OPT-MVAC ReSaG 3 – Summary Note
Theme: Strengthening pharmacovigilance systems to support malaria vaccine rollout
Webinar recording (password: U+sT1kq5)
Date: 4 June 2026

Period reviewed: 15 October 2025 – 15 March 2026

Objective: To review findings from ReSaG Report 3, assess progress in malaria vaccine safety surveillance across OPT-MVAC countries, discuss challenges affecting reporting and investigation of adverse events, and identify priorities for strengthening pharmacovigilance systems at country level.

1. Key highlights (Report 3 – RCC)

Twelve of the fourteen OPT-MVAC countries had introduced a malaria vaccine by the end of the reporting period. Guinea-Bissau became the latest country to introduce vaccination, resulting in an even distribution between countries using RTS,S and those using R21/Matrix-M.

A total of 656 adverse events following immunization (AEFIs) related to malaria vaccines were reported during the six-month period. Most reports were associated with R21/Matrix-M, reflecting broader deployment and increased reporting activity in countries using this vaccine.

The overall safety profile remained consistent with previous reporting periods. Most reported events were non-serious and primarily involved fever, gastrointestinal disorders and general systemic symptoms commonly observed following vaccination.

Eighteen serious cases were reported, including two deaths. However, participants noted that available information was often incomplete and that causality assessments had not been conducted for several serious cases. As in previous reports, the absence of thorough investigations limited interpretation and highlighted the need for stronger case follow-up mechanisms.

One of the most notable developments during the reporting period was the substantial increase in reporting from Burkina Faso. The number of reports increased markedly compared with previous reporting cycles, reflecting both expanded vaccine deployment and strengthened reporting practices. Participants welcomed this progress while noting that several countries continued to report few or no cases, raising questions about reporting completeness and surveillance performance.

2. Reporting quality and investigation remain key challenges

Discussion following the report focused heavily on the quality of reported data rather than reporting volume alone.

Participants emphasized that an effective pharmacovigilance system extends beyond case notification. The full pharmacovigilance cycle includes detection, reporting, investigation, causality assessment and communication of findings. While reporting rates have improved in some countries, significant gaps remain in the investigation and documentation of serious cases.

Several recurring challenges were highlighted:

- Incomplete clinical information in reports
- Delayed or absent investigations of serious cases
- Limited documentation supporting causality assessments
- Inconsistent reporting practices between countries
- Lack of access to denominator data, including vaccine doses administered

Participants noted that improving data quality is essential to generating meaningful evidence and maintaining confidence in malaria vaccination programmes.

3. Assessing pharmacovigilance capacity across OPT-MVAC countries

A second presentation reviewed the status of pharmacovigilance systems across the 14 OPT-MVAC partner countries.

Using available information from national assessments, VigiBase data and previous consortium discussions, countries were grouped according to pharmacovigilance maturity, operational capacity and demographic context.

The assessment highlighted significant diversity across the consortium:

- Group A: Established systems facing high operational demand

Countries such as Cameroon, Côte d'Ivoire, Ghana and Nigeria have relatively mature pharmacovigilance structures supported by regulatory authorities, established reporting mechanisms and substantial technical expertise. However, these countries also face significant demographic pressures and large-scale vaccination programmes, creating operational challenges despite strong institutional foundations.

- Group B: Emerging systems with growing integration

Countries including Benin, Burkina Faso, Mali, Niger, Senegal and Togo have demonstrated notable progress in integrating pharmacovigilance into routine health programmes. Increased reporting, stronger programme coordination and growing digitalization were identified as strengths. However, these systems often remain dependent on external support and continue to face resource constraints.

- Group C: Developing systems with fragile foundations

Countries such as Chad, The Gambia, Guinea and Guinea-Bissau have made important progress in recent years but continue to face structural limitations. While some have demonstrated strong performance during specific vaccination campaigns, maintaining routine pharmacovigilance activities remains a challenge. Capacity building and sustained institutional support remain priorities.

Participants stressed that these categories are intended to guide discussion and support planning rather than rank countries. The exercise highlighted the need for tailored approaches that reflect each country's specific context, strengths and constraints.

4. **Strengthening collaboration between programmes**

A recurring theme throughout the webinar was the importance of collaboration between national malaria programmes, immunization programmes and pharmacovigilance centres.

Experience across OPT-MVAC countries has shown that vaccine safety surveillance is most effective when these programmes work in close coordination. Stronger collaboration can improve reporting, facilitate investigations, strengthen data sharing and support more rapid responses to safety concerns.

Participants noted that progress has been uneven across countries. While some have established effective mechanisms for coordination, others continue to operate through parallel systems with limited interaction. Strengthening these relationships was identified as a key priority for future activities.

5. **From assessment to action**

The webinar also reviewed efforts to better understand country needs through a pharmacovigilance baseline assessment questionnaire distributed across the consortium.

The objective is to move beyond describing challenges and towards the development of practical, country-specific solutions. Information gathered through the questionnaire will help identify gaps in areas such as governance, workforce capacity, reporting systems, investigations, digital tools and programme coordination.

This work will inform a strategic action plan designed to provide tailored support to participating countries rather than applying a uniform approach across all settings.

Participants welcomed this direction and emphasized the importance of aligning support activities with national priorities and existing health system structures.

6. **Key recommendations and next steps**

The following priorities emerged from discussions:

- Improve the completeness and quality of serious case investigations.
- Strengthen causality assessment processes and documentation.
- Increase consistency of reporting across participating countries.
- Improve access to denominator data, including vaccine doses administered.
- Strengthen coordination between malaria, immunization and pharmacovigilance programmes.
- Expand the use of digital reporting and data management tools.
- Use country assessments to develop tailored pharmacovigilance strengthening plans.
- Continue ReSaG knowledge-sharing activities to facilitate peer learning and exchange of best practices.

7. Conclusion

ReSaG 3 demonstrated continued progress in malaria vaccine safety surveillance across OPT-MVAC countries while highlighting important gaps that remain in reporting quality, investigation and system performance. Discussions reinforced the view that malaria vaccine introduction presents a valuable opportunity not only to monitor vaccine safety, but also to strengthen national pharmacovigilance systems more broadly. By combining regional learning, country assessments and targeted support, the consortium aims to build more sustainable and effective pharmacovigilance systems capable of supporting both current and future malaria control interventions.