



# EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

806968 – EHDEN

European Health Data & Evidence Network

WP5 – Data Workflow Implementation & Service Deployment

## D5.1 Report on SME Certification Procedure and Data Source Grant Awarding developed and implemented

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	<b>D5.1 – Report on SME Certification Procedure and Data Source Grant Awarding developed and implemented</b>		
	<b>WP5 – Data Workflow Implementation &amp; Service Deployment</b>	<b>Version: v1.2 – Final</b>	
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V1.2	07 Oct 2019	Revised version for consortium review
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## DEFINITIONS

Participants of the EHDEN Consortium are referred to herein according to the following codes:

<b>EMC</b>	Erasmus Universitair Medisch Centrum Rotterdam- The Netherlands <b>(Project Coordinator)</b>
<b>Synapse</b>	Synapse Research Management Partners S.L. - Spain
<b>UOXF</b>	The Chancellor, Masters and Scholars of the University of Oxford - United Kingdom
<b>UTARTU</b>	Tartu Ulikool - Estonia
<b>UAVR</b>	Universidade de Aveiro – Portugal
<b>The Hyve</b>	The Hyve BV – the Netherlands
<b>Odysseus</b>	Odysseus Data Services SRO – Czech Republic
<b>EPF</b>	Forum Europeen des Patients (FPE) - Luxembourg
<b>NICE</b>	National Institute for Health and Care Excellence – United Kingdom
<b>UMC</b>	Stiftelsen WHO Collaborating Centre for International Drug Monitoring - Sweden
<b>ICHOM</b>	International Consortium for Health Outcomes measurement LTD - United Kingdom
<b>Janssen</b>	Janssen Pharmaceutica NV - Belgium <b>(Project Lead)</b>
<b>Pfizer</b>	Pfizer Limited – United Kingdom
<b>Abbvie</b>	AbbVie Inc - United States
<b>IRIS</b>	Institut De Recherches Internationales Servier - France
<b>SARD</b>	Sanofi Aventis Recherche & Developpement - France
<b>Bayer</b>	Bayer Aktiengesellschaft - Germany
<b>Lilly</b>	Eli Lilly and Company Limited – United Kingdom
<b>AZ</b>	AstraZeneca AB - Sweden
<b>Novartis</b>	Novartis Pharma AG - Switzerland
<b>UCB</b>	UCB Biopharma SPRL - Belgium
<b>Celgene</b>	Celgene Management SARL - Switzerland

<b>Grant agreement</b>	The agreement signed between the beneficiaries and the IMI JU for the undertaking of the EHDEN project (806968).
<b>Project</b>	The sum of all activities carried out in the framework of the Grant Agreement.
<b>Consortium</b>	The EHDEN Consortium, comprising the above-mentioned legal entities.
<b>Consortium agreement</b>	Agreement concluded amongst EHDEN participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

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## PUBLISHABLE SUMMARY

The European Health Data & Evidence Network (EHDEN) aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care. Our mission 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 sources standardized to a common data model.

This deliverable describes the development and implementation process of procedures for the certification of Small and Medium-sized Enterprises (SMEs) and onboarding of Data Partners in the EHDEN eco-system. The SMEs are trained to provide services to Data Partners to standardise their health data to the OMOP Common Data Model and install the analytical infrastructure for federated study execution.

We discuss how we worked closely with “WP 4 – Technical Implementation”, our stakeholders, and IMI, to come to a first version of the procedures that are tested in Pilot Calls and are further optimized in upcoming calls.

This deliverable is complementary to “D7.1 - Full package on EHDEN open calls for applications” that presents the procedures in more detail and contains several artefacts that resulted from the work described in this deliverable. The focus in this deliverable is primarily on the application portals for both types of calls and the initial work done to develop the EHDEN Academy.

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## 1. INTRODUCTION

The European Health Data and Evidence (EHDEN) project aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care. Our mission 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 sources standardized to a Common Data Model (CDM). To realize this mission, we must create a sustainable eco-system including a technical infrastructure and active community containing a diverse set of stakeholders such as academia, industry, regulators etc. We have to **Build** this but also **Fuel** it with data and **Drive** it with high impact studies to improve patient care. As shown in Figure 1, EHDEN will harmonise large amounts of health data, build tools to perform federated studies, engage with a diverse community, and train our stakeholders to ultimately enable outcomes driven health care at a European level.

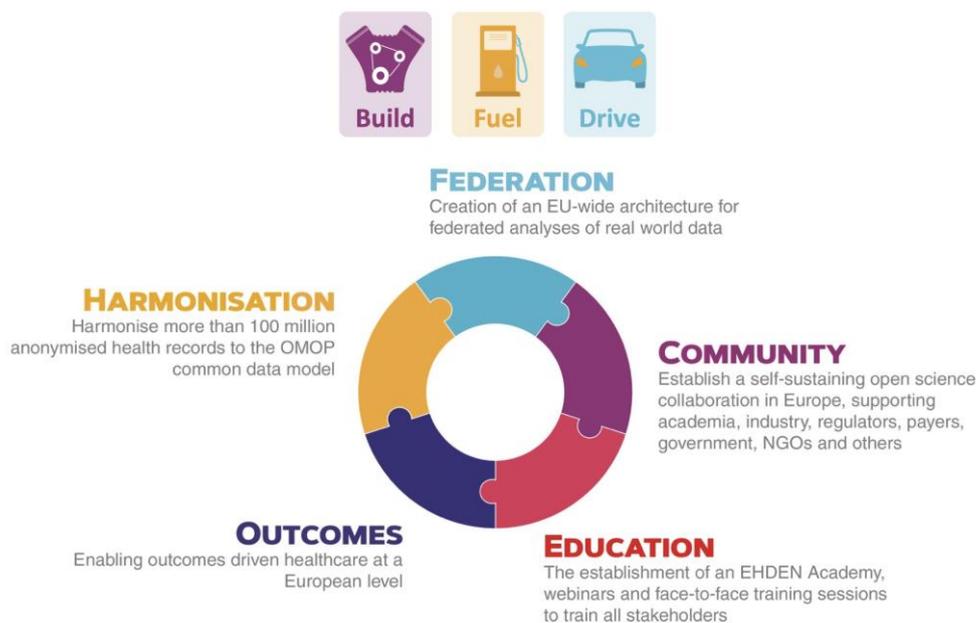


Figure 1. The Components of the EHDEN project

In EHDEN a fund of 17 million Euro is available to support the data standardisation efforts across Europe. To ensure a fair, transparent and efficient use of these funds, open calls for awarding financial support have to be periodically launched. A sub-grant agreement needs to be developed that must be signed by the Harmonisation Fund Holder (our partner EMC) and the Data Partner.

In parallel, EHDEN must train and certify Small and Medium-sized Enterprises (SMEs) across Europe that will support Data Partners and other stakeholders in standardising and using the data. Multiple open calls for SMEs will follow to obtain a good geographic spread of SMEs and allow data partners to interact with local SMEs as much as possible.

The Data Partner can use the funding to pay a certified SME to provide support in the standardisation process and installation of the analytical infrastructure or can use this to perform the work themselves if they have the necessary competences. Both the data standardisation and analytical infrastructure do however need to pass inspection by a certified SME before the last part of the financial support will be released. The selection of the SME by the Data Partner will take place after the financial support has been awarded as shown in Figure 2.

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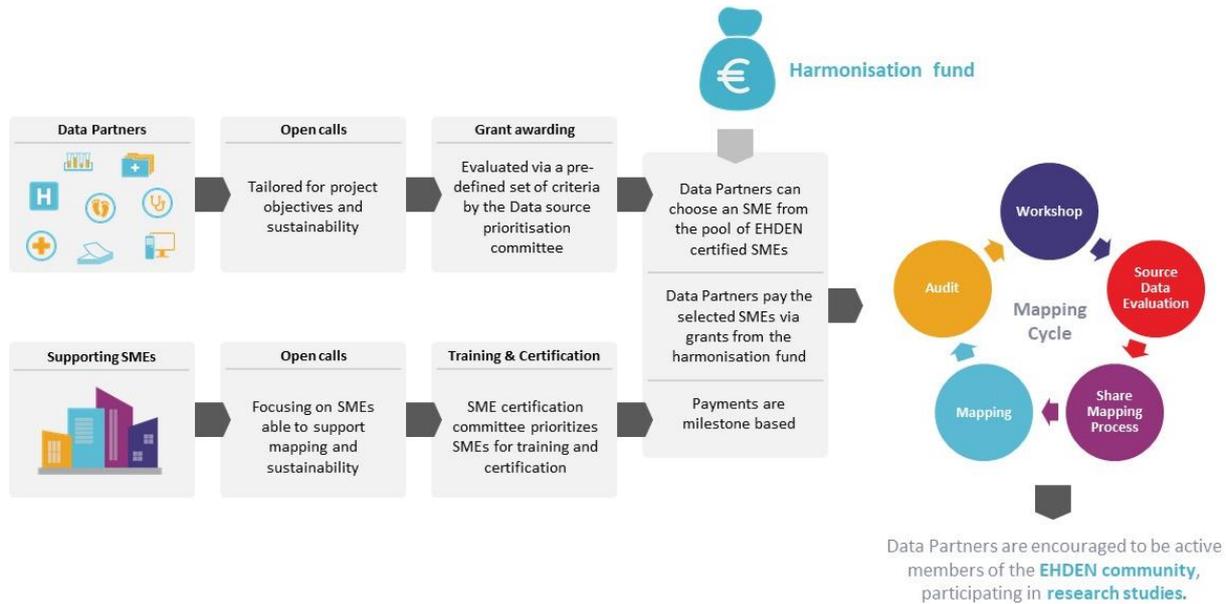


Figure 2. EHDEN's Open Calls for Data Partners (top) and Small and Medium-sized Enterprises (bottom), and how both are subsequently interrelated.

In this deliverable we describe how we developed and implemented the procedures for SME Certification and the grant awarding for the Data Partners to support the standardization of their data source(s) with a focus on the application portals and the EHDEN Academy.

## 2. DEVELOPMENT AND IMPLEMENTATION APPROACH

To develop these procedures, we applied the following approach for the development and implementation of the procedures:

1. It was decided in the Excom that we would not spend human resources on the development of a **submission portal** for open calls but would use the system available from the company [WizeHive](#) that was selected after a thorough market scan in the IMI EPAD project in which our partner SYNAPSE was involved. The EHDEN project management office (PMO) had an initial call with the company and the tool clearly was a perfect fit, it was highly customisable and allowed for the implementation of all foreseen procedure steps. More details on the implementation can be found in section 3.1.
2. **Initial development** was driven by WP5 in close collaboration with WP4 – Technical Implementation. The development of the procedures was started during the EHDEN kick-off meeting in January 2019 in Rotterdam. We started with a brainstorm session on issues we had to solve or make decisions about and prioritised those to kickstart the procedure development (see Figure 3).
3. Throughout the process it was important to have **full transparency** to the EHDEN consortium. All discussions took place in the WP 5 section of the EHDEN forum that was accessible to all the partners. Furthermore, we posted minutes and recordings of our meetings on the EHDEN SharePoint.

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4. Development and evaluation were performed using an **agile** approach. We developed small parts of the procedures, implemented those, and evaluated them with the team before we further expanded. We included multiple EHDEN partners in the final evaluation steps and logged their issues in a tracker: <https://github.com/EHDEN/ApplicationPortals/issues> and on our internal forum. For both procedures we decided to take a pilot approach in which we made it clear to the applications that we are in the process of procedure refinement and needed their feedback. In this way we could learn by doing and could manage expectations with our stakeholders.
5. The **final approval** of the procedures was made by the Excom and shared with the consortium. Furthermore, we consulted the IMI officer and the IMI legal experts to provide feedback on the Data Partner Call description and sub-grant agreement developed by the team, prior to public release.

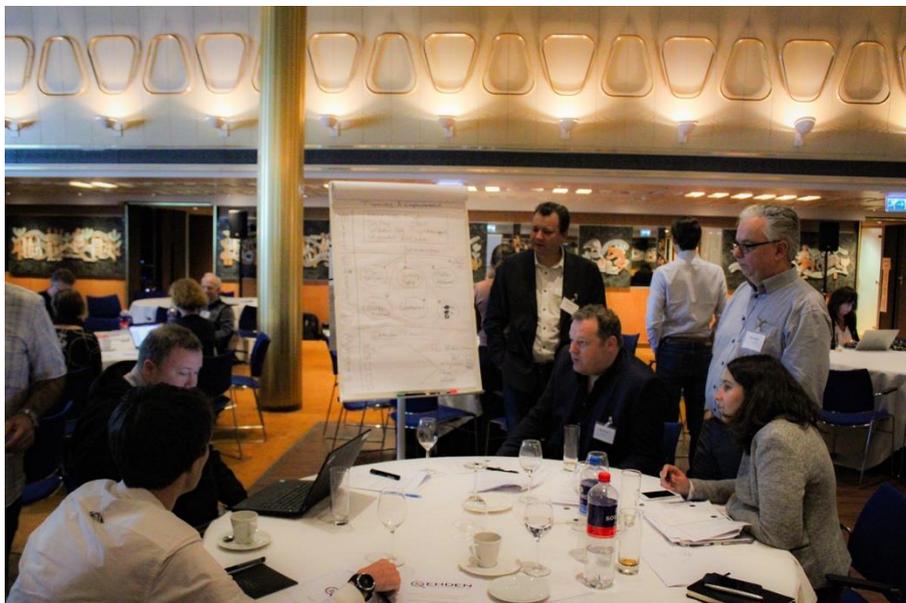


Figure 3. Brainstorm session at the EHDEN kick-off meeting in Rotterdam.

In the next sections we will describe the development and implementation of both procedures in more detail. We start from their initial description in our Description of Action (DoA) and explain the refinements made.

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### 3. SME CERTIFICATION PROCEDURE

Figure 4, describes the procedure as proposed in our Description of Action (DoA). Here we first discuss briefly where we deviated from these initial thoughts and describe the final procedure we developed in WP5 in more detail.

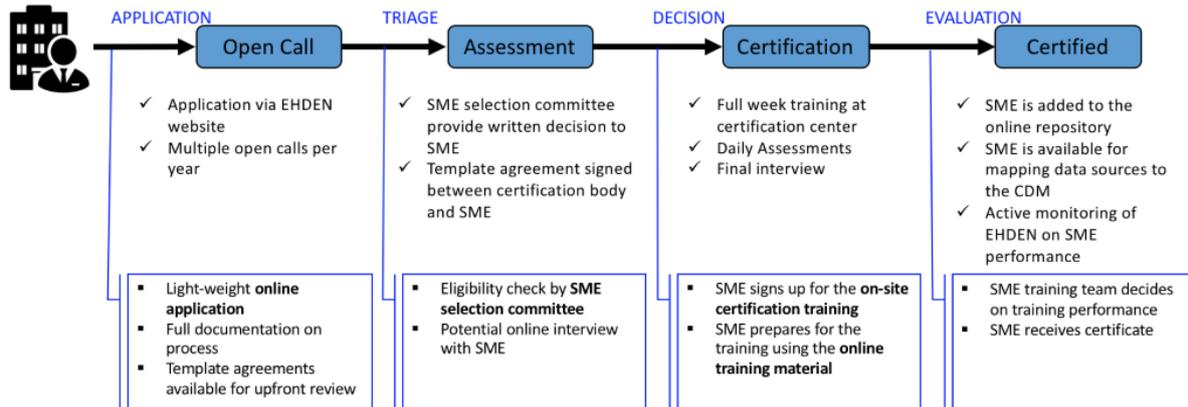


Figure 4. SME Certification Procedure as proposed in the Description of Action

#### Open Call

We have added a section on the EHDEN website (<https://www.ehden.eu/open-calls/process-overview/>) that provides all the information for the applicants, including value propositions developed together with WP6 “Outreach and Sustainability”. Together with WP7 “Project Management and Dissemination” we worked on a communication plan for the open calls through several communications channels (see D7.4 Communication Plan and Initial Toolset). We have implemented an application portal that is accessible via the EHDEN website ([www.ehden.eu](http://www.ehden.eu)). The development of this portal is described in more detail in section 3.1. We have provided full documentation of the call and a template for the sub-grant agreement. These documents are available on our website and are added in D7.1 “Full package on EHDEN open calls for applications” and therefore not repeated in this deliverable.

#### Assessment

In close collaboration with WP7 the SME Certification Committee (SMECC) was initiated that will be in charge of reviewing and selecting SMEs for certification, through the open call and application process. The SMECC is composed of four EHDEN consortium members and two external members, including one chair member. For the SMECC we had to develop evaluation criteria (see D7.1) and had to develop a review portal that implements this evaluation procedure (see section 3.2).

#### Certification

The initial idea for the SME training was to organize a 5-day face-to-face training session with daily assessments and a final interview session. We deviated from this idea and decided to go for a blended learning approach with online training and a two-day face-to-face assessment meeting for the following reasons:

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- It appeared to be difficult for the SMEs to come with a team for a full week to Rotterdam. We decided that two days for a final certification session was more realistic. This did imply that the SME had to obtain the necessary competences prior to that session.
- We think it is valuable if the trainees can train at their own pace and can interact with the course faculty outside the face-to-face meeting.
- We like to scale up to train not only SMEs but all our stakeholders and onsite training would not be sustainable.
- We like to involve collaborators from the Observational Health Data Sciences and Informatics (OHDSI) initiative that are mainly located in the US.

The certification process is described in more detail in section 3.4.

### Certified

We are currently working on the implementation of a directory that holds the information of the certified SMEs. The initial mapping exercises will be guided by our internal team of experts.

### 3.1 SME Application Portal

All applications had to be processed through an application portal and communication had to take place through the applicant's email address as specified in their profile form. The application portal was developed in close collaboration with implementation experts of WizeHive and our WP5 team.

This work started with obtaining consensus in the team on multiple artefacts:

- The questions in the SME profile
- The application form questions that would allow for proper assessments by the SMECC (See Annex 1)
- The layout of the tool and instructions provided on the pages and in the call description text (See below)
- The email messages send to the users after procedural steps had been completed.

Subsequently, the procedure was implemented in the Zengine environment of WizeHive driven by an initial statement of work that was further refined during the implementation process.

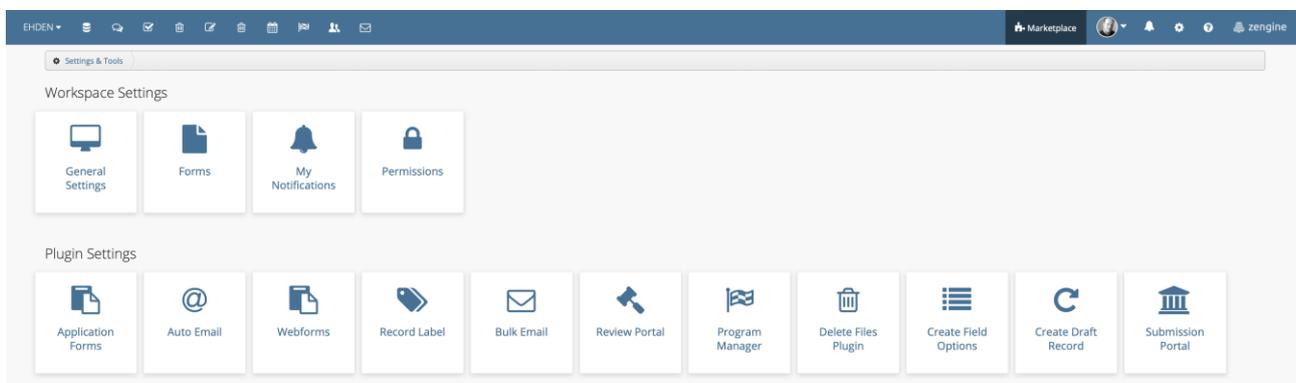
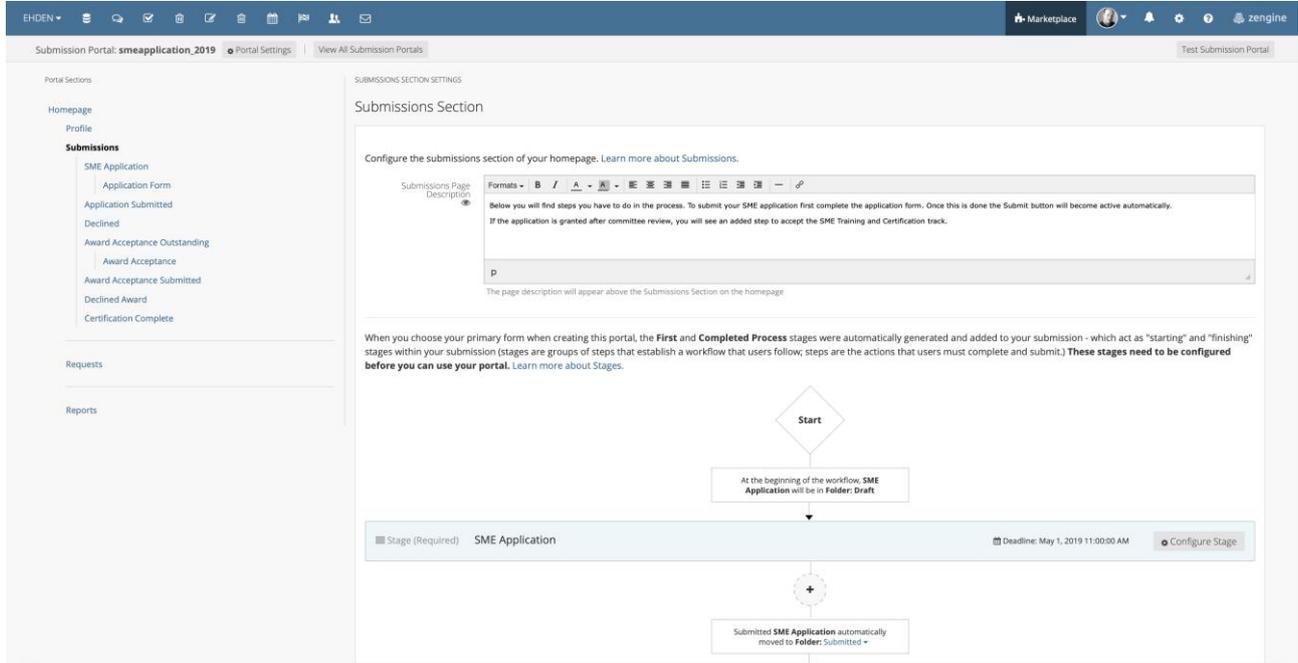


Figure 5. EHDEN workspace in administrative backend of Zengine (WizeHive).

We received training from WizeHive on the implementation process and their role in this. Furthermore, we received training on how we could make further adjustments once the initial version was implemented.

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As shown in Figure 6 below, the tool allows to specify a workflow containing procedural steps. These steps can hold forms and can generate email notifications once the application changed state such as “Application Submitted”, “Award Acceptance Outstanding” etc.



The screenshot displays the Zengine interface for configuring a workflow. On the left, a sidebar lists 'Submissions' with various status options. The main workspace is titled 'Submissions Section' and includes a rich text editor for adding content. Below the editor, a workflow diagram is visible, starting with a 'Start' node, leading to a stage named 'SME Application' (marked as required) with a deadline of 'May 1, 2019 11:00:00 AM'. The workflow concludes with a node indicating that the 'Submitted SME Application' is automatically moved to a 'Submitted' folder.

Figure 6. Development of a workflow in Zengine from WizeHive.

Below we will briefly discuss the steps during the application process.

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## Step 1. Sign Up

The first step is to sign up in the portal. This email address is used to login to the portal and to get access to the SME Profile and Application form.



**Welcome to the SME Application Portal**

This portal implements an application process for Small to Medium Enterprises (SMEs) to apply for the training and certification program in the EHDEN project.  
More information can be found on the [EHDEN Website](#).

**Sign In/Sign Up Instructions**

**For New Users:**  
By clicking **Sign Up**, you will be prompted to enter your email address and create a password. *Your password must be at least 8 characters in length.* Once you have chosen your password, and have read and accepted the privacy policy, your account will be created and you will gain access to the portal.

**For Returning Users:**  
Sign into the portal using the email address and the password you created when you originally signed up for the portal. If you have forgotten your password, click **"Forgot your password?"** and follow the prompts to reset your password.

**Sign In**

Email

Password  Forgot your password?

**Need an Account?**

## Step 2. Create Profile

By clicking on the + Create Profile button the Profile form can be filled in.



Welcome, smeapplicant@gmail.com

**Homepage**

**Profile**

Welcome to the SME Application Portal. Here you can apply for the SME training and certification procedure offered by the EHDEN project. After you created your profile, you need to fill in an application form that will be reviewed by an independent committee. For more information about the SME call and the review process please see our [website](#).

Please click "+ Create a Profile to Get Started" if you do not have a profile yet.

You can save your profile as a draft to complete at a future time. When a profile is saved as a draft, it will have a status of "In Progress". Clicking on the "Eye" icon will allow you to view a read-only version of the draft; you can edit the profile by clicking on the "Pencil" icon.

Once the profile has been completed and is saved (the status will change to "Complete"), you can start your application. Please note: the profile is always editable.

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[Homepage](#) > Applicant Profile Input Draft

## Company Details

**Company Name \***

**Chamber of Commerce ID**  
  
ID of registration at the local Chamber of Commerce if publicly available.

**VAT Number**

**Legal Form \***  
  
For example: Sole proprietor, Private limited company, Public limited company, etc

**Sector of Activity \***  
  
For example: Health Care

**Year of Incorporation \***  
  
Year the company was officially registered at the chamber of commerce.

**Number of Employees as of December 31st 2018 \***

**Annual Turnover 2018 (Euro) \***

## Company Address

**Street Address \***

The fields that are required have a red asterisk. An incomplete form can be saved using “Save Draft” in which case there is no check of all the required fields. Once you have completed the full form, save the form using the Save button at the bottom of the screen:

### Step 3. Fill in the application form

If the user clicks on the Get Started button and the following screen will appear:



Welcome, smeapplicant@gmail.com

[Homepage](#) > *Untitled*

Below you will find steps you have to do in the process. To submit your SME application first complete the application form. Once this is done the Submit button will become active automatically.  
 If the application is granted after committee review, you will see an added step to accept the SME Training and Certification track.

**SME Application**

**Application Form** Action Required

If you have not started the application form step, please click the "Start Now" button to the right. Once started, this step will be labeled "In Progress". Click on the "Eye" icon to view a read-only version of the draft; click on the "Pencil" icon to access/edit this step. **Once the application has been submitted, it can only be opened in a read-only state.**

**Application Submission**

When you have completely filled in and saved the application, the "Submit this Application" button to the right will become green and active/clickable, and the application can be submitted.

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The application form can now be filled in by pressing the pencil icon. The form contains questions about the experience and expertise of the SME in relevant technologies, terminology systems, and the resources available in the SME. The form had to be entered in English, submissions in other languages will be declined.

We highly recommended to provide concise but clear answers to all the questions in the form to allow proper evaluation by the SME Certification Committee.

The user could save a draft and come back to finalize the form, but finally needs to press the “Save” button.

The Submit button now becomes active and green. The application then needs to be submitted by pressing this button. After this the application can only be viewed but not edited anymore. If editing of a submitted application were needed for some reason, our team can facilitate this.

The email address for the Applicant in this form is then used for all communications. The applicant receives an email confirming he/she has completed this step.

The application is then checked for eligibility by the PMO and evaluated by the SME Certification Committee following the procedure described below. If the SME is selected they have to accept the training and certification track by agreeing on the follow terms in the portal:

***I hereby certify that my organisation:***

- 1. is committed to participate in the training and certification process;*
- 2. is aware that travel costs for final certification assessments are not provided by the EHDEN project;*
- 3. is committed to be available to support Data Sources as described in the call once certification is obtained;*
- 4. has stable and sufficient sources of funding to maintain its activity.*

***My organisation is not in one of the situations which would exclude it from receiving training support funded by the EHDEN project, i.e. it:***

- 1. is not bankrupt or being wound up, is not having its affairs administered by the courts, has not entered into an arrangement with creditors, has not suspended business activities, is not the subject of proceedings concerning those matters, or is not in any analogous situation arising from a similar procedure provided for in national legislation or regulations;*
- 2. it has not been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State which has the force of res judicata;*
- 3. is in compliance with its obligations relating to the payment of social security contributions and the payment of taxes, in accordance with the legal provisions of the country in which it is established;*
- 4. it has not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such illegal activity is detrimental to the EU's financial interests.*

After this step the SME was onboarded in the Training and Certification process described in section 3.3.

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### 3.2 SME Review Portal

The applications are evaluated by an SME Certification Committee (SMECC) that consists of four EHDEN Consortium members and two independent external experts. These independent experts are drawn from a panel of international experts that act as advisors to EHDEN. Independent experts involved in the evaluation are required to have skills and knowledge appropriate to the SME Call. They have a high level of professional experience in the public and/or private sector and are internationally recognised in their field of expertise.

The WP5 team developed a procedure to be used by the SMECC and implemented this in a review portal. Here we focus on the development of this portal, for more details on the procedure see Annex 2 and D7.1. The Zengine tool has functionality for reviewing the applications we could easily customise to fit our needs.

The EHDEN Project Management Office (PMO) first assigns applications to the reviewers. A call is then setup with the reviewers to explain the use of the tool and the evaluation process.

These reviewers receive an email notification that new applications must be reviewed. They can login into the system and submit their reviews following the steps described below.

#### Step 1. Email notification about new applications to review

After the PMO enters a reviewer’s email address in the system, the reviewer automatically receives an invitation to create an account on the review portal.



Dear SME Reviewer,

A new application for has been submitted for your review. Please log into the [review portal](#) and provide your feedback when you first have a chance. We like to receive your feedback within one week if possible.

If this timeline is not feasible or you have questions, do not hesitate to send an email to: [enquiries@ehden.eu](mailto:enquiries@ehden.eu)

We thank you for your support to the EHDEN project.

The EHDEN team.

---

 [www.ehden.eu](http://www.ehden.eu)
 [@IMI\\_EHDEN](https://twitter.com/IMI_EHDEN)
 [IMI\\_EHDEN](https://www.linkedin.com/company/IMI_EHDEN)
 [github.com/EHDEN](https://github.com/EHDEN)





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.

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**Step 2. Fill in email address and receive a confirmation email.**



# EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

## SME Application Review Portal

**Sign In/Sign Up Instructions**

**For New Users:**  
Please enter your email address and we will verify if you are in our system. If your email is part of our system, a confirmation will be sent to that address. *If your email is not in our system or you do not receive a confirmation email, please contact us at enquires@ehden.eu.*

Upon confirmation of your email, you will be taken to the **Sign Up** screen where you can choose a password to create an account. *Your password must be at least 8 characters in length.* Once you have chosen your password, your account will be created and you will gain access to the portal.

**For Returning Users:**  
Please enter your email address to the right, and we will verify if you are in our system. When found, you can enter your password and then gain access to the portal.

For more information about the Review process and the Review Portal we refer to the Reviewer Instructions sent to you separately.

If you have any questions or concerns, please contact us via enquires@ehden.eu. Thank you!

**Welcome!**

To get this process started, new and returning users please enter your email address below.

**Email**  
smreviewer1@gmail.com

You will receive a confirmation email shortly with a confirmation code which will allow you to choose a password, create an account and log in. Please check and confirm or [Resend Email](#).

Already have a confirmation code?

POWERED BY  
wizehive

**Step 3. Create an account**



# EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

## SME Application Review Portal

**Sign In/Sign Up Instructions**

**For New Users:**  
Please enter your email address and we will verify if you are in our system. If your email is part of our system, a confirmation will be sent to that address. *If your email is not in our system or you do not receive a confirmation email, please contact us at enquires@ehden.eu.*

Upon confirmation of your email, you will be taken to the **Sign Up** screen where you can choose a password to create an account. *Your password must be at least 8 characters in length.* Once you have chosen your password, your account will be created and you will gain access to the portal.

**For Returning Users:**  
Please enter your email address to the right, and we will verify if you are in our system. When found, you can enter your password and then gain access to the portal.

For more information about the Review process and the Review Portal we refer to the Reviewer Instructions sent to you separately.

If you have any questions or concerns, please contact us via enquires@ehden.eu. Thank you!

**Sign Up**

Choose a password below. Once your account is created you will be logged into the portal.

**Email**  
smreviewer1@gmail.com

**Password**

- Must contain at least one lowercase letter
- Must contain at least one uppercase letter
- Must contain one number
- Must be between 8-32 characters
- Must not be an email address

**Confirm Password**

Passwords must match

We will use your information in accordance with our [Privacy Policy](#) to respond to your inquiries and fulfill your requests with regards to the creation of an SME application profile, as necessary for our legitimate interest and possibly to comply with our legal obligations.

I have read and agree to the [Terms of Service](#) and [Privacy Policy](#).

POWERED BY  
wizehive

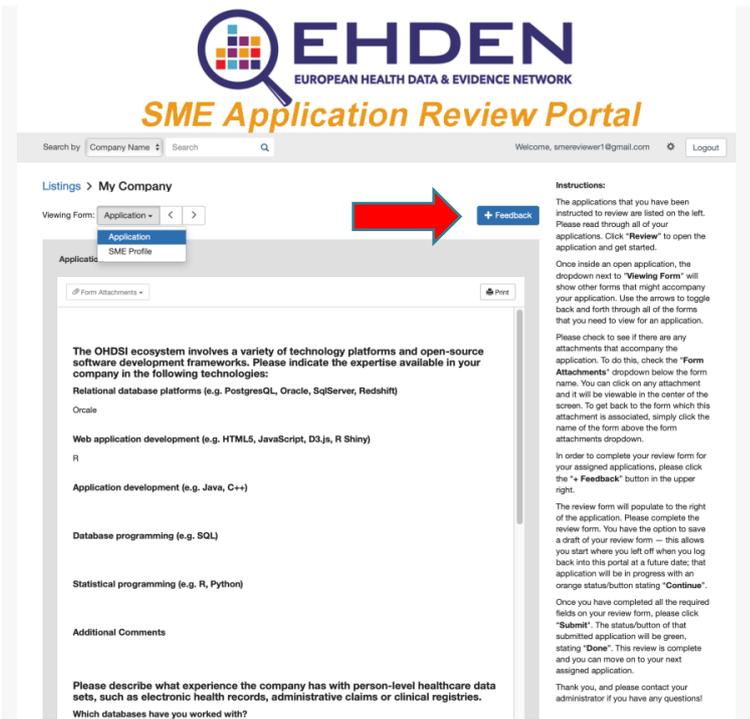
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**Step 4. Select the application to review from the list of assigned applications.**



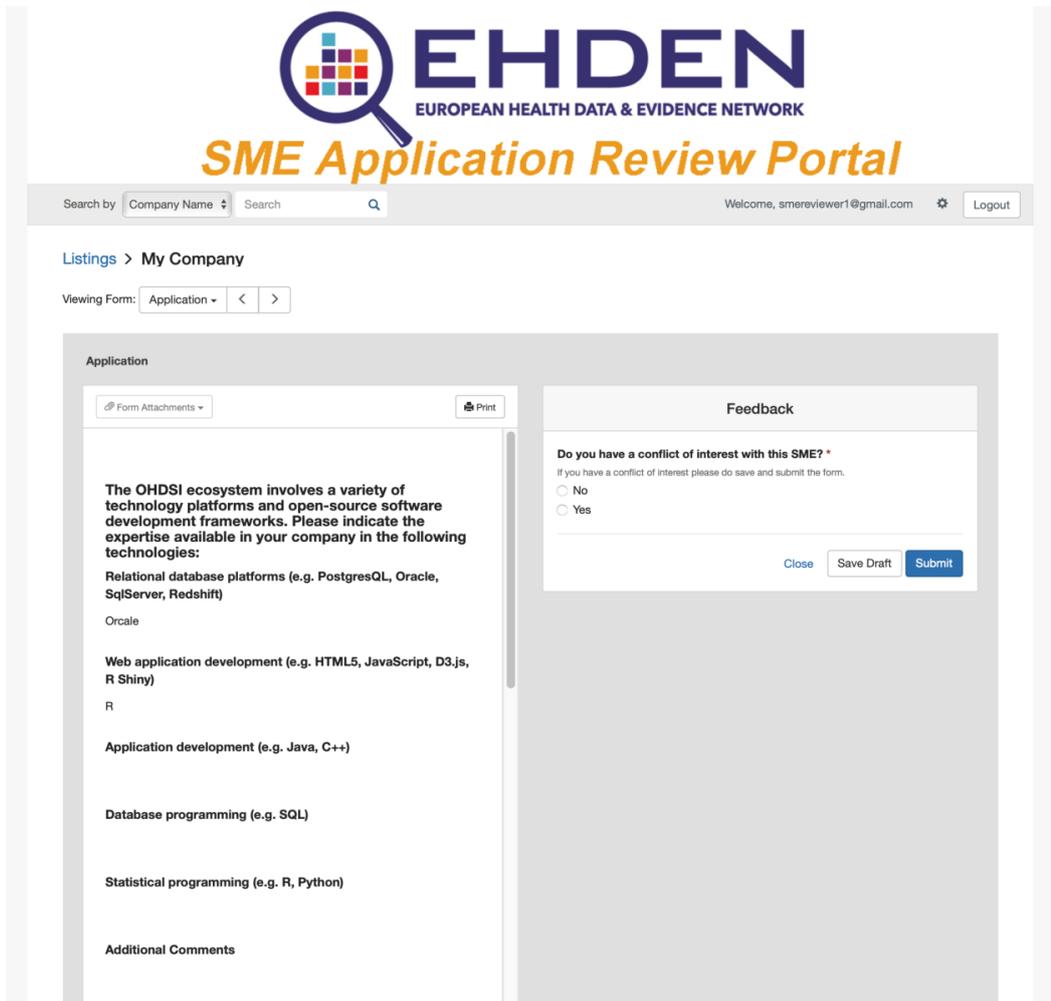
**Step 5. Read the application and profile information**

The reviewer can select the application or profile as shown in the image below



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**Step 6. Click on + Feedback (see red arrow above) and inform us about a conflict of interest.**



The screenshot shows the 'SME Application Review Portal' interface. The main content area is titled 'Application' and contains a text field with the following text: 'The OHDSI ecosystem involves a variety of technology platforms and open-source software development frameworks. Please indicate the expertise available in your company in the following technologies: Relational database platforms (e.g. PostgreSQL, Oracle, SqlServer, Redshift), Oracle, Web application development (e.g. HTML5, JavaScript, D3.js, R Shiny), R, Application development (e.g. Java, C++), Database programming (e.g. SQL), Statistical programming (e.g. R, Python), and Additional Comments. To the right, there is a 'Feedback' section with the question 'Do you have a conflict of interest with this SME?' and radio buttons for 'No' and 'Yes'. Below the radio buttons are buttons for 'Close', 'Save Draft', and 'Submit'.

If the reviewer has a conflict of interest, he/she does not have to fill in the rest of the form and can simply press Submit. We then reassign the application to another reviewer.

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## Step 7. Provide your feedback and Submit

**Feedback**

**Do you have a conflict of interest with this SME? \***  
If you have a conflict of interest please do save and submit the form.

No  
 Yes

Below you can score the application. Do not hesitate to ask for clarity using the following email address: enquiries@ehden.eu

**Score for the expertise/experience in the field. \***

**Score the perceived capacity to actively engage with the EHDEN community. \***

**What is your overall score to grant the certification training? \***

**Do you recommend an interview with the SME before a final decision is made? \***

Yes  
 No

**Please provide a rationale for all the scores above. \***

Let us know if you missed information in the form or reviewer instructions to improve the review process.

Close
Save Draft
Submit

The form contains three scores:

1) Score for expertise/experience in the field.

Try to make an assessment whether this SME has enough expertise to perform the task assigned. The focus is on the ability to perform the ETL.

2) Score for perceived capacity to actively engage with the EHDEN community.

Try to make an assessment if you think this SME has the right motivation, capacity, and vision to become an active participant in the EHDEN and OHDSI communities. Ideally, they are open to sharing ideas and like to help to develop or improve data conversion and analysis tools

3) Overall score to grant the training.

Considering all the information received provide the overall score.

The rationale for **all** these three items needs to be filled in the box lower in the form.

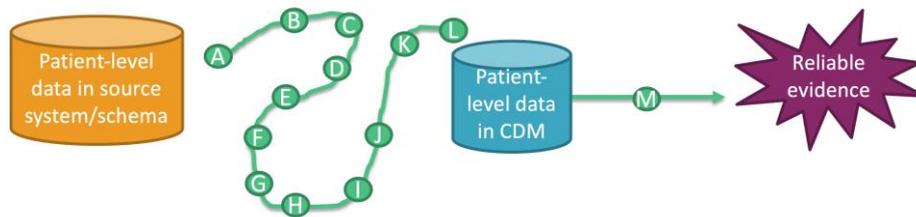
Furthermore, there is the question whether the reviewer thinks an interview is needed to make a final decision. For the pilot call we organized calls with all these SMEs but it is interesting to understand if the reviewer thinks they are able to make a proper decision based on the form or needed other information so we can further optimize the procedure.

For the consensus meeting, the PMO created an overview of all the scores from the reviewers and presented this to the Committee that then decided on the selected SMEs. All SMEs received the outcome through the application portal and an explanation for the decision via email.

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### 3.3 Training and Certification Program

For the training of the SMEs we decided to build an e-learning environment, the EHDEN Academy (<https://academy.ehdn.eu>). This environment will become available to the full community (OHDSI and EHDEN). The community is growing strongly, and we have a challenge but also an obligation to train all the stakeholders. We need to assure they are trained on all the important steps in the journey from source data to reliable evidence.



The EHDEN Academy is implemented in the world’s most popular open source learning platform, Moodle ([www.moodle.com](http://www.moodle.com)). This tool is used in many universities and companies around the world. It is a highly flexible platform to create a fully customized learning environment. The SMEs in the Pilot Call are the first to participate in the training and certification program and we will further optimize based on the feedback received.



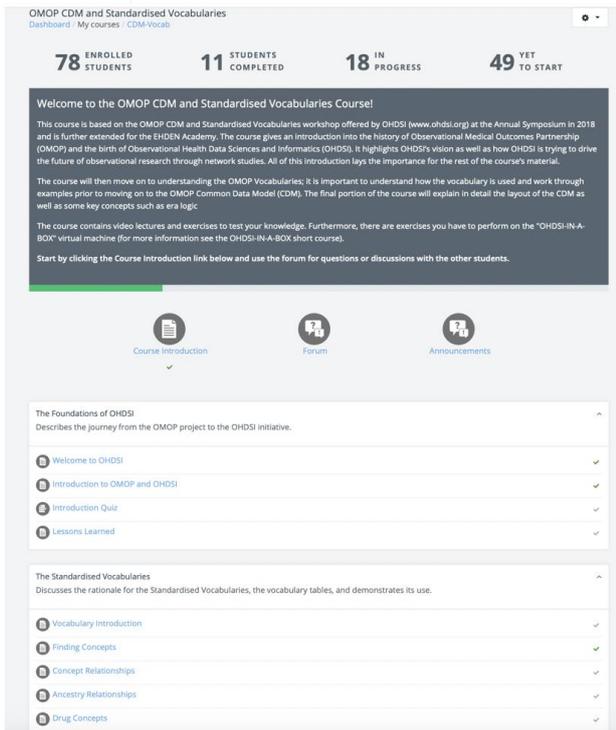
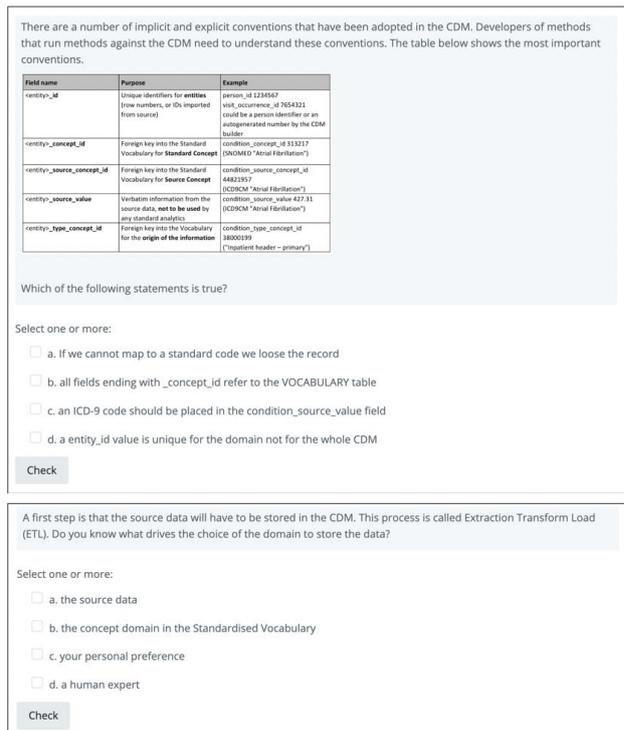
The process of mapping data to the OMOP CDM is a team effort in close collaboration with the data custodian. In the training program multiple employees from the SME, that may have different types of expertise, can participate. Therefore, we will certify the SME as a company instead of the individual. The aim of the program is that the SME will obtain all the necessary competencies to onboard a data source in the EHDEN federated data network following the establish quality standards. This includes, but is not limited to:

- Foundational Knowledge about the EHDEN project and its objectives.
- Expertise on the OMOP-CDM and the Standardized Vocabularies.
- Knowledge about the Extract, Transform, and Load steps and their implementation with OHDSI tools and approaches developed in EHDEN.
- Understand the fundamentals of proper documentation of the ETL process in close collaboration with the data custodian, to assure transparency and reproducibility.
- Expertise in the installation and use of the OHDSI Tools for federated data analyses such as those described here: <https://www.ohdsi.org/analytic-tools/>

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We currently have implemented 6 courses covering the above topics and included an instruction video on the use of the EHDEN Academy. An instruction document for new users was also developed and can be found in Annex 3.

As shown below, each course has a landing page that allows the trainee to keep track of progress. The courses contain video lectures, quizzes, final exams and exercises to test the trainees. Each course contains a dedicated forum for questions to the faculty.

Field name	Purpose	Example
entity_id	Unique identifiers for entities (row numbers, or IDs imported from source)	person_id 1234567 visit_occurrence_id 7654321 (could be a person identifier or an autogenerated number by the CDM loader)
entity_concept_id	Foreign key into the Standard Vocabulary for Standard Concept	condition_concept_id 333217 (NCDICD9 "Atrial Fibrillation")
entity_source_concept_id	Foreign key into the Standard Vocabulary for Source Concept	condition_source_concept_id 4482397 (ICD9CM "Atrial Fibrillation")
entity_source_value	Verbatim information from the source data, not to be used by any standard analysis	condition_source_value 427.31 (ICD9CM "Atrial Fibrillation")
entity_type_concept_id	Foreign key into the Vocabulary for the origin of the information	condition_type_concept_id 3800299 ("Patient header - primary")

Importantly, the curriculum also contains mapping exercises on simulated datasets. This is offered through access to a virtual machine called OHDSI-IN-A-BOX that we have developed together with OHDSI and Amazon Web Services (AWS). It is available on the OHDSI GitHub: <https://github.com/OHDSI/OHDSI-in-a-Box>



The OHDSI-IN-A-BOX can be easily instantiated by the trainees in the Amazon cloud infrastructure. It contains many OHDSI tools, a CDM database with simulated data and a source database that is used in the EHDEN Academy to train on mapping. We have developed a short course in the Academy that explains how to set up this environment easily.

Furthermore, we developed the OHDSI-INSTALL-SERVER VM available on our EHDEN Github:

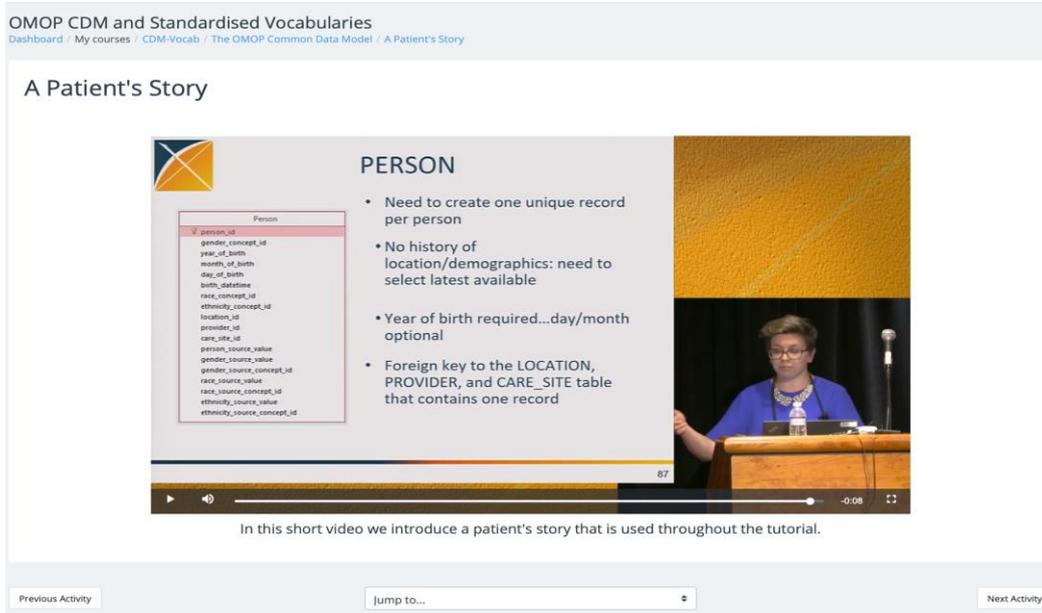
<https://github.com/EHDEN/OHDSI-Install-Server>

This VM is used in the OHDSI Tools course in the EHDEN academy. This course provides training on how to install all the OHDSI tools. The server only includes Postgres and Notepad++ and the goal for the student is to install all the OHDSI tools.

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All the SMEs received credits made available by AWS to instantiate multiple VMs for their employees.

The EHDEN Academy will be further developed in the upcoming period together with all EHDEN WPs and OHDSI. It will include many more courses, e.g. on personalized medicine (WP3).



OMOP CDM and Standardised Vocabularies  
Dashboard / My courses / CDM-Vocab / The OMOP Common Data Model / A Patient's Story

A Patient's Story

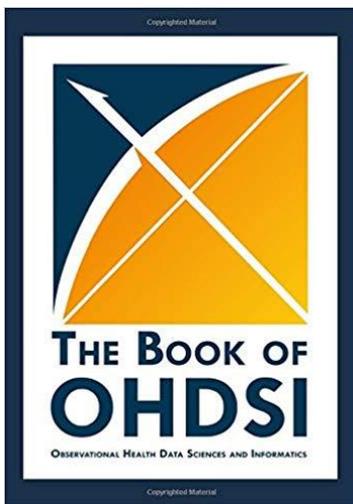
**PERSON**

- Need to create one unique record per person
- No history of location/demographics: need to select latest available
- Year of birth required...day/month optional
- Foreign key to the LOCATION, PROVIDER, and CARE\_SITE table that contains one record

In this short video we introduce a patient's story that is used throughout the tutorial.

Figure 7. Example of a video lecture developed together with the CDM and Vocabularies team of OHDSI

## The Book of OHDSI



The Book of OHDSI was recently released as an [online version](#) and is available as a paper version on [Amazon](#). The book describes OHDSI and describes all the methods and tools for ETL and study execution. Our consortium members contributed to several chapters in the book. The 470 pages book is a perfect resource for new and veterans in the community and will be offered to all the SMEs participating in our training as additional reading material. The book describes OHDSI and describes all the methods and tools for ETL and study execution. Our consortium members contributed to several chapters in the book.

## Certification

To obtain the certification, the SME must finish all e-learning courses and participate in a face-to-face 2-day workshop. The first day of this workshop is used mainly to provide additional training and allow the SMEs to ask questions. On the second day the SME will have to map a database to the OMOP-CDM that we make available in a virtual machine. The data custodian will provide information about the database in a presentation and the SME is asked to define the ETL using the tools and map source vocabularies to the

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standardized vocabularies. Furthermore, we will have an interview with each SME to understand how competent they are. For the pilot run we will also evaluate the whole process with the SMEs.



Figure 8. Certificate received by the SME.

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Once the SME receives the certificate (see Figure 8) it obtains the following benefits:

**1. Certified SME Catalogue**

All SMEs that are certified will be mentioned on the public EHDEN website. This serves as reference for interested data sources that want to apply for funding through the EHDEN Harmonization fund in the upcoming Data Source Grant Awarding Open Calls. The Catalogue will contain KPIs such as the number of data sources mapped by the SME.

**2. Certification Badge**



Certified SMEs are allowed to add the certification badge to their website. The badge will indicate the year of certification and the colour will indicate critical factors such as how many years the SME has been certified and is actively mapping data sources.

**3. Member of the EHDEN SME Community**

During the EHDEN project we like to actively engage the SME Community that will support the development of the eco-system. This can include invites to additional training sessions, hack-a-thons to improve the open source tools or invites to study-a-thons in which researchers and data sources will collaboratively execute studies to generate reliable evidence. Furthermore, we foresee an online forum for moderated discussions in the SME Community.

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## 4. DATA PARTNER GRANT AWARDING PROCEDURE

Figure 9, describes the procedure as proposed in the EHDEN Description of Action (DoA). Here we briefly describe how we further developed and implemented each step in the procedure. For more details see D7.1 containing the final Call Description Document and Sub-grant agreement.

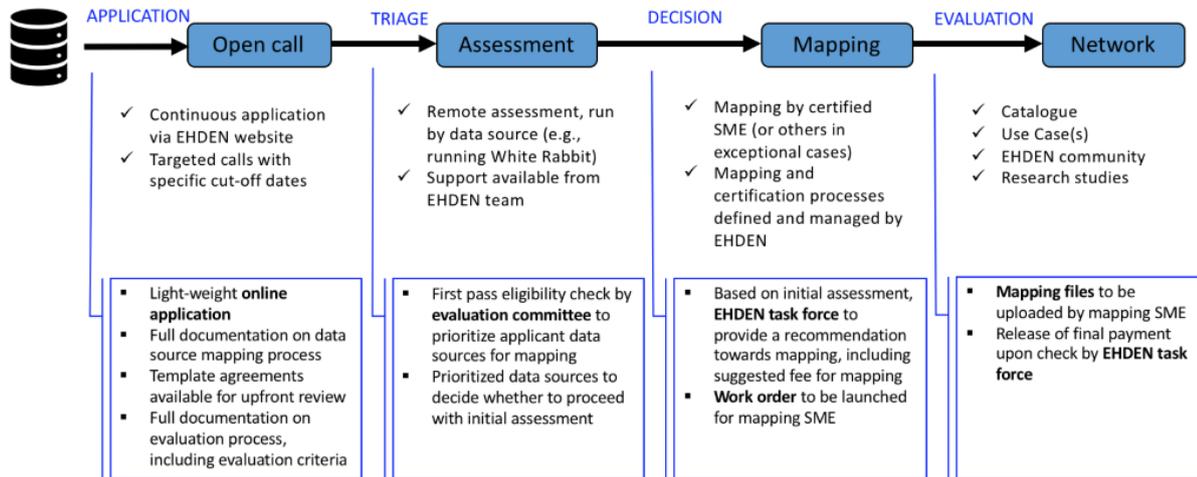


Figure 9. Data Partner Grant Awarding Procedure as defined in the EHDEN DoA.

### 1. Open Call

In several iterations we developed all procedural steps and created all documentation for the call. We decided to first make this available for public review from July 15th till Aug 15th 2019. This allowed us to further improve the procedure and the call description. As a result, we created a FAQ section on the website that covered the questions we received from potential Data Partners. Furthermore, we discussed procedures with the IMI officer and the IMI legal team to come to a final version of the Call Description Document published online at Sept 1st.

To allow different kinds of Data Partners to benefit from the available funding we defined the following types of activities that can receive financial support:

#### A. Create new Data Transformation and Analytical Infrastructure

This activity is intended for Data Partners that have not mapped their data to the OMOP-CDM yet. It includes the data source profiling, development and implementation of the ETL process and quality control assessments. Additionally, the analytical tools will be deployed at the local site and the data custodian will receive training. After passing inspection for both the data transformation and analytical infrastructure by a certified SME, the data source meta data in the Database Catalogue will be modified to reflect this. The Data Partner can then fully participate in the community and data network.

#### B. Revise Existing Data Transformation and Analytical Infrastructure

This activity is intended for data sources that are already partially mapped to the CDM, to add additional domains (e.g. measurements, procedures) or add new source vocabulary mappings. The financial support will also be used for quality assessment of the ETL, tool deployment, training and the inclusion in the

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Database Catalogue after passing inspection for both the data transformation and analytical infrastructure by a certified SME. This activity enables these Data Partners to utilise the expertise in EHDEN to further improve and extend their CDM mapping.

### C. Inspect Completed Data Transformation and Analytical Infrastructure

This activity consists of a standardised procedure developed in EHDEN which needs to be applied by a certified SME to ascertain the quality of the ETL and status of the analytical infrastructure. If the quality of the ETL, including its documentation, is at the level required by EHDEN and the deployed tools are successfully tested at the local site, the data source will be added in the Database Catalogue with the information that this validation has been performed. If the quality of the mapping is below the standard, the Data Partner could fix this and a second inspection will take place. If substantial changes are needed the Data Partner could apply for additional funding to remedy this (Activity B).

The Data Partner can only apply for one of the types of activity above per call round, but could potentially apply for funding for multiple types of activities during the course of the EHDEN project. However, the total amount of funding granted for all types of activities during the EHDEN project cannot exceed 100.000 Euro per Data Partner.

#### Sub-grant agreement

The sub-grant agreement was published together with the Call Description document. This was developed by the legal team of the partners EMC, Synapse, and Janssen, and IMI legal experts. It was made available to the Excom and partner leads for approval prior to publication.

The final Data Partner Call Description and sub-grant agreement can be found in deliverable D7.1 and on the EHDEN website.

## 2. Data Source Assessment

The assessment is made by the Data Source Prioritisation Committee based on the application form presented in Annex 4. This form has been developed together with the OHDSI leadership and experts in OMOP data transformation in the Consortium. It contains a list of questions to assess the impact of the content of the data source on the EHDEN eco-system, the impact on network research, the ability of the data source to share metadata, and question to assess the complexity of the necessary data mapping.

The application form also 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. This 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. This information will be used to assess the complexity of the data source which will drive the level of maximum financial support. Furthermore, this self-assessment exercise provides insight in the technical capabilities of the local team to run such a tool and the database readiness for the standardisation exercise. ‘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>

If the data partner is not able to run this tool or is unable to share the results, this will not necessarily exclude the data source from being granted Financial Support, but the Data Partner will be asked to explain why this

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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.

The reviewers are invited to assess the applications using the reviewer portal described below.

### 3. Mapping

The execution phase starts with defining a workplan together with the Data Partner that is added as part of the sub-grant agreement. The sub-grant agreement will contain a milestone-based schedule for payment of the grant. By default, the following milestone payments for all three (A, B, C) type of activities are proposed:

Milestone	Grant Percentage	Estimated Timelines*
Shared ETL documentation	30%	Month 3
ETL Implemented and Infrastructure Operational	40%	Month 6
Database catalogue entry following final inspection by certified SME	30%	Month 7

\*starting at the date of signature

These milestones are indicative and are understood as the default option. For information see D7.1.

The Data Partner can select a certified SME from the Service Provider Directory that is currently under development and should setup the contract for the work to be performed. This will initiate the mapping process following the best practices as defined in the EDHEN ETL course.

### 4. Network

Once the final milestone is reached and the Data Source is added in the EHDEN Catalogue the Data Partner can participate in network studies and obtains the benefits described in the Call Description Document, such as extra education and training, invitations for events etc. The process for the study execution itself is out-of-scope for this deliverable but will be described in D5.5 “Report on Federated Network Studies”.

#### 4.1 Data Partner Application Portal

The application form for the data partners was developed by the WP5 team through interactions in the EHDEN forum and TCs. We included extensive input from our OHDSI collaborators and IMI in this process. The implementation of the Data Partner Application portal was performed in close collaboration with the application specialists of WizeHive following the same process as described in more detail for the SME portal above.

#### 4.2 Data Partner Review Portal

The applications are evaluated by a Data Source Prioritisation Committee (DSPC) that consists of 4 EHDEN Consortium members and 4 independent external experts. These independent experts are drawn from a panel of international experts that act as advisors to EHDEN. All experts involved in the evaluation are required to have skills and knowledge appropriate to the Data Source Call. They have a high level of professional experience in the public and/or private sector and are internationally recognised in their field of expertise.

For the DSPC we created a review portal comparable to the one developed for the SMECC in the SME certification procedure as described in section 3.2. Annex 5, contains the instructions for reviewers on the

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use of the portal including screenshots of the portal. The Call Description document available on our website and part of D7.1 describes the evaluation procedure itself in more detail.

## 5. CONCLUSION

We have developed and implemented all necessary procedures and tools to initiate the Pilot Calls for the SMEs and Data Partners. Both calls have been successfully launched and there was large interest in both calls. The first Pilot Call for the SME certification was open in April 1<sup>st</sup>, 2019 and closed in April 30<sup>th</sup>, 2019. A total of 28 SME applications were submitted to this first Pilot Call. 11 SMEs have been selected for training and are currently going through the certification process. The first Pilot Call for the Data Partners was open for public review in July 15<sup>th</sup>, 2019. The grant application portal was open from September 1<sup>st</sup>, 2019 to September 15<sup>th</sup>, 2019. A total of 49 Data Partners registered their profile in the application portal, and a total of 28 applications of 14 different European countries have been received. The evaluation process is ongoing now.

These Pilot Calls were initiated to further improve our processes and we will discuss all feedback received from the applications and other stakeholders. This evaluation will be presented in deliverable D5.3 Yearly Report on SME Certification and Data Source Grant Awarding.

Future calls will be announced on our communication channels and we look forward to enlarging the EHDEN network of Data Partners and Service Partners in the upcoming years.

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## 6. ANNEXES

### Annex 1: Application Form SMEs

<b>Questions</b>	
<i>The OHDSI ecosystem involves a variety of technology platforms and open-source software development frameworks. Please indicate the expertise available in your company in the following technologies:</i>	
Relational database platforms (e.g. PostgreSQL, Oracle, SqlServer, Redshift)	
Web application development (e.g. HTML5, JavaScript, D3.js, R Shiny)	
Application development (e.g. Java, C++)	
Database programming (e.g. SQL)	
Statistical programming (e.g. R, Python)	
Additional Comments	
<i>Please describe briefly what experience the company has with person-level healthcare datasets, such as electronic health records, administrative claims or clinical registries.</i>	
Which databases have you worked with?	
What was your level of familiarity with the data's structure and content?	
What was your role in performing data management or statistical analysis of these data?	
We invite you to add links (max 5) to publicly-available material, e.g., journal papers, presentations, or videos to demonstrate the activities and qualifications.	
<i>Please describe what experience you have with healthcare terminologies, such as SNOMED-CT, ATC, RxNorm, Read, ICD, LOINC..</i>	
Which terminologies have you worked with?	
What was your level of familiarity with the terminology's structure and content?	
What has been your role in performing data management or statistical analysis using these terminologies?	
We invite you to add links (max 5) to publicly-available material, e.g., journal papers, presentations, or videos to demonstrate the activities and qualifications.	
Finally, please answer the general questions below.	
In which cities and countries does your company have local offices?	
Which languages does your company routinely use for written or oral communication, within your company and with others?	
How many people could you dedicate to a single data conversion at a time?	
How many such teams could you field at the same time?	

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<p>How will you maintain expertise about the common data model in your company over time, particularly as people leave and join?</p>
<p>Describe your proposed approach to engaging with the EHDEN project and OHDSI open source community.</p>
<p>Describe your approach to project management and cost control for providing data service.</p>
<p>Describe any processes (and/or certifications) your company has in place with regards to compliance with privacy and clinical data regulations as well as compliance with information security standard.</p>
<p>Please add any other information about the company you think is relevant (max 500 words)</p>

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## Annex 2: SME Reviewer Instructions

# Small and Medium-sized Enterprise Certification



## Reviewer Instructions

**The EHDEN Consortium**

2/5/2019

V1.0

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## Document History

Version	Date	Description
V0.1	1-5-2019	First Draft, Review PMO
V1.0	2-5-2019	Final version

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## Introduction

This document describes in detail the Pilot Call for Small to Medium-sized Enterprises (SMEs) in the European Health Data and Evidence Network (EHDEN) project ([www.ehdn.eu](http://www.ehdn.eu)). It is meant to inform the reviewers and instruct them to review the application using the online review portal. To provide the necessary context we will first briefly introduce the project and the value proposition for the SMEs.

## The EHDEN Project

The EHDEN project is a public-private partnership, set up under the framework of IMI2 (<https://www.imi.europa.eu/>). The EHDEN consortium consists of twenty-two partners, including academia, 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 sources 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](http://www.ohdsi.org)), and others. The ultimate aim is to generate 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 eco-system to make this ambition come true, supporting the disease-specific projects in the IMI Big Data for Better Outcomes (BD4BO) programme ([www.BD4BO.eu](http://www.BD4BO.eu)) as well as academia, pharmaceutical and life sciences companies, and regulatory authorities.

The ambitions of the EHDEN project are high. We aim to standardize more than 100 million patient records across Europe from different geographic areas and different data sources, e.g. hospital data, registries, population databases, etc. Mapping of 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.

Two types of Open Calls are initiated in EHDEN as described in Figure 1.

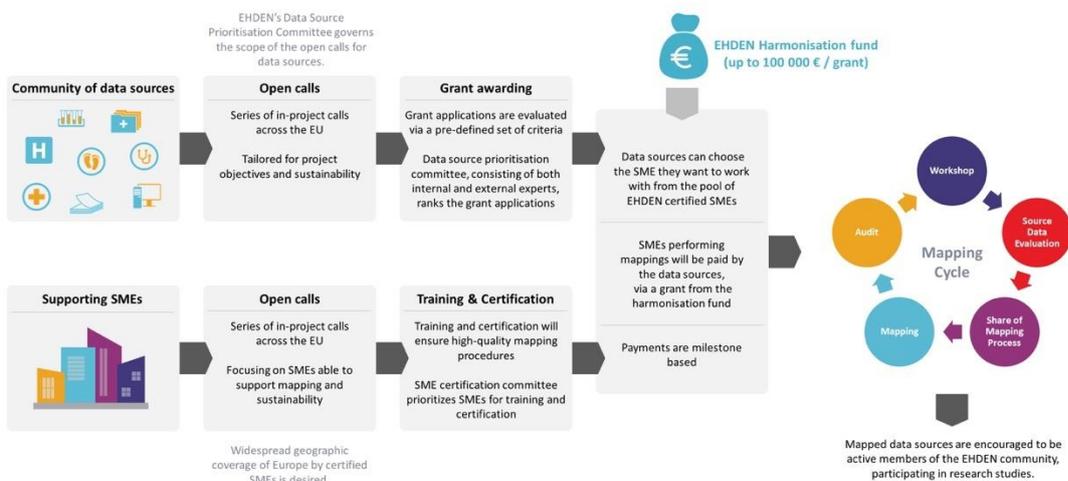


Figure 1. EHDEN’s Open Calls for Data Sources (top) and Small to Medium-sized Enterprises (bottom), and how both are subsequently interrelated.

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## 1. Data Source Calls

Institutions holding health data can benefit from seed funding that will be made available via a “Harmonization Fund” to subsidize a set of conversions to the OMOP CDM performed by certified SMEs. Per data source there will be a maximum amount of funding of 100.000 Euro, the final amount being dependent on the type of call and complexity of the mapping. We anticipate a continuously growing market for conversions because of the increasing interest into the OMOP CDM. Initial outreach efforts indicate the data custodians are expected to have a strong willingness to map their data in order to benefit from being part of the federated ecosystem.

## 2. SME Calls

The EHDEN project also wants to facilitate the creation of an SME eco-system in Europe that supports data sources and other stakeholders in mapping and using data. For this purpose, EHDEN has created calls through which SMEs can apply for training and certification to convert health data from various formats to the OMOP common data model.

This implies that for each of the data sources, an Extraction Transform and Load (ETL) process has to be implemented that:

1. Extracts the data from the source database.
2. Transforms these in the right table structure and Standardized Vocabularies.
3. Loads the data in the OMOP-CDM.

The ETL process needs high involvement of the data custodian who knows the data and its provenance best, and also deep expertise in OMOP-CDM and its Standardized Vocabularies, programming and engineering skills, and advanced expertise in database management systems, among other skills. The data transformation needs to be of high quality and should follow all best practices with respect to transparency and reproducibility in order to fulfil the ultimate objective pursued by EHDEN.

SMEs who receive training and certification through EHDEN will learn how to perform conversions for data sources consistently and reliably, and so help to build the data network. We also hope that they will become active members of the community, sharing ideas and possibly helping to develop or improve data conversion and analysis tools.

The SME Call is described in detail in this document.

## Value proposition for SMEs

### Expand your existing market

If the company is already operating in the data science, health data interoperability, bioinformatics or medical informatics fields, EHDEN offers a gateway into multiple opportunities for growth.

#### a. Expand your customer base

EHDEN will create an eco-system where a variety of stakeholders (hospitals, health data sources, pharmaceutical and related industries, authorities, HTA, regulators, etc.) will be able to seamlessly network and collaborate. This will be an unmatched opportunity for your company to expand your customer base, including data users interested in deploying and developing tools, and a plethora of data sources willing to be mapped to the OMOP CDM asking for support. Up to 100 million European health records are expected to be mapped to the OMOP CDM thanks to EHDEN, underpinning a newly populated landscape for health data solutions.

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b. Expand the range of services and products you can offer

EHDEN will allow the data skills of the SME to be taken to the next level. New products and services will flourish within the EHDEN eco-system thanks to an extraordinary improvement in our capacity to re-use health data for better decision-making. IT-centred companies will be able to expand their range of products and services to act as data sciences providers, opening doors to scientific endeavours beyond the technical realm.

c. Expand your geographical reach

EHDEN is a European project, so its scope includes hundreds of data users and providers scattered all over Europe. Additionally, EHDEN builds on and will be deeply connected with OHDSI, an international open community promoting the OMOP CDM, which is now widely adopted from the USA to South Korea. Participating in EHDEN opens the door for the company to be exposed to a growing worldwide market.

**Contribute to the creation of emerging, new markets for data sciences**

Beyond established markets, there are huge opportunities arising derived from a brand-new way of understanding and using health data. EHDEN aspires to facilitate the creation of new markets that support the needs of both data users and providers, a currently incipient field where your company could play a pivotal role:

a. Health data mapping to the OMOP CDM

EHDEN will foster and financially support mapping of European data sources to the OMOP CDM using certified SMEs. This will offer short-term opportunities for service provision. As a critical mass of mapped data sources is reached and reliance on interoperability standards increases, a ‘snowball’ effect will raise the need of many other data sources to also adopt the OMOP CDM, in what is likely to be an expanding market.

b. Data analysis services for small and medium biomedical companies

Beyond large pharmaceutical companies, the biomedical field is populated by numerous small/medium-size pharmaceutical companies, biotech and medical device companies that cannot or do not want to staff data analysis expertise internally, for efficiency reasons. The same can apply to other public and private institutions. Certified SMEs with knowledge and experience in using the OMOP CDM will be able to benefit from these outsourcing opportunities to develop new services related to data analysis.

c. Enabling high throughput studies by bridging data users and providers

Beyond infrastructure, certified SMEs may also directly facilitate the undertaking of studies and other ways of using health data for a variety of purposes. This facilitating role may be especially important in the future due to the growing requirement to carry out multi-centre international studies in a transparent way to ensure that the best evidence is used for decision making purposes.

d. Training on the use of OHDSI tools and observational analyses

SMEs engaging with EHDEN will have unique access to specialised knowledge and hands-on training. This will allow the SME to in turn train others on both technical and scientific aspects of the OMOP CDM and its application, from ETL to high-efficiency analytics.

e. Ongoing support and maintenance of connected data and provided solutions

In a fast-changing world, all new products and services developed in this emerging field, no matter how novel or revolutionary they might be, will need continuous support and maintenance. The potential of health data use will only grow with time. For certified SMEs, providing ongoing support may represent a stable revenue source that helps offset the risks of further research and investment in new products.

**Early adopters will gain competitive advantage on specialised skill set**

In most of these emerging markets, there are currently no dominant players that cover all the potential services. Early adopters of the EHDEN training and certification mechanism will possess a competitive advantage and will be uniquely placed to innovate and benefit from privileged market positioning. They will have early experience on deploying the OMOP CDM and its application in different contexts and use

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cases. This will enable long term growth strategies, focussing on relative strong areas and developing a solid customer base before the markets mature.

### **Possibility to contribute to a change of paradigm benefitting health of citizens**

EHDEN aims to be truly revolutionary in how the wealth of existing health data can be best used for the ultimate benefit of the patient – enabling better decision making by health professionals, better drugs being developed earlier, better understanding of disease processes... all of which will create positive feedback loops on our ability to generate, analyse and use data. Companies contributing to the ecosystem will help develop such learning healthcare systems, for the benefit of all. Profit making is essential for any company, but nothing equals the feeling of having decisively contributed to a better world.

### **Short-term income generation to offset skill investment**

EHDEN will launch periodic calls for data sources that are interested in being mapped to the OMOP CDM. Data sources that are evaluated positively will receive funding in the form of a grant, and they will be able to use it to hire certified SMEs for mapping services. This will offer an opportunity for SMEs to generate revenue, but most importantly, to acquire experience in real-life scenarios all over Europe.

### **Free training and certification**

The best part – the EHDEN training and certification programme for SMEs is free of charge. You will still have to of course invest time and cover your own costs for travel, etc., but EHDEN covers the full cost of the programme so that you can be up and running as soon as possible.

### **Open source community boosts opportunities**

EHDEN is deeply connected with the OHDSI worldwide initiative, which gathers a very active open source community that is continuously developing and improving software tools for better data analysis and use. By participating in EHDEN, SMEs interested in the development of software tools will be able to contribute to this dynamic community, share the burden of development and validation, build services on top of such tools and benefit from the many opportunities that a worldwide, ever growing peer community offers to boost adoption and exploitation of the OMOP CDM.

### **Thriving community facilitates hands-on training of new staff**

Besides tool and service development, the OHDSI and EHDEN communities conform a perfect space for hands-on training of new personnel, facilitating expertise acquisition, a fast learning curve and continuing career development in a way that no SME could afford internally by itself.

### **Synergic ecosystem facilitates exposure and brand recognition with key stakeholders**

EHDEN will gather many different types of stakeholders: hospitals and other data custodians, pharmaceutical companies, regulatory and health technology assessment agencies, healthcare authorities, software developers, patient representatives, ... Participating in EHDEN will immediately help your company to be exposed to such a variety of institutions in Europe and, through OHDSI, worldwide, in the context of a collaborative environment, facilitating contacts with different types of potential customers and allies, helping market positioning and brand recognition in a much faster way than any marketing or outreach campaign would be able to achieve.

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## SME Pilot Call

The Pilot call is the first SME call for training and certification offered by EHDEN. In this call the SME Certification Committee will prioritize the SME application. The aim of the Pilot call is to further optimize the application, review, training and certification procedures. The selected SMEs will receive all necessary guidance from EHDEN to succeed.

## Who can Apply?

The call is open to Small and Medium-sized Enterprises under the official EU definition:

- < 250 staff
- <= € 50m Turnover or <= € 43m Balance sheet total
- Legally established as a business and based in an EU Member State or H2020 Associated Country (for a complete list see Appendix 1).

See for more details: [http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition\\_en](http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en)

## How to Apply?

The SMEs register in the SME Certification Portal on the [EHDEN Website](#), and then complete their application electronically in English before May 1<sup>st</sup> at 17:00 CET. All applications will be processed through the application portal and communication will take place through the applicant's email address as specified in the application form.

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## Evaluation Process

### The SME Certification Committee

The applications are evaluated by an SME Certification Committee that consists of four EHDEN Consortium members and two independent external experts.

The independent experts are drawn from a panel of international experts that act as advisors to EHDEN. Independent experts involved in the evaluation are required to have skills and knowledge appropriate to the SME Call. They have a high level of professional experience in the public and/or private sector and are internationally recognized in their field of expertise.

The names of the independent experts assigned to individual proposals are not made public.

An appointment letter binds each independent expert to a code of conduct and establishes the essential provisions regarding confidentiality.

EHDEN takes all necessary steps to avoid conflicts of interest. To this end, independent experts are required to sign off for each application, stating that no such conflict of interest exists at the time of their review.

By submitting an application to the EHDEN calls, applicants accept the evaluation and selection procedures established by the project.

### Evaluation Process and Criteria

All proposals submitted are evaluated using the following procedure:

- 1) Eligibility Check by the EHDEN project management office  
If the applicant does not meet the EU criteria for Small and Medium-sized Enterprises, the application is incomplete or not in English language, the application will be declared as non-eligible and not be evaluated further.
- 2) Application evaluation by the SME Certification Committee

Each application will be individually reviewed by at least two Committee members. Each member will review the application independently and provide scores on three criteria:

- a. Expertise/experience of the SME in the field. (Score 1-10)
- b. Perceived capacity of the SME to actively engage with the EHDEN community. (Score 1-10)
- c. Overall score to grant the training and certification program (Score 1-10)

For all criteria, a score value of 1 represents “Very Poor”, and a value of 10 represents “Excellent”.

Committee members are required to provide comments to clarify and/or justify each of their scores. These comments must be consistent with any scores awarded and serve as input to any consensus discussion and related consensus report.

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Once all the committee members have completed their individual evaluations and communicated them to the EHDEN Project Management Office (PMO), the evaluation progresses to joint assessment. This entails a unique consensus panel meeting in which differing scores are discussed and a consensus view is reached on scores, comments and recommendations.

As part of this joint evaluation of applications, committee members will discuss to provide recommendations for priority order of the proposals that pass the evaluation thresholds, resulting in an overall ranking. The evaluation thresholds are defined as:

1. All three scores should be at least 6.
2. The sum of all scores should be at least 20.

The consensus discussion is moderated by a chairperson ("the moderator"). The role of the moderator is to seek a consensus between the individual views of independent members without any prejudice for or against a particular application or company involved, and to ensure a fair and equitable evaluation of each application according to the defined evaluation criteria.

The moderator will designate one of the independent experts participating in/attending the consensus panel ("the rapporteur") to be responsible for drafting and signing off a Consensus Evaluation Report(s). Such report will include the consensus scores and comments for each eligible application, and the overall ranking. Comments to each application should be suitable for feedback to the respective applicants.

If during the consensus discussion it is found that, despite all reasonable efforts to reach consensus, it is impossible to bring all the experts to a common point of view, the moderator may propose actions to reach resolution, which may include an interview with one or several of the applicant SMEs.

## How to review the applications?

The EHDEN Project Management Office (PMO) will assign applications to the reviewers. In this section we will explain how the applications will be reviewed in the portal.

### Step 1. Email notification about new applications to review

You will automatically receive an invite by email to create an account on the review portal. PMO has entered your email address in our system to start this process.

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Dear SME Reviewer,

A new application for has been submitted for your review. Please log into the [review portal](#) and provide your feedback when you first have a chance. We like to receive your feedback within one week if possible.

If this timeline is not feasible or you have questions, do not hesitate to send an email to: [enquiries@ehden.eu](mailto:enquiries@ehden.eu)

We thank you for your support to the EHDEN project.

The EHDEN team.

---

 [www.ehden.eu](http://www.ehden.eu)

 [@IMI\\_EHDEN](https://twitter.com/IMI_EHDEN)

 [IMI\\_EHDEN](https://www.linkedin.com/company/IMI_EHDEN)

 [github.com/EHDEN](https://github.com/EHDEN)







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.

**Step 2. Fill in your email account and you will receive a confirmation email.**



## SME Application Review Portal

**Sign In/Sign Up Instructions**

**For New Users:**  
Please enter your email address and we will verify if you are in our system. If your email is part of our system, a confirmation will be sent to that address. *If your email is not in our system or you do not receive a confirmation email, please contact us at [enquiries@ehden.eu](mailto:enquiries@ehden.eu).*

Upon confirmation of your email, you will be taken to the **Sign Up** screen where you can choose a password to create an account. *Your password must be at least 8 characters in length.* Once you have chosen your password, your account will be created and you will gain access to the portal.

**For Returning Users:**  
Please enter your email address to the right, and we will verify if you are in our system. When found, you can enter your password and then gain access to the portal.

For more information about the Review process and the Review Portal we refer to the Reviewer Instructions sent to you separately.

If you have any questions or concerns, please contact us via [enquiries@ehden.eu](mailto:enquiries@ehden.eu). Thank you!

**Welcome!**

To get this process started, new and returning users please enter your email address below.

**Email**  
smereviewer1@gmail.com

You will receive a confirmation email shortly with a confirmation code which will allow you to choose a password, create an account and log in. Please check and confirm or [Resend Email](#).

Already have a confirmation code?



**Step 3. Create an account**

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## SME Application Review Portal

### Sign In/Sign Up Instructions

**For New Users:**  
Please enter your email address and we will verify if you are in our system. If your email is part of our system, a confirmation will be sent to that address. If your email is not in our system or you do not receive a confirmation email, please contact us at [enquiries@ehden.eu](mailto:enquiries@ehden.eu).

Upon confirmation of your email, you will be taken to the **Sign Up** screen where you can choose a password to create an account. Your password must be at least 8 characters in length. Once you have chosen your password, your account will be created and you will gain access to the portal.

**For Returning Users:**  
Please enter your email address to the right, and we will verify if you are in our system. When found, you can enter your password and then gain access to the portal.

For more information about the Review process and the Review Portal we refer to the Reviewer Instructions sent to you separately.

If you have any questions or concerns, please contact us via [enquiries@ehden.eu](mailto:enquiries@ehden.eu). Thank you!

### Sign Up

Choose a password below. Once your account is created you will be logged into the portal.

**Email**  
smreviewer1@gmail.com

**Password**

- Must contain at least one lowercase letter
- Must contain at least one uppercase letter
- Must contain one number
- Must be between 8-32 characters
- Must not be an email address

**Confirm Password**

- Passwords must match

We will use your information in accordance with our [Privacy Policy](#) to respond to your inquiries and fulfill your requests with regards to the creation of an SME application profile, as necessary for our legitimate interest and possibly to comply with our legal obligations.

I have read and agree to the [Terms of Service](#) and [Privacy Policy](#).

[Create Account](#)

powered by 

**Step 4. Select the application to review from the list of assigned applications.**



## SME Application Review Portal

Search by Company Name

Welcome, smreviewer1@gmail.com [Logout](#)

1 listing in total Show: All

Company Name: My Company	<a href="#" style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Review</a>
--------------------------	--

1 - 1 of 1

### Instructions:

The applications that you have been instructed to review are listed on the left. Please read through all of your applications. Click "Review" to open the application and get started.

Once inside an open application, the dropdown next to "Review Form" will show other forms that might accompany your application. Use the arrows to toggle back and forth through all of the forms that you need to view for an application.

Please check to see if there are any attachments that accompany the application. To do this, check the "Form Attachments" dropdown below the form name. You can click on any attachment and it will be viewable in the center of the screen. To get back to the form which this attachment is associated, simply click the name of the form above the form attachments dropdown.

In order to complete your review form for your assigned applications, please click the "+ Feedback" button in the upper right.

The review form will populate to the right of the application. Please complete the review form. You have the option to save a draft of your review form – this allows you start where you left off when you log back into this portal at a future date; that application will be in progress with an orange status/button stating "Continue".

Once you have completed all the required fields on your review form, please click "Submit". The status/button of that submitted application will be green, stating "Done". This review is complete and you can move on to your next assigned application.

Thank you, and please contact your administrator if you have any questions!

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## Step 5. Read the application and profile information

You can select the application or profile as show in the image below



**Instructions:**

The applications that you have been instructed to review are listed on the left. Please read through all of your applications. Click "Review" to open the application and get started.

Once inside an open application, the dropdown next to "Viewing Form" will show other forms that might accompany your application. Use the arrows to toggle back and forth through all of the forms that you need to view for an application.

Please check to see if there are any attachments that accompany the application. To do this, check the "Form Attachments" dropdown below the form name. You can click on any attachment and it will be viewable in the center of the screen. To get back to the form which this attachment is associated, simply click the name of the form above the form attachments dropdown.

In order to complete your review form for your assigned applications, please click the "+ Feedback" button in the upper right.

The review form will populate to the right of the application. Please complete the review form. You have the option to save a draft of your review form – this allows you start where you left off when you log back into this portal at a future date; that application will be in progress with an orange status/button stating "Continue".

Once you have completed all the required fields on your review form, please click "Submit". The status/button of that submitted application will be green, stating "Done". This review is complete and you can move on to your next assigned application.

Thank you, and please contact your administrator if you have any questions!

**Step 6. Click on + Feedback (see red arrow above) and inform us about a conflict of interest.**

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## SME Application Review Portal

Search by Company Name  Q Welcome, smreviewer1@gmail.com ⚙ Logout

[Listings](#) > [My Company](#)

Viewing Form: Application < >

**Application**

Form Attachments
Print

**The OHDSI ecosystem involves a variety of technology platforms and open-source software development frameworks. Please indicate the expertise available in your company in the following technologies:**

**Relational database platforms (e.g. PostgreSQL, Oracle, SqlServer, Redshift)**

Oracle

**Web application development (e.g. HTML5, JavaScript, D3.js, R Shiny)**

R

**Application development (e.g. Java, C++)**

**Database programming (e.g. SQL)**

**Statistical programming (e.g. R, Python)**

**Additional Comments**

**Feedback**

**Do you have a conflict of interest with this SME? \***

If you have a conflict of interest please do save and submit the form.

No

Yes

Close
Save Draft
Submit

If you have a conflict of interest, you do not have to fill in the rest of the form and you can simply press Submit. We will than reassign the application to another reviewer.

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## Step 7. Provide your feedback and Submit

**Feedback**

**Do you have a conflict of interest with this SME? \***  
If you have a conflict of interest please do save and submit the form.

No  
 Yes

Below you can score the application. Do not hesitate to ask for clarity using the following email address: enquiries@ehden.eu

**Score for the expertise/experience in the field. \***

**Score the perceived capacity to actively engage with the EHDEN community. \***

**What is your overall score to grant the certification training? \***

**Do you recommend an interview with the SME before a final decision is made? \***

Yes  
 No

**Please provide a rationale for all the scores above. \***

Let us know if you missed information in the form or reviewer instructions to improve the review process.

The form contains three scores:

4) Score for expertise/experience in the field.

Try to make an assessment whether this SME has enough expertise to perform the task assigned. The focus is to the ability to perform the ETL.

5) Score for perceived capacity to actively engage with the EHDEN community.

Try to make an assessment if you think this SME has the right motivation, capacity, and vision to become an active participant. Ideally, they are open to sharing ideas and like to help to develop or improve data conversion and analysis tools

6) Overall score to grant the training.

Considering all the information received provide the overall score.

The rationale for **all** these three items needs to be filled in the box lower in the form.

Furthermore, there is the question whether you think an interview is needed to make a final decision. For the pilot call we will most probably organize calls with all these SMEs but it is interesting to understand if you think you are able to make a proper decision based on the form or need other information (please provide details in the last text box).

We realize that for the first pilot call we may have to further optimize the Feedback form or even the application form. In the consensus call we will evaluate the process with all the reviewers.

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## Feedback on the evaluation process

The EHDEN Project Management Office (PMO) will send an information letter, together with the Consensus Evaluation Report relative to the specific application, to the applicant. The aim is to give the applicant a prompt indication of how the application fared in the evaluation.

The applications found to be ineligible or failing to reach any of the threshold scores for evaluation criteria will be formally rejected by the SME Certification Committee. Rejection doesn't prevent an SME to apply again to subsequent calls.

The applications that reach the threshold scores and are among the top 5 in the overall ranking will be deemed successful and immediately invited to participate in the training and certification program corresponding to the Pilot Call. Applications that reach threshold scores but are not among the top 5 will be offered to participate in the next training and certification program round (anticipated to happen in Q4 2019).

## Appeal Procedure

The Applicant has 20 calendar days 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 PMO at the email address [enquiries@ehden.eu](mailto:enquiries@ehden.eu). Upon receipt, the PMO will check if all review procedures have been fully respected and no content has been inadvertently omitted or overseen during evaluation (e.g. due to technical problems with the portal), and will answer to the applicant within 20 calendar days from the date of reception of the letter of complaint. 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 SMECC.

## Training and Certification Program

EHDEN is currently developing the Training and Certification Program together with the OHDSI Community. The SMEs in the Pilot Call will be the first to participate. This implies that EHDEN will more actively interact with these first SMEs in the initial version of the training and certification program.

The process of mapping data to the OMOP CDM is a team effort in close collaboration with the data custodian. In the training program multiple employees from the SME, that may have different types of expertise, can participate. The aim of the program is that the SME as a company will obtain all the necessary competencies to onboard a data source in the EHDEN federated data network following the establish quality standards. This includes, but is not limited to:

- f. Foundational Knowledge about the EHDEN project and its objectives.
- g. Expertise on the OMOP-CDM and the Standardized Vocabularies.
- h. Knowledge about the Extract, Transform, and Load steps and their implementation with OHDSI tools and approaches developed in EHDEN.
- i. Understand the fundamentals of proper documentation of the ETL process in close collaboration with the data custodian, to assure transparency and reproducibility.
- j. Expertise in the installation and use of the OHDSI Tools for federated data analyses such as those described here: <https://www.ohdsi.org/analytic-tools/>

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## Blended Training

The training will be offered through blended training, i.e. online and face-to-face.

A curriculum will be available through online e-learning courses in the EHDEN Academy that focus on all competencies described above.



<https://academy.ehden.eu>

These courses are implemented in a customized Moodle training environment ([www.moodle.org](http://www.moodle.org)) and will contain video lectures, quizzes, tests, etc. Importantly, the curriculum will also contain mapping exercises on simulated datasets. This will be offered through access to a virtual machine that will host a source database and mapping tools. The exercises will be monitored by the EHDEN consortium and support will be offered through an online forum in the training environment.

The final certification will contain a face-to-face training and assessment session in which a data source will be mapped by the SME.

## Certification

Once the SME receives the certificate it obtains the following benefits:

### 4. Certified SME Catalogue

All SMEs that are certified will be mentioned on the public EHDEN website. This serves as reference for interested data sources that want to apply for funding through the EHDEN Harmonization fund in the upcoming Data Source Grant Awarding Open Calls. The Catalogue will contain KPIs such as the number of data sources mapped by the SME.

### 5. Certification Badge

Certified SMEs are allowed to add the certification badge to their website (see a draft version below). The badge will show the year of certification and the colour will indicate how many years the SME has been certified and is actively mapping data sources.



### 6. Member of the EHDEN SME Community

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During the EHDEN project we like to actively engage the SME Community that will support the development of the eco-system. This can include invites to additional training sessions, hack-a-thons to improve the open source tools or invites to study-a-thons in which researchers and data sources will collaboratively execute studies to generate reliable evidence. Furthermore, we foresee an online forum for moderated discussions in the SME Community.

## How to contact us?

If you have questions or suggestions to improve the review procedure please let us know by email: [enquiries@ehden.eu](mailto:enquiries@ehden.eu)



## Reviewer Instructions Appendix 1. Eligible Countries

To be eligible the SME should be legally established as a business and based in an EU member state or H2020 associated country.

### 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	United Kingdom

### H2020 Associated countries

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

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## Annex 3: Instructions EHDEN Academy



# EHDEN Academy Instructions

**Peter Rijnbeek, Henrik John**

29/7/2019

V1.1

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## Introduction

EHDEN has developed an e-learning environment for the training called the EHDEN Academy (<https://academy.ehden.eu/>). The Academy uses Moodle ([www.moodle.org](http://www.moodle.org)) as a framework that is being populated with multiple courses. Initially, the focus is on Small to Medium-sized Enterprises (SMEs) that can obtain certification for standardising health data to the OMOP Common Data Model and setting up the local analytical framework. The curriculum will be expanded over time to accommodate courses relevant to all our stakeholders, e.g. the EHDEN Data Partners, regulators etc. The EHDEN Academy will be made publicly available for all external parties that want to be part of the EHDEN and OHDSI journey to improve patient care.

This short document explains how to use the EHDEN Academy and can be used as reference next to the short instruction video. Note that this document will be frequently updated driven by the active development of the Academy.

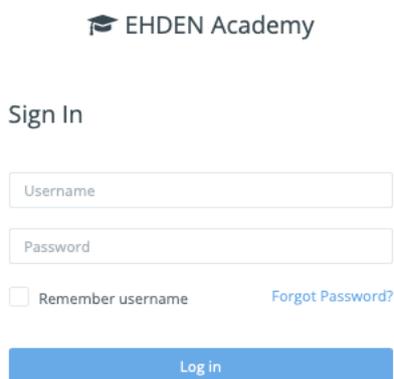
## Setup

### Get an account

Access to the Academy will in the initial phase only be provided to the SMEs that are part of the training and certification program and EHDEN consortium members. If you do not have access let us know by sending an email to [academy@ehden.eu](mailto:academy@ehden.eu)

### Login

To login to the academy you visit <https://academy.ehden.eu> and click the Sign In button on the top right. The following login screen will be shown:



 EHDEN Academy

Sign In

Username

Password

Remember username      [Forgot Password?](#)

Log in

Figure 1. Login screen.

At the moment you can only login with the provided Username and Password. We will enable Authentication through third party providers such as [Elixer AAI](#), Github, and will enable Single Sign On (SSO).

You will be asked to change your password the first time:

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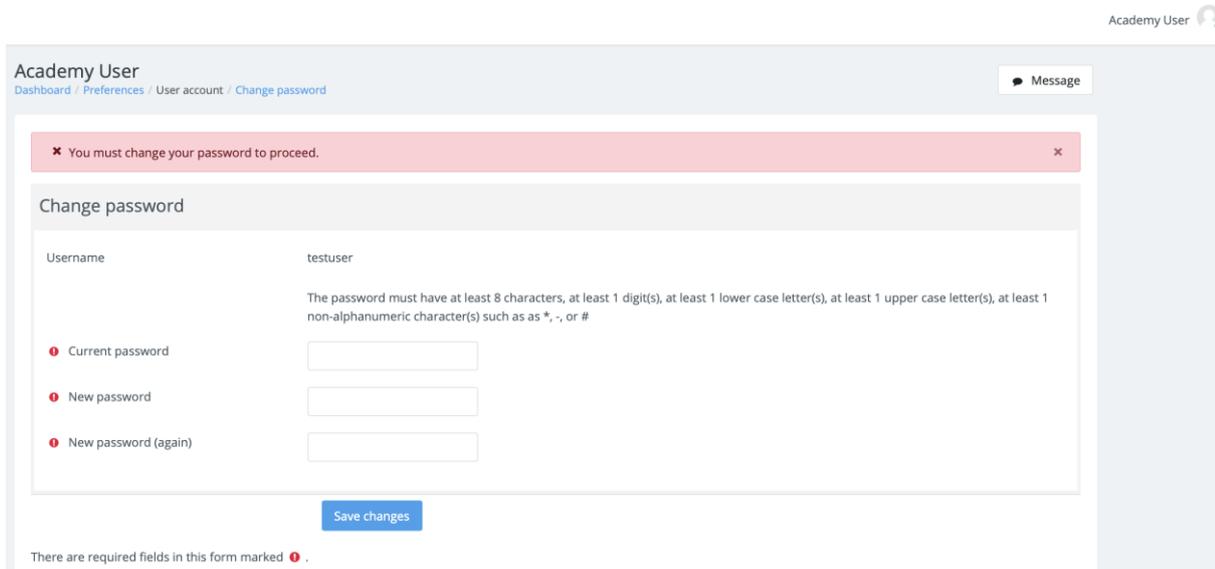


Figure 2. Change Password

You will then be sent to the Dashboard page and will be guided in a small tour.

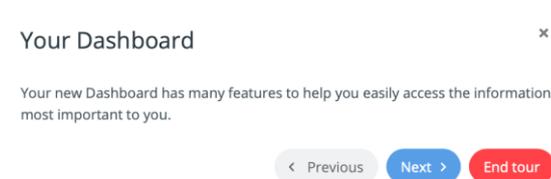
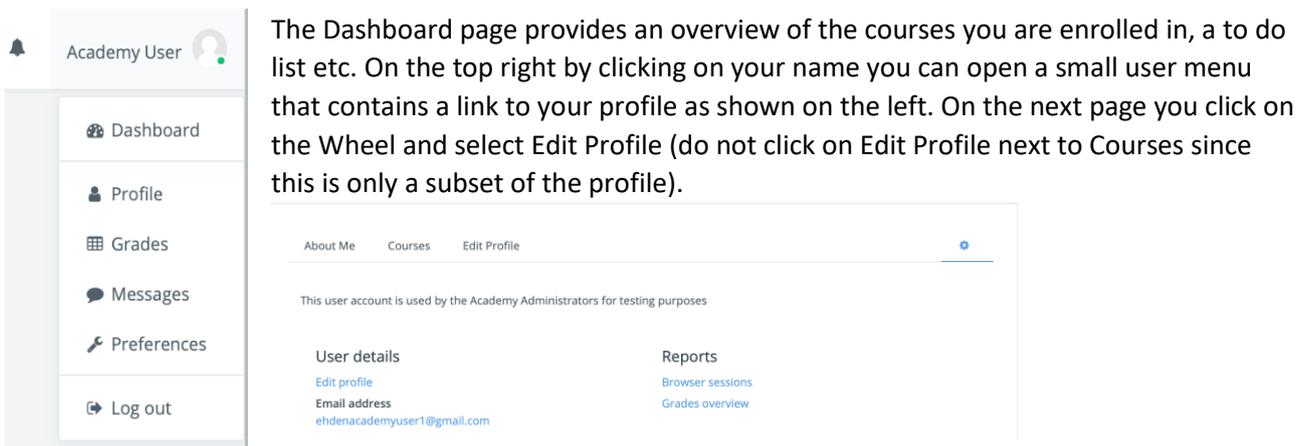


Figure 3. Initial platform tour.



The Dashboard page provides an overview of the courses you are enrolled in, a to do list etc. On the top right by clicking on your name you can open a small user menu that contains a link to your profile as shown on the left. On the next page you click on the Wheel and select Edit Profile (do not click on Edit Profile next to Courses since this is only a subset of the profile).

Figure 4. Updating your profile.

This will open a larger form where you can fill in all the information you would like to share (use Expand all on the top right). For SMEs that participate in the training and certification program please also fill in the Company Name under “Other fields”. We like all users to add a photo to their profile to make the interactions on Forums etc more personal.

## Forum preferences

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In the user menu (top right) under preferences you can setup how you like to interact with the forum for example if you would like to receive emails.

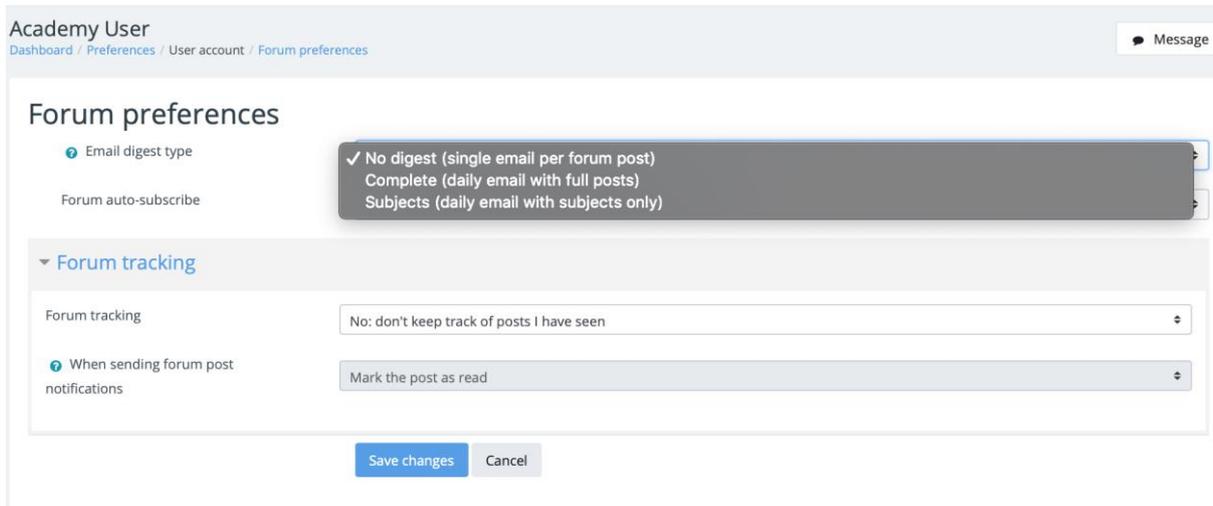
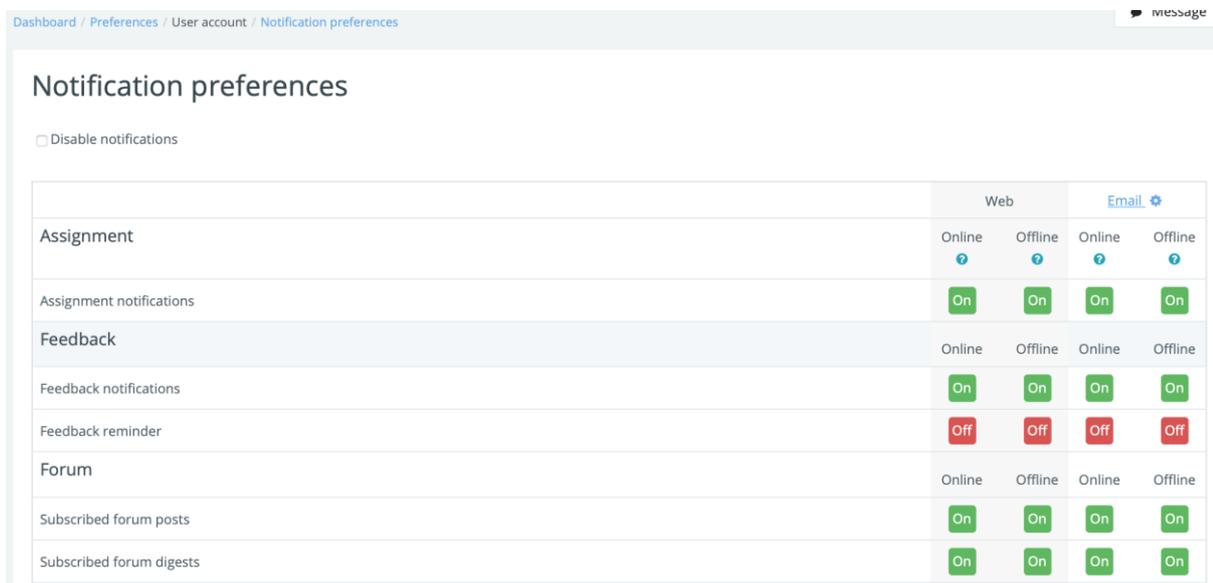


Figure 5. Forum Preferences.

You can also setup your notification preferences. These notifications are shown to the user with the small bell on the top right next to your name or as email notifications. Some of these are switched on by default, e.g. notifications about forum posts. You can of course customise these as you prefer.



	Web		Email 	
	Online	Offline	Online	Offline
Assignment	Online 	Offline 	Online 	Offline 
Assignment notifications	On	On	On	On
Feedback	Online	Offline	Online	Offline
Feedback notifications	On	On	On	On
Feedback reminder	Off	Off	Off	Off
Forum	Online	Offline	Online	Offline
Subscribed forum posts	On	On	On	On
Subscribed forum digests	On	On	On	On

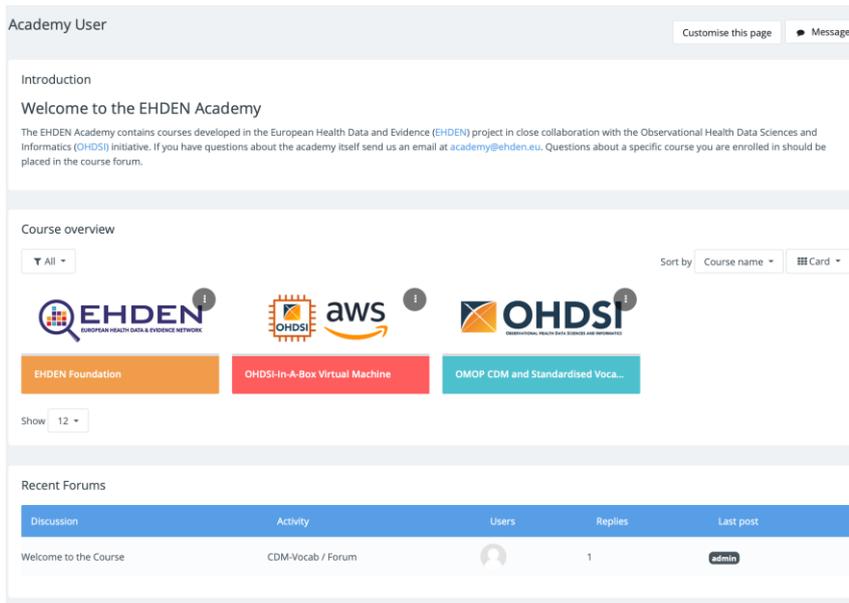
Figure 6. Notification Preferences.

## Courses

You will be enrolled in courses by the Course Faculty. In the SME training and certification program new courses will be made available according to a training schedule.

The Course Overview section on the Dashboard shows the courses you currently have access to.

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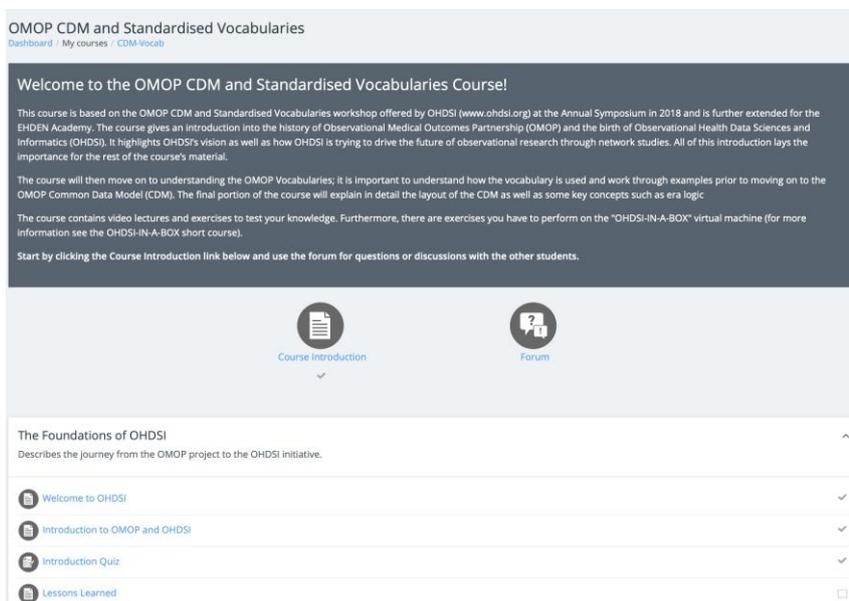


The screenshot shows the 'Academy User' interface. At the top, there are options to 'Customise this page' and 'Message'. Below is an 'Introduction' section with a welcome message and contact information. The 'Course overview' section features a filter set to 'All', a sort option for 'Course name', and a view toggle for 'Card'. Three course cards are displayed: 'EHDEN Foundation', 'OHDSI-In-A-Box Virtual Machine', and 'OMOP CDM and Standardised Vocab...'. A 'Show 12' dropdown is visible below the cards. The 'Recent Forums' section has a table with columns for Discussion, Activity, Users, Replies, and Last post. A row shows a forum titled 'Welcome to the Course' with 1 reply from 'admin'.

Figure 7. Enrolled courses.

Automatically, a Recent Forums section is added that will show the posts in the forums of all the courses you are enrolled in.

If you click on a course, you will be sent to its landing page.



The screenshot shows the landing page for the 'OMOP CDM and Standardised Vocabularies' course. It includes a breadcrumb trail: 'Dashboard / My courses / CDM-Vocab'. The main heading is 'Welcome to the OMOP CDM and Standardised Vocabularies Course!'. The introductory text explains the course's origin and goals. Below the text are two buttons: 'Course Introduction' and 'Forum'. A section titled 'The Foundations of OHDSI' is expanded, showing a list of course items: 'Welcome to OHDSI', 'Introduction to OMOP and OHDSI', 'Introduction Quiz', and 'Lessons Learned'.

Figure 8. Course Landing Page.

Each course has the same structure. On the top you can find a Course Introduction section containing a short video or information about the course. Next to this you can find the Course Forum where you can interact with other students and with the faculty of the course. We invite you to actively participate in the forum discussions.

Courses contain sections, e.g. The Foundations of OHDSI section show in Figure 6. These contain lectures and quizzes.

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OMOP CDM and Standardised Vocabularies  
 Dashboard / My courses / CDM-Vocab / The OMOP Common Data Model / A Patient's Story

### A Patient's Story



**PERSON**

- Need to create one unique record per person
- No history of location/demographics: need to select latest available
- Year of birth required...day/month optional
- Foreign key to the LOCATION, PROVIDER, and CARE\_SITE table that contains one record



In this short video we introduce a patient's story that is used throughout the tutorial.

Previous Activity  Next Activity

Figure 9. Example of Video Lecture.

The sections can contain multiple-choice questions in the form of quizzes or exercises the user has to perform on actual data using the OHDSI-IN-A-BOX virtual machine as described in more detail below. Most courses will have a Final Exam to test the student's understanding of the topic. Instructions on how to pass a course are provided on the course introduction page and at each individual assessment page.

## OHDSI-IN-A-BOX



The OHDSI-IN-A-BOX is a virtual machine (VM) that can be easily instantiated by the trainees in the Amazon cloud infrastructure. It contains many OHDSI tools, a CDM database with simulated data and a source database that can be used in the EHDEN Academy to train on mapping. We have developed a short course in the Academy that explains how to setup your own environment easily.

**OHDSI-In-A-Box Virtual Machine**

For questions about the VM please use the forum in the course and support will be provided if needed.

## Questions

Questions about the use of the EHDEN Forum can be posted in the support forum. All Course related questions should be placed in the corresponding Course Forums. If you have questions that you do not like to share with the rest of the users please use our email address: [academy@ehden.eu](mailto:academy@ehden.eu)


[www.ehden.eu](http://www.ehden.eu)

[@IMI\\_EHDEN](https://twitter.com/IMI_EHDEN)

[IMI\\_EHDEN](https://www.linkedin.com/company/IMI_EHDEN)

[github.com/EHDEN](https://github.com/EHDEN)

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	<b>WP5 – Data Workflow Implementation &amp; Service Deployment</b>		<b>Version: v1.2 – Final</b>
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## Annex 4: Application Form Data Partners

Question	Hints/Options
<b>Data Source Description</b>	
Provide a brief description of the data source (max 250 words)	Provide the data source introduction you would normally use in a publication.
Provide links to max of 5 publications or publicly available links that describe the data source and demonstrate its use.	
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?	<ul style="list-style-type: none"> <li>• Inpatient (hospital) care</li> <li>• Outpatient general practitioner care</li> <li>• Outpatient specialist care</li> <li>• Long term/ skill nursing facility care</li> <li>• Pharmacy care</li> <li>• Other (free text)</li> </ul>
What data capture process(es) are used?	<ul style="list-style-type: none"> <li>• Insurance/administrative claims</li> <li>• Outpatient electronic health records</li> <li>• Inpatient hospital electronic health records</li> <li>• Inpatient hospital billing systems</li> <li>• Registries</li> <li>• Biobank</li> <li>• Other (free text)</li> </ul>

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Specify the inclusion criteria for patients to enter the population, if any.	
When did the data collection start?	
Is the data collection on-going?	<p>If not, when did the data collection end.</p> <p>If yes, explain the frequency of source data updates</p>
Which of these age categories are included in your data source?	<ul style="list-style-type: none"> <li>• infants and toddlers (0 days to 23 months)</li> <li>• children (2 to 11 years)</li> <li>• adolescents (12 to 17 years)</li> <li>• 18 to 45 years</li> <li>• 46 to 65 years</li> <li>• 66 years and over</li> </ul>
What is the gender of the data source population?	<ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> <li>• Both</li> </ul>
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.	<ul style="list-style-type: none"> <li>• Person</li> <li>• Observation Period</li> <li>• Visit Occurrence</li> <li>• Visit Details</li> <li>• Condition Occurrence</li> <li>• Death</li> <li>• Drug Exposure</li> <li>• Procedure Occurrence</li> <li>• Device Exposure</li> <li>• Measurement</li> <li>• Observation</li> <li>• Specimen</li> <li>• Survey</li> <li>• Provider</li> <li>• Location</li> <li>• Care Site</li> <li>• Payer Plan Period</li> </ul>

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	<ul style="list-style-type: none"> <li>• Cost</li> </ul>
Does the data source contain free text?	<p>If yes:</p> <p>In what language is the free text?</p> <p>Explain how you are using the free text in your current studies.</p>
Are there any data domains not described above you like to include?	
<b>Data Source Governance and Ethics</b>	
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 academics

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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)	
<b>Technical Details</b>	
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.
Are you willing to share the Extraction Transform and Load Document for your data transformation with the EHDEN project?	
<p><i>If possible, we like to obtain information about the structure of the source database using a profiling tool called <u>White Rabbit</u>. 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: <a href="mailto:applicants@ehden.eu">applicants@ehden.eu</a></i></p>	

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*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?	<ul style="list-style-type: none"> <li>• DB Admins</li> <li>• data managers</li> <li>• informaticians</li> <li>• statisticians</li> <li>• epidemiologists</li> <li>• clinical researchers</li> <li>• other (free text)</li> </ul>
Are you already involved in the OHDSI community? If so, please describe how.	

**Activity selection**

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Select the activity you are applying for.	<p>For more details see the Call Description Document</p> <ul style="list-style-type: none"> <li>• Create new Data Transformation and Analytical Infrastructure</li> <li>• Revise Existing Data Transformation and Analytical Infrastructure</li> <li>• Inspect Completed Data Transformation and Analytical Infrastructure</li> </ul>
<i>For the last two options additional questions are asked:</i>	
Describe which tables have already been populated in your OMOP-CDM.	
Describe the status of the source code mapping for the domains you have populated.	
Explain how you like to revise or extend the existing data transformation.	
Do you have documentation of the current data transformation?	<p>If yes, can you share this document. If yes, please upload the document.</p> <p>If no, please explain why not.</p>
Describe the current status of the analytical infrastructure.	Which OHDSI tools and methods libraries are currently used on your data?
Describe who implemented the Extraction, Transform, and Load (ETL) procedure for your current CDM version	For example a specific SME, internal experts.
<b>Motivation</b>	
Describe why you want to apply for financial support.	
<b>Signature</b>	
<i>Are you able and willing to go through the EHDEN application evaluation procedure, described in the call text?</i>	
Declaration	Check box: i am fully authorized to submit this application on behalf of the data partner.

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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

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## Annex 5: Data Partner Reviewer Instructions



# Data Partner Grant Awarding Reviewer Instructions

**The EHDEN Consortium**

22/9/2019

V1.0

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## Document History

Version	Date	Description
V0.1	1-9-2019	First Draft, Review PMO
V1.0	22-9-2019	Final version

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## Introduction

This document aims to explain the reviewers how to use the online review portal. For the introduction to the Data Partner Call and the full evaluation procedure we refer to the Call Description Document that is available on our website and provided to the reviewers.

## How to review the applications?

The EHDEN Project Management Office (PMO) will assign applications to the reviewers. In this section we will explain how the applications will be reviewed in the portal.

### Step 1. Email notification about new applications to review

You will automatically receive an invite by email to create an account on the review portal. PMO has entered your email address in our system to start this process.



Dear Reviewer,

A new application for has been submitted for your review. Please log into the [review portal](#) and provide your feedback when you first have a chance. We like to receive your feedback within one week if possible.

If this timeline is not feasible or you have questions, do not hesitate to send an email to: [enquiries@ehden.eu](mailto:enquiries@ehden.eu)

We thank you for your support to the EHDEN project.  
The EHDEN team.

 [www.ehden.eu](http://www.ehden.eu)

 [@IMI\\_EHDEN](https://twitter.com/IMI_EHDEN)

 [IMI\\_EHDEN](https://www.linkedin.com/company/IMI_EHDEN)

 [github.com/EHDEN](https://github.com/EHDEN)







This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (IMI) under grant agreement No 800666. The IMI receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

### Step 2. Fill in your email account.

You will receive a confirmation email from the system containing information on the next step.



## Data Partner Review Portal

**Sign In/Sign Up Instructions**

**For New Users:**  
Please enter your email address and we will verify if you are in our system. If your email is part of our system, a confirmation will be sent to that address. *If your email is not in our system or you do not receive a confirmation email, please contact your administrator.*

Upon confirmation of your email, you will be taken to the **Sign Up** screen where you can choose a password to create an account. Once you have chosen your password, your account will be created and you will gain access to the portal.

**For Returning Users:**  
Please enter your email address to the right, and we will verify if you are in our system. When found, you can enter your password and then gain access to the portal.

If you have any questions or concerns, please contact your administrator. Thank you!

**Welcome!**

To get this process started, new and returning users please enter your email address below.

**Email**

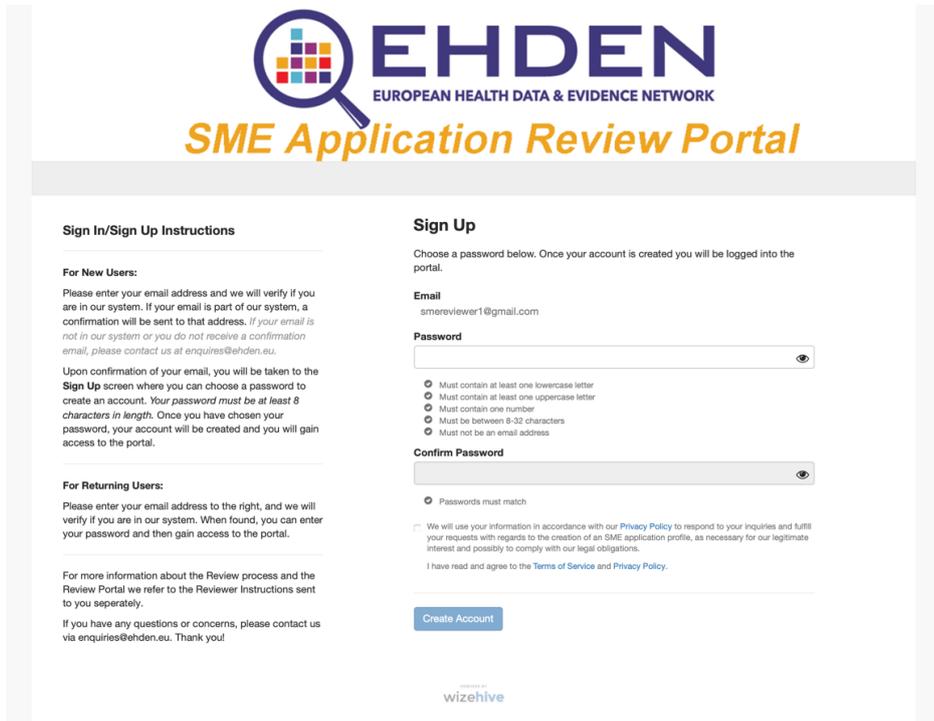
Already have a confirmation code?

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### Step 3. Create an account

You can now create an account after accepting our Terms of Service and Privacy policy. If you at any point like to be removed from the system inform the Project Management Office.



The screenshot shows the 'SME Application Review Portal' sign-up page. It features the EHDEN logo and title. The page is divided into two main sections: 'Sign In/Sign Up Instructions' and 'Sign Up'.

**Sign In/Sign Up Instructions:**

- For New Users:** Please enter your email address and we will verify if you are in our system. If your email is part of our system, a confirmation will be sent to that address. Upon confirmation of your email, you will be taken to the Sign Up screen where you can choose a password to create an account. Your password must be at least 8 characters in length.
- For Returning Users:** Please enter your email address to the right, and we will verify if you are in our system. When found, you can enter your password and then gain access to the portal.

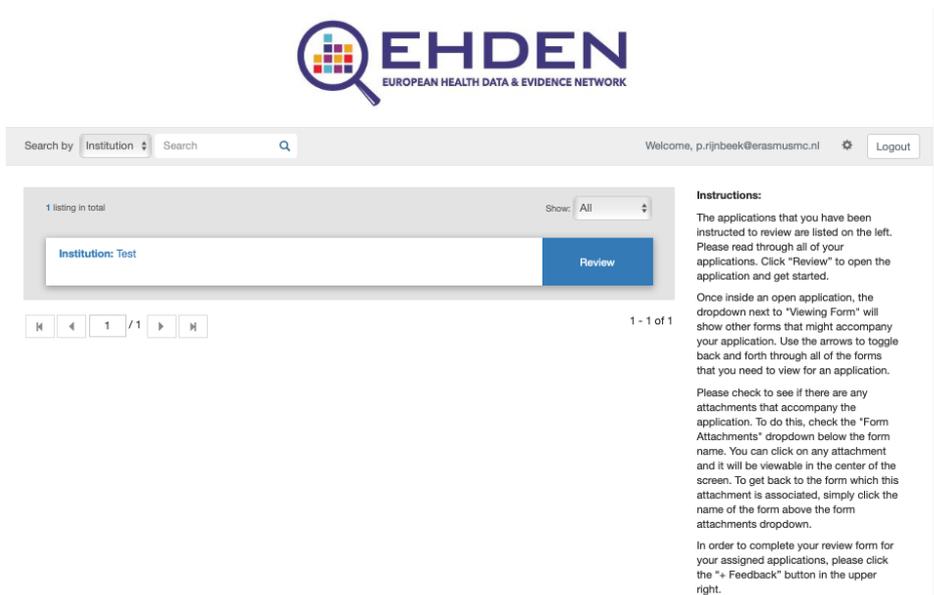
**Sign Up:**

- Choose a password below. Once your account is created you will be logged into the portal.
- Email:** smereviewer1@gmail.com
- Password:** A text input field with a visibility toggle.
- Confirm Password:** A text input field with a visibility toggle.
- Requirements:**
  - Must contain at least one lowercase letter
  - Must contain at least one uppercase letter
  - Must contain one number
  - Must be between 8-32 characters
  - Must not be an email address
- Agreements:**
  - Passwords must match
  - We will use your information in accordance with our Privacy Policy to respond to your inquiries and fulfill your requests with regards to the creation of an SME application profile, as necessary for our legitimate interest and possibly to comply with our legal obligations.
  - I have read and agree to the Terms of Service and Privacy Policy.
- Create Account:** A blue button to submit the form.

At the bottom, it says 'powered by wizehive'.

### Step 4. Select the application to review

In the next screen you will see all the applications you have to reviews. For additional instructions see the section on the right.



The screenshot shows the application selection screen. It features the EHDEN logo and a search bar at the top. The search bar contains 'institution' and a search icon. The user is logged in as 'p.rijnbeek@erasmusmc.nl'.

**Search Results:**

- 1 listing in total
- Show: All
- Listing: Institution: Test
- Review button
- Page navigation: 1 / 1

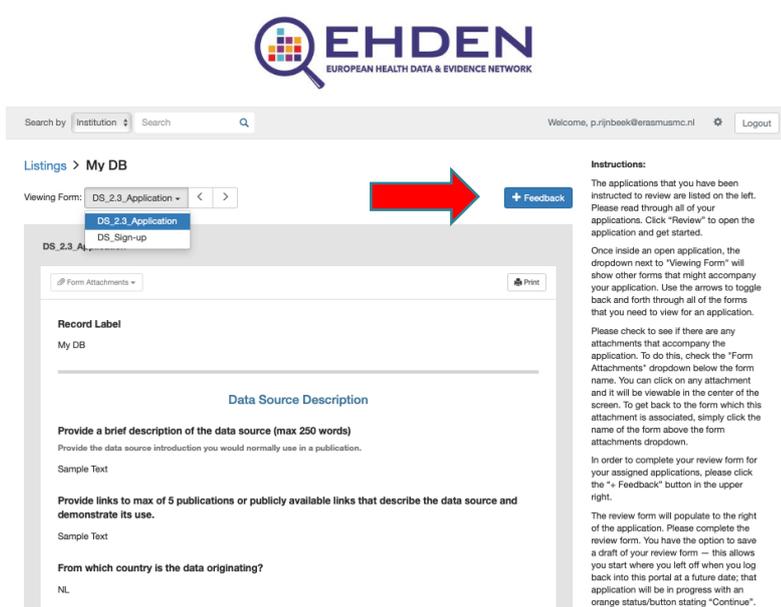
**Instructions:**

- The applications that you have been instructed to review are listed on the left. Please read through all of your applications. Click "Review" to open the application and get started.
- Once inside an open application, the dropdown next to "Viewing Form" will show other forms that might accompany your application. Use the arrows to toggle back and forth through all of the forms that you need to view for an application.
- Please check to see if there are any attachments that accompany the application. To do this, check the "Form Attachments" dropdown below the form name. You can click on any attachment and it will be viewable in the center of the screen. To get back to the form which this attachment is associated, simply click the name of the form above the form attachments dropdown.
- In order to complete your review form for your assigned applications, please click the "+ Feedback" button in the upper right.

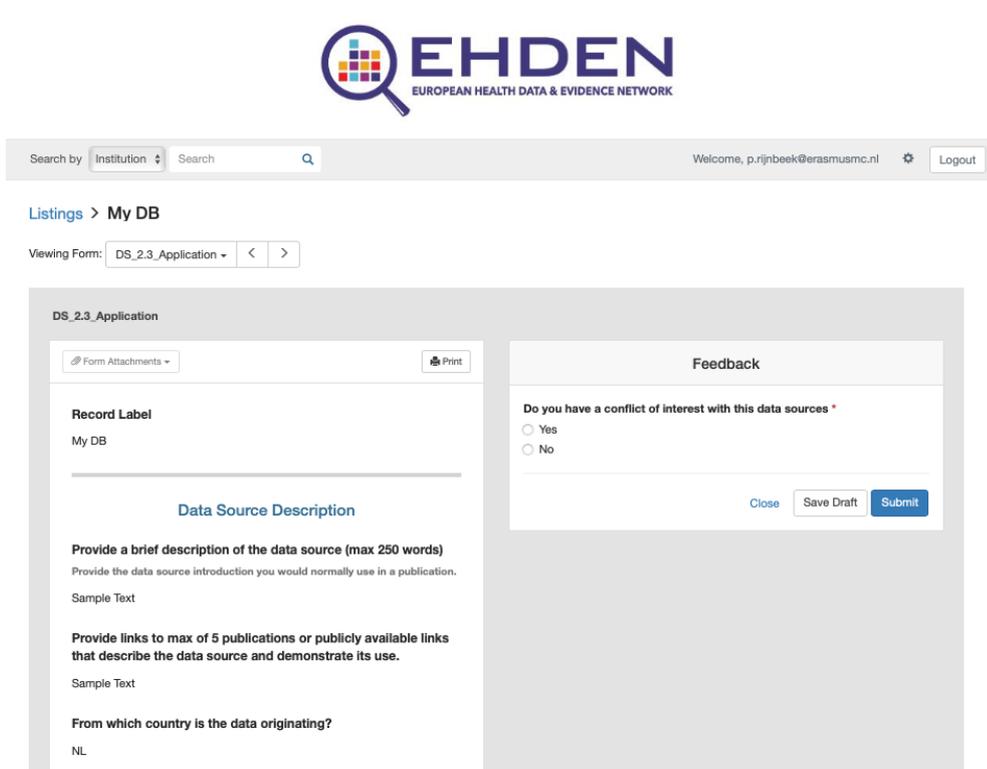
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**Step 5. Read the application and profile information**

You can now review the application, including the profile (DS\_Sign-up) and attachments uploaded by the Data Partner.



**Step 6. Inform us about a conflict of interest.**



If you have a conflict of interest, you do not have to fill in the rest of the form and you can simply press Submit. We will then reassign the application to another reviewer.

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## Step 7. Provide your feedback and Submit

**Feedback**

**Do you have a conflict of interest with this data sources?**

Yes

No

Below you can score the application. Do not hesitate to ask for clarity using the following email address: [enquiries@ehden.eu](mailto:enquiries@ehden.eu)

**Data Impact (Score 1-10):** Score in terms of expected impact of mapping the proposed dataset(s) for the EHDEN eco-system, considering:

1. Dataset(s) size
2. Dataset(s) coverage
3. Dataset(s) uniqueness
4. Perceived quality

Due to the possibility of multiple applicants with similar or even partially overlapping datasets, the reviewers is asked to consider the following guiding principles when providing a score:

1. Data sources with more persons within the same data source type get a higher score.
2. Data sources that have more complete coverage from different care settings get a higher score.
3. Data sources that have a more complete representativeness of the underlying population get a higher score.
4. Data sources with more data domains and comparable number of persons get a higher score.
5. Data sources within the same data source type that have longer follow-up time get a higher score.

**What is your score with respect to Data Impact? \***

**Please provide a rationale for the Data Impact score. \***

**Feedback**

**Network Impact (Score 1-10):** Score in terms of expected impact of the Data Partner for the EHDEN eco-system, considering:

1. Willingness to participate in federated network studies, including feasibility assessments.
2. Availability of information about applicable ethical and governance mechanisms for use of the data in federated network studies.
3. Track record of previous studies and collaborations using the data source.

**What is your score with respect to Network Impact? \***

**Please provide a rationale for the Network Impact score. \***

**Meta Data Sharing (Score 1-10):** Score on the ability and willingness to share meta data about the data source to populate the Database Catalogue.

This should at least include information about the data provenance, available domains of data, database size, univariate statistics on concept level, and the summary findings from the SME inspection. Furthermore, data sources that are willing to share the ETL documentation will receive a higher score.

**What is your score with respect to Meta Data Sharing? \***

**Please provide a rationale for the Meta Data Sharing score. \***

**Feedback**

**What is your assessment of the complexity of the data source? \***

**Please provide a rationale for the complexity score. \***

**Additional Comments**

**Do you recommend an interview with the applicant before a final decision is made? If yes, why? \***

Yes

No

Let us know if you missed information in the form or reviewer instructions to improve the review process. \*

You are asked to fill in all the questions and provide a rationale for them. For more guidance see the Call Description Document. Furthermore, there is the question whether you think an interview is needed to make a final decision. It is interesting to understand if you think you are able to make a proper decision based on the form or need other information (please provide details in the last text box).

We realize that for the first pilot call we may have to further optimize the Feedback form or even the application form. In the consensus call we will evaluate the process with all the reviewers.

Note that if you need help in interpreting the White Rabbit output let us know and our team will provide additional support.

## How to contact us?

If you have questions or suggestions to improve the review procedure please let us know by email: [enquiries@ehden.eu](mailto:enquiries@ehden.eu)

