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# Safety by Numbers

Highlighting collaboration and data to support vaccine safety communication

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## News & updates

### Lead article: The next generation of pharmacovigilance



*Dr. Robert T. Chen, Project Lead, SPEAC / Scientific Director, Brighton Collaboration*

Historically, much of the safety assessment of a new vaccine was deferred to post-introduction. Safety assessments within pre-approval clinical trials tended to be separate from post-approval Real-World Evidence (RWE). There were barriers to implementing a vaccine lifecycle approach, including a disconnect between separate teams and staff for pre- versus post-approval. Applicability in low- and middle-income countries (LMICs) and high-income countries (HICs) was also limited. In fact, LMICs were often missing large administrative datasets.

As discussed at the recent conference of the International Alliance for Biological Standardization (IABS), Real-World Evidence offers opportunities to break down these barriers to implementation in LMICs and improve regulatory and public health decision-making. The Safety Platform for Emergency vACcines (SPEAC) supports the harmonisation of safety evaluation in clinical trials and in the generation of RWE.

SPEAC is a major initiative by CEPI and the Brighton Collaboration to develop tools for vaccine safety assessment in the pre-introduction phase that harmonises with the post-introduction phase. To do so, we are establishing a RWE infrastructure for vaccine safety during early deployment.

Our work in the monitoring of clinical trials and the development of case definitions, companion guides, and codes that can be used in RWE will advance this vision. We are conducting landscape assessments for sites that can conduct pharmacovigilance in LMICs with the aim of linking with sites that may be trained and engaged for safety evaluations.

SPEAC's work focuses on new vaccines being developed against CEPI's priority pathogens, including Lassa fever, Chikungunya, Nipah virus, and MERS. However, SPEAC's RWE framework for CEPI pathogens can be adapted for other pathogens. We look forward to future opportunities to expand this work to other pathogens.

Dr. Robert T. Chen



**The journey to a vaccine-empowered  
Pacific**



*Attendees of the Pacific Islands Health Research Symposium (PIHRS) in Fiji*

In the heart of Fiji, the Pacific Islands Health Research Symposium (PIHRS) held between 4th and 6th September, provided a platform for fostering unity and progress in the Pacific region. Sponsored by the South Pacific Community (SPC) and hosted by the Fiji National University (FNU), the PIHRS aims to provide a platform for Pacific Island nations to collaborate, engage, and support one another on healthcare advancements.

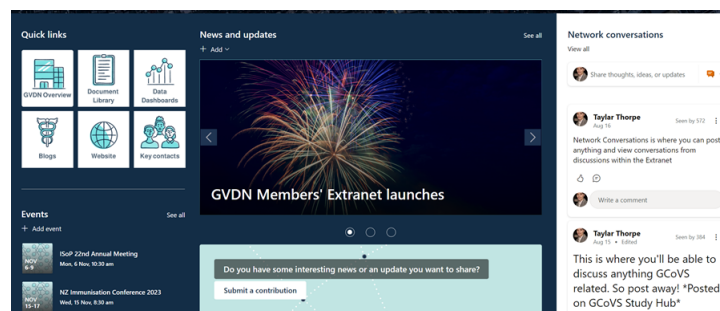
Hazel Clothier, a Global Vaccine Data Network (GVDN) epidemiologist who attended the PIHRS, offered reflections of the symposium that echo the GVDN and the Regional Enhanced and Vaccine Capacity in the Pacific (REVCAP) ambitions to empower vaccine research in Pacific Island nations. One of the central questions raised at the event was, "Is this vaccine safe for me as a Pacific Islander?"

To ensure that this question is addressed appropriately, it is imperative that Pacific data informs Pacific programs. Each island nation is a melting pot of cultures, ethnicities, and languages; no single nation will have the same requirements for its population. As a result, the need to address vaccine safety concerns must be specific to these communities and addressed by those within these communities. To answer this, GVDN and REVCAP aim to consider the unique profiles of non-communicable diseases and co-morbidities prevalent in the Pacific region, such as diabetes,

obesity, and adverse events following immunisation (AEFI).

The message is clear: relying on safety data from non-Pacific Island countries or ethnicities isn't sufficient. Instead, the focus should be on context-specific concerns, embracing Indigenous knowledge, and recognising the strength and resilience of Pacific communities. As we move forward, it is essential we work with the Pacific Large Oceanic Nations to work within existing systems and limited resources. The approach must be Pacific-prioritised, Pacific-led, and Pacific-published research. Maintaining these key factors will ensure sustainability and purpose in our shared journey toward a safer and more connected Pacific region.

## **GVDN Members' Extranet launched**



*Home page view of the GVDN Members' extranet*

We are thrilled to announce the GVDN Members' Extranet launch, your exclusive gateway to all things GVDN! This platform will serve as your central hub for the latest news, and resources and to engage with one another!

You would have received an email invitation from [myHub@auckland.ac.nz](mailto:myHub@auckland.ac.nz), enabling you to collaborate with the University of Auckland. If you haven't received the email notification, please email [gvdnsecretariat@uniservices.co.nz](mailto:gvdnsecretariat@uniservices.co.nz). Once you receive the notification, accept the invitation and you'll have full access to the GVDN Members' Extranet.

If you haven't viewed what's on offer just yet, here are a few features you may be interested in:

**Quick links:** Easily access essential components of our work, including the Document Library, Data Dashboards, Blogs, Website, Key Contacts, and Network conversations.

**Document library:** We've migrated files and folders into the Extranet, offering better access controls and editing options.

**News and updates:** Stay informed with the latest news and updates from our network and beyond, including our quarterly newsletter.

**Network conversations (live discussion):**

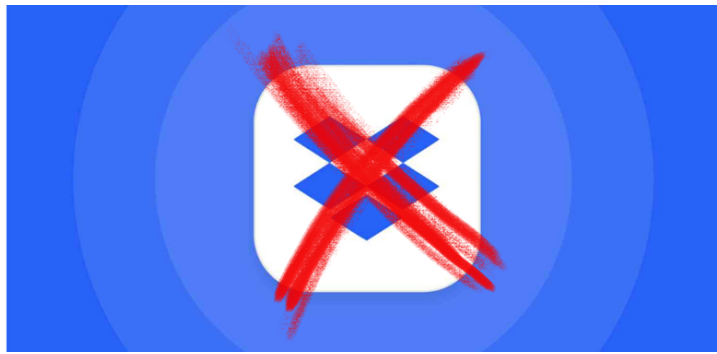
Engage with fellow members through Viva Engage, similar to social media platforms. Share thoughts, feedback, questions, and connect with the global health community.

**Social feeds:** Explore social media feeds from our partner organisations, collaborators, and global health influencers.

This is just the beginning of our Extranet, we want to enhance your experience continually, so please share all feedback with us at [gvdnsecretariat@uniservices.co.nz](mailto:gvdnsecretariat@uniservices.co.nz).

Don't forget to bookmark the Members' Extranet for easy access. We hope you enjoy your journey through the GVDN Members' Extranet—your window to a world of global health knowledge and collaboration!

**GVDN Dropbox closure**



Due to the GVDN Members' Extranet and utilisation of the Document Library feature within it, we will be ending the use of Dropbox **from November 2023**.

To ensure a smooth transition, we have sent several reminders to current Dropbox users to keep everyone well-informed about this change.

All Dropbox content has been successfully copied to our Extranet platform. Rest assured, users with Dropbox access will receive equivalent document access on the Extranet.

During the adjustment phase to the new platform, it's essential that you notify the GVDN Secretariat - [gvdnsecretariat@uniservices.co.nz](mailto:gvdnsecretariat@uniservices.co.nz) of any changes, uploads, or deletions of documents within Dropbox. This will help maintain the correctness and currency of documentation on the Extranet.

To those using the Dropbox, thank you for your understanding as we work through this process.

### **GVDN website revamp**



The official [GVDN website](#) is about to undergo an exciting transformation over the next month. This redevelopment is set to enhance the online experience of our users and provide a more accessible platform.

Some structural work has already been completed, most notably on the [‘Our People’](#) and [‘News’](#) sections. More structural work is yet to be completed. In the meantime, we are doing a full review of the content that currently exists so that we can look to improve this going forward. As part of this review, we will also be working on the overall design to ensure consistency and visual appeal. Check out the GVDN website over the next few weeks to see what’s changed!

As always, we’re keen to hear your thoughts on what could be improved, so let us know by emailing [gvdnsecretariat@uniservices.co.nz](mailto:gvdnsecretariat@uniservices.co.nz).



## **Sensorineural hearing loss (SNHL), Lassa fever, & vaccines**

**SPEAC**

**Webinar: Sensorineural Hearing Loss (SNHL), Lassa fever disease and vaccines**

September 22<sup>nd</sup> at 9 AM EDT / 3 PM CEST

Brighton CEPI

**Recording disclaimer and webinar instructions**

This webinar will be recorded and the recording will be made public.

During the discussion session all audience members will be muted. If you have questions, please use the Q&A box. The questions will be answered at the end of each session. Please add your name and affiliation before the question to help others recognize you.



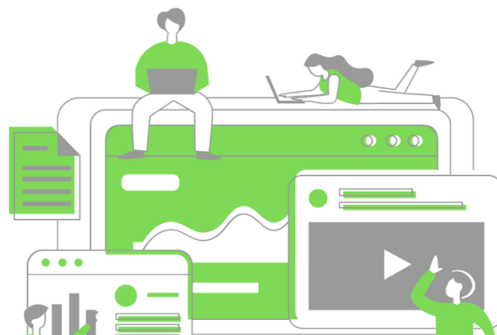
SPEAC hosted the Sensorineural Hearing Loss (SNHL), Lassa Fever and Vaccines webinar on September 22. The aim of the event was to review what is known regarding SNHL, Lassa fever disease, and vaccines, and to discuss how hearing abnormalities that may occur during clinical trials should be evaluated and monitored.

**Discussion topics included:**

- Assessing hearing loss in clinical trials
- Lassa Fever Disease and SNHL
- Mouse models of Lassa and SNHL
- NHP Models of Lassa and SNHL
- Discussion of an optimal approach

Even though hearing loss has not been recognised in early clinical trials, assessing hearing loss in larger trials will be important.

**New digital platforms for Brighton Collaboration**



Brighton Collaboration’s website has a new look! Visit [BrightonCollaboration.org](https://BrightonCollaboration.org) to access all Brighton case definitions, safety templates, and recent news.

The SPEAC project launched its new website! Visit [speacsafety.net](https://speacsafety.net) to access adverse event of special interest (AESI) lists, case definition companion guides, vaccine safety templates, guidance documents, and more.



**COVID Vaccine Monitor project completion  
with closing event  
in Utrecht**



*Members of the CVM consortium gathered for a group photo at the Villa Jongerius in Utrecht, the Netherlands October 2023.*

VAC4EU proudly hosted the closing event of the CVM project on the 10th of October in Utrecht, The Netherlands.

This closing event, titled “*Lessons Learned about the Methods of Monitoring COVID-19 Vaccine Safety*” was jointly organised by VAC4EU and the European Pharmacoepidemiology and Pharmacovigilance (EU PE & PV) Research Network. Key leaders in COVID-19 vaccine research shared their findings and provided insights into the future of vaccine safety methods. They are working on a manuscript to share these learnings with the wider public – Stay tuned!

CVM was an EMA-sponsored extension of the Early COVID-19 Vaccine Monitor (ECVM) project conducted by the EU PE & PV Research Network in collaboration with VAC4EU. The research conducted in CVM built upon this body of work by focusing on populations of special interest and using primary data collection. Over 680,000 vaccinated people were approached about

vaccine-related side effects.

Available pseudonymised European electronic health records were also utilised to efficiently assess and quantify associations between adverse events and COVID-19 vaccinations. Finally, the project evaluated methodologies used in vaccine safety monitoring, aiding in future study conduction. Links to all protocols can be found on the [VAC4EU website](#) and all deliverable reports are available on the [VAC4EU Zenodo community](#), including the two final reports.

We would like to also congratulate the study teams for the completion of yet another vital vaccine research project!

### **The seventh General Assembly Meeting (GAM) in home city of Utrecht**

VAC4EU hosted their seventh GAM in Utrecht on the 11th of October. The Executive Board and Secretariat were delighted to welcome close to 100 representatives of the 27 member organisations online and live in The Netherlands for the event which included reflections on this year's accomplishments and plans for engagement over 2024.

Drawing on a rich background and expertise in vaccine safety, effectiveness and coverage research, VAC4EU anticipates continued growth and adaptation along with the evolving ecosystem and landscape of vaccine research. The network is currently in the stage of consolidating, harmonising and aligning to the post-COVID-19-pandemic period.

The event launched with an engaging course on Target Trial Emulation (TTE), given by three prominent experts in the field of pharmacoepidemiology: Xabier García de Albéniz (RTI Health Solutions), Susana Monge (Institute of

Health Carlos III), and Elisa Martín-Merino (Spanish Agency of Medicines and Medical Devices).

This course highlighted the TTE framework to aid in preventing self-inflicted bias in observational studies where conducting a randomised control trial would be unfeasible.



The Foundation for the National Institutes of Health (FNIH) and Institute for Vaccine Safety (IVS) at Johns Hopkins University co-hosted a meeting on Capitalizing on Opportunities in Post-Authorization Vaccine Safety Science on Friday, October 13, 2023 that was well-attended by experts in the field. The goal of the meeting was to identify challenges, opportunities, and capacity in post-authorisation vaccine safety science and to discuss the value proposition and potential formats of a public-private partnership to advance post-authorisation vaccine safety science.

Michael Santos of FNIH facilitated the call and an esteemed group of global experts presented on these topics, including Daniel Salmon (Institute for Vaccine Safety), Robert Chen (Brighton Collaboration), Steve Black (Global Vaccine Data Network), Bruce Carleton (British Columbia Children's Hospital), Karina Top (University of Alberta), Heidi Larson (The Vaccine Confidence Project), and Alena Khromava (Sanofi Pasteur) and Sarah Frise (AstraZeneca) on behalf of the Beyond COVID Monitoring Excellence (BeCOME) Steering Committee.

A robust discussion covered various topics, including:

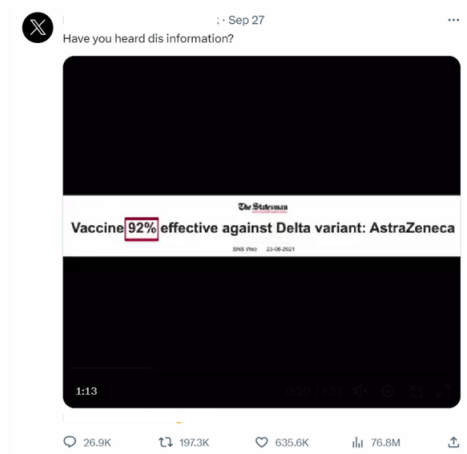
- Engaging all the appropriate stakeholders and accommodating the rules of engagement for some partners.
- Determining the appropriate process for convening a partnership and aligning partners and resources.
- Balancing the fact that vaccine safety science is an ongoing need with practical constraints on funding periods.
- Identifying activities of the partnership, such as establishing a mechanism for quick response to changing needs; developing a surveillance system integrated with health system strengthening or regulatory system strengthening; building capacity for larger observational studies; and considering workforce development to support the next generation of vaccine safety science experts.

Immediate next steps include soliciting interest in continuing the conversation, including from additional partners not able to participate on the call, and to develop a concept note for consideration by public and private stakeholders.

If you would like to receive future updates on this effort, please email Michelle Goryn at [mgoryn1@jh.edu](mailto:mgoryn1@jh.edu).



**Social media CEO shares COVID-19 vaccine misinformation video**



*Screenshot of the viral tweet and video*

A viral video that tracks the decline in the reported effectiveness of COVID-19 over time insinuates that early headlines about the vaccines being “100 percent effective” were disinformation. Shared by a social media CEO, the video has been viewed over 70 million times.

The CEO also claimed that the COVID-19 booster almost sent him to the hospital and argued against vaccine mandates. The viral video is highly misleading because it does not distinguish between trial efficacy and real-world effectiveness, or between effectiveness against severe disease and effectiveness against infection.

The Public Health Communications Collaboration has answers to many of the vaccine effectiveness FAQs to support people in understanding the misinformation presented in the video. Click the button below to find out more.

Source: [Public Health Communications Collaboration](#)

[Read more](#)



**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. GVDN Co-Director, Jim Buttery, will be presenting during this conference.

[Read more](#)



**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. GVDN Co-Director, Helen Petousis-Harris, and three of the GCC team will be presenting at this conference.

[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, case-studies, and panel discussions from industry and regulatory leaders involved in the planning, building, and approving of the “facilities of the future”.

[Read more](#)

## Spotlight



Dr. Wan-Ting Huang is an adjunct instructor at the National Taiwan University Global Health Program.

In 2021, the National Taiwan University Health Data Research Center partnered with GVDN. Dr. Huang became the lead investigator for the site and helped ensure that all study implementations and data sharing comply with scientific standards and Taiwan’s policies. Her team contributed the background incidence of AESI in Taiwan to GVDN’s Global COVID Vaccine Safety project and is looking forward to contributing more COVID-19 vaccine safety data soon.



She has served on the Brighton Collaboration Science Board since 2018, leads the SPEAC project's quality assurance and continuous improvement efforts, and serves as the lead investigator for GVDN's site in Taiwan. [Learn more about Dr. Wan-Ting Huang's career in the vaccine safety field.](#)

If you have someone or a team from across the global network that you wish to spotlight, send your contributions to [gvdnsecretariat@uniservices.co.nz](mailto:gvdnsecretariat@uniservices.co.nz).



Seen some interesting research? Maybe something awesome is 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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