TransThera Privacy Notice

**Effective on: [2024-07-01]**

**Last Modified on: [2024-07-01]**

## Introduction and Scope

TransThera Sciences (Nanjing), Inc. and TransThera (US), Inc. (“**TransThera**”, “**we**”, “**us**”, “**our**”) sponsors ethically approved clinical trials. When your Personal Data is processed by us pursuant to your participation or work in one of the clinical trials (“**Trial**” or “**Trials**”) we sponsor or for other purposes, you trust us with your personally identifiable information (“**Personal Data**”). We are committed to keeping that trust, and that starts with us helping you understand our privacy practices. Please read this Notice to learn what we are doing with your Personal Data, how we protect it, and how you can exercise your privacy rights.

This TransThera Privacy Notice applies to clinical trials conducted in the European Union or the collection of personal information in the European Union.

## Contact Information

If you are an individual patient and have any questions about this Notice or our processing of your Personal Data, or you would like to exercise [your data protection rights](#_Your_Privacy_Rights), please first speak with your study doctor or the study site. TransThera generally only has access to key-coded data, and we will not be able to identify you if we receive a request from you directly.

Please allow up to one month for us to reply.

## *Clinical Trial Sponsor*

Legal Entity Name: TransThera Sciences (Nanjing), Inc.

Physical Address:

3rd FL, 9th Building, Accelerator Phase 2

Biotech and Pharmaceutical Valley

Jiangbei New Area, Nanjing, China, 210032

Phone Number: 025-58216206

Email Address: tt420c2308clinfo@transtherabio.com

## *Sponsor’s Data Protection Officer*

For the attention of: Katie Hennessy, Senior Clinical Project Manager

Physical Address: TransThera Sciences (US), Inc. 9711 Washingtonian Blvd, Suite 550, Gaithersburg, MD 20878

Phone Number: 267.627.0150

Email Address: katie\_hennessy@transtherabio.com

## *Sponsor’s Data Protection Representative in the EU*

VeraSafe

Plaza de la Solidaridad 12, planta 5

Malaga

Andalucía 29006

Spain

Contact form: <https://verasafe.com/public-resources/contact-data-protection-representative>

## *Sponsor’s Data Protection Representative in the UK*

VeraSafe United Kingdom Ltd.

37 Albert Embankment

London

SE1 7TL

United Kingdom

Phone: +44 (20) 4532 2003

Contact form: <https://verasafe.com/public-resources/contact-data-protection-representative>

## Scope of this Notice

## *What is Covered by this Notice?*

This Notice specifically applies to:

* individual patients and potential Trial participants in connection with our Trials and use of our experimental pharmaceutical products and/or future commercialized pharmaceutical products (if any);
* health care providers and other study site personnel, in connection with our Trials;
* individuals whose Personal Data we receive and process to help us facilitate the sponsorship of Trials, such as business partners and contractors;
* the website visitors of [https://www.transthera.com](https://www.transthera.com/En/Index/index.html), including those who contact us pursuant to communication methods outlined in our website; and
* individuals whose Personal Data we receive and process for marketing, advertising, and promoting our business, including on our official social media accounts.

## *What is Not Covered by this Notice?*

## *Human Resources Personal Data*

This Notice does not apply to Personal Data collected by any other means or in other contexts, such as the Personal Data of TransThera’s employees, job applicants, contractors, business owners, officers, directors, or staff of TransThera. This means, for example, that this Notice does not describe our processing of your Personal Data nor your data protection rights when you apply to one of our [job openings](https://www.transthera.com/En/Article/lists/category/lcyxk.html).

## *Information Which Does Not Constitute Personal Data*

If we maintain information in a manner that cannot reasonably identify, relate to, describe, be capable of being associated with, or be linked, directly or indirectly, with a particular individual or household, such information is not considered Personal Data and this Notice will not apply to our processing of that information.

## Controllership

Within the scope of this Notice, TransThera acts as a data controller for the Personal Data we process. This means that we alone determine the purpose and means of the processing of your Personal Data. (i.e., how and why Personal Data is collected and processed).

In some jurisdictions, we are considered a “joint controller” with another organization, such as the study site where the Trial is being conducted. This means that we jointly, together with the other organization, determine the purpose and means of the processing of your Personal Data. If you would like to know more about any other data controllers who might be joint controllers together with TransThera, you may ask your study doctor or the study site for further details, specifically relating to the Trial that you are participating in.

## Categories of Personal Data

## *Personal Data of Individual Trial Participants*

Even though we are a data controller for the Personal Data processed in the context of our Trials, TransThera itself does not have access to *identifiable* Personal Data, meaning that we are unable to identify you personally from the information we have access to. Personal Data is collected by our service providers like the study site (the clinic or other healthcare facility where the Trial is being run) or other third parties, such as your doctors or our clinical research organizations. When any information relating to you is shared with us by our service providers, it will first be key-coded (also known as “pseudonymized”) so that we cannot identify you by any direct personal identifier (such as your name, social security number, address, or telephone number).

The following types of Personal Data of individual Trial participants may be processed in the context of our Trials:

* basic identifying information, such as your first and last name;
* contact information, such as your phone number, physical address, and email address;
* financial information, such as information needed for payment processing;
* location information, such as the location of your testing site and Trial location (i.e., study site);
* health care information, such as the identity and contact information of your doctors and other health care providers;
* health information, such as your medical history, medications, current health status, and reaction to the Trial drug or treatment;
* your genetic information and racial and ethnic origin;
* images (such as photographs, scans, and recordings);
* audio recordings of entry and exit interviews;
* recordings of telemedicine (virtual) consultations with health care providers; and
* identifiers and device information, such as IP address and associated location, operating system, and device IDs (e.g. when you visit a Trial-specific website).

You can ask your study doctor if you are unsure whether or not any specific Personal Data that you are being asked to provide is required as part of your participation in the Trial.

## *Personal Data of Healthcare Providers and Other Study Site Personnel*

We may process the following types of Personal Data about healthcare providers and other study site personnel in the context of our Trials:

* basic identifying information, such as your first and last name;
* contact information, such as your phone number, physical address, and email address;
* professional and employment-related information, such as your qualifications, experience and job titles; and
* location information, such as the location of your testing site and Trial location (i.e., study site).

## *Personal Data of Individuals Who Help Us Facilitate the Sponsorship of Trials*

We may process the following types of Personal Data about those who help us facilitate the sponsorship of Trials, including business partners and contractors:

* basic identifying information, such as your first and last name;
* contact information, such as your phone number, physical address, and email address;
* business records information, such as company name and billing information; and
* professional and employment-related information, such as your qualifications and job titles.

## *Personal Data of Website Visitors*

We may process the following types of Personal Data about website visitors, including those who contact us pursuant to communication methods outlined in our website:

* basic identifying information, such as your first and last name;
* contact information, such as your phone number, physical address, and email address;
* information about your interaction with our website, such as when your visit occurred, whether you have been to our website before, and what site referred you to specific pages of our website; and
* whatever information you may share with us when you contact us.

## *Personal Data of Individuals Who We Direct Our Marketing, Advertising, and Business Promotion Activities Towards*

We may process the following types of Personal Data about those we market, advertise, and promote our business towards, including on our official social media accounts:

* basic identifying information, such as your first and last name;
* contact information, such as your phone number, physical address, and email address; and
* browsing history, search history, or information about your interaction with us on our marketing materials, advertisements, or official social media accounts.

## How We Receive Personal Data

We may receive your Personal Data when:

* you provide it directly to us (including when you provide your Personal Data to one of our service providers acting on our behalf);
* a study doctor (also known as an “investigator”) or other healthcare personnel at the study site provides it to us, or your healthcare provider provides it to us;
* we receive it from the clinical research organization that conducts the Trial on our behalf;
* you visit one of our Trial-specific websites or online portals;
* you provide it to us, the clinical research organization, or a study doctor when you complete a pre-screening questionnaire to confirm your eligibility to participate in the Trial;
* you provide it to us through your interactions with our marketing materials, advertisements, or official social media accounts; and
* you provide it to publicly available platforms and third-party sources such as LinkedIn.

## Purposes of Processing

We may process your Personal Data for the purposes of:

* responding to your requests or questions (including requests to exercise [your data protection rights](#_Your_Privacy_Rights));
  + This may also include reviewing other information that we have about you in order to respond to your requests or questions;
* managing and facilitating the Trial;
* enabling your participation in the Trial;
* answering the research questions for the Trial and aggregating data to generate statistics relating to the Trial and/or study drug or health treatment;
* arranging for the delivery of drugs to you and collection of unused drugs from you in relation to the Trial;
* arranging your transportation to or from the study site and overnight accommodations, as needed;
* sending you reminders about your appointments at the study site, or to take your medication on time;
* monitoring and reporting on any adverse events, such as negative side effects;
* developing new medicinal drugs or health treatments;
* communicating with you on the status of the Trial;
* payment processing;
* complying with legislation governing Trials;
* disclosing your Personal Data to the appropriate regulatory authorities, auditors, and ethics committees, if required by law;
* fulfilling legal obligations and enforcing our rights;
* addressing legal issues;
* marketing, advertising, and promoting our business;
* developing and improving our website; and
* maintaining the functionality and security of our website.

We also process your Personal Data for the specific purposes described in the Informed Consent Form (ICF) provided to you by Trial personnel.

## Basis of Processing

We may process your Personal Data on the basis of:

* Consent: We may ask for your consent to collect and process your Personal Data, including special categories of Personal Data, such as your health status and medical history.
* Contract: We may process your Personal Data to fulfill a contract we have with you.
* Legitimate Interests: We may process your Personal Data based on our legitimate interests in facilitating and managing our Trials.
* Compliance with Legal Obligations: We may need to process your Personal Data for us to comply with applicable laws or regulations, such as the laws regulating the safety and reliability of our Trials.
* Public Interest: We may process your Personal Data for reasons of public health interests to ensure adequate standards of quality and safety of the drugs or treatments we are developing.
* Any other ground, as required or permitted by law.

Where we process your Personal Data based on your consent, you may withdraw your consent at any time. However, this will not affect the lawfulness of our processing before you withdraw your consent. It will also not affect processing performed on other lawful grounds. If you withdraw your consent, you may be ineligible to participate in the Trial.

Where we receive your Personal Data as part of a contract we may have with you, we require such Personal Data to be able to carry out the contract. Without that necessary Personal Data, we will not be able to fulfill our contractual obligation to you.

Where we process Personal Data on the basis of our legitimate interests, you have the right to ask us more about how we decided to choose this legal basis. To do so, please use the contact details provided [here](#_Identity_and_Contact).

Since we process special categories of Personal Data, such as your health status and medical history, the EU General Data Protection Regulation (“**GDPR**”) requires that we must have an additional legal ground to process this type of information. TransThera may process your special categories of Personal Data on the basis of your explicit consent, or where the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes.

The specific grounds on which we process your Personal Data, including your health data, may vary somewhat from the above in order to comply with the requirements of local laws in jurisdictions where we sponsor Trials. If you are a participant in a Trial, please refer to the informed consent form you signed when you joined the Trial for more information about the legal grounds on which we process your Personal Data.

## Automated Individual Decision-Making

If you participate in a Trial we sponsor, you will be assigned a unique patient identification number. For a given trial, this number may be used as part of an automatic process that randomly determines if you will receive the experimental drug product or treatment that is being evaluated in the Trial, or if you will receive a placebo or different treatment. This number may also be used as part of an automatic process that randomly determines what level dose of the experimental drug product you will receive. This type of automated decision-making is required in order to ensure that the applicable Trial is conducted in an ethical way, and in accordance with the pharmaceutical industry’s standards.

For decisions that may seriously impact you, you have the “right not to be subject to automatic decision-making, including profiling." But in those cases, we will always explain to you when we might do this, why it is happening, and the potential effect on you.

## Cookies

A “cookie” is a small file stored on your device that contains information about your device. We may use cookies to provide website functionality, authentication (session management), usage analytics (web analytics), and to remember your settings, and to generally improve our websites.

For more information on how we use cookies, please refer to the cookie notice available on our website.

## Data Retention

We will retain your Personal Data for as long as it is necessary to fulfil the purpose(s) for which we collected your Personal Data (listed [above](#_Purpose_of_Processing)) and any other permitted purpose, and to comply with our data retention policies as applicable from time to time. For example, we will retain and use your Personal Data to the extent necessary to comply with our legal obligations (for example, if we are required to retain your data to comply with applicable laws), resolve disputes, and enforce our legal agreements and policies.

If your Personal Data is used for more than one purpose, we will retain it until the purpose with the longest retention period expires; but we will stop using it for the purpose with a shorter retention period once that period expires. Our retention periods are also based on our business needs and good practice.

Once your information has been entered into the Trial records, we cannot remove it without affecting the accuracy of the Trial and the test results. Some laws require us to keep Trial records for at least 25 years after the conclusion of the Trial. We will ensure that your Personal Data is safeguarded at all times.

## Sharing Personal Data With Third Parties

We may share Personal Data with our affiliates, as well as our service providers who process Personal Data on our behalf, and who agree to use the Personal Data only to assist us in fulfilling the purposes of processing as described in Section 7 above, or as required by law. Our service providers may include the following parties, either currently or in the future:

* contract/clinical research organization service providers;
* patient recruitment service providers;
* pathology laboratories;
* clinical pharmacology service providers;
* laboratory service providers;
* data management and biostatistics service providers;
* cardiac safety service providers;
* Trial oversight, imaging, and digital patient service providers;
* quality assurance, safety, and pharmacovigilance software and related service providers;
* data storage and archiving software and related service service providers;
* data analytics and reporting software and services service providers;
* providers of services related to the collection, storage, testing, and transportation of biological material;
* providers of software that randomly decides which dose level or treatment you will receive during the Trial;
* logistics and transport service providers;
* electronic data capture software and hardware providers;
* infrastructure services providers;
* internet service providers;
* cloud service providers;
* office tools and supplies providers;
* payment processing providers;
* customer survey providers;
* email service providers;
* web analytics providers;
* enterprise open-source solutions providers; and
* project management tool providers.

## International Transfers of Personal Data

The GDPR only allows us to transfer Personal Data outside of the European Union (“**EU**”) or the European Economic Area (“**EEA**”) if the country that the Personal Data is being transferred to offers an adequate level of protection for the Personal Data which is equivalent to EU law. TransThera operates in China and the United States of America (“**USA**”), both being outside the EU/EEA. We have implemented various safeguards to protect Personal Data, which enables us to receive EU Personal Data in China and the USA.

Some of our third-party service providers described [above](#_Sharing_Personal_Data) may also be located in countries outside of the EU/EEA. We will only transfer EU Personal Data to third parties outside the EU/EEA when there are appropriate safeguards in place. These safeguards may include the [Standard Contractual Clauses](https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en) as approved by the European Commission under [Article 46.2 of the GDPR](https://gdpr.verasafe.com/article-46/).

## Other Disclosure of Your Personal Data

We may disclose your Personal Data:

* with regulators or competent authorities, to the extent necessary to comply with applicable laws, regulations, and rules (including, without limitation, federal, state, or local laws);
* to the extent required by law, or if we have a good-faith belief that we need to disclose it in order to comply with official investigations or legal proceedings (whether initiated by governmental/law enforcement officials or private parties);
* if, in the future, we sell or transfer, or consider selling or transferring, part or all of our company, business, shares, or assets to a third party, and we disclose your Personal Data to such third party in connection with the sale or transfer; and
* in the event that we are acquired by, or merged with, a third-party entity, or in the event of bankruptcy or a comparable event, we reserve the right to transfer, disclose, or assign your Personal Data in connection with the foregoing events.

If we have to disclose your Personal Data to governmental/law enforcement officials, we may not be able to ensure that those officials will maintain the privacy and security of your Personal Data.

## Data Integrity and Security

We have implemented and will maintain technical, administrative, and physical measures that are reasonably designed to help protect Personal Data from unauthorized processing. This includes unauthorized access, disclosure, alteration, or destruction.

## Your Data Protection Rights

You have specific rights regarding your Personal Data that we collect and process.

For individual patients: To exercise the rights we explain below, **please first speak with your study doctor instead of contacting us directly.**

To exercise your data protection rights, **[INSERT COMMUNICATION METHOD].** Please provide as much information that you consider fit to help us identify you and swiftly treat your request.

## *Right to Know What Happens to Your Personal Data*

This is called the “right to be informed.” It means that you have the right to obtain from us all information regarding our data processing activities that concern you (or your child), such as how we collect and use your Personal Data, how long we will keep it, and with whom it will be shared with, among other things.

We are informing you of how we process your Personal Data with this Notice.

## *Right to Know What Personal Data TransThera Has About You*

This is called the “right of access.” This right allows you to ask for full details of the Personal Data we hold about you.

Once we receive and confirm that the request came from you or your authorized agent, we will disclose to you:

* the categories of your Personal Data that we process;
* the categories of sources from which we collect your Personal Data;
* our purposes for processing your Personal Data;
* where possible, the retention period for your Personal Data, or, if not possible, the criteria used to determine the retention period;
* the categories of third parties with whom we share your Personal Data;
* if we carry out automated decision-making, including profiling, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for you;
* the specific pieces of Personal Data we process about you in an easily sharable format;
* the categories of parties that received your Personal Data from us;
* if we rely on legitimate interests as a lawful basis to process your Personal Data, the specific legitimate interests; and
* the appropriate safeguards used to transfer Personal Data from the EEA to a third country, if applicable.

## *Right to Change Your Personal Data*

This is called the “right to rectification.” It gives you the right to ask us to correct anything that you think is wrong with the Personal Data we have on file about you (or your child), and to complete any incomplete Personal Data.

## *Right to Delete Your Personal Data*

This is called the “right to erasure,” “right to deletion,” or “right to be forgotten.” This right means that you can ask for your Personal Data to be deleted.

Sometimes, we can delete your information. But other times, it is not possible for either technical or legal reasons. If either of those reasons is the case, we will consider if we can [limit how we use your Personal Data](#_Right_to_Ask). We will also inform you of our reason for denying your deletion request.

## *Right to Ask Us to Limit How We Process Your Personal Data*

This is called the “right to restrict processing.” It is the right to ask us to only use or store your Personal Data for certain purposes. You have this right in certain instances, such as where you believe the data is inaccurate or the processing activity is unlawful.

## *Right to Ask Us to Stop Using Your Personal Data*

This is called the “right to object.” This is your right to tell us to stop using your Personal Data. You have this right where we rely on a legitimate interest of ours (or of a third party). **You may also object at any time to the processing of your Personal Data for direct marketing purposes.**

We will stop processing the relevant Personal Data unless: (i) we have compelling legitimate grounds for the processing that override your interests, rights, or freedoms; or (ii) we need to continue processing your Personal Data to establish, exercise, or defend a legal claim.

## *Right to Port or Move Your Personal Data*

This is called the “right to data portability.” It is the right to ask for and receive a portable copy of your Personal Data that you have given us, so that you can:

* move it;
* copy it;
* keep it for yourself; and/or
* transfer it to another organization.

We will provide your Personal Data in a structured, commonly used, and machine-readable format. When you request this information electronically, we will provide you a copy in electronic format.

## *Right Related to Automated Decision-Making*

We [sometimes use computers to study your Personal Data](#_Automated_Individual_Decision-Makin). For decisions that may seriously impact you, you have the right not to be subject to automated decision-making, including profiling. But in those cases, we will always explain to you when we might do this, why it is happening and the effect.

## *Right to Withdraw Your Consent*

Where we rely on your consent as the legal basis for processing your Personal Data, you may withdraw your consent at any time. If you withdraw your consent, our use of your Personal Data before you withdraw is still lawful.

As discussed [above](#_Basis_of_Processing), if we requested your consent to process your Personal Data, you have the right to withdraw your consent at any time. However, this will not affect the lawfulness of our processing before you withdraw your consent. It will also not affect processing performed on other lawful grounds. If you withdraw your consent, you may be ineligible to participate in the Trial.

## *Right to Lodge a Compliant with a Supervisory Authority*

If the GDPR applies to our processing of your Personal Data, you have the right to lodge a complaint with a supervisory authority if you are not satisfied with how we process your Personal Data.

Specifically, you can lodge a complaint in the Member State of the European Union of your habitual residence, place of work, or the alleged violation of the GDPR.

## Verification of Authority

If you are submitting a request on behalf of somebody else, we will need to verify your authority to act on behalf of that individual. When contacting us, please provide us with proof that the individual gave you signed permission to submit this request, a valid power of attorney on behalf of the individual, or proof of parental responsibility or legal guardianship. Alternatively, you may ask the individual to directly [contact us](#_Identity_and_Contact) by using the contact details above to verify their identity with TransThera and confirm with us that they gave you permission to submit this request.

## Privacy of Children

Our Trials are generally not directed at, or intended for use by, children under the age of 13.

## Changes to this Notice

If we change this Notice, we will publish the revised Notice on our website. We will also update the “Effective” date.