SESSION WRAP-UP

Ways Forward from a Statistical & Methodological Perspective

Key takeaways from the talks and breakouts across both days, and where we go next.

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Statistical and methodological takeaways

Definition and measurement of the endpoint

- **Preterm birth isn't one thing.** Assess its granularity — degrees of prematurity and clinical severity — not a single binary cut-off.
- **Case definition and gestational-age dating are the foundation.** Everything downstream depends on them, and GA assessment remains genuinely difficult.

Statistical methods and adjustment

- **Adjustment for gestational age at vaccination is essential.** Earlier vaccination means more time at risk.
- **No single endpoint, no single model.** Pair the initial definition with a package of sensitivity analyses before drawing conclusions.
- **Analyse the dyad, not just the infant.** Randomisation is of the mother–infant pair; counting outcomes only in the infant misses the unit that was randomised.

Interpretation of the signal

- **Scale the evidence bar to biological plausibility.** Where plausibility is high, a small statistical signal should prompt action; where it's low, demand stronger statistical evidence before acting (Bayesian?)
- **Use graphical methods** to avoid premature action; interrogate the handful of cases driving the signal.

Statistical and methodological takeaways

Design and analysis

- Engage range of experts (not just stats!)
- Design for immortal time bias (target trial, extended Cox model)
- No single analysis suffices — pre-specify a protocol with multiple analyses, designs and comparison groups
- Think carefully about confounders (healthy-vaccinee effect and indication bias) and how to adjust for them
- Match the method to the data you have
- Connecting maternal and pediatric care – supports RWD

Interpretation

- Measure residual confounding
- Value of RWD and large multi-site/country collaborations
- Heterogeneity – don’t hide it, learn from it, interpret accordingly
- Read confidence intervals with humility — they don't capture all the uncertainty in non-randomised studies, and small "protective" effects are usually residual healthy-vaccinee bias

Thank You

To all speakers, session chairs, and delegates — for a rich and rigorous two days.

Continuing the conversation

IABS International Alliance for Biological Standardization · iabs.org

Global Vaccine Data Network · gvdn.org

WHO / Brighton Collaboration · brightoncollaboration.org

GAIA Global Alignment of Immunization safety Assessment in pregnancy (GAIA) project