

DATA DELIVERY AGREEMENT

Erasmus MC Medical University, Rotterdam, the Netherlands, an institution organised in accordance with the public law of the Netherlands, more specifically acting for and on behalf of its Department of General Practice, in particular for the OA Trial Bank, having its administrative offices at 's Gravendijkwal 230 in (3015 CE) Rotterdam, the Netherlands, duly represented in this matter by **[M van Middelkoop]**

and

[_____]

Jointly referred to as the "Parties"

Whereas:

- Osteoarthritis (OA) is a very heterogeneous disease;
- Given the wide range of available treatments in OA and their small to moderate effectiveness, there is a need for research on clinical predictors of response to different treatments;
- Combining individual patient data from several randomised clinical trials on specific types of treatment would facilitate researchers in defining the clinical predictors of response;
- Erasmus MC intends to create a central databank including data from several randomised clinical trials evaluating one or more interventions in patients with OA of the knee or hip (the OA Trial Bank) in order to enable researchers to perform meta-analyses on individual patient data to define sub-groups that are specifically responsive to certain treatments;
- The OA Trial Bank will be supervised by the OA Trial Bank Steering Committee;
- The Data Deliverer is an experienced researcher in the field of OA and is willing to provide Erasmus MC with data resulting from one or more randomised clinical trials for the OA Trial Bank.

And therefore the Parties agree as follows:

1. Definitions

1.1 In this Agreement, the following words and phrases have the following meanings:

Input Data: pseudonymised or anonymised digital data resulting from one or more clinical trials provided by the Data Deliverer, described in **Annex 1**;

IPR: patents, trade marks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature, or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered, and including applications for registration of any of them;

OA: osteoarthritis;

OA Trial Bank: databank including data from randomised controlled trials evaluating one or more interventions in patients with OA of the knee or hip;

OA Trial Bank Steering Committee: the team of international OA researchers, renown in the field, representing the main disciplines in clinical OA research, supervising the access to and use of data in the OA Trial Bank, setting rules for data sharing, development of study questions and of data pooling and analysis;

Output Data: the data and other material generated through analysis and/or manipulation of the Input Data provided by the Data Deliverer as well as equivalent data provided by other participating centres;

Permitted Users: the people who are authorised by the OA Trial Bank Steering Committee to access and use (parts of) the OA Trial Bank, including, but not confined to, the research coordinator of the OA Trial Bank, members of the OA Trial Bank Steering Committee for monitoring and/or auditing purposes as well as Data Deliverers that are actively involved in data analyses.

2. Delivery of Input Data for the OA Trial Bank

- 2.1** The Data Deliverer grants Erasmus MC a royalty-free, non-exclusive licence in respect of Input Data to import and include such Input Data in the OA Trial Bank so as to allow the use and processing of such Input Data for further statistical and research analysis by Permitted Users in accordance with the rules set by the OA Trial Bank Steering Committee and in accordance with **Annex 1**.
- 2.2** The Data Deliverer will be contacted and its permission will be requested for additional analyses not described in **Annex 1**.
- 2.3** The Data Deliverer acknowledges that Input Data will be integrated with data provided by other participating centres in order to enable Permitted Users to conduct further research in accordance with **Annex 1** and to create Output Data.

3. Input Data

- 3.1** The Data Deliverer warrants and undertakes that the Input Data are the result of one or more randomised clinical trials conducted in accordance with Good Clinical Practice and Academic Standards, in accordance with the laws and procedures as to the direction and conduct of medical studies involving patients applicable in the country where the clinical trial is performed, in particular in accordance with the rules and regulations regarding patient's informed consent. These Standards, Procedures and Laws are considered compliant with the requirements of the Declaration of Helsinki (amended by the 59th WMA General Assembly, Seoul, October 2008) on the subject of Clinical Trials.
- 3.2** The Data Deliverer warrants and undertakes that it has complied with and shall continue to comply with all relevant legislation, regulations, codes of practices, guidance and other requirements of any relevant government or governmental agency as may apply to the Data Deliverer's possession and disclosure of the Input Data to Erasmus MC.

3.3 The Data Deliverer warrants that it has the authority to enter into this Agreement and that the processing of the Input Data by Erasmus MC in the manner envisaged by this Agreement does not and shall not breach any provision of any applicable legislation or agreement or understanding with other parties or individuals.

3.4 The Data Deliverer shall indemnify and hold harmless Erasmus MC against any and all loss, claim or expense suffered by Erasmus MC as a result of the Data Deliverer's breach of this clause.

4. Obligations of Erasmus MC/ OA Trial Bank

4.1 Erasmus MC will process any data comprised within the Input Data only for such purposes as are reasonably necessary in accordance with this Agreement. Erasmus MC will ensure that it has in place and will maintain appropriate technical and organisational measures against unauthorised or unlawful processing of the Input Data and against accidental loss or destruction of or damage to the Input Data.

5. IPR

5.1 All IPR on the Input Data is and will remain with the Data Deliverer. All IPR on the Output Data is and will remain the exclusive property of Erasmus MC. Neither Party will make any claim against the IPR of the other Party.

6. Term and termination

6.1 This Agreement shall become effective on the date this Agreement is signed by the last Party and shall remain in force until termination in accordance with this clause.

6.2 Either Party may terminate this Agreement subject to six months' notice in writing to the other Party.

6.3 Either Party may terminate this Agreement with immediate effect by giving notice in writing to the other Party upon the occurrence of any of the following events:

a.) If the defaulting Party commits a material breach of its obligations under this Agreement and (if the breach is capable of remedy) fails to remedy the breach within 30 days of being specifically required to do so in writing by the non-defaulting Party;

b.) If any distress, execution, sequestration or other similar process is levied or enforced upon or against property of the defaulting Party which is not discharged within thirty days, or an encumbrancer takes possession of, or an administrator, an administrative receiver, a receiver, a trustee or a liquidator is appointed over the whole or any substantial part of the defaulting Party's undertaking, property or assets, or an order is made or a resolution is passed for the winding-up or analogous proceedings in any jurisdiction of the defaulting Party.

6.4 In the event that Erasmus MC identifies serious and/or persistent non-compliance with the obligations outlined in clause 3.1 of this Agreement, Erasmus MC will have the right

to terminate the Agreement with immediate effect and to remove the Input Data from the OA Trial Bank.

- 6.5** In the event of termination, Input Data that have already been analysed and used to generate Output Data will be kept available by the Data Deliverer for monitoring and/or auditing purposes for a period of 15 years after termination.

7. Authorship and publication

- 7.1** Erasmus MC intends to publish the results of the analyses of the Input Data in reputable scientific and medical journals and at scientific conferences.

- 7.2** Authorship and acknowledgements follow the criteria established by the International Committee of Medical Journal Editors (ICMJE). According to these guidelines, authorship credit is based only on (i) substantial contribution to concept and design, or acquisition of data, or analysis and interpretation of data; and (ii) drafting or revising the manuscript for essential intellectual content; and (iii) approval of the final version to be published. All three aforementioned criteria must be fulfilled. Consistent with these and major journal guidelines, those individuals who meet all authorship criteria should be named as authors and those who do not should be acknowledged elsewhere, if appropriate.

- 7.3** In addition to clause 7.2, the Parties agree on the fact that the research coordinator will be first author in case the data analysis is performed by the research coordinator. Where a Data Deliverer or one of its employees is willing to perform the data analyses under the supervision of the research coordinator and is permitted to do so by the OA Trial Bank Steering Committee, the Data Deliverer or one of its employees will be first author while the research coordinator will be mentioned as co-author. At least two members of the OA Trial Bank Steering Committee will be named as co-author in each publication, in accordance with clause 7.2.

- 7.4** Where a Data Deliverer or one of its employees is willing to perform the data analyses and is permitted to do so by the OA Trial Bank Steering Committee, the Data Deliverer and the research coordinator will agree upon a timeframe for the analyses of the Data, writing a draft publication and submitting this publication to a renowned medical journal.

- 7.5** Where several Data Deliverers are willing to perform the data analysis and the parties involved disagree about the right person to do so, the parties involved shall make all reasonable efforts to settle disputes arising from or in connection with this issue in an amicable way. Any disputes that remain unresolved shall be decided upon by the OA Trial Bank Steering Committee, taking into account the amount of Input Data delivered by each Data Deliverer and the experience of the Data Deliverers in comparable data analyses.

8. Notices

- 8.1** Any notices which are required to be given or which shall be given under this Agreement shall be in writing delivered by facsimile or by regular mail (airmail if not domestic) addressed to the Parties as follows:

Erasmus MC:

Data Deliverer:

9. Assignment

9.1 This Agreement shall not be assignable by either Party without the prior written consent of the other Party.

10. Independent contractor

10.1 For the purposes of this Agreement and all services to be provided hereunder, each Party shall be, and shall be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party shall have the authority to make any statements, representations or commitments of any kind or to take any action which shall be binding on the other Party, except as may be explicitly authorised by the other Party in writing.

11. Governing law

11.1 The validity and interpretation of this Agreement and the legal relationship of the Parties to it shall, in all respects, be governed by the laws of the Netherlands. Any and all disputes between the Parties that cannot be settled amicably shall be subject to the exclusive jurisdiction of the court having competence in any such matter at Rotterdam, the Netherlands, except for disputes described in clause 7.5.

12. Entire agreement

12.1 Unless otherwise specified, this Agreement (including the annexes thereto) embodies the entire understanding between Erasmus MC and the Data Deliverer, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this Agreement shall be effective unless made in writing and signed by authorised representatives of the Parties.

AGREED AND SIGNED BY BOTH PARTIES:

Erasmus MC:

Data deliverer:

Name: _____

Name: _____

Date: _____

Date: _____

Signature:

Signature:

Annex 1: Description of data provided by the Data Deliverer and research protocol for analysis of Input Data