Strengthening quality assurance in clinical research in resource-constrained settings: The ethical imperative to develop, implement, and evaluate ancillary care policies

IABS & IABS-EU Workshop on Assessing Consequences of Maternal Immunization on Foetal Outcomes, June 8, 2026
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Framing 1/2

"[…] Since medical research takes place in the context of various structural inequities, researchers should carefully consider **how the benefits, risks, and burdens are distributed**. Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to **share their priorities and values**; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating result." (Article 6)

Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants, World Medical Association, 2024

Framing 2/2

Clinical research in resources-limited settings. A consensus by a CIOMS Working Group. Geneva, Switzerland: Council for International Organizations of Medical Sciences (CIOMS), 2021.

4.2.3 Caring for participants' health needs

Researchers have an ethical obligation to care for participants' health needs during research and, if necessary, for the transition of participants to care when the research is concluded. Even though such care may be an incentive for participants in low-

resource settings, it should not be considered an undue influence.[1, Guideline 6] In

4.3.1 Justifying the burden of research

Clinical research has not only benefits (see 1.5), but also represents a burden for the study population. It exposes study participants to a degree of inconvenience and potential risks, and may absorb scarce individual or health systems resources. In a fair collaborative partnership, the host country should determine for itself whether these burdens are offset by the expected benefits for the community's health,[131] or by other benefits such as the provision of ancillary medical care or the donation of medical equipment, although weighing such indirect benefits requires a great degree of effective independent oversight by RECs.[132]

PregInPoxVac

Pregnancy & Infancy mPox Vaccine study

- Phase 3, open-label, monocentric, randomised Mpox vaccine trial
  - Sponsor: University of Antwerp
  - Principal investigator: University of Kinshasa
- Trial setting: Boende, Tshuapa Province, DRC
- Timeframe: 24-25 months (start June 2025)
- Population: 362 pregnant/postpartum women
  - Evaluate the safety, reactogenicity, and immunogenicity of the MVA-BN vaccine

→ Ancillary Care (AC) built into trial design and protocol

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Background & ethical rationale

Context:

- Maternal vaccine trial in low resource setting
- Limited access to quality (antenatal) care
- Delays in care
- Expected high baseline morbidity

Ethical grounding:

- Principles of beneficence, justice, and respect for persons
- AC obligations arise when healthcare access is lacking or in contexts of vulnerability

Scientific grounding:

- Risk of under ascertained adverse events: incompleteness/bias
- Implications for data validity and quality

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AC policy development in PregInPoxVac

General considerations:

- Known community and research setting
- Participant population with specific 'scientific complexities'
- Micro-level care (participants) versus macro-level (health system) strengthening efforts
- AC for participant population only: inequalities, unfairness
- Limitations of local available care
- (Influence of) traditional medicine and self-medication
- Ineligible participants and screened-out

→ **Pre-trial participatory workshops**

→ **EC approval + participant IC**

Ancillary care algorithm for PregInPoxVac in Boende (DRC)

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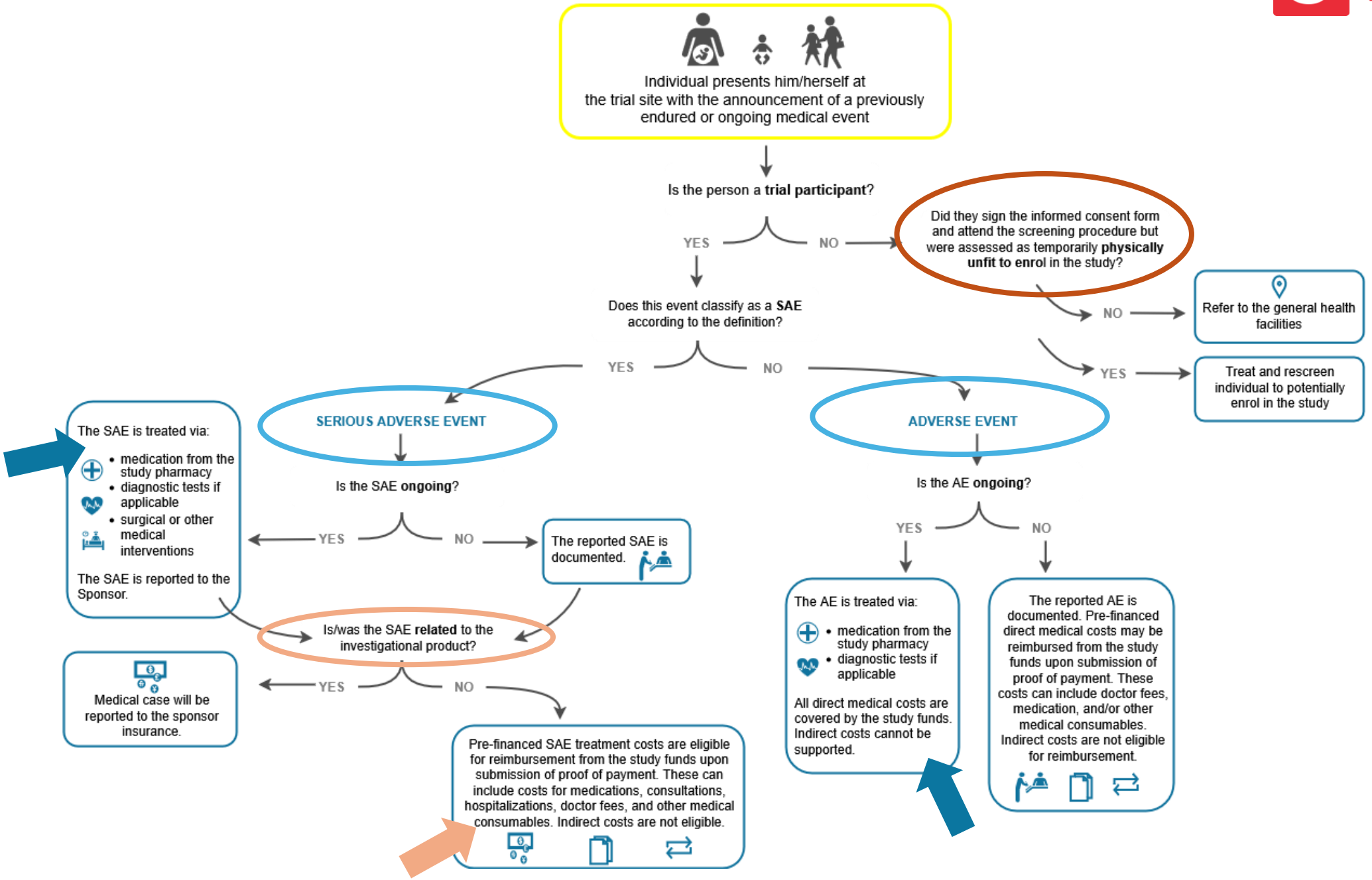

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Preliminary results*: AC uptake & morbidity burden 1/3

***UNCLEANED, RAW DATA, UNSCHEDULED VISTS ONLY**

Total of events reported	477
Total unscheduled visits (UV)	430
Individual participants	212
Mean number of events reported during an UV	2,25

From trial start end of June 2025 to mid-April 2026

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Preliminary results*: AC uptake & morbidity burden 2/3

*UNCLEANED, RAW DATA, UNSCHEDULED VISTS ONLY

Event	Incidence
Flu-like syndrome	122
Urogenital infection	109
Mild threat of preterm delivery	73
Malaria	69
Gastrointenstinal issue	33
Hypertension	7
Skin condition	6
Threatened miscarriage	5
Anemia	5
Other (<5 incidences)	48
Maximum severity during assessment	
Mild	439
Moderate	32
Severe	6
Study intervention	
Unchanged	474
Withdrawn	0

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Preliminary results*: AC uptake & morbidity burden 3/3

*UNCLEANED, RAW DATA, UNSCHEDULED VISTS ONLY

Causality assessment	
Not related	342
Unlikely	4
Not Applicable	131
Related	0
Treatment location	
Study site / study doctor	390
Hospital	3
Health centre	1
Other	3
Type of AC support	
Direct medical assistance to treat the event	55
Concomitant medication	470
Total of medication prescribed/provided	917
Treatment or medication sought elsewhere than at the study site/pharmacy	
No	463
Yes	13
Not applicable	1

Budget projection
(1/2)

1. Direct costs (trial level)

- Dedicated AC budget: USD 170,000 (planned from study outset) → 1.1% of total project budget
- Covers medical expenses:
  - Medications (incl. Study pharmacy medication and external pharmacies)
  - Diagnostic tests
  - Surgical or other interventions
  - Hospitalizations
- Operational costs:
  - Outpatient consultations and FU
  - Staff time for AE/SAE management (tracked via time registration)
- Captured through central accounting framework

Budget projection

(2/2)

2. Indirect costs (Participant / Household Level)

- Non-medical, out-of-pocket expenses related to care:
  - Transportation to health facilities
  - Loss of income due to illness or caregiving
  - Time spent seeking care
  - Other household expenditures linked to illness
- Assessed via surveys and qualitative methods

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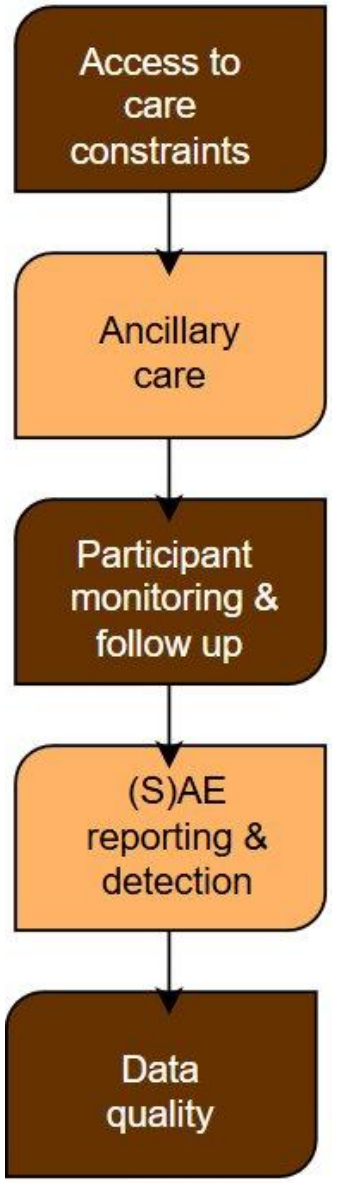
Interpretation: value of AC

Ethical value:

- Responsiveness to participants' real health needs
- Improved wellbeing and trust in research

Scientific value:

- More complete AE capture
- Improved monitoring and follow-up
- Contributing to participant retention
- Timely clinical management reduces misclassification
- Stronger validity of (maternal) safety conclusions



Beyond low-income settings

Food for thought:

- Universal Health Coverage ≠ High or Middle Income Country
- Barriers exist in many settings
- Access to care is context-specific, even in HICs

https://www.pexels.com/nl-nl/foto/handen-aarde-grond-planeet-7048012

→ *Ancillary care is not only ethical in LICs; it may be context-dependent globally*

Thank you

Any questions?

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