

# DARWIN EU<sup>®</sup> DATA PARTNER FRAMEWORK AGREEMENT

between

**ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM**

as **representative of the DARWIN EU<sup>®</sup> Coordination Centre**

having its statutory address

at Dr. Molewaterplein 40, Rotterdam 3015 GD, Netherlands

(hereinafter "**DARWIN EU<sup>®</sup> Coordination Centre**")

and

xx

having its statutory address

at.....

(hereinafter "xx")

Version 4.2

November 2023

This DARWIN EU® Data Partner Framework Agreement (hereinafter referred to as the “**Agreement**”) for engaging a Data Partner in the DARWIN EU® Data Network is entered into by and between the following Parties:

on the one part,

**ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM** (Erasmus MC) representing the DARWIN EU® Coordination Centre (hereinafter referred to as DARWIN EU® Coordination Centre), established in Dr. Molewaterplein 40, Rotterdam 3015 GD, Netherlands, with VAT number NL8071811997B01, duly represented for the purposes of signing the Agreement by Head of Department of Medical Informatics, Prof. dr. ir. Peter R. Rijnbeek;

and on the other part,

[**ORGANISATION NAME**], established in [Legal Address], with VAT number [VAT\_number], duly represented by [Legal Representative], [Legal Representative Position], hereinafter referred to as the DARWIN EU® **Data Partner or Contractor**, providing the Data Base(s) xxx.

Hereinafter individually or collectively referred to as “**Party**” or “**Parties**”.

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The contracting Parties **HAVE AGREED** to the following terms and conditions including those in the following annexes, which form an integral part of the Agreement. The Agreement is composed of:

- A. Definitions
- B. Preamble
- C. Terms and conditions

**Annex 1:** Work Order Agreement (*sample*)

**Annex 2:** Data Partner Bank Information

**Annex 3:** Modes of exploitation and use of the Results

**Annex 4:** DARWIN EU® Conflict of Interest Policy

## A. DEFINITIONS

For the purpose of this Agreement, the following definitions apply:

**'Annual Period'** refers to the period from the 8<sup>th</sup> of February of a given year until the 7<sup>th</sup> of February of the next year, ending the last Annual Period under this Agreement on the 7<sup>th</sup> of February 2027.

**'Anonymous Data'**: information which does not relate to an identified or identifiable natural person or Personal Data rendered anonymous in such a manner that the data subject is not or no longer identifiable [Recital 26 of Regulation (EU) 2016/679];

**'Confidential Information'**: any information or document received by either Party from the other or accessed by either Party, in any format either in writing or orally, in the context of the performance of this Agreement, that any of the Parties has identified as confidential or can reasonably be assumed to be confidential or of a confidential nature. In case of orally disclosed information, Parties will identify and confirm the confidential information in writing within 15 days of such oral disclosure. It may not include information that is publicly available;

**'Creator'**: means any natural person who contributes to the production of the Result;

**'DARWIN EU<sup>®</sup> Data Partner(s)'**: shall have the meaning ascribed to it in paragraph b. of the Preamble of this Agreement;

**'DARWIN EU<sup>®</sup> Data Partners Network' or 'DARWIN EU<sup>®</sup> Network'**: shall have the meaning ascribed to it in paragraph a. of the Preamble of this Agreement.

**'Data Partner'** refers to **[ORGANISATION NAME]** being a DARWIN EU<sup>®</sup> Data Partner in this Agreement;

**'EMA'**: European Medicines Agency;

**'Investigator'**: means an individual responsible for the conduct of the feasibility analysis, the development of the protocol, statistical analysis plan and/or the report of a DARWIN EU<sup>®</sup> Study with the ability to contribute to the Study design, data collection, data analysis and/or interpretation of the Results.

In this context, the following persons are **not** considered Investigators:

- Analysts or programmers of product or disease-agnostic analytical pipelines;
- Project managers and administrative support staff;
- Individuals (including within the DARWIN EU<sup>®</sup> Data Partner) whose only role is to execute or run an algorithm, query, or software code.

**'Party' or 'Parties'**: the legal entities that are signatories of this Agreement.

**'Personal Data'** means any information relating to an identified or identifiable natural person ('data subject') i.e., a patient or healthcare professional in the context of DARWIN EU<sup>®</sup> Study; where an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (see Article 4(1) of Regulation (EU) 2016/679);

**'Personnel'**: individuals employed directly or indirectly or contracted by the Data Partner to perform this Agreement including the Work Order(s);

**'Pre-existing Material'**: any material, document, technology or know-how which exists prior to the Data Partner using it for the production of a Result in the performance of the Agreement;

**'Pre-existing Right(s)'**: any industrial and intellectual property right on Pre-existing Material; it may consist in a right of ownership, a licence right and/or right of use belonging to the Data Partner or the Creator as well as to any other third parties;

**'Raw Data'** shall mean all patient-level Personal Data from which re-identification of an individual patient is possible either directly or indirectly with the use of additional information, even if such additional information is kept separately subject to technical and organisational measures;

**'Result'**: shall have the meaning ascribed to it in Section 7.2. of this Agreement;

**'Services'**: shall have the meaning ascribed to it in paragraph c. of the Preamble of this Agreement;

**'Start Date'** shall have the meaning ascribed to it in Section 13.1. of this Agreement;

**'Study' or 'DARWIN EU® Study'**: A non-interventional study or observational analysis performed by the DARWIN EU® Coordination Centre in the context of the DARWIN EU® Network; with the objective of ascertaining the safety and/or efficacy of medicinal products. The observational analyses and studies may be defined based on their anticipated level of complexity and can refer to the following categories which may be flexible: a routine repeated analysis, off-the-shelf Study, complex Study, or very complex Study. **'Work Order'**: shall have the meaning ascribed to it in paragraph c. of the Preamble of this Agreement;

## B. PREAMBLE

- a. Erasmus MC, as signatory to this agreement, acts as a single entity representing the DARWIN EU® Coordination Centre. DARWIN EU® is an European Medicines Agency (EMA) initiative to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union (EU). The DARWIN EU® Coordination Centre, will support EMA on its work to build a distributed data network ("**DARWIN EU® Data Partners Network**"); to conduct Studies and answer research questions supporting regulatory decision-making by EMA scientific committees and the [European medicines regulatory network](#); and to maintain a catalogue of real world data sources for use in the regulatory context and their metadata.
- b. The DARWIN EU® Data Partners Network includes entities such as hospitals, specialist clinics, universities, companies, research foundations. All Data Partners ("**DARWIN EU® Data Partners**") are subject to invitation by the DARWIN EU® Coordination Centre to participate in DARWIN EU® Studies in the framework of this Agreement.
- c. This Agreement shall form the contractual agreement under which the DARWIN EU® Coordination Centre, and the DARWIN EU® Data Partner will perform Services for the conduct of DARWIN EU® Studies (the "**Services**") as specified in a specific Work Order for which a template is included in **Annex 1**. The Work Order shall be executed by the Parties as

expressly referenced to this Agreement ("**Work Order**"). The DARWIN EU<sup>®</sup> Coordination Centre and DARWIN EU<sup>®</sup> Data Partners shall regularly coordinate and cooperate with each other in the course of conducting the Services.

- d. The scope of the Service and applicable terms and conditions shall be indicated in each Work Order and its schedules which shall form an integral part of this Agreement. Once agreed by the Parties and incorporated into this Agreement, execution of a Work Order shall be deemed a commitment to provide a Service in respect of that particular Work Order.
- e. The DARWIN EU<sup>®</sup> Coordination Centre and the relevant DARWIN EU<sup>®</sup> Data Partner shall perform the Service in accordance with this Agreement and the relevant Work Orders and in compliance with state-of-the-art scientific standards, particularly with the ENCePP Code of Conduct<sup>1</sup>, on a best effort basis.
- f. The DARWIN EU<sup>®</sup> Coordination Centre shall timely provide the DARWIN EU<sup>®</sup> Data Partner with all required information, material and assistance reasonably necessary for the DARWIN EU<sup>®</sup> Data Partner to be able to perform the Services.
- g. The DARWIN EU<sup>®</sup> Coordination Centre and the DARWIN EU<sup>®</sup> Data Partner are responsible that their respective employees, subcontractors and collaborators will comply with their obligations under this Agreement.

## C. TERMS AND CONDITIONS

### 1. Order of priority of provisions

1.1. The Work Orders and its schedules form an integral part of this Agreement and shall have the same force and effect as if expressly set out in the body of the Agreement. Any reference to the Agreement shall be understood as including all Work Orders and schedules.

1.2. If there is any conflict between different provisions in this contractual agreement, the following rules must be applied:

- a) The provisions set out in this Framework Agreement take precedence over those in the Work Order.
- b) The provisions set out in the Work Order take precedence over those in its schedules.

### 2. General rights and obligations to properly implement the Service

2.1. The Data Partner:

- a. agrees to join the DARWIN EU<sup>®</sup> Data Partners Network;

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<sup>1</sup> [https://www.encepp.eu/code\\_of\\_conduct/documents/ENCePPCodeofConduct.pdf](https://www.encepp.eu/code_of_conduct/documents/ENCePPCodeofConduct.pdf)

- b. agrees to participate in Studies promoted by DARWIN EU<sup>®</sup>, subject to the applicable ethics and other approvals required by the Data Partner's governance structure. In this regard, the DARWIN EU<sup>®</sup> Coordination Centre will assure scientific independence, freedom to decline Studies by the Data Partner and respect for each institution's own approval procedures;
  - c. agrees to maintain and update the Data Base(s) [*name of the DB to be added*] [*updating frequency as reported in the Onboarding Document to be added*];
  - d. agrees that the Data Base(s) [*name of the DB to be added*] are mapped and available in the version of the OMOP CDM necessary to execute Studies (as detailed in the Work Orders);
  - e. has full responsibility for implementing the Services properly, including the sharing of Confidential Information with the DARWIN EU<sup>®</sup> Coordinator Centre and the processing of any Personal Data in relation to the performance of the Services, as described in **Annex 1** and in compliance with the provisions of this Agreement and all legal obligations under applicable EU, international and national law;
  - f. shall execute the Service in line with the highest quality standards in light of the DARWIN EU<sup>®</sup> Conflict of Interest Policy (**Annex 4**);
  - g. agrees to be included in the EMA Catalogue of Real-World Data Sources and DARWIN EU<sup>®</sup> communication materials intended for the public as a "**DARWIN EU<sup>®</sup> Data Partner**"; the DARWIN EU<sup>®</sup> Data Partner will be responsible for collating and uploading the necessary information in the EMA Catalogue of Real-World Data Sources and keeping this up-to-date on a yearly basis;
  - h. agrees to be included in the catalogue and data dashboards maintained by the DARWIN EU<sup>®</sup> Coordinator Centre and update this information with each data refresh or upon request.
- 2.2. The DARWIN EU<sup>®</sup> Coordination Centre will provide periodic training and workshops to the DARWIN EU<sup>®</sup> Data Partner, offered via an e-learning environment, for the Data Partner to be aware of the latest practice in data use and management.
- 2.3. The DARWIN EU<sup>®</sup> Coordination Centre shall monitor the implementation of the Service, including the timely delivery of the milestones described in **Annex 1** and the quality of the Services, and approve in writing any milestones achieved.
- 2.4. Notwithstanding Section 13.3 and 11.4 of this Agreement, if the DARWIN EU<sup>®</sup> Data Partner does not deliver the Service, or fails to provide the Service in accordance with the expected quality levels specified in the agreed Work Order, the DARWIN EU<sup>®</sup> Coordination Centre reserves the right to withhold the corresponding payment(s). This includes in particular the cases where the DARWIN EU<sup>®</sup> Coordination Centre cannot approve milestone(s) as defined in the agreed Work Order, after the DARWIN EU<sup>®</sup> Data Partner has submitted the required information, correction or new version(s) following relevant request by DARWIN EU<sup>®</sup> Coordination Centre.

### 3. Payment Terms

- 3.1. In consideration of the performance of the Services, the DARWIN EU<sup>®</sup> Coordination Centre will reimburse the DARWIN EU<sup>®</sup> Data Partner in accordance with the Work Order. Unless otherwise indicated in the Work Order, the DARWIN EU<sup>®</sup> Coordination Centre shall make payment against the invoice within thirty (30) days of its receipt of the invoice. The DARWIN EU<sup>®</sup> Data Partner

shall send the invoice on the date and to the address specified in the applicable Work Order.

- 3.2. Unless otherwise indicated in the Work Order, invoices shall be submitted in electronic format and shall specify the Purchase Order number, the protocol number for the DARWIN EU® Study to which the Services relate, the amount payable in the contract currency, the VAT rate and amount if applicable, the fee breakdown, description of the Services performed, the dates on which the Services were performed, the DARWIN EU® Data Partner's bank details including IBAN and SWIFT codes where applicable. DARWIN EU® Data Partner's final invoice in respect of a particular Work Order shall be submitted within (30) thirty days after completion of the Services relating to such Work Order and shall clearly state "Final Invoice".
- 3.3. The DARWIN EU® Coordination Centre cannot be held responsible for any fiscal consequences of these payments to the DARWIN EU® Data Partner. For the avoidance of doubt, all charges and/or fees imposed by the Data Partner's banks shall be for the account of the DARWIN EU® Data Partner. The DARWIN EU® Coordination Centre, has no obligation to discharge the same or any other similar administrative changes.
- 3.4. All costs, currency and rates set forth in the Work Order shall remain firm for the duration of the Services, unless otherwise agreed to in writing by the DARWIN EU® Data Partner and the DARWIN EU® Coordination Centre.
- 3.5. Independently of any Work Orders, the DARWIN EU® Coordination Centre shall pay a basic fee of €20,000 on a yearly basis (considering the Annual Period), to compensate the DARWIN EU® Data Partner for costs related to the maintenance and update of its data sources and related infrastructure that is needed to implement studies. This amount could change based on annual re-assessment by the DARWIN EU® Coordination Centre at least 30 days in advance of the start of the next Annual Period. If there is no notification in this regard from the DARWIN EU® Coordination Centre to the DARWIN EU® Data Partner within that period, the amount indicated in this section will be considered the same for the next Annual Period. Updated amounts will be reflected in amendments to this Agreement according to section 15. The DARWIN EU® Data Partner shall invoice for this basic fee upon signature of this Agreement, and then on an annual basis thereafter considering Annual Periods (as per the definition of Annual Period under this Agreement) thereafter.
- 3.6. Invoices shall be payable by the DARWIN EU® Coordination Centre no later than thirty (30) days after receipt by the DARWIN EU® Coordination Centre, represented by Erasmus MC of the DARWIN EU® Data Partner's invoice. The Data Partner will submit invoices, referencing the period and amounts due, to:

*Erasmus University Medical Center Rotterdam, Department of Medical Informatics  
Attn: accounts payable, cost centre 113271 /  
PO Box 21455  
3001 AL Rotterdam  
The Netherlands  
Reference: Prof.dr.ir. P.R Rijnbeek  
VAT number: NL807181997B01*

3.7. Payments in connection with this Agreement will be made following the indications of **Annex 2**, to:

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## 4. Reports

- 4.1. Unless the Work Order specifies more detailed reporting requirements, the DARWIN EU® Data Partner shall submit an Executive Summary to the DARWIN EU® Coordination Centre within 30 (thirty) days after the completion of the Services under a particular Work Order, describing the work performed.
- 4.2. The DARWIN EU® Data Partner shall strive that each Executive Summary (and any other report specified in the Work Order) submitted to the DARWIN EU® Coordination Centre is true, complete and correct, and accurately reflects the progress and Result of the corresponding Services.

## 5. Work Order

- 5.1. In accordance with Section 1, the terms of each Work Order, signed by the DARWIN EU® Coordination Centre and the DARWIN EU® Data Partner, shall be incorporated into this Agreement and shall form an integral part of it.

## 6. Data Management

- 6.1. The DARWIN EU® Data Partner shall make available to DARWIN EU® Coordination Centre Anonymous Data within the Results provided in relation to its Services. The DARWIN EU® Data Partner takes full responsibility for providing Anonymous Data to the DARWIN EU® Coordination Centre within the Results provided in relation to its Services, and assumes full liability with regard to and against identified data subjects (if any).
- 6.2. The DARWIN EU® Data Partner warrants that it has verified that there is an appropriate legal ground (including but not limited to any mandatory approvals within its institution) for the provision of the Anonymous Data to DARWIN EU® Coordination Centre.
- 6.3. Without prejudice to the foregoing, all Parties shall refrain from tracing and/or identifying any data subject and will not try to link the Anonymous Data to other data (including but not limited to third party data) for any such purpose.
- 6.4. In the event that any data subject, for whatever reason, becomes identifiable to a Party, that Party agrees to preserve, at all times, the confidentiality of information pertaining to such data subject and the protection of the Personal Data and inform the responsible DARWIN EU® Data Partner in writing of such identification.
- 6.5. In case of a security incident including Personal Data breaches, the breaching Party will inform the other Party without undue delay and in any case not later than 48 hours after becoming



aware of it; and comply with all applicable legal requirements in relation to the handling of such incidents, including the rules on the management of Personal Data breaches.

## 7. Intellectual property rights

- 7.1. Unless otherwise indicated in the Work Order, all aggregated data and DARWIN EU® Study Results, information and documents provided to the DARWIN EU® Coordination Centre in connection with this Agreement, whether in paper, oral, electronic or any other form, shall remain the sole property of the DARWIN EU® Coordination Centre. DARWIN EU® Data Partner shall acquire no rights therein.
- 7.2. The materials, results, information, documents, reports and analysis not being and/or incorporating Raw Data and directly resulting from or arising out of performing the Services in connection with a Work Order and all intellectual property rights therein (the "**Results**") are hereby assigned to and shall be the exclusive property of the DARWIN EU® Coordination Centre and may be used and/or transferred by the DARWIN EU® Coordination Centre, for any purpose as stated in **Annex 3** to any party (including, but not limited to, EMA) at their sole discretion with no further payment or other obligation to the DARWIN EU® Data Partner.
- 7.3. The DARWIN EU® Data Partner licenses any Pre-existing Rights on a perpetual, royalty-free, non-exclusive and irrevocable basis to the DARWIN EU® Coordination Centre with the right to sublicense to EMA, which may use the Pre-existing Materials for all the modes of exploitation and for any purposes.
- 7.4. The DARWIN EU® Data Partner warrants that it is entitled to provide all aggregated data and DARWIN EU® Study Results as required in the applicable Work Orders and that the Results and the Pre-existing Materials incorporated in the Results are free of rights or claims from Creators or from any third parties for any use that the DARWIN EU® Coordination Centre and EMA may envisage according to **Annex 3**.

## 8. Publications

- 8.1. Authorship on scientific publications related to the Services will comply with the guidelines established by the International Committee of Medical Journal Editors (ICMJE) 'Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals'<sup>2</sup>. Publications related to studies implemented by the DARWIN EU® Data Partner will be coordinated by the DARWIN EU® Coordination Centre and will include authorship of relevant contributing researchers from the DARWIN EU® Data Partner, and include proper acknowledgements.

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<sup>2</sup> <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#:~:text=2.-Who%20is%20an%20Author%3F,for%20important%20intellectual%20content%3B%20AND>

8.2. The DARWIN EU® Data Partner agrees with the publication of DARWIN EU® Study information (including the protocol and the report) in the EU PAS Register®.

## 9. Confidentiality and restricted use of Confidential Information

9.1. The DARWIN EU® Coordination Centre and the DARWIN EU® Data Partner must treat any Confidential Information with strict confidentiality.

9.2. Each Party must:

- a. not use Confidential Information for any purpose other than to perform its obligations under this Agreement without the prior written agreement of the other Party;
- b. ensure the protection of such Confidential Information with the same level of protection as its own Confidential Information and in any case with due diligence;
- c. not disclose, directly or indirectly, Confidential Information to third parties without the prior written agreement of the other Party.

9.3. The confidentiality obligations set out in this Section are binding on the Parties during the performance of the Service and for as long as the information or documents remain confidential unless:

- a. the disclosing Party agrees to release the receiving Party from the confidentiality obligation earlier;
- b. the Confidential Information become public through other means than a breach of the confidentiality obligation (either by the Parties or any third party);
- c. the applicable law requires the disclosure of the Confidential Information.

9.4. The DARWIN EU® Data Partner must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the performance of the Service, a commitment that they will comply with this Section. At the request of the DARWIN EU® Coordination Centre the contractor must provide a document providing evidence of this commitment.

## 10. Personal Data Protection

10.1. The DARWIN EU® Data Partner confirms and warrants that in the course of its regular operations and activities the DARWIN EU® Data Partner processes Personal Data, including special categories of Personal Data such as data concerning health strictly in compliance with Regulation (EU) 2016/679 and any applicable national data protection legislation of Union Member States. Accordingly, the DARWIN EU® Data Partner warrants and undertakes that if any of its activities related to the performance of the Service and this Agreement requires the processing of Personal Data, including anonymisation, it shall comply with applicable Union data protection legislation as referenced above. In particular, but not limited to, the DARWIN EU® Data Partner shall implement controls for anonymisation. In accordance with Section 6 (Data Management) of this Agreement, the DARWIN EU® Data Partner shall be responsible to implement appropriate controls (including technical and organisational measures) to prevent

the unauthorised reversal of the Anonymous Data provided to the DARWIN EU® Coordination Centre within the Results in relation to the Services.

- 10.2. The DARWIN EU® Data Partner confirms that it complies with all applicable laws, rules, regulations, and directives, including legislation on the protection of Personal Data as applicable.
- 10.3. The DARWIN EU® Coordination Centre shall refrain from actively tracing and/or identifying any natural person.
- 10.4. In the course of the performance of this Agreement and the Work Orders it is not expected that any international transfer of Personal Data within the meaning of Chapter V of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725 will need to be performed. Nevertheless, the Parties agree and undertake that in case any such international transfer of Personal Data will take place in relation to the performance of this Agreement and the related Work Order(s), it shall comply with Chapter V of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable.

## 11. Liability

- 11.1. Each Party represents and warrants that (i) it has the full right and authority to enter into and perform its obligations as set forth in this Agreement; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part; (iii) it will not grant any licenses or rights in conflict with any of the rights and licenses granted in or to be granted in accordance of this Agreement; (iv) the rights and licenses granted pursuant to this Agreement do not and will not infringe with any third party rights and, notwithstanding the foregoing, it will notify the other Parties promptly after becoming aware of any third party right infringement.
- 11.2. The DARWIN EU® Coordination Centre is not liable for any damage or loss caused by the DARWIN EU® Data Partner, including any damage or loss to third parties during or as a consequence of performance of this Agreement.
- 11.3. The DARWIN EU® Data Partner is liable for any loss or damage caused, direct or indirect, to the DARWIN EU® Coordination Centre or EMA during or as a consequence of performance of this Agreement, but only up to an amount not exceeding three times the total amount under this Agreement. However, if the damage or loss is caused by the gross negligence or wilful misconduct of the DARWIN EU® Data Partner or of its Personnel or its subcontractors, as well as in the case of an action brought against the the DARWIN EU® Coordination Centre or EMA by a third party for breach of its intellectual property rights, the DARWIN EU® Data Partner is liable for the whole amount of the damage or loss.
- 11.4. If the DARWIN EU® Data Partner fails to perform its contractual obligations within the applicable time limits set out in the corresponding Work Order, the DARWIN EU® Coordination Centre may claim liquidated damages for each day of delay in case the DARWIN EU® Coordination Centre gets confronted by EMA with liquidated damages (as evidenced by written records) based upon a delay caused by DARWIN EU® Data Partner using the following formula:

$$0.3 \times (V/d)$$

where

$V$  is the price of the relevant milestone or Results as specified in the corresponding Work Order or, failing that, the price specified in Section 3.1;

$d$  is the duration specified for delivery of the relevant milestone or Results or, failing that, the duration of the Services specified in the corresponding Work Order expressed in days.

## 12. Conflict of Interest

12.1. The Studies conducted in DARWIN EU<sup>®</sup> are performed with scientific independence and in line with the DARWIN EU<sup>®</sup> Conflict of Interest Policy (**Annex 4**).

12.2. Investigators of a Study promoted by DARWIN EU<sup>®</sup> must complete a Declaration of Interest (DoI) form (included in **Annex 4**) before the start of the first DARWIN EU<sup>®</sup> Study they are involved in. The DoI form is updated annually or any time changes of interests occur.

12.3. The DARWIN EU<sup>®</sup> Data Partner agrees with the storage of the DoIs on a specific portal where EMA will have access. The DoIs are subject to be made available to the public.

12.4. The DARWIN EU<sup>®</sup> Data Partner must take all the necessary measures to prevent any situation of conflict of interest as described in the DARWIN EU<sup>®</sup> Conflict of Interest Policy.

## 13. Term and Termination

13.1. This Agreement enters into force on the day of the signature by the last Party (the “**Start Date**”) until 7<sup>th</sup> of February [year to be defined depending on contractual period applicable between EMA & the CC]. By expiration of the latter, the agreement is renewed automatically for twelve (12) months each (the “Annual Period”), unless it is terminated earlier according to section 13.2, 13.3 and 13.4.

Without prejudice to the above, the last Annual Period shall end on 7<sup>th</sup> of February 2027.

13.2. The DARWIN EU<sup>®</sup> Coordination Centre reserves the right to reassess annually (considering the Annual Period) the continuation of the DARWIN EU<sup>®</sup> Data Partner in the DARWIN EU<sup>®</sup> Data Partners Network and its terms and conditions. If there is no notification in this regard from the DARWIN EU<sup>®</sup> Coordination Centre to the DARWIN EU<sup>®</sup> Data Partner at least 30 days in advance of the start of the next Annual Period, the terms indicated in this Agreement will be considered the same for the next Annual Period. Any change to the terms of this Agreement will be reflected in amendments to this Agreement according to section 15.

13.3. The DARWIN EU<sup>®</sup> Coordination Centre reserves the right to terminate this Agreement if the DARWIN EU<sup>®</sup> Data Partner fails to comply with its obligations as stated in this Agreement prior to completion at any time, by giving 30 days prior written notice to the DARWIN EU<sup>®</sup> Data Partner.

13.4. Notwithstanding section 16.4, the DARWIN EU<sup>®</sup> Coordination Centre reserves the right to terminate this Agreement prior to completion if the EMA finalises the contractual relationship with the representative of the DARWIN EU<sup>®</sup> Coordination Centre at any time, by giving 30 days prior written notice to the DARWIN EU<sup>®</sup> Data Partner, except if EMA and a new representative

of the DARWIN EU® Coordination Centre together informs the DARWIN EU® Data Partner in writing about succession as regards the entity representing the DARWIN EU® Coordination Centre, in which case Section 16.4 of this Agreement shall apply.

13.5. In the event of termination, the DARWIN EU® Data Partner commits to return to the DARWIN EU® Coordination Centre all Confidential Information of a returnable nature that may have been provided by the DARWIN EU® Data Partner. Also in this event, payments will be made for all work performed up to the date of termination and reasonable non-cancellable costs incurred in connection with the work in accordance with the terms of this Agreement.

## 14. Notices

14.1. All notices required to be in writing under this Agreement shall be delivered personally, by courier or mailed to the Parties at the addresses set forth below or such other addresses as the Parties may designate in writing.

If to <b>Erasmus University Medical Center</b> Rotterdam (as representative of the DARWIN EU® Coordination Centre):	If to the <b>DARWIN EU® Data Partner</b>
Attn: Prof. dr. ir Peter R. Rijnbeek Erasmus University Medical Center Rotterdam Dr. Molewaterplein 50 PO Box 2040 3000 CA Rotterdam The Netherlands e-mail: p.rijnbeek@erasmusmc.nl	Attn: xx       e-mail: xx
Contact person: Prof. dr. ir. Peter R. Rijnbeek	Contact person: xx

## 15. Amendments

15.1. Any amendments or revisions to this Agreement must be proposed in writing by either Party and accepted in writing by the other Party before they shall become effective and binding.

## 16. Miscellaneous

16.1. The DARWIN EU® Data Partner undertakes to comply with all applicable laws, rules, regulations, ordinances, and directives.

16.2. This Agreement represents the entire understanding between the Parties and supersedes all other agreements, express or implied, between the Parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the Parties and, consequently, shall not be strictly construed against either Party.

16.3. The DARWIN EU® Data Partner agrees not to assign this Agreement nor any right and/or obligation under this Agreement to any third party, without the written prior consent of the

DARWIN EU® Coordination Centre; such consent shall be separately required for each case of assignment.

16.4. The DARWIN EU® Data Partner hereby irrevocably agrees to any novation of this Agreement and irrevocably agrees that the DARWIN EU® Coordination Centre is entitled to and may lease, assign or transfer the rights of the DARWIN EU® Coordination Centre in respect of this Agreement to the EMA or a new DARWIN EU® Coordinator Centre. Upon such novation, lease, assignment or transfer, the DARWIN EU® Data Partner shall release Erasmus MC from any and all liability under this Agreement by which the Erasmus MC is bound in representation of the DARWIN EU® Coordinator Centre from and after the date of transfer to the EMA and or a potential new DARWIN EU® Coordinator Centre.

## 17. Governing law

17.1. The Agreement shall be governed and construed exclusively in accordance with the laws of the Netherlands (excluding its conflict of law provisions).

17.2. In the event a dispute arises between or among the Parties over the interpretation and application of this Agreement, the Parties shall attempt to settle such dispute first by negotiation and consultation between themselves. The Parties also will consider alternative dispute resolution as a means of resolving any such dispute.

17.3. All disputes arising out of or in connection with this agreement which could not have been resolved in accordance of the previous section 16.2, will be resolved by the Amsterdam District Court following proceedings in English before the Chamber for International Commercial Matters ("**Netherlands Commercial Court**" or "**NCC District Court**"), to the exclusion of the jurisdiction of any other courts.

<<< SIGNATURES WILL FOLLOW ON THE NEXT PAGE >>>

**IN WITNESS WHEREOF**, the Parties have executed this Agreement in duplicate originals by their duly authorized officers or representatives,

On behalf of the DARWIN EU© Coordination Centre:

**ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM**

.....

**Name:** Prof. dr. ir Peter Rijnbeek

**Title:** Head of Department of Medical Informatics

**Date:**

and

As DARWIN EU® Data Partner:

**[NAME]**

.....

**Name:**

**Title:**

**Date:**

## ANNEX 1. WORK ORDER AGREEMENT (SAMPLE)

### WORK ORDER AGREEMENT

Between

**ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM**

**as the representative of the DARWIN EU® Coordination Centre**

having its statutory address

at Dr. Molewaterplein 40, Rotterdam 3015 GD, Netherlands

(hereinafter “DARWIN EU® Coordination Centre”)

and

xx

having its statutory address

at.....

(hereinafter "xx")

This work order (“**Work Order**”) shall be effective as of the Effective Start Date below. Performance of the Work Order (“Performance Start Date” or “T0”) is the date at which the data partner is expected to initiate work on the study, as detailed in Section 1 and Schedule B. This Work Order is subject to the terms of the DARWIN EU® Data Partner Framework Agreement (“**Agreement**”) signed between the DARWIN EU® Coordination Centre represented by Erasmus MC and XX effective on xx of 202X, which provisions take precedence over those in this Work Order unless otherwise stated herein.

#### 1. CONTRACT RESEARCH-RELATED INFORMATION

Effective Start Date:	
Performance Start Date or T0:	
Planned Completion Date:	
DARWIN EU® Study Name and Number:	



## 2. SERVICES

XX agree to perform the Services in accordance with the terms of this Agreement and with the DARWIN EU® Study specifications as set out in Schedule B as well as the budget and payment schedule included in Schedule A.

## 3. RESPONSIBILITIES OF THE PARTIES

The roles of the Parties are specified in Schedule B, which specifies the responsibilities and the tasks to be performed for this Work Order.

In the performance of the Services, XX shall be bound by the terms and conditions of the Agreement and the Work Order.

## 4. NOTICE

Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date if it is sent by post or e-mail, and addressed to the Party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing, as well as any persons so designated under the Agreement itself:

If to the DARWIN EU® Coordination Centre, represented by Erasmus MC:

Invoicing and Payments Matters:	[indicate name, email and address of the responsible person]
Administrative / Contractual Matters:	[indicate name, email and address of the responsible person]
Technical Matters:	[indicate name, email and address of the responsible person]

If to XX:

Invoicing and Payments Matters:	[indicate name, email and address of the responsible person]
Administrative / Contractual Matters:	[indicate name, email and address of the responsible person]
Technical Matters:	[indicate name, email and address of the responsible person]

## 5. COST AND PAYMENT

Payment shall be made to XX according to Schedule A appended hereto and incorporated herein by reference. All costs outlined on Schedule A shall remain firm for the duration of the Services, unless otherwise agreed to in writing by XX and the DARWIN EU® Coordination Centre, represented by Erasmus MC. It is the responsibility of the DARWIN EU® Coordination Centre, represented by Erasmus

MC, to pay the budget corresponding to the contributions of **XX** in a time and manner that ensures satisfactory completion of the Services.

**6. SPECIFIC PROVISIONS FOR THIS CONTRACT SERVICES *[if applicable]*:**

**6.1. The DARWIN EU® Study Sponsorship and leadership**

**6.2. Reports** *[In case specific or additional terms are to be applicable in relation to Section 4 of the Framework Agreement]*

**6.3. Intellectual property rights** *[In case specific or additional terms are to be applicable in relation to Section 7 of the Framework Agreement]*

**6.4. Confidentiality** *[In case specific or additional terms are to be applicable in relation to Section 9 of the Framework Agreement]*

**6.5. Data Protection and Security** *[In case specific or additional terms are to be applicable in relation to Section 6 and 10 of the Framework Agreement]*

6.x. (any other necessary provisions)

**7. LIST OF ATTACHMENTS:**

- Budget and Payment Schedule (Schedule A)
- The DARWIN EU® Study Specification Worksheet (Schedule B)

IN WITNESS WHEREOF, the Parties hereto have executed this Task Order in duplicate by proper persons thereunto duly authorised

<p><b>The DARWIN EU® Coordination Centre, represented by Erasmus MC,</b></p> <p>By:</p> <p>Name:</p> <p>Title:</p> <p>Date:</p>	<p><b>XX</b></p> <p>By:</p> <p>Name :</p> <p>Title :</p> <p>Date :</p>
---	--

**Schedule A**

**BUDGET AND PAYMENT SCHEDULE**

The DARWIN EU® Coordination Centre agrees to pay to **XX** a fee in the amount of \_\_\_ **EUR** plus VAT if applicable to a total amount of \_\_\_\_\_ **EUR** for the execution of the Services specified in this Working Order.

In consideration of the satisfactory performance of the Services, the DARWIN EU® Coordination Centre will make payment in accordance with the following payment schedule. **xx** will submit to the DARWIN EU® Coordination Centre invoices for the following amounts upon successful milestone completion:

<b>Milestone</b>	<b>Delivery Date</b>	<b>Estimated % of Total</b>	<b>Estimated Amount in XXX (Currency)</b>
<b>TOTAL:</b>		<b>100%</b>	

Schedule B

DARWIN EU® STUDY DESCRIPTION AND SPECIFICATIONS

Description of the Work

Roles and contributions

The responsibilities of the Parties are set out in the table hereunder. The "R" indicates the responsible Party for the particular task.

Task / Activity	DARWIN EU® Coordination Centre	DARWIN EU® Data Partner	Estimated delivery date	Comments
xxx				In collaboration with XX
xxx				
xxx				
xxx				

## ANNEX 2. DARWIN EU® DATA PARTNER BANK INFORMATION

### FINANCIAL IDENTIFICATION

Please use CAPITAL LETTERS and LATIN CHARACTERS when filling in the form.

<b><u>BANKING DETAILS</u></b> ①	
ACCOUNT NAME ②	
IBAN/ACCOUNT NUMBER ③	
CURRENCY	
BIC/SWIFT CODE	BRANCH CODE ④
BANK NAME	
<b>ADDRESS OF BANK BRANCH</b>	
STREET & NUMBER	
TOWN/CITY	POSTCODE
COUNTRY	
<b><u>ACCOUNT HOLDER'S DATA (AS DECLARED TO THE BANK)</u></b>	
ACCOUNT HOLDER	
STREET & NUMBER	
TOWN/CITY	POSTCODE
COUNTRY	
REMARK	
<b>BANK STAMP + SIGNATURE OF BANK REPRESENTATIVE</b> ⑤	<b>DATE (Obligatory)</b>
	<b>SIGNATURE OF ACCOUNT HOLDER (Obligatory)</b>

- ① Enter the final bank data and not the data of the intermediary bank.
- ② This does not refer to the type of account. The account name is usually the one of the account holder. However, the account holder may have chosen to give a different name to its bank account.
- ③ Fill in the IBAN Code (International Bank Account Number) if it exists in the country where your bank is established
- ④ Only applicable for US (ABA code), for AU/NZ (BSB code) and for CA (Transit code). Does not apply for other countries.
- ⑤ It is preferable to attach a copy of RECENT bank statement. Please note that the bank statement has to confirm all the information listed above under 'ACCOUNT NAME', 'ACCOUNT NUMBER/IBAN' and 'BANK NAME'. With an attached statement, the stamp of the bank and the signature of the bank's representative are not required. The signature of the account-holder and the date are ALWAYS mandatory.

### ANNEX 3. MODES OF EXPLOITATION AND USE OF THE RESULTS

In accordance with Section 7.2 of this Agreement, the DARWIN EU® Coordination Centre acquires ownership of the Results defined therein. These Results may be used for any of the following modes of exploitation:

- (a) use for its own purposes:
  - making available to the staff of the DARWIN EU® Coordination Centre and EMA;
  - making available to the persons and entities working for the DARWIN EU® Coordination Center and EMA or cooperating with it, including contractors, subcontractors whether legal or natural persons, Union institutions, agencies and bodies, Member States' institutions and other national entities involved in the analysis or delivery of healthcare services;
  - installing, uploading, processing;
  - arranging, compiling, combining, retrieving;
  - copying, reproducing in whole or in part and in unlimited number of copies.
- (b) distribution to the public in hard copies, in electronic or digital format, on the internet including social networks as a downloadable or non-downloadable file;
- (c) communication through press information services;
- (d) inclusion in widely accessible databases or indexes such as, but not limited to, the European Union Post Authorisation Safety Studies Register ('EU PAS Register'), via 'open access' or 'open data' portals, or similar repositories, whether freely accessible or accessible only upon subscription;
- (e) modifications by the the DARWIN EU® Coordination Centre, EMA or by a third party in the name of the DARWIN EU® Coordination Centre or EMA, including:
  - shortening;
  - summarising;
  - modifying the content, the dimensions;
  - making technical changes to the content (necessary correction of technical errors), adding new parts or functionalities, changing functionalities, providing third parties with additional information concerning the Results (e.g. source code) with a view to making modifications;
  - addition of new elements, paragraphs, titles, leads, bolds, legend, table of content, summary, graphics, subtitles, sound;
  - addition of metadata, for text and data-mining purposes; addition of right-management information; addition of technological protection measures;
  - preparation in audio form, preparation as a presentation, animation, pictograms story, slide- show, public presentation;
  - extracting a part or dividing into parts;
  - incorporating, including by cropping and cutting, the Results or parts thereof in other works, such as on websites and webpages;
  - using/inserting/labelling with branding assets available to the DARWIN EU® Coordination Center, such as, but not limited to, EMA and DARWIN EU®;

- translating, inserting subtitles, dubbing in different language versions: all official languages of EU;
- (f) rights to authorise or license the modes of exploitation set out in any of the points (a) to (e) to third parties, provided however that this does not apply to Pre-existing Rights and Pre-existing Materials.
- (g) other adaptations which the parties may later agree; in such case, the following rules apply: the DARWIN EU® Coordination Center must consult the DARWIN EU® Data Partner . If necessary, the DARWIN EU® Data Partner must in turn seek the agreement of any Creator or other right holder and must reply to the DARWIN EU® Coordination Center within one month by providing its agreement, including any suggestions of modifications, free of charge. The DARWIN EU® Data Partner may refuse the intended modification only if a Creator can demonstrate that the intended modification may harm his/her honour or reputation, thereby violating his/her moral rights.

The list above is in addition to whatever rights already accrued to the DARWIN EU® Coordination Center or EMA on the basis of existing exceptions in the applicable legislation, such as the copyright exception to ensure the proper performance or reporting of administrative proceedings, in cases where such exceptions apply.

In addition to above, all Pre-existing Rights incorporated in the Results, if any, are licensed to the the DARWIN EU® Coordination Center with the right to sublicense.

## ANNEX 4. DARWIN EU® CONFLICT OF INTEREST POLICY

### GENERAL PRINCIPLES

The studies and analyses conducted in DARWIN EU® shall be conducted in accordance with the principle of scientific independence, as set out under the [ENCePP Code of Conduct](#). Where relevant, the definitions and principles set out under [EMA Policy 044](#) shall also be applied.

Declarations of interests (Dols) will be evaluated at the individual level for each Investigator participating in the Study team for each particular DARWIN EU® Study.

### DEFINITIONS

#### Investigator of a DARWIN EU® Study

Investigator means an individual responsible for the conduct of the feasibility analysis, the development of the protocol, statistical analysis plan and/or the report of a DARWIN EU® Study with the ability to contribute to the Study design, data collection, data analysis and/or interpretation of the Results. In this context, the following persons are **not** considered Investigators:

- Analysts or programmers of product or disease-agnostic analytical pipelines;
- Project managers and administrative support staff;
- Individuals (including within the DARWIN EU® Data Partner) whose only role is to execute or run an algorithm, query, or software code.

#### DARWIN EU® Study

A non-interventional study or observational analysis performed by the DARWIN EU® Coordination Centre in the context of the DARWIN EU® Network; with the objective of ascertaining the safety and/or efficacy of medicinal products. The observational analyses and studies may be defined based on their anticipated level of complexity and can refer to the following categories which may be flexible: a routine repeated analysis, off-the-shelf Study, complex Study, or very complex Study..

#### Direct interests

Direct interests are defined as having any of the following:

- employment with a pharmaceutical company
- a consultancy to a pharmaceutical company
- a strategic advisory role for a pharmaceutical company
- financial interests in a pharmaceutical company
- involvement in the repurposing of a medicinal product

#### Indirect interests

Indirect interests are defined as any of the following:

- being a principal Investigator for a pharmaceutical company
- having involvement of the expert's organisation in the repurposing of a medicinal product
- being an investigator for a pharmaceutical company
- having a grant or other funding from a pharmaceutical company to the expert's organization or institution
- having a close family member with a direct interest in a pharmaceutical company



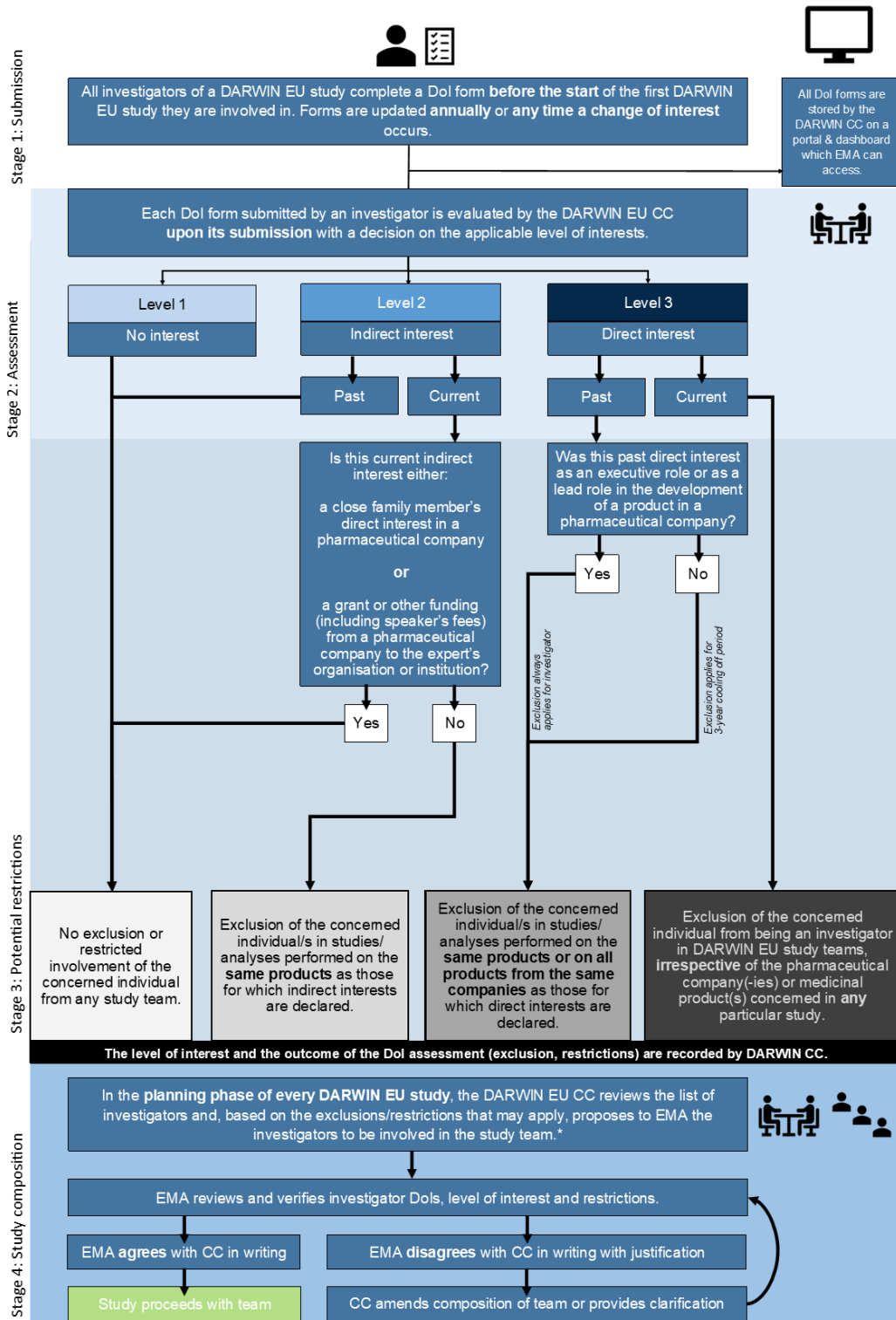
### **Past interests**

Past interests are interests that have occurred:

- in a period of 0 to 3 years before the start of the DARWIN EU® Study,  
*or*
- at **any** time in the past in the case of employment in a pharmaceutical company in an executive role or as the lead role in the development of a product.

### **PROCESS**

The process of CoI management is reported below, with all steps illustrated in [Figure 1](#).



\*For routine repeated analysis where the same protocol and analysis plan is re-used and there are no changes to the DoIs of the involved investigators, the DARWIN CC may only confirm that the same study team as used in previous analyses is involved.

Figure 1: The Conflict of Interest process.