**Appendix: Simulation results**

**= log(1.0) = log(1.1) = log(1.2)**

**Scenario B: OR = 2.0 for AE37**

Chart, histogram

Description automatically generatedChart, histogram

Description automatically generatedChart, histogram

Description automatically generated

**Scenario C: OR = 2.0 for AE37 and 1.5 for remaining AEs in SOC8**

Chart, histogram

Description automatically generatedChart, histogram

Description automatically generatedChart, histogram

Description automatically generated

**Scenario D: OR = 2.0 for all AEs in SOC8**

Chart, histogram

Description automatically generatedChart, histogram

Description automatically generatedChart, histogram

Description automatically generated



**Figure 5.** Power curves comparing Bayesian decision criteria (logistic regression) with the adjusted and unadjusted Fisher’s exact tests for detecting a vaccine-AE association at each interim: control AE risk = 5% , OR = 2.0 & sample size = 10,000 per arm.

AE: adverse event; SOC: systems organ clas

**= log(1.0) = log(1.1) = log(1.2)**

**Scenario B: OR = 2.0 for AE37**

Chart, line chart, histogram

Description automatically generatedChart

Description automatically generatedChart, line chart

Description automatically generated

**Scenario C: OR = 2.0 for AE37 and 1.5 for remaining AEs in SOC8**

Chart, line chart

Description automatically generatedChart, line chart, histogram

Description automatically generatedChart, line chart

Description automatically generated

**Scenario D: OR = 2.0 for all AEs in SOC8**

Chart, line chart

Description automatically generatedChart, line chart

Description automatically generatedChart, line chart

Description automatically generated

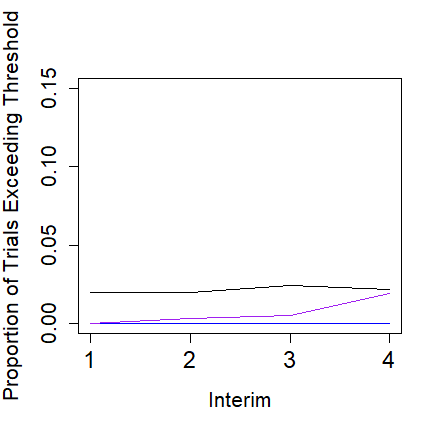
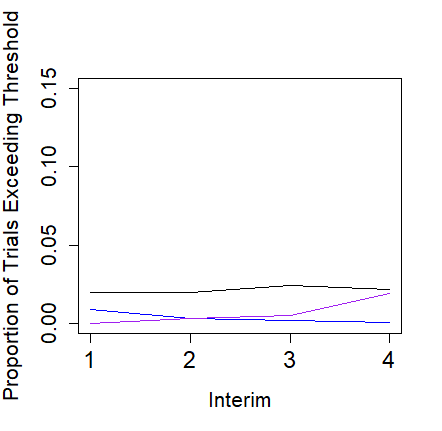
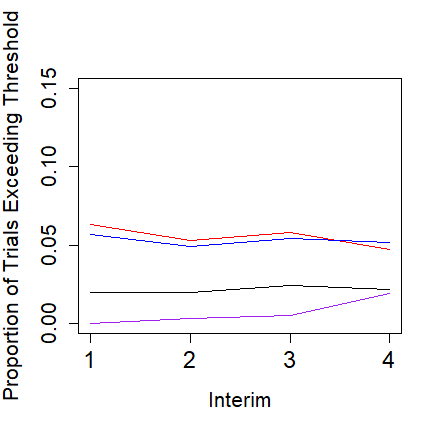


**Figure 6.** Power curves comparing Bayesian decision criteria (logistic regression) with the adjusted and unadjusted Fisher’s exact tests for detecting a vaccine-AE association at each interim: control AE risk = 1% , OR = 2.0 & sample size = 2,000 per arm.

AE: adverse event; SOC: systems organ class

**= log(1.0) = log(1.1) = log(1.2)**

**= 0.95**

****

**= 0.975**

****Chart, line chart

Description automatically generatedChart, line chart

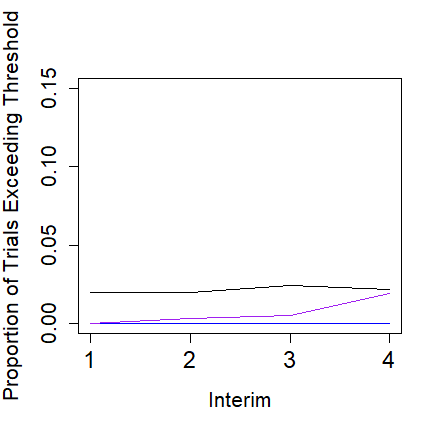
Description automatically generatedChart, line chart

Description automatically generated

**= 0.99**

****Chart, line chart

Description automatically generatedChart, line chart

Description automatically generated

A picture containing logo

Description automatically generated

**Figure 7.** Type I error curves comparing the different Bayesian decision-making criteria with the adjusted and unadjusted Fisher’s exact tests at each interim: control AE risk = 5% & sample size = 10,000 per arm. In some instances, the logistic and Poisson models have almost identical curves may be represented by a single blue line.

: posterior exceedance probability threshol

**= log(1.0) = log(1.1) = log(1.2)**

**Scenario B: OR = 1.5 for AE37**

Chart, line chart

Description automatically generatedChart

Description automatically generatedChart

Description automatically generated

**Scenario D: OR = 1.5 for all AEs in SOC8**

Chart, line chart

Description automatically generatedChart, line chart

Description automatically generatedChart, line chart

Description automatically generated



**Figure 8.** Power curves comparing Bayesian decision criteria (logistic regression) with unadjusted and adjusted Fisher’s exact tests for detecting a vaccine-AE association at each interim: control AE risk = 1% , OR = 1.5 & sample size = 2,000 per arm.

AE: adverse event; SOC: systems organ class