Safety Analysis Report

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This compares the number of subjects that are observed with at least one AE (0,1) and the count of AEs per subject accounting for follow-up time. All subjects that received at least one vaccination should be included here, because safety motioning starts as soon as a subject receives a vaccination. Comparisons are between 46 vaccinated subjects and 47 placebo subjects. Vaccine is always 'sample 1' and placebo is always 'sample 2' below.

## Over All AE and AE by Grade and Relationship

 melded binomial test for ratio

data: sample 1:(44/46), sample 2:(44/47)
proportion 1 = 0.9565, proportion 2 = 0.936, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.8528816 1.1177552
sample estimates:
ratio (p2/p1)
 0.9787234

 Wilcoxon rank sum test with continuity correction

data: outcount$AEcount[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$AEcount[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1056, p-value = 0.8505
alternative hypothesis: true location shift is not equal to 0



## Grade 3

 melded binomial test for ratio

data: sample 1:(5/46), sample 2:(4/47)
proportion 1 = 0.1087, proportion 2 = 0.085, p-value = 0.9723
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.1645184 3.4175098
sample estimates:
ratio (p2/p1)
 0.7829787

 Wilcoxon rank sum test with continuity correction

data: outcount$grade3count[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$grade3count[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1106, p-value = 0.7136
alternative hypothesis: true location shift is not equal to 0



## Grade 2

 melded binomial test for ratio

data: sample 1:(10/46), sample 2:(14/47)
proportion 1 = 0.2174, proportion 2 = 0.298, p-value = 0.5165
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.6324645 3.1183739
sample estimates:
ratio (p2/p1)
 1.370213

 Wilcoxon rank sum test with continuity correction

data: outcount$grade2count[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$grade2count[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 982, p-value = 0.3247
alternative hypothesis: true location shift is not equal to 0



## Grade 1

 melded binomial test for ratio

data: sample 1:(38/46), sample 2:(37/47)
proportion 1 = 0.8261, proportion 2 = 0.787, p-value = 0.8333
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.7521777 1.2016377
sample estimates:
ratio (p2/p1)
 0.9529675

 Wilcoxon rank sum test with continuity correction

data: outcount$grade1count[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$grade1count[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1086.5, p-value = 0.9692
alternative hypothesis: true location shift is not equal to 0



## Related (everything that is possibly, probably or definitely related)

 melded binomial test for ratio

data: sample 1:(9/46), sample 2:(15/47)
proportion 1 = 0.1957, proportion 2 = 0.319, p-value = 0.2609
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.7476198 3.8404634
sample estimates:
ratio (p2/p1)
 1.631206

 Wilcoxon rank sum test with continuity correction

data: outcount$relatedcount[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$relatedcount[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 960, p-value = 0.2285
alternative hypothesis: true location shift is not equal to 0



## Unrelated (everything that is not possibly, probably or definitely related)

 melded binomial test for ratio

data: sample 1:(44/46), sample 2:(40/47)
proportion 1 = 0.9565, proportion 2 = 0.851, p-value = 0.1683
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.7429694 1.0415407
sample estimates:
ratio (p2/p1)
 0.8897485

 Wilcoxon rank sum test with continuity correction

data: outcount$unrelatedcount[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$unrelatedcount[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1167.5, p-value = 0.5082
alternative hypothesis: true location shift is not equal to 0



## Malaria

Malaria comparison by Grade.

## Grade 3

 melded binomial test for ratio

data: sample 1:(2/46), sample 2:(3/47)
proportion 1 = 0.0435, proportion 2 = 0.064, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.176053 16.959285
sample estimates:
ratio (p2/p1)
 1.468085

 Wilcoxon rank sum test with continuity correction

data: outcount$malaria3[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$malaria3[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1057, p-value = 0.6441
alternative hypothesis: true location shift is not equal to 0



## Grade 2

 melded binomial test for ratio

data: sample 1:(4/46), sample 2:(7/47)
proportion 1 = 0.087, proportion 2 = 0.149, p-value = 0.548
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.4683389 7.5294848
sample estimates:
ratio (p2/p1)
 1.712766

 Wilcoxon rank sum test with continuity correction

data: outcount$malaria2[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$malaria2[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1013, p-value = 0.355
alternative hypothesis: true location shift is not equal to 0



## Grade 1

 melded binomial test for ratio

data: sample 1:(16/46), sample 2:(17/47)
proportion 1 = 0.3478, proportion 2 = 0.362, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.5635091 1.9326171
sample estimates:
ratio (p2/p1)
 1.039894

 Wilcoxon rank sum test with continuity correction

data: outcount$malaria1[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$malaria1[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1062.5, p-value = 0.8715
alternative hypothesis: true location shift is not equal to 0



### Solicited

 melded binomial test for ratio

data: sample 1:(7/46), sample 2:(9/47)
proportion 1 = 0.1522, proportion 2 = 0.191, p-value = 0.8212
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.4551194 3.6700016
sample estimates:
ratio (p2/p1)
 1.258359

 Wilcoxon rank sum test with continuity correction

data: outcount$Solicitedcount[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$Solicitedcount[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]
W = 1030, p-value = 0.555
alternative hypothesis: true location shift is not equal to 0



## Solicited AE Binary only

1= observed having this AE during follow-up, 0= not observed having this AE during follow-up

[1] "BRADYCARDIA"

 melded binomial test for ratio

data: sample 1:(0/46), sample 2:(1/47)
proportion 1 = 0, proportion 2 = 0.021, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.02564238 Inf
sample estimates:
ratio (p2/p1)
 Inf

[1] "GRANULOCYTE COUNT DECREASED"

 melded binomial test for ratio

data: sample 1:(4/46), sample 2:(2/47)
proportion 1 = 0.087, proportion 2 = 0.043, p-value = 0.6565
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.04591296 3.23967690
sample estimates:
ratio (p2/p1)
 0.4893617

[1] "HEADACHE"

 melded binomial test for ratio

data: sample 1:(7/46), sample 2:(7/47)
proportion 1 = 0.1522, proportion 2 = 0.149, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.316775 3.024982
sample estimates:
ratio (p2/p1)
 0.9787234

[1] "PYREXIA"

 melded binomial test for ratio

data: sample 1:(0/46), sample 2:(1/47)
proportion 1 = 0, proportion 2 = 0.021, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.02564238 Inf
sample estimates:
ratio (p2/p1)
 Inf

[1] "MALAISE"

 melded binomial test for ratio

data: sample 1:(0/46), sample 2:(1/47)
proportion 1 = 0, proportion 2 = 0.021, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.02564238 Inf
sample estimates:
ratio (p2/p1)
 Inf

[1] "INJECTION SITE PAIN"

 melded binomial test for ratio

data: sample 1:(0/46), sample 2:(4/47)
proportion 1 = 0, proportion 2 = 0.085, p-value = 0.1222
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.6748939 Inf
sample estimates:
ratio (p2/p1)
 Inf

[1] "DIASTOLIC HYPERTENSION"

 melded binomial test for ratio

data: sample 1:(1/46), sample 2:(0/47)
proportion 1 = 0.0217, proportion 2 = 0, p-value = 0.9892
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.00000 37.41406
sample estimates:
ratio (p2/p1)
 0

[1] "SCHISTOSOMIASIS"

 melded binomial test for ratio

data: sample 1:(1/46), sample 2:(2/47)
proportion 1 = 0.0217, proportion 2 = 0.043, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.1055245 113.1573254
sample estimates:
ratio (p2/p1)
 1.957447

[1] "ALANINE AMINOTRANSFERASE INCREASED"

 melded binomial test for ratio

data: sample 1:(2/46), sample 2:(0/47)
proportion 1 = 0.0435, proportion 2 = 0, p-value = 0.4839
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.000000 5.044912
sample estimates:
ratio (p2/p1)
 0

[1] "BLOOD CREATININE INCREASED"

 melded binomial test for ratio

data: sample 1:(0/46), sample 2:(1/47)
proportion 1 = 0, proportion 2 = 0.021, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.02564238 Inf
sample estimates:
ratio (p2/p1)
 Inf

[1] "FATIGUE"

 melded binomial test for ratio

data: sample 1:(3/46), sample 2:(1/47)
proportion 1 = 0.0652, proportion 2 = 0.021, p-value = 0.6005
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.006355636 3.890366854
sample estimates:
ratio (p2/p1)
 0.3262411

[1] "HEMOGLOBIN DECREASED"

 melded binomial test for ratio

data: sample 1:(3/46), sample 2:(3/47)
proportion 1 = 0.0652, proportion 2 = 0.064, p-value = 1
alternative hypothesis: true ratio is not equal to 1
95 percent confidence interval:
 0.1373882 6.9751403
sample estimates:
ratio (p2/p1)
 0.9787234

none of these are significantly different.