

Advances in the Science & Methods of Pharmacovigilance: Session 2

Study Guide When Reviewing Each of the Two Assigned Articles^{1,2}

1. What question(s) did each of the studies attempt to answer?
2. What type of study design was used in each study?
3. How was exposure measured?
4. How were outcomes measured?
5. What were the authors' main findings?
6. Discuss strengths and limitations of each study.
7. Can the methods (or results) apply to your population and/or your priority pharmacovigilance questions?

¹ Ndagije HB, Nambasa V, Manirakiza L, Kusemererwa D, Kajungu D, Olsson S, Speybroeck N. The Burden of Adverse Drug Reactions Due to Artemisinin-Based Antimalarial Treatment in Selected Ugandan Health Facilities: An Active Follow-Up Study. *Drug Saf.* 2018 Aug;41:753-765.

² Tinto H, Sevene E, Dellicour S, Calip GS, d'Alessandro U, Macete E, Nakanabo-Diallo S, Kazienga A, Valea I, Sorgho H, Valá A, Augusto O, Ruperez M, Menendez C, Ouma P, Desai M, ter Kuile F, Stergachis A. Assessment of the safety of antimalarial drug use during early pregnancy (ASAP): protocol for a multicenter prospective cohort study in Burkina Faso, Kenya and Mozambique. *Reproductive Health.* 2015 Dec, 12:112.