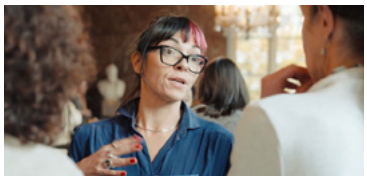
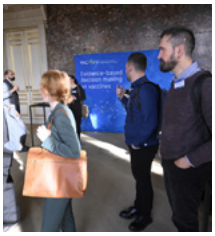
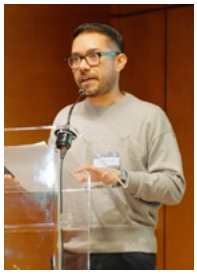
VAC4EU

Vaccine monitoring collaboration for Europe

5th Anniversary Edition







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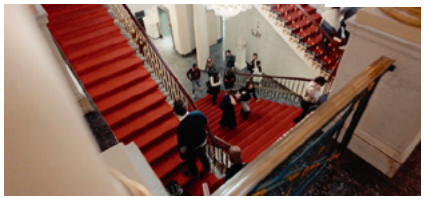

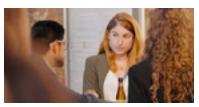
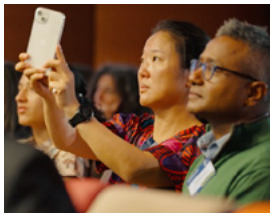

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Reflecting on 5 years of VAC4EU

Miriam Sturkenboom
VAC4EU PRESIDENT & CO-FOUNDER

In 2020, VAC4EU was established with the ambition to build on the foundations of the IMI ADVANCE initiative, including its governance model, data access framework, and methodological expertise, to create a sustainable infrastructure for vaccine monitoring in Europe. The organisation was launched at the onset of the COVID-19 pandemic during a period characterised by urgency and uncertainty. This required rapid mobilisation to support emerging public health needs.

In 2020, VAC4EU was established with the ambition to build on the foundations of the IMI ADVANCE initiative, including its governance model, data access framework, and methodological expertise, to create a sustainable infrastructure for vaccine monitoring in Europe. The organisation was launched at the onset of the COVID-19 pandemic during a period characterised by urgency and uncertainty. This required rapid mobilisation to support emerging public health needs.

Over the past five years, VAC4EU has evolved into a mature, trusted, and sustainable network, bringing together stakeholders across Europe to generate robust real-world evidence on vaccine safety and effectiveness. In 2025, this maturity was reflected in the continued delivery of studies through its members, in addition to investment in tools, dissemination of scientific outputs, collaborations and community structures that underpin the network.

VAC4EU has directly supported multiple large-scale safety studies with COVID-19 vaccine manufacturers, commissioned by international regulatory bodies. In 2025, several final reports were delivered and approved by regulators, each involving millions of vaccinated individuals, reflecting both the scale and the regulatory quality of VAC4EU's scientific contributions.

In addition, VAC4EU tools and methodologies have been widely applied in vaccine studies conducted under the European Medicines Agency (EMA) framework agreement by the EU PE&PV Research Network. These initiatives have generated critical evidence on vaccine benefits and risks, including the identification and contextualisation of adverse events of special interest and the evaluation of vaccination outcomes in specific populations.

Equally significant has been the development of a robust and scalable research infrastructure. VAC4EU has operationalised a distributed data network covering over 180 million individuals across eight European countries, supported by the ConcePTION Common Data Model. In 2025, this work continued to mature through work on the VAC4EU Catalogue, CodeMapper, case validation processes, the Pregnancy Algorithm, and other reusable and scalable tools supporting data quality, semantic harmonisation, and analysis. This has enabled efficient study execution while maintaining high standards of scientific rigour and transparency.

VAC4EU has continued to make sustained investments in people and capacity building.. In 2025 this can be seen through investment in the VAC4EU Academy, a bottom-up funding call and the relaunch of the Journal Club, as well as continued collaboration through the four core working groups. These activities have strengthened expertise across Europe and fostered a community of researchers capable of conducting complex real-world evidence studies within a shared methodological framework.

Looking back, the achievements of the past five years reflect not only the scale of the work delivered, but also the strength of the collaborative model underpinning VAC4EU. In 2025, this model was put into practice through active engagement with European Health Data Space developments, continued collaboration with partner networks, a growing public presence at scientific events, and the collective contributions of member organisations across studies, tools and working groups.

On behalf of the leadership and founding members, I would like to express my sincere appreciation to all member organisations, partners, and contributors whose dedication and expertise have made these achievements possible. I invite you to explore the activities and impact of VAC4EU in 2025 in this 5th Anniversary Edition of the Annual Report.

2025 in numbers

4 new studies kicked off
5 final reports submitted
4 academic articles published
25 poster and oral presentations
11 events attended as guest speakers

The Vaccine Monitoring Collaboration for Europe (VAC4EU) is a not-for-profit international association of institutions

CHECK OUT OUR NEW WEBSITE FOR MORE INFORMATION!

We strive towards evidence-based decision-making on vaccines

Our mission is to deliver timely and robust real-world evidence on vaccines and cutting-edge methodology through a European community of expert organisations

Who we are

A diverse, pan-European community of 29 member organisations

Public and private research centres, public health institutions and regulators

A well-characterised network of 14 real-world data sources covering over 185 million people

Experts in pharmaco-epidemiology, vaccinology, statistics, data science, medicine, innovation and project management

What we do

Collaborative studies

We conduct collaborative post-marketing studies on vaccines utilising primary and secondary health data.

Harmonised workflows

We harmonise workflows through a common framework, shared tools, and a comprehensive quality management system.

Co-creation

We build synergies across stakeholders through working groups and taskforces.

Innovation

We actively invest in new tools, methodologies and workflows in the rapid generation of RWE on vaccines.

Knowledge sharing

We stimulate scientific discussion and debate among members and the wider scientific community.

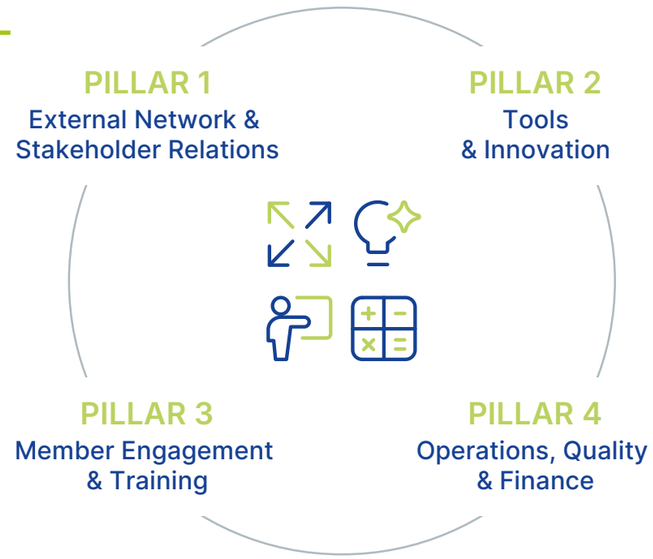
The Executive Board

The Executive Board of VAC4EU is elected by the General Assembly to steer and monitor the organisation. Their task is to hone their expertise to lead VAC4EU towards achieving our mission, providing key strategic vision and a consolidated annual plan of activities for the network. The Board is organised into four pillars covering different components of strategy.

The full VAC4EU Executive Board together at the 5th anniversary celebration in Brussels in November. From left to right: Patrick Mahy, Elisa Barbieri, Rosa Gini, Giampiero Mazzaglia, Eva Molero, Debabrata Roy, Vincent Bacchau, Miriam Sturkenboom, Naomi Boxall, Daniel Weibel.

5-Year Strategy

In 2024, the four strategic pillars within VAC4EU developed a comprehensive strategic and investment plan for 2025 and beyond, representing their strategic vision for the growth of VAC4EU. Key investments included a revamped website, a new learning platform, a GDPR GAP analysis and Secretariat expansion.



Eva Molero
EXECUTIVE CO-LEAD

Giampiero Mazzaglia
EXECUTIVE CO-LEAD

Daniel Weibel
SECRETARIAT SUPPORT

Ashton Babcock
SECRETARIAT SUPPORT

Pillar 1

External Stakeholder Engagement

Pillar 1 is policy-driven and reputation-focused, primarily concerned with the institutional relations of VAC4EU.

We have worked hard to strengthen VAC4EU's relationships with external stakeholders. Participation in events, policy consultations, and strategic collaborations has enhanced our scientific visibility and recognition across Europe.

Giampiero Mazzaglia

Progress

- Began strategic work on consolidating VAC4EU's network of partnerships, identifying areas for further investment
- Developed plan for VAC4EU's participation in events and congresses throughout 2026
- Coordinated responses from the network on several documents up for review on EHDS, while also engaging with relevant stakeholders such as TEHDAS2
- Launched rebranded, updated VAC4EU website
- Established biannual public newsletter for the scientific community

Spotlight: Engagement with European Health Data Space

EHDS is highly relevant to VAC4EU as it directly impacts how health data can be securely accessed, shared, and utilised across Europe. As Pillar 1's focus is interaction with the wider policy ecosystem, a primary activity throughout 2025 was to engage with key stakeholders in the EHDS landscape including TEHDAS2 (Towards the European Health Data Space 2), an EU-funded project providing guidance and practical recommendations on implementation.

VAC4EU Vice President Rosa Gini participated in the TEHDAS Multistakeholder Forum in Warsaw in January, focusing on key topics including data discoverability, access, security, and data processing.

One of the main deliverables in the TEHDAS2 project is the coordination of three waves of public consultations on various guidelines and technical specifications related to EHDS. VAC4EU members have provided feedback on several documents up for consultation including a draft guideline for data users on how to use data in a secure processing environment. These responses reflected VAC4EU's commitment to shaping policy and ensuring that the perspectives of network members were considered in the evolving European health data landscape. Additionally, our comments were reflected in the final published guidelines.

What is EHDS?

The European Health Data Space (EHDS) is a set of regulations from the European Commission aimed at creating a unified framework for the secure exchange and use of health data across EU member states. The regulation is designed to empower all stakeholders, including patients, healthcare providers, researchers, regulators, industry and more. 26 March 2025 marked the beginning of a phased roll-out on these regulations.

Miriam Sturkenboom
EXECUTIVE BOARD CO-LEAD

Naomi Boxall
EXECUTIVE BOARD CO-LEAD

Daniel Weibel
SECRETARIAT SUPPORT

Sima Mohammadi
SECRETARIAT SUPPORT

Taylor Brown
SECRETARIAT SUPPORT

Amirreza Dehgha
SECRETARIAT SUPPORT

Pillar 2

Tools & Innovation

Pillar 2 strengthens and harmonises infrastructure across VAC4EU by aligning tools and workflows.

Exciting to see the pipeline of tools become more mature to test AI-based support.

Miriam Sturkenboom

Progress

- Guided and supported innovation various tools in the data pipeline, particularly those involved in semantic harmonisation and case validation
- Signed contract with VHIR for 16 available REDCap forms and their maintenance for case validation
- Drafted a support contract with ARS for maintenance of the ConcePTION CDM and its use for ETL, and for maintenance and innovation on the VAC4EU Catalogue
- Executed contract with UNIFI for support and updating of the ConcePTION Pregnancy Algorithm, along with establishing a help desk route for tool and alignment on code list updates
- Contracted with UMCU for support and innovation on INSIGHT, a tool employed for quality checks

Spotlight: Improving the VAC4EU Tools Workflow

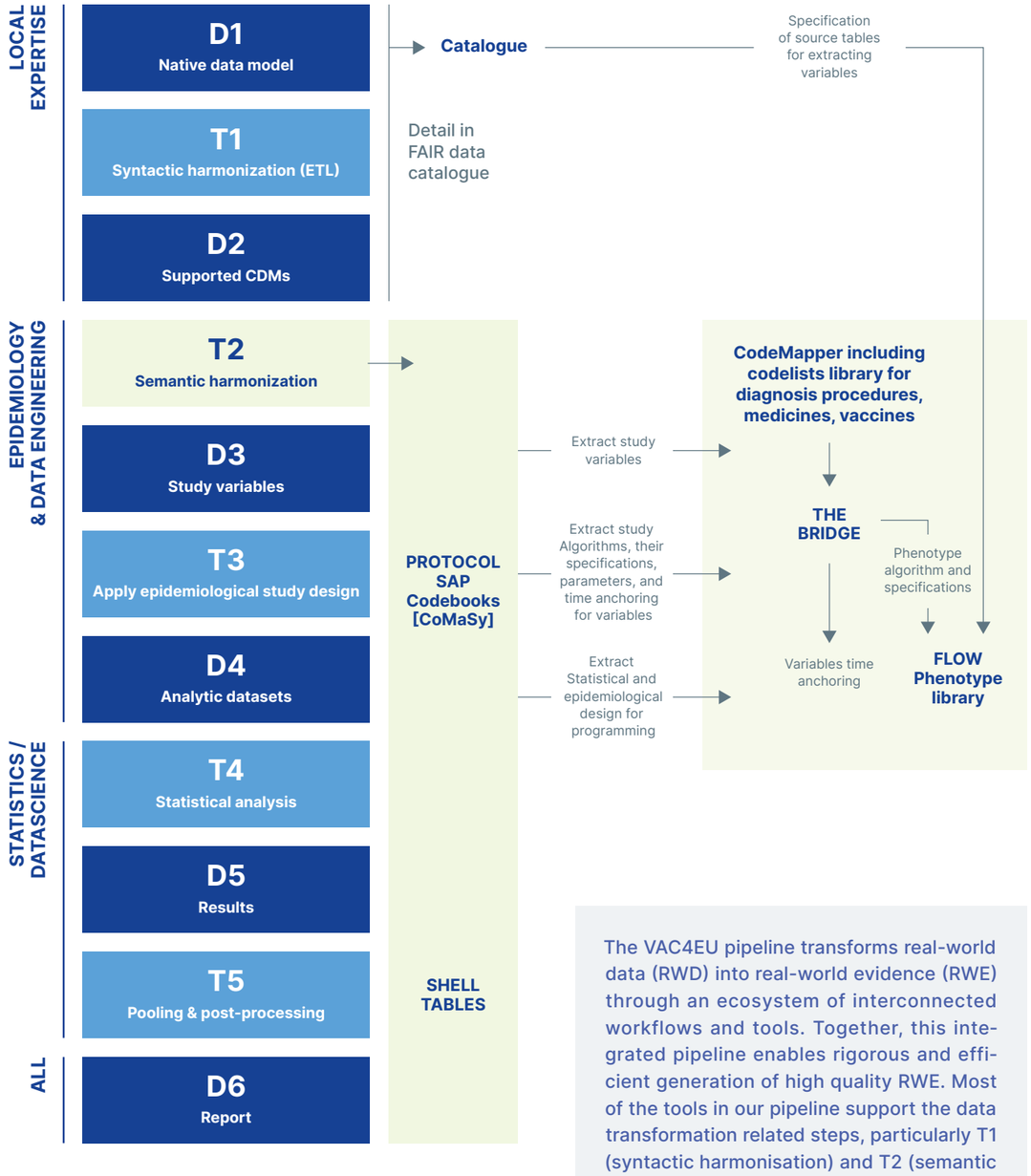
In 2025, Pillar 2 continued foundational work towards a unified, interoperable suite of tools anchored in the VAC4EU data pipeline. In 2025, Pillar 2 drafted and approved a service contract for support and maintenance of the VAC4EU Catalogue, a database of detailed metadata on each of our RWD sources which ensures consistent, structured and governed documentation. This tool was licensed from Molgenis and developed through the ConcePTION and MINERVA projects, while working with the DEAPs to curate the data is handled by Pillar 3.

CodeMapper, developed during ADVANCE and iterated by VAC4EU alongside original developer Benedikt Becker, is a web-based tool to facilitate the semi-automatic mapping of clinical case definitions to structured medical vocabularies. In 2025, substantial CodeMapper upgrades were made, including a full transition from SharePoint to the CodeMapper environment, added functionality to modify, tag and export code lists directly from the application, and more. The team also developed a plan for integration of the FLOW phenotype library and AI-supported code tagging.

The Programming Task Force provided recommendations for code books to allow for transparency in steps T2 to T5 which are now under final review. There is also ongoing evaluation as to whether a tool should be developed for deploying these code books.

Pillar 2 has led innovation on the case validation pipeline as well, including extensive consultation with the CEPI-funded SPEAC project investigating how to implement definitions in RWD and sublevels, as well as how the ABC tool could be used. Additionally, Pillar 2 has engaged with the VAC4EU-funded SeValid project team with narratives on cases to investigate their use for training an LLM on validation tasks.

The VAC4EU tool ecosystem



The VAC4EU pipeline transforms real-world data (RWD) into real-world evidence (RWE) through an ecosystem of interconnected workflows and tools. Together, this integrated pipeline enables rigorous and efficient generation of high quality RWE. Most of the tools in our pipeline support the data transformation related steps, particularly T1 (syntactic harmonisation) and T2 (semantic harmonisation).

These tools are regularly revised, updated and improved as the VAC4EU network matures and consolidates learnings under the coordination of Pillar 2.

Rosa Gini — EXECUTIVE CO-LEAD
Elisa Barbieri — EXECUTIVE CO-LEAD
Daniel Weibel — SECRETARIAT SUPPORT
Henriëtte Mulder — SECRETARIAT SUPPORT

Pillar 3

Membership Engagement & Training

Pillar 3 is member-focused, driven predominantly by the need for capacity-building and networking.

We hope to continuously shape VAC4EU into a space where our members can lead, learn, and grow together — turning shared effort into real impact.

Elisa Barbieri

Progress

- Strengthened member engagement by monitoring participation in the Working Groups and encouraging rotation of chairs, also supporting smooth onboarding of new chairs
- Continued collaboration with external partners on the VAC4EU Catalogue, with an ambition to make the tool public to non-members in 2026
- Created, developed and maintained the VAC4EU Academy, our open access platform for e-learning

Spotlight: Bottom-up Funding Call

Pillar 3 coordinated the call for bottom-up funding proposals in 2025, as well as subsequent Executive Board review. Three projects were awarded funding:

- The Data Expert & Access Partners (DEAP) Working Group: Applying of component algorithm strategy to better understand how different data prompts contribute to case identification. The project is led by ARS.
- The Pregnancy Algorithm Task Force (part of the PI Working Group): Towards more granular pregnancy-related outcomes. The project is led by University of Florence.
- The Primary Data Collection Task Force (part of the PI Working Group): To understand the evidence needed for vaccines to be perceived as safe, and trustworthy. The project is led by Vall d'Hebron.

What is bottom-up funding?

VAC4EU provides funding for members active in Working Groups and Task Forces to carry out research projects relevant to VAC4EU's mission, vision and strategy. Each year, Pillar 3 launches a call to each group, known as "bottom-up funding." So far, VAC4EU has awarded and funded six studies, with three awarded in 2025 alone.

Patrick Mahy — EXECUTIVE CO-LEAD
Debabrata Roy — EXECUTIVE CO-LEAD
Daniel Weibel — SECRETARIAT SUPPORT
Taylor Brown — SECRETARIAT SUPPORT
Henriëtte Mulder — SECRETARIAT SUPPORT

Pillar 4

Operations, Quality & Finance

Pillar 4 is quality-driven with a broad focus on operations for a sustainable trajectory.

Pillar 4 has played an important role in strengthening how VAC4EU operates, through work on internal guidance, GDPR implementation, contracts, and governance. These improvements help support quality, consistency, and the long-term sustainability of the network.

Debabrata Roy

Progress

- Worked towards the creation of a VAC4EU branch registered in the Netherlands. Administrative and legal procedures are expected to be finalised in 2026.
- Developed and piloted procedures for annual evaluation, including planning for an Executive Board evaluation in 2026
- Implemented environmental, social, and governance (ESG) good practices in VAC4EU contracts and documents, adhering to the new European legislation starting in January 2026
- Wrote and implemented an internal guideline on "VAC4EU Participation in European Projects and Competing Proposals"
- Drove discussion on Executive Board decision-making processes

Spotlight: General Data Protection Regulation (GDPR)

With a focus on upholding quality standards and aligning internal processes with audit requirements, Pillar 4 began the implementation of GDPR across the organisation in 2025 in consultation with a legal advisory firm.

This process will be completed by the end of Q1 2026 with the revision of VAC4EU's privacy statement, the development of a Data Breach Procedure and Data Subject Rights Request (DSR) Procedure, and the inclusion of various website features that collect consent related to data matters.

Pillar 4 continues to be dedicated to adherence to quality within VAC4EU and plans to embark on similar ventures in 2026.

What is GDPR?

GDPR is a data protection law in the European Union that sets standards for how organisations process and protect personal data. Additionally, GDPR gives individuals rights over their data, such as the ability to edit or delete information.

Working group progress in 2025

VAC4EU coordinates four core working groups (WG) to support various roles across studies. These groups meet biweekly or monthly, primarily functioning as community spaces to share best practices, lessons learned, and innovation within the field, supporting standardisation initiatives across studies and collaboration with other working groups to improve. Additionally, each working group hosts several specific task forces (TFs) to handle emerging needs.

Principal Investigators' Working Group (PI WG)

What is a Principal Investigator (PI)?

The PI in a VAC4EU study is responsible for the leadership and conduct of a research study. PIs ensure that the study is conducted in accordance with the protocol and all relevant EU legislation, while complying with all applicable VAC4EU procedures. PIs are the central figure in all phases from study design, protocol development, statistical analysis plan including measurement of variables (Catalogue, code lists, metadata, validation), analysis, and reporting.

Progress

- Provided a space for regular updates on each ongoing VAC4EU study, along with the opportunity to discuss and address issues
- Featured presentations from the PIs of completed studies reporting on results and learnings, with subsequent discussion from the group
- Information sharing on functionality updates for various VAC4EU tools, including CodeMapper, the VAC4EU Catalogue, and the Pregnancy Algorithm
- Updates and discussions on common processes for case validation
- Established the Primary Data Collection Task force

Task Forces

- Pregnancy Algorithm
- Catalogue
- Code List
- Primary Data Collection **NEW!**

In the past five years, valuable insights have been built from conducting many VAC4EU studies. By actively sharing knowledge and experiences of these studies with other PIs and VAC4EU members in the WG PI, a deeper collective understanding of study requirements towards implementation has been developed. Currently we are improving and refining methods and technologies to further consolidate our studies.

Hilda de Jong

Leadership

- Hilda de Jong (UMCU) CURRENT CHAIR
- Daniel Weibel (VAC4EU) FORMER CHAIR

Methods, Statistics and Programming Working Group (MSP WG)

RWE studies are inherently complex, both methodologically and technically. No single group can cover all aspects, so collaboration across organisations and expertise is essential. The MSP WG helps bring diverse perspectives together.

Yeon Choi

What is a Statistical Programmer?

A statistical programmer combines knowledge of statistics, data analysis, and programming to create analytical workflows that transform raw data into reliable, consistent, and reproducible study results. They collaborate with statisticians in VAC4EU studies to design codebooks based on statistical analysis plans and develop quality control central analytical pipelines to run against the CDM. Their role is to generate estimates tailored to answering the research question(s) of the study.

In practice, statisticians and (statistical) programmers work across methods, statistics, and programming. This means translating study design and variable definitions into data and code, implementing the planned statistical analyses, and ensuring everything runs in a way that is efficient, transparent, and reproducible within the VAC4EU distributed pipeline.

Progress

- Developed R function and associated procedure to harmonise the cleaning of lab values in VAC4EU studies using ConcePTION CDM
- Planned for the transition from CSV files to Parquet files for data instances of ConcePTION CDM (tests, simulations, limits)
- Discussed the complexity inherent to secondary data disclosure control with several potential options

Task Forces

- Programming
- Catalogue
- Simulated Data
- SCRI

Leadership

- Yeon Choi (UMCU) CURRENT CHAIR
- Jeremy Jove (BPE) FORMER CHAIR

Lead Operating Center/ Project Management Working Group (LOC/PM WG)

What I value most about the LOC-PM WG is the supportive, solution oriented environment. Collaborating with colleagues from diverse organisations, exchanging experience and information pushes us to innovate and continuously improve how we work. It contributes to a better study management and informs also VAC4EU quality standards.

Alessandra Nardone

What is a Lead Operating Centre (LOC) and what do Project Managers do?

Each VAC4EU study involves one organisation that coordinates and manages the study, known as the Lead Operating Center (LOC). The LOC takes on the responsibility of oversight and coordinates study activities between different study roles according to the set study budget and timelines. The LOC ensures and documents that standards of quality requirements are applied and represent the primary contact for all study partners, including the funder. Project Managers and other specialists from LOCs are experienced, agile, and knowledgeable of requirements from all involved parties and are the spinning wheel behind every project.

Progress

- Reviewed and provided feedback on several policies, SOPs and guidelines to be used in VAC4EU
- Established a task force with the objective to predict the time it takes to perform various processing tasks in collaboration with the DEAPs WG

Task Forces

- Processing Times NEW!

Leadership

- Alessandra Nardone (Fondazione Penta ETS) CURRENT CHAIR
- Daniel Weibel (VAC4EU) FORMER CHAIR
- Marjolein Jansen (JCR) FORMER CHAIR

Data Expert & Access Partner Working Group (DEAP WG)

What I treasure most about the DEAP WG is how willingly everyone shares their expertise across such a diverse group of organisations. The open communication and exchange of ideas creates a true sense of community, where we are pushed to think more critically and see our work through different eyes.

Arantxa Urchueguía Fornes

What is a Data Expert & Access Partner?

Data Expert & Access Partners (DEAPS) are VAC4EU organisation members with access to large observational healthcare data sources and the specialised knowledge required to apply them in VAC4EU studies. Within the VAC4EU network, 14 DEAPs manage data from over 185 million individuals across Europe and play a key role in all phases of pharmacoepidemiological studies.

The data sources participating in VAC4EU are highly diverse, differing in the purpose for which data are collected, the healthcare events that trigger recording (e.g., primary care visits, hospitalisations, emergency care, medication dispensing claims, etc), the content of available records (e.g., captured information items, coding dictionaries), and the underlying healthcare system organisation and culture. In this context, a deep knowledge of the peculiarities of each data source is fundamental for the generation of high-quality evidence.

Progress

- Finalised guidelines on best practices for study result review and approval
- Developed a proposal for the VAC4EU bottom-up funding call with the aim of developing pilot tools to facilitate the systematic implementation of a “component algorithm strategy”

Task Forces

- Best Practice for Results Review TF
- Case Validation TF

Leadership

- Arantxa Urchueguía Fornes (FISABIO) CURRENT CO-CHAIR
- Denise Morris (DSRU) CURRENT CO-CHAIR
- Giuseppe Roberto (ARS) FORMER CHAIR
- Anna Girardi (ARS) FORMER CHAIR
- Felipe Villabos (IDIAP) FORMER CHAIR

Study activity in 2025

AstraZeneca Vaxzevria® PASS

FINAL REPORT AVAILABLE

Members

RTI-HS, UMCU, ARS, DSRU, IDIAPJGoI, PHARMO, FISABIO

Data sources

CPRD, SIDIAP, PHARMO, VID

Protocol

A post-authorisation/post-marketing observational study to evaluate the association between exposure to AZD1222 and safety concerns using existing secondary health data sources

About

This study aimed to evaluate the incidence and relative risk of AESI after receiving the AstraZeneca COVID-19 vaccine.

Progress

Following submission of the final report at the end of 2024, activities in 2025 focused on dissemination of results.

Results

The study assessed the safety of the AstraZeneca COVID 19 vaccine in more than five million recipients across the UK, Spain, and the Netherlands using multiple comparator cohorts. Overall, the findings are consistent with the established safety profile of Vaxzevria®, with absolute risks of serious events remaining very low.

Read more

- Final Report - A post-authorisation/post-marketing observational study to evaluate the association between exposure to AZD1222 and safety concerns using existing secondary health data sources (COVID 19)
- Peer-reviewed publication: Forns J, et al. Risk of venous thrombosis with thrombocytopenia syndrome after vaccination with AZD1222: a European VAC4EU post-authorisation safety study
- Presentation at ISPE Annual Meeting - Risk of venous thrombosis with thrombocytopenia syndrome after vaccination with AZD1222: a European VAC4EU post-authorisation safety study

READ THE FINAL REPORT

Janssen Ad26COV2S PASS

FINAL REPORT AVAILABLE

Members
UMCU, RTI-HS, IDIAP JGol, PHARMO, FISABIO, MediCom

Data sources
SIDIAP, PHARMO, VID

Protocol
An Observational Post-Authorisation Safety Study to Assess the Safety of Ad26.COV2.S Using European Healthcare Data through VAC4EU

About
The first aim of the study was to conduct a feasibility assessment on a safety evaluation study on the Janssen COVID-19 vaccine, then to assess the risk of developing AESI after receiving it.

Progress in 2025
- → Study finalised
- → Final report delivered in January 2025
- → 2 manuscripts drafted

Results
The study evaluated the safety of the JCOVDEN vaccine in over 500,000 vaccinated individuals across three European data sources, analysing 36 adverse events of special interest using SCRI and matched cohort designs. The study confirmed known JCOVDEN related risks, such as thrombocytopenia, as described in the prescribing information. However, its overall robustness was limited by substantial heterogeneity between data sources, including differences in coding systems and/or availability of hospital data.

Read more
- Final report - An Observational Post-Authorisation Safety Study to Assess the Safety of Ad26.COV2.S Using European Healthcare Data through VAC4EU
- Presentations at ISPE Annual Meeting:
  - Evaluating the Safety Profile of the Janssen COVID-19 Vaccine (JCOVDEN): A VAC4EU Post-Authorization Safety Study
  - Evaluating the Diagnostic Accuracy of Adverse Events of Special Interest Following Janssen COVID-19 Vaccine (JCOVDEN) Using the VAC4EU Validation Pipeline

READ THE FINAL REPORT

Moderna Spikevax® PASS

FINAL REPORT AVAILABLE

Members
Aarhus University, Julius Clinical, ARS Toscana, DSRU, IDIAP JGol, UIO

Data sources
Danish National registries, CPRD Aurum, SIDIAP, Norwegian National registries

Protocol
Post-authorization active surveillance safety study using secondary data to monitor real-world safety of Spikevax in Europe

About
The primary objective of this study is to assess whether vaccination with the Moderna COVID-19 vaccine is associated with increased rates of AESI in the general population, with a secondary objective to assess safety in defined subgroups.

Progress in 2025
- → Study finalised
- → Final report delivered in March 2025

Results
The results of this report confirm findings from other studies that original Spikevax is associated with increased rate of anaphylaxis 0-2 days after vaccination in females and males aged 12 years or older and increased rate of myocarditis and pericarditis 0-14 days after vaccination in males aged 12-39 years with the highest increase after the second dose. There was no indication found that original Spikevax was associated with the other examined AESIs. Among patients diagnosed with myocarditis or pericarditis, we did not find any indication that those vaccinated with original Spikevax before the myocarditis or pericarditis diagnosis had worse outcomes than those not vaccinated with any type COVID-19 vaccine before the myocarditis or pericarditis diagnosis.

Read more
- Final report - Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of Spikevax in Europe
- Presentation at ISPE Annual Meeting - Monitoring the Safety of mRNA-1273 COVID-19 Vaccine in the General Population: Results of a Regulator-Mandated Post-Authorisation Safety Study in Denmark, Norway, Spain, and the United Kingdom (EUPAS44273)

READ THE FINAL REPORT

Moderna Spikevax® PASS (pregnancy)

FINAL REPORT AVAILABLE

Members

Aarhus University, Julius Clinical, DSRU, IDIAP JGoI, UIO

Data sources

Danish National registries, CPRD Aurum, SIDIAP, Norwegian National registries

Protocol

Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries (COVID-19)

About

The primary objective of this study is to assess whether there is a higher risk of pregnancy and/or neonatal complications or adverse outcomes after exposure to the Moderna COVID-19 vaccine, with a secondary objective to describe utilisation of Spikevax amongst pregnant women.

Progress in 2025

- → Study finalised
- → Final report delivered in January 2025
- → FDA requests being addressed

Results

The results of this study indicate that Spikevax vaccination during pregnancy, regardless of prior or concurrent receipt of other COVID-19 vaccines, is not associated with adverse pregnancy, birth, or neonatal outcomes when compared with not receiving any COVID-19 vaccines during pregnancy. Utilisation of Spikevax was aligned with the reported country-specific vaccination policies.

Read more

- Final report - Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries
- Presentation at ISPE Annual Meeting - Monitoring Safety of Moderna COVID-19 Vaccines in Pregnancy: A Multi-Database Study in Denmark, Norway, Spain and the United Kingdom. A Regulator-Mandated Postauthorisation Safety Study in the VAC4EU Network (EUPAS44450)

READ THE FINAL REPORT

Moderna Spikevax® myocarditis and pericarditis study

FINAL REPORT AVAILABLE

Members

JCR, Aarhus, DSRU, IDIAP, UIO, FISABIO

Data sources

Danish registries, CPRD, SIDIAP, VID, Norwegian registries

Protocol

Clinical course, outcomes and risk factors of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2

About

The primary objective of this study is to identify risk factors for myocarditis and pericarditis after vaccination with the Moderna COVID-19 vaccine, as well as to characterise the clinical course of myocarditis and pericarditis of varying origin.

Progress in 2025

- → Study finalised
- → Final report delivered in June 2025

Results

Consistent with existing knowledge on the epidemiology of myocarditis and pericarditis, this study found that younger age and male sex are associated with an increased risk of developing myocarditis and/or pericarditis following Spikevax vaccination. Moreover, older age, higher CCI score, pre-existing comorbidities and prior healthcare use were identified as potential risk factors for severe outcomes in the clinical course. Risk factors were similar between cases following Spikevax vaccination and cases not associated with COVID-19 vaccination.

Read more

- Final report - Clinical course, outcomes and risk factors of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2
- Peer-reviewed publication: Zwiers, L et al.- Clinical Course, Outcomes, and Risk Factors of Myocarditis and Pericarditis Following Administration of mRNA-1273 Vaccination: A Protocol for a Federated Real-World Evidence Vaccine Safety Study Using Data from Five European Data Sources
- Presentations at ISPE Annual Meeting:
  - Risk factors for myocarditis/pericarditis following mRNA-1273 vaccination: interim analysis of a VAC4EU case-cohort study
  - Clinical course and outcomes of myocarditis/pericarditis cases following mRNA-1273 vaccination compared to cases not following COVID-19 vaccination: interim analysis of a VAC4EU cohort study

READ THE PUBLICATION

Pfizer/BioNTech Comirnaty® PASS

FINAL REPORT AVAILABLE

Members

UMCU, RTI-HS, Teamit, ARS, HSD, DSRU, IDIAP JGol, PHARMO, Penta, IACS, UIO, Medicom

Data sources

CPRD, SIDIAP, PHARMO, Pedianet, EpiChron, Norwegian registries

Protocol

Post-conditional approval active surveillance study among individuals in Europe receiving the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine

About

The primary aim of this study is to determine whether there is an increased risk of select adverse events of special interest (AESI) after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine.

Progress in 2025

- → Submission of the Final Report
- → Submission of protocol Amendment V8.0
- → Submission of SAP Amendment V6.0
- → Study finalised

Results

- → The final report follows a retrospective cohort design using data from 6 European electronic health record data sources in 5 countries, covering 11,496,929 recipients vaccinated with ≥1 dose of Comirnaty and matched 1:1 with unvaccinated on age, sex and other demographic and clinical factors.
- → Results are expressed as pooled HR (95% CI) from the 6 data sources. Prior AESIs identified as risks in risk management plans were myocarditis (1.32; 0.74–2.34) and anaphylaxis (2.52; 0.27–23.28). AESIs identified as signals and discussed by PRAC were idiopathic thrombocytopenia (0.77; 0.50–1.17), thrombosis with thrombocytopenia syndrome (1.24; 0.44–3.46), myositis (1.05; 0.86–1.29), erythema multiforme (0.87; 0.35–2.14), glomerulonephritis (0.92; 0.62–1.38), hypermenorrhoea (1.24; 1.02–1.51), secondary amenorrhoea (1.14; 0.90–1.44), and multisystem inflammatory syndrome (1.11; 0.42–2.96). Other events reported in the literature included acute cardiovascular injury (1.22; 1.04–1.42), arrhythmia (1.22; 1.05–1.42), heart failure (1.01; 0.73–1.38), stress cardiomyopathy (1.23; 0.77–1.96), coronary artery disease (1.14; 0.87–1.50), coagulation disorders (0.85; 0.76–0.95), cerebral venous sinus thrombosis (0.74; 0.06–8.83), single organ cutaneous vasculitis (0.82; 0.03–2.25), and subacute thyroiditis (1.89; 1.20–2.96).
- → There was no increased risk for most AESIs. Confidence intervals for hypermenorrhoea, acute cardiovascular injury, arrhythmia and subacute thyroiditis were compatible with increased risk. Effect estimates on myocarditis and anaphylaxis were concordant with prior studies. For the cardiovascular AESIs with 365-day risk windows (arrhythmia, acute cardiovascular injury, small elevations in HR) seem to be due to selective censoring due to unvaccinated individuals being vaccinated, and unique unvaccinated individuals remaining in the cohort for the entire follow-up.

Read more

- Final report abstract - Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

READ THE ABSTRACT OF THE FINAL REPORT

Pfizer/BioNTech Comirnaty® myocarditis and pericarditis study

FINAL REPORT AVAILABLE

Members

UMCU, Penta, RTI-HS, DSRU, IACS, IDIAP JGol, ARS, HSD, Penta, UIO, PHARMO, Medicom

Data sources

CPRD, SIDIAP, PHARMO, Pedianet, EpiChron, Norwegian registries

Protocol

Post-authorisation active surveillance study of myocarditis and pericarditis among individuals in Europe receiving the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine

About

The aim of this study is to characterise the clinical course of myocarditis and/or pericarditis diagnosed after receiving the Pfizer-BioNTech COVID-19 vaccine

Progress in 2025

- → Submission of the final report and approval by regulators.
- → Submission of protocol Amendment V5.0
- → Submission of SAP Amendment V4.0
- → Study finalised and approved
- → 2 manuscripts drafted

Results

- → A retrospective multi-database cohort study was conducted using electronic healthcare data from six databases covering 34.5 million individuals between December 2020 and July 2023 following Comirnaty vaccination. Among 3,142 myocarditis and 5,966 pericarditis cases identified, vaccinated cases were generally older and had a higher comorbidity burden.
- → Hospitalisations clustered around the time of diagnosis, with little increase in cumulative risk after 3 months. 12-month first incident heart failure risks ranged from adjHR: 0.51 [0.24–1.07] to 0.92 [0.64–1.32]) for myocarditis and adjHR: 0.21 [0.03–1.36] to 1.18 [0.92–1.52] for pericarditis. Twelve-months crude cumulative risks of cardiogenic shock, fulminant myocarditis, constrictive pericarditis, recurrent and chronic myocarditis or pericarditis were low in both vaccinated and unvaccinated cases. Adjusted 12-month mortality did not differ substantially between vaccinated and unvaccinated cases. Treatment patterns were similar by vaccination status and frequency of heart transplantation, pacemaker or defibrillator implantation, pericardiocentesis, and pericardiectomy, was rare (<2%).
- → These findings support a favourable long-term prognosis for myocarditis and pericarditis following Comirnaty vaccination. Longer follow-up beyond one year may be warranted to better characterise delayed recovery, persistent heart failure, and arrhythmias that require advanced cardiac interventions, which may not have been fully captured due to limited follow-up.

Read more

- Final report - Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

READ THE FINAL REPORT

HIPRA BIMERVAX® PASS

ONGOING

Members

RTI-HS, ARS, IDIAP JGol, FISABIO, IACS

Data sources

SIDIAP, VID, EpiChron

Protocol

VAC4EU Postauthorisation Safety Study of BIMERVAX® vaccine in Europe

About

This study aims to evaluate the risk and risk differences of pre-specified AESIs comparing recipients of BIMERVAX with recipients of other coronavirus disease 2019 (COVID-19) vaccines with the same indication.

Progress in 2025

- → Study team established and contracts executed
- → Study registered in the HMA-EMA Catalogue
- → Kickoff meeting performed on 9 December 2025
- → Data management tasks ongoing for LOC, Co-PI and DEAPs study teams, in preparation for first data extraction planned to occur during Q3-Q4 2026

Results

Interim report 1 results planned to be available by Q3 2027.

HIPRA BIMERVAX® PAES

ONGOING

Members

RTI-HS, ARS, IDIAP JGol, FISABIO, IACS

Data sources

SIDIAP, VID, EpiChron

Protocol

VAC4EU Postauthorisation Effectiveness Study of BIMERVAX® Vaccine in Europe

About

This study aims to evaluate the risk of COVID-19–related outcomes after vaccination with BIMERVAX compared with vaccination with other COVID-19 vaccines for the same indication.

Progress in 2025

- → Study team established and contracts executed
- → Study registered in the HMA-EMA Catalogue
- → Kickoff meeting performed on 9 December 2025
- → Data management tasks ongoing for LOC, Co-PI and DEAPs study teams, in preparation to first data extraction planned to occur during Q3-Q4 2026

Results

Interim report results planned to be available by Q3 2027.

Pfizer/BioNTech Comirnaty® bivalent PASS

ONGOING

Members

UMCU, RTI-HS, Teamit, Pedianet, PHARMO, IDIAPJGol, DSRU, IACS, UIO, MediCom

Protocol

Post-Authorisation Safety Study of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in Europe

Data sources

Pedianet, PHARMO, SIDIAP, CPRD, EpiChron, Norwegian registries

Protocol

Post-Authorisation Safety Study of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in Europe

About

The aim of this study is to determine whether there is an increased risk of pre-specified adverse events of special interest (AESIs) in individuals exposed to Comirnaty Original/Omicron BA.1 (bivalent BA.1) or Comirnaty Original/Omicron BA.4-5 (bivalent BA.4-5), either as primovaccination or as a booster, compared with unexposed individuals with comparable vaccination history.

Progress in 2025

- → Submission of Interim Report 1
- → Submission of protocol V4.0 and approval by regulators
- → Submission of SAP V3.0 and approval by regulators
- → ETLing done, LCs 1 and 2 approved and signatures in place for Final Report
- → Pipelines being created and QCed for Final Report

Results

For the interim report, a matched cohort using electronic healthcare records from Pedianet (IT), NHR (NO), and SIDIAP (ES) from September 2022 to June 2024 was created.

Overall, 855,178 exposed individuals were matched 1:1 to unvaccinated individuals based on vaccination history, age, sex, and other demographic and clinical factors (Pedianet: 31, NHR: 155,033, SIDIAP: 700,114). Median age in years was 13 in Pedianet, 69 in NHR, and 71 in SIDIAP. No AESIs occurred in Pedianet. Event rates for AESIs were low with wide 95% CIs in NHR and SIDIAP. Arrhythmia was the most frequently observed AESI: the aHR was 0.94 (95% CI: 0.86–1.03) in NHR and 1.02 (95% CI: 0.99–1.06) in SIDIAP. Guillain–Barré syndrome was rare but observed in NHR, with an aHR of 4.25 (95% CI: 0.47–38.30) and 1.33 (95% CI: 0.37–4.86) in SIDIAP. Acute respiratory distress syndrome showed an aHR of 2.73 (95% CI: 0.53–14.05) in NHR and 1.56 (95% CI: 0.95–2.57) in SIDIAP. Other AESIs with aHR > 2 included myositis and myocarditis or pericarditis (1–21 days risk window). As a conclusion, this analysis did not show an increased risk for any AESIs. Short follow-up in NHR (<4 months) restricted AESIs estimates with longer risk window. Results from the final study report will include additional data from Pedianet, NHR, SIDIAP and three other databases (PHARMO [NL], EpiChron [ES], and CPRD Aurum [UK]), analyses of the pregnancy cohort and other subpopulations, SCRI, sensitivity analyses, pooled estimates, and validated AESIs, thus providing more comprehensive evidence for the safety of bivalent vaccines.

Pfizer ABRYSVO® PASS (hepatically and renally impaired older adults)

ONGOING

Members

UMCU, Analysis Group, BPE, DSRU, FISABIO, IACS, IDIAP-JGol, Penta

Data sources

CPRD, EpiChron, SIDIAP, SNDSVID

Protocol

A post-authorisation safety study of ABRYSVO in immunocompromised, or renally or hepatically impaired adults aged 60 years and older in a real world setting in Europe and UK

About

The primary objective of the study is to estimate the incidence rates and rate ratios of safety events of interest in immunocompromised or renally or hepatically impaired adults aged 60 years and older who receive ABRYSVO compared to a relevant comparator group who does not receive ABRYSVO (evaluated as separate populations and if appropriate, as a combined population).

Progress in 2025

- → The project commenced in June
- → Submission of Progress Report 2025 to regulators in September
- → Data collection started in October
- → Ethic approvals obtained for all data sources in July

Results

The Progress Report submitted to the EMA in September 2025 highlighted that although ABRYSVO vaccine has been approved for use in older adults across the EU and UK by the regulators, the status of vaccine reimbursement and access for older adults varies between countries. Data on ABRYSVO uptake are not yet available in France and Spain. In France the reimbursement of RSV vaccines for older adults has been put on hold, and in 3 regions in Spain another RSV vaccine has been introduced in the vaccination programme. In England (CPRD Aurum), where the ABRYSVO vaccine is reimbursed by NHS: approximately 340,000 immunocompromised individuals are eligible, with 2,800 vaccinated with ABRYSVO; 171,000 renally impaired eligible, with 1,616 vaccinated; 26,000 hepatically impaired eligible, with 135 vaccinated.

These findings indicate that data on ABRYSVO uptake in the target populations are available in the CPRD. This data source will be used as the source for the data analysis in the interim report. Efforts will also prioritise the inclusion of additional DEAPs across Europe and beyond to enhance coverage and extend generalisability. Scotland is in process of being onboarded to the VAC4EU infrastructure and will be able to provide data for the final study report in 2029. Switzerland, Germany, Poland and Slovenia have been assessed to explore their potential participation, however, due to limited vaccine availability, reimbursement status and limited access to vaccine brands, these countries are being closely monitored for future study participation. Other countries will be explored and monitored throughout 2026.

Read more

- Progress report 1 - A Post-authorization Safety Study of ABRYSVO in Immunocompromised, or Renally or Hepatically Impaired Adults Aged 60 Years and Older in a Realworld Setting in Europe and the UK

Pfizer ABRYSVO® PASS (pregnancy)

ONGOING

Members

UMCU, Teamit, ARS, JC, IDIAP-JGol, UiO, AU, PHARMO, BPE, DSRU, FISABIO, IACS

Data sources

SIDIAP, NHR, DHR, PHARMO, SNDS, CPRD, VID, EpiChron

Protocol

A Post-Authorisation Safety Study(PASS) of ABRYSVO (Respiratory Syncytial Virus Stabilised Prefusion Subunit Vaccine)in Pregnant Women and their Offspring in a Real World Setting in Europe and UK

About

The purpose of this study is to assess the safety profile of the Pfizer RSV vaccine in women who receive the vaccine during pregnancy and their offspring.

Progress in 2025

- → Submission of Progress Report 1 to regulators in June
- → Updated Progress Report 1 on September 2025
- → Submission of Progress Report 2 to regulators in December
- → Submission of Protocol Amendment (Version 3.0) in December

Results

Progress Report 2 submitted to regulators in December highlighted that national public health guidelines recommend maternal ABRYSVO vaccination at 28 weeks to the end of pregnancy in the UK, at 32 weeks seasonally in Denmark, and 32-36 weeks in France. By early 2025, only France and the UK recommended and reimbursed ABRYSVO; Denmark and Norway recommended it at the end of 2025, while Spain and Netherlands have prioritised neonatal monoclonals. In the UK, among 130,752 pregnancies that reached > 24 weeks of gestation between 23 August 2023 and 19 December 2024, 10,709 received ABRYSVO. Most vaccinations occurred in Q3-Q4 2024, mainly between 24-36 weeks' gestation (65.78%), with sizable use after 36 weeks (21.16%). Denmark and Norway showed out-of-pocket uptake in late 2024 (1.3% and 1.6%). After the start of the free-of-charge programme on 1 October 2025 in Denmark, uptake among women at > 30 weeks' gestation was 29.9%. Uptake in France was around 6.9% in 2024. No exposure was identified in PHARMO, SIDIAP, and VID. In Epichron exposure from private market use could not be estimated.

Read more

- Progress report 1 - A Post-Authorisation Safety Study (PASS) of ABRYSVO (Respiratory Syncytial Virus Stabilised Prefusion Subunit Vaccine) in Pregnant Women and their Offspring in a Real World Setting in Europe and UK

Pfizer ABRYSVO® PASS (GBS in pregnancy)

ONGOING

Study led by HPHCI in collaboration with VAC4EU

Members

UMCU, Teamit, JC, UiO, AU, BPE, DSRU, FISABIO

Data sources

NHR, DHR, SNDS, CPRD, VID

Protocol

A Post-Marketing Study to Evaluate the Safety of ABRYSVO™ on the Risk of Guillain-Barré Syndrome (GBS) in Pregnancy

About

The purpose of this study is to assess the epidemiology and natural history of GBS during pregnancy and the postpartum period and the risk of GBS after exposure to ABRYSVO during pregnancy.

Progress in 2025

- → Kick-off meeting
- → Submission of Protocol to regulators in November
- → Writing of SAP

Results

Start of data collection expected June 2028 and first report (GBS Natural History Final report) expected June 2029.

Safety of Paxlovid During Pregnancy

ONGOING

In collaboration with SIGMA

Members

RTI-HS, BPE University, IDIAP JGol, UMCU, ARS

Data sources

SNDS (France), SIDIAP (Spain), CPRD (UK)

Protocol

Use and Safety of Paxlovid During Pregnancy

About

This post authorisation safety study conducted within the SIGMA Consortium aims to evaluate the prevalence and comparative safety of adverse pregnancy, offspring, and maternal outcomes following Paxlovid exposure during pregnancy. Using descriptive and comparative analyses of secondary European electronic health record and claims data, outcomes among Paxlovid exposed pregnancies are compared with those exposed to molnupiravir, where available, and with COVID 19–affected pregnancies unexposed to antiviral treatment.

Progress in 2025

- → Poster presented in the ISPE Annual Meeting in August 2025
- → Submission of Interim report 2 to the EMA in December 2025
- → Programming for the final report

Results

The following was presented in the 2025 ISPE Annual Meeting:

- → Very few Paxlovid exposed pregnancies were identified during the study period, with five eligible pregnancies observed in SIDIAP, of which four were ongoing and one resulted in a spontaneous preterm delivery.
- → In CPRD, no pregnancies were exposed to Paxlovid; one pregnancy was exposed to molnupiravir and had an unknown outcome, and no additional primary or exploratory outcomes were observed.
- → In France, Paxlovid use was common in the general population but pregnancy specific exposure could not be assessed.

The limited number of exposed pregnancies was consistent with existing literature and product label recommendations, and future analyses will include longer follow up and individual level data from France.

- → Interim Report 2
- → ISPE 2025 Poster & Presentation

Read more

- Presentation at ISPE Annual Meeting - Preliminary results from a European post authorisation study to assess the safety of Paxlovid in pregnancy
- Interim report 2 - Use and safety of Paxlovid during pregnancy (C4671037)

Safety of Paxlovid Among Patients with Moderate or Severe Hepatic or Renal Impairment

ONGOING

In collaboration with SIGMA

Members

RTI-HS, BPE, IDIAP JGol, UMCU, ARS

Data sources

SNDS, SIDIAP, CPRD

Protocol

Safety of Paxlovid Among Patients with Moderate or Severe Hepatic or Renal Impairment

About

This post authorisation safety study conducted within the SIGMA Consortium is designed to evaluate the comparative safety of Paxlovid in patients with moderate or severe hepatic or renal impairment. Using descriptive and comparative analyses of secondary European electronic health record and claims data, the study compares the incidence of predefined clinical outcomes among Paxlovid exposed patients with those treated with molnupiravir, where available, and with high risk COVID 19 patients unexposed to antiviral therapy.

Progress in 2025

- → Poster presented to the ISPE annual conference on August 2025
- → Submission of Interim Report 2 to the EMA on December 2025
- → Programming for the Final Report

Results

The following was presented in the 2025 ISPE Annual Meeting

- → The number of Paxlovid exposed patients with moderate or severe hepatic or renal impairment was low across data sources.
- → In SIDIAP, hepatic transaminase elevations were observed in 1 of 35 patients with hepatic impairment, while among patients with renal impairment, post exposure events included headache and hypertension, the latter largely reflecting prevalent conditions.
- → In CPRD, no Paxlovid users with hepatic impairment were identified, and few post exposure events were observed among patients with renal impairment.

Most data driven outcomes were related to COVID 19 associated conditions, and overall findings were consistent with limited Paxlovid use during the observation period.

Read more

- ISPE Annual Meeting presentation - Preliminary results from a European post authorisation study to assess the safety of Paxlovid among patients with moderate or severe hepatic or renal impairment
- Interim report 2 - Use and safety of Paxlovid among patients with moderate or severe hepatic or renal impairment (C4671047)

FLOW

ONGOING

Members

UMCU

About

This project was awarded by an open competition from VAC4EU (top down). It aims to review available phenotype libraries and design tools for implementation of a VAC4EU phenotype library.

The Phenotype Representation Model project (PRM) offers its users to handle the creation, visualisation, analysis and, storage of phenotype libraries using a graphical user-friendly approach.

In the context of electronic health records (EHRs), a “phenotype”, is a clinical condition or characteristic that can be ascertained by means of a computerised query to an EHR system or clinical data repository using a defined set of data elements and logical expressions.

PRM aims to become an important tool for researchers that want to investigate and model the interactions of phenotypes in the data to quickly validate, exchange and safely reuse their algorithms, hopefully improving collaboration and increased efficiency.

PRM is open-source project and compatible to execute the T2 step of the ConcePTION pipeline on multiple Common Data Models (CDMs, OMOP, CDISC, FIHR, ConcePTION, Sentinel) based on the CDM-agnostic computable phenotype libraries that are compliant with VAC4EU guidelines for scripting.

PRM use a FAIR approach to data management to improve scientific research.

Progress in 2025

- → The final report was submitted and reviewed
- → The code associated with FLOW was reviewed, assessed and it is ready for further development

Results

The VAC4EU FLOW application is a developing tool designed to support the creation, visualisation, analysis, and storage of computable phenotypes using a user friendly graphical environment. FLOW enables researchers to model complex clinical phenotypes derived from electronic health records through structured logic, code collections, temporal rules, and algorithmic operations.

- → Integration of FAIR principles for improved scientific reproducibility and data governance.
- → Compatibility with multiple Common Data Models, including OMOP, CDISC, FHIR, ConcePTION, and Sentinel, enabling CDM agnostic phenotype execution.
- → Addition of a visual Algorithm Designer, allowing researchers to build and save phenotype logic diagrams using boolean rules, temporal constraints, and nested logic.
- → Provision of R based tools for converting CSV files to SQLite to ensure proper processing within the application.
- → Development of a complete technical stack, including a React/TypeScript front end, Node.js/Prisma back end, and SQLite support for offline data handling.

SeValid

ONGOING

Members

ARS, UNIFI, UMCU, VAC4EU

Data sources

Administrative health records of Careggi Hospital, Florence, Italy

About

This study aims to test a novel methodology to assess the validity of algorithms used to identify cases of myocarditis and deep vein thrombosis in administrative healthcare records. Notably, SeValid introduces an innovative approach by estimating the sensitivity of a 'narrow' phenotype through the positive predictive value of a 'screening' phenotype. To achieve this, the study follows a two-step approach. First, it develops screening phenotypes for both conditions. Secondly, it validates cases identified by both narrow and screening phenotype using both human review and a large language model and compares their assessments against a defined gold standard to evaluate the potential of LLMs as tools to support case validation studies. Validation is conducted through a structured questionnaire based on the Brighton Collaboration definition of myocarditis.

Progress in 2025

- Creation of a sensitive screening phenotype for myocarditis based on structured clinician interviews
- Design and operationalise a hybrid validation approach, combining human and LLM-based medical chart review for myocarditis cases identified by both narrow and screening phenotype

Results

Based on the output of clinician interviews three main potential reasons for misclassification of myocarditis have been identified:

- Overlapping clinical presentations
- Diagnostic prioritisation of more severe conditions
- Administrative/coding practices

A hybrid validation approach (human and LLM) has been successfully implemented and used within the framework of narrow myocarditis case validation.

The procedure for LLM-based validation of myocarditis cases identified through a screening phenotype has been established. This includes: i) creation of dummy cases in both English and Italian for model training, ii) LLM performance evaluation based on dummy cases these cases by testing different prompt formulations and conducting multiple runs per model to assess reproducibility.

Read more

- ISPE 2025 Annual Meeting presentation: An experiment from SeValid: Integration of Artificial Intelligence in the Clinical Validation Pipeline of the VACcine Monitoring Collaboration for Europe (VAC4EU)
- The SeValid project introduction

CoMaSy

ONGOING

Members

ARS, UMCU, RTI, JC

About

This study aims to develop open-source software that facilitates the creation and iterative revision of codebooks and can generate Directed Acyclic Graphs (DAGs) to showcase data processing pipelines. The tool will be used for study teams in VAC4EU and similar organisations to enhance their workflow efficiency and capacity in following programming guidelines.

The development of the software is a 'Bottom up' initiative of the ExBo and was included as a priority investment in the Strategy Meeting of October 2024.

Progress in 2025

- Secured funding for 30K + 5K for dissemination
- Piloted the process of codebook development and use in the PAXLOVID & RSV studies
- Completed publication of 2 open source repositories of EMA studies
- VAC4EU Course on Codebooks development started
- Outline for the manuscript developed and presented
- Regular update to the Methods WG and Monthly ExBo WG Feedback session
- Interviewed a software company interested to develop the product, signed a Non Disclosure Agreement

Collaboration with the EU PE&PV Research Network

LEARN MORE ABOUT THE EUPE&PV RESEARCH NETWORK

VAC4EU has been a close collaborator with the EU PE&PV Research Network (EU PE&PV) since 2020. The EU PE&PV Research Network is a public academic partnership coordinated by the Division of Pharmacoepidemiology & Clinical Pharmacology at the Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University. Since its inception in 2015, this network has completed 13 projects spanning various therapeutic areas.

VAC4EU has contributed to three EU PE&PV-led projects in 2025, each funded by the European Medicines Agency.

EU PE&PV RESEARCH NETWORK

The SAFETY-VAC Project: Framework for the post-authorisation SAFETY Evaluation of VACcines in the EU

The primary aim of this project was to assess capacity and fitness for purpose to conduct vaccine safety studies with RWD sources from both networks. Additionally, the team aimed to create operational phenotypes to estimate the background and cumulative incidence of the flares of 10 pre-defined autoimmune diseases and identify immunocompromised populations in the RWD sources, while also analysing the contribution of different provenances of data. Both studies employ a retrospective, multi-database, population-based cohort design using data from 2017 up to the most recent updates.

VAC4EU members

UMCU, Aarhus, IDIAP JGol, BPE, IACS, ARS, FISABIO, AEMPS, UIO, Teamit, Pedianet

VAC4EU contribution in 2025

In collaboration with the EU PE&PV Research Network, VAC4EU members contributed to all three studies including design, execution, and finalisation. Additionally, our members have been involved in the preparation of manuscripts as well as presenting results at events.

Study 1. Network of data sources for vaccine safety evaluation

This study aims to provide and describe a network of real-world data sources to evaluate vaccine safety signals and to assess its fitness for the purpose of conducting vaccine safety studies.

The published study report describes the content of 9 data instances from 6 countries that were available at the time of the contract signature (February 15, 2024). Seven RWD sources from 5 countries produced the requested results (attrition, prevalence of covariates, coverage of selected vaccines, and incidence and prevalence rates of 39 outcomes). This fitness-for-purpose assessment was performed on available data instances based on datasets originally extracted and used for previous COVID-19 vaccine research. Up-to-date data instances and a new fitness for purpose assessment will be conducted for 10 RWD sources across seven EEA countries and published in a manuscript. For a new study, the time to analyse and produce results based on new data instances within the SAFETY-VAC study framework is 3 to 6 months depending on the data source and the specific design and data requirements.

Study 2. Immunocompromised populations

This study aims to provide a consolidated approach to identify and characterise immunocompromised populations in RWD sources and to produce incidence and prevalence rates for these populations using electronic healthcare records databases.

Definitions of immunocompromised status varied widely, with studies combining diagnostic codes, free text terms and medication records. From 56 studies, the authors consolidated these elements into seven categories covering genetic conditions, infections, malignancies, transplants, other high risk conditions, immunosuppressive medicines and autoimmune diseases requiring treatment. These inputs informed a modular operational phenotype using diagnoses, drug exposure windows and selected tests, designed to be both specific, applicable, and adaptable across EHR systems. This work delivers the first integrated, scalable benchmark for identifying immunocompromised populations in real world research.

READ THE REPORT

Study 3. Background rates of pre-existing chronic diseases

This study aims to assess the feasibility of participating European data sources in estimating the background and cumulative incidence of 10 selected autoimmune disease flares.

Clinical definitions and operational phenotypes for flares of 10 autoimmune diseases have created and background and cumulative incidence calculated across participating RWD sources. Rates were consistently high across all ten diseases, though absolute values varied widely by condition and data source. First flares were always the most frequent, with rates dropping for second and third episodes. Most flares were detected via new medication use, which may slightly overestimate incidence. Cohort demographics matched known epidemiology, and pregnancy-specific flare estimates were possible but based on very small numbers. The study establishes the first large-scale real world benchmarks for background flare rates to support future vaccine safety evaluation.

READ THE REPORT

CoVE Project: COVID-19 Vaccines Effectiveness

A new peer-review publication in collaboration with EU PE&PV Research Network and led by AEMPS was accepted:

- Impact and Effectiveness of COVID-19 mRNA Vaccination Against COVID-19 Hospitalisation in Paediatrics: A Cohort Study Using Two Linked Data Sources in Spain. Castillo-Cano et al. Pharmacoepidemiology & Drug Safety. October 2025.

READ THE REPORT

CVM Project: COVID-19 Vaccine Monitor

Two peer-reviewed publications in collaboration with EU PE&PV Research Network were published in 2025:

- Cohort event monitoring of booster COVID-19 vaccine safety using patient-reported outcomes in pregnant women. Maisonneuve et al. Drug Saf. Regulation., December 2025.
- Applying two approaches to detect unmeasured confounding due to time-varying variables in a self-controlled risk interval design evaluating COVID-19 vaccine safety signals, using myocarditis as a case example. Bots et al. American Journal of Epidemiology. January 2025.

Collaborations

In addition to its 29 member organisations, VAC4EU maintains active collaboration with several other networks and institutions. These partnerships, strengthened in 2025 through the concerted efforts of Pillar 1 of the Executive Board, the Communication Team and the new Business Development team, have enabled the expansion of existing alliances and the exploration of new opportunities.

Active Citizen Network (ACN)

Active Citizen Network (ACN) is the European and international branch of the Italian civic participation organisation Cittadinanzattiva. It acts as a flexible network of European civic organisations, encouraging citizen participation in European policy-making.

The collaboration between VAC4EU and ACN seeks to combine VAC4EU's scientific expertise with ACN's citizen outreach.

Progress

- Engaged with ACN at the Patient Engagement Forum meeting in June and at 5th Anniversary Symposium
- Set plans for 2026, including participation in citizen engagement workshops at the EU Parliament in Brussels

ECRAID

Ecraid is a European network of clinical, primary care and laboratory sites with the goal of advancing clinical research in the field of infectious disease. There is strong potential in a collaboration with Ecraid, by combining VAC4EU's expertise in the secondary use of RWD and advanced methodologies with Ecraid's strength in clinical research and trial infrastructure.

Progress

- Ongoing discussion and planning on how to combine respective expertise of the networks to support pragmatic trial design

European Patients' Academy on Therapeutic Innovation (EUPATI)

EUPATI aims to empower partnerships between patients and researchers through provision of accessible, well-structured, and reliable education about the lifecycle of medicines research and development and upskilling professionals on meaningful patient involvement. Like VAC4EU, EUPATI was initially launched as an IMI project but is now an independent non-profit organisation.

VAC4EU launched its partnership with EUPATI to explore involvement of patients in vaccine research with a focus on vaccine post-authorisation safety and effectiveness studies.

Progress

- Participated in two co-creation workshops at the Patient Engagement Forum

The International Network of Special Immunization Services (INSIS)

INSIS is an international research consortium hosted through the University of Alberta combining clinical and systems biology approaches to investigate rare adverse events of special interest detected after vaccination, with a focus on understanding the molecular signatures and mechanisms underlying these events.

VAC4EU's collaboration with INSIS supports knowledge sharing on vaccine safety, pharmacoepidemiology and real-world evidence, including discussion of statistical and epidemiological methods, scientific outputs, research opportunities and areas of mutual interest.

Progress

- Maintained active collaboration following the signing of the Memorandum of Understanding in April 2024
- Preparations for in-person meeting in Bologna to explore shared scientific interests and future opportunities

The Global Vaccine Data Network (GVDN)

GVDN is a multinational, investigator-led network evaluating safety concerns through analysis and evaluation of large clinical databases, focussing on rare events, while also evaluating effectiveness and coordinating responses to other vaccine-related issues such as vaccine hesitancy.

VAC4EU is an active member of the GVDN and collaborates with them on studies.

Progress

- Active contribution to the GCoVS project

The SIGMA Consortium

SIGMA is a network of research sites that provides trusted pharmacoepidemiologic and real-world evidence from real-world data, delivered through a federated professional network following the ENCePP Code of Conduct. The consortium acts as a hub for the design, contracting, execution, delivery and interpretation of European pharmacoepidemiology and real-world evidence studies, including pre-approval and post-marketing medication use, safety and effectiveness studies.

VAC4EU's collaboration with SIGMA supports shared work on pharmacoepidemiology and real-world evidence studies, including knowledge sharing, methodological alignment and the development of shared expertise, information and tools.

Progress

- Continued collaboration through the Paxlovid studies

SPEAC

SPEAC is a project initiated by the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration in 2019. The project aims to enhance safety of vaccine studies and vaccine safety expertise through development of standards, tools and vaccine safety templates, methodological support and support for active safety surveillance by CEPI sites.

VAC4EU is collaborating with SPEAC in the development and refinement of standards and clinical definitions for vaccine safety studies.

Progress

- Work towards a joint publication detailing how case definitons can be used in a RWE context

5 years of VAC4EU

From ADVANCE to VAC4EU

The need for better integration of electronic health records and surveillance systems was highlighted during the 2010 H1N1 pandemic, when scientists from across Europe called for an improved approach to post-authorisation vaccine evaluation. The IMI project ADVANCE (2013-2018) brought together public health institutions, universities, regulators and vaccine manufacturers to create a collaborative platform for vaccine monitoring across Europe.

In 2019, VAC4EU was established as ADVANCE's sustainability solution to provide real-world evidence on vaccine safety and effectiveness. The founders created governance, operational principles, and a legal framework. The organisation became operational in 2020, just in time for another pandemic...

5th Anniversary Celebration

Celebrating 5 years of VAC4EU

In 2025, VAC4EU celebrated its fifth anniversary and established role in the vaccine safety and effective landscape across Europe via contribution to key evidence on the effects of COVID-19 vaccines and continuous innovation of RWE infrastructure in Europe. We marked the occasion with a symposium, "Celebrating 5 Years of VAC4EU: Advancing Real-World Evidence for Vaccine Monitoring Towards Future Pandemic Preparedness" at the Royal Academies for Science and the Arts of Belgium in Brussels on 4 November 2025. The hybrid event welcomed 150 participants, including members, regulators, the EMA and IHI colleagues, industry representatives, and other stakeholders.

Check out our website for the full agenda, a gallery of photos, and recordings from each session!

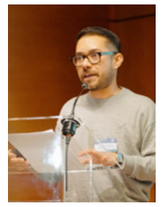
Insights from the symposium

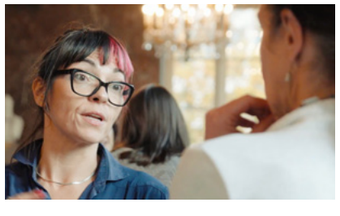
Opening reflections by the founders highlighted the significance of the venue, which hosted the ADVANCE Closing Event. The keynote lecture by Heidi Larson (The Vaccine Confidence Project) addressed the challenge of building trust in vaccines amid widespread misinformation. Panel discussions featured representatives from the EMA, Pfizer, RTI Health Solutions and The Vaccine Confidence Project. Panels explored the importance of timely evidence generation, the value of primary data collection, and the need for effective communication and citizen engagement. A recurring theme was the challenge of communicating scientific evidence with appropriate nuance, while maintaining transparency and fostering public trust.

Discussions focused on real-world evidence in low- to middle-income countries, the necessity of international collaboration, and the implications of forthcoming EHDS legislation. The expertise of VAC4EU's Data Expert & Access Partners was identified as a unique strength. Closing remarks from the EMA and VAC4EU Board underscored the network's contributions to pandemic preparedness, methodological innovation, and the ecosystem of trust in vaccine safety science.

Looking ahead

VAC4EU's five-year journey highlighted the critical role of transparent and proactive communication, the importance of patient and citizen engagement, and the ongoing need to adapt to an evolving technological and regulatory landscape. VAC4EU remains committed to advancing vaccine safety, improving data timeliness, and serving as a centre for evidence generation and communication.





VAC4EU in the ecosystem

VAC4EU has attended a variety of conferences, symposia, debates, workshops and other events, covering broad topics within the VAC4EU remit from patient and citizen engagement to the implications of AI adoption in real-world evidence research. Members have presented their work or represented VAC4EU in 11 different events throughout 2025.

Multi Stakeholder Workshop on RWD in Regulatory/HTA Decision Making

6 February, Bonn, Germany

The workshop brought together EU-funded Horizon projects and regulators to discuss the use of real-world data in regulatory and HTA decision-making. VAC4EU as invited to attend. Rosa Gini (ARS) participated in a workshop:

→ Collaboration opportunities and results from 6 Horizon Europe–funded projects

World Vaccine Congress Washington 2025

23 April, Washington DC, USA

The WVC is a major global vaccinology congress featuring scientific sessions, regulatory discussions, and industry showcases. Martín Solórzano and Felipe Villalobos (IDIAPJGol) presented work from within the network:

→ Integrating SIDIAP Health Database into the ConCEPTION CDM

FAIB Lunch Debate: Cross Border Mobility of Associations

24 April, Brussels, Belgium

This session was a policy debate focused on the legal implications and opportunities for NGOs and research organisations operating across European borders. Patrick Mahy (VAC4EU Financial Officer) attended to follow legal developments affecting nonprofits like VAC4EU.

Patient Engagement Open Forum

11 June, Baveno, Italy

This event is an engagement focused meeting discussing patient involvement in health research and development. VAC4EU contributed as vaccine and RWE expert, with Daniel Weibel (Secretary General) participating in the following workshop:

→ Vaccine development and awareness powered by patients and patient communities

The event was primarily focussed on the importance of informing and educating patient representatives on RWD and RWE applications to augment existing knowledge from clinical evidence.

International Society for Pharmacoepidemiology (ISPE) 41st Annual Meeting 2025

22–26 August, Washington, DC, USA

The ISPE Annual Meeting (formerly known as ICPE) is the world's leading pharmacoepidemiology conference. VAC4EU had a major presence with an exhibition booth as well as 14 presentations. Results presented at the event focussed primarily on case validation and results from PAS studies:

→ Monitoring safety of mRNA 1273 vaccine in pregnancy (Moderna PASS)
→ Pfizer Comirnaty PASS interim results
→ Janssen (JCOVDEN) diagnostic accuracy & safety
→ AZD1222 TTS post authorisation safety analysis
→ Paxlovid safety studies (general & pregnancy)
→ SeValid AI driven signal detection / outcome validation
→ Myocarditis/pericarditis risk factors & outcomes (Moderna)
→ Multiple GCoVS, SAFETY VAC, and CVM network presentations

VAC4EU demonstrated its key role in pharmacoepidemiology work worldwide via participation in a wide range of pharmacovigilance studies across the ecosystem. The booth served as a central location for the 16 VAC4EU member organisations who were present at the conference.

Annual Summit of the Spanish Society of Pharmacovigilance

5 September, Gran Canaria, Spain

This summit was a Spanish pharmacoepidemiology and pharmacovigilance meeting. Martín Solórzano (IDIAP JGol) presented work from the SAFETY VAC project:

→ Enhancing Vaccine Safety: Developing Case Definitions to Improve Detection of Disease Flare Ups

Martín's presentation highlighted how the SAFETY-VAC team designed and validated operational algorithms across heterogenous RWD sources to improve detection of autoimmune flare-ups.

ISPE LATAM 2025
10 October, São Paulo, Brazil

ISPE LATAM is the Latin American regional congress of ISPE, the leading pharmacoepidemiological association. Martín Solórzano (IDIAP JGol) presented work from the SAFETY VAC project:

→ Autoimmune Disease Flares in Europe (SAFETY VAC)

World Vaccine Congress Europe 2025
13 October, Amsterdam, The Netherlands

WVC Europe is part of the world's leading vaccine conference, bringing together regulators, manufacturers, academics, and more. VAC4EU led and contributed to multiple workshops on AI, signal detection, epidemiological methods, and data quality with Executive Board members Debabrata Roy (DSRU), Miriam Sturkenboom (UMCU) and Rosa Gini (ARS):

→ Advanced AI Driven Signal Detection
→ One Size Doesn't Fit Data
→ Enhancing Global Vaccine Safety: Definitions, Data, and Public Trust

The primary focus of the 2025 meeting was how RWE could expand into Phase III safety and effectiveness assessments and inform vaccine development outside typical Phase VI surveillance applications. It is important to stay informed on other phases of the vaccine life cycle, especially as RWE becomes increasingly important throughout the cycle.

BRAVE Annual Meeting
July, Ghana

The CEPI funded BRAVE project, aims to calculate background rates of AESI in Africa. Miriam Sturkenboom was invited to speak about distributed analytics and common data models

International Society of Pharmacovigilance Annual Meeting
25 October, Cairo, Egypt

This premier event brings together professionals, researchers, and regulators to discuss advances and challenges in drug safety and pharmacovigilance. VAC4EU was invited to attend, with Fabio Riefolo (Teamit) presenting on work from the SAFETY-VAC project:

→ European Framework for Post-Authorisation Vaccine Safety Monitoring Using Real-World Data (SAFETY-VAC project)

General Assembly Meeting

11th VAC4EU General Assembly Meeting
7–8 April 2025 | Valencia, Spain

VAC4EU's 11th General Assembly Meeting (GAM) combined a scientific symposium with strategic and governance sessions, bringing together VAC4EU members for knowledge exchange and collaborative discussions. The event was hosted by VAC4EU member FISABIO.

The scientific symposium focused on a scientific symposium dedicated to fit-for-purpose assessments of data and data sources for RWE vaccine studies. Presentations covered methodological approaches, practical experience, and regulatory considerations.

The second day was dedicated to the General Assembly Meeting, with discussions on VAC4EU strategy for 2025 and beyond, business development activities, and engagement across Working Groups. Members discussed participation and content development, with contributions from the PI, LOC, MSP and DEAP Working Groups.

Meet the new Business Development team

Fabio Riefolo | **Alba Ortega Flores** | **Alfonsina Milito**

We are pleased to welcome Fabio Riefolo, Alba Ortega Flores and Alfonsina Milito to the VAC4EU team. They will join as the new Business Development team, playing a vital role for the association in shaping the strategy that guides study acquisition and start-up processes.

We would like to thank Teamit for their continued support in providing these personnel, as well as previous members Gianmarco Di Mauro and @Dana Danielescu for the valuable work they started in establishing the team.

VAC4EU Journal Club

Relaunched and refreshed

Sima Mohammadi

Martin Solorzano

Giorgio Limoncella

After a year long hiatus, the Journal Club was relaunched in September of 2025 with new topics, a new team, and renewed energy!

We'd like to introduce the new Organising Committee:

- Sima Mohammadi (VAC4EU)
- Martín Solórzano González (IDIAP JGol)
- Giorgio Limoncella (BPE)

These three committee members have taken over from previous organisers Rosa Gini and Giuseppe Roberto (ARS), bringing fresh ideas and new momentum to the relaunch.

The VAC4EU Journal Club is a monthly informal gathering designed for researchers at all levels, but particularly early career professionals. We explore and discuss scientific papers across a wide range of topics related to vaccines, health data, safety monitoring, real world evidence, and methodology.

The 2025 Season: A Recap

Killing the Common Data Model?! Generative AI Takes Over

Sima Mohammadi (VAC4EU)
25 September

Over 50 people joined this inaugural session, representing a diverse array of fields including epidemiology, vaccinology, medicine, policy and regulatory affairs. Sima's presentation explored whether and how LLM driven automation could transform distributed data network analyses, potentially even replacing the common data model altogether. The resulting discussion led to the feasibility of validated model pipelines, the cost effectiveness of automation, and real world experiences using generative AI for semantic and syntactic harmonisation. Attendees concluded that a hybrid future combining CDMs and AI would be the most realistic path forward.

Paper: "Will generative AI make common data models obsolete in future analyses of distributed data networks?"

2 Lives, 1 Vaccine: A Target Trial Protocol for Vaccine Safety in Pregnancy

Samantha Duckworth
29 October

Samantha's session focused on real world RSV vaccine safety in pregnancy, introducing a target trial emulation protocol designed to minimise bias in observational studies. The session addressed maternal and infant safety outcomes, including pregnancy specific and birth related indicators, and highlighted the importance of robust matching strategies to ensure valid comparisons. The discussion focused on key methodological challenges in applying target trial emulation to maternal RSV vaccine safety studies, particularly how to define the hypothetical target trial, align time zero appropriately, and avoid immortal time bias. Participants also explored whether matching alone is sufficient for confounding control, highlighting the importance of gestational-age-based sequential trial emulation and the practical limitations of real-world data availability for robust causal inference.

Paper: "A Post-Authorisation Safety Study of a Respiratory Syncytial Virus Vaccine in Pregnant Women and Their Offspring in a Real-World Setting: Generic Protocol for a Target Trial Emulation"

FAIR Play: Making RWE Reproducible and Transparent, While Git-ting Along

Davide Messina
26 November

Davide presented an introduction to applying FAIR (Findable, Accessible, Interoperable, Reproducible) principles to real world evidence workflows, focusing on how transparent documentation and version controlled analytic pipelines improve research reproducibility. The session highlighted practical considerations for adopting Git as a version control system, including when it adds value, how it supports collaborative workflows, and why structured, reproducible analytic environments are increasingly essential in modern RWE studies. The discussion raised important points about the practical challenges of maintaining full research transparency, particularly when teams manage multiple file versions, documentation updates, and code changes over time. Participants also reflected on how tools such as Git and GitHub can support collaboration while ensuring that research outputs remain traceable, reproducible, and openly accessible.

Paper: "The FAIRification of research in real world evidence: A practical introduction to reproducible analytic workflows using Git and R" (Weberpals & Wang, 2024)

How to stay connected with the Journal Club

STAY UP TO DATE	PRESENT A PAPER	REGISTER FOR THE NEXT SESSION
Subscribe to the mailing list to receive regular news including new sessions, recaps and recordings.	We are always looking for volunteers to present a paper. If you're interested, fill out the survey above!	To check when the next session will take place, please visit the Journal Club webpage.

Member contribution

Aragon Health Sciences Institute (IACS)

The EpiChron Research Group on Chronic Diseases belongs to the Spanish National Health System through IACS and the IIS Aragon. EpiChron has a multidisciplinary team composed of 21 members (including clinicians, epidemiologist, pharmacist and statisticians) with background and expertise in the study of chronic diseases and multimorbidity, public health, pharmacoepidemiology and vaccine safety studies.

Studies
- DEAP for SAFETY-VAC
- DEAP for Pfizer Comirnaty vaccine studies
- DEAP for RSV vaccines

Working Groups and Taskforces
- Active in DEAPs WG

Community engagement
- Attended General Assembly Meeting in Valencia
- Attended 5th Anniversary Symposium in Brussels
- Attended Extraordinary General Assembly Meeting online
- Attended online General Assembly Meeting

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

The Spanish Agency of Medicines and Medical Devices (AEMPS) is a public agency responsible for guaranteeing, from a public service perspective, the quality, safety, efficacy and correct information of medicines. AEMPS sponsors BIFAP to serve as a real world data source to study the use and effects of medicines in the population.

Studies
- DEAP for SAFETY-VAC
- DEAP for ADEPT

Working Groups and Taskforces
- Active in DEAPs WG
- Attending meetings of Methods & Stats WG

Community engagement
- Attended General Assembly Meeting in Valencia
- Attended Extraordinary General Assembly Meeting online
- Attended online General Assembly Meeting
- Attended 5th Anniversary Symposium online

Agenzia Regionale di Sanità della Toscana (ARS)

ARS is an agency of the Tuscany Region and acts as a technical and scientific consultant to the regional government and the Regional Council. The Pharmacoepidemiology Unit provides expertise in vaccine safety studies for the design, implementation and development of programmes and scripts, with expertise in data diversity, transparency, reproducibility, and scientific independence.

Studies
- Led SeValid
- Led CoMaSy requirements
- Methodological expertise for AZ PASS
- Methodological expertise for Moderna PASS
- Methodological expertise for Pfizer PASS
- CoPI and Quality check for T2-T3 in HIPRA
- Programming for 2 studies in SAFETY-VAC
- Programming for 5 studies in TARGET-EU
- Quality check for T2-T3 in PAXLOVID pregnancy and PAXLOVID hepatic-renal
- Quality check for T2-T3 in Pfizer RSV maternal

Tools
- VAC4EU Catalogue (awarded top-down Service Contract for maintenance of the Catalogue)
- ConcePTION CDM (awarded top-down Service Contract for maintenance of the ConcePTION CDM)
- VAC4EU Academy (course content and review for Catalogue, CDM/ETL and Codebooks courses)

Executive Board
- **Vice President – Rosa Gini**
  Co-leading Strategic Pillar 3 (Member Engagement & Training)

Working Groups and Taskforces
- Co-led DEAPs WG
- Co-led Results Review TF
- Active in MSP WG
- Led Programming TF
- Active in DEAPs WG
- Active in PI WG
- Led Catalogue TF
- Participated in Pregnancy TF
- Participated in Codelist TF

Community engagement
- Facilitated handover of Journal Club to new Organising Committee
- Presented at VAC4EU Journal Club
- Presented at ISPE Annual Meeting
- Participated in online General Assembly Meeting
- Presented at General Assembly Meeting in Valencia
- Participated in a panel at the World Vaccine Congress
- Presented at 5th Anniversary Symposium
- Co-led a proposal for bottom-up funding and participated in a second proposal, both awarded

Aarhus University – Department of Clinical Epidemiology (DCE-AU)

AARHUS UNIVERSITY

The Department of Clinical Epidemiology at Aarhus University (DCE-AU) is a leading world expert in designing, planning, coordinating, and conducting pharmacoepidemiological studies using real world data sources in Denmark, Europe, and North America. DCE-AU is a large academic department with multidisciplinary in-house expertise in epidemiology, clinical medicine, biostatistics, and data science.

Studies

- PI, DEAP and statistical expertise for Moderna main PASS and pregnancy
- DEAP for Moderna myocarditis and EMA SAFETY-VAC
- DEAP for EMA SAFETY-VAC
- Supported protocol, DMP and DOM development for Pfizer RSV (maternal)

Working Groups and Taskforces

- Active in PI WG
- Active in Methods & Stats WG
- Active in Pregnancy Algorithm TF
- Active in Codelists TF

Tools

- VAC4EU Academy (content and review)
- Pregnancy Algorithm

Community engagement

- Presented at General Assembly Meeting in Valencia
- Attended 5th Anniversary Symposium live
- Participated in online General Assembly Meeting

Drug Safety Research Unit (DSRU)

DSRU Drug Safety Research Unit

DSRU is the UK's leading pharmacovigilance and pharmacoepidemiology unit. The DSRU uses a variety of methods to conduct a wide range of studies, including PASS in primary and secondary care, EHR studies including CPRD , drug utilisation studies, registries, risk minimisation studies, benefit-risk assessments, active surveillance studies and systematic reviews.

Studies

- DEAP for Pfizer Comirnaty vaccine studies
- DEAP for Pfizer ABRYSVO studies
- DEAP for AZ PASS
- DEAP for Moderna studies
- DEAP for GCoVS project
- DEAP for SAFETY-VAC
- Case validation expertise

Working Groups and Taskforces

- Coordinator of the DEAPs WG
- Supporting the Code List TF
- Active in the Primary Data Collection T

Community engagement

- Participated in the General Assembly Meeting in Valencia
- Attended the 5th Anniversary Symposium
- Began preparations for the 2026 GAM (to be hosted by DSRU)
- Participated in online General Assembly Meeting
- Participated in the online Extraordinary General Assembly Meeting
- Participated in a panel at the World Vaccine Congress

Tools

- Supporting the CodeMapper validation
- Supporting the DrugSet validation

Executive Board

- **Administrator – Debabrata Roy**
  Co-leading Strategic Pillar 4 (Finance, Operations & Quality)

Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunidad Valenciana (FISABIO)

Fisabio is a non-profit scientific foundation in the Valencian Community (Spain) dedicated to promoting and developing health and biomedical research and innovation. The foundation supports researchers and specialists working on research, innovation, and clinical studies. The Vaccine Research Department at FISABIO provides evidence to contribute to a better understanding of infectious diseases that are preventable or potentially preventable through vaccination, as well as evaluating the efficacy and safety of vaccines.

Studies

- DEAP for AZ PASS
- DEAP for Moderna myocarditis
- DEAP for SAFETY-VAC
- DEAP for Janssen PASS
- DEAP for GCoVS
- DEAP for Pfizer ABRYSVO vaccine studies

Working Groups and Taskforces

- Co-led the DEAPs WG

Community engagement

- Participated in online General Assembly Meeting
- Hosted General Assembly Meeting at FISABIO in Valencia
- Attended 5th Anniversary Symposium

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol)

IDIAPJGol is a centre of reference in research and health promotion at the primary health care level in Catalonia, Spain, that aims to promote and develop innovation, clinical, epidemiological and health services research in the field of primary health care.

Studies

- DEAP for Pfizer Comirnaty vaccine studies
- DEAP for AZ PASS
- DEAP for Moderna Spikevax studies
- DEAP for Janssen PASS
- DEAP and scientific activities for GCoVS
- DEAP for SAFETY-VAC
- DEAP for CVM
- DEAP for CoVe
- DEAP for HIPRA

Working Groups and Taskforces

- Co-led the VAC4EU Journal Club
- Co-led the DEAPs WG
- Active in Results Review TF

Community engagement

- Attended the General Assembly Meeting in Valencia
- Panellist in the 5th Anniversary Symposium
- Participated in online General Assembly Meeting
- Attended Extraordinary General Assembly Meeting online
- Presented at ISPE Latam in Sao Paulo, Brassil
- Presented at ISoP annual meeting in Cairo, Egypt
- Presented at the Spanish Epidemiology Society Congress in Las Palmas, Spain

Julius Clinical Research BV (JCR)

Clinical research organisation with a unique combination of scientific leadership, site networks, and operations. Early, late phase and RWE services with focus on neurological diseases, cardio-metabolic, renal, and infectious diseases & vaccines.

Studies

- LOC and QC Programming for Moderna PASS studies
- LOC for Moderna Natural History Study
- LSC/PI for Moderna Natural History Study
- QC Statistician for Pfizer Maternal studies

Working Groups and Taskforces

- Active in Programming Guidelines TF
- Ad-hoc participation in Methods & Stats WG

Community engagement:

- Presented at the General Assembly Meeting in Valencia
- Participated in online General Assembly Meeting
- Presented at ISPE Annual Meeting

Fondazione Penta ETS

Penta

Penta is an international, independent, scientific collaboration working to advance research that improves the prevention and management of infections in pregnancy, infancy, childhood and adolescence. Penta is focused on developing scientific evidence to inform guidelines, policies and practice, accelerated through strategic partnerships, especially in countries where there is the greatest need.

Studies
- LOC for Pfizer studies
- Data management and DEAP role on behalf of SoSeTe

Working Groups and Taskforces
- Active in LOC WG
- Active in DEAPs WG

Community engagement
- Attended the General Assembly Meeting in Valencia
- Participated in online General Assembly Meeting

PHARMO Institute

PHARMO

PHARMO Institute delivers high-quality, real-world research to help the healthcare industry understand how medicines perform beyond the clinical trial setting. Since 1999, PHARMO have been analysing healthcare data to identify side effects earlier, improve patient safety and outcomes, and guide better treatment decisions. The PHARMO team consists of specialists in epidemiology, statistics, and data science, deliver tailor-made observational studies that answer complex research questions about safety, effectiveness, and the value of medicines. PHARMO has direct access to anonymised patient-level data from multiple healthcare settings in the Netherlands, linked through validated algorithms.

Studies
- DEAP for Pfizer Comirnaty studies
- DEAP for Pfizer RSV studies
- DEAP for AZ PASS
- DEAP for Janssen PASS

Working Groups and Taskforces
- Active in the DEAPs WG

Community engagement
- Attended the General Assembly Meeting in Valencia
- Participated in online General Assembly Meeting

Executive Board
- **Naomi Boxall – Administrator**
  Co-leading Strategic Pillar 2 (Tools & Science)

RTI Health Solutions

RTI (h)(s) Health Solutions

RTI is an independent not-for-profit research institute. One of its specialised units, RTI Health Solutions (RTI-HS) is dedicated to advancing pharmaceutical and health research. RTI-HS's areas of expertise include pharmacoepidemiology and real world evidence (RWE), risk management, benefit-risk evaluation, pharmacovigilance, patient reported outcomes, health preference assessment, implementation science, medical communications, and more.

Studies
- PI, LOC and statistical expertise for AZ PASS
- Co-PI and statistical support for Janssen PASS
- Co-PI and statistical support for three Pfizer vaccine PASS studies (main, myocarditis and bivalent)
- PI, LOC, statistical expertise and DEAP for two SIGMA Pfizer Paxlovid studies (pregnancy and hepatic and renal impairment)
- PI, LOC and lead programming centre for the HIPRA Bimervax PASS & Effectiveness studies
- Contribution to SeValid project

Tools
- SCRI methods package (supporting development)
- Codebooks (contribution to creation, programming guidelines)
- Offer programming tips and tracking releases
- Pregnancy Algorithm (contributed to manuscript on including additional outcomes)
- VAC4EU Catalogue (Support updating the CPRD entry and ETL design)

Working Groups and Taskforces
- Contributed as team members to a successfully funded proposal aimed at extending the pregnancy algorithm to additional outcomes.
- Active in LOC WG
- Active in PI WG
- Active in Code list WG
- Active in Validation TF
- Active in MSP WG
- Active in Predicting Processing Times TF
- Active in Simulations TF
- Active in DEAPs WG

Community engagement:
- Participated in General Assembly Meeting in Valencia
- Panellist at 5th Anniversary Symposium.Participated Extraordinary General Assembly Meeting online

Società Italiana dei Medici di Medicina Generale e delle Cure Primarie (SIMG)

SIMG is an autonomous and independent association created to promote, enhance and support the professional role of general practitioners in Italy and beyond. SIMG is the home of the Health Search research centre, which conducts and coordinates clinical studies on behalf of SIMG by providing clinical, epidemiological, statistical, and IT skills.

Studies
- DEAP for Pfizer main

Working Groups and Taskforces
- Active in the DEAPs WG

Community engagement
- Attended the Valencia General Assembly Meeting online

Societa Servizi Telematici (SoSeTe)

Societa' Servizi Telematiciis a SME based in Padova affiliated with the Pedianet Network, which is an independent network of Italian family paediatricians involved in the systematic collection of clinical and epidemiological data to support scientific research and contribute to the improvement of paediatric healthcare. In addition to access to this database, Societa' Servizi Telematici also provides data management, regulatory, statistical and methodological expertise.

Studies
- DEAP for Pfizer PASS studies
- DEAP for SAFETY-VAC

Tools
- VAC4EU Academy (course review)

Working Groups and Taskforces
- Active in DEAPs WG

Community engagement
- Participated in online General Assembly Meeting
- Attended the General Assembly Meeting in Valencia

Executive Board
- **Administrator – Elisa Barbieri**
  Co-leading Strategic Pillar 3 (Member Engagement & Training)

University of Bordeaux (BPE)

BPE is a research platform of the University of Bordeaux dedicated to real-world research with extensive experience in designing and implementing studies, especially using the SNDS French Nationwide claims database.

Studies
- DEAP for SAFETY-VAC
- DEAP for PAXLOVID pregnancy and PAXLOVID hepatic-renal
- Co-PI for Pfizer RSV older adults
- DEAP for Pfizer RSV maternal
- DEAP for Pfizer RSV GBS

Working Groups and Taskforces
- Co-Led the MSP WG
- Active in the DEAPs WG
- Active in Pregnancy Algorithm TF

Community engagement
- Attended the General Assembly Meeting in Valencia
- Participated in the online General Assembly Meeting
- Co-led the VAC4EU Journal Club
- Participated in ISPE Annual Meeting
- Participated in ISoP

University of Oslo

The Pharmacoepidemiology and Drug Safety Research groups at UiO have 15+ years of experience using Norwegian health registry data to study medicine and vaccine use and safety.

Studies
- DEAP for Pfizer studies
- DEAP for Moderna main and pregnancy studies
- DEAP for SAFETY-VAC

Working Groups and Taskforces
- Active in DEAPs WG
- Active in Methods & Stats WG

Tools
- VAC4EU Academy as course review

Community engagement
- Presented at and attended VAC4EU Journal Club
- Attended the General Assembly Meeting in Valencia
- Participated in online General Assembly Meetings
- Presented at ISPE Annual Meeting

Teamit Institute

Teamit Institute is a research management organisation specialising in the regulatory science of health innovations and health data, and real world evidence (RWE) research. Teamit Institute has a proven track record in scientific investigation, quality assurance, risk management, scientific communication, and operational management of large, multi-country and multi-stakeholder RWE studies, especially in innovative AI-powered pipelines' initiatives, pharmacoepidemiology, safety, and efficacy studies related to medications, medical devices, and vaccines.

Studies

- Project Management for Pfizer Comirnaty studies
- Scientific Management and investigators for SAFETY-VAC
- LOC and Project Management for Pfizer RSV maternal
- LOC and Project Management from VAC4EU for GCoVS
- Scientific Management for ADEPT
- Project Management for TARGET-EU

Working Groups and Taskforces

- Active in LOC WG
- Active in Predicting Processing Times TF

Community engagement

- Represented VAC4EU at World Vaccine Congress
- Represented VAC4EU at ISPE Annual Meeting
- Presented at ISoP
- Presented at the General Assembly Meeting in Valencia
- Participated in online General Assembly Meeting
- Presented at 5th Anniversary Symposium

Executive Board

- **Eva Molero (Administrator)**
  Co-leading Strategic Pillar 1 (External Relations)
  Contributor Strategic Pillar 4

Outsource personnel

- **Gianmarco Di Mauro** *(Partnerships)*
- **Dana Danielescu** *(Project Manager)*
- **Sofia Sintoris** *(Scientific Communication)*
- **Fabio Riefolo** *(Regulatory Science & Business Development)*
- **Alba Ortega Flores** *(Business Development)*
- **Alfonsina Milito** *(Business Development)*

Fundació Hospital Universitari Vall d'Hebron – Institut de Recerca (VHIR)

VHIR is a public sector institution that promotes and develops medical research, innovation, and teaching at Vall d'Hebron University Hospital. The aim of the Clinical Pharmacology group is to investigate the use of medicines and evaluate its benefit/risk relationship in usual clinical practice.

Studies

- Case validation and genomic sample collecting for GCoVS
- Regional coordinator for other centers for GCoVS

Working Groups and Taskforces

- Active in DEAPs WG
- Active in Codelist TF
- Co-led Primary Data Collection TF

Tools

- REDCap Managing Center

Community engagement

- Attended the General Assembly Meeting in Valencia
- Attended Journal Club
- Attended online Extraordinary General Assembly Meeting online
- Attended 5th Anniversary Symposium in Brussels and online
- Participated in GVDN Symposium

University of Milan-Bicocca (UNIMIB)

The Center for Public Health Research (CESP), positioned within the Department of Medicine and Surgery of UNIMIB, supports and encourages research to promote and safeguard public health. CESP is a multidisciplinary team with background and expertise in public health, health technology assessment, health services research, pharmaceutical and regulatory sciences, pharmacoepidemiology and pharmacovigilance, medical statistics, and data science.

Community engagement

- Participated in online General Assembly Meeting
- Attended the General Assembly Meeting in Valencia
- Attended Extraordinary General Assembly Meeting online
- Attended the 5th Anniversary Symposium in Brussels

Executive Board

- **Giampiero Mazzaglia (Administrator)**
  Co-leading Strategic Pillar 1 (External Relations)

MediCom Consult

MediCom Consult offers medical and scientific writing and editorial services for manuscripts for journal submission, conference abstracts, posters and oral presentations, clinical and epidemiological study documentation (reports, protocols, SAPs etc.), internal reports and white papers.

Studies
- Medical writing and editing for Pfizer studies
- Medical writing and editing for Janssen PASS
- Medical writing and editing for Pfizer RSV

Community engagement
- Attended the General Assembly Meeting in Valencia
- Attended the 5th Anniversary Symposium

University Hospital Verona (UNIVR)

The team of section of Pharmacology, affiliated at the Department of Diagnostics and Public Health of University of Verona has expertise in the field of pharmacoepidemiology, pharmacovigilance, medical informatics, ICT innovative solution development for pharmacovigilance, biostatistics as well as web application and machine learning. VAC4EU activities in 2025:

Studies
- WP leader in ADEPT
- DEAP for ADEPT
- Scientific expertise for SAFETY-VAC

Working Groups and Taskforces
- Active in Primary Data Collection TF
- Active in PI WG

Community engagement
- Attended the General Assembly Meeting in Valencia
- Attended Extraordinary General Assembly Meeting online
- Attended the 5th Anniversary Symposium in Brussels
- Attended online General Assembly Meeting

London School of Hygiene and Tropical Medicine (LSHTM)

LSHTM is one of the world's leading public health universities, with one of the largest groups of epidemiologists and medical statisticians in Europe. There is an active Electronic Health Records research group and a Vaccine Research Centre.

Community engagement
- Participated in online General Assembly Meeting
- Attended the General Assembly Meeting in Valencia
- Attended the 5th Anniversary Symposium
- Participated in ISPE Annual Meeting

Analysis Group

Analysis Group is a global healthcare consulting firm with strong expertise in epidemiology, biostatistics and health outcomes research. AG provides rigorous methodological insights and data analysis to biopharmaceutical companies and healthcare organisations, supporting research across multiple therapeutic areas.

Studies
- Protocol writing, scientific support and QC programming for Pfizer RSV (older adults)

Community engagement
- Participated in online General Assembly Meeting
- Attended the 5th Anniversary Symposium in Brussels

Working Groups and Taskforces
- Active in PI WG

University of Florence

UNIVERSITÀ DEGLI STUDI FIRENZE

UNIFI is an Italian public research institution, having participated in multiple pharmacoepidemiology studies using Italian and Tuscan administrative data, taking on roles ranging from principal investigator to statistician and R programmer.

Working Groups and Taskforces
- Active in Pregnancy Algorithm TF

Community engagement
- Attended the General Assembly Meeting in Valencia
- Attended the 5th Anniversary Symposium

Lareb

bijwerkingen centrumlareb

The Netherlands Pharmacovigilance Centre Lareb identifies risks associated with the use of medicines in daily practice and is the Knowledge Centre for adverse drugs reactions (ADRs). Lareb is an independent foundation and is funded by the Dutch Medicines Evaluation Board and the Ministry of Health.

Studies
- Contributed to manuscript for CVM

Community engagement
- Attended the General Assembly Meeting in Valencia
- Participated in online General Assembly Meeting
- Attended 5th Anniversary Symposium in Brussels

Working Groups and Taskforces
- Active in Primary Data Collection Task Force

Sciensano

sciensano

Sciensano is a knowledge centre for epidemiology, studying the factors that influence the physical, mental, and social health of the population, as well as potential risks to public health. They also conduct studies on the surveillance of vaccine-preventable diseases in humans and can collect and analyse data from various sources.

Community engagement
- Attended General Assembly Meeting in Valencia
- Panellist for 5th Anniversary Symposium

Leibniz Institute for Prevention Research and Epidemiology (BIPS)

BIPS Leibniz Institute for Prevention Research and Epidemiology – BIPS

BIPS develops strategies for the prevention of chronic, non-communicable diseases with a research focus on early detection of diseases and drug safety (among other things). They cover methodological development, identification of causes of diseases, and intervention and implementation research, while also offering information to politicians and the public, and providing academic qualification to young scientists.

- No contributions in 2025.

Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

RIVM is a Dutch agency concerned with public health and the environment, under the Netherlands Ministry of Health. They work towards a healthy population and a sustainable, safe and healthy environment through four specific domains of expertise, including infectious diseases and vaccinology. RIVM pursues those goals based on independent scientific research.

- No contributions in 2025.

University Medical Center Utrecht (UMCU)

UMC Utrecht

Care, research and education are the three mainstays of UMCU in their ongoing efforts to improve people's health, leading scientific research, groundbreaking innovation, and collaboration with patients and other interested parties form the basis of their first-rate healthcare. The Real-World Evidence group at UMCU, the largest team from UMCU that contributes to VAC4EU, envisions best evidence from real world data in a learning healthcare system.

Studies

- PI & lead programming for Pfizer studies
- Programming and statistics for AZ PASS
- Co-PI & programming for Paxlovid studies PI & programming for Janssen PASS
- PI & programming Pfizer Abrysvo studiesScientific coordination SAFETY-VAC
- Scientific coordination & programming for ADEPT
- PI of 2 studies in TARGET-EU
- PI for GCoVS studies
- Led FLOW project
- Led Metasyn project

Working Groups and Taskforces

- Led PI WG
- Led Methods and Stats WG
- Led Code List TF
- Led Case Validation TF
- Led Programming Guidelines TF

Tools

- Provide access to anDREa, a digital research environment
- Provide expertise on INSIGHT level checks and training
- Provide expertise on CodeMapper development and training
- Development of instructions
- Development of AI roadmap

Community engagement

- Presented at online General Assembly Meetings
- Presented at General Assembly Meeting in Valencia
- Represented VAC4EU at ISPE Annual Meeting
- Presented at World Vaccine Congress
- Presented at 5th Anniversary Symposium in Brussels
- Presented at Journal Club
- Presented at PAHO
- Presented at BRAVE Annual Meeting

Executive Board

- **President – Miriam Sturkenboom**
  Co-leading Strategic Pillar 2 (Tools & Science)

Outsource personnel for secretariat

- **Secretary General – Daniel Weibel**
- **Electronic Health Record Review – Sima Mohammadi**
- **Case Validation Coordinator - Amirreza Dehghan Tarazjani**
- **Communication – Ashton Babcock**
- **Tools and study support – Taylor Brown**

VAC4EU impact

VAC4EU is a leading, trusted provider of high-quality RWE that has supported evidence-based vaccine regulatory and public health decisions across Europe over the last 5 years. The expert network strives for improved post marketing vaccine safety and effectiveness research across Europe, a goal which unites our members to produce high quality outputs, spearheading the vaccine RWE landscape across Europe and beyond.

VAC4EU has had tangible impact through the establishment of a study portfolio covering post-authorisation safety and effectiveness monitoring of vaccines for SARS-CoV-2 and RSV, EMA-funded studies via collaboration with EU PE&PV and CDC studies via the GVDN project, demonstrating clear impact across the European and global vaccine monitoring landscape. Efficient study execution has led to the publication of 20 peer-reviewed manuscripts and over 50 EMA and industry-aligned public deliverables alongside over 60 presentations at major pharmacoepidemiology and vaccine conferences including ISPE and WVC.

VAC4EU drives forward innovation through development and improvement of a set of open-source and bespoke tools to enhance European readiness infrastructure. We promote capacity-building among our members via the VAC4EU Academy and the wider scientific community with webinars and resources like our Journal Club.

Community Engagement

VAC4EU is committed to building a unique community of vaccine experts.

- VAC4EU has grown its network of experts to 29 member organisations spanning the entire RWD to RWE pipeline
- VAC4EU has developed focussed Working Groups wto share knowledge and expertise across studies
- Developed by the VAC4EU community to build capacity, the VAC4EU Academy provides practical training resources on methods to generate RWE from diverse RWD sources
- VAC4EU has hosted over 20 Journal Club sessions to an estimated audience of 300+, covering a variety of topics from study design to FAIR principles to perception on science communication

The VAC4EU Journal Club has become a valuable space for open and respectful scientific discussion, bringing together researchers from diverse backgrounds to critically explore study design, data sources, analytical methods, real-world evidence, and vaccine safety topics. It strengthens collaboration, continuous learning, and community engagement across the VAC4EU network and beyond.

Martín Solórzano,
Journal Club Organising Committee

Scientific Leadership

VAC4EU is a leading scientific voice in RWE, accelerating vaccine safety and effectiveness research in Europe. Over the last five years VAC4EU has had tangible impact across the pharmacovigilance landscape:

- VAC4EU has designed and implemented a bespoke RWD to RWE pipeline to effectively/efficiently answer diverse research questions representing both the general population and at-risk groups
- Our network of RWD sources covers a population of over 185M people across 8 countries, representing a diverse cross-section of Europe
- The VAC4EU network has developed (and improved) open-source tools which have been used within and outside the network for efficient, rigorous execution of RWE studies

Learn more about the achievements of the VAC4EU network

Regulatory Decision-Making & Public Health

Regulators encourage integration of real-world evidence into decision-making. The results of VAC4EU studies add to this body of clinical evidence:

- VAC4EU produces stringent safety reports, allowing regulatory decision makers to assure continuity in provision of safe vaccines to the public
- VAC4EU provided evidence to regulators to assure post-marketing safety of the novel mRNA vaccine development platform, widely rolled out during the COVID-19 pandemic.
- VAC4EU contributes to several EMA projects directly informing regulators on safety and effectiveness of vaccines

Learn more about the regulatory and public health impact of VAC4EU

Shaping the Landscape

VAC4EU is recognised as a European leader in clinical evidence generation. The community has established several collaborations to cover the entire vaccine monitoring landscape.

- VAC4EU has been cited as an example of a collaborative network for vaccine monitoring, inspiring other countries to build similar infrastructures
- VAC4EU collaborates with patient organisations, serving as content expert to help build meaningful narratives for the public
- VAC4EU has been invited to contribute to development of the EHDS as a European reference in pharmacoepidemiology, shaping the future of health data research across Europe
- VAC4EU responded to 7 documents up for public consultation in 2025, 5 of which have now been published with comments implemented

Feedback from the VAC4EU network was incorporated into five TEHDAS2 documents published last year:

- Technical specification on implementing secure processing environments
- Guidelines on data minimisation, pseudonymisation, anonymisation and synthetic data
- Guidelines on data description duties for health data holders
- Technical specifications on the national metadata catalogue
- Guidelines for good application and access practice for users

Explore finalised TEHDAS documents

Closing remarks

Patrick Mahy
CO-FOUNDER AND FINANCIAL OFFICER

As we look ahead, VAC4EU is well positioned to build on our strong foundation. With expanding activities beyond COVID-19, continued innovation in methods and tools, and a growing network of partners, the organisation will remain a key contributor to vaccine monitoring and pharmacoepidemiology in Europe and beyond. Now what else is in store for VAC4EU over the next 5 years?

We will continue to extend our scientific collaboration with like-minded groups both within Europe and worldwide to advance our shared vision for global vaccine monitoring. In the next 5 years, we aim to enhance our public health impact through these partnerships.

As mRNA technology enables the development of vaccines for rare or emerging diseases, VAC4EU will be able to leverage its extensive expertise to generate evidence on their effects in real-time, while also being able to provide risk profiles in special populations.

Still, there are challenges on the horizon including the spread of misinformation and disinformation about vaccines, coupled with general declining trust in institutions. VAC4EU is already part of an ecosystem of trust by generating evidence on vaccine safety. However, it's clear that facts are not enough, and it is how science is communicated that matters. We want to harness our role as experts to build confidence among the public, crafting meaningful messages to support mutual understanding.

Moreover, new opportunities and challenges are stemming from the use of AI in research, demanding agility and the willingness to rapidly adapt to new developments. VAC4EU is committed to embrace these innovations responsibly, ensuring our network remains responsive to trends, while keeping humans at the forefront. We are already investigating how to leverage generative AI to automate aspects of our pipeline, working towards an AI road map for the next 5 years.

The impact of the European Health Data Space (EHDS) has already begun with a phased roll-out starting in 2025. We will continue our engagement with key stakeholders in this field, such as TEHDAS2, and secure opportunities to respond to public consultations.

Despite the steep learning curve and the challenges of today, it is our clear vision and mission that keeps VAC4EU agile and innovating along with the times. Our dedication to public health has fuelled our resilience, enabling us to learn, grow, and persevere.

AARHUS UNIVERSITY

ARS TOSCANA agenzia regionale di sanità

université de BORDEAUX

DSRU

UNIVERSITÀ DEGLI STUDI FIRENZE

Fundació Fisabio

iacs INSTITUTO ARAGONÉS DE CIENCIAS DE LA SALUD

IDIAP JORDI GOL

Julius Clinical

bijwerkingen centrumlareb

BIPS Leibniz Institute for Prevention Research and Epidemiology – BIPS

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

agencia española de medicamentos y productos sanitarios

MediCom Consult

UNIVERSITÀ DEGLI STUDI DI MILANO BICOCCA

UNIVERSITY OF OSLO

PEDIANET

Penta

PHARMO

Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

RTI (h)(s) Health Solutions

sciensano

SIMG

teamit INSTITUTE

UMC Utrecht

Vall d'Hebron

UNIVERSITÀ di VERONA

ANALYSIS GROUP

VAC4EU Vaccine monitoring collaboration for Europe

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