Advisory Agreement

between 22 Consortium Members as listed in Appendix 1

- hereinafter jointly referred to as "**Consortium**" -

and *[Name and private address of Advisor]*

- hereinafter referred to as "**Advisor**" -

WHEREAS,

(A) The Consortium has been formed under the Innovative Medicines Initiative 2 ("**IMI**") for the purpose of establishing the project called "European Health Data and Evidence Network (EHDEN)" (IMI Grant Agreement No. 806968) (the "**Action**"). It consists of the participants listed in Exhibit 1 hereto (collectively the "**Participants**"), including Janssen Pharmaceutica NV acting as the "**Project Leader**". The Participants are parties to an IMI Consortium Agreement for EHDEN effective as of 01/11/2018 (the "**Consortium Agreement**").

Subject to the Consortium Agreement, a Data Source Prioritisation Committee (DSPC) is established to evaluate applications received from data sources applying to have their data mapped to the OMOP Common Data Model, according to the procedures and criteria transparently disclosed, as set forth in Appendix 2 - Roles and Responsibilities of the DSPC.

Advisor, who is employed by *[name and address of employer]*, has extensive experience, scientific and/or industrial prominence and leadership in the field of *[field of expertise]* relating to the Action.

The Consortium is interested to have the Advisor to be part of the DSPC.

Each Participant has authorized the Coordinator to execute this Advisory Agreement (the "**Agreement**") on its behalf.

Therefore, it is agreed as follows:

1. SUBJECT MATTER OF THE AGREEMENT

Advisor shall provide consultative and advisory services to the Consortium according to the terms and conditions of the Consortium Agreement and this Agreement as set forth below (hereinafter referred to as the "**Services**"):

[In case Advisor is to be a member of a committee:

Further details of the Services will be agreed between the parties.

For the term of this Agreement Advisor agrees to declare in an appropriate way that he/she is an advisor to the Consortium whenever he/she writes or speaks in public about a topic that is the subject matter of this Agreement or any other issue relating to the Action.

COMPENSATION

The parties agree that the Advisor shall not be compensated for the performance of the Services.

The **Consortium** will, in compliance with the applicable laws, regulations and codices, offer to pay for reasonable travel expenses and hospitality, such as flights (business class airfare for intercontinental flights and economy class airfare for intracontinental flights), train travel, accommodation (up to 4-star rating), work related meals and transportation. In addition, Advisor shall be reimbursed by **Consortium** for other reasonable travel expenses actually incurred by Advisor in connection with providing the Services, subject to the receipt of invoices or receipts. Costs for meals and drinks are not considered as travel expenses.

Any payments will be made by **Consortium** within 90 days to an account nominated by the Advisor previously in writing upon receipt of a correct invoice (i) complying with applicable legal and tax requirements and (ii) containing the original receipts. Further details will be agreed between the parties. Advisor acknowledges and agrees that the amounts paid will be reported to the members of the Consortium as well as the country to which the amount is paid.

Advisor shall be responsible for all other taxes payable on account of payments made hereunder.

Advisor agrees that the Consortium (by stating Advisor's private information) may store, process and publish any payments made by the Consortium under this Agreement, if such disclosure is required by statutory or internal regulation or any binding Code of Conduct.

CONFIDENTIALITY, ARCHIVING, DATA PROTECTION

Advisor undertakes to hold in strict confidence any information, in particular without limitation scientific, technical or commercial information relating to the business, products or research of the Consortium, which becomes known to Advisor during the course of this collaboration, together with any information regarding the Action and all results of the cooperation with the Consortium, to use such information and results only for the purposes of this Agreement, and not to disclose such information or results to any third party without a prior written consent of the Consortium. The foregoing restrictions on use and disclosure will not apply to any of such information which: (a) at the time of receipt by Advisor is available to the public; or (b) becomes public knowledge other than by an act or omission on the part of Advisor; or (c) which Advisor can prove was known to Advisor before the date of its disclosure to Advisor by the Consortium; or (d) is legally acquired by Advisor from a third party not bound to Consortium or any of its Participants by any express or implied obligation of secrecy, or (e) Advisor can prove was developed independently by him/her without reference to or use of the information.

Furthermore, Advisor may disclose such information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that Advisor shall give reasonable advance notice to the Consortium and on request, shall cooperate with the Consortium to seek a protective order or other appropriate remedy. The Advisor will use his/her reasonable efforts to secure confidential treatment of any such information that will be disclosed.

Information shall not be deemed to be or have become public knowledge merely because any part of such Information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.

Advisor agrees to duly preserve all information and documentation provided to Advisor and to ensure that no third parties gain access thereto. Any documentation provided must be returned to the Consortium at Consortium's request during the term of this Agreement, and shall be returned to the Consortium, without being asked, upon the termination of this Agreement.

This confidentiality and non-use obligation shall remain in effect for ten (10) years after the Consortium Agreement expires or is terminated.

In the event the performance of Services or the preparation thereof requires Advisor to use or process any personal data, Advisor agrees to use such personal data only for the Services provided hereunder and in compliance with applicable data protection laws.

RIGHTS TO RESULTS

In case that results are generated by Advisor including intellectual property rights relating thereto (collectively "**Results**") Advisor shall promptly disclose any Results to the Project Leader in writing. All rights, title and interest in any Results will be owned exclusively by the Participants in equal shares, and Advisor shall assign (or cause to be assigned) and does hereby assign fully to each of the Participants in equal shares all rights, title and interest in and to any Results, without payment of any additional compensation to Advisor. At a Participant's request and expense, Advisor shall also reasonably assist such Participant in obtaining, perfecting, or defending such Participant's rights, title, and interest in any Results, including, without limitation, the drafting, filing and prosecution of any patent applications. As between the Participants, such results shall be deemed to be *Foreground* and rights thereto shall be exploited and shared pursuant to the terms of the Consortium Agreement. With regard to any copyrights, Advisor consents to the right to reproduce, modify and use all copyrightable works designed or made by the Advisor by each of the Participants.

COMPLIANCE

The parties declare that this Agreement is in no way associated with any business or sales activities between the parties hereto and in particular Advisor is by no means obligated to prescribe, recommend or purchase any goods from the Consortium.

Advisor agrees to comply with all applicable laws and regulations in the performance of the Services pursuant to this Agreement.

Advisor represents and warrants that: (a) Advisor has received all necessary approvals in connection with entering into this Agreement and performing the Services to be provided hereunder; (b) compliance with the terms of this Agreement and performance of the Services do not and will not breach or conflict with (i) any other agreement or arrangement, to which Advisor is a party, or (ii) any statutory or internal regulations Advisor is subject to; (c) compliance with the terms of this Agreement and performance of the Services do not and will not breach any agreement to keep in confidence information acquired in confidence or in trust; and (d) during performance of the Services, Advisor will not disclose to Consortium, or induce Consortium to use, any information belonging to a third party.

Advisor further represents and warrants that he/she has fully informed the management of his/her medical agency/institution or other employer, or any other organizations or authorities, if necessary, about the execution and content of this Agreement and that he/she has obtained the necessary written approvals of such employer that are required for the performance of this Agreement.

The Advisor represents that in performing the Services he has not and he will not use in any capacity the services of anyone debarred, disqualified, blacklisted or banned or under investigations or threat of investigations by any regulatory authority for debarment, disqualification, blacklisting or any similar regulatory action in any jurisdiction anywhere in the world. Furthermore, the Advisor represents and warrants that neither he, nor its employees, agents, representatives or permitted sub-contractors have been debarred, disqualified, blacklisted or banned by any regulatory authority, nor that they are currently to the best of his knowledge, the subject of such a debarment, disqualification, blacklisting or banning proceeding. During the term of this Advisory Agreement, the Advisor shall promptly notify the Project Leader should the Advisor, any of its employees, agents, representatives or permitted sub-contractors become subject of such debarment, disqualification, blacklisting or banning proceeding.

TERM

This Agreement comes into force upon signature by the parties and continues effective until all parties' obligations pursuant to Section 1 and 2 hereof have been fulfilled.

The terms set forth in Sections 3, 4, 6.2 and 7.1 shall survive any termination or expiration of this Agreement.

MISCELLANEOUS

Advisor shall not use any name, logos or trade names or product trademarks owned by a member of the Consortium, IMI or the Consortium as such in any public announcement, press release or other public document without prior written consent of the Consortium and/or the member of the Consortium that owns the name, logos or trade names or product trademarks.

Advisor shall be deemed for all purposes to be an independent contractor. Advisor shall not have the authority to enter into agreements or make any representations on behalf of or otherwise bind the Consortium.

This Agreement contains the entire agreement between the Advisor and the Consortium. Any amendments to this Agreement shall be made in writing. If any provision of this Agreement is or becomes invalid or unenforceable, this shall not affect the remaining provisions hereof. The parties shall in this case replace the invalid or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid or unenforceable provision.

Each Participant is intended to be a third party beneficiary with the ability to enforce the terms of the Agreement in its own name and as if it was a party to this Agreement.

This Agreement shall be construed, controlled and interpreted by the laws of Belgium, regardless of its conflict of laws provisions. Exclusive place of jurisdiction shall be Brussels.

REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in threefold in their own name and in case of Project Leader in addition in the name and on behalf of the Participants as their duly authorized representatives.

Janssen Pharmaceutica NV, JANSSEN ***[Advisor]***

(**Project Leader**)

_____ _____

Name: Name:

Function: Function

Place: _____ Place: _____

Date: _____ Date: _____

Acknowledged and agreed

Erasmus Universitair Medisch Centrum Rotterdam, EMC

(Coordinator)

_____

Name:

Function:

Place: _____

Date: _____

Approval of Employer: *[Insert name of employer]*

We have read the foregoing Advisory Agreement between the Consortium and *[Insert name of advisor]* and approve the content and the conclusion of such Agreement:

Name: _____

Place/Date: _____

Signature/Seal: _____

EXHIBIT 1

Names and addresses of EHDEN Consortium Participants

(1) **Erasmus Universitair Medisch Centrum Rotterdam**, whose administrative offices are at Dr. Molenwaterplein 40, 3015GD Rotterdam, Netherlands, "EMC" ;

(2) **Synapse Research Management Partners SL**, whose administrative offices are at CalleVelázquez 94-1, 28006 Madrid, Spain, "SYNAPSE" ;

(3) **The Chancellor, Masters and Scholars of the University of Oxford**, whose administrative offices are at Wellington Square, University Office, OX1 2JD Oxford, England, "UOXF";

(4) **Tartu Ulikool,** whose administrative offices are at Ulikooli 18, 50090 Tartu, Estonia, "UTARTU";

(5) **Universidade De Aveiro,** whose administrative offices are at Campo Universitario de Santiago, 3810 193 Aveiro, Portugal, "UAVR";

(6) **The Hyve BV,** whose administrative offices are at Arthur Van Schendelstraat 650, 3511 MJ Utrecht, Netherlands, "THE HYVE";

(7) **Odysseus Data Services s.r.o,** whose admninistrative offices are at Na Havrůnce 1508/14, 143 00 Praha, Czech Republic, "ODYSSEUS";

(8) **Forum Européen Des Patients,** whose admninistrative offices are at rue Dicks 14, 1417 Luxembourg, Luxembourg, "EPF";

(9) **National Institute for Health and Care Excellence,** whose admninistrative offices are at Level 1A, City Tower Piccadilly Plaza, M1 4BT, Manchester, England, "NICE";

(10) **Stiftelsen WHO Collaborating Centre for International Drug Monitoring**, whose administrative offices are at Bredgrand 7, S-75140 Uppsala, Sweden, "UMC";

(11) **International Consortium for Health Outcomes Measurement LTD,** whose administrative offices are at 1 Eversholt Street, NW1 2DN London, England, "ICHOM";

(12) **Janssen Pharmaceutica NV,** whose administrative offices are at Turnhoutseweg 30, B-2340 Beerse, Belgium, "JANSSEN";

(13) **Pfizer Limited,** whose administrative offices are at Ramsgate Road, Sandwich, Kent, CT139NJ, England, "Pfizer";

(14) **AbbVie INC,** whose administrative offices are at 1 N. Waukegan Road, North Chicago, IL 60063, USA, "AbbVie";

(15) **Institut de Recherches Internationales Servier,** whose administrative offices are at 50 rue Carnot, 92284 Suresnes Cedex, France, « SERVIER »;

(16) **Sanofi-Aventis Recherche & Développement,** whose administrative offices are at 1 Avenue Pierre Brosselette, 91380 Chilly Mazarin, France, "SANOFI";

(17) **Bayer AG**, whose administrative offices are at Müllerstraße 178, 13353 Berlin, Germany, "BAYER";

(18) **Eli Lilly and Company Limited** whose administrative offices are at Lilly House Priestly Road, Basingstoke, Hampshire RG24 9NL, United Kingdom, "LILLY";

(19) **AstraZeneca AB,** a company incorporated in Sweden under no. 556011-7482 and with administrative offices at SE-431 83 Mölndal, Sweden, "AZ";

(20) **Novartis Pharma AG,** whose administrative offices are at Lichtstrasse 35, 4056 Basel, Switzerland, "Novartis";

(21) **UCB,** whose administrative offices are at Allée de la recherche 60, 1070 Brussels, Belgium, "UCB";

(22) **Celgene Management Sarl,** whose administrative offices are at Route de Perreux 1, 2017 Boudry, Switzerland, "CELGENE"

Appendix 2: Roles and Responsibilities of the Data Source Prioritization Committee (DSPC)

The DSPC will be in charge of evaluating applications received from data sources applying for funding to have their data mapped to the OMOP Common Data Model, according to the procedures and criteria described in sections 1.3.4 and 4.3 of the EHDEN Description of the Action (DoA), and to be further elaborated in Deliverable 5.1 – Report on SME Certification Procedure and Data Source Grant Awarding Procedure.

Besides the provisions regarding membership of the DSPC included in Clause 11.8 of the EHDEN CA, to be deemed eligible as a candidate DSPC member, any expert would be required to:

- Be experienced in the use of RWD for observational research and real-world evidence generation (also demonstrated by e.g. publication history), with recognition as a thought leader in this domain
- Have participated in multi-centre, multi-country (cross border) research, and/or held a position of conducting such research at a data source level
- Have familiarity with the technical constructs within EHDEN, specifically the OMOP CDM and OHDSI global collaboration, as well as the tooling required for observational research in an open science, open source setting
- Be able to recuse themselves from decisions that may apply to institutions or organisations they would have any specific interest in (e.g. employment)