



We are pleased to share recent updates from SPEAC, including new safety tools, real-time evidence resources, global engagement activities, and capacity-building efforts across partner networks.

Our focus remains consistent:

**Support CEPI awardees, developers, and public health partners in implementing strong, trusted, and globally aligned vaccine safety systems for epidemic-prone diseases.**

Over the past several months, we have advanced work in four key areas:

- Expanding independent safety oversight expertise
- Strengthening AESI tools for priority pathogens
- Providing continuously updated evidence on new vaccines
- Working alongside regional partners to operationalize safety practice

Thank you for your continued partnership and collaboration.



## Training & Capacity Building

### Expanding DSMB Expertise for Clinical Trials and Emergency Studies

SPEAC's Data and Safety Monitoring Board training program continues to support growth of a global community of experts prepared to oversee vaccine trials — including in outbreak-response and rapid-deployment contexts.

- **March & June cohorts:** 30 graduates
- **October cohort:** In partnership with Africa CDC, 40+ participants, our largest group to date, representing multiple African regions and technical backgrounds

[Read more](#)

### How partners benefit

- Access to a broader pool of qualified DSMB members
- Consistent, evidence-driven oversight approaches
- Increased readiness for emergency vaccine studies

Learn more: <https://speacsafety.net/dsmb-support/>

If your organization anticipates DSMB needs or wishes to nominate participants, please connect with us here: [bc-coordinator@gmail.com](mailto:bc-coordinator@gmail.com)

**Current DSMB Pool**



## Tools & Resources

### Updated AESI Lists for Marburg & Rift Valley Fever

SPEAC has released updated AESI lists for **Marburg virus disease (MVD)** and **Rift Valley fever (RVF)**—reflecting new literature, biological rationale, clinical observations, and platform-specific considerations, including pregnancy and other special populations. These updates support partners planning upcoming clinical studies and outbreak-response activities.

**How partners can use them**

- Select and justify protocol safety endpoints
- Harmonize case finding and classification
- Train investigators and study teams
- Support ethics and regulatory submissions
- Strengthen preparedness for rapid-response studies

**Marburg AESI List:** <https://speacsafety.net/tools/aesi-lists/marburg/>  
**RVF AESI List:** <https://speacsafety.net/tools/aesi-lists/rift-valley-fever/>



## Active Safety Surveillance Dashboard

A practical reference tool summarizing LMIC experience with active safety surveillance across multiple vaccines and platforms.

Use this to:

Benchmark real-world surveillance models

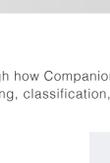
Plan safety monitoring in similar contexts

Identify approaches for priority groups (e.g., pregnancy)

Communicate examples to ministries, ethics boards, or funders

Explore the dashboard: <https://active-surveillance.speacsafety.net/description>

### Partner Tip — Try This in Under 60 Seconds



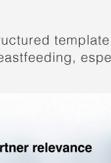
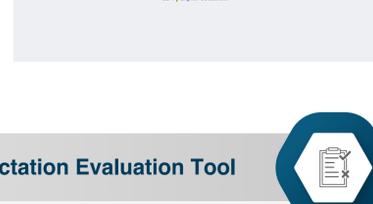
Looking at post-deployment safety planning?

Filter the Active Surveillance Dashboard by:

**Population - Pregnant women**

to see real-world monitoring models in LMIC settings.

[Explore dashboard](#)



## Brighton Companion Guide Explainer

This short video walks through how Companion Guides translate Brighton case definitions into practical steps for case finding, classification, and documentation.

**Helpful for**

- Study teams
- PV officers
- Regulatory or ethics briefings

**Read more:** <https://speacsafety.net/cd-companion-guide-explainer-video/>

**Watch:** [https://youtu.be/d\\_g0OW-CNE?si=T9mTl0Ays5FBdVt5](https://youtu.be/d_g0OW-CNE?si=T9mTl0Ays5FBdVt5)

**Brighton Collaboration Case Definition Companion Guides**



## Pregnancy & Lactation Evaluation Tool

Structured template for evaluating vaccines intended for use during pregnancy and breastfeeding, especially in emergencies or when evidence is limited.

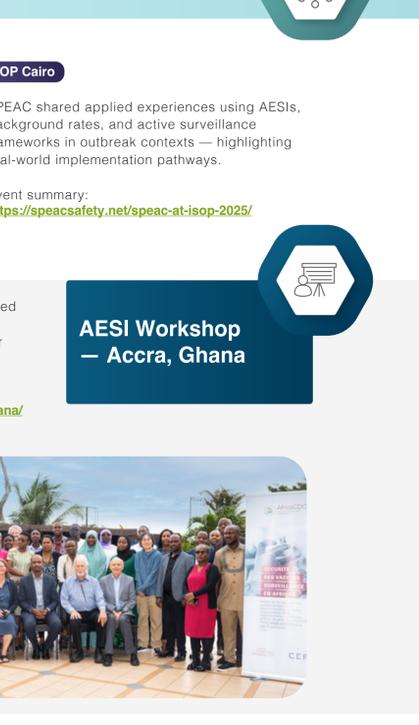
**Partner relevance**

Transparent, consistent assessment of benefit-risk

Supports regulatory and ethics review

Facilitates internal decision-making

**Access template:** <https://www.sciencedirect.com/science/article/pii/S0264410X25008102>



## Living Systematic Reviews

Continuous evidence review for high-priority pathogens. Current LSRs available include:

Mpox

Lassa fever

Chikungunya

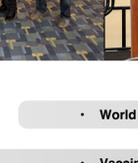
**Partner value**

- One source for continuously updated safety evidence
- Supports regulatory and scientific engagement
- Identifies data gaps to inform study planning

**Explore LSRs:** <https://speacsafety.net/tools/living-systematic-reviews/>



## Global Engagement & Implementation



### ISOP Cairo

SPEAC shared applied experiences using AESIs, background rates, and active surveillance frameworks in outbreak contexts — highlighting real-world implementation pathways.

**Event summary:** <https://speacsafety.net/speac-at-isop-2025/>

With Africa CDC and CEPI, SPEAC supported AESI capacity building for 40 participants from 20 countries, reinforcing readiness for emerging disease responses.

**Workshop recap:** <https://speacsafety.net/aesi-workshop-in-ghana/>

### AESI Workshop — Accra, Ghana



## Additional Events

• **World Vaccine Congress (DC):** [special populations & outbreak safety](#)

• **Vaccine Congress (Kyoto):** [SPEAC five-year reflection poster](#)

• **CEPI Clinical Office Week (London):** [alignment with CEPI safety mission](#)

• **ISPE (DC):** [AESI-X approach for novel platforms](#)

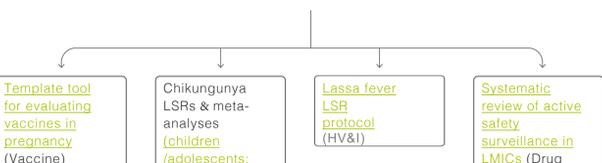
• **GVIRF (Rio):** maternal and pediatric safety



## Publications & Scientific Contributions

**SPEAC-Led**

Methods and frameworks supporting harmonized safety assessment:



These and all SPEAC publications can be found [HERE](#)



## Authored by SPEAC Experts

Independent contributions to global vaccine safety science, including:

• **"Risk of Guillain-Barré syndrome after COVID-19 vaccination or SARS-CoV-2 infection: A multinational self-controlled case series study."** Steve Black, Clare L. Cutland, Vaccine

• **"A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for the emergent vesicular stomatitis virus (VSV) viral vector vaccine for Lassa fever"** (Brighton Collaboration). R T Chen, Emily R Smith, Vaccine

• **"Longitudinal Meta-cohort study protocol using systems biology to identify vaccine safety biomarkers,"** R T Chen, Vaccine



## Team News



**SPEAC Team Meeting — Atlanta**

Focused on strengthening digital tools, expanding access to training, and aligning with CEPI's evolving priorities.

**Read more:** <https://speacsafety.net/speac2foctober2025/>



### Recognizing Dr. Steven Black

As Dr. Black begins transitioning at the end of 2025, we acknowledge his leadership, mentorship, and contributions to global vaccine safety science and SPEAC's mission.

Website: <https://speacsafety.net>  
LinkedIn: <https://linkedin.com/company/speac-safety>  
Contact: [bc-coordinator@taskforce.org](mailto:bc-coordinator@taskforce.org)

**Stay Connected**

We look forward to continued collaboration in strengthening vaccine safety systems for epidemic-prone diseases and emergency response.