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 Dr. Molewaterplein 40 in (3015 GD) Rotterdam, the Netherlands, duly represented in this matter by [M van Middelkoop, Asc/prof., coordinator OA Trial Bank], hereinafter to be referred to as "**Erasmus MC**";

and

[**FULL LEGAL NAME OF RELEVANT ENTITY**], a company organised in accordance with the public law of [country], having its registered office at [street name and number] ([postal code]) [place], [country], duly represented in this matter by [full name, position], hereinafter to be referred to as "**Data Deliverer**";

Erasmus MC and Data Deliverer will collectively be referred to as "**Parties**", or separately as "**Party**";

Whereas:

(A) Osteoarthritis (OA) is a very heterogeneous disease;

(B) 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;

(C) Combining individual patient data from several randomised clinical trials on specific types of treatment would facilitate researchers in defining the clinical predictors of response;

(D) 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;

(E) The OA Trial Bank will be supervised by the OA Trial Bank Steering Committee;

(F) 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

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

1.1 Agreement: this Data Delivery Agreement, including its recitals and Annexes thereto, and any alteration, substitution, update or later versions thereof;

1.2 Applicable Law: the law(s) or any other (local) regulations, guidelines or policies, instructions or recommendations of any competent governmental authority applicable to the processing of the Personal Data, including any amendments, replacements, updates or other later versions thereof;

1.3 Data Breach: any event leading to (potential) accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to the Personal Data transmitted, stored or otherwise processed, including where such destruction, loss, alteration, disclosure or access to the Personal Data cannot reasonably be ruled out;

1.4 Data Subject: the person to whom the Personal Data relate;

1.5 Employees: the employees and other persons engaged by a Party for the performance of the Agreement, who fall under the responsibility of such Party;

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

1.7 IPR: patents, trademarks, 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;

1.8 OA: osteoarthritis;

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

1.10 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;

1.11 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;

1.12 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.

1.13 Personal Data: any data relating to an identified or identifiable living natural person, as meant under the Applicable Law, processed by a Party or its contractors in relation to the execution of the Agreement;

2 Delivery of Input Data for the OA Trial Bank

2.1 The Data Deliverer grants Erasmus MC a royalty-free, non-exclusive, irrevocable, perpetual and sublicensable right to use the Input Data and 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**.

Please choose one of two options for the following provision (provision 2.2).

2.2 The Data Deliverer will be contacted and its permission will be requested for additional analyses not described in **Annex 1**.

OR

The Data Deliverer also grants Erasmus MC a royalty-free, non-exclusive, irrevocable, perpetual and sublicensable right to use the Input Data and import and include such Input Data in the OA Trial Bank so as to allow the use and processing of such Input Data for additional analyses not described in Annex 1, provided that these additional analyses are compatible with the analyses described in Annex 1, that the Data Deliverer will be informed about these additional analyses, and that Erasmus MC complies with the obligations as laid down in article 6 sub 4 of the General Data Protection Regulation.

Please choose one of two options for the following provision (provision 2.3).

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.

OR

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 and to create Output Data.

2.4 Data Deliverer shall deliver the Input Data as soon as reasonably and practically possible.

2.5 After delivery of the Input Data, the Input Data will be kept available by the Data Deliverer for monitoring and/or auditing purposes for a period of 15 years.

2.6 Erasmus MC has no obligation to destroy any Input Data that has already been received.

2.7 All Input Data will also be imported and stored in a separate database by Erasmus MC for data retention and back-up purposes.

3 Warranties and indemnifications

3.1 The Data Deliverer warrants that the Input Data are the result of and/or collected in 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) on the subject of Clinical Trials as applicable at the time the clinical trial was conducted (the Declaration of Helsinki is last amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013)

3.2 The Data Deliverer warrants 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, it may grant the rights of use to the Input Data 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 Law or agreement or understanding with other parties or individuals.

3.4 The Data Deliver shall indemnify and hold harmless Erasmus MC against any and all damages, loss, claims or expense suffered by Erasmus MC as a result of: i) Data Deliverer's breach of this clause and ii) the exercise by Erasmus MC of the right(s) of use granted to it herein in accordance with this Agreement.

4 Privacy

4.1 Within the framework of the Agreement and including annexes, Parties process Personal Data, for which they qualify as (separate) data controllers in accordance with Applicable Law.

4.2 Each Party will only process personal data in accordance with Applicable Law. Parties will provide each other with all information reasonably necessary to demonstrate that the relevant requirements of the Applicable Law are met.

4.3 Parties shall solely disclose the Personal Data to those Employees and/or contractors who necessarily need (access to) the Personal Data for the performance of the obligations of each Party under the Agreement, and for the remainder keep confidential, unless otherwise required under the Applicable Law.

4.4 Parties shall impose the obligations laid down in this Agreement, including the security and confidentiality obligations, to their Employees and/or contractors engaged by them to the extent these Employees and/or contractors are not bound by an appropriate statutory confidentiality obligation. Parties shall ensure that these Employees and/or contractors engaged by them, comply with these obligations.

4.5 Parties shall implement appropriate technical and organizational security measures to ensure an appropriate level of security in relation to the Personal Data, in accordance with the Applicable Law, taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons.

4.6 As soon as one of the Parties detects a Data Breach or reasonably suspects that there has been a Data Breach, it shall notify the other Party as soon as possible, and in any case within 24 hours upon detection or suspicion of the Data Breach. A Party shall notify the other Party by e-mail and by telephone to the the contact person(s) reffered to in Annex 2.

4.7 Parties shall provide each other with all reasonable assistance and shall share with each other all necessary or by the other Party requested information, so that either Party will be able to notify, if applicable, their Data Subject(s) that was (were) (possibly) affected and/or the competent governmental authorities, of the Data Breach in a timely manner.

5 IPR

5.1 All IPR on the Input Data is and will remain with the Data Deliverer or its license source. All IPR on the Output Data exclusively vest in Erasmus MC. Neither Party will make any claim against the IPR of the other Party.

6 Authorship and publication

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

6.2 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.

6.3 In addition to clause 6.2, 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 6.2.

6.4 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.

6.5 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.

7 Notices

7.1 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**:
[…]	**[…]**

8 Assignment

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

9 Independent contractor

9.1 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.

10 Governing law

10.1 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 6.5.

11 Entire agreement

11.1 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 Medical University	[Full legal name of Data Deliverer]
Name:	Name:
Function:	Function:
Date:	Date:

Annex 1

[To be completed by Parties]

DESCRIPTION OF DATA PROVIDED BY THE DATA DELIVERER AND RESEARCH PROTOCOL FOR ANALYSIS OF INPUT DATA

Annex 2

[To be completed by Parties]

Contacts

Erasmus MC	Name and job title	Telephone number	Email address
Primary contact	Marienke van Middelkoop	+31-107032114	m.vanmiddelkoop@erasmusmc.nl
Data Protection Officer (DPO)	Hanneke Luth, DPO		Functionaris.gegevensbescherming@erasmus.nl

Data Deliverer	Name and job title	Telephone number	Email address
Primary contact			
Data Protection Officer (DPO)			