

## STARTone Portal Data Privacy Policy

This website is operated by EMD Serono, Inc. ("EMD Serono", "we", "us" or "our"). Further details can be found in the Legal imprint [<https://www.emdgroup.com/en/legal-disclaimer.html>].

With this data protection declaration we explain to you which personal data is processed for which purposes. Certain sections contain a field with "more details" where you can call up additional information.

### 1. Which data do we process and for which purpose?

#### a) When do we collect which categories of personal data?

##### aa) Registering and Log-in<sup>1</sup>:

As the information we provide on this portal is legally restricted to qualified healthcare personnel, we require you to register and log-in to access our portal. In order to register and complete your profile, we collect your name, title, email address, phone number, country of residence, profession, therapeutic area, CV, medical professional license information, and institution name and address where you work.

##### bb) Data we collect when interacting with you (offline and online)

We collect data you communicate to us for your ISS ideas, proposals, protocols, and all related documentation for the governance review and approval process. In addition, if your ISS submission is approved, we collect information for contracting including tax verification data and

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<sup>1</sup> Legal basis: Art. 6 (1) b) EU General Data Protection Regulation (hereafter GDPR).



contracting contact or institution name and address. During the study conduct phase, we collect data you communicate to us through status reports including study submission documents, study milestone and recruitment information, payment milestone information, and study reports and publications.<sup>2</sup>

We collect information on your full IP address for the purpose of tracking the login session. We also track the date and duration of the login sessions.

We do not collect data about your online behavior (which pages you visited, which links you clicked on) and when using our emails (if you open our emails, which links you clicked on etc.).<sup>3</sup>

cc) Public sources and third parties

If applicable based on regulations for your region, we may also collect data from publicly available sources and third parties to confirm your eligibility for conducting clinical studies in your respective region.<sup>4</sup>

dd) Browsing data (not connected to users)

We collect browsing data related to your full IP address for the purpose of geo-tagging to direct you to the correct portal landing page. We do not collect any other browsing information such as the name of the internet service provider or the website from which you access our website.<sup>5</sup>

b) Purposes of data use

aa) Providing you with services you requested

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<sup>2</sup> Legal basis: Art. 6 (1) f) GDPR.

<sup>3</sup> Legal basis: Art. 6 (1) a) GDPR.

<sup>4</sup> Legal basis: Art. 6 (1) f) GDPR.

<sup>5</sup> Legal basis: Art. 6 (1) f) GDPR.

We use your data to provide you access to our portal for the purposes of evaluating and processing your ISS submissions.<sup>6</sup> We can also individualize the content based on the information we collected about you.<sup>7</sup>

bb) Providing you information that may interest you

We aim to present you only information that could be of interest to you and to communicate seamlessly over various channels without sending redundant information. Our communication with you is based on the information we collected about you and are permitted to use.

For example, our Information Page shows general information regarding the ISS process and our ISS programs. All communication from the system is specifically related to your ISS submissions.<sup>8</sup>

***Further information:***

This is not a subscription to general information. Email communication is only used to provide you with information about your specific ISS submissions and actions you may be required to take within the portal. That includes the following:

- Notifications of review decisions
- Notification of actions such as monthly reports or feedback
- Possible requests from you, e. g. request for modifying submission information during the review process

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<sup>6</sup> Legal basis: Art. 6 (1) b) GDPR.

<sup>7</sup> Legal basis: Art. 6 (1) f) GDPR.

<sup>8</sup> Legal basis: Art. 6 (1) a) and f) GDPR.

All communication is done using the email address provided during registration. Local study representatives may contact you via telephone or email outside of the portal.

cc) Legal obligations and legal enforcement

In some cases we are under a legal obligation to process personal data. A typical example is the processing within the scope of the so-called pharmacovigilance, i.e. the obligation to investigate and share data when potential side effects of drugs become known.<sup>9</sup>

Where required, we can also use your data to enforce our third party rights (such as copyright infringements).<sup>10</sup>

dd) General statistics, website security:

We do not do general statistics on browser data.<sup>11</sup>

We do collect data about the location of the devices accessing our website for geo-tagging redirection and security monitoring.<sup>12</sup>

## 2. Cookies and Analytics

a) Cookies:

We use cookies in order to enable and facilitate the use of the portal (e.g. to optimize the presentation). We only use cookies that are session-based. Session cookies exist only during one session. They disappear from your computer when you close your browser software or turn off your computer. We use the following cookies:

- **CookiePurposeExpiresjsessionid** This cookie is used to maintain an active user session between your computer and the application. It stores

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<sup>9</sup> Legal basis: Art. 6 (1) c) GDPR.

<sup>10</sup> Legal basis: Art. 6 (1) f) GDPR.

<sup>11</sup> Legal basis: Art. 6 (1) f) GDPR.

<sup>12</sup> Legal basis: Art. 6 (1) f) GDPR

your current session identifier, a randomly generated string of letters and numbers, generated by the application server.

- **loginuserid** This cookie is used for improved user experience to allow you to easily re-login after a session timeout. It stores your unique user identifier, commonly a 6-digit number, that is used within the database.
- **logincaptcha** This cookie is used to determine whether a CAPTCHA verification step is required for a page. It stores a true/false flag that is set upon different conditions such as multiple failed logins.
- **SS Origin** This cookie is optionally employed to improve your user experience upon logout. It stores the URL that a user came from prior to reaching the login screen. It is enabled when the logout redirect option is configured to remember and return the user to a previous address that they were on before navigating to the portal.

You can disable or block cookies in your browser software; however, this may result in restrictions regarding the usability of this website.

***Further information:***

- A “cookie” is a file containing an identifier, composed of a string of letters and numbers, that is sent by a web server to your computer when you visit a website. Your computer will then send this identifier back to the web server as it communicates with it. The reason for doing this is to create an improved user experience for you.
- Typically, cookies will be one of either of these types; persistent, or session. A persistent cookie will be stored by a web browser and will remain valid until its set expiry date, unless deleted by the user before the expiry date. A session cookie, on the other hand, will expire at the end of the user session, when the web browser is closed.
- Cookies do not typically contain any information that personally identifies a user, but other personal information stored about you may be linked to the information stored in and obtained from cookies.

### **3. Recipients of personal data; data transfer to third countries**

#### **a) Adverse events or enforcement of rights:**

If we become aware of potential cases of adverse reactions to one of our products, we are required by law to document and share the relevant information, including personal information with authorities worldwide and, where necessary for further assessment, to contact the reporting parties.

In order to enforce our rights or to protect our rights or the rights of third parties with the holders of such rights, consultants and authorities.

#### **b) External service providers for data processing:**

We use service providers which support us to provide our services. These service providers process data only in accordance with the instructions and under the control of EMD Serono and exclusively for the purposes described in this privacy policy.

EMD Serono will take all steps reasonably necessary to ensure that the data you provide is adequately protected according to the requirements of the data protection laws of the European Union by means of Standard Contractual Clauses approved by the EU Commission.

#### **c) Data transfer to the EMD Serono group companies**

As part of a global group of companies, our ISS study teams are made up of worldwide personnel. These personnel process the data solely for the purposes set out in this Privacy Notice.

### **4. Data Retention**

We store data for as long as necessary for the provision of the service requested by you. For example, when you submit an ISS idea, proposal, or protocol for review, if the submission is not approved, we will store the information for up to 10 years. For ISS submissions which are approved and result in the conduct of a clinical or non-

clinical study, we will store all information related to the ISS for as long as the related EMD Serono products are still in development or available commercially. General information such as user profile information will be kept and updated as long as we consider engaging with you.

Data which is collected while browsing our website and which can legally be considered personal data (such as the complete IP address) is stored for up to one year for security monitoring purposes.

Data without any personal identifiable information may be stored permanently.

## 5. Data protection rights and contact

### a) General rights:

You can request information about the data stored about you and have the right to receive the data provided by you in a common and machine-readable format. Furthermore, in justified cases, you may also request the deletion, correction or limitation of the processing of your data. If your personal data is transferred to a country outside the EU which does not provide appropriate protection, you can request a copy of the contract that implements the appropriate protection of personal data.

### b) Right to object:

Furthermore, in justified cases you can **object to the processing of personal data concerning you** where we process your personal data based on our legitimate interest (this is the case if the legal basis is Art. 6 f) GDPR as indicated in the footnotes).

### c) Revocation of your consent:

When you have given your consent to the processing of personal data concerning you on the website, you can revoke your consent at any time with effect for the future.

### d) Contact person:

To exercise these rights, please contact our data protection officer at [privacy@emdgroup.com](mailto:privacy@emdgroup.com). In addition and in case of concerns, you can also contact the competent data protection authority which is for us:

Hessian Commissioner for Data Protection and Freedom of Information  
Prof. Dr. Michael Ronellenfitsch  
Gustav-Stresemann-Ring 1  
65189 Wiesbaden

Data protection declaration as of: November 25, 2019



# STARTone Portal. Terms of Use

## 1. Introduction

These Terms of Use regulate the use of the STARTone Portal accessible through the login page (hereinafter “the portal”).

The portal is operated by EMD Serono, Inc. (hereinafter also “Company”, “we”, “us” or “our”). Further details can be found in the Legal Imprint [<https://www.emdgroup.com/en/legal-disclaimer.html>].

Access to and use of the portal and its contents are subject to the following conditions. Should you disagree with these conditions or should you not meet the Access Conditions, you will not be granted access to the portal.

The portal is intended to provide a platform for healthcare professionals acting as Investigator Sponsors to submit Investigator Sponsored Studies (ISS) and related documents for consideration to our ISS governance board. The portal will be used for the governance process as well as for investigator communication and status reporting against all approved studies. By using the portal, you declare that you use it and its content at your own risk.

The content of the portal is intended only for qualified healthcare professionals, to provide the above-mentioned information needed for the management of ISS.

This portal should be used exclusively by researchers (Healthcare Professionals) to submit their ISS related documents to Company for review and potential approval, and to allow for the submission of status reporting and updating of this information when necessary.

Company is not responsible for the ISS information and related documents that the user uploads to the portal. By accepting these Terms of Use, the user declares that the uploading of the ISS information and related documents does not infringe the rights of third parties and undertakes to indemnify Company in case any claim related to the uploaded content occurs. Without prejudice to the foregoing, the portal and all underlying technology (other than the ISS data and documentation provided by the researchers) is the property of Company or third parties who have authorized Company for this use.

## 2. Access Conditions

THE INFORMATION WE PROVIDE ON THE PORTAL IS LEGALLY RESTRICTED TO QUALIFIED HEALTHCARE PROFESSIONALS. By accepting these Terms of Use you represent that you are a Healthcare Professional. In addition, we require you to register and log-in to access our portal.

Please be aware that users may be subject to provisions under local legislation.

## 3. Exclusion of Liability

We have compiled the content of the portal carefully, and in accordance with its current state of knowledge. However, we give no warranty, neither expressly nor tacitly, for the completeness or correctness of the details provided on the portal. Please be aware that the details we provide may no longer be up-to-date.

We accept no liability for loss, damage or compensation claims due to missing or incorrect details.

#### **4. Legal Notes**

The portal is operated by Company. All rights to the portal or arising from the same shall remain with Company.

We may modify this portal and/or discontinue its operation at any time without prior announcement, either wholly or in parts, at its own discretion and without accepting liability. Neither is Company under an obligation to update the content of the portal.

All documents and information entered or uploaded into the portal by the researchers are under the sole ownership of the researcher. Unless otherwise indicated, all documents and information published on our portal by us are under the sole ownership of Company. Unless written consent has been obtained from us, (Corporate Communications Department), no permission is given to import published and copyrighted content from our portal to other programs or websites or to use such content in any other way. All product names, whether or not appearing in large print or with the trademark symbol, are trademarks of Company, its affiliates, related companies or its licensors or joint venture partners, unless otherwise noted.

Access to this portal is subject to the Terms of Use and requires registration. Please be aware that users may be subject to provisions under local legislation.

#### **5. Personal Data**

Company is particularly concerned to ensure the protection of your personal data. You will find information on the use of personal data in the Data Privacy and Cookie Policies found within the Privacy and Security section of the portal.

#### **6. Content**

All information is provided for informational purposes only, under no circumstances may it be used or understood as a substitute for healthcare professional advice and is not to be used for diagnosis of any health problem or disease.

Patients should always consult a doctor or another healthcare professional for medical advice or information about diagnosis and treatment.

The portal may also include links to third-party websites. Such links are provided merely as a convenience. The content of third-party websites is beyond our control and we make no warranties or representations regarding the accuracy or validity of such information. Neither do the links represent any kind of support or endorsement of the linked third-party website's contents. Access to and use of sites connected via links takes place at the user's own risk.

#### **7. Date of Preparation and Disclaimer**

Date of preparation: 22 November 2019

**Disclaimer.** The information held within the portal may not always be completely up to date and, for this reason, such information is provided on an "as is" and "as available" basis.

# STARTone Portal Cookie Policy

## About Cookies

A cookie is a file containing an identifier, composed of a string of letters and numbers, that is sent by a web server to your computer when you visit a website. Your computer will then send this identifier back to the web server as it communicates with it. The reason for doing this is to create an improved user experience for you.

Typically, cookies will be one of either of these types; persistent, or session. A persistent cookie will be stored by a web browser and will remain valid until its set expiry date, unless deleted by the user before the expiry date. A session cookie, on the other hand, will expire at the end of the user session, when the web browser is closed.

Cookies do not typically contain any information that personally identifies a user, but other personal information stored about you may be linked to the information stored in and obtained from cookies.

## Cookies We Use

The portal only uses cookies that are session-based. Session cookies exist only during one session. They disappear from your computer when you close your browser software or turn off your computer.

- **CookiePurposeExpiresjsessionid** This cookie is used to maintain an active user session between your computer and the application. It stores your current session identifier, a randomly generated string of letters and numbers, generated by the application server.
- **loginuserid** This cookie is used for improved user experience to allow you to easily re-login after a session timeout. It stores your unique user identifier, commonly a 6-digit number, that is used within the database.
- **logincaptcha** This cookie is used to determine whether a CAPTCHA verification step is required for a page. It stores a true/false flag that is set upon different conditions such as multiple failed logins.
- **SS Origin** This cookie is optionally employed to improve your user experience upon logout. It stores the URL that a user came from prior to reaching the login screen. It is enabled when the logout redirect option is configured to remember and return the user to a previous address that they were on before navigating to the portal.

## Managing Cookies

Most browsers allow you to refuse to accept cookies, and to delete them. The methods for doing so vary from browser to browser, and from version to version so you will need to consult the manufacturer website of your browser to learn how to do this.

To find out more about cookies, including how to see what cookies have been set and how to manage and delete them, visit [www.wikipedia.org](http://www.wikipedia.org).

Please note that the application may not function properly, and certain features will not be available once cookies are disabled.