from time to time.

If we change this privacy notice, we will notify you of the changes by way of a banner on our Website. Where changes to this privacy notice will have a fundamental impact on the nature of the processing or otherwise have a substantial impact on you, we will give you sufficient advance notice so that you have the opportunity to exercise your rights (e.g. to object to the processing).

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