



## DATA ACCESS AGREEMENT

**University of Turin - Department of Medical Sciences** (hereinafter referred to as “Provider”), a public institution with a principal place of business at Corso Dogliotti n. 14, 10126 Turin, represented by Prof. Elisabetta Bugianesi, Head of the Department

AND

XXXXXXXXXXXXXXXXXXXXXXXXXXXX, (hereinafter referred to as “Recipient”), an institution with a principal place of business at XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX, represented by XXXXXXXXXXXXXXXXXXXXXXX

Individually identified as a “Party” and collectively referred as to the “Parties”

### Background

- Provider has collected certain personal data in the NINFEA Cohort study
- Recipient wishes to have access to a subset of these data, the “NINFEA Data” (as specified in Annex 1), in order to carry out the Project XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX as specified in Annex 2;
- The Parties further acknowledge that the use of the NINFEA Data by Recipient shall be governed by the terms of the present agreement

### THE PARTIES AGREE AS FOLLOWS:

#### 1. DEFINITIONS

1.1 The terms used herein shall have the meaning outlined below:

- a. Applicable Law: European law and regulation applicable to processing (e.g. collecting, storing, processing, transfer, and use) of Personal Data, and any implementation thereof in the Italian Law (incl. the EU General Data Protection Regulation (EU) 2016/679 as of May 25th, 2018).
- b. NINFEA Data: aggregated summary statistics (being anonymous data) generated by the Provider through the processing of the data-copies/subsets (Personal Data) from the original cohort in the DataSHIELD system, such aggregated summary statistics made available by the Provider under this Data Access Agreement and the DataSHIELD system.



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- c. Coded: Processed through reliable and safe information and communication technologies, in such manner that the Recipient cannot, without disproportional efforts, identify any individual Subject involved.
- d. Informed Consent: The written, signed and dated consent from the Subject or its legal representative, based on sufficient and understandable information, covering for the processing, collecting, storage and use of its Personal Data.
- e. Permitted Use: The purpose for which the Personal Data are made available to Recipient under this Data Access Agreement which purpose is limited to those described in Section 3 below.
- f. Personal Data: Has the meaning as defined by the Regulation (EU) 2016/679. For the purpose of this Agreement Personal Data will be Coded Personal Data only.
- g. Project: The specific project for which Aggregated Data of the NINFEA Cohort study is requested by one of the Parties, as outlined in the Project-Specific Annex (annex 2).
- h. Provider: the Party making available the NINFEA Data to Recipient.
- i. Recipient: Includes any employee, agent and person receiving access to Personal Data pursuant to this agreement.
- j. Registered User: shall mean a Researcher (or an individual conducting Research under the supervision of a Researcher) that is employed by the Recipient and is bound by confidentiality and non-use obligations in respect of Data and who has signed this Agreement and has received acknowledgement of its acceptance. For the avoidance of doubt, "Registered User" may also include students, visiting academics, contractors, sub-contractors or independent consultants provided that any such individual is bound by confidentiality and non-use obligations no less onerous than those binding the Recipient's employees;
- k. Security Breach: Any unauthorized use, access or processing of Personal Data.
- l. Subject: The individual from whom the Personal Data originates.

## **2 PURPOSE**

- 2.1. The Recipient agrees to use NINFEA Data only for the Project attached to the current DAA (Annex 2) and that for further use, a new project must be presented to the Provider scientific responsible person.

## **3. SCOPE AND REPRESENTATION**

- 3.1. The Recipient shall only receive NINFEA Data, that is fully anonymised data. In the event that the Recipient becomes aware they have received any Personal Data, they will notify the Provider promptly and follow the Provider's instructions to return or destroy the Personal Data. The Parties agree to abide by all Applicable Laws.



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- 3.2. Provider represents that to the extent applicable; it has obtained Informed Consent from each Subject in accordance with its Applicable Law, which Informed Consent allows for the transfer of the Personal Data for the Permitted Use.

**4. PERMITTED USE**

- 4.1. Recipient shall use the NINFEA Data for the sole purposes of performing the Project. Use outside of the Project and/or use after the Project ends shall be subject to separate written agreement(s) with the Provider.

**5. RESTRICTIONS AND SPECIFIC OBLIGATIONS OF RECIPIENT**

- 5.1. Recipient shall refrain from any other use of the Personal Data than the Permitted Use.
- 5.2. Recipient agrees not to give access to the Personal Data, in whole or part, to any third party without Provider's prior written consent.

**6. PRIVACY, SECURITY AND PROTECTION**

- 6.1. It shall be the responsibility of each Party to effect and maintain all registrations for the processing of Personal Data that are required by Applicable Law. Each Party shall be responsible for its own processing of Personal Data in accordance with all Applicable Law. Provider shall be responsible for obtaining the proper Informed Consents obtained from Subjects.
- 6.2. Parties shall adopt appropriate technical and organizational measures to prevent any Security Breach. Recipient shall promptly inform the Provider of any Security Breach and Parties shall take all reasonable actions necessary to remedy such Security Breach.

**7. CONFIDENTIAL INFORMATION AND PUBLICATION**

- 7.1. Parties shall ensure the confidentiality of the information communicated as well as the communication and publication of the results of the Project under the present Agreement.
- 7.2. Parties are obliged to maintain confidentiality when processing the data.
- 7.3. In fulfilling their obligations under this Agreement, Parties undertake to employ only employees or other agents who are committed to confidentiality in the handling of personal data provided and who have been appropriately familiarized with the requirements of data protection. Upon request, each party shall provide to the other with evidence of the confidentiality commitments.
- 7.4. During the term of this agreement and for three (3) years thereafter, the Recipient shall keep confidential any Information and shall not disclose such Information to any third party without prior written consent of the Provider. The Recipient's rights to publication of results as defined under Section 7.5 herein remain unaffected.
- The secrecy obligations shown in this Section shall not apply to information as can be established by reasonable proof which:
- a) was already known to the receiving party or independently developed by such party prior to the disclosure of the information by the other party; or
  - b) was or becomes public knowledge through no fault of the receiving party; or



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- c) was obtained by the receiving party from a third party entitled to use and disclose the same as a matter of right; or
- d) the receiving party is required to disclose by law.

The foregoing restrictions will not prevent the Provider from using any Information for those activities which are authorised or licensed under Clause 8.

- 7.5. The Recipient shall have the right to publish its own findings and results related to the Data, provided that the Provider is cited as the source of the Data (i.e. acknowledgement). The Recipient shall provide the Provider with a copy of all publications directly arising from the Recipient's use of the Data not later than three (3) calendar months after the corresponding date of publication.
- 7.6. The Recipient shall agree authorship guidelines with the collaborators at the start of the Project to avoid later disputes. Authorship on papers must follow standard practice that all authors must have made a substantial contribution to the conception and design of the study, or analysis and interpretation of data, and drafting the paper.

## **8. INTELLECTUAL PROPERTY**

- 8.1. The Recipient recognises that nothing in this Agreement shall operate to transfer to the Recipient or its Registered Users any Intellectual Property rights in or relating to the NINFEA Data.
- 8.2. All intellectual property rights and all results, data and discoveries arising out of the Recipient's use of the Data shall belong to the Recipient. The Provider shall have no right or licence in respect of such intellectual property rights, results, data and/or discoveries.
- 8.3. Whilst the Provider will not claim ownership of any Modifications produced as a result of the Recipient's research with the Data, the Provider retains sole ownership of any intellectual property rights in the form of the Original Data included therein.
- 8.4. The Recipient shall be free to file patent application(s) claiming inventions (including Modifications) made through the use of the Data but agrees, under confidential disclosure, to notify the Provider upon filing a patent application claiming Modifications or method(s) of manufacture or use(s) of the Data.  
Inventorship shall be determined by mutual agreement between the parties taking into account applicable patent law and the role and contributions of the parties involved in the development of the invention.
- 8.5. Subject to Section above, if the Recipient is the sole inventor of any invention arising from the research it conducts under this Agreement, then the Recipient shall be free to dispose of such invention as it sees fit.
- 8.6. If the Recipient files any application for a patent in respect of an invention directly arising from its use of the Data, the Recipient shall grant to the Provider a nonexclusive, worldwide, royalty-free, assignable, sub-licensable, fully paid-up license to use such invention for the Provider's own internal, non-profit making research and teaching purposes and to allow Provider to continue to distribute the Data to third parties.
- 8.7. At the Provider's request, the Recipient agrees to provide the Provider with reasonable quantities of published materials developed, made or discovered directly through the Recipient's research studies using the Data, for use in the Provider's own internal, non-profit-making research and teaching activities, always provided that Recipient may fulfil this obligation with reasonable effort. Such transfer shall be free of charge, but Recipient may charge an appropriate handling/shipping fee.
- 8.8. Except as expressly provided in this Agreement no rights are provided to the Recipient under any intellectual property rights or other proprietary rights vested in the Provider.



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8.9. In the event that the Recipient wishes to exploit or use any Data or Modifications for any Commercial Purpose, they will make a formal written request to the Provider seeking whether, at its discretion, a license may be granted to use the Data for such purpose and upon what terms such a license may be granted.

**9. TERM**

9.1. This Agreement is made at the last date of signature by the Parties and until DD/MM/YYYY.

9.2. The terms of this Agreement can be modified or extended only by a written amendment signed by the authorised signatories of the Parties to this Agreement.

**10. WARRANTIES**

10.1. The Provider warrants that it is authorized to allow access to the NINFEA Data to the Recipient and that it has obtained them in accordance with applicable laws. The Provider warrants that all NINFEA Data provided to the Recipient has been collected in accordance with the legislation / regulations.

10.2. The Recipient accepts access to the NINFEA data "as is" and in the manner determined by the Provider.

10.3. Subject to clause 10.1, the Provider and its directors, officers, employees or agents assume no responsibility and make no representations in relation to the use of the NINFEA Data by the Recipient.

**11. LIABILITY**

11.1. Each of the Parties is liable, under the conditions of common law, for any damage that it, including its staff or property and any staff or property under its control, causes to the other Parties or to third parties as a result of or during performance of the Agreement.

11.2. The Parties mutually waive the right to demand compensation from one another for consequential damage that might arise in the context of the Agreement.

**12. GENERAL TERMS**

12.1. The Agreement may be terminated by either party at any time for any reason upon thirty (30) days written notice.

12.2. No party shall be entitled to assign or transfer this Agreement or the rights and obligations hereunder to any third party without the prior written approval of the other Party.

12.3. This Agreement including its annexes represents the entire understanding between or among the Parties related to the Project and supersedes all previously or contemporaneously executed agreements related to the same purpose.

12.4. No failure or delay on the part of any party hereto to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof.

12.5. The parties hereto are independent contractors. Nothing contained herein shall be deemed or construed to create between or among the parties hereto a partnership or joint venture or employment or principal-agent relationship. No party shall have the authority to act on behalf of any other party or to bind another party in any manner.

**13. JURISDICTION**

13.1. This Agreement shall be construed according to the Italian law and to the European Union legal sources.



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13.2 Any dispute arising from the interpretation and/or implementation of this Agreement, which cannot be settled amicably, shall be brought before a competent court of first instance in the city of Turin.

**DSM - UniTo (Provider)**

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Prof. Elisabetta Bugianesi  
Head of the Department

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Prof. Lorenzo Richiardi  
PI of the NINFEA cohort

**Recipient (Recipient)**

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Legal Representative

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PI of the project

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Investigator(s)



## ANNEX 1

### Description of the NINFEA DATA

#### Tables and variables

*Please specify table name and for each table list the variables needed for the purpose of the project. Refer to the following website for a detailed list of dictionary version, tables' and variables' names: <https://github.com/lifecycle-project/ds-dictionaries/tree/master/dictionaries>*

#### CORE VARIABLES

Table name	Variables
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#### OUTCOME VARIABLES

Table name	Variables
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**ANNEX 2**

**Project description**

<b>Title of the project</b>	
<b>Brief description of the project</b>	
<b>New harmonised data needed</b>	
<b>If yes, detail variables to be harmonized</b>	
<b>Principal Investigator</b>	
<b>Investigators</b> The following Investigators may have access to the Aggregated Data under this Agreement:	