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Accelerated Development of VAccine beNefit-risk Collaboration in Europe

Grant Agreement n°115557

D3.4 Catalogue and meta-profiles of data sources for vaccine benefit-risk monitoring (Supplementary documentation)

WP3 – Data sources for rapid and integrated benefit-risk monitoring

V 2.0

Lead beneficiary: SURREY

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	D3.4 Catalogue and meta-profiles of data sources for vaccine benefit-risk monitoring		
	WP3 – Data sources for rapid and integrated benefit-risk monitoring		Version: v2.0
	Author(s): Harshana Liyanage (SURREY), Simon de Lusignan (SURREY), Alena Khromava (SP)		Security: 2/22

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DOCUMENT INFORMATION


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Description of the deliverable	This document provide supplementary information about the ADVANCE web catalogue used for storing meta-data profiles collected using the AIRR survey. The deliverable is hosted at : https://emif-catalogue.eu
Key words	Web catalogue, data sources, AIRR survey

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DOCUMENT HISTORY

NAME	DATE	VERSION	DESCRIPTION
Harshana Liyanage (SURREY), Simon de Lusignan (SURREY), Alena Khromava (SP), Charlotte Switzer (SP), Filipa Ferreira (SURREY)	07/09/2016	1.0	First draft
Harshana Liyanage (SURREY), Simon de Lusignan (SURREY), Alena Khromava (SP), Charlotte Switzer (SP), Filipa Ferreira (SURREY)	06/10/2016	2.0	Revisions based on feedback from internal review

DEFINITIONS¹

- Participants of the ADVANCE Consortium are referred to herein according to the following codes:
 - **EMC.** Erasmus Universitair Medisch Centrum Rotterdam (Netherlands) - Coordinator
 - **UNIBAS.** Universitaet Basel (Switzerland) - **Managing entity of the IMI JU funding**
 - **EMA.** European Medicines Agency (United Kingdom)
 - **ECDC.** European Centre for Disease Prevention and Control (Sweden)
 - **SURREY.** The University of Surrey (United Kingdom)
 - **P95.** P95 (Belgium)
 - **SYNAPSE.** Synapse Research Management Partners, S.L. (Spain)
 - **OU.** The Open University (United Kingdom)
 - **LSHTM.** London School of Hygiene and Tropical Medicine (United Kingdom)
 - **PEDIANET.** Società Servizi Telematici SRL (Italy)
 - **KI.** Karolinska Institutet (Sweden)
 - **ASLCR.** Azienda Sanitaria Locale della Provincia di Cremona (Italy)
 - **AEMPS.** Agencia Española de Medicamentos y Productos Sanitarios (Spain)
 - **AUH.** Aarhus Universitetshospital (Denmark)
 - **UTA.** Tampereen Yliopisto (Finland)
 - **WIV-ISP.** Institut Scientifique de Santé Publique (Belgium)
 - **MHRA.** Medicines and Healthcare products Regulatory Agency (United Kingdom)
 - **SSI.** Statens Serum Institut (Denmark)
 - **RCGP.** Royal College of General Practitioners (United Kingdom)
 - **RIVM.** Rijksinstituut voor Volksgezondheid en Milieu * National Institute for Public Health and the Environment (Netherlands)
 - **GSK.** GlaxoSmithKline Biologicals, S.A. (Belgium) – EFPIA Coordinator
 - **SP.** Sanofi Pasteur (France)
 - **NOVARTIS.** Novartis Pharma AG (Switzerland)


¹ To be completed with terms and abbreviations related to the actual content of the document

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- **SP MSD.** Sanofi Pasteur MSD (France)
 - **CRX.** Crucell Holland BV (Netherlands)
 - **PFIZER.** Pfizer Limited (United Kingdom)
 - **TAKEDA.** Takeda Pharmaceuticals International GmbH (Switzerland)
- **Grant Agreement.** The agreement signed between the beneficiaries and the IMI JU for the undertaking of the ADVANCE project (115557).
 - **Project.** The sum of all activities carried out in the framework of the Grant Agreement.
 - **Work plan.** Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
 - **Consortium.** The ADVANCE Consortium, comprising the above-mentioned legal entities.
 - **Project Agreement.** Agreement concluded amongst ADVANCE 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.

ABBREVIATIONS

- AIRR – ADVANCE International Research Readiness
- EMIF – European Medical Informatics Framework

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Chapter 1 – Overview of the AIRR instrument

The ADVANCE work package has been tasked to identify data sources in Europe that can potentially contribute to vaccine benefit-risk studies. In the process of achieving this aim, we developed the AIRR (ADVANCE International Research Readiness) instrument which is capable of assessing the readiness for participating in vaccine research studies. It contains a range of questions that can be used to gain a high level understanding about a given database as indicated in Table 1.1.


Table 1.1 Structure of the AIRR survey (ver 3.2)

Question type	Number of questions
1. Database identification and basic information	4
2. Database contact information	2
3. Database classification	2
4. Population	3
5. Geographical coverage	2
6. Data period & access times	3
7. Database linkage	2
8. Availability of vaccine data	2
9. Data access, ethics & governance	3
10. Auditing and data quality	3
11. Publications associated to database	1

Data sources identified through the AIRR instrument allowed work package 5 (i.e. the core work package that will conduct proof-of-concept studies) of ADVANCE to determine the type of studies that can be conducted for proof-of-concept studies. It also informed about the gap in available data to conduct future vaccine studies according to the study types analysed by methodological experts in WP4 of ADVANCE.

The AIRR survey also provided an opportunity for databases to register their interest to participate in a range of proof-of-concept studies that will be carried out during the period of the project. Suitable data source owners for specific studies were contacted and asked to complete study specific eligibility surveys prior to participating in the initial proof-of-concept studies. Participating in the AIRR readiness assessment did not require sharing any patient data and therefore, does not usually require any governance/ethical approval. Further details about designing the AIRR survey are available in *D3.2 First report on data access, linkage and integration for POC studies* and *D3.3 Final Report on Technical Requirements Analysis*.

Figure 1.1 shows the key deliverables associated to the AIRR survey instrument and the project work that contributed to developing these deliverables. The initial version of the instrument was developed by studying previous instruments used for similar purposes in other projects and by detailed examination of vaccine use cases and vaccine study data requirements. The initial survey instrument was piloted within the consortium and the responses contributed towards profiling databases that could contribute to the ADVANCE proof-of-concept studies. Using the feedback received for the initial version, an improved AIRR survey was developed and disseminated outside of the consortium. Further details about dissemination of AIRR are given in Chapter 2. The responses received from both rounds were used to build the ADVANCE meta-data catalogue. The timelines for steps in the process described above are given in Figure 1.2.

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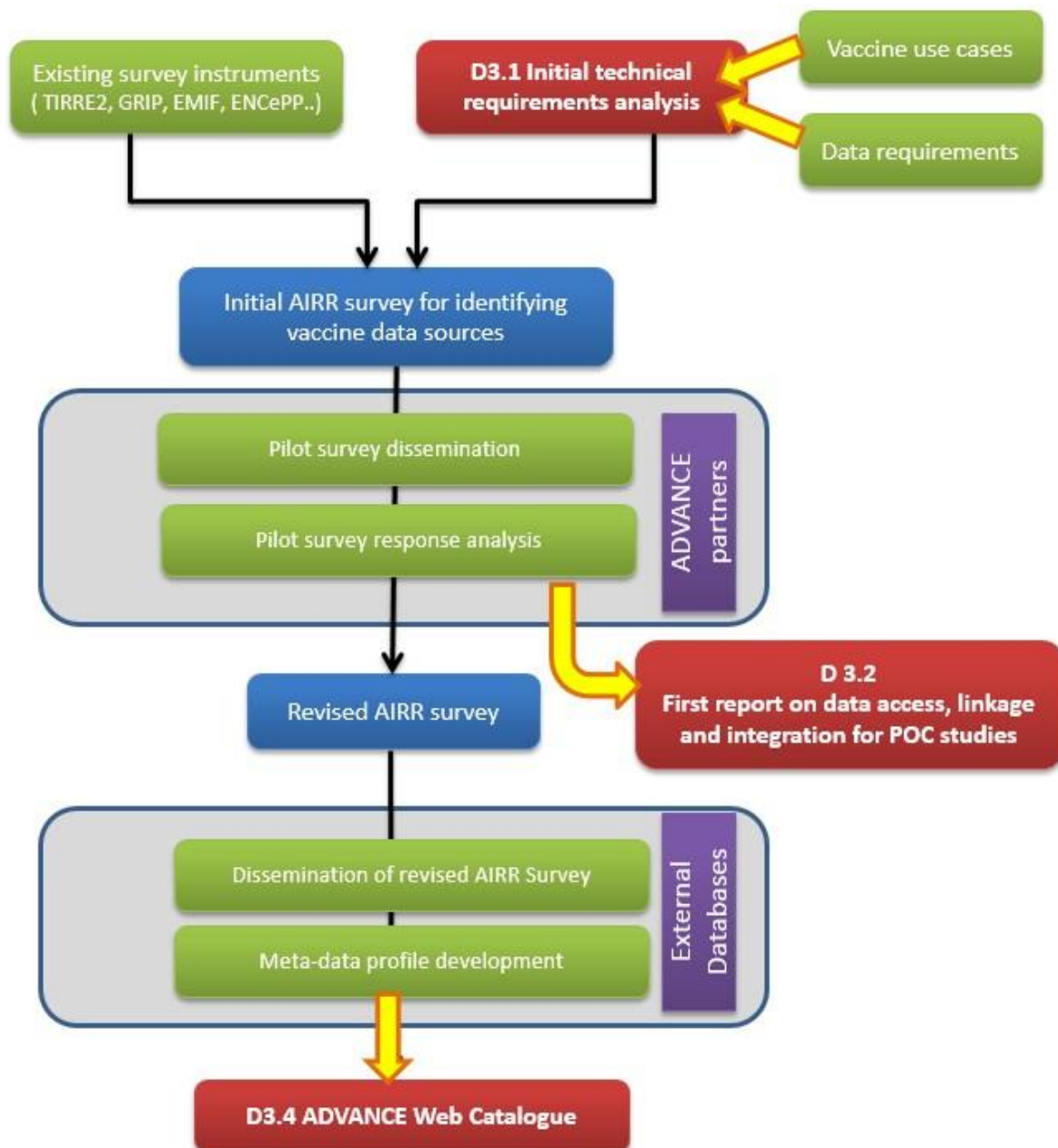



Figure 1.1 Task/ deliverable flow relevant to the AIRR survey instrument

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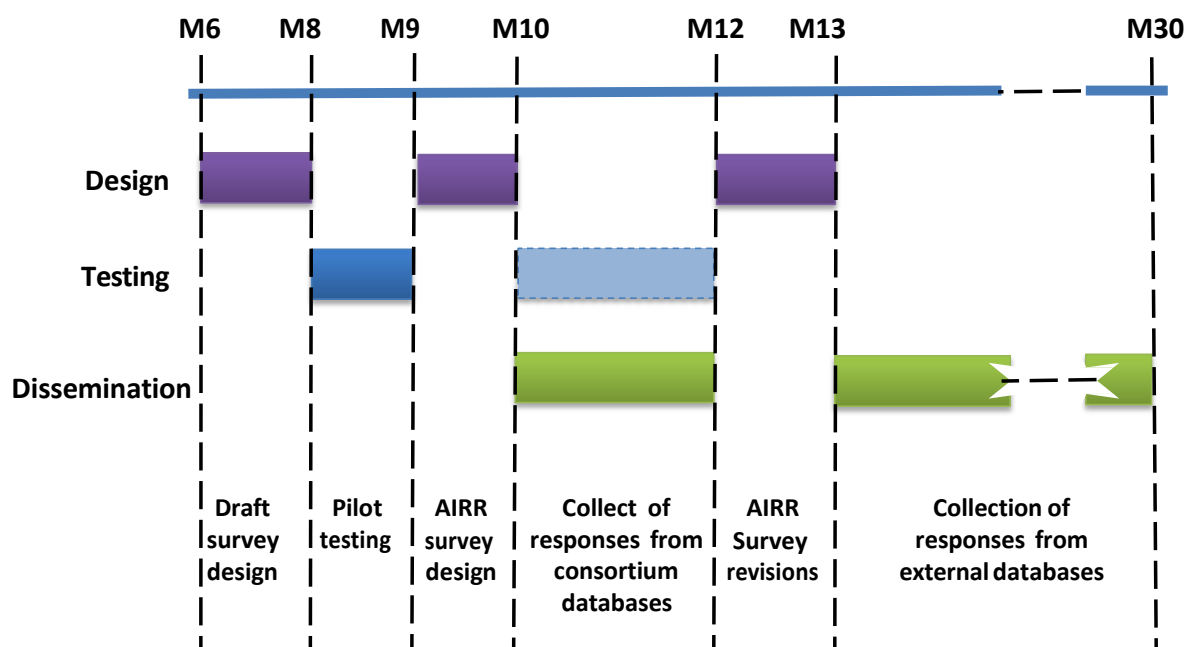


Figure 1.2 Design, testing and dissemination timeline

Building the ADVANCE web catalogue


Once we collected the responses to the AIRR survey, we were in need of an effective mechanism to share the information gathered with all researchers in the ADVANCE consortium. Through ADVANCE WP2, the work package responsible for building external synergies, we were informed about similar initiatives that we could potentially reach out to, in order to accelerate this process by leveraging on experiential learning of other projects. We shortlisted two projects that had built solutions for sharing meta-data profiles.

1) **PARENT:** PARENT was a joint effort by Member States (MSs) and the European Commission as a direct response to the objective set in Article 14 (2) of the Directive on cross-border healthcare to improve secondary use of data from patient registries in a cross-border setting for both public health and research needs.¹ The PARENT initiative set up the **Registry of patient Registries (RoR)**, a database of patient registries from MSs and EU-level projects and corresponding **assessment tool** that enables registry self-assessment and benchmarking for MS registries and institutions, on data quality and interoperability.²


2) **EMIF:** The European Medical Informatics Framework worked to develop a framework for re-using medical data across a number of organisations in Europe. One of their core processes involved fingerprinting databases, where information was collected from databases about their content, procedures and their capabilities. The collected information was then shared through the **EMIF Web-Catalogue**, a web-based platform for sharing meta-data for multiple projects.³

We had face-to-face meetings with members of these two projects to gain an understanding about which solution would be more suitable to implement/ re-use within the context of ADVANCE. We finally arrived at the decision to select the EMIF web-catalogue for information sharing needs within ADVANCE. The key strength of the EMIF web-catalogue was the ability to host ADVANCE meta-data on its existing implementation.

In order to establish ADVANCE catalogue on the EMIF platform, we first requested the creation of a new community space on the platform. This was followed by the task of providing page templates that matched the

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structure of the AIRR survey. With the provided information, the EMIF administration team was able to create a community that allowed uploading of meta-data collected using the AIRR survey. The ADVANCE community is managed by a member of the WP3 team and is capable of authorizing new users to the ADVANCE-specific community on the website (the process of accessing is described in chapter 4).

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Chapter 2 - AIRR survey dissemination

Round 1

The AIRR survey was disseminated during two rounds during the ADVANCE project. Round 1 of dissemination targeted databases owned by organisations that were partners or associated partners of the ADVANCE consortium. This pilot round was conducted using the original version of the AIRR survey which was developed using the initial vaccine use cases reported in the initial technical requirements analysis report. The responses received during this round were reported in deliverable *D3.2 First report on data access, linkage and integration for POC studies*. The results described in D3.2 were used to identify databases suitable for contributing to the first proof-of-concept study in ADVANCE.

Round 2

In order to achieve wider dissemination, multiple strategies for dissemination were used during this second round.

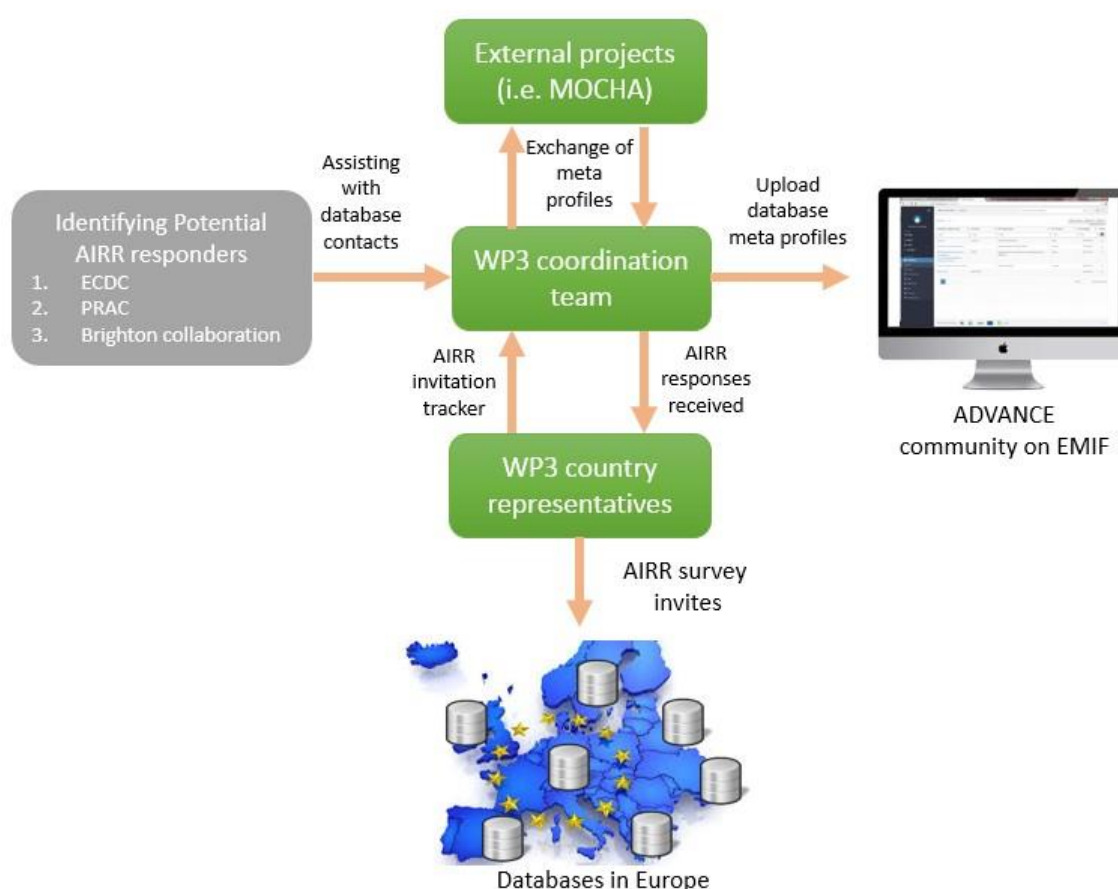



Figure 2.1 – Dissemination strategies adopted in round 2

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Dissemination through established European/Global networks

We explored disseminating the survey through currently established networks related to vaccines. We initially reached out to the PRAC (Pharmacovigilance Risk Assessment Committee) through the European Medicines Agency who is a partner of the ADVANCE consortium. However, PRAC was supporting a similar survey initiative and was not able to extend their support to ADVANCE at the time of the request. We also reached out to representatives of ECDC in the ADVANCE consortium to access the National Coordinators of ECDC Competent Bodies. However, only six national coordinators responded to this communication (One of the six national coordinators was also a member of the ADVANCE consortium).

AIRR survey dissemination monitoring

WP3 members sending out invitations were requested to periodically report to the WP3 coordination team to allow monitoring of the dissemination process. The information requested to be shared included database name, country, database contact person name, database contact person email and date on which initial invitation was sent. At the same time, the WP3 coordination team periodically provided an update of AIRR survey responses to all members of WP3.


Meta-data exchange with H2020 MOCHA project

MOCHA (Models of Child Health Appraised) is a European project which is currently conducting a database profiling/mapping exercise for ADVANCE. This MOCHA project has developed a survey instrument named MOCHA International Research Opportunity Instrument (MIROI) which collects essential metadata from databases that have the potential for contributing to child health studies. The metadata schemes of AIRR and MIROI have a considerable overlap as indicated in Table 2.2. As the core interest of the MOCHA project was not related to vaccines, particulars related to vaccines were not inquired by MIROI. Nevertheless, the metadata available through MIROI gives sufficient information for ADVANCE study teams to assess if a particular data source has the potential of contributing to benefit risk studies and suitable for participating in study specific surveys developed by ADVANCE study teams.

The MOCHA project has country agents appointed for 30 EU/EEA countries and therefore currently has a wider reach than ADVANCE. In addition, they have a formal agent communication mechanism which is built-in to the core project process that has resulted in a higher response rate to MIROI. The country agents are funded from the project to identify databases in their countries. The contact information given in the metadata profile will also give the opportunity to appointed country representatives from WP3 to contact databases to collect the metadata gap for additional vaccine specific metadata required for completing AIRR.

Table 2.2 Common meta-data schema for AIRR and MIROI


Database Name	Database website URL	Database description
Data custodian description	Database content type	Time period covered
Database update frequency	Time lag to release data for research	Total number of registered subjects
Total number of registered children	Population denominator	Geographic coverage
Written database governance policy	Database access charge	Database scientific contact

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Database authorisation contact	Data access request evaluation mechanism	
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Table 2.3 AIRR meta-data not available through MIROI

Linkage between vaccine events and follow up data	Linkage between clinical data to prescription data	Completeness of vaccine data (for specific vaccines)
Availability of data fields related to vaccine administration (batch no, lot no, brand etc)	Number of industry sponsored studies	Provision for database to be audited by external parties
Data quality criteria	Availability of quality controls	Relevant publications

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Chapter 3 - Summary of database meta-profiles stored in the ADVANCE web catalogue

In the pilot round, the AIRR survey profiled 19 databases associated with the ADVANCE project covering 7 countries. The subsequent round involved profiling 15 databases using the revised AIRR survey. We were also able to obtain a large number of relevant database profiles through the Memorandum of Understanding (MoU) setup between ADVANCE and MOCHA. The responses collected will assist to identify databases appropriate for the 2nd proof-of-concept studies conducted by ADVANCE. We have summarised the profiles per country in Figure 3.1.

Table 3.1 Summary of the AIRR responses received

Dissemination stage	Response received
AIRR Survey - Round 1	19
AIRR Survey - Round 2	15
MOCHA MoU	73

Total : 107

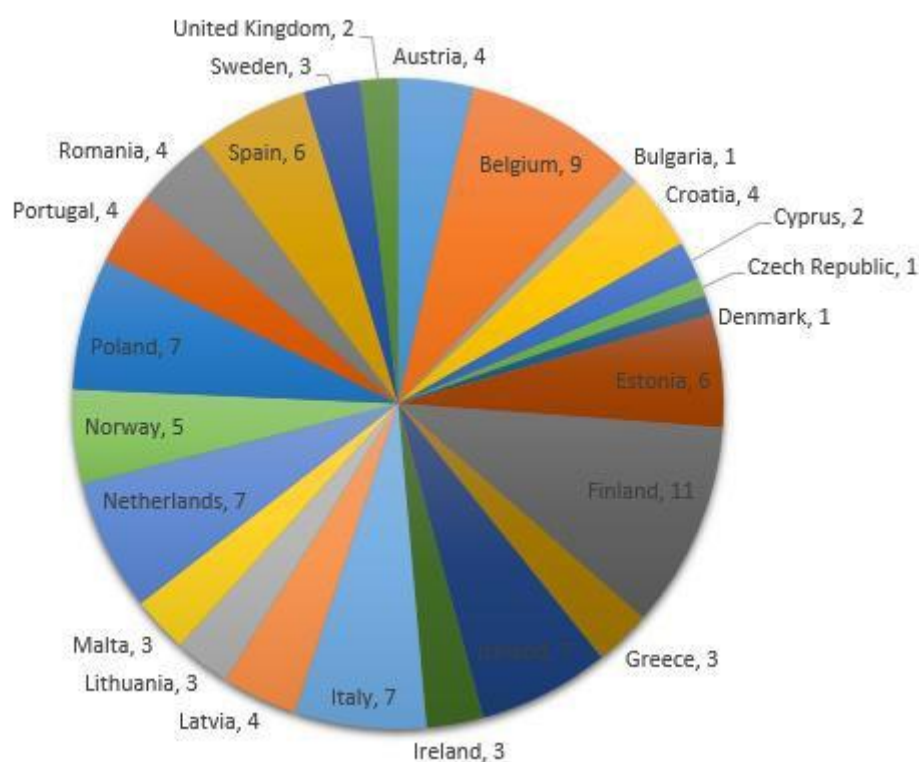



Figure 4.1 Meta-data profiles in the ADVANCE web-catalogue

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Chapter 4 - ADVANCE web catalogue user guide

This guide provides instructions for accessing AIRR survey results shared on the EMIF web catalogue. The process involves 2 steps:

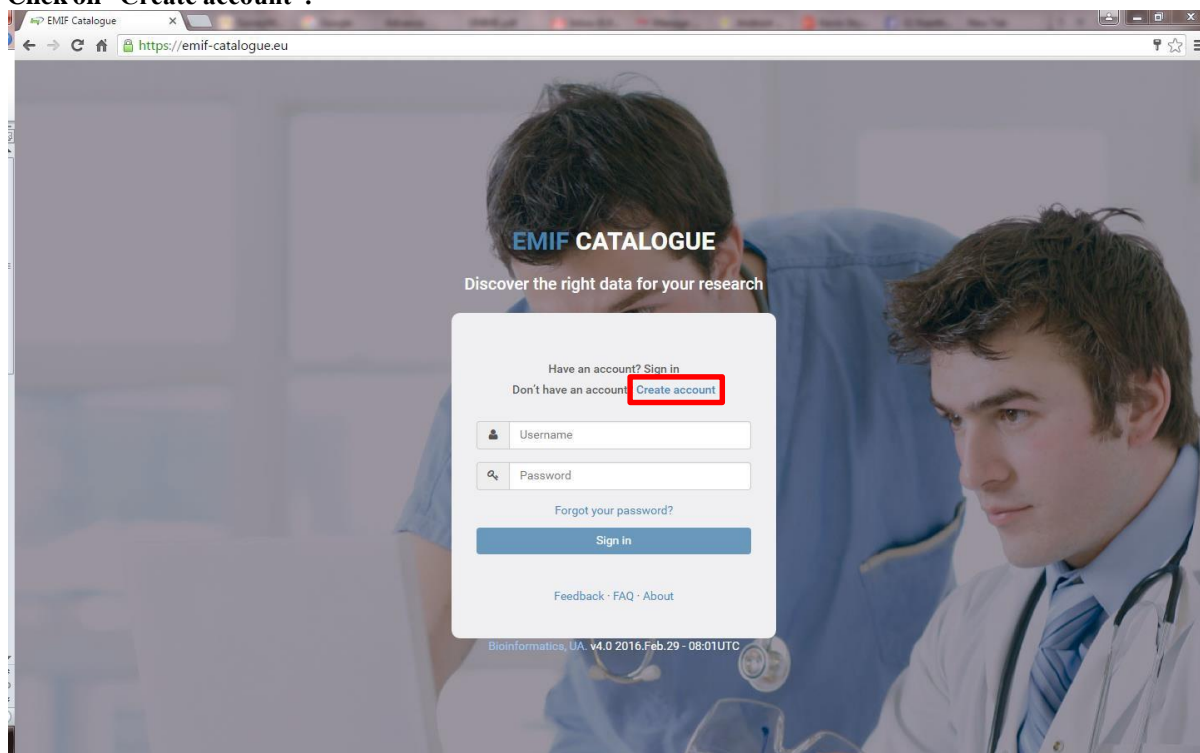
Step 1: Creating an account on the EMIF catalogue


Step 2: Obtaining approval to view ADVANCE community (i.e. AIRR results)

4.1 Creating an account on the EMIF catalogue

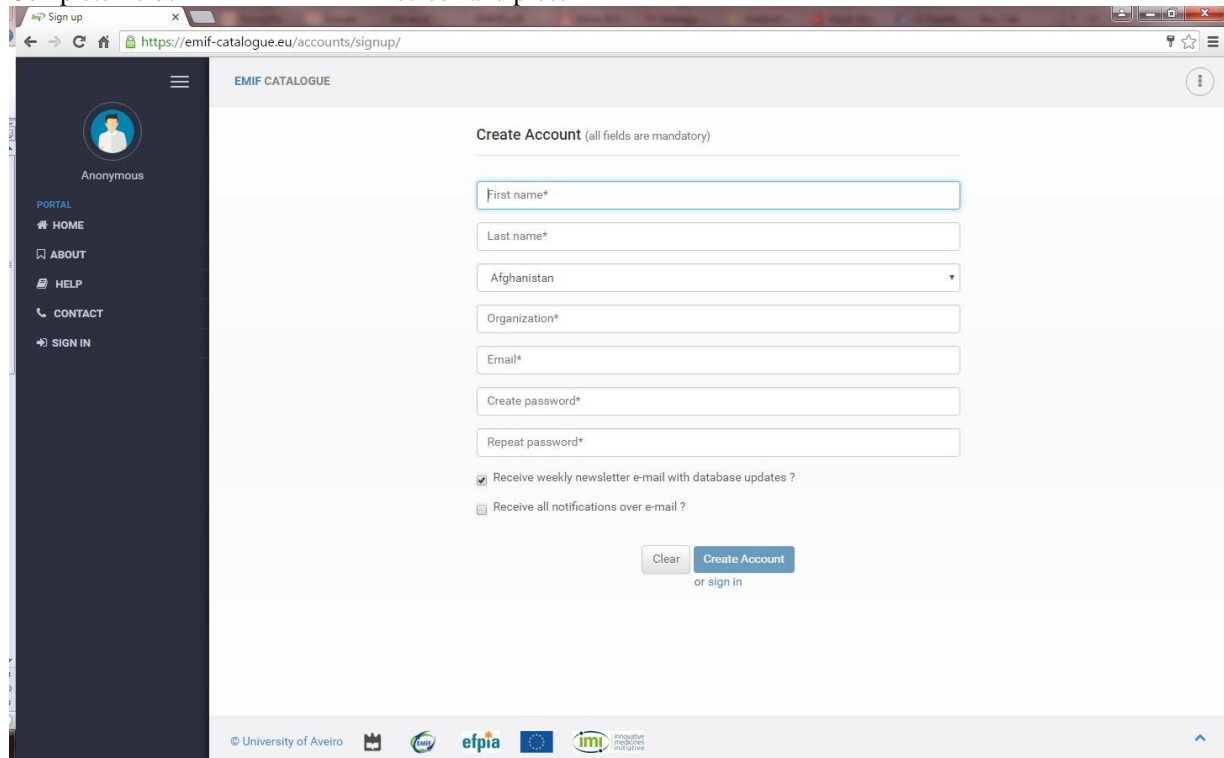
Visit <https://emif-catalogue.eu>

Click on “Create account”.

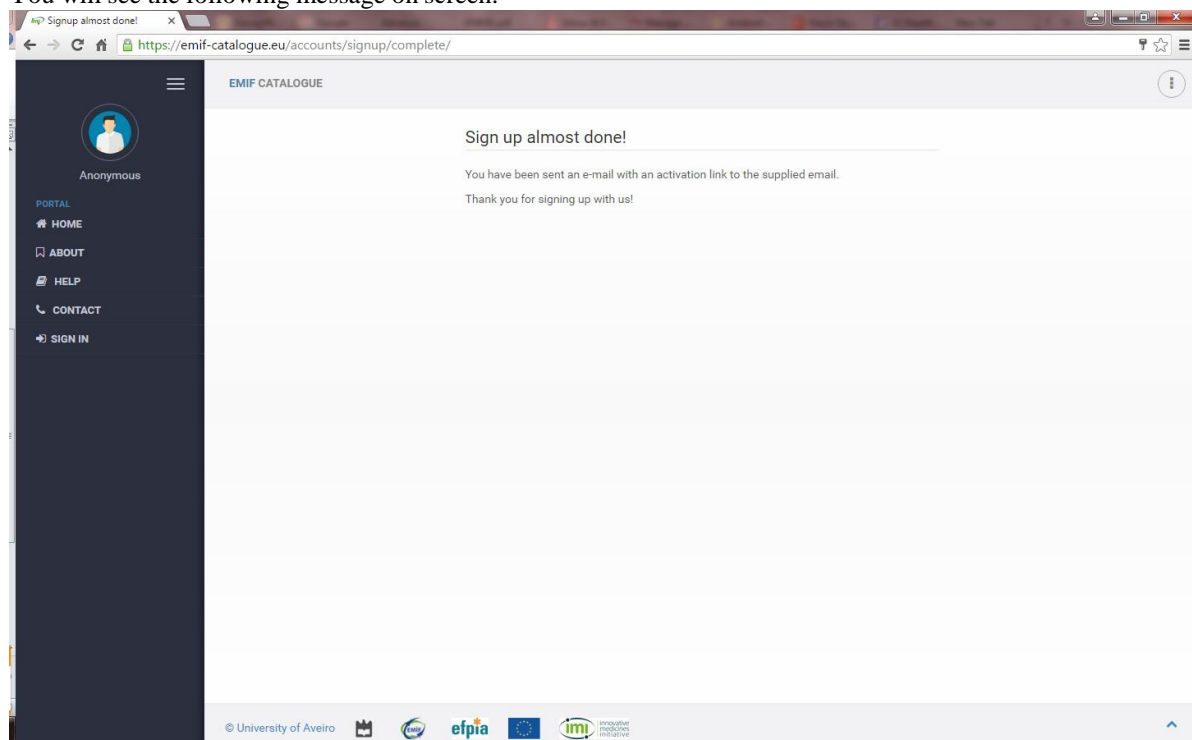



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Complete fields in “Create account” screen and press “Create account”

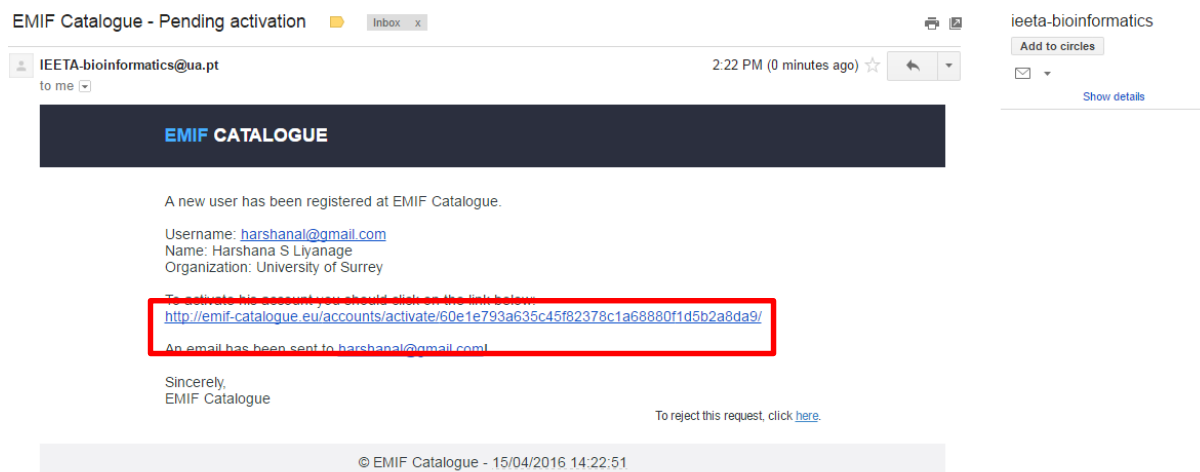


You will see the following message on screen.

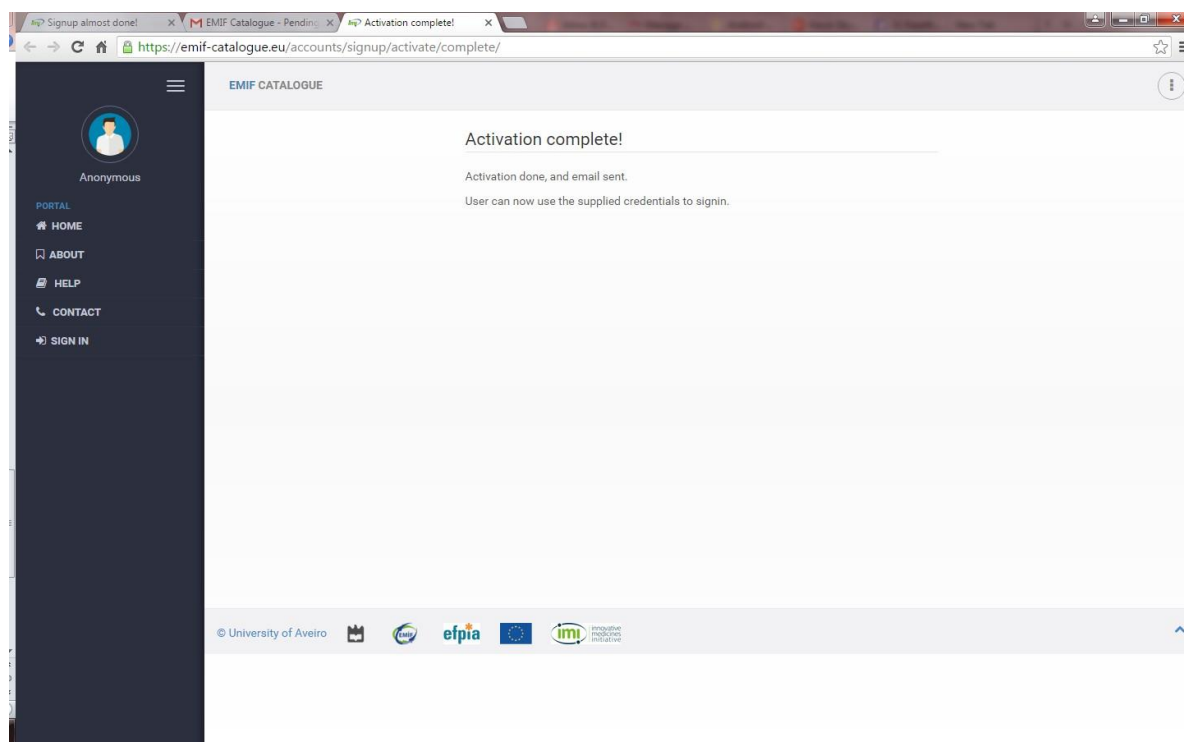



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Access the inbox of the email address provided. You will see an email similar to the following. Click on the activation link.

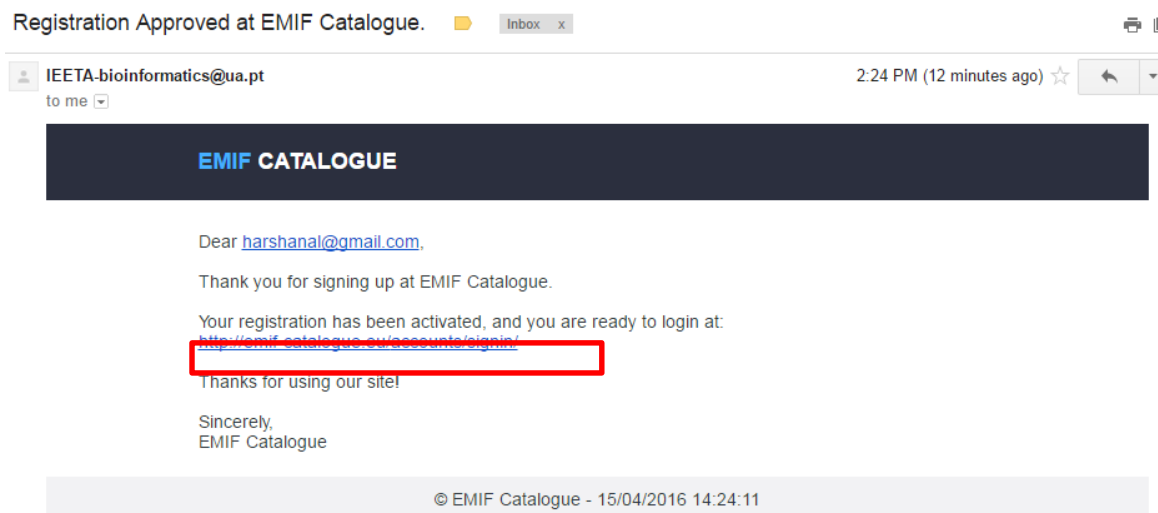


You will see the following page on the web catalogue indicating successful activation.

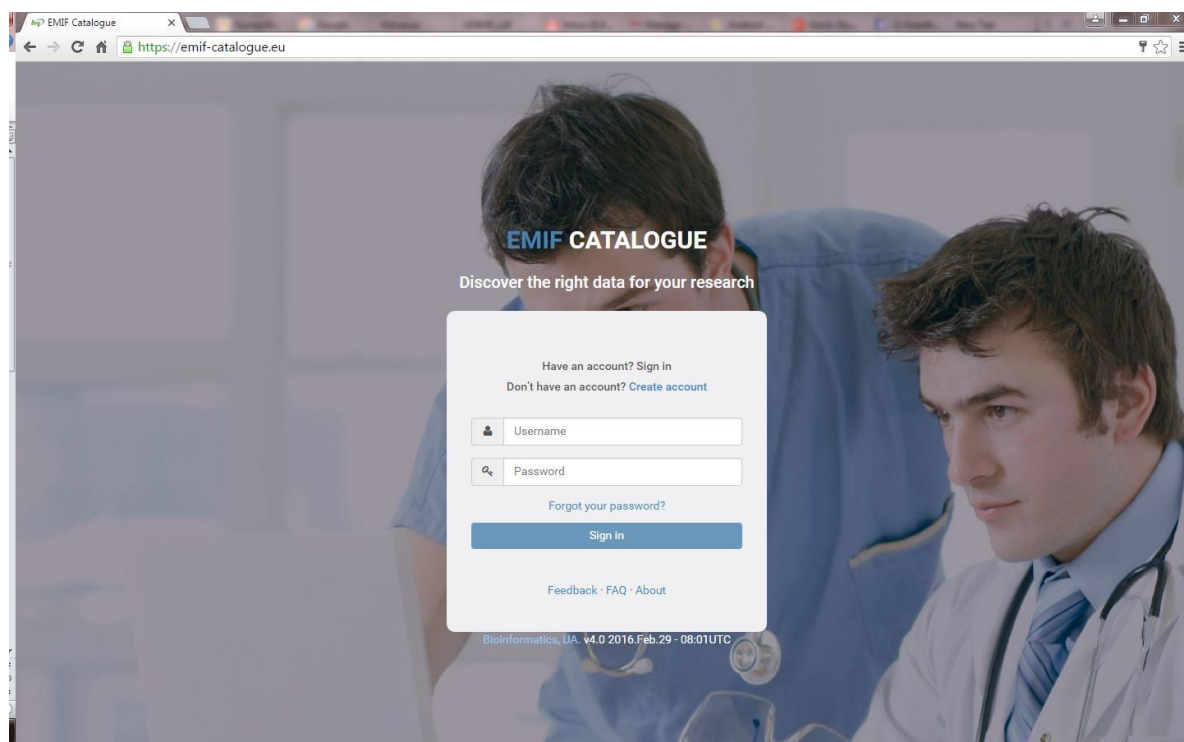



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You will also receive the following email indicating successful account creation. Click on the sign in link.

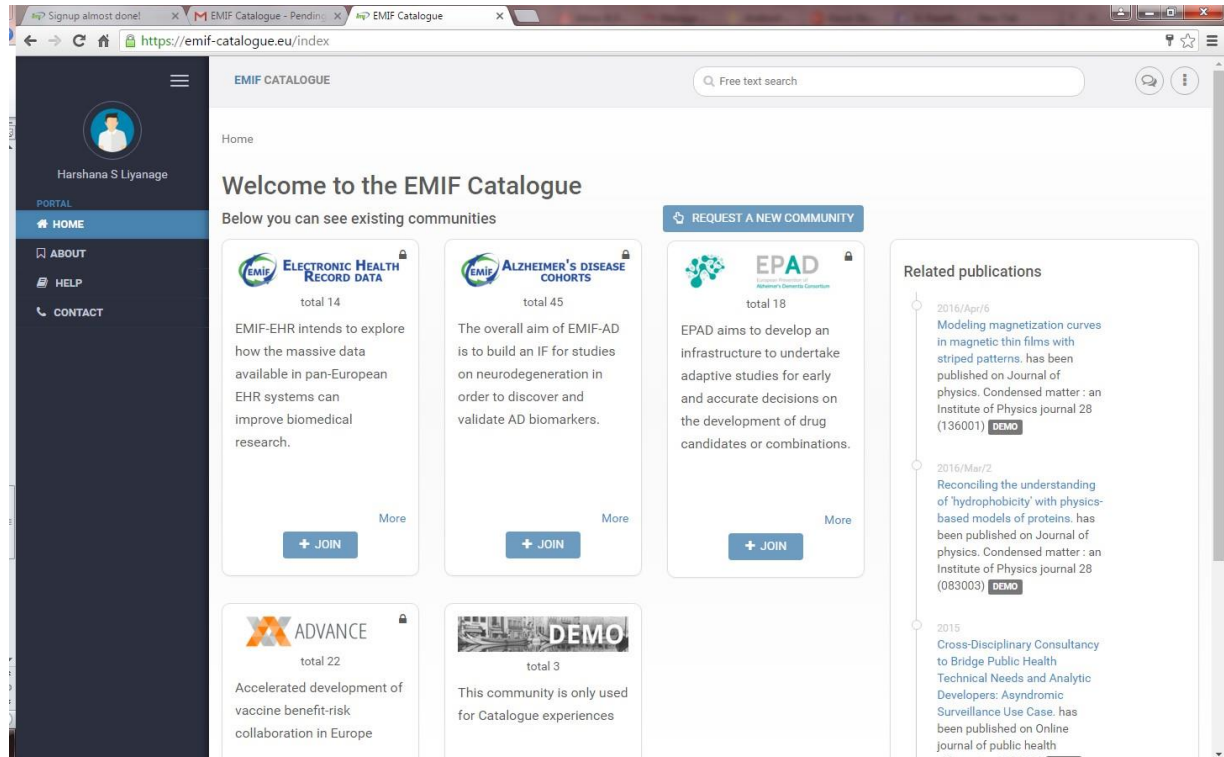


Provide your user name and password to log on to the EMIF catalogue.



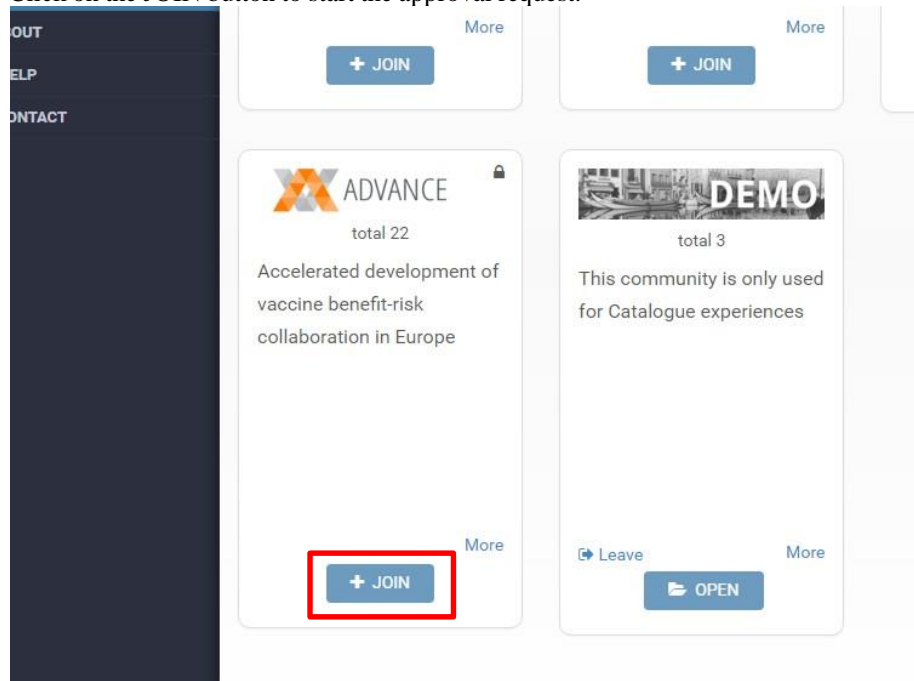
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You have now successfully registered with the EMIF catalogue.



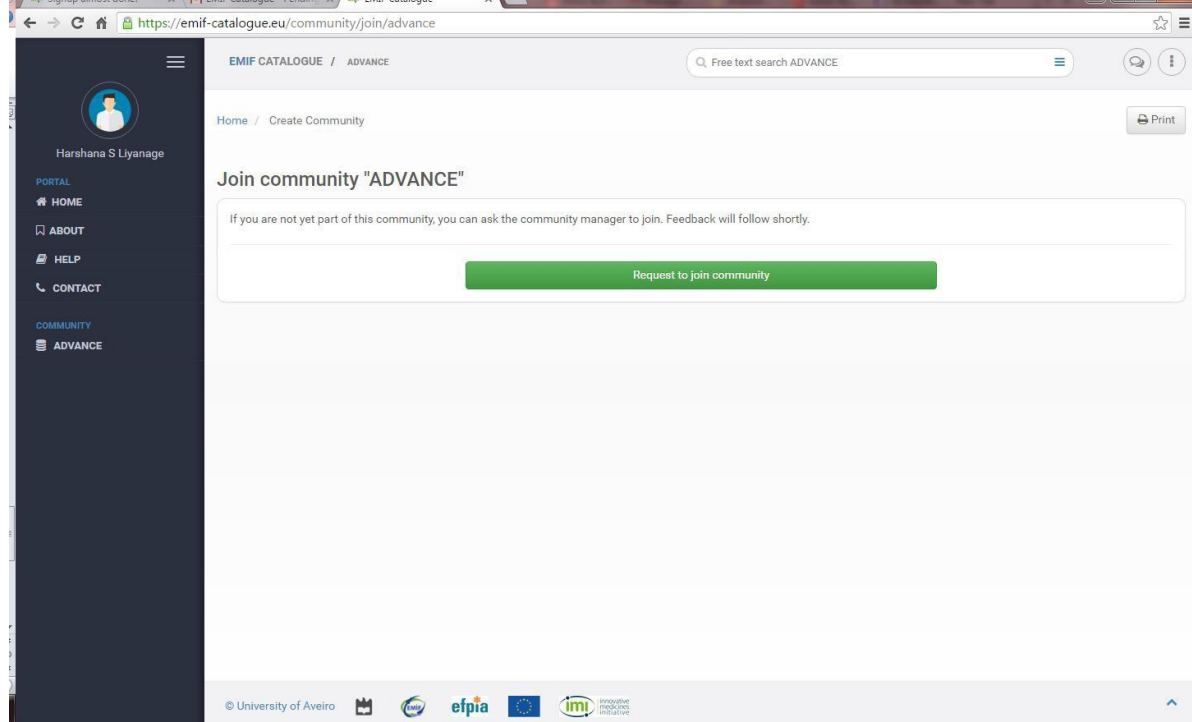
4.2 Approval to view ADVANCE community (i.e. AIRR results)

Click on the JOIN button to start the approval request.



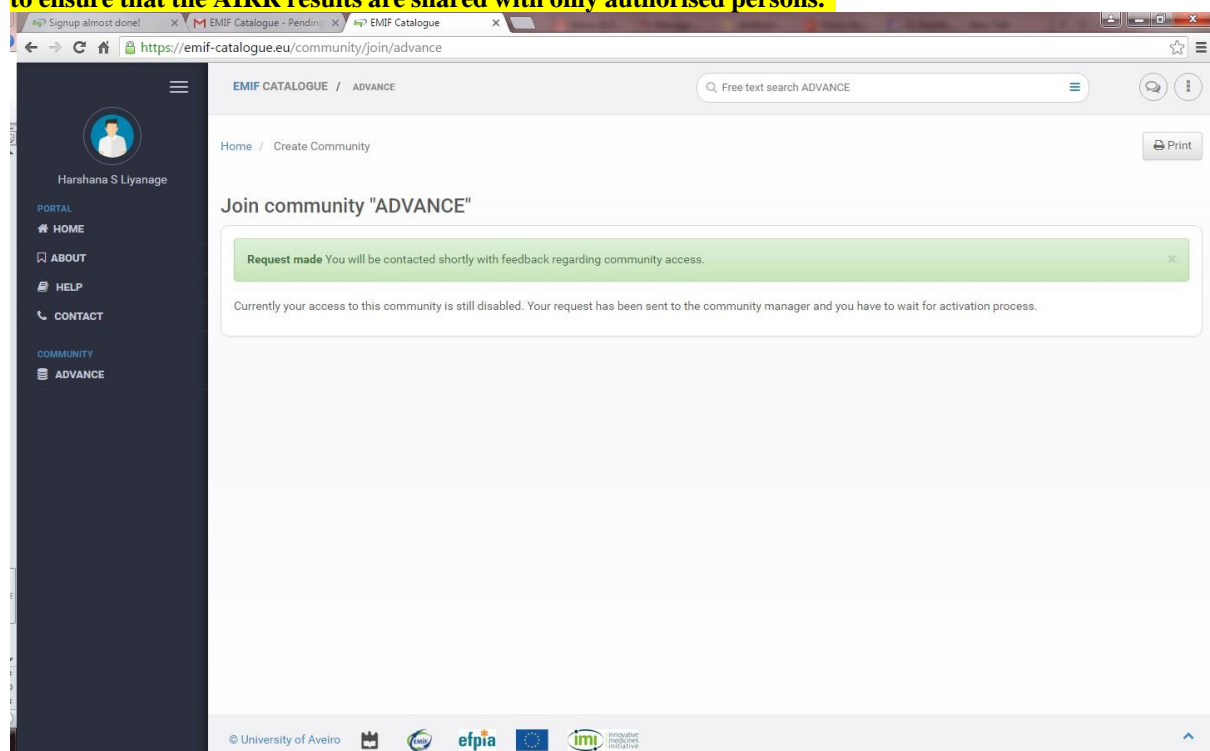
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Click on “Request to join community” button



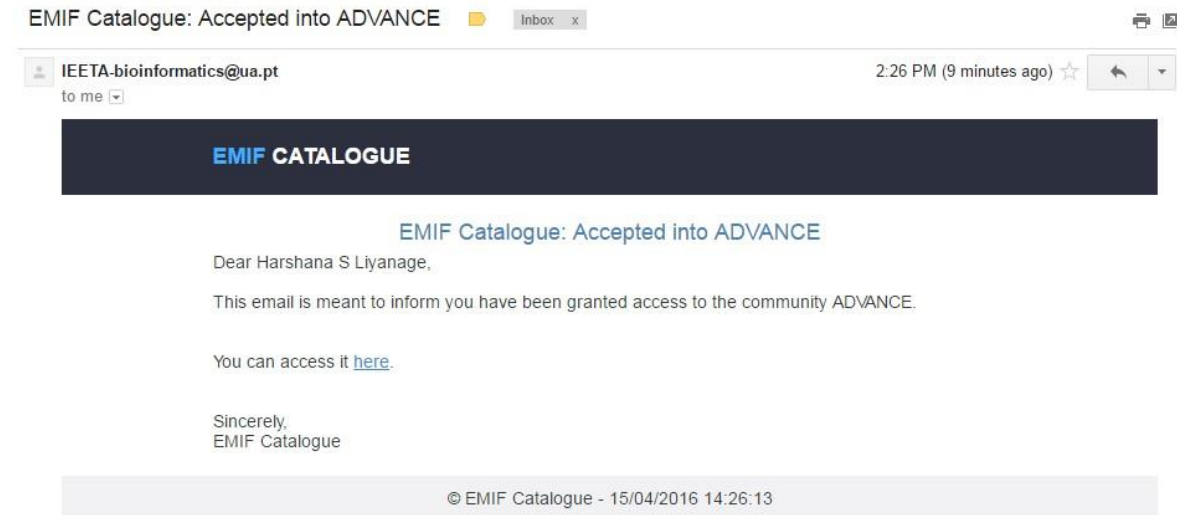
You will see the following message.

Please note that the approval process for joining the ADVANCE community is a manual process and you may not receive an instant response. The ADVANCE community manager will be screening each request to ensure that the AIIR results are shared with only authorised persons.

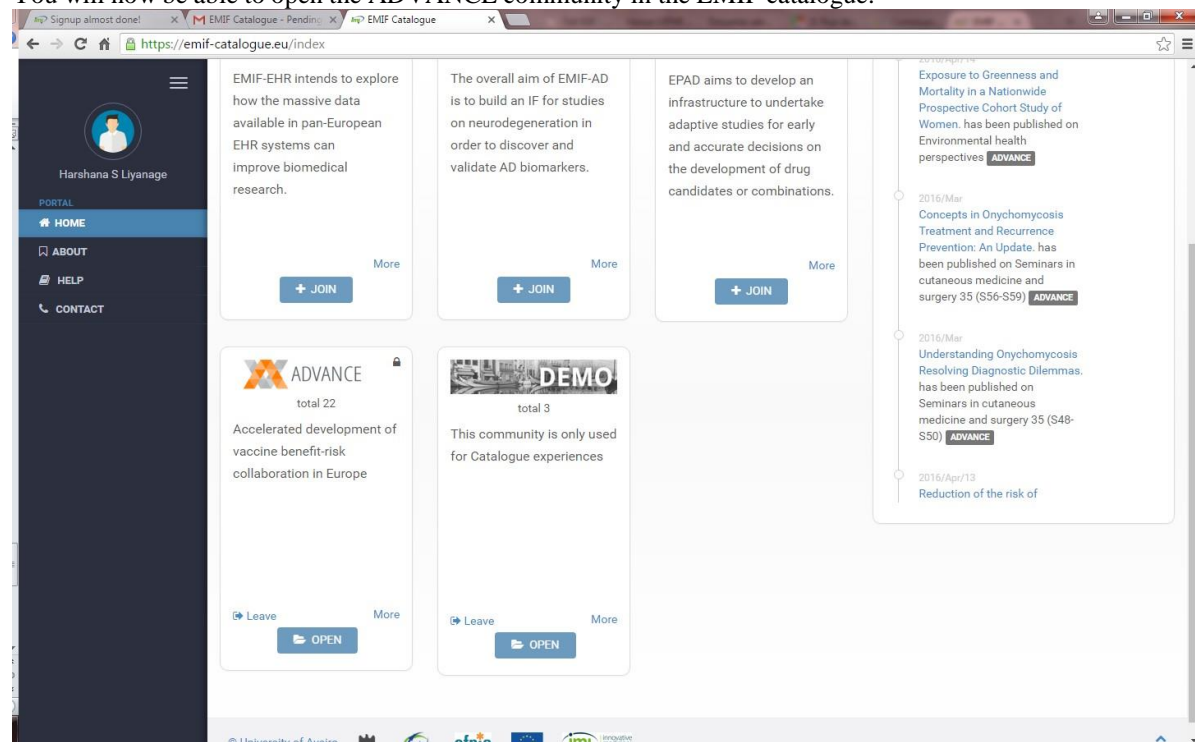



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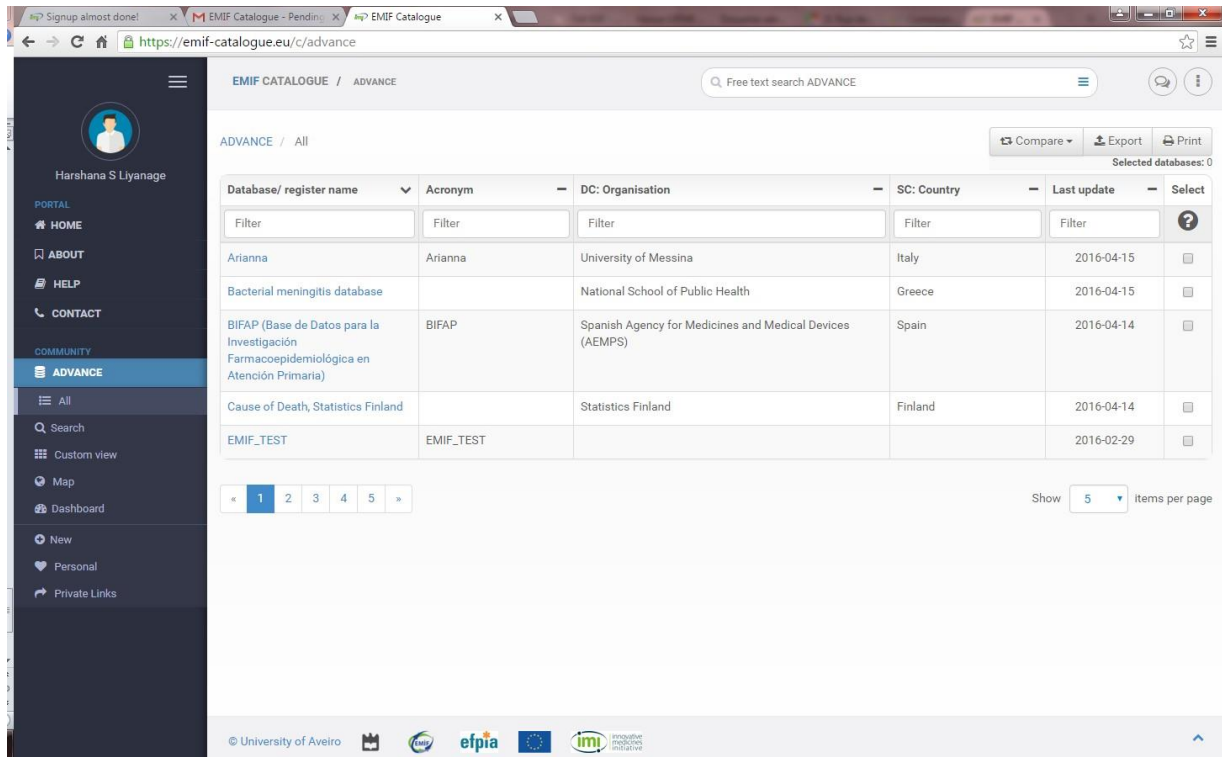
When approval is granted, you will be receiving the following email.



You will now be able to open the ADVANCE community in the EMIF catalogue.



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The screenshot shows the EMIF Catalogue ADVANCE web application. The interface includes a sidebar with navigation links (HOME, ABOUT, HELP, CONTACT, ADVANCE) and a main content area displaying a table of databases. The table has columns for Database/register name, Acronym, DC: Organisation, SC: Country, Last update, and Select. The following table represents the data shown in the screenshot:

Database/ register name	Acronym	DC: Organisation	SC: Country	Last update	Select
Arianna	Arianna	University of Messina	Italy	2016-04-15	<input type="checkbox"/>
Bacterial meningitis database		National School of Public Health	Greece	2016-04-15	<input type="checkbox"/>
BIFAP (Base de Datos para la Investigación Farmacoepidemiológica en Atención Primaria)	BIFAP	Spanish Agency for Medicines and Medical Devices (AEMPS)	Spain	2016-04-14	<input type="checkbox"/>
Cause of Death, Statistics Finland		Statistics Finland	Finland	2016-04-14	<input type="checkbox"/>
EMIF_TEST	EMIF_TEST			2016-02-29	<input type="checkbox"/>

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	D3.4 Catalogue and meta-profiles of data sources for vaccine benefit-risk monitoring		
	WP3 – Data sources for rapid and integrated benefit-risk monitoring		Version: v2.0
	Author(s): Harshana Liyanage (SURREY), Simon de Lusignan (SURREY), Alena Khromava (SP)		Security: 22/22

Chapter 5 - Conclusion

In this supporting document to the ADVANCE web-catalogue deliverable, the online web-catalogue for sharing meta-profiles, we have provided an outline of the AIRR survey and the associated processes followed to develop the database meta-profiles of candidate databases. We have also provided an indication about the current state of the web-catalogue and procedural information about how to access the meta-profiles through the EMIF platform.

References

- ¹ Directive on cross-border patient safety (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>)
- ² PARENT RoR and Assessment Tool: <http://www.parent-ror.eu/>
- ³ EMI Webcatalogue – <https://emif-catalogue.eu>