EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

Data Partner
Rapid Collaboration Call
on COVID-19

The EHDEN Consortium

15/04/2020

V1.4

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 806968.
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1 DOCUMENT HISTORY

Version	Date	Description
V1.4	15-4-2020	Final version

2 DOCUMENT CHANGES

Version	Date	Section	Description

3 INTRODUCTION

At the time of writing, the SARS-CoV-2 pandemic has accounted for 1.6 million confirmed infections, and almost 100,000 deaths attributed to COVID-19 worldwide. The global pandemic is characterised by clinical and management challenges which are un-addressable without current and relevant data for research. Most of the studies trying to shed a light on this brand-new global threat is based on limited data sets, frequently constrained by the characteristics of a limited population and a specific local, regional or national context. However, the global nature of COVID-19 demands fast and reliable evidence supported by the, unfortunately now, increasing amounts of data that are being continuously generated in tens of countries where the pandemic is having a tragic impact.

As a consequence, and inspired by our recent collaborations in the COVID-19 OHDSI study-a-thon, EHDEN proposes to conduct a rapid, specific call for Data Partners with COVID-19 data which can assist us with supporting open science research in characterising infection and disease, as well as assessing potential clinical management and therapeutic options. The objective is to be able to:

- Involve as many Data Partners as possible as soon as possible
- Map their data to the OMOP Common Data Model in a remote and expedited way
- Apply the EHDEN/OHDSI analytical toolkit on the mapped data to get evidence-based responses to some of the most urgent research questions in a matter of days rather than weeks.

We expect applicants will be interested to contribute to key areas of research, including recently prioritised questions by the OHDSI and EHDEN communities. Examples of these include the characterisation of patients diagnosed and/or admitted to hospital with COVID-19, the training and validation of algorithms to identify subjects at risk of poor outcomes or in need of intensive care, and the study of the safety and potential anti-viral effectiveness of target treatments such as hydroxychloroquine, prednisolone or anti-retroviral therapies. The different phases in the disease trajectory we aim for and their data types of interest are shown in the table in Appendix 2.

This document describes the Rapid Collaboration Call on COVID-19 in the European Health Data and Evidence Network (EHDEN) project (www.ehden.eu) **that opens Thursday April 16th 2020 at 12:00 CET and closes May 14th 17:00 CET**.

3.1 The EHDEN Project

The EHDEN project is a public-private partnership, set up under the framework of the IMI2 programme (www.imi.europa.eu). The EHDEN consortium consists of twenty-two partners, including academia, Small and Medium-sized Enterprises (SMEs), patient associations, regulatory authorities and pharmaceutical companies. EHDEN is led by the Erasmus Medical Centre, The Netherlands, and Janssen Pharmaceutica N.V., Belgium. The mission of EHDEN is to provide a new paradigm for the discovery and analysis of health data in Europe, by building a large-scale, federated network of data partners across Europe.

Central to EHDEN will be the standardisation of health data to the Observational Medical Outcomes Partnership (OMOP) common data model (CDM), and the utilisation of analytical tools such as those developed by the international Observational Health Data Sciences and Informatics (OHDSI) open science collaboration (www.ohdsi.org), and others. The ultimate aim is to facilitate the generation of valid real-world evidence to improve patient care and to enable medical outcomes-based research at an unprecedented scale. The EHDEN consortium will provide the infrastructure and ecosystem to

make this ambition come true, supporting academia, healthcare professionals and authorities, patients, pharmaceutical and life sciences companies, and regulatory authorities.

The ambitions of the EHDEN project are high. We aim to standardise more than 100 million patient records across Europe from different geographic areas and different data sources, e.g. hospital data, registries, population databases, etc. Standardising such data to the OMOP-CDM will facilitate their use for a variety of purposes, enhancing and accelerating research and healthcare decision-making for global benefit. For this specific COVID-19 call, we are aiming to accelerate meaningful evidence generation for those providing care, managing care, and responding to this pandemic.

Through EHDEN, data custodians of longitudinal, person-level observational health data can benefit from financial support to standardise their data to the OMOP-CDM and locally install the analytical tools. Once the Data Source is standardised and the tools are operational, the Data Partner becomes a member of the EHDEN community and Federated Data Network and can participate in research studies following their own governance rules. To ensure diversity and representativeness of data in the network, the open calls may include specific priorities, focused on for example certain data source types, geographic locations, or disease areas (as in the current call). Such priorities will be transparently and publicly disclosed as part of the call information published on the EHDEN website.

Wider benefits of participating in the EHDEN data network are explained in more detail here on the EHDEN web site.

We highly recommend watching the EHDEN webinars which include conversations with researchers and data custodians that are already part of this evolving journey (webinars). Also, the presentations given at the OHDSI Symposia are a valuable resource (www.ohdsi-europe.org and www.ohdsi.org) if you want to become more familiar with the vibrant community. A good example of a network study on characterizing treatment pathways at scale can be found in this link.

4 RAPID COLLABORATION CALL ON COVID-19[1]

Due to impending global urgency to provide evidence-based insight into COVID-19 patients, their treatment and prognosis, EHDEN is launching this extraordinary call to invite any institution in Europe holding relevant COVID-19 data to apply in order to contribute to a world-class rapid response research collaboration. Each Data Partner that is willing to map their COVID-19-related data and to contribute such data to our federated studies will be awarded a sub-grant of maximum EUR 50,000 to compensate for their effort in preparing the data and collaborating with EHDEN in both the mapping exercise and subsequent research studies. Participation in these studies will of course depend on the established approval processes of the data source. All participating Data Partners will be given the opportunity to co-author scientific publications stemming from those studies. For the overall COVID-19 Call, EHDEN has allocated up to 1 Million Euro in total to cover sub-grants to Data Partners, but EHDEN will re-evaluate the call progress and Call budget accordingly.

The application and evaluation process for this extraordinary call has been streamlined to both minimise overhead for applicants and accelerate onboarding. The following sections describe this simplified procedure. In essence, the envisaged process is:

1. Data Partners complete an application form and submit via the EHDEN application portal.
2. EHDEN reviews each application rapidly upon receipt, within a maximum of one week.

[1] EHDEN also issues regular, periodic Data Partner calls, for more info please see: https://www.ehden.eu/open-calls/data-source-selection/

3. Successful applications are invited to sign a sub-grant agreement that regulates the grant award.
4. An accelerated process to remotely map the Data Partner COVID-19-relevant data to the OMOP CDM is undertaken by an EHDEN Task Force in collaboration with the Data Partner.
5. Once mapped, the Data Partner is expected, subject to its consent, to participate in studies initiated by EHDEN within a federated network of other Data Partners.

During the whole process, including mapping to the common data model, the Data Partner is NEVER ASKED to transfer any patient-level data. SUCH DATA WILL ALWAYS REMAIN LOCAL IN THE PREMISES OF THE DATA PARTNER. However, the Data Partner will be asked to run analytical programmes on their data to allow for this mapping and running of studies of scientific general interest. The Data Partner will be welcome to actively contribute to the research carried out by EHDEN, with due acknowledgement and recognition in terms of co-authorship as applicable, inclusive of the opportunity to collaborate with the ongoing OHDSI COVID-19 study-a-thon.

5 APPLICATION PROCESS

The COVID-19 call opens April 16th **at 12:00 CET and closes May 14th 17:00 CET** for Data Partners that meet the eligibility criteria described in section 6.1.2. All applications are to be completed electronically in English through the application portal which is available on the EHDEN Website. The application form contains a list of questions that can be found in Appendix 1. Applications can be sent at any point in time after the opening of the call on April 16th. All applications received before the deadline at the closure date will be reviewed on a 'first come, first served' basis. If an applicant has any issues with applying, they can contact us via applicants@EHDEN.eu.

5.1 Technical Self-Assessment

The application form contains a technical assessment section in which the data custodian is **invited** to execute the profiling software tool called 'White Rabbit' against the data source. We do realise that in the current COVID-19 situation it may be difficult to give this a priority. If the data partner is not able to run this tool or is unable to share the results, this will not affect the evaluation decision, but the Data Partner is asked to explain why this is not possible. The application form also contains questions that allow evaluators to assess the complexity of the data source. In some cases, and if needed, an online/phone interview with the applicant data partner might be requested by the evaluators to be held during the consensus meeting of the evaluation process.

However, if the Data Partner can run the tool it would help accelerate the process of evaluation and onboarding of the Data Partner. The White Rabbit tool simply extracts information about the data source: the number of tables, the individual fields in the tables, and the frequency of values in the fields. 'White Rabbit' can run locally on the data source so EHDEN does not need any access to the data source. More information about 'White Rabbit' can be found here:

https://www.ohdsi.org/web/wiki/doku.php?id=documentation:software:whiterabbit

6 EVALUATION PROCESS

6.1 Eligibility Check

Upon receipt, each application will be first assessed by EHDEN against the admissibility and eligibility criteria described below.

If the proposal is considered inadmissible or ineligible, the applicant will be informed together with the reasons why and how to appeal (see section 5.5).

6.1.1 Admissibility criteria

- The proposal is submitted through the application portal before 14th May 2020, 17:00 CET
- The proposal is submitted in English
- The proposal is complete with all relevant fields
- The data partner is legally established and based in an EU Member State or H2020 Associated Country (for a complete list see Appendix 3).

6.1.2 Eligibility criteria

- The data partner is the legitimate custodian of longitudinal, person-level observational health data of one of the following data source types:
  - Electronic Health Records
  - Claims Data
  - Hospital Data
  - Registry Data
  - COVID-19 Cohort Data

- The data source should contain data as presented in Appendix 2. Note that genetic data and omics data are out of scope in this current call.

6.2 Evaluation

Once the admissibility and eligibility criteria have been checked, a fast-track evaluation will be carried out.

Two members of the EHDEN Data Source Prioritisation Committee (DSPC), consisting of experts belonging to the EHDEN Consortium or external institutions, will evaluate each application based on the information available in the application form. The DPSC Chair has a casting vote to expedite decision-making.

If deemed necessary for adequate evaluation, the data custodian can be invited to an online/phone interview to discuss their application and data available in more detail. This will enable the EHDEN team to learn more about the applicant's data and ability to run open source tools in the current infrastructure.

More details on DSPC and the evaluation process are described in the next sections.

6.2.1 Evaluation Criteria

During evaluation, experts are asked to judge each application individually on the basis of three criteria:

1. **Relevance to COVID-19 research**, is based on the following components:
    a. Dataset(s) size (e.g. number of COVID-19 tested individuals)
    b. Dataset(s) coverage (e.g. availability of data (see Appendix 2), number of data points, etc.)
    c. Dataset(s) uniqueness (e.g. in terms of geographical coverage)

2. **Recency and prospective follow-up**, i.e. how updated the data set is, frequency of updating, possibility of future updates, etc.

3. **Willingness and ability to participate in federated COVID-19 studies**; applicants are expected to not only collaborate in the mapping of their data to the OMOP Common Data Model, but also to participate in the subsequent COVID-19 studies, subject to local approval. This criterion will also relate to availability of information about applicable ethical and governance mechanisms for use of the data in federated network studies.

Evaluators will be asked to judge whether the application is acceptable or not acceptable on each of the three criteria above. Consensus will be required across the two reviewers per application. Applications not deemed acceptable on any of the three criteria will not be considered for financial support.

Additionally, the evaluators will be asked to assess complexity of the mapping work to be done. This will be used to set the financial support offered (see section 7.2 below) for those applicants that pass all three criteria above. Two levels of complexity are envisaged, High or Low. The complexity level is determined by assessing if the terminology system that needs to be mapped is already available, and the type of data domains that will be included in the process.

6.2.2 Feedback on the evaluation process

Once evaluation is completed, EHDEN will send an information email to the applicant, indicating whether the application has been successful or not, and the financial support offered. If any, comments from the evaluators may be included in such email. As an indication, the objective is that feedback is provided to each applicant within a maximum of one week from the application submission date.

Rejection does not prevent a Data Partner to apply again to subsequent calls, including EHDEN ordinary Data Partner calls.

The applications that are successful will be informed about the process going forward for the COVID-19 call. Successful applications can also still apply for extension of their mapping in upcoming regular EHDEN Data Partner Calls to obtain a maximum of EUR 50.000 additional financial support.

6.3 Appeal Procedure

Applicants have one week from the date of sending of the formal decision letter to appeal on the outcome of the evaluation process. This can be done by submitting a reasoned complaint in writing to the EHDEN Project Management Office (PMO) at the email address applicants@ehden.eu. The PMO will confirm receipt and check if all review procedures have been fully respected and no content has been inadvertently omitted or overlooked during evaluation (e.g. due to technical problems with the

portal), and will answer to the applicant within one week from the date of reception of the complaint email. The PMO will not re-evaluate the proposal and consequently will not call into question the judgement of the appropriately qualified group of experts that form the DSPC.

7 EXECUTION PHASE

7.1 Grant Signature

Successful Data Partners will be invited to sign a simplified sub-grant agreement with EHDEN that establishes the terms and conditions under which the financial support is offered. The sub-grant agreement model is included as Annex 4 to this document. Erasmus MC is the Academic Co-ordinator in EHDEN and will sign on behalf of the EHDEN Consortium.

7.2 Financial Support

EHDEN has the public responsibility to make sure it utilises the available funding optimally for the inclusion of as many high-quality data sources as possible without sacrificing equal opportunity and fairness in the process. Therefore, a maximum amount of financial support is set per level of complexity; Low: EURO 30.000 and High: EURO 50.000. The funding bands are based on prior experience in mapping diverse data sources in the other projects, including the OHDSI global collaboration. They are also compliant with the grant bands established in the EHDEN project for extensions or partial data transformations and analytical infrastructure installation.

The sub-grant agreement contains a schedule for payment of the grant. The grant is awarded as a lump sum to compensate for the workload of the Data Partner based on the complexity assessment of the DSPC. This amount will be transferred to the Data Partner in two instalments: 50% upon signature of the Grant Agreement; 50% upon completion of mapping of the data set and registration in the EHDEN database catalogue. Participation in research studies will be discussed with the Data Partner during the process.

7.3 Process for mapping of datasets to the OMOP Common Data Model

We realise that standardising data during this pandemic crisis is challenging due to all kind of practical limitations. The amount of resources at the local site will be more limited than under normal circumstances. The Taskforce that has been formed by EHDEN therefore contains the best experts in the field to support the mapping process and will be driving this exercise. However, local database expertise will be required, and commitment is needed to expedite the process. In this effort we will prioritize data domains that are relevant to the research questions but aim to be as extensive as feasible within a short timeframe. The Taskforce will develop a workplan with each successful Data Partner to accommodate this.

Since face-to-face meetings will not be possible, we will setup a remote collaboration environment to interact and keep track of the process. No patient-level data will ever be shared with the Taskforce, unless this is explicitly agreed upon with the Data Partner. However, the structure of the source database and source terminology system information needs to be shared with team. For this the tool White Rabbit (link) can help which creates a profile of the database containing all the table and fieldnames as described above. For more information about the mapping process we refer to the Chapter Extract Transform and Load in The Book of OHDSI (link).

An important part of the process will be the installation of the Analytical Infrastructure. The EHDEN Taskforce will provide support in this work which includes for example the installation of ATLAS and the analytical pipeline in R. More details on these can also be found in The Book of OHDSI (link).

7.4 Data Partner Onboarding

After successful completion of the mapping and standardisation activity, the Data Partner will be considered part of the EHDEN community and be able to benefit from:

1. **Exclusive invitations for events**

   The Data Partner will receive personal invitation to OHDSI and EHDEN events. This can include invites to symposia or invites to study-a-thons in which researchers and data sources will collaboratively execute studies to generate reliable evidence. Furthermore, EHDEN will organise data network meetings for the Data Partners to stimulate interaction with all the key stakeholders.

2. **Education and training**

   The Data Partner will be offered continuous access to the EHDEN Academy for continuous training. Furthermore, we aim to offer face-to-face training throughout Europe from leading researchers in the EHDEN and OHDSI community on how to design and execute your own research.

3. **Research study invitations**

   EHDEN Data Partners will be kept up to date on the progress of ongoing network studies and opportunities to participate in new studies. Additionally, EHDEN will provide support when the Data Partner wants to initiate a network study.

4. **Exclusive EHDEN Forum Membership**

   A private section in the EHDEN forum will be accessible to the EHDEN Data Partners to interact directly with other Data Partners and EHDEN consortium members.

5. **Possibility to apply to future Data Partner calls**

   Data Partners stemming from this COVID-19 call will still be able to apply to EHDEN's ordinary calls in the future, for extension of the mapping of additional data domains, and receive additional funding (up to maximum of EUR 100.000 during the EHDEN project time).

8 QUESTIONS

If you have questions, please send us an email at applicants@ehden.eu. We have also created a Frequent Asked Questions section on the EHDEN Website that you may find helpful.

If you like to stay informed about EHDEN and upcoming calls, please sign up for the newsletter on the website.

APPENDIX 1. APPLICATION FORM

Question	Hints/Options
Data Source Description	
Provide a brief description of the data source (max 250 words)	Provide the data source introduction you would normally use in a publication.
From which country is the data originating?	
Describe the geographic coverage.	For example, a certain region or city
Is the data source containing patients with a specific socioeconomic status?	For example, Medicaid is a state and federal program that provides health coverage if you have a very low income.
Is the data source containing patients from a specific health system (insured/uninsured, public vs. private)	We refer here to all the patients in the data source, e.g. a private insurance data source.
What care setting(s) are covered?	• Inpatient (hospital) care • Outpatient general practitioner care • Outpatient specialist care • Long term/ skill nursing facility care • Pharmacy care • Other (free text)
What data capture process(es) are used?	• Insurance/administrative claims • Outpatient electronic health records • Inpatient hospital electronic health records • Inpatient hospital billing systems • Registries • Biobank • Other (free text)
Specify the inclusion criteria for patients to enter the population, if any.	
When did the data collection start?	
Is there any lag in the data capture?	We need to understand how recent your data will be
What is the frequency of source data updates?	This is important to understand if frequent CDM updates would be in scope
Which of these age categories are included in your data source?	• infants and toddlers (0 days to 23 months) • children (2 to 11 years) • adolescents (12 to 17 years) • 18 to 45 years • 46 to 65 years • 66 years and over
What is the gender of the data source population?	• Male • Female • Both
What is the approximate total (cumulative) number of subjects in your data source?	

What is the current approximate number of active patients?	
What is the average follow-up period per patient in years?	
Specify all data domains that are covered by your source database.	• Person • Observation Period • Visit Occurrence • Visit Details • Condition Occurrence • Death • Drug Exposure • Procedure Occurrence • Device Exposure • Measurement • Observation • Specimen • Survey • Provider • Location • Care Site • Payer Plan Period • Cost
Select all the COVID related elements that are covered by your database	• COVID 19 Test Presence • COVID 19 Test Type • COVID 19 Test Result • Hospital admission date • In Hospital drugs • In Hospital procedures • In Hospital devices • ICU admission date • In ICU drugs • In ICU procedures • Cause of Death
What is the current number of COVID-19 tests?	
What is the current number of positive COVID-19 Cases?	
How many patients with a COVID-19 test are currently in the database?	
How many patients with a COVID-19 diagnosis are currently in the database?	
Does the data source contain free text?	If yes: In what language is the free text? Explain how the free text could be useful for COVID-19 research.
Are there any additional comments you like to make about the available data?	
Data Source Governance and Ethics	

Is your institute the data custodian?	Please explain if you are the "Owner" of the data source or acquired the data source from another party, or simply have access to it
Information about the Governance Board procedures for federated data analysis, including timeliness.	
Do you have an ethical committee / governance board?	
Do you have a publicly available document that details the procedure by which approval can be requested?	
Describe briefly the process of obtaining approval	
What is the average duration of the approval process?	
Which studies have to be registered to ENCePP?	
Are there any areas of use or research that have been explicitly barred by approval bodies or participants?	
Are you allowed to use this data in collaboration with external parties?	For example, mention if this is only allowed with academic researchers
Are you authorized to share aggregated analysis results for research purposes?	
Are you able to contact the health care provider to obtain additional information about the patient?	
Are you able to contact the patient to obtain additional information?	
Are you able to obtain biological samples from the patient?	
Are you able to gather additional information about the patients (for example, environmental data documenting the air pollution in the area where the patient lives)?	
Technical Details	
What database management system is used for your data source?	
Are all your data currently co-located in one database?	
Do you have a document available that describes the database structure?	If yes, can you share this document. If yes, please upload the document. If no, please explain why not.
Which terminology systems are used in your database?	For example, ICD9, ICD10, local coding system etc.
Has any part of your source data already been mapped to the OMOP-CDM?	

If possible, we like to obtain information about the structure of the source database using a profiling tool called White Rabbit. This tool will extract all the table names, their fields, and most frequent values in the fields. Your data needs to be stored in a single relational database management system that is supported by the tool. If you need support send us an email: applicants@ehden.eu *Note that if you are not able to execute the tool or share its results, this will not by definition exclude your data source from the program. It would however be very useful for the committee to understand the complexity of your data source.*	
Are you able to execute the tool?	If not, please explain why
Are you able to share the results of the tool?	If not, please explain why. If yes, please upload.
Interest and ability to participate in distributed research	
EHDEN will maintain a public database catalogue that contains contact information and meta data. This meta data consists of information like the governance procedure, but also aggregated data such as total number of patients over time, cumulative patient time etc. We like to know what information you are able to share.	
Do you want to share contact information?	
Please specify what type of aggregated data can be shared.	
Do you intend to ask research questions and design network studies to generate evidence from the rest of the network? Please explain.	
Do you intend to use the OHDSI tools to conduct research locally?	
Do you plan to participate in network studies lead by others in the network?	
What type(s) of staff at your site are commonly used to conduct database analyses and would likely be involved in federated research?	• DB Admins • data managers • informaticians • statisticians • epidemiologists • clinical researchers • other (free text)
Are you already involved in the OHDSI community? If so, please describe how.	
How quickly will you be able to initiate the work in collaboration with the EHDEN Taskforce after the grant awarding?	
Motivation	
Describe why you want to apply for financial support and why your data would be of interest for the COVID-19 research.	
Signature	
Are you able and willing to go through the EHDEN application evaluation procedure, described in the call text?	

Declaration	Check box: i am fully authorized to submit this application on behalf of the data partner.
Do you confirm you agree with the Terms of Service and Privacy Policy?	Check box: I agree
Do you agree with the Terms of Service?	Check box: I agree
Signature	Fill in the full name of the applicant

APPENDIX 2. DATA OF INTEREST

Timeline	*Items*
Health pre-COVID19	*Demographics*
	Conditions
	Drugs
	Health service utilization
COVID19 presentation	*Recent health behaviour*
	Measurements/tests/lab
	Conditions
	Drugs
Test time	*COVID19 test presence*
	COVID19 test type
	COVID19 test results
Admission for COVID19	*Inpatient services*
	Complications (eg AKI, sepsis)
	ICU
	In hospital drugs
	Procedures (eg tracheostomy)
	Devices (eg ECMO)
ICU Admission detail	*Date of ICU admission*
	In ICU drugs
	BPAP/CPAP/Intubation/etc
	Procedures (eg tracheostomy)
	Devices (eg ECMO)
Mortality	*Date of death*
	Cause of death
Health post-COVID19	*Demographics*
	Conditions
	Drugs
	Health service utilization

APPENDIX 3. ELIGIBLE COUNTRIES

To be eligible for financial support, the Data Partner should be legally established and based in an EU member state or H2020 associated country for the duration of the sub-grant agreement.

EU Member States

Austria	Estonia	Italy	Portugal
Belgium	Finland	Latvia	Romania
Bulgaria	France	Lithuania	Slovakia
Croatia	Germany	Luxembourg	Slovenia
Cyprus	Greece	Malta	Spain
Czechia	Hungary	Netherlands	Sweden
Denmark	Ireland	Poland	

H2020 Associated countries

Albania	Georgia	Montenegro	Switzerland
Armenia	Iceland	North Macedonia	Tunisia
Bosnia and Herzegovina	Israel	Norway	Turkey
Faroe Islands	Moldova	Serbia	Ukraine
			United Kingdom

SIMPLIFIED SUB-GRANT AGREEMENT MODEL

For provision of financial support to third parties

Version 1.0

10 April 2020

This EHDEN Sub-Grant Agreement for providing financial support to the Data Partner (hereinafter referred to as the "**Agreement**") is entered into by and between the following parties:

on the one part,

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (EMC), established in Dr. Molerwaterplein 40, Rotterdam 3015 GD, Netherlands, with VAT number NL8071811997B01, duly represented for the purposes of signing the Agreement by Dean and Member of the Executive Board, Prof. dr. J.P.T.M. (Hans) van Leeuwen, hereinafter referred as the "**Harmonization Fund Holder**" and acting as Coordinator of the Research and Innovation Action "*European Health Data and Evidence Network*" (hereinafter referred to as "**EHDEN**") and representing the EHDEN consortium members;

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 **Data Partner**,

Hereinafter individually or collectively referred to as "**Party**" or "**Parties**".

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

- Preamble
- Terms and conditions
- **Annex 1**: Call Description
- **Annex 2**: Data Partner bank information

A. PREAMBLE

The Innovative Medicines Initiative 2 Joint Undertaking (hereinafter referred as "**IMI**"), and the Harmonization Fund Holder have signed the Grant Agreement no. 806968 for the implementation of the Action "European Health Data and Evidence Network" (hereinafter referred as "**EHDEN**"). The EHDEN Consortium has also signed a Consortium Agreement, further detailing some of the provisions in the Grant Agreement. EHDEN includes specific activities aimed at incentivising the standardisation of health data sources in Europe to the Observational Medical Outcomes Partnership Common Data Model (hereinafter referred as "**OMOP CDM**"). Such activities comprise the launch of periodic EHDEN open calls to interested Data Partners to receive financial support for mapping their data to the OMOP CDM. Such financial support is granted based on transparent, fair and equitable evaluation criteria.

The Data Partner applied for a "Rapid Collaboration Call on COVID-19" (hereinafter referred to as "the Call") organised in the framework of the EHDEN activities as foreseen in the above-mentioned Grant Agreement, and has been selected to receive Financial Support.

The rights and obligations contained in this Agreement are derived from the EHDEN Grant Agreement and Consortium Agreement. The Harmonization Fund Holder is willing to sign this Sub-Grant Agreement on behalf of the EHDEN consortium in compliance with both the EHDEN Grant Agreement and the Consortium Agreement.

The Harmonization Fund Holder is willing to provide Financial Support to the Data Partner for the implementation of the activities indicated in the Call, and the Data Partner is willing to receive the Financial Support under the terms and conditions of this Agreement.

B. TERMS AND CONDITIONS

1. Subject of the Agreement

1.1. This Agreement sets out the rights and obligations of the Parties as well as the terms and conditions applicable to the provision of the Financial Support awarded to the Data Partner for implementing the activities indicated in the Call launched in the framework of the EHDEN project, as described in the Call Description in **Annex 1** of this Agreement.

1.2. The Harmonization Fund Holder receives funding from the Innovative Medicines Agency 2 Joint Undertaking to undertake Open Calls for Grant Awarding to Data Partners. Under the EHDEN Grant Agreement and the Consortium Agreement, some of the obligations of the Harmonization Fund Holder have to be imposed on the Data Partner. Those obligations are reflected in this Agreement.

1.3. The Data Partner acknowledges and agrees that the obligations comprised in this Agreement are fully applicable and shall do everything that is necessary to comply with these obligations, being understood that the Data Partner is bound to this Agreement only and not to the EHDEN Grant Agreement or Consortium Agreement, unless otherwise stated.

2. Financial Support to the Data Partner

2.1. The Data Partner is awarded with [**€ 30.000/50.000** (thirty/fifty thousand Euro)] as financial support ("**Financial Support**") to implement the activities foreseen in the Call, according to the description in **Annex 1**.

2.2. The Financial Support is awarded to the Data Partner as a lump sum and intended to cover all reasonable, actual costs associated to the implementation of the necessary work to support implementation of the activities described in the Call. It shall never provide any profit to the Data Partner. The Financial Support is to be considered as a maximum amount and will not be increased in any case, including a situation where the actual costs related to implementing the activities exceed such Financial Support.

2.3. The Data Partner shall manage the Financial Support with due diligence, solely for the purposes of implementing the activities described in the Call and complying with all applicable laws and its own usual policies. The Data Partner shall record the costs associated with such activities in its own accounts, allowing information on such costs to be easily identifiable and available to the Harmonization Fund Holder upon request.

2.4. The awarded Financial Support will be made available to the Data Partner in Euro. No compensation for potential gains or losses due to exchange rates will be considered by either Party. Furthermore it is understood that any taxes (e.g. VAT) are to be considered included in the amount mentioned in section 2.1. The Data Partner is solely responsible in respect of the proper tax treatment of the Financial Support.

3. General obligations

3.1. The Data Partner:

a. shall collaborate with EHDEN representatives on the implementation of the activities indicated in the Call in line with the highest quality standards and state-of-the-art scientific and technological development, and in compliance with the provisions of this Agreement and all legal obligations under applicable EU, international and national law;

b. agrees to be included, without any compensation, in the EHDEN Database Catalogue and EHDEN communication materials intended for the public as an EHDEN "**Data Partner**";

c. agrees to participate in at least one research study promoted by EHDEN, subject to the applicable ethics and other approvals required by the Data Partner's governance structure.

3.2. On behalf of the EHDEN Consortium, the Harmonization Fund Holder shall monitor the implementation of the activities indicated in the Call towards their successful completion.

4. General obligations to inform the Harmonization Fund Holder

4.1. The Data Partner must provide any information requested by the Harmonization Fund Holder in writing at any time to verify the proper implementation of the activities in compliance with the obligations under the Agreement, including information about actual costs incurred.

4.2. The Data Partner must immediately inform the Harmonization Fund Holder of any situation affecting implementation of the activities foreseen in the Call. In particular the Data Partner must promptly provide any relevant information on:

a. any obstacles and/or limitations that may prevent or are likely to affect or delay implementation of the activities foreseen in the Call;

b. any relevant changes in the Data Partner legal, financial, technical, organisational or ownership status that may affect implementation of such activities;

c. any circumstances that may affect the Data Partner's due diligence in the management of the Financial Support or the compliance with the obligations of this Agreement.

5. Payments

5.1. The Financial Support indicated in provision 2.1 of this Agreement will be paid by the Harmonization Fund Holder to the Data Partner in a series of installments as follows:

- 50% upon signature of this agreement
- 50% upon completion of mapping of the data set and registration in the EHDEN database catalogue.

5.2. The Harmonization Fund Holder has the right to withhold payment of the above instalments if the corresponding work has not been completed for any reason, including force majeure or circumstances outside the control of either Party. In such a situation, the Harmonization Fund Holder will inform the Data Partner in writing of such withholding.

5.3. Payments by the Harmonization Fund Holder are considered to have been carried out on the date when they are debited to the Data Partner's bank account.

5.4. Payments will be made by the Harmonization Fund Holder by bank transfer to the account indicated in **Annex 2** to this Agreement. The Data Partner shall notify the Harmonization Fund Holder of any changes in the information contained in **Annex 2** as soon as possible. The Harmonization Fund Holder shall not in any case be liable for any late payment derived from a change in the financial information of the Data Partner.

5.5. The Harmonization Fund Holder shall bear the cost of transfers charged by its bank. The Data Partner shall bear the cost of transfers charged by its bank. The Party causing a repetition of a transfer shall bear the cost of the repeated transfer.

6. Consequences of non-compliance

6.1. If the Data Partner fails to comply with any of the obligations set in this Agreement, the Harmonization Fund Holder may suspend any payment and require additional information for clarification.

6.2. If the Data Partner fails to comply with their obligations within one month following a written request for clarification, the Harmonization Fund Holder may terminate the Agreement.

7. Confidentiality

7.1. During implementation of the Work Plan and for **four (4) years** after the period of 66 months as of 1 November 2018, the EHDEN consortium members and the Data Partner must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ("**Confidential Information**"). If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure. Unless otherwise agreed between the Data Partner and the EHDEN consortium, they may use Confidential Information only to implement the activities indicated in the Call.

7.2. The Data Partner may ask the Harmonization Fund Holder to request to the IMI2 JU to keep such information confidential for an additional period beyond the initial four years.

7.3. The Data Partner may disclose confidential information to their personnel, or third parties involved in the action only if they:
(a) need to know to implement the activities foreseen in the Call, and

(b) are bound by an obligation of confidentiality.

7.4. The confidentiality obligations mentioned in this article no longer apply if:
(a) the disclosing Party agrees to release the other Party;
(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;
(c) the recipient proves that the information was developed without the use of confidential information;
(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, I(e) the disclosure of the information is required by EU or national law.

7.5. It is understood by the Data Partner that the IMI2 JU may disclose Confidential Information to its staff, other EU institutions and bodies. It may disclose Confidential Information to third parties, if:
(a) this is necessary to implement the EHDEN Grant Agreement or safeguard the EU's or IMI2 JU's financial interests, and
(b) the recipients of the information are bound by an obligation of confidentiality.

7.6. The consequences of non-compliance as mentioned in article 6 of this Agreement ('*Consequences of non-compliance'*) are applicable accordingly.

8. Visibility of EHDEN and the Data Partner

8.1. The Data Partner declares their willingness to support EHDEN by attending its public events on invitation and by presenting the results of the activities developed in relation with this Agreement.

8.2. When promoting the activities and the derived results, the Data Partner shall display the EHDEN logo, the IMI2 JU and EFPIA logos, and the EU emblem and include the following text: "This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement no 806968. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA".

8.3. The Data Partner authorizes the Harmonization Fund Holder to use the Data Partner's logo and name for all purposes related to communication of EHDEN activities.

9. Liability

9.1. 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 rights in conflict with any of the rights granted in this Agreement; (iv) the rights 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.

9.2. The Data Partner agrees that the IMI2 JU cannot be held liable for any damage caused to and/or by the Data Partner as a consequence of implementing any action in the framework of the EHDEN Project.

10. Term and Termination

10.1. Unless terminated earlier in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the date of its full signature and shall remain in effect until the completion of the activities indicated in the Call and associated payment of the last instalment of the

Funding Support in accordance with article 5 of this Agreement, with a maximum duration of 12 months, unless this period is extended by mutual agreement of the Parties in writing.

10.2. The Agreement is automatically terminated at the end of the EHDEN Project.

10.3. Termination for Breach. Either party may terminate this Agreement if the other party materially breaches a provision of this Agreement and fails to cure such breach within thirty (30) days of receipt of written notice describing the breach in reasonable detail.

11. Conflict of Interest

11.1. The Data Partner agrees to take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ("**Conflict of Interests**").

11.2. The Data Partner must formally notify to the Harmonization Fund Holder without delay of any situation constituting or likely to lead to a Conflict of Interests and immediately take all the necessary steps to rectify this situation.

11.3. The Harmonization Fund Holder may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

11.4. The consequences of non-compliance as mentioned in article 6 of this Agreement ('*Consequences of non-compliance*') are applicable accordingly.

12. Miscellaneous

12.1. The Data Partner undertakes to comply with all applicable laws, rules, regulations, ordinances, and directives. In addition to the foregoing, the Data Partner acknowledges that this Agreement is a derivative of the EHDEN Grant Agreement. The Data Partner explicitly agrees to comply with the EHDEN Grant Agreement as if it is a Beneficiary, to the extent its specific applicable articles are mentioned in this Simplified Sub Grant Agreement.

12.2. The Data Partner agrees to ensure that the IMI2 JU, the European Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights of Checks, Reviews and Audits as well as Evaluation of the Impact if necessary in respect of the EHDEN project, as established in the EHDEN Grant Agreement.

13. Governing law

13.1. This Agreement shall be governed by and interpreted in accordance with the law of the Netherlands.

13.2. Any dispute which cannot be settled amicably shall be finally settled by the court of Rotterdam, the Netherlands.

<<< 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 EHDEN consortium:

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

……

Name: Prof. dr. J.P.T.M. (Hans) van Leeuwen

Title: Dean and Member of the Executive Board

and

As Data Partner:

[NAME]

…….

Name:

Title:

ANNEX 1. CALL DESCRIPTION

Call text shall be added to sub-grant agreement prior to signature.

ANNEX 2. DATA PARTNER BANK INFORMATION

FINANCIAL IDENTIFICATION

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

BANKING DETAILS ①	
ACCOUNT NAME ②	
IBAN/ACCOUNT NUMBER ③	
CURRENCY	
BIC/SWIFT CODE	BRANCH CODE ④
BANK NAME	
ADDRESS OF BANK BRANCH	
STREET & NUMBER	
TOWN/CITY	POSTCODE
COUNTRY	

ACCOUNT HOLDER'S DATA (AS DECLARED TO THE BANK)	
ACCOUNT HOLDER	
STREET & NUMBER	
TOWN/CITY	POSTCODE
COUNTRY	

BANK STAMP + SIGNATURE OF BANK REPRESENTATIVE ⑤	DATE (Obligatory)
	SIGNATURE OF ACCOUNT HOLDER (Obligatory)

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.