1. **(Guanlin) Safety Signal**

Fit the Berry & Berry (2004) hierarchical model and compare to an independent model. Is there a safety signal? Use the data below:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Treatment (*NT*=320) | | | Control (*NC*=320) | |
| b | j | Type of SAE *Abj* | *Ybj* | Rate |  | *Xbj* | Rate |
| 1 | 1 | Arrhythmia | 0 | 0.000 |  | 1 | 0.003 |
| 1 | 2 | Increased BP | 3 | 0.009 |  | 3 | 0.009 |
| 1 | 3 | Other CB AEs | 0 | 0.000 |  | 2 | 0.006 |
| 1 | 4 | Pre-eclampsia | 8 | 0.025 |  | 6 | 0.019 |
| 2 | 1 | Emesis | 0 | 0.000 |  | 1 | 0.003 |
| 2 | 2 | Other GI AEs | 0 | 0.000 |  | 1 | 0.003 |
| 3 | 1 | Depression | 0 | 0.000 |  | 1 | 0.003 |
| 3 | 2 | Headache | 0 | 0.000 |  | 1 | 0.003 |
| 3 | 3 | Other HNMB AEs | 1 | 0.003 |  | 0 | 0.000 |
| 4 | 1 | Gestational Diabetes Mellitus | 2 | 0.006 |  | 0 | 0.000 |
| 4 | 2 | Other MAN AEs | 0 | 0.000 |  | 1 | 0.003 |
| 5 | 1 | Chorioamnionitis | 0 | 0.000 |  | 2 | 0.006 |
| 5 | 2 | Decreased Fetal Movement | 1 | 0.003 |  | 2 | 0.006 |
| 5 | 3 | Endomyometritis | 1 | 0.003 |  | 0 | 0.000 |
| 5 | 4 | Miscarriage | 0 | 0.000 |  | 1 | 0.003 |
| 5 | 5 | Other PD AEs | 3 | 0.009 |  | 1 | 0.003 |
| 5 | 6 | Postpartum Hemorrhage | 1 | 0.003 |  | 0 | 0.000 |
| 5 | 7 | Premature Delivery | 5 | 0.016 |  | 5 | 0.016 |
| 5 | 8 | Premature ROM | 2 | 0.006 |  | 10 | 0.031 |
| 5 | 9 | Preterm Contractions | 2 | 0.006 |  | 4 | 0.013 |
| 6 | 1 | Other RESP AEs | 0 | 0.000 |  | 1 | 0.003 |
| 6 | 2 | Shortness of Breath | 0 | 0.000 |  | 1 | 0.003 |
| 7 | 1 | Other UG AEs | 1 | 0.003 |  | 0 | 0.000 |
| 7 | 2 | Pyelnephritis | 1 | 0.003 |  | 4 | 0.013 |
| 7 | 3 | Urinary Tract Infection | 1 | 0.003 |  | 1 | 0.003 |
| 7 | 4 | Vaginal Bleeding | 1 | 0.003 |  | 1 | 0.003 |
| 8 | 1 | Abdominal Pain | 1 | 0.003 |  | 2 | 0.006 |
| 8 | 2 | Other BODY AEs | 0 | 0.000 |  | 3 | 0.009 |
| 8 | 3 | PD012 | 2 | 0.006 |  | 0 | 0.000 |
| 8 | 4 | Pelvic Pain | 1 | 0.003 |  | 0 | 0.000 |
| 8 | 5 | Polyhydramnios | 0 | 0.000 |  | 1 | 0.003 |