CLINICAL TRIALS PRIVACY POLICY

Overview

Retrophin, Inc., and its subsidiaries ("Retrophin" or "Company") is a biopharmaceutical company specializing in identifying, developing, and delivering life changing therapies to people living with rare diseases. In order to fulfill our mission, it is necessary that the Company engages in research and conduct clinical trials. Retrophin is committed to respecting the rights to privacy and data protection of all individuals that are involved in our clinical trials and the Company follows applicable privacy and data protection legislation. For our general approach to privacy, please see Retrophin's Privacy Policy which is posted on our website.

This policy addresses how Retrophin ensures individuals' privacy when conducting clinical trials. Retrophin will contract with service providers, such as Contract Research Organizations (CROs), or other service partners to collect and analyze clinical trial data. To enhance privacy, individual's names and other direct identifiers are not attached to records or samples collected by Retrophin or our service providers during the research process.

Who We Are

You may contact us, Retrophin, Inc., via mail at 3721 Valley Centre Drive, San Diego, CA 92130, Suite 200, Attn: Legal Department, via email at dataprotection@retrophin.com, or you can call us at +1-888-869-7879.

For the purposes of European Union (EU) and other data protection laws, Retrophin establishes the legitimate reasons to use an individual's data for clinical trials and have established the means/methods of processing this data for research purposes. Chosen service partners, including CROs, are selected based on qualifications that include ensuring patient privacy. Retrophin maintains an audit schedule for approved vendors involved in the clinical trials and reviews privacy adherence during these inspections. CROs are often involved in managing patient data for clinical trials. Depending on the nature of each trial, Retrophin is either the controller or joint-controller of the processing operations associated with the clinical trial.

Patients enrolled in Retrophin clinical trials can contact the Company, as noted above, if there are questions related to how a patient's data is being collected or processed within the trial.

Types of Personal Data Retrophin Collects and Uses

"Personal data" or "data" is defined as any information related to an identified or identifiable individual. Depending on the context in which Retrophin processes personal data, Retrophin will collect and otherwise process:

The pseudonyms of trial subjects (unique codes assigned to every subject); Professional profiles, identification data and contact information of healthcare providers that participate in the trial as investigators; Information related to clinical trial execution by investigators and supporting staff during the trial; Financial disclosure information, CVs and medical licenses for principal and sub-investigators conducting the clinical research.

What Retrophin Does With Personal Data

In the pre-trial phase, through the CROs, Retrophin collects identification and contact information of healthcare professionals that are considered for study participation. Retrophin collects this data from our own or the CROs' databases, from public sources, referrals or third party vendors.

Through the Company's CROs, Retrophin collects, uses, stores and analyzes data and bio-medical samples related to clinical trial subjects. The subjects' names and other direct identifiers are not attached to records or samples. Instead, each subject is assigned a unique code (pseudonym). An individual's identity is maintained by the clinical trial investigators and authorized study personnel at the clinical trial sites. Only authorized individuals including study staff, CROs, and monitors may access named subject records at the source under limited conditions.

As a trial sponsor, Retrophin may occasionally request access certain data directly. Retrophin does so only when this is necessary to comply with legal obligations, legal requests from authorities or for accountability purposes.

Our Policy Towards Children

Some of Retrophin's clinical trials involve participants that are children. Retrophin only processes a child's personal data with parental consent or the consent of a legal representative and in accordance with the laws where the clinical trial is being conducted.

Purposes for Collecting and Processing Data

Retrophin processes the personal data enumerated above for the following purposes: Research; Identify potential investigators to participate in a clinical trial; Pharmacovigilance; Evaluating the patient recruitment performance of clinical research centers.

Grounds for Processing

For those processing activities that fall under the EU data protection law, the legitimate grounds for processing data that Retrophin relies on are:

Written consent, for all personal data related to health, biometric and genetic data, as well as any other sensitive information, such as race, ethnicity, and sexual orientation that may be collected pre-trial or revealed through the trial. Retrophin's legitimate interest to conduct clinical research efforts to advance treatment for rare diseases. The necessity to enter and execute legal agreements with clinical trial investigators. Compliance with legal obligations and best practices.

Who Has Access to The Data

Due to the inherent sensitivity of the activity and information quality surrounding a clinical trial, access to personal data is very limited and it is granted on a "need to know" basis for the purpose of managing and conducting clinical trials. Retrophin will also give access to data

following legal requests for access made by government and enforcement authorities, or to comply with any other legal requirement. Clinical trial auditors can also obtain access to personal data as necessary.

Data Integrity

Retrophin takes reasonable steps to ensure that data is reliable for its intended use, accurate, complete, and is current. Retrophin also ensures data is limited to the information relevant for purposes of processing.

Transfers of Data Overseas & Privacy Shield Principles

If a clinical trial participant is located outside the United States (US) and participates in one of Retrophin's clinical trials, their personal data would be transferred to the US.

If the clinical study participant is based in the EU, the EEA or Switzerland, the US has not obtained an adequacy decision for the level of protection afforded to personal data. However, Retrophin provides appropriate safeguards for data in the US, as the company subscribes to the EU-US Privacy Shield and the Swiss-US Privacy Shield.

How Clinical Trial Participants Control Their Data

If clinical trial participants reside or otherwise find themselves in the territory of the EU, Retrophin is committed to facilitate the exercise of their rights granted by EU data protection law in a timely manner – the right of clinical trial participants to access their data, to ask for erasure, correction, portability of their data or to object to the processing of their data. In order to be able to reply to their request and if Retrophin is not certain of the clinical patient's identity, Retrophin may need to ask them for further identification data to be used only for the purposes of replying to the request. If the clinical trial participant has any inquiries, they can email dataprotection@retrophin.com or contact us as noted above via phone or postal mail.

For clinical trials, Retrophin will ensure contractually that the CROs provide all required support to comply with lawful requests made by persons whose data Retrophin controls or processes.

Automated Decisions

Retrophin does not use personal data to engage in automated decision-making as part of the clinical trial process.

Data Security

Retrophin is committed to processing data in a secure manner. The Company has put in place specific technical and organizational measures to prevent research data from being accidentally or deliberately compromised, including requirements for high security standards from service providers contracted by Retrophin.

Clinical trial participants can withdraw consent at any time suspending further data collection efforts. All data collected and processed prior to the withdrawal of consent is lawful to be used by Retrophin.

Concerns

Clinical trial participants can contact Retrophin's Chief Compliance & Privacy Officer at dataprotection@retrophin.com or via phone or postal mail as noted above to discuss concerns or questions about how their personal data is used, or if they want to exercise their rights granted under the EU data protection law. Retrophin will promptly respond to address the concern.

Clinical trial participants should also consider contacting their investigative site directly.

If, after attempting to address privacy questions or concerns with Retrophin directly you still have a specific privacy concern that has not been resolved, you may utilize any of the following methods for resolution:

Choose to mediate your concern by the neutral third party, the American Arbitration Association, for the personal data that falls under the EU-US Privacy Shield and/or the Swiss-US Privacy Shield. Submit your unresolved privacy concern to the American Arbitration Association for resolution.

American Arbitration Association
Case Filing Services
877.495.4185: Toll free
877.304.8457: Fax
casefiling@adr.org

Contact your Data Protection Authority: If you are based in the EU or the EEA, you may choose to contact your local Data Protection Authority ("DPA"), or the Swiss Federal Data Protection and Information Commissioner, if you are based in Switzerland. Your DPA or the Swiss Commissioner may refer your complaint directly to the Department of Commerce on your behalf. In this case, the Privacy Shield Team will then work to resolve your concern.

US Department of Commerce's Privacy Shield Framework: you may also have the option to select binding arbitration for the resolution of your complaint under certain circumstances. For more information on binding arbitration, see US Department of Commerce's Privacy Shield Framework.

For purposes of enforcing compliance with Privacy Shield, Retrophin is subject to the investigatory and enforcement authority of the US Federal Trade Commission. For more information about Privacy Shield and to view Retrophin's certification page, please visit the website of the US Federal Trade Commission on Privacy Shield located at: (https://www.privacyshield.gov).

Changes to This Notice

Retrophin reserves the right at any time, to modify, alter, or update this policy as warranted. The date of last revision is indicated by the date stamp on the policy.

This Policy was last updated on August 2, 2019.