
WHEREAS:

- A. Since January 1st, 2014, Biopharmaceutical companies, which are members European Federation of Pharmaceutical Industries and Associations (EFPIA) and/or the Pharmaceutical Research and Manufacturers of America (PhRMA), are committed to enhancing public health through responsible sharing of clinical trial data with researchers in a manner that is consistent with the following Principles: (i) safeguarding the privacy of patients, (ii) respecting the integrity of national regulatory systems, (iii) maintaining incentives for investment in biomedical research (EFPIA "*Principles for Responsible Clinical Trial Data Sharing: Our Commitment to Patients and Researchers*"¹).
- B. Servier conducts clinical studies alone or with partner(s). According to the above-mentioned *Principles for Responsible Clinical Trial Data Sharing*, Servier supports provision of access to said clinical studies data to qualified researchers who have a scientifically valid research proposal.
- C. In order to conduct specific analyses, Contractor wants to be provided with specific data collected by Servier in the framework of its clinical studies. Servier and Contractor intend to establish this agreement in order to set up the general terms and conditions for the supply of Servier's data to Contractor.
- D. The time required to deliver data will depend on a number of factors, including the amount of data being sought and the amount of work required to anonymize the patient-level data for sharing, being understood that Servier reserves the right to refuse the access to data which could have any risk of re-identification of the patients.

ARTICLE 1 – DEFINITIONS

"Affiliate" means, with respect to a Party, any person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such person, whether by the ownership of more than fifty percent (50%) of the voting stocking of such person, by contract or otherwise. For Servier, Affiliates are especially, without limitation, any company affiliated to Servier S.A.S.

"Agreement" means this agreement and its schedules.

¹ <https://www.phrma.org/codes-and-guidelines/phrma-principles-for-clinical-trial-data-sharing>

“Analysis” means the specific analysis to be performed by Contractor with Servier's Data as described in the Research Proposal Form.

“Analysis Period” means the twelve (12) month period starting on the date of provision of Servier's Data by Servier to Contractor.

“Authorized Person” means any person identified in Schedule A, who is authorized to access Servier's Data to perform the Analysis.

“Contractor's Intellectual Property” means all results, discoveries, inventions (whether patentable or not), improvements, know-how, or trade secrets made or obtained by Contractor as a result of the Analysis and/or the use of any Servier's Data.

“De-identified patient-level data” means data from which all personal identifiers have been removed, such that it is no longer possible by all means reasonably likely to be used, to link the data back to an identifiable individual (including by combining that data with other data).

“Research Proposal Form” means the research proposal form submitted to Servier by the Contractor and describing why the Contractor requested to have access to Servier's Data and the limited person(s) who will have access to Servier's Data. The Research Proposal Form is attached hereto in Schedule A.

“Servier's Confidential Information” means any information or data, regardless of form which are not publicly known (whether written, oral, photographic, electronic, magnetic, computer or otherwise) disclosed by Servier to Contractor and any Authorized Person(s), which is treated or designated by Servier as confidential or which by nature of the information disclosed, the Contractor and/or the Authorized Person(s) reasonably should know that such information is confidential. Servier's Confidential Information includes, but is not limited to, Servier's Data, any information related to Servier's Data, research specifications or clinical trial/study protocols, reports, specifications.

“Servier's Data” means all information and data, including but not limited to De-identified patient-level data, regardless of form, owned or controlled by Servier, and disclosed by Servier to Contractor according to this Agreement.

ARTICLE 2 – SCOPE AND PURPOSES OF THIS AGREEMENT

Servier and Contractor agree that Servier will provide the Contractor with access to Servier's Data from the Servier-sponsored clinical studies listed in Schedule B for the sole purpose of performing the Analysis and for no other purpose.

ARTICLE 3 – ACCESS TO AND USE OF SERVIER'S DATA

3.1. When providing Servier's Data to Contractor, Servier will disclose to Contractor:

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- De-identified patient-level data from the Servier-sponsored clinical studies listed in Schedule B, in a manner that makes impossible the identification of the patients; and
 - other data such as protocol, study level data, clinical study report or appendices of clinical study report as set forth in the Research Proposal Form.

3.2. Contractor may only use Servier's Data to perform the Analysis. Contractor undertakes not to perform any analysis or any other work other than the Analysis without Servier's prior written approval.

Should Contractor want to perform any other analysis or any other work, it shall submit a new request through Servier's data sharing website. If Servier approves the new request, the Parties shall enter into a new contractual document (which may be either an amendment to this Agreement or a new data sharing agreement).

Should Contractor perform any analysis or any other work other than the Analysis without Servier's prior written approval, it will be considered as a breach to this Agreement, and the penalty set forth in article 9 below shall apply.

3.3. Only Authorized Person(s) will be authorized to access to and use of Servier's Data. Such Authorized Person must acknowledge and agree to the terms and conditions of this Agreement. Servier may request evidence of such Authorized Person's commitment to Contractor.

3.4. Contractor undertakes to take all reasonable and necessary measures to prevent the access to and use of Servier's Data to any person who is not an Authorized Person.

3.5. Should Contractor wish to modify the Authorized Persons listed in Schedule A, Contractor shall provide Servier prior written notice of any addition/deletion/replacement of any Authorized Person. Such modification shall be first approved in writing by Servier to become effective, except for the deletion of an Authorized Person which will be effective as soon as Servier received the information from Contractor. Contractor shall have full responsibility to ensure that any new Authorized Person acknowledges and agrees to the terms and conditions of this Agreement. Servier may request evidence of such Authorized Person's commitment to Contractor.

3.6. Contractor agrees to restrict analysis, and to cause all Authorized Persons to restrict analysis of Servier's Data, to the Analysis, and will not perform or allow other person(s) to perform any analysis that is not specified in the Research Proposal Form without prior written agreement from Servier.

3.7. Contractor may include Servier's Data in database containing other data, only if such database allows to restrict the access to Servier's Data to the Authorized Person. Otherwise, Servier's Data cannot be included in such database.

3.8. Contractor shall be liable for any direct damages or liability arising from any non-compliance of any Authorized Person, or any Contractor's employees who are not an Authorized Person, with the access and use conditions of Servier's Data set forth in this Agreement.

3.9. Servier disclaims all liability to Contractor or to any Authorized Person in connection with access to or use of the Servier's Data.

3.10. However, access to Servier's Data may be authorized to journal reviewer's as set forth in article 6.2 for publication purpose, provided that such journal reviewer's shall not disclose the Servier's Data to any third party and shall comply with confidentiality provisions included in this Agreement.

3.11. Servier's Data is provided 'AS IS' and Servier makes no representations or warranties regarding the suitability of Servier's Data to perform the Analysis.

3.12. Contractor agrees that Servier's Data provided by Servier are Servier confidential information, and it shall not disclose or use it for any purpose other than to perform the Analysis, except to journal reviewers as set forth in article 6.2 for publication purpose.

ARTICLE 4 – OBLIGATIONS OF CONTRACTOR

4.1. Contractor shall comply with applicable laws, regulations, codes, and guidelines, regarding handling, analysing and reporting analyses of clinical trial data.

4.2. Contractor warrants to comply with all applicable data protection legislations and not to seek to re-identify the patients concerned nor to combine Servier's Data with other sources of data that would lead to the identification of any individual.

4.3. Contractor shall perform the complete Analysis within the Analysis Period. After the Analysis Period, Contractor undertakes to stop using Servier's Data to perform any analysis.

4.4. Contractor shall inform Servier within twenty-four (24) hours of any safety issue identified as part of the Analysis and Servier may take measures regarding such safety issues including but not limited to the information of regulatory authorities and/or publication of the safety issue, even in advance of publication of the Analysis by Contractor (as set forth in article 6 "Publication").

4.5. For the sole purpose of reproducing the Analysis, Contractor agrees to provide access and reasonable assistance to Servier to use and implement any method, formula or tool used by Contractor in the conduct of the Analysis.

4.6. After completion of the Analysis, Contractor shall publish the Analysis results according to article 6.2.

4.7. Contractor shall destroy all Servier's Data still in its possession at the latest six (6) months after the Analysis Period, and shall provide a certificate evidencing such destruction within thirty (30) days of such destruction.

[OPTIONAL (4.8 to be included if needed on a case by case basis):

4.8. Contractor certifies to be the holder of an applicable scientific/medical dictionaries. This is a condition for the transfer of Servier's Data.]

ARTICLE 5 – CONFIDENTIALITY

5.1. Contractor agrees and warrants that **it/he/she** will not transfer Servier's Data to any person or third party who is not identified in the Research Proposal Form. Contractor shall use the same level of care to prevent any unauthorized use or disclosure of Servier's Data as **it/he/she** exercises in protecting its own information of a similar nature, but in no event less than a reasonable standard of care. In any way, Contractor shall be liable for any unauthorized use or disclosure of Servier's Data by **him/her/itself** or by any third party identified in the Research Proposal Form.

5.2. However, Contractor may disclose the De-identified patient-level data according to article 6 "Publication" of this Agreement.

5.3. Servier agrees that the Research Proposal Form contains Contractor's confidential information and shall not disclose or use it for any other purpose than this Agreement, including consultation of the Independent Review Board that could have been consulted before entering into this Agreement.

5.4. The obligations of confidentiality and limited use under this article 5 shall not extend to any information:

(i) which is or becomes publicly available, except through breach of this Agreement;

(ii) which Contractor can demonstrate that it possessed prior to, or developed independently from, disclosure under this Agreement;

(iii) which Contractor receives from a third party which is not legally prohibited from disclosing such information; or

(iv) which Contractor is required by law to disclose, provided that Servier is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.

5.5. This obligation of confidentiality shall remain valid for a period of fifteen (15) years after the end of this Agreement.

ARTICLE 6 – PUBLICATIONS – COMMUNICATIONS

6.1. Contractor consents that the title of the Research Proposal Form, name of the Contractor', affiliation, funding source, summary of the proposed Analysis, and requested studies (all as provided by the Contractor in the Research Proposal Form) will be posted on clinicaltrials.servier.com after this Agreement is executed.

6.2. Within twelve (12) months after the Analysis Period, , Contractor agrees to submit the Analysis results for publication in a peer-reviewed journal as described in the Research Proposal Form, with such publication appropriately disclosing the strengths and weaknesses of the Analysis methodology. For that purpose, Contractor shall be authorized to give access to Servier's Data to the journal reviewers.

If for any reason the Analysis cannot be disclosed in a manner consistent with the publication plan, a brief summary of any activity performed, any outcome of the Analysis, and the reason for non-completion, has to be addressed to Servier. In any case Contractor agrees that the reason why the Analysis cannot be performed or disclosed will be published.

6.3. Contractor shall submit to Servier any public disclosure of the Analysis results (including a copy of the manuscript or a brief summary if for any reason the Analysis cannot be disclosed in a manner consistent with the publication plan) at least thirty (30) days prior to any public disclosure, such as submission to a scientific congress or journal, or publicly-available Internet register to permit Servier to make comments on the public disclosure regarding scientific accuracy, review for patentable subject matter, and request deletion of Servier's Confidential Information. Contractor shall be under no obligation to implement any comments on the public disclosure received from Servier provided that Contractor shall not include any information that is Servier's Confidential Information for which Servier has requested deletion. For the avoidance of doubt the prior submission to Servier also applies in the cases set forth in article 6.1 and 6.2 above.. Should not the Contractor and/or the Authorized Person submit a public disclosure to Servier before submission to a scientific congress or journal, the Contractor and/or Authorized Person will not publish.

6.4. Should Contractor need to have access to Servier's Data after the end of the Agreement in order to publish the Analysis results, Contractor shall contact Servier and Servier agrees to give new access to Servier's Data to Contractor for this specific

purpose and for a limited period, suitable to ensure the publication. In this case, an amendment to this Agreement is to be established.

6.5. Any public disclosure to be supplied to Servier according to this article 6 shall be sent to the following address *<to be adapted >*.

6.6. Any public disclosure of such results shall acknowledge the participation of Servier by providing its data

6.7. The obligations of this article 6 shall survive termination of this Agreement.

ARTICLE 7 – INTELLECTUAL PROPERTY/

7.1. Servier's Data

7.1.1. Servier's Data, and all tangible expressions in any media, are and shall remain the sole property of Servier or of its licensors, if the case may be.

7.1.2. Access to Servier's Data by Contractor shall not transfer or otherwise assign to Contractor any title or ownership in Servier's Data or any right to use Servier's Data, including any intellectual property rights (including copyright) therein, for any purpose other than to perform the Analysis.

7.2. Contractor's Intellectual Property

7.2.1. Contractor will notify Servier in writing of any new Contractor's Intellectual Property that is directly resulting from Servier's Data as soon as possible. Contractor's Intellectual Property will be the sole property of Contractor.

7.2.2. Contractor grants to Servier a perpetual, fully-paid up, royalty-free, non-exclusive, worldwide license for Servier uses, with right to sublicense, all Contractor's Intellectual Property which Contractor may have obtained, without additional consideration from Servier, for internal research and development only.

7.2.3. Moreover, Contractor grants to Servier and its Affiliates an **[depending on the context: exclusive / non-exclusive]** option, to be exercised within one hundred and eighty (180) days from notice of the Contractor's Intellectual Property to negotiate in good faith an exclusive, fee bearing, worldwide license with right to sublicense.

7.2.4. If Servier exercises its option to negotiate an **[depending on the context: exclusive / non-exclusive]** license, Servier and Contractor will negotiate in good faith, for up to one hundred and eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an **[depending on the context: exclusive / non-exclusive]**, worldwide, fee-bearing license, including the right to sublicense, for Servier and its Affiliates to make, have made, use, sell or otherwise dispose of the Contractor's Intellectual Property or products which cannot be

developed, used, manufactured, imported, exported and/or otherwise commercially exploited without implementing Contractor's Intellectual Property. [to be included if the Contractor needs to obtain the approval of any other entity for the commercial exploitation: No commercial exploitation of any Contractor's Intellectual Property shall take place without the consent of [XXX], such consent to be requested by Contractor. Contractor undertakes to request such consent within the fifteen (15) days following Servier's request for commercial exploitation rights.]

7.2.5. In the event that Servier does not exercise its option to negotiate a license or, in the event Contractor and Servier fail to agree to commercially reasonable license terms following good faith negotiation, Contractor may negotiate further non-exclusive license terms with third parties. Should any terms be agreed with a third party in accordance with this article 7.2.5, then during the five (5) years after the effective date of this Agreement, Contractor will notify Servier of the identity of the third party, within thirty (30) days of the effective date of any such agreement with said third party.

7.3. Contractor's assistance

Upon Servier's request, Contractor will provide reasonable assistance to Servier, upon commercially reasonable terms that are at least as favorable to Servier as the terms agreed with any other licensee for such assistance, to facilitate Servier in fully utilizing any Contractor's Intellectual Property and Analysis results.

ARTICLE 8 – REPRESENTATION AND WARRANTIES

8.1. Contractor represents and warrants that it/he/she does not have, and will not enter into, any legal or contractual obligations that would prevent it/he/she from complying with its/his/her obligations under this Agreement, including without limitation, the obligations of Section 7 (Intellectual Property) without the written approval of Servier.

8.2. Contractor shall be responsible for the compliance of its/his/her employees and/or collaborators and any other persons working on its/his/her authority to the terms of this Agreement.

8.3. Contractor represents and warrants that it/he/she has the authority to bind to the terms of this Agreement any individual proposed by Contractor to have access to Servier's Data.

8.4. Contractor represents and warrants that it/he/she has or will obtain any regulatory or ethical approvals necessary for the conduct of the Analysis by Contractor.

8.5. Contractor acknowledges the importance of data privacy of individuals to whom accessed data may relate, and commits to comply with all applicable data privacy legislation, not to attempt to identify subjects, and not to combine accessed data with other sources of data that would lead to the identification of any individual. In no case, Contractor will identify one or several individuals. Contractor undertakes to immediately inform Servier of any breach of anonymisation.

8.6. Contractor shall assume full responsibility for any damages Servier may suffer arising out of any breach or failure to comply with the provisions of the Agreement and shall hold Servier harmless against all losses and claims they may suffer arising out of a direct or indirect breach by Contractor of the Agreement.

ARTICLE 9 – PENALTY

Servier agrees to provide the Servier's Data to Contractor free of charge in order to improve scientific knowledge. As a consequence, in the event of a breach of any of the provisions of articles 3 to 7, and in particular, without limitations, if Contractor:

- performed analysis or any other work other than the Analysis without Servier's prior written approval, or
- did not comply with the obligations set forth in articles 3, 4 and 6 (such as communicate the results to Servier, or publish the results without first informing Servier, or transfer or give access to Servier's Data to any non-Authorized Person, etc.), or
- did not provide Servier with the Servier's Data destruction certificate,

the Contractor shall be liable to Servier for an immediately due and payable penalty of twenty thousand euros (EUR 20,000) excluding taxes per breach, without prejudice to any other rights provided for by law or under this Agreement such as the right to specific performance, the right to an injunction or the right to claim damages in lieu of this penalty.

ARTICLE 10 – DATA PRIVACY

Prior to and during the course of this Agreement, Servier will process personal data of the Authorized Persons or other Contractor's employees according to the applicable data protection laws. Terms and conditions of processing by SERVIER of personal data is attached in Schedule C.

ARTICLE 11 – TERM AND TERMINATION

11.1. Duration

The term of this Agreement shall commence on the last signature date and shall terminate twelve (12) months after the Analysis Period, unless early termination according to this Agreement.

11.2. Termination

11.2.1. Each Party may terminate this Agreement for any reason whatsoever with respect to a thirty (30) days prior written notice to the other Party.

11.2.2. Contractor's use of any of Servier's intellectual property rights in violation of any law or of any terms or limitations imposed by this Agreement shall be a violation of this Agreement and Servier may immediately terminate the rights granted under this Agreement unless earlier terminated as set forth in article 11.2.3. below.

11.2.3. Servier may, in addition to any other rights and remedies available to Servier, terminate this Agreement by giving Contractor written notice of such termination in the event Contractor materially breaches any of the terms and conditions of this Agreement and fails to cure such breach or default as promptly as practicable and, in any event, not more than thirty (30) days after Servier gives Contractor written notice specifying the details thereof..

11.3. Effect of termination

11.3.1. At the term of this Agreement for any reason whatsoever, Contractor shall destroy all Servier's Data according to article 4.7.

11.3.2. Certain provisions of this Agreement survive termination of this Agreement as expressly set forth herein.

ARTICLE 12 – MISCELLANEOUS

12.1. Affiliates

All rights granted to Servier according to this Agreement shall automatically benefit to Servier's Affiliates.

Moreover, Servier shall be entitled to assign or otherwise transfer, wholly or partly, the rights and obligations resulting from this Agreement to any Affiliates subject to the prior written information of the Contractor. Without such information, Servier will remain liable of the execution of the terms and conditions of this Agreement.

12.2. Assignment / Subcontracting

12.2.1. Servier may assign the Agreement at any time to a third party (i.e. other than Affiliates), who may be a natural person or a legal entity, on the understanding that, before delegating its rights, it must inform the Contractor of the delegation and of

the fact that the third party will exercise all the rights and obligations delegated to it in the place of Servier.

12.2.2. Contractor is not permitted to assign or subcontract any or all of its rights and/or obligations under this Agreement, without Servier's prior written consent.

12.3. Entire Agreement

With regard to the subject matter herein, this Agreement constitutes the entire agreement of the Parties, and supersedes all previous written or oral representations, agreements and understandings between Servier and Contractor regarding the scope and purpose of this Agreement.

12.4. Invalidity

In the event a term or clause of this Agreement is invalid, illegal, or unenforceable, the Parties shall meet and agree on a new term or a new clause that is legal, valid, and enforceable and that is as close as possible to their intention as defined by the original term or in the original clause. All the other provisions of the Agreement will remain valid.

12.5. No waiver

No waiver by either Party in relying on the existence or a breach of the whole or part of a provision of this Agreement regardless of the duration, will constitute an amendment or deletion of said provision or a waiver by the relevant Party of the right to rely on any prior, simultaneous, or subsequent breach of the same or other provisions.

12.6. Amendments

This Agreement may only be amended by virtue of a supplemental agreement signed by the Parties.

12.7. Independent contractors

The relationship of the Contractor to Servier in the performance of this Agreement is that of an independent contractor for any purpose whatsoever, and not of an agent, representative or employee. Furthermore, the Agreement may not be deemed to constitute any joint venture or partnership between the Parties.

12.8. Entire agreement - Prevailing terms

12.8.1. This Agreement set forth the Parties' entire agreement with respect to the subject matter thereof. It supersedes any written or verbal agreements, letters, or other documents previously exchanged between the Parties in relation to the same subject matter.

12.8.2. In the event of contradiction between two provisions, the provision issued from the contractual document with the highest value shall prevail.

12.8.3. These contractual documents are prioritized in the following order, from the document with the highest value (Agreement) to the document with lowest value (Schedules):

- (i) The Agreement;
- (ii) The Schedules.

12.9. Survivability

Notwithstanding term or termination of this Agreement for any reason whatsoever, the rights and obligations under articles 4.8, 5, 6, 7 shall remain in full force and effect.

12.10. Notification

12.10.1. Unless otherwise set forth in this Agreement, (a) all legal notices shall be in writing and given by registered letter with acknowledgement of receipt or by express courier (e.g., DHL, Federal Express, etc.), and (b) all other information or communication between the Parties shall be in writing by email, to the appropriate Party at the address or email set out below or such other address or email as may be notified in writing to the other Party:

To Servier:	To Contractor:
Institut de Recherches Internationales Servier 50 rue Carnot 92284 SURESNES CEDEX France	XXX
Email: 	Email:

12.10.2. Each notice shall indicate the reference number of this Agreement.

12.10.3. Legal notices shall be deemed received (i) if solely by registered letter, on the date of receipt as stated on the return receipt, or (ii) if by express courier, on the date signed for or rejected as reflected in the courier's delivery.

12.10.4. Should there be no amendment modifying the address (postal or email) mentioned in this article, any communication or notice made by a Party to the other Party to the above-mentioned address is deemed valid, even if the recipient Party's address changed.

ARTICLE 13 – GOVERNING LAW

13.1. This Agreement and any dispute related thereof shall be governed by, and construed in accordance with the laws of France, without prejudice to the application of the rules and provisions of [country of Contractor] law to the extent local public order should so require

13.2. In the event of a dispute arising out of or in connection with this Agreement, the Parties shall endeavour to solve the problem amicably. Should the Parties fail to do so within one (1) month after notification by a Party of the dispute, such dispute shall be exclusively settled by the competent court of Nanterre (92), France.

ARTICLE 14 – SIGNATURE

The Parties may expressly intent to sign electronically this Agreement. No Party may oppose or dispute the validity and/or probative force of the Agreement signed electronically.

Made in [CITY], on [DATE].

**INSTITUT DE RECHERCHES
INTERNATIONALES SERVIER**

CONTRACTOR

By:

Title:

By:

Title:

List of schedules:

- Schedule A: Research Proposal Form
 - Schedule B: Clinical trial study(ies)
 - Schedule C: Processing of Personal Data
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