

PRIVACY INFORMATION NOTICE FOR CLINICAL TRIAL PARTICIPANTS

Introduction

This privacy information notice ("Notice") is intended to provide participants in clinical studies conducted by Byondis B.V. ("Byondis") with an overview of the measures taken by Byondis to protect the privacy of the participants.

Byondis sponsors clinical studies under the control of the European Medicine Agency ("EMA"), the U.S. Food and Drug Administration ("FDA") and other governmental authorities regulating the development of medicinal products ("Regulatory Authorities").

When you participate in a clinical study sponsored by Byondis (the "Study"), your participation is completely voluntary. Prior to participating, you must give informed consent in writing to the scope of the research to be conducted using your personal data gathered during the Study ("Personal Study Information"). This Personal Study Information may include, but is not limited to, your medical history, disease state (if applicable), information regarding biological samples (e.g. blood, urine or tissue samples) and adverse events.

All your personal data will be protected in accordance with the applicable data protection laws, which includes - for the European Economic Area ("EEA") - the General Data Protection Regulation ("GDPR").

In this Notice, we explain what personal data will generally be processed as part of the Study and what rights you have with respect to your privacy. For more information about the background, purpose and operation of the Study, please see the Patient/Subject Information Sheet, the Informed Consent Form or other information provided to you when you entered the clinical study process.

What is the role of Byondis in the Study?

As sponsor of clinical studies, Byondis is responsible for processing and controlling Personal Study Information. We will involve external parties such as contract research organizations (CROs), sites (i.e. the location where your study doctor is based) or other research organizations to process the Study Information.

Purpose of processing and legal basis

We process Personal Study Information to support the clinical study, as described in the Subject/Patient Information Sheet and Informed Consent Form, and to fulfill our statutory obligations with respect to each Study. We need to process your Personal Study Information to draw conclusions from the result of the Study and to receive authorization from relevant Regulatory Authorities to market our pharmaceutical products. We may also publish the results of the Study.

We will only process personal data if we have a valid legal justification for doing so. Therefore, we will only process your Personal Study Information if:

- you have given your prior consent by signing the Informed Consent Form;
- this is necessary to comply with our legal or regulatory obligations, such as the regulations on conducting clinical studies;
- this is necessary for medical reasons to protect your vital interests or those of another individual (matters of life and death).

We do not use personal data to execute automatic decision-making or profiling.

Confidentiality

Your Personal Study Information is recorded using a unique study number to prevent your identity being revealed. The link between your unique study number and your identity is only known to your study doctor and is not provided to Byondis or made publicly available. All information to be held by Byondis as part of the Study is identified by this study number and not by your name. This is considered pseudonymized data. We will treat this data accordingly.

How long do we retain your Personal Study Information?

We will only retain personal data for as long as necessary to fulfill the purpose for which it was collected or to comply with legal, regulatory or internal policy requirements. After such time periods have expired, we may either delete your personal data or retain it in a form such that it does not identify you personally.

How do we protect your Personal Study Information?

Byondis takes the security and privacy of the Personal Study Information very seriously. We will therefore implement reasonable and appropriate security measures to protect your personal data from loss, misuse and unauthorized access, disclosure, alteration and destruction. In doing so, we take into account the risks involved in processing and the nature of such personal data and comply with applicable laws and regulations.

With whom is your Personal Study Information shared?

We are required to disclose the personal data we control in response to lawful requests by governmental authorities, including for the purpose of meeting requirements of national security or law enforcement. We may also disclose personal data to other third parties when compelled to do so by governmental authorities or required by law or regulations including, but not limited to, in connection to court orders.

We may disclose your Personal Study Information to governmental authorities for regulatory and supervision purposes. We may also disclose your Personal Study Information to public and/or private researchers, consistent with the principles of this Notice.

Personal Study Information may also be shared with third party service providers who we engage to assist us in conducting the Study. As a sponsor, for example, we may instruct a third party to monitor and support the study on behalf of Byondis. If this is the case, Byondis will enter into an agreement with this third party which will also safeguard the security and confidentiality of the processing of your Personal Study Information by such third party on behalf of Byondis.

Access to Personal Study Information

If you are participating in a Study, we strongly recommend that you request access to your Personal Study Information directly from your study doctor as explained to you via the Informed Consent Form or other information provided to you when you entered the clinical study process. As we only possess pseudonymized data, we cannot identify which Personal Study Information relates to you without asking your study doctor to reveal your identity and linking the pseudonymized data to you. This may violate applicable law regulating clinical studies and is not in your interest.

At your request, we will confirm whether your Personal Study Information is being processed in a Study and take measures to provide you with any of your personal data that is processed in such

Study within a reasonable time. You have the right to access, correct, amend or delete your personal data in the event that it is inaccurate or has been processed in violation of this Notice. We may require payment or refuse your request if this request is manifestly unfounded or excessive, or if compliance with the request would be in conflict with our obligations under applicable law regulating clinical studies.

If you withdraw or are asked to be withdrawn from a Study, your Personal Study Information collected prior to your withdrawal may still be processed along with other Personal Study Information collected as part of the Study, as stated in the Informed Consent Form.

Important notice for all participants in Studies conducted or on behalf of Byondis

Byondis complies, as a Dutch company, with the European General Data Protection Regulation (GDPR) regarding the collection, use and retention of personal data of participants in Studies for which it is a sponsor. Byondis has certified that it adheres to the GDPR privacy principles. If there is a conflict between this Notice and the GDPR privacy principles, the GDPR privacy principles will prevail.

Byondis is committed to resolving complaints about your privacy and our collection or use of your personal data. If you are not satisfied with the way Byondis handles your personal data, you may file a complaint to the appropriate Supervisory Authority.

Your personal data might be transferred to a country that does not have the same level of personal data protection as the EEA. This may be necessary because we work with third party service providers or need to share the findings of a study with supervisory authorities outside the EEA. If your data is transferred outside the EEA, Byondis is responsible for protecting your personal data and will take all the reasonable steps to protect your privacy. This includes putting in place suitable safeguards to ensure that such transfer is carried out in compliance with applicable data protection rules.

Changes to this privacy information notice

This Notice may be subject to amendments. Any future changes or additions to the processing of personal data as described in this Notice affecting you will be communicated to you through an appropriate channel, in line with how we normally communicate with you.

How to contact us

If you have any questions about this Notice, please e-mail us at dataprivacy@byondis.com

We can also be contacted via letter:

Byondis B.V.
Attn: Privacy officer
P.O. Box 6570
6503 GB Nijmegen
The Netherlands

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