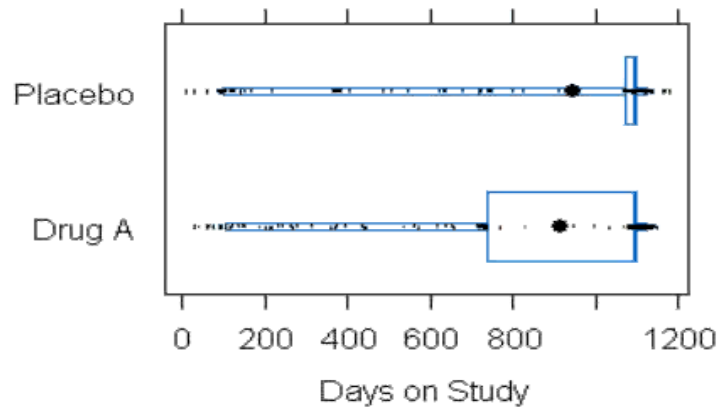Summary of Safety Subjects Exposure by Treatment
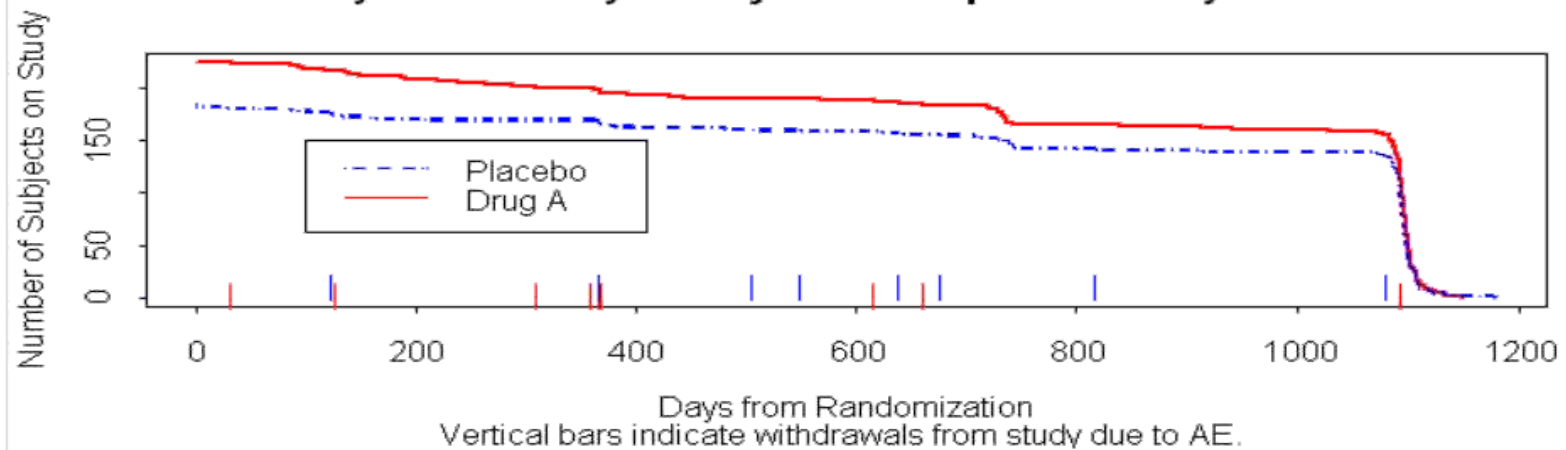
Distribution of Days on Study to AE Onset for Subjects with AE

21
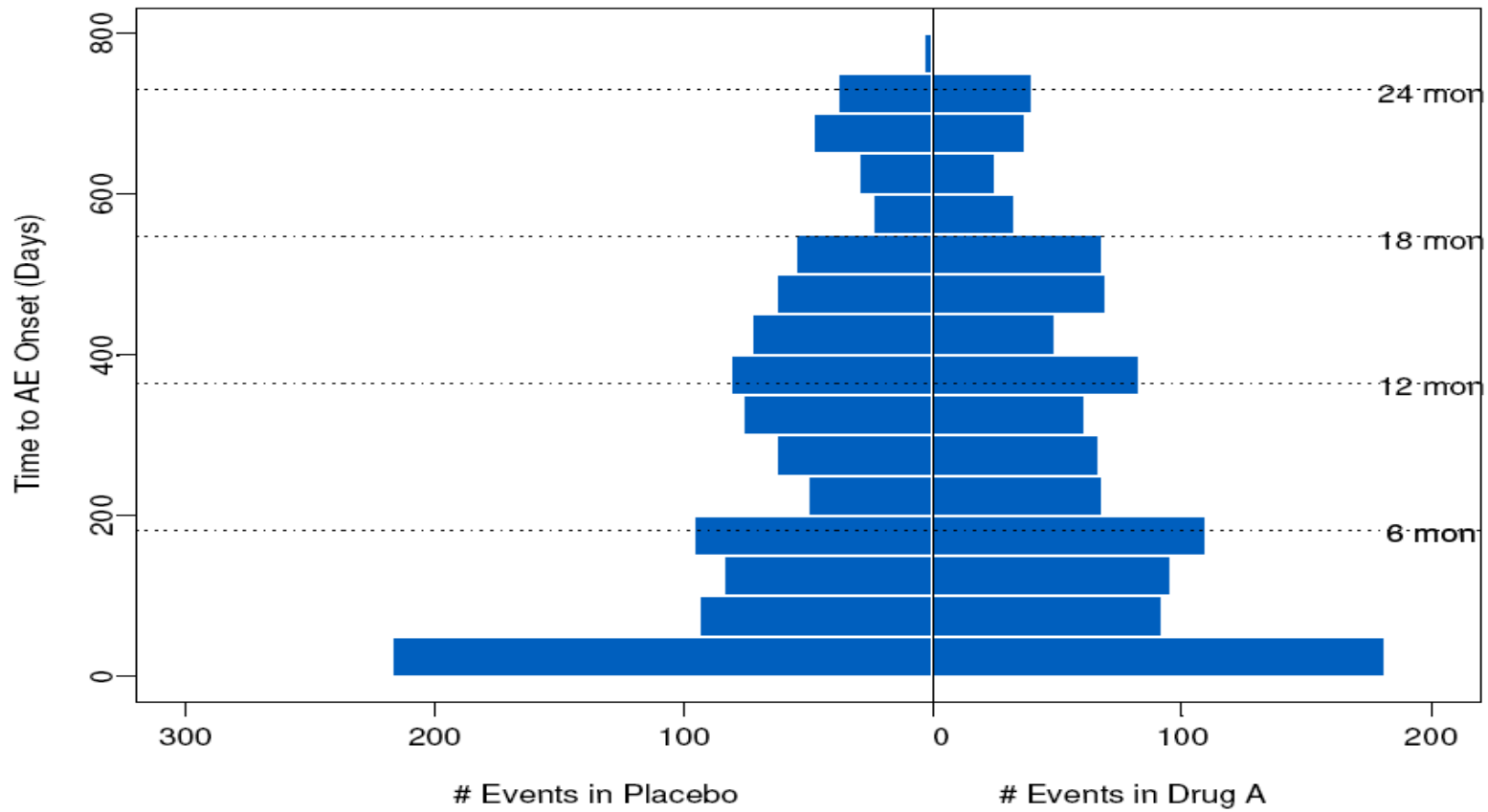
# Risk Over Time Plot for Adverse Event



risk

Legend:
- ×—×—× Hazard (subj-mon)
- Cumulative
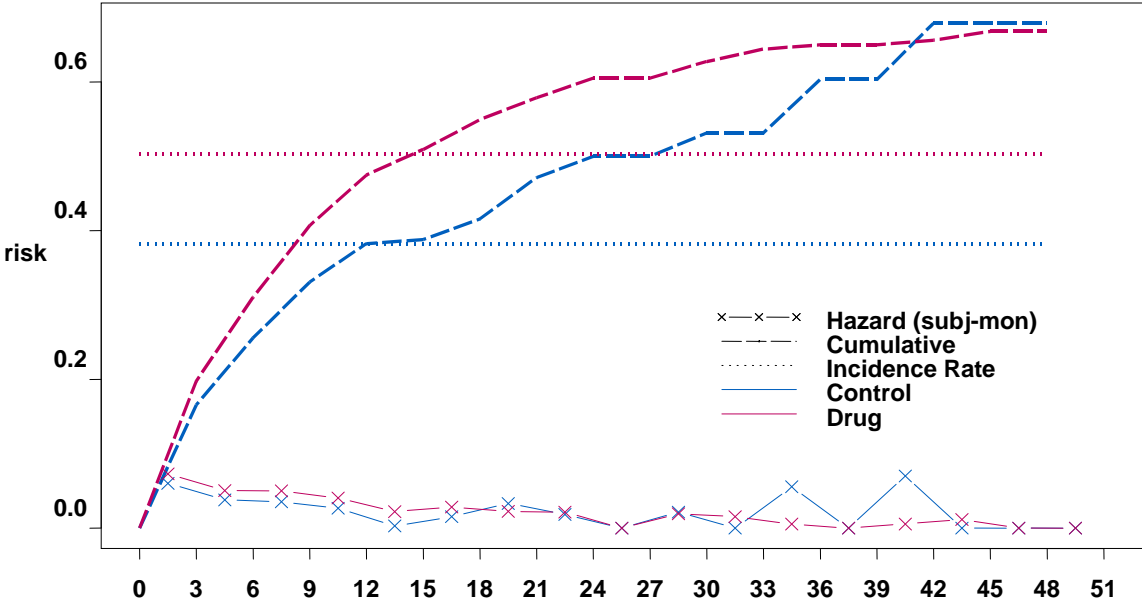- Incidence Rate
- Control
- Drug

exposure in month

| | 0 | 3 | 6 | 9 | 12 | 15 | 18 | 21 | 24 | 27 | 30 | 33 | 36 | 39 | 42 | 45 | 48 | 51 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Num. Events: | | 104 | 56 | 46 | 25 | 1 | 1 | 2 | 1 | 0 | 1 | 0 | 2 | 0 | 2 | 0 | 0 | 0 |
| Num. At Risk: | | 632 | 520 | 459 | 409 | 213 | 22 | 21 | 19 | 17 | 16 | 15 | 13 | 11 | 11 | 8 | 8 | 5 |
| Num. Events: | | 241 | 135 | 112 | 67 | 20 | 14 | 10 | 8 | 0 | 4 | 3 | 1 | 0 | 1 | 2 | 0 | 0 |
| Num. At Risk: | | 1229 | 971 | 810 | 681 | 423 | 172 | 156 | 141 | 107 | 71 | 67 | 62 | 61 | 59 | 58 | 56 | 33 |