BOEHRINGER INGELHEIM International GmbH
Investigator Privacy Notice

Privacy Notice

Boehringer Ingelheim Pharma GmbH & Co. KG. (hereinafter “Boehringer Ingelheim”, “we”, “our”, “us”) takes the protection of your personal data seriously. We use physical, electronic and procedural measures to protect people’s personal data in accordance with data protection legislative requirements. You can find more information about Boehringer Ingelheim here:

With this Privacy Notice we inform you how we will use, collect, store and disclose (hereinafter together “process”) personal data collected about you in the context of your involvement in clinical trials and other related research projects (hereinafter “Trial(s)”) performed by or on behalf of Boehringer Ingelheim or other members of the Boehringer Ingelheim Group of Companies (hereinafter “Boehringer Ingelheim Affiliates”).

We will only process your personal data in accordance with applicable data protection and privacy laws.

1. Data controller
Boehringer Ingelheim Pharma GmbH & Co. KG.
Binger Straße 173
D-55216 Ingelheim am Rhein
Germany
Email: datenschutz@boehringer-ingelheim.com

2. Personal data we collect about you
In connection with a Trial Boehringer Ingelheim is processing the following categories of personal data: name, date of birth, work experience and professional qualifications, specialisations, board certification, publications, resumes and educational background, contact data (phone, fax, email, business address), your participation in Trial(s), your Trial role (e.g. principal investigator), associated clinical sites/centres.

During a Trial Boehringer Ingelheim may also grant you access to the Boehringer Ingelheim Clinical Trial Portal (“BICTP”). The purpose of the BICTP is to support and facilitate Trials performed by or on behalf of Boehringer Ingelheim at all levels (site, country, trial level) and throughout the complete lifecycle of a Trial and the collaboration between investigational site users (e.g., investigators, Trial coordinators, administrative site staff), BI employees, external staff working on BI’s behalf (e.g., Contract Research Organization (CROs), other third party vendors, freelancers), competent governmental or regulatory authorities, investigators, and ethics committees/institutional review boards. In addition to the personal data mentioned above we may process account and/or login information relating to the BICTP.

3. Purposes for which we process your personal data
Boehringer Ingelheim will process your personal data for the following purposes:

a) Administering the Trial by processing your name, date of birth, work experience and professional qualifications, specialisations, board certification, publications, resumes and educational background, contact data (phone, fax, email, business address), bank details, your participation in Trial(s), your Trial role (e.g. principal investigator), associated clinical
sites/centres and including processing personal data related to the BICTP as well as processing personal data as part of an e-consent solution.

**Legal basis:** Fulfilment of a contractual obligation in accordance with Article 6 (1) lit. b GDPR and/or BI’s legitimate interests (to enable us to conduct Trials) in accordance with Article 6 (1) lit. f GDPR.

b) **Conducting the Trial** pursuant to the respective Trial protocol including monitoring, source data / document verification, audits, pharmacovigilance and related risk management according to applicable laws and Good Clinical Practice as provided by the International Conference on Harmonisation (ICH) and including processing personal data related to the BICTP.

**Legal basis:** Compliance with a legal obligation in accordance with Article 6 (1) lit. c GDPR, performance of a task carried out in the public interest in accordance with Article 6 (1) lit. e GDPR and/or BI’s legitimate interests (to enable us to conduct Trials) in accordance with Article 6 (1) lit. f GDPR.

c) **Sharing with ethics committees / institutional review boards and governmental or regulatory authorities,** such as the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) or reimbursement authorities where necessary to fulfil legal and regulatory requirements, namely when required:  
   o in an application, approval, inspection or other regulatory procedure,  
   o in a Health Technology Assessment (HTA) / reimbursement procedure,  
   o to ensure transparency about financial arrangements with investigators (especially as required by the FDA), or  
   o for pharmacovigilance purposes.

**Legal basis:** Compliance with a legal obligation in accordance with Article 6 (1) lit. c GDPR and/or performance of a task carried out in the public interest in accordance with Article 6 (1) lit. e GDPR.

d) **Selection of investigators for future Trials** including processing personal data related to the BICTP, processing data in an investigator registry and routine controls with international sanction lists.

**Legal basis:** BI’s legitimate interests (to enable us to conduct Trials) in accordance with Article 6 (1) lit. f GDPR.

e) **Providing transparency about the Trial** by  
   o registering the Trial on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (disclosure of data is limited to name or title, telephone number, and email address of the principal investigator) and on [www.encepp.eu](http://www.encepp.eu) (disclosure of data is limited to name, address, and email address of the primary (lead) investigator), and  
   o sharing of Trial data, reports and other Trial related documents with third parties in accordance with the principles for responsible data clinical trial data sharing.
f) **Processing personal data in an investigator registry** including processing personal data with other authorized pharmaceutical companies and service providers,

- in order to facilitate better collaboration and information-sharing across the biopharmaceutical research and development community.
- to contact an investigator for the purposes of conducting feasibility surveys, site identification, assessment, and qualification for Trial opportunities, and other operational purposes related to Trial conduct such as training and document exchange.

**Legal basis:** Compliance with a legal obligation in accordance with Article 6 (1) lit. c GDPR and/or BI's legitimate interests (to enable us to conduct Trials and to fulfil legal obligations arising from non-EU countries) in accordance with Article 6 (1) lit. f GDPR.

4. **Who do we share your personal data with**

To fulfil the purposes described above, we may share your personal data internally or externally as follows:

a) Your participation in a Trial may be made available to other departments at Boehringer Ingelheim that communicate with you, such as medical scientific liaisons, who will interact with you and advise you in the most efficient way.

b) We may share your personal data for the purposes mentioned above also with other Boehringer Ingelheim Affiliates.

c) As a pharmaceutical company, we are subject to specific regulations, such as pharmacovigilance. Some of these laws require us to send your reports to regulators or other authorities worldwide. We only provide authorities with personal data if we are legally obliged to do so.

d) We may share your personal data with third party service providers, including as part of the investigator registry mentioned above also with the operator and host of this registry, DrugDev, Inc., the world headquarters of which is at 1170 Devon Park Drive, Suite 300, Wayne, PA 19087, United States of America.

e) We may share your personal data as part of the investigator registry mentioned above also with other pharmaceutical companies. A list of current pharmaceutical companies authorized to access the investigator registry is available [here](#).

Your personal data may be accessed by staff or suppliers in, transferred to, and/or stored at, a destination outside the European Economic Area (EEA) in which data protection laws may be of a lower standard than in the EEA. Regardless of location or whether the person is an employee or contractor we will impose the same data protection safeguards that we deploy inside the EEA and have, in compliance with applicable law, taken steps to ensure that your personal data remains secure. For example, we put in place contractual protections that have been approved by competent bodies in the EU. Should you wish to receive more information...
about these transfers or a copy of the agreements, please contact us using the address information in Section 8.

5. Retention of Personal Data
Boehringer Ingelheim processes your personal data for as long as necessary for the purpose of the processing.

As we are obliged to demonstrate that the Trial(s) has / have been conducted in accordance with legal and regulatory requirements, we will store your personal data relating to Trials for a maximum period of thirty (30) years.

We store your user account data (login, profession, name etc.) relating to the BICTP for as long as you maintain a user account with us or as long as we are legally obliged to store the personal data.

6. Cookies
In the context of your Trial involvement you may be asked to submit data via the BICTP.

BI uses “cookie” technology on its BICTP website. A cookie is a small text file, downloaded on to a device when the user accesses certain websites. These cookies are stored on your computer by your browser. When you log in, the cookie tells Boehringer Ingelheim whether you have visited the BICTP before or you are a new visitor. The cookie does not obtain any personal information about you or provide Boehringer Ingelheim with any way to contact you and the cookie does not extract any information from your computer.

This website uses only technical cookies to provide basic functionality of this website such as re-establishing a user’s session at login if their previous session was cancelled due to user inactivity. These technical cookies are strictly necessary to use to the BICTP.

7. Data Protection Rights
As a person affected by our data processing, you have certain rights:

a) Right of access: You have a right to be provided with access to any data held about you and to request a copy of the personal data collected about you.

b) Right to rectification: You have the right to request the completion or rectification of incorrect personal data concerning you if it is incorrect or incomplete.

c) Right to erasure: You may request the deletion of your personal data. If applicable, we will take reasonable steps to inform other controllers that are processing the personal data that you have requested the erasure of any links to, copies or replication of it.

d) Right to restriction of processing: You may request the restriction of the processing of certain personal data for the duration of a complaint procedure or for specific other reasons.

e) Revocation of consent: In general, we only process your data to fulfil the contract and do not ask for your consent for any further processing. If you have nevertheless given us your consent to further processing of your personal data in individual cases, you can revoke this
consent and prevent further data processing, provided that no other justification is relevant. This right of revocation does not apply to the data that we store for the purpose of fulfilling the contract.

f) **Right to data portability**: You may request that we transfer electronically your personal data that you have provided to us and which we have still stored to another person in charge.

g) **Right to complain**: You can complain about our data processing to us or to the competent data protection authority. Boehringer Ingelheim is supervised by:

Der Landesbeauftragte für den Datenschutz und die Informationsfreiheit Rheinland-Pfalz
Prof. Dr. Dieter Kugelmann
Hintere Bleiche 34
55116 Mainz

Phone: +49 (0) 6131 208-2449
Fax: +49 (0) 6131 208-2497
Website: [https://www.datenschutz.rlp.de/](https://www.datenschutz.rlp.de/)
Email: poststelle@datenschutz.rlp.de

Please note that there are exceptions to the above rights and that you cannot exercise these rights in every situation.

8. **Your contact for any queries**

Please send your request or any question you have in relation to our processing of your personal data to:

Boehringer Ingelheim Pharma GmbH & Co. KG
– Data Protection Officer –
Binger Straße 173
D-55216 Ingelheim am Rhein
Germany
Email: [datenschutz@boehringer-ingelheim.com](mailto:datenschutz@boehringer-ingelheim.com).