

A fresh new look

Welcome to the revamped 'Safety by Numbers'! This is the first edition that will feature our new look - nothing like a fresh coat of digital paint right? However, we will continue to make further improvements to refine how we present all the great news and updates from across the sector to you. We would love to hear any ideas and/or general thoughts that you may have on the newsletter, so click the button below and let us know!



Bridging borders The **GVDN** contributions

The GVDN is currently receiving data for several of the GCoVS suite of studies and data checking and analyses are rapidly progressing, with results for the association studies expected to be released by the early part of next year.

The reach of the GVDN has now expanded to encompass an astounding population of roughly 300 million, a significant milestone in the Network's brief history. The Network's coverage will soon be further extended with the onboarding of new sites in both Latin America and Asia. The inclusive nature of the Network continues to grow, allowing for a more comprehensive and global representation.

The GVDN's collaboration with the ALIVE Network and our South Africa site and the successful implementation of the hospital surveillance model of event monitoring in nine African countries has been a positive partnership and enabled collective contribution to the global <u>GCoVS project</u>. GVDN has been a technical partner for this Gavi-funded work.

The receipt and analysis of global observed over expected data have ushered in a fresh wave of opportunities for signal detection. However, it has also brought forward certain challenges in signal thresholds, dissemination, and communication, which the network is working to address.

On the scholarly front, the GVDN has made substantial strides. Their first publication has been submitted, with the second one underway. Furthermore, a commitment to studies on vaccine-mediated enhanced disease (VMED) and maternal immunisation has been made by a number of sites, aimed at extending the breadth of the GCoVS studies. The GVDN has a number of new opportunities in the pipeline and hope to be able to share details soon.

The GVDN's Epi/Bio team has been expanding to a more distributed model, incorporating additional global expertise into their team. The Network warmly welcomes Hazel Clothier and Muhammad Javed based in Melbourne, and of course, our Lead Epidemiologist Jennifer Griffin is based in Los Angeles. The GVDN looks forward to further development and expansion of this global expertise.

Finally, the GVDN encourages its partners to lead initiatives and opportunities for the Network. This participatory approach ensures an inclusive, dynamic, and effective collaboration, pushing the boundaries of what the Network can achieve in the field of global health.



What is SPEAC and The Brighton Collaboration? **Brighton Collaboration** contributions

The Brighton Collaboration was launched in 2000 and is focused on the continual improvement of vaccine safety monitoring by developing internationally accepted standards. The Safety Platform for Emergency vACcines (SPEAC) is a major Brighton Collaboration project that is funded by the Coalition for Epidemic Preparedness Innovations (CEPI) through the Task Force for Global Health.

CEPI's mission is to accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks. To achieve this CEPI is supporting the development of a wide range of vaccine candidates and platform technologies against prioritised targets. SPEAC aims to support this emerging CEPI portfolio by creating capacity and solutions for harmonised safety assessment of vaccines.



SPEAC experts join BeCOME conference

Several SPEAC experts joined the BeCOME Conference at Les Pensières Center for Global Health in Annecy, France from June 11–13, 2023.

BeCOME, which stands for Beyond COVID Monitoring Excellence, was initiated to create a sustainable forum where experts in pharmacovigilance and pharmacoepidemiology from key stakeholders (industry, public health, regulators, academics) can collectively discuss and develop innovations for post-marketing monitoring of benefits and risk of vaccines, leveraging the learnings and keeping the momentum of progress made in response to the COVID emergency.

The three-day conference engaged experts in workshops and discussions on background incidence rates, safety studies, pregnancy surveillance, vaccine benefits, safety signals, digital solutions, and studies in low- and middle-income countries (LMICs), among other topics.



SPEAC and CEPI meet to build safety into vaccine development

The SPEAC team met with CEPI's Clinical Development Team in London the week of June 12, 2023, to discuss progress and strategies to build safety into every step of CEPI's approach to vaccine development.

Over the two-day meeting, SPEAC experts presented progress and challenges in their work to develop tools, resources, and the digitalisation needed to link and grow vaccine safety expertise and support CEPI-sponsored vaccine developers.

Additional partners participated in the meeting, including CEPI's Pharmacovigilance lead, Alex Precioso, the Child Health and Mortality Prevention Surveillance (CHAMPS) network, and The Global Health Network. The SPEAC team looks forward to continuing to collaborate with the Clinical Development Team and making SPEAC tools accessible to CEPI-funded developers and the broader vaccine safety community.







What is VAC4EU? <u>VAC4EU</u> contributions

The Vaccine monitoring Collaboration for Europe (VAC4EU) is a not-for-profit international association that facilitates the collaborative benefit-risk monitoring of vaccines in Europe through the generation of Real-World Evidence (RWE). Members met in person for the first time last year for our General Assembly Meeting in Barcelona. VAC4EU will also be present at ICPE this year with a booth and several poster presentations. See below some of the latest updates from the VAC4EU team.

Early COVID-19 Vaccine Monitor (ECVM) results published

ECVM was a large EMA-sponsored research project carried out during the initial vaccination cycle for four COVID-19 vaccinations, spanning several European countries with the aim to investigate incidence rates of adverse events, using both primary and secondary data sources.

VAC4EU members recently <u>published a paper</u> on one of the studies from this project. The article details a prospective cohort event monitoring study on self-reported adverse reactions from over 100,000 patients. The results of this study were consistent with clinical trial data, showing a high frequency of site reactions, headaches, and fatigue, with rare incidences of serious complications or adverse events of special interest (AESI).

Other results from the ECVM project can be viewed on the VAC4EU Zenodo community, including a <u>retrospective cohort design study</u> with near real-time monitoring of 29 AESI in over 25 million subjects. Rates of AESIs were compared between post and prevaccination in the same population. Results showed 10 potential safety signals, most of which had previously been identified through other sources and discussed by EMA.

COVID-19 Vaccine Monitor (CVM) completion, to be presented at ICPE

VAC4EU is proud to announce the completion of CVM project! One aim of CVM was to continue the cohort event monitoring initiated in ECVM by extending to populations of special interest (pregnant, lactating, immunocompromised, or paediatric populations and those with histories of allergies or prior SARS-CoV-2 infection). A total of 642,632 vaccinated persons were included across 13 countries through four data sources. The <u>executive summary</u> is publicly available, and the full report will be uploaded to Zenodo soon.

Fit-for-purpose assessments were also performed on each of the different data sources. These showed that depending on the type of outcome data covered, for example GP data sources, underestimated AESI which typically required hospitalisation. Fit-forpurpose data sources were used for several EMA study requests related to the incidence of multi-inflammatory syndrome, paediatric COVID-19 severity, and association with myocarditis. A paper on this association is now available to read.

The final component of this project focused on methodology and explored confounding, assumptions of self-controlled designs, and misclassification. The executive summary of results is available on the EUPAS register. Several VAC4EU members will present findings from CVM at ICPE.

COVID-19 Vaccines Effectiveness (CoVE)

The EMA-sponsored CoVE project closed in April of 2023. This project aimed to expand scientific understanding of waning immunity after primary and booster vaccinations. Approximately 67 million adults and adolescents with at least two years of records since their first COVID-19 vaccination were included, obtained from a variety of data sources across several European countries.

One objective of the retrospective cohort study was to investigate how different vaccination schedules might affect vaccine effectiveness. This involved a comparison of patients who received homologous versus heterologous vaccination schemes and various SARS-CoV-2 infection-related outcomes. These included the incidence of severe and nonsevere COVID-19, as well as COVID-19 mortality.

The results are consistent with current recommendations to mix brands (heterologous vaccination schemes). The final study report can be found on VAC4EU Zenodo. Manuscripts are also being prepared to submit for publication. We will highlight papers from this project as soon as they are published.



What is the Vaccine Confidence Project? <u>Vaccine Confidence Project</u> contributions

The Vaccine Confidence Project (VCP) at the London School of Tropical Hygiene & Medicine has been monitoring vaccine confidence for over a decade through nationally representative country surveys. Survey collection has been conducted through collaboration with ORB International along with Africa CDC, the European Commission, the Philippines Survey and Research Center, UNICEF, Wellcome Global Monitor and WHO.



UNICEF 2023 State of the World's Children Report

The report highlighted the re-emergence of preventable diseases previously wellcontrolled by vaccination programs. Causes included delays to routine health care, vaccine misinformation, and lack of support and empowerment of the predominantly female health workforce. Many countries showed declines in child vaccine confidence, particularly for women, and especially for younger (< 35) age groups. The data showed that more effort is required to address vaccine misinformation.

Read more

World VCI map % of respondents who somewhat or strongly agree: 100% 309 65% Year Country Question No country selected Base map by Ben Hodgson, licenced under CC BY-SA 3.0

New vaccine confidence index map now available

Media

The newly launched Vaccine Confidence Index Map produced by the Vaccine Confidence Project enables instant comparison of vaccine confidence by country from 2015–2022. Data includes confidence in importance, safety, effectiveness, and compatibility with personal beliefs. Users can select a country and get a detailed summary and age group breakdown of the data.



'Post-vac'/'long vax' syndrome reports

The German biotech firm BioNTech is facing compensation claims for alleged side effects from its Comirnaty vaccine. DW is one of the latest outlets to report on 'post-vac' or 'longvax' syndrome. Other notable outlets with recent stories on the topic include Forbes, Science, and the Daily Mail.

Below are five quick key messages you can utilise in response to any queries you may receive from individuals concerned about this topic:

- 1. Diving into the detail reveals limited evidence to support such a syndrome.
- 2. Studies show that COVID-19 vaccines are associated with a reduction in the development of long-COVID.
- 3. COVID-infection carries a risk of developing long-COVID and vaccines have been shown to reduce this risk.
- 4. There are some known risks associated with COVID-19 vaccines, these are extremely rare, and the risks of getting COVID-19 are far more significant.
- 5. So far, even after over 13 billion vaccine doses, there is no evidence to indicate vaccines increase the risk for chronic fatigue syndrome.

Supporting references:

- Protective effect of COVID-19 vaccination against long COVID syndrome: A systematic review and meta-analysis. Vaccine. 2023 Feb 8.

- Effect of covid-19 vaccination on long covid: systematic review.2023;2(1).

- <u>A Systematic Review and Meta-analysis. Brain, Behavior, and Immunity. 2023 Mar 27</u>.





The International Society of Pharmacovigilance (ISoP) 22nd Annual Meeting | 6 - 9 Nov. 2023

This year's conference will take place at the Sanur Prime Plaza Hotel Bali. The theme of this year's conference is Putting Patients First in Pharmacovigilance: International

Perspectives from Global South. Sessions will include clinical aspects of pharmacovigilance, ecopharmacovigilance, medical devices, women's medicines, vaccine

pharmacovigilance and drug safety in older patients. Co-directors of the GVDN, Steve Black and Jim Buttery will be presenting during this conference.



Aotearoa New Zealand Immunisation **Conference 2023 and** pre-conference Workshop | 15-17 Nov. 2023

Hosted by Immunisation Advisory Centre (IMAC) this two-day Conference, preceded by a one-day Workshop will aim to increase your understanding of vaccine-preventable disease control and immunisation delivery services. The Conference provides an excellent opportunity for researchers to present their academic research. and other delegates to present their experiences and practices related to service delivery or policy decisions. Helen Petousis-Harris, Co-Director for GVDN will be

in attendance presenting.

Read more



024 ISPE Europe Annual Conference | 16-18 Apr. 2024

Next year's conference will take place in Lisbon, Portugal. This conference will explore innovations in facility design and delivery, emerging trends in technologies, manufacturing, and support areas such as laboratories and warehousing. Attendees will gain insight from exciting technical presentations, casestudies, and panel discussions from industry and regulatory leaders involved in the planning, building, and approving of the "facilities of the future".

Read more

Read more

Spotlight

Has someone in your team or wider organisation done something amazing that others should hear about? Or maybe they're just an all-around great person to work with? In each issue, we want to celebrate those across our network who have made an impact. We're keen to profile these superstars, so send a brief profile of them with an accompanying image.

Respond



Seen some interesting research? Maybe something really awesome happening in your line of work? Or do you want to celebrate a recent milestone? Whatever it is, send your contributions to the Safety by Numbers Editorial Board

Respond



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