

APPENDIX V
Data Sharing Agreement

UZH DATA SHARING AGREEMENT
(Controller – Controller)

This Data Sharing Agreement was provided by the Legal Services and Data Protection Office of the University of Zurich and adapted to the purposes of the specific project.

THE UNDERSIGNED:

Balgrist University Hospital, University of Zurich, represented by Dr Lorenz Leitner hereinafter referred to as “**Data Importer**”;

[Institution], represented by [Person] hereinafter referred to as the “**Data Exporter**”.

The foregoing entities are solely referred to as “**Party**” and collectively referred to as “**Parties**”.

WHEREAS:

- The Data Importer is the host of the Phagistry, the international patient registry for phage therapy, further referred to as the “**Registry**”.
- The Data Exporter is willingly participating in the Registry by contributing their Data.
- The Parties consider the present Data Sharing Agreement, hereinafter referred to as “**Agreement**”, as a subcontract and integral part of the Registry Regulation hereinafter referred to as the “**Main Contract**”.
- Data Importer wishes to perform analyses on anonymized patient data, which will be used for the purpose of fulfilling the goals of the Registry.
- The Data Exporter will or has previously collected patient-related data from human patients planned to receive or having been treated with phage therapy.
- The Data Exporter is willing to provide Data Importer such anonymized, retrospective Data which is necessary for the purpose of the Registry.
- The Parties now desire to enter into this Agreement to confirm the terms and conditions upon which the Data Importer agrees to process the Data for the purpose of the Registry and upon which the Data Exporter agrees to transfer the Data.

Now, therefore, in consideration of their mutual promises to each other, hereinafter stated, the Parties agree as follows:

Definitions

- a) "Data" means the information which the Data Exporter will transfer to the Data Importer. "Personal Data" is any data concerning an identified or identifiable natural person, processed or to be processed. The Data transferred for the purposes of the Registry by the "Data Importer" in any way within the context of the Main Contract is to be anonymized and should not contain Personal Data.
- b) "The Data Exporter" shall mean the controller who provides the Data.
- c) "The Data Importer" shall mean the controller who agrees to receive from the Data Exporter the Data for further processing in accordance with the terms of these clauses.
- d) "Confidential Information" means any proprietary information, know-how, data or procedure related to the Data and disclosed by Data Exporter to Data Importer to its rights or obligation under this Agreement.
- e) "Controller", "Data Subject", Processing, "Processor" and "Supervisory Authority" or "Authority" shall have the meaning as in the General Data Protection Regulation (EU) 2016/679.

Clause 1. The processing of Data

- 1.1 The Data Exporter will provide the Data Importer with the Data for purposes and tasks of the Registry in accordance with the terms of this Agreement.
- 1.2 The Data Exporter warrants and undertakes that:
 - a) the Data have been collected, processed and transferred in accordance with the laws applicable for anonymized data to the Data Exporter;
 - b) it has obtained any regulatory approvals necessary to collect the Data and transfer the Data to the Data Importer;
 - c) it has full authority to transfer the Data to the Data Importer (such as consent of the Data Subject from whom the Data was collected, or ethical approvals or waivers); Data Subjects must have been provided with the information necessary to ensure fair processing (such as information about the purposes of processing and about the transfer).
 - d) it will respond to enquiries from Data Subjects and the Authority concerning the information to be provided in line with Art. 15 General Data Protection Regulation (EU) 2016/679 in respect of the processing of the Data by the Data Importer, unless the Parties have agreed subject to the single case that the Data Importer will so respond, in which case the Data Exporter will still respond to the extent reasonably possible and with the information reasonably available to it if the Data Importer is unwilling or unable to respond. Responses will be made within a reasonable time.
- 1.3 The Data Importer warrants and undertakes that:
 - a) it will process the Data in accordance with the laws applicable to the Data Importer and the instructions of the Data Exporter;
 - b) it will not process the "Data" for any purpose other than described in the Main Contract and its Annexes determined by the Data Exporter;
 - c) it will process the Data for the sole purpose of the Registry in accordance with the permitted uses of the Data specified in the consent form of the Data Subjects from whom the Data was collected;

- d) it will treat all Data strictly confidential and shall have in place procedures so that any third party, which is authorised to have access to the Data, including (Sub)Processors, will respect and maintain the confidentiality and security of the Data. Any person or organisation acting under the authority of the Data Importer, including a (Sub)Processor, shall be obligated to process the Data only on instructions from the Data Importer. This provision does not apply to persons authorised or required by law or regulation to have access to the Data;
- e) it shall implement appropriate technical, physical and organizational measures to ensure the security of the Data. These measures shall include in any case:
 - (1) measures to ensure that the Data can be accessed only by authorized personnel for the purpose of the Registry.
 - (2) measures to protect the Data against accidental or unlawful destruction, accidental loss or alteration, unauthorized or unlawful storage, processing, access or disclosure;
 - (3) measures to identify vulnerabilities with regard to the processing of Data in systems used by the Data Importer;
- f) it will provide upon request of the Data Exporter documentation about the methods and processes used to enforce the technical, physical and organizational measures as described in item e);
- g) it will inform the Data Exporter without delay about any security-related incidents (loss of data, hacker attack, unlawful access) that occurs affecting Data and/or Confidential Information of the Data Exporter.

Clause 2. Confidentiality

- 2.1 The Data Importer agrees not to disclose Data and Confidential Information to third parties without the consent of the Data Exporter and under an agreement by the third party to be bound by the obligations of this Clause 2.
- 2.2 The obligations under this Clause 2 shall not extend to any data:
 - which is or becomes publicly available through no breach of this Agreement;
 - which Data Importer can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement;
 - which Data Importer receives from a third party which is not legally prohibited from disclosing such information; or
 - which Data Importer is required by law to disclose.
- 2.3 The obligations of this Clause 2 shall survive this Agreement after termination or expiration of this Agreement. The Parties agree to destroy all Data and copies of Data after termination or expiration of this Agreement; however, that the Parties shall be entitled to retain Data to ensure compliance with legal or regulatory retention obligations.

Clause 3. Results

- 3.1 All discoveries, developments, databases, inventions (whether patentable or not), methods, reports, know-how, or trade secrets which are made by the Data Importer as a result of the conduct of the Analyses (hereinafter: "**Results**") shall be the sole property of the Data Importer.
- 3.2 The Data Importer shall grant the Data Exporter a non-exclusive, royalty-free and sublicensable license to utilize all such Results for all non-commercial research and educational purposes.

Clause 4. Publication

The Parties contemplate jointly publishing the Analyses in one or more peer reviewed journals. The Parties agree that authorship will be determined in accordance with the publication policy set forth in the Main Contract.

Clause 5. Place of Data Processing

The Parties will perform the processing and the retention of the Data at their main establishment as defined in Recital 36 General Data Protection Regulation (EU) 2016/679. Transfers to other places are only permitted with the prior written permission of the Data Exporter. Both Parties must keep up to date the documentation of the content and the location for the processing and retention of the Data.

Clause 6. Assignment

The rights and obligations as determined in the Agreement may not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

Clause 7. Engagement of third Parties or subcontractors

- 7.1 The Data Importer is not permitted to make use of third parties, among which subcontractors and sub-processors of the sub-contractors, within the scope of the Agreement without the Data Exporter's prior written permission; such permission may be subject of further conditions.
- 7.2 The Data Importer will in any case ensure that these third parties undertake in writing the same obligations as agreed between the Data Exporter and the Data Importer. The Data Importer guarantees proper compliance with these obligations by these third parties and, in the event of any errors committed by these third parties, will be liable for any damage and/or loss as if the Data Importer itself had committed the error(s). The Data Importer indemnifies the Data Exporter against any claims in this respect.

Clause 8. Contacts

The following contacts are in charge to respond to enquiries from the other Party, Data Subjects or third parties or Authorities concerning the processing of the Data:

For the Data Importer: Lorenz Leitner, Phagistry Principal Coordinator, Lorenz.leitner@balgrist.ch

For the Data Exporter: [name, function and contact details]

Clause 9. Liabilities and indemnification

- 9.1 The Data Exporter cannot and shall not be held liable for any claims, cost or damages by Data Importer or any third party, in connection with or as a direct or indirect result of use of the Data by Data Importer.
- 9.2 The Data Importer shall not be liable toward the Data Exporter for any claims, costs or damages by Data Exporter, in connection with or as a direct or indirect result of use of the Data by Data Exporter.
- 9.3 The Parties shall in no case be liable for any indirect, incidental or consequential damages (including without limitation, lost business or profits, loss of data or loss of use of equipment) suffered by the other Party.

Clause 10. Duration and termination of the Agreement

Subject to Clause 2.3 this Agreement shall become effective on the date of the last Party's signature below, and shall remain in force until termination or expiration of the Main Contract.

Clause 11. Entire Agreement and Modifications

This Agreement represents the entire understanding in respect of legal data protection obligations when sharing data between the Parties and supersedes any previous or contemporaneous agreements, whether written or oral. Modifications, changes and extensions to this Agreement are only binding after they have been agreed upon in writing and signed by the Parties.

Clause 12. Force Majeure

In case of force majeure the concerning Party is entitled to suspend the obligations for the duration and extent of the force majeure, provided that the other Party has been notified in writing of the force majeure. Force majeure situations will concern those situations which prevent the execution of the Agreement and which are not imputable to the concerning Party pursuant to law, Agreement or according to generally accepted standards and as a result will not be attributable to that Party.

Clause 13. Severability

The invalidity or unenforceability of any particular provision of this Agreement shall not affect any other provisions therein. This Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted.

Clause 14. Governing law

14.1 This Agreement will be governed by [specification of the applicable law].

14.2 All disputes which may arise from this Agreement, or from the execution of this Agreement will be submitted to the competent court [specification of the place of jurisdiction].

On behalf of the Data Exporter:

On behalf of the Data Importer:

.....
[Name]

.....
[Name]

.....
[Date]

.....
[Date]

.....
[Signature]

.....
[Signature]

APPENDIX VI

Publication policy

This publication policy refers to publications arising from analysis of Registry data to achieve the Registry goals and undertaken on behalf of the Registry, as well as for publications from local or national Registries. It aims to uphold best scientific practices, ensure proper acknowledgment of contributions, and maintain the integrity and transparency of publications resulting from the registry data.

1 Authorship Criteria and Merit Contribution

- 1.1 Individuals who have made significant and direct contributions to the research, including conception, design, execution, interpretation, data collection, analysis, or manuscript preparation, should be listed as authors.
- 1.2 Authorship on publications on behalf of Registry and by members of the Registry organizational structures will adhere to best scientific practices, with authorship awarded based on merit contribution.
- 1.3 Authorship disputes can be brought forth to the Steering Committee and/or Scientific Advisory Board for remediation.

2 Acknowledgment of Registry and Contributors

- 2.1 All publications utilizing data from the registry should acknowledge the Registry and the individuals and institutions that contributed data. This includes publications resulting from local or national data analysis, as well as from the scientific use and access policy, where members of the Registry organizational structures may or may not be directly involved.
- 2.2 This acknowledgment should be made with the following text: "We would like to acknowledge the Phagistry, (Zurich, Switzerland), the international registry for patients treated with phage therapy, and the associated individuals and institutions who contributed to the Phagistry, for the collection and accessibility of the data required, in part or in full, to complete this work".

3 Communication with Steering Committee

All publications utilizing data from the Registry should be communicated to the Steering Committee by email for tracking and recording purposes. Members of the Steering Committee are happy to provide feedback on manuscripts prior to submission and should be requested by email with at least 4 weeks notice prior to the intended submission date.

4 General principles

- 4.1 Transparency: Contributions of each author should be transparently noted ensuring accountability and recognition of individual contributions.
- 4.2 Integrity: The policy prohibits practices like ghost authorship and honorary authorship, ensuring that all listed authors have legitimately contributed to the research.