OPT-MVAC ReSaG 2 – Summary Note
Theme: Pharmacovigilance and surveillance of AEFIs related to malaria vaccines (RTS,S / R21)
Webinar recording: (password: 3*97JXaR)

Period: May → October 2025
Countries reviewed in depth: Benin – Burkina Faso – Ghana
Objective: to share the findings of Report 2, compare national approaches, and identify pharmacovigilance (PV) priorities to strengthen.

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1) Key highlights (Report 2 – RCC)

- **Data sources:** VigiBase + OPT-MVAC dashboard (administered doses).
- **Top 3 countries by number of reports:** Benin, Ghana, Burkina Faso.
- **Reporter profile:** the majority of reports are submitted by non-physician health workers, which may limit clinical quality (diagnosis, investigations, level of detail).
- **Frequently reported symptoms:** fever, gastrointestinal disorders, local reactions.
- **Focus on serious cases:** deaths have been reported (mainly in Ghana and Burkina Faso in the dataset reviewed).
- **Limitation:** WHO causality assessment / medico-legal assessment is often missing or incomplete → highlighting the need for more robust investigations.

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2) Country summaries

BJ Benin

- **37 AEFIs** (during the period)
  - 35 non-serious, 2 serious, 0 deaths.
- **Main symptoms:** fever, with some cases of cough, vomiting, diarrhoea, and convulsions.
- **Organisation:** reporting at health facility level with data entry via focal points (district → national).
- **Limitation:** WHO causality assessment not yet finalised (incomplete files / committee pending).

BF Burkina Faso

- **Mixed system:** Med Safety–type application plus paper-based reporting.
- **Strong emphasis on sensitisation:** some “common” adverse events tend to be normalised → under-reporting risk.

- **Serious case/death discussed:** possible co-exposure context (e.g. SMC: SP + amodiaquine); no autopsy performed; diagnosis retained by the committee: gastroenteritis; causality assessed as coincidental.

GH Ghana

- **RTS,S:** introduced in 2019; **R21:** introduced in the last quarter of the previous year.
- **R21 surveillance:** strong active surveillance component (Cohort Event Monitoring).
- **Data May–Oct 2025:** 96 R21 reports
  - 89 active, 7 passive
  - **Symptoms:** fever, diarrhoea, vomiting
  - **3 serious cases** (hospitalisation): mostly assessed as coincidental, except for one product-related local reaction.
- **Limitations:** incomplete clinical files and delayed investigations → difficult causality assessment.

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3) Main technical discussion: "Malaria" after vaccination

- **Key debate:** can malaria be reported as an AEFI?
  - **Position 1:** malaria is an independent disease → not a vaccine "effect".
  - **Position 2:** malaria may be reported as an event if confirmed, then classified after investigation (coincidental / vaccine failure / other).
- **Sensitive issue:** very early malaria cases (Day 0–Day 25) → may reflect prior exposure, incomplete immunity (incomplete series), or reporting quality issues.
- **Consensus:** investigation, timeline, doses received, and context are required before interpretation.

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4) Methodological reminders (Ghita Benabdallah)

- **PV chain:** detection → reporting → investigation → WHO causality assessment → communication.
- **Critical elements:**
  - confirmed diagnosis (clinical + laboratory investigations),
  - chronology (time to onset, dose administered),
  - completeness of serious case files (including deaths, autopsy or verbal autopsy where possible).
- **Objective:** reduce false signals and maintain confidence in vaccination.

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5) Next steps (questionnaire & action plan)

- A questionnaire will be sent to countries to prioritise PV actions (budget optimisation, field needs).
- **Indicative timeline:**
  - questionnaire sent: shortly
  - responses due: mid-January
  - recommendations validated: consortium
  - implementation start: March
- Vaccinovigilance/causality training is already planned by the consortium and should be integrated into country planning.

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6) Proposed actions (to be followed up)

1. Strengthen quality and completeness of serious case documentation (diagnosis, investigations, chronology, doses).
2. Harmonise management of post-vaccination malaria cases (reporting vs classification).
3. Reduce investigation timelines (especially for deaths and hospitalisations).
4. Promote digital tools (e.g. Med Safety–type applications) with field-level support.
5. Link vaccination data (doses administered) with AEFI data to better characterise safety profiles.