



# Non-Disclosure Agreement

between

Pediatric Research International GmbH  
Freiheit 1  
45128 Essen  
Germany

– hereinafter referred to as “PRI” –

and

[Company name]  
[Street]  
[Postal code Town]  
[Country]

– hereinafter referred to as “Partner” –

– PRI and Partner hereinafter referred to individually as “Party“ or jointly as the “Parties“–

## **Project:**

[Purpose/project, the NDA will be set up for]

## **Preamble**

1. The Parties have entered into negotiations concerning the establishment of business relationships and/or are working jointly on a project.
2. During the course of the negotiations and/or the project, the Parties may have or will exchange Confidential Information. In order to protect any such Confidential Information, the Parties have decided to enter into this Agreement.

Now therefore, the Parties agree as follows:

## **1. Confidential Information**

**“Confidential Information”** pursuant to this Agreement include any non-published business, financial, technical, legal, tax and other information disclosed (including data, records, know-how, direct experience, project data, schedules, clinical study protocols and study designs, Pediatric Investigation Plans, patient population data and epidemiological data, investigator and site information, regulatory submissions and correspondence, biomarker data and laboratory results, compound and drug combination data, pharmacovigilance data, measurement results, descriptions, specifications, methods, ideas, samples, tables, lists etc., non-published patent rights and other work results of any kind, as well as business and operational secrets), which relate to the sharing Party which is made available directly or indirectly to the receiving Party by the sharing Party or which comes to be known by the receiving Party in any way regardless of whether this information is made available in writing, verbally, on data storage media, through electronic data transfer, by visual inspection or in any other way.

## **2. Exceptions**

The term “Confidential Information“ does not include such information which has been verifiably

- 2.1 made public at the time it is shared or that is made public thereafter through no fault of the receiving Party, or
- 2.2 made known to the receiving Party prior to it being shared or which has been shared with the same thereafter by a third party who is not subject to the non-disclosure of the information, or
- 2.3 developed or is verifiably being developed by the receiving Party independent of the Confidential Information, or
- 2.4 proven to not relate to internal matters and has been disclosed without restriction of confidentiality by the disclosing Party, or
- 2.5 expressly designated as non-confidential by the disclosing party.

## **3. Duty of Confidentiality**

The Parties agree to

- 3.1 keep all Confidential Information obtained or acquired by them from the other respective contractual party by virtue of or in relation to the negotiations and/or the project strictly confidential, in other words not allow access to the same by third parties, either directly or indirectly, verbally or in writing or in any other way, and to use the Confidential Information strictly in connection with the negotiations and/or the project and not for their own nor for other purposes;

- 3.2 only make the Confidential Information available to employees of the receiving Party who are needed to take part in the examination of the intended collaborative work and the discussions and/or the project and who have signed an Agreement pursuant to the present Agreement before they are provided access to the Confidential Information; the signing of such an Agreement is unnecessary if equivalent non-disclosure obligations are already in place through an employment contract;
- 3.3 ensure, to the best of their ability, that the Agreement is adhered to by the employees of the receiving Party listed above in Section 3.2;
- 3.4 take appropriate precautions to prevent access by third parties to the Confidential Information;
- 3.5 not reproduce the Confidential Information conveyed (including data, data storage media, etc.) photo mechanically or in any other way;
- 3.6 not disassemble, decompile or otherwise translate software obtained from the sharing Party into another form of code, and not to open or disassemble samples or prototypes received unless done so with the expressed written permission of the sharing Party; and
- 3.7 return the Confidential Information provided by the sharing Party and any prepared photocopies or other duplications and data storage media, any prepared records, etc. in their entirety upon the request of the sharing Party at any time and to delete any Confidential Information stored in electronic form, said deletion being in such a manner as to make restoration of the data impossible. Copies that are to be safely guarded and which the receiving contractual party safeguards for purposes of providing evidence of the contents and development of the project or which must be maintained as required by law are excluded from the relinquishment and deletion obligation.
- 3.8 Exceptions to the above obligations are only permitted with the prior written authorization of the other contractual party.
- 3.9 Regarding personal data, each Party shall adhere to statutory data protection regulations and shall take all required technical and organizational safety measures, for example measures against unauthorized access, unauthorized modification or sharing, in particular when transferring data in a network.

#### **4. Disclosure Requirements**

In the event that one Party or any of its employees is subject to a statutory obligation or a legitimate court or official order to disclose Confidential Information, the Party obliged to disclosure shall

- 4.1 immediately notify the other Party in writing by fax or by e-mail of this obligation and on request assist the other Party as far as possible in protecting the Confidential Information;

4.2 to the extent that no other protective measures are taken, disclose only such Confidential Information which must be disclosed by reason of the statutory obligation or order and use its best endeavours to ensure that the Confidential Information disclosed is treated as far as possible in accordance with this Agreement.

## **5. No acquisition of title, no liability, no obligation**

- 5.1 The Confidential Information-sharing Party retains all rights to the Confidential Information provided to the receiving Party (including copyrights and the right to file for commercial property rights such as patents, utility models, topography protections, etc.).
- 5.2 The receiving Party may derive no rights to prior use with regard to the contents of such patent filings, nor may it claim prior public use in opposition to such filings based on the Confidential Information obtained under this Agreement.
- 5.3 No ownership, licensing, reproduction, usage, exploitation or other rights whatsoever are conceded to either Party through this Agreement and the mutual sharing of Confidential Information and transfer of data, drawings, models, etc., regardless of whether property rights exist or not. If one Party is interested in acquiring a license accordingly, the conclusion of a separate contract will be necessary.
- 5.4 No Party may file for any patent or apply any immaterial rights without the prior written permission of the other Party if it relates to Confidential Information obtained by that Party from the other Party.
- 5.5 The sharing Party assumes no liability for the completeness, correctness or utility of the Confidential Information shared under this Agreement, or for its freedom from the rights of others. Likewise, except for its statutory liability, the sharing contractual party is not liable for any damages to the receiving Party or to others caused by the Confidential Information shared by it.

## **6. Miscellaneous**

- 6.1 This Agreement comprises the entire Agreement between the Parties concerning the subject matter hereof and supersede and replace all oral and written declarations of intention made by the Parties.
- 6.2 Changes or amendments to this Agreement (including this Section 6.2) shall be made in writing unless any stricter form is legally required.
- 6.3 This Agreement shall be executed in both German and English language. In the event of any inconsistency between the German version and the English version, the German version shall prevail.
- 6.4 This Agreement shall be governed by, and be construed in accordance with the laws of the Federal Republic of Germany. The place of jurisdiction shall be Essen.



- 6.5 In the event that one or more current or future provisions of this Agreement shall be, or shall be deemed to be, fully or partially invalid or unenforceable, the validity and enforceability of the other provisions of this Agreement shall not be affected thereby. The same shall apply in the event that the Agreement contains any gaps. The invalid or unenforceable provision shall be replaced by such appropriate provision that, to the extent legally permissible, comes closest to the actual or assumed intention of the Parties as of the Signing Date or the date of the amendment of this Agreement, as the case may be, in case they had taken such issue into account.



Pediatric Research International

Partner

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Name