These **Terms & Conditions** govern the access to, and any use of, any part of the **Boehringer Ingelheim Clinical Trial Portal (hereinafter “BICTP”),** any document, material or other information, including text, images, sound and software (hereinafter “Information”) made available on the BICTP and your relationship with the owner of the BICTP, Boehringer Ingelheim Pharma GmbH & Co. KG, and its affiliates, subsidiaries, parent companies and/or other members of the Boehringer Ingelheim Group of Companies, including but not limited to the companies listed in the current Boehringer Ingelheim annual report (available under [http://www.boehringer-ingelheim.com/corporate_profile/annual_report.html](http://www.boehringer-ingelheim.com/corporate_profile/annual_report.html)), (hereinafter jointly “BI”). **By clicking “I Accept”, you confirm that you have read and understood the Terms & Conditions and that you accept them.** If you do not agree to be bound by these Terms & Conditions you may not use the BICTP.

**PART I: GENERAL PROVISIONS**

For additional particular provisions concerning the access to, and any use of the BICTP from and in the countries Brazil, China, Spain and United States of America, please see also Part II of these Terms & Conditions.

1 **PURPOSE OF THE BICTP, MODIFICATIONS, ACCESS**

1.1 The purpose of the BICTP is to support and facilitate clinical trials and other related research projects (hereinafter “Trial[s]”) performed by or on behalf of BI 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 for the following activities:

- Distribution, collection, review, and electronic approval of regulatory documents required for site initiation and maintenance;
- Distribution of safety relevant information to institutions / investigators;
- Provisioning of Trial documentation, templates, manuals and tools for Trial conduct;
- Distribution and tracking of essential written communications during the course of the Trial;

The BICTP must not be used by investigators/institutions:

- For the reporting of adverse events to BI outside of the AE/SAE reporting procedures defined for the BI Trial
- For uploading or sharing documents/records containing patient/subject identifying information
- For official filing of site generated documents. Original site generated documents must be filed locally at the respective site.

According to regulatory requirements and in order to be compliant with Good Clinical Practices (GCP), this requires also a managed database containing individual records of investigators, site staff and other persons involved or planned to be involved in a Trial.

1.2 BI reserves the right to modify (including a change in the system environment), limit or discontinue - in full or in part - the BICTP at any time, to restrict access to the BICTP and to deny, at its sole discretion, any user’s access to the BICTP or any part thereof. In case BI does modify, limit or discontinue the BICTP, in full or in part, restricts access to the BICTP and/or denies a user’s access to the BICTP or any part thereof and any such actions results in an institution not having full access to the Information, BI will, at the institution’s discretion, transfer Information necessary to comply with mandatory statutory provision and/or regulations to the institution. Afterwards or, if the institution does not require transfer and/or access to the Information, BI might at its discretion permanently delete the respective Information. BI shall give notice to the institution in case of a modification, limitation or
discontinuation of the BICTP, restriction or denial of access to the BICTP or any part thereof with a reasonable lead
time, unless such notice is not feasible due to temporal or factual circumstances.

2 USER OBLIGATIONS, REGISTRATION, PASSWORD

2.1 Users of the BICTP must comply with all applicable laws and regulations. They must refrain from violating or
attempting to violate the BI's network security, and, in particular, from uploading onto BICTP or attaching to
communication via BICTP virus-containing or corrupted files or any software or programs that might damage the
operation of the BICTP or another user’s computer.

2.2 The use of the BICTP requires prior registration. Users must ensure to provide correct and complete information
when registering, and update it if necessary without undue delay. They must not misuse any access authorization
granted to them (for example by transferring data to unauthorized third persons).

2.3 Upon registration the user will be provided with an access code, comprising a unique user ID and a password
("User Data"). On first access the user shall promptly change the password received from BI into a password
known only to the user.

2.4 Registered users are responsible for maintaining the confidentiality of their account and password to prevent
unauthorized access to that account. Users must take all necessary steps to keep their password secure and must
inform BI immediately if it is being or could be used without authorization. Users must not attempt to access the
personal data of any other user of the BICTP. Users must not provide their login details to other users and users
must not login with another person’s User ID.

2.5 Each user agrees not to contribute content that may be infringing of a third party’s intellectual property or that
contain any material which is defamatory, obscene, indecent, abusive, offensive, harassing, violent, hateful,
inflammatory or otherwise objectionable. Furthermore, the user shall not intentionally provide any false or
misleading information; including misrepresentation of affiliation with any person or organization.

2.6 In case a user contributes content that contains personal data or the personal data of other persons, such user
represents and warrants that it has complied with relevant privacy laws, including, without limitation, obtaining
consents required thereunder.

3 INTELLECTUAL PROPERTY

3.1 BI owns all right, title and interest, including all intellectual property rights related to the BICTP. It equally owns all
intellectual property rights to, or is licensed to use, all material uploaded by BI onto the BICTP. BI shall remain the
sole owner of all such intellectual property rights, and BI reserves the right to pursue any infringement of its
intellectual property rights.

3.2 BI grants the user a non-exclusive, non-transferable and limited right (i) to access and use the BICTP as well as the
Information provided by BI on the BICTP, and (ii) to download the Information accessible to the user onto the hard
drive of its computer(s) for the sole purpose of its internal professional business with regard to the BI Trials. For
this purpose, users of the BICTP may print off a copy, and may download extracts, of any page(s) provided on or
through the BICTP by BI. Users must not modify the paper or digital copies of any materials provided by BI they
have printed off or downloaded in any way, and must not use any illustrations, photographs, video or audio
sequences or any graphics separately from any accompanying text. Further, users must not sub-license the
information related to the BICTP and provided by BI to any third party.
3.3 No license is granted in these Terms & Conditions to use any trade name or trademark of BI or its affiliated companies. Users of the BICTP shall not assert any claim or ownership to any trade names or trademarks or to the goodwill or reputation of BI or its affiliated companies. BI’s status (and that of any identified contributors) as the authors or owners of material provided on the BICTP must always be acknowledged.

3.4 Users of the BICTP must not use any part of the materials provided on the BICTP for commercial purposes other than the participation in a BI Trial without obtaining a license to do so before from BI or BI’s licensors.

3.5 If you use, print off, copy or download any part of or content provided on the BICTP in breach of these Terms & Conditions, your right to use the BICTP will cease immediately in accordance with the provisions set out in Section 1.2.

3.6 Notwithstanding mandatory statutory limitations, no rights other than those expressly referred to herein shall be assigned to the user.

3.7 Each user is and remains responsible for all content it contributes to or on the BICTP, including text, photos, videos, audio and links. By contributing content to the BICTP, the user grants BI a worldwide, non-exclusive, perpetual, irrevocable, royalty-free, sub-licensable, transferable licence to use such content limited to the purpose set out in Section 1 and Section 8. The user retains all copyright and any other rights that it holds on such content. In case BI is alleged to be infringing any rights of third parties arising from the use of such content, any user who contributes the content to the BICTP shall indemnify and hold BI harmless from and against any liabilities, claims, demands and expenses arising from the above use.

4 TECHNICAL ERRORS AND MALFUNCTIONS, AVAILABILITY

4.1 BI aims at minimising technical errors and malfunctions. However, some data or other parts of the Information may have been created or structured in files or formats that are not error-free. BI cannot guarantee that the underlying files and the formats used are error-free and will not cause the user's systems to malfunction.

4.2 BI aims at ensuring that the availability of the BICTP will be essentially uninterrupted and that transmissions will be error-free. However, this cannot be guaranteed. Access to the BICTP may also occasionally and temporary be suspended, restricted or impeded to permit repairs, maintenance or the introduction of new services or facilities. Furthermore, if the BICTP is overloaded or malfunctioning, or if an overload or malfunction is imminent, this may restrict access to the BICTP or close it down altogether. For such situation, BI provides access to back-up documents and ensure continued access to relevant documents.

4.3 Although BI aims at keeping the BICTP free from viruses, BI cannot make any guarantee that it is virus-free. The user shall, for its own protection, take the necessary steps to ensure appropriate security measures and shall utilize a virus scanner before downloading any information, software or documentation.

5 CONFIDENTIAL MATERIAL

5.1 User acknowledges that all data, know-how, material, and other information provided on the BICTP shall be considered confidential information, either of BI or of the user, depending on who uploaded the respective material onto the BICTP (“Confidential Information”).

5.2 All Confidential Information uploaded on the BICTP by BI is proprietary, confidential information of BI and its affiliated companies. By logging on to the BICTP, the user agrees to keep this information strictly confidential and not to disclose the Confidential Information to any third party whatsoever.
5.3 The user may disclose such Confidential Information only to persons who require access thereto for purposes relating to the respective BI Trial, provided, however, that prior to making any such disclosures user must bind such person by a written confidentiality obligation.

5.4 Nothing contained herein will, however, in any way restrict or impair any party’s right to use, disclose, or otherwise deal with any information which at the time of its receipt:

5.4.1 is generally available in the public domain or becomes available to the public through no act of the party receiving said Confidential Information; or
5.4.2 is independently known by the party receiving the Confidential Information, prior to receipt thereof, which said party can demonstrate by documented proof; or
5.4.3 is lawfully given to the receiving party by a third party who is not bound by any obligation to preserve it as confidential, or
5.4.4 is required by any law, rule, regulation, order, decision, decree or subpoena or other judicial, administrative or legal process to be disclosed.

6 ELECTRONIC SIGNATURES

Certain documents provided in the BICTP for the conduct of a BI Trial may request you to provide an electronic signature by giving your username and password. You agree and acknowledge that provided electronic signatures shall form a legally binding agreement. This electronic signature shall be equivalent to your hand-written signature.

7 THIRD PARTY WEBSITES AND LINKS

7.1 BI is not responsible for the content of any third-party website providing links to the BICTP.

7.2 The BICTP may contain links to websites/references to third-party websites. BI makes no warranties, undertakings or representations of any kind as to the legality of the contents, accuracy, currency, quality, completeness or fitness for purpose of any information contained in such websites and shall have no liability for any loss, damage or cost of any kind arising from such information. Inclusion of any third party link does not imply an endorsement or recommendation by BI. The use of such websites is at the sole risk of the user.

7.3 The BICTP must not be framed on any other website, nor may users create a link to any part of the BICTP other than the home page without BI’s prior written permission. BI reserves the right to withdraw linking permission at any time. The website used for linking must comply in all respects with the content standards set out in these Terms & Conditions.

8 HANDLING OF MATERIAL OF THE INVESTIGATOR/INSTITUTION

Users acknowledge and agree that BI may preserve and disclose materials and other information posted and/or provided by the user on the BICTP, including Confidential Information of the user, if required (i) by law or legal process, (ii) in the course of inspections governmental or regulatory, (iii) to enforce these Terms & Conditions, (iv) to respond to claims that such material violates the rights of third parties, (v) to protect BI’s rights and/or property, or rights and/or the property of other users of the BICTP and the general public and/or (vi) in accordance with the purposes detailed in Section 1.
9 LIMITATION OF LIABILITY

9.1 BI's liability in contract, tort (including negligence or breach of a statutory duty), misrepresentation or otherwise, for damages arising directly or indirectly out of or in connection with the provision of the services related to the BICTP or any delay in providing any such services shall be limited to the liability arising from the following reasons:

9.1.1 violation of essential contract obligations, i.e. obligations the fulfilment of which serve to make the correct and proper execution of the contract possible in the first place and on the compliance with which the user relies and may reasonably place its trust. Such liability shall be limited to direct and/or tangible (material) and/or bodily damages in relation with the performance of these Terms and Conditions and foreseeable at the time of contract closure;

9.1.2 gross negligence, wilful conduct, fraudulent concealment of a defect or the acceptance of a guarantee;

9.1.3 injury to life, body or health.

9.2 The BICTP is provided by BI, free of charge, without any warranties or guarantees. Notwithstanding Section 9.1 above, BI shall not be liable and accepts no representation or responsibility for (i) access to or availability of the BICTP, or (ii) the accuracy, adequacy, completeness, comprehensiveness, usefulness, reliability, timeliness, quality of the Information, computer viruses or other harmful components, or (iii) technical errors and malfunctions, communication line failure the user encounters as a result of using the BICTP or any linked external sites, or (iv) for the speed of access or slowdown in the communication of information through the BICTP.

9.3 Notwithstanding Section 9.1 above, BI is not liable for any material or immaterial damages that are caused directly or indirectly through the use of the Information provided on the BICTP.

9.4 Notwithstanding Section 9.1 above, BI expressly disclaims all warranties and representations of any kind with respect to the information and related materials, whether expressed or implied, including any implied warranties of fitness for a particular purpose, non-infringement or non-interference with title. Due to the number of sources from which information is obtained on the BICTP, and the inherent hazards of electronic distribution, there may be delays, omissions, or inaccuracies. The information and related materials could include technical or other inaccuracies or typographical errors, and may not be available without interruption. These provisions are not intended to limit BI's liability in breach of any national law applicable or to exclude its liability for matters which cannot be excluded under such law.

10 SEVERABILITY

If any provision of these Terms & Conditions is for any reason held to be invalid, illegal or otherwise unenforceable, such unenforceability does not affect any other provision; the Terms & Conditions are then to be construed as if they had never contained the provision(s) in question and are to be interpreted, in so far as possible, in such a way as to maintain their original intent.

11 GOVERNING LAW

Your use of the BICTP and these Terms & Conditions shall in all respects be governed by the laws of Germany without reference to any conflict-of-law rules.

12 LANGUAGE

The Parties declare that they have requested and do hereby confirm their request that this Agreement be in English only. Herewith, the Parties confirm that they fully understand the English language.
13 RELATIONSHIP TO THE BI TRIALS

Section 1.2 also applies in case BI discontinues any BI Trial for any reason.

In case BI discontinues any BI Trial for any reason, BI will, at the institution’s discretion, either transfer Information necessary to comply with mandatory statutory provision and/or regulations to the institution. Afterwards, or, if the institution does not require transfer and/or access to the Information, at BI’s discretion permanently delete the respective Information. BI shall give notice to the institution in case of a modification, limitation or discontinuation of the BICTP, restriction or denial of access to the BICTP or any part thereof with a reasonable lead time, unless such notice is not feasible due to temporal or factual circumstances.

PART II: COUNTRY SPECIFICATIONS

1 BRAZIL

Regarding the access to and the use of the BICTP from and in Brazil, the following additional provision shall apply:

Section 11 of these Terms and Conditions shall be changed to the following paragraphs:

“Your use of the BICTP and these Terms & Conditions shall in all respects be governed by the laws of Brazil without reference to any conflict-of-law rules.

Any dispute arising out of or in connection with these Terms & Conditions or over their validity shall be resolved through friendly consultation. If no agreement can be reached within thirty (30) days after the dispute has arisen, the dispute shall, be decided by the judicial courts of São Paulo.”

2 CHINA

Regarding the access to and the use of the BICTP from and in China, the following additional provision shall apply:

Section 11 of these Terms and Conditions shall be supplemented by a second paragraph:

“Any dispute arising out of or in connection with these Terms & Conditions or over their validity shall be resolved through friendly consultation. If no agreement can be reached within thirty (30) days after the dispute has arisen, the dispute shall, to the exclusion of the ordinary courts of law, only be submitted for arbitration to Zurich Chamber of Commerce, and shall be decided according to the Arbitration Rules of the Swiss Chambers of Commerce on the date of submitting the request for arbitration. The place of arbitration shall be Zurich. All arbitration proceedings shall be conducted in English language.

The arbitration tribunal shall consist of three (3) arbitrators. Each Party shall appoint one (1) arbitrator. The third arbitrator, who shall act as chairman of the arbitration tribunal and shall be of neither German nor Chinese nationality, shall be jointly appointed by the above-mentioned arbitrators. If a Party fails to appoint its arbitrator within one (1) month after receipt of the notice of arbitration by the arbitration commission or in case the arbitrators fail to reach an agreement on the chairman within 1 (one) month after they have been appointed, the respective arbitrator or the chairman shall be appointed by the Chairman of the Zurich Chamber of Commerce.
The arbitral award shall be final and binding on all Parties. The arbitration fee and the winning Party’s reasonable expenses, including lawyers’ fees, shall be borne by the losing Party except awarded otherwise by the arbitration tribunal. Petition for enforcement of the arbitral award may be filed with any court having jurisdiction thereof.

During the arbitration proceedings, the Parties shall continue to perform these Terms & Conditions except for the provisions which are under dispute.”

3 SPAIN

Ownership of the BICTP website
Boehringer Ingelheim Pharma GmbH & Co. KG. Binger Straße 173
D-55216 Ingelheim am Rhein
Commercial Register: Registration Court Mainz HR A 22206 VAT Identification Number: DE 143290578
Tel: +49 69 170 776 743
Fax: +49 2151 780 9701
E-Mail: bi@cts-helpdesk.com

General
If any provision in these Terms & Conditions conflicts with or is inconsistent with any Spanish law or regulation, the applicable Spanish law or regulation shall pre-empt that provision.

Additional to the Terms & Conditions set out here, your acceptance and consent to the BICTP Data Protection Information (provided separately) is also a Term and Condition of using BICTP.

The Terms & Conditions and Cookies Policy of the Boehringer Ingelheim Clinical Trial Portal (BICTP) will be provided by Boehringer Ingelheim España, S.A. to the users of such portal duly translated in Spanish.

4 UNITED STATES OF AMERICA

4.1 General

4.1.1 Notwithstanding the forgoing, if this agreement is made with an agency of the Federal Government, it shall be governed by U.S. Federal law, as applied by the Federal courts in the District of Columbia.

4.1.2 If any provision in these Terms & Conditions conflicts with or is inconsistent with any U.S. Federal law or regulation, the applicable U.S. Federal law or regulation shall pre-empt that provision.

4.2 Copyright Policy – U.S. Digital Millennium Copyright Act

4.2.1 BI takes copyright violations very seriously and it is BI’s policy to respond to clear, complete notices of alleged copyright infringement that comply with the U.S. Digital Millennium Copyright Act and other intellectual property laws. This section describes how to submit a notice of infringement. The form of notice specified below is consistent with the form suggested by the United States Digital Millennium Copyright Act but we will do our best to respond to notices from any jurisdiction.

4.2.2 BI’s response to these notices may include removing or disabling access to material claimed to be the subject of infringing activity and/or terminating subscribers. In some circumstances, in order to notify the subscriber, account holder or host who provided the allegedly infringing content to which we have disabled access, we may forward a copy of a valid Notice including name and email address to the
subscriber or account holder, or may forward a copy of a valid Notice (with personally identifiable information removed) to Chilling Effects (http://www.chillingeffects.org) for publication.

4.2.3 To file a notice of infringement with us, you must provide a written communication (by fax or regular mail - not by email, except by prior agreement) that sets forth the items specified below. Please note that you could be liable for damages (including costs and attorneys' fees) if you submit a fraudulent notice or misrepresent that a product or activity is infringing your copyrights.

Please use the following format (including section numbers):

a) Identify in sufficient detail the copyrighted work that you believe has been infringed and its location. The title, nature, ISBN or other identifying number of the work, a brief description of the work, plus a specific URL, that is the Web address or other location where it appears.

b) Identify the material that you claim is infringing the copyrighted work listed in item #1 above, along with a copy of the specific URL where the allegedly infringing work appears.

c) Provide information reasonably sufficient to permit BI to contact you (email address is preferred).

d) Provide information, if possible, sufficient to permit BI to notify the owner / administrator of the allegedly infringing webpage or other content (email address is preferred).

e) Include the following statement: "I have a good faith belief that use of the copyrighted materials described above as allegedly infringing is not authorized by the copyright owner, its agent, or the law."

f) Include the following statement: "I swear, under penalty of perjury, that the information in the notification is accurate and that I am the copyright owner or am authorized to act on behalf of the owner of an exclusive right that is allegedly infringed."

g) Sign the paper.

h) Send the written communication to the following address:

Boehringer Ingelheim Pharmaceuticals Inc. Attn: BI Legal Support, DMCA Complaints
P.O. Box 368 900
Ridgebury Road Ridgefield, CT 06877-0368 OR fax to: 203-791-6183
Attn: BI Legal Support, DMCA Complaints

4.3 Counter Notification
The provider of allegedly infringing Content may make a counter notification pursuant to sections 512(g) (2) and (3) of the U.S. Digital Millennium Copyright Act. When we receive a counter notification, we may reinstate the material in question.

To file a counter notification with us, you must provide a written communication (by fax or regular mail - not by email, except by prior agreement) that sets forth the items specified below. Please note that you could be liable for damages (including costs and attorneys' fees) if you make a material misrepresentation in a counter notice as to whether material is infringing or not. Accordingly, if you are not sure whether certain material infringes the copyrights of others, we suggest that you first contact an attorney.

To expedite our ability to process your counter notification, please use the following format (including section numbers):

a) Identify the specific URLs or other unique identifying information of material that BI has removed or to which BI has disabled access.
b) Provide your name, address, telephone number, email address, and a statement that you consent to the jurisdiction of Federal District Court for the judicial district in which your address is located (or the federal and state courts located in the State of Connecticut, USA if your address is outside of the United States), and that you will accept service of process from the person who provided notification under subsection (c)(1)(C) or an agent of such person.

c) Include the following statement: "I swear, under penalty of perjury, that I have a good faith belief that each search result, message, or other item of content identified above was removed or disabled as a result of a mistake or misidentification of the material to be removed or disabled, or that the material identified by the complainant has been removed or disabled at the URL identified and will no longer be shown."

d) Sign the paper.

e) Send the written communication to the following address:

Boehringer Ingelheim Pharmaceuticals Inc. Attn: BI Legal Support, DMCA Complaints
P.O. Box 368 900 Ridgebury Road Ridgefield, CT 06877-0368 OR fax to:
203-791-6183
Attn: BI Legal Support, DMCA Counter Notification

CONTACT: IF YOU HAVE ANY QUERIES OR COMPLAINTS REGARDING THE BICTP, PLEASE E-MAIL US AT BI@CTS-HELPDESK.COM

TERMS AND CONDITIONS HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Effective Date</th>
<th>Description of Changes</th>
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<tbody>
<tr>
<td>1.0</td>
<td>15 Aug 2016</td>
<td>Initial version</td>
</tr>
<tr>
<td>2.0</td>
<td>20 Sep 2016</td>
<td>Added “Inspector Addendum”</td>
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| 3.0     | 15 Aug 2017    | Section 3.2: removed restriction to the number of copies a user may print
            “Inspector Addendum” section removed due to the elimination of the technical reasons that made it necessary |
| 4.0     | 12-Feb-2019    | Update of Section 1.1 and 1.2 to fully reflect purpose and termination process
            Added Section 13 to reflect regular trial close-out
            Other editorial updates |