Numab Therapeutics AG
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Switzerland
numab.com

Privacy Notice for Clinical Study Participants

15. December 2022

1. Introduction

This Privacy Notice ("Notice") intends to provide participants in clinical studies conducted by or on behalf of Numab Therapeutics AG ("Numab") with an overview of the measures taken by Numab to protect the privacy of the participants.

Numab sponsors clinical studies under the control of the Swiss Agency for Therapeutics Products ("Swissmedic"), the European Medicines Agency ("EMA"), the United States Food and Drug Administration ("US FDA"), and other governmental authorities regulating the development of medicinal products ("Regulatory Authorities").

When you participate in a Numab-sponsored clinical study ("Study"), your participation is voluntary, you may refuse to participate, or you may withdraw from the Study at any time. Prior to participating, you must give your informed consent to the scope of the research to be conducted. This includes your consent to 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 Study Information is protected according to the applicable data protection laws. This includes the Swiss Federal Act on Data Protection ("DPA"), the European Economic Area ("EEA") General Data Protection Regulation ("GDPR"), and other country-specific privacy legislation, when applicable.

In this Notice, we explain what personal data is generally processed as part of the Study and what rights you have with respect to your privacy. For more information about the background, purpose, conduct, and reporting of the Study, please refer to the Patient/Subject Information Sheet, the Informed Consent Form, or other information provided to you during the clinical study.

2. What is the role of Numab in the Study?

As sponsor of clinical studies, Numab is responsible for processing and controlling Personal Study Information. We involve third parties to process your Personal Study Information, such as contract research organizations (CROs), study site personnel (e.g., study doctors, nurses) or other research organizations. As sponsor, Numab is also the controller of your Personal Study Information.

3. Purpose of processing and legal basis

We process Personal Study Information for the 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 and for 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 only process your Personal Study Information if we have a valid legal justification for doing so. Therefore, we only process your Personal Study Information if you or your legally acceptable representative have given your prior consent by signing the Informed Consent Form; this is necessary to establish, exercise or defend a legal claim in court.

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

4. Confidentiality

Your Personal Study Information is recorded using a unique study participant number to prevent your identity from being revealed. The link between your unique study participant number and your identity is only known to your study site personnel and to individuals monitoring and auditing the study site. Your identity is not provided to Numab or made publicly available. All information held by Numab as part of the Study is identified by this study participant number and not by your name. This is considered pseudonymized data.

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5. How long do we retain your personal Study Information

We only retain Personal Study Information for as long as necessary to fulfill the purpose for which it was collected and to comply with legal and regulatory requirements. This is defined in internal policies and retention schedules. After such time periods have expired, we may either delete your personal data or retain it in a form such that it can no longer be used to identify you personally. Personal Study Information may be retained longer if this is necessary for scientific research purposes..

6. How do we protect your Personal Study Information

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

7. With whom is your Personal Study Information shared

We are required to disclose Personal Study Information 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 Study Information 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 Numab. If this is the case, Numab enters into an agreement with this third party which also safeguards the security and confidentiality of the processing of your Personal Study Information.

8. Access to Personal Study Information

If you are participating in a Study and you wish to access your personal data, we strongly recommend that you request this 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 is your Personal Study Information without asking your study doctor to reveal your identity and linking the pseudonymized data to you. This may violate applicable laws regulating clinical studies.
At your request, we ask the study doctor to inform you if 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 your personal data and to request corrections or amendments. Clinical study data already collected may only be corrected or amended by your study doctor. It may not be deleted. This is because of scientific and legal obligations regarding the Study. While these requests are free of charge, we may require payment or refuse your request if the 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 is still processed along with other Personal Study Information collected as part of the Study, as stated in the Informed Consent Form.

9. Important notice for all participants in Studies conducted by or on behalf of Numab

As a Swiss company, Numab complies, with the DPA and, for Studies conducted in the EEA the GDPR, regarding the collection, use, and retention of Personal Study Information in Studies for which Numab is a sponsor. If there is a conflict between this Notice and the DPA or GDPR privacy principles, the DPA and GDPR privacy principles prevail. Numab is committed to resolving complaints about your privacy and our collection or use of your Personal Study Information. If you are not satisfied with the way Numab handles your personal data, you may file a complaint to the appropriate supervisory authority.

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Your Personal Study Information may be transferred to a country outside Switzerland and 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, Numab is responsible for protecting your Personal Study Information and takes all the reasonable steps to protect your privacy. This includes putting in place suitable safeguards to ensure that such transfers are carried out in compliance with applicable data protection rules.

10. Changes to this Notice

This Notice may be subject to amendments. Any future changes or additions to the processing of Personal Study Information as described in this Notice affecting you is communicated to you through an appropriate channel (e.g., updated Informed Consent Form), in line with how we normally communicate with you. Minor changes that do not impact your rights and freedoms with regard to Personal Study Information are not communicated directly.

11. How to contact us

If you have any questions about this Notice, please email us at dataprotection@numab.com.

We can also be contacted via mail:
Numab Therapeutics AG
Attn: Data Protection Officer
Bachtobelstrasse 5
CH-8810 Horgen
Switzerland

Inhabitants of the EEA can also contact our EU GDPR representative Vivenics Consultancy B.V. by email to representative@vivenics.com.

Inhabitants of the UK can also contact our UK GDPR representative AssureMore by email to representative@assuremore.com.

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Expanded Access Policy

Expanded Access Policy Numab Therapeutics AG (Numab) is committed to developing multi-specific antibody-based therapeutics for patients with serious cancers. Numab aims to provide access to our investigational therapies primarily through ongoing clinical trials. “Expanded Access” refers to the use of an investigational therapy for potential treatment of a serious condition in a patient, where such use is not within a clinical trial setting. The US Food and Drug Administration has set forth guidelines when considering expanded access. They include:

- The disease or condition must be serious or immediately life-threatening with no adequate alternative therapy options available;
- There must be sufficient evidence that, based on available safety and efficacy information, the potential benefit to the patient would likely outweigh any potential risks; and
- Provision of the investigational drug for expanded access use will not interfere with, or delay, ongoing or planned clinical development programs, completion of which would enable therapy access for many more patients.

Certain therapies, like those developed by Numab, are made through complex manufacturing processes. Numab seeks to retain the ability to make and supply product in a fair and equitable manner and in a volume that assures adequate manufacturing capacity for our clinical trial development programs. Numab believes that participation in clinical trials is the most appropriate way to access these investigational therapies. At this time, Numab is not currently making its unapproved therapies available on an expanded access basis. In the event Numab decides to consider expanded access in the future, Numab will evaluate and respond to each request that it receives on a case-by-case basis. In the meantime, you can find current information about our ongoing clinical trials at https://clinicaltrials.gov. If you have additional questions, please speak with your physician or contact clinicaltrials@numab.com. Consistent with the 21st Century Cures Act, Numab may revise this policy at any time.