

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, associate professor and coordinator of the 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 **Input Data**: pseudonymised or anonymised digital data resulting from one or more clinical trials provided by the Data Deliverer, described in **Annex 1**;
- 1.3 **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;

- 1.4 OA: osteoarthritis;
- 1.5 OA Trial Bank: databank including data from randomised controlled trials evaluating one or more interventions in patients with OA;
- 1.6 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;
- 1.7 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;
- 1.8 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, 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 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 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 data controllers in accordance with applicable law. This means that the parties (jointly) determine the purposes and means of the processing of personal data.

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 As (joint) controllers, Parties have entered into a Data Protection Agreement with each other with regard to the processing of the personal data and set out their respective roles and responsibilities for the fulfilment of their obligations under the applicable law, in particular with regard to their responsibilities towards each other and their roles and obligations towards data subjects. The Data Protection Agreement is attached as Annex 2 to this Agreement.

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:

Function:

Date:

Name:

Function:

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

DATA PROTECTION AGREEMENT (CONTROLLER-CONTROLLER)

THE UNDERSIGNED:

- (1) **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, position]**, hereinafter to be referred to as "**Erasmus MC**";

and

- (2) **[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) On **[date]** Parties have concluded the Agreement, relating to the delivery of data by the Data Deliverer to Erasmus MC;
- (B) In the context of the performance of the Agreement, Parties process Personal Data for which they both qualify as data controllers in accordance with the Applicable Law, meaning that the Parties jointly determine the purposes and the means of the processing of the Personal Data;
- (C) Being joint data controllers, Parties will have to make arrangements as to the processing of the Personal Data reflecting their respective roles and responsibilities for compliance with the Applicable Law, in particular as regards their respective responsibilities vis-à-vis each other and their respective roles and duties vis-à-vis the Data Subjects, among which their information duties and the exercising of the rights of Data Subjects;
- (D) In this Controller-Controller Data Protection Agreement, Parties wish to lay down their arrangements relating to the processing of the Personal Data in the context of the Agreement in accordance with the Applicable Law. This Controller-Controller Data Protection Agreement complements and forms an annex to the Agreement.

HAVE AGREED AS FOLLOWS:

1 Definitions

Non-capitalized terms not defined herein that are defined under the Applicable Law, such as processing, data controller, data processor, shall have the same meaning as meant under such the Applicable Law. All definitions included in the Agreement shall also apply to this Controller-Controller Data Protection Agreement, unless stipulated otherwise in this Controller-Controller

Data Protection Agreement. In addition, thereto the following definitions apply to this Controller-Controller Data Protection Agreement.

- 1.1 Agreement: the Data Delivery Agreement between Parties dated [date] based on which each Party performs its Processing Activities, including its recitals and annexes, and any updates 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 Controller-Controller Data Protection Agreement: this Controller-Controller Data Protection Agreement, including its recitals and Schedules thereto, and any alteration, substitution, update or later versions thereof;
- 1.4 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;
- 1.5 Data Subject: the person to whom the Personal Data relate;
- 1.6 Employees: the employees and other persons engaged by a Party for the performance of the Agreement, who fall under the responsibility of such Party;
- 1.7 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;
- 1.8 Processing Activities: the processing activities of Personal Data (to be) performed by the relevant Party in relation to the execution of the Agreement;
- 1.9 Schedule: attachment to the Controller-Controller Data Protection Agreement, which forms part of the Controller-Controller Data Protection Agreement;
- 1.10 Third Country: country that does not provide an adequate level of data protection according to the Applicable Law.

2 Subject of this Controller-Controller Data Protection Agreement

- 2.1 In connection with the execution of the Agreement, each Party shall be the *data controller* for the processing of Personal Data and qualify as (joint) controllers as set forth in the Applicable Law.
- 2.2 Each Party shall process the Personal Data in accordance with the Applicable Law. Parties shall make available to each other all information reasonably necessary to demonstrate compliance with the relevant requirements under the Applicable Law.
- 2.3 This Controller-Controller Data Protection Agreement complements and forms an annex to the Agreement and sets aside any (oral and/or written) arrangements of an earlier date relating to

the processing of the Personal Data between Parties acting as data controllers, in respect of the Personal Data, if applicable.

- 2.4 In case of any discrepancies between the provisions of this Controller-Controller Data Protection Agreement and/or the body of the Agreement, including any annexes thereto other than this Controller-Controller Data Protection Agreement, the provisions of this Controller-Controller Data Protection Agreement shall prevail, unless explicitly stipulated otherwise in this Controller-Controller Data Protection Agreement.

3 Processing of the Personal Data

- 3.1 Schedule A to this Controller-Controller Data Protection Agreement contains a description of the Processing Activities performed by each Party and their respective roles vis-à-vis each other and roles and responsibilities vis-à-vis the Data Subjects.

- 3.2 Taking into account the nature of the data processing and the information available to each Party, Parties shall assist each other in ensuring compliance with the obligations that rest upon the Parties under the Applicable Law, more in particular the obligations in relation to the security of Personal Data, data protection by design and by default requirements, Data Breach notification and documentation duties, and the execution of data protection impact assessments, including prior consultation of a competent governmental authority.

- 3.3 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.

- 3.4 Parties shall impose the obligations laid down in this Controller-Controller Data Protection Agreement and the 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 Contractors

- 4.1 If a contractor acting as data processor under the Applicable Law has been engaged for the processing of the Personal Data by a Party or by both Parties, the relevant Party/ Parties, shall conclude and enforce a written data processing agreement with such data processor in line with the requirements under the Applicable Law. If Parties hire a contractor to process Personal Data, Parties remain fully responsible and liable for the performance of their obligations under the Agreement and/or the Applicable Law.

5 Security Measures

Data Deliverer 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.

6 Reporting of Data Breaches

- 6.1 Data Deliverer shall maintain adequate procedures designed to detect and respond to any Data Breaches, including procedures for preventive and corrective actions, and also to avoid recurrence of any Data Breaches. These procedures have been established in such a manner that both Parties will be able to meet their notification and documentation duties in relation to Data Breaches under the Applicable Law.
- 6.2 As soon as Data Deliverer detects a Data Breach or reasonably suspects that there has been a Data Breach, it shall notify Erasmus MC as soon as possible, and in any case within 24 hours upon detection or suspicion of the Data Breach. Data Deliverer shall notify Erasmus MC by e-mail and by telephone to the (back-up) contact person(s) of Erasmus MC referred to in Schedule B.
- 6.3 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 and to prove compliance with their Data Breach notification duties in accordance with the Applicable Law. Parties shall enable each other to prove compliance with the Applicable Law in relation to either Party's Data Breach notification duties. Parties will consult each other on how and when the Data Subjects will be notified in a timely manner, if applicable, in accordance with the Applicable Law.

7 Audit Rights of Erasmus MC

- 7.1 Taking into account a prior notice period of two weeks, Erasmus MC may perform (or have carried out) an audit on the data processing activities to verify whether Data Deliverer collects the personal data in accordance with Good Clinical Practice and Academic Standards as stated in article 3.1 of the Agreement, and processes the personal data in accordance with the Applicable Law, and whether Data Deliverer has indeed notified Erasmus MC of all Data Breaches and of the preventative and corrective measures taken in that respect, including any measures to avoid the recurrence of a Data Breach, in a correct and timely manner.
- 7.2 Erasmus MC will bear the expenses in relation to an audit. However, if the audit reveals any material non-compliance by Data Deliverer with any of its obligations under the Agreement, Data Deliverer will reimburse Erasmus MC the audit costs, and following receipt of such audit findings, remediate such non-compliance as soon as possible but no later than thirty (30) days at its own costs, or provide Erasmus MC with a corrective action plan outlining the steps and expected timelines to remediate the non-compliance.

8 Transfer of the Personal Data

- 8.1 Parties shall fully cooperate at all times so that all requirements under the Applicable Law will be met to legitimize any transfer to a Third Country, from which follows that an adequate level of data protection is safeguarded in such jurisdiction.

9 Information Duties towards Data Subjects and Rights of the Data Subjects

- 9.1 Parties will consult each other on how and when the Data Subjects will be informed on the processing of their Personal Data and the essence of this Controller-Controller Data Protection Agreement; such information may include the designation of a contact point for the Data Subjects.
- 9.2 Parties shall also fully cooperate with each other so that both Parties can live up to their obligations under the Applicable Law as data controller if a Data Subject exercises its rights under the Applicable Law.
- 9.3 Parties acknowledge that irrespective of the terms of the Controller-Controller Data Protection Agreement, the Data Subjects may not be deprived to exercise their rights under the Applicable Law towards Parties.

10 Indemnity

- 10.1 Data Deliverer shall indemnify Erasmus MC against any claim by a third party, including by any of the Data Subjects, imposed against Erasmus MC as a result of a breach of the Applicable Law, which can be attributed to Data Deliverer or any of its Employees or any contractors engaged by Data Deliverer.

11 Term and Termination

- 11.1 This Controller-Controller Data Protection Agreement enters into force on the date that Parties first process the Personal Data for the performance of the Agreement.
- 11.2 This Controller-Controller Data Protection Agreement shall remain in effect for the duration of the Agreement. In the event the Agreement ends, this Controller-Controller Data Protection Agreement ends as well by operation of law, without further legal action. Early termination of this Controller-Controller Data Protection Agreement by either Party is not possible.
- 11.3 If the Processing Activities of both Parties are inextricably linked, each Party, upon termination of the Agreement, shall safeguard that no irregularities or Processing Activities to the detriment of the Data Subjects shall come to pass.
- 11.4 Any obligation arising from this Controller-Controller Data Protection Agreement that by nature has post-contractual effect shall continue to be in effect after the termination of this Controller-Controller Data Protection Agreement.

12 Deviations and Renegotiation

- 12.1 Deviations from and additions to this Controller-Controller Data Protection Agreement shall only be valid if they have been expressly agreed in writing.
- 12.2 Erasmus MC is entitled to renegotiate this this Controller-Controller Data Protection Agreement if this would reasonably result from a change in circumstances. If Parties do not reach an agreement in aforementioned renegotiations, Erasmus MC will have the right to terminate the Agreement, without being liable for any damages resulting from such termination.

AGREED AND UNDERSIGNED:

Erasmus MC Medical University

[Full legal name of Data Deliverer]

Name:

Function:

Date:

Name:

Function:

Date:

Schedule A

Overview of the Processing Activities

Purposes of the Processing Activities	Duration of the Processing Activities <i>Maximum and minimum retention periods</i>	Categories of Data Subjects	(Types of) Personal Data processed by the relevant Party or Parties <i>Where applicable differentiated based on sensitivity</i>	The data controller(s) and its (their) respective duties towards the Data Subjects

AGREED AND UNDERSIGNED

Erasmus MC Medical University

[Full legal name of Data Deliverer]

Name:

Function:

Date:

Name:

Function:

Date:

Schedule B

[To be completed by Parties]

Contacts and back ups

Erasmus MC	Name and job title	Telephone numbers	Other information, including email addresses
Primary contact			
Back up contact 1			
Back up contact 2			

Data Deliverer	Name and job title	Telephone numbers	Other information, including email addresses
Primary contact			
Back up contact 1			
Back up contact 2			

AGREED AND UNDERSIGNED

Erasmus MC Medical University

[Full legal name of Data Deliverer]

Name:

Function:

Date:

Name:

Function:

Date: