Safety Analysis Report

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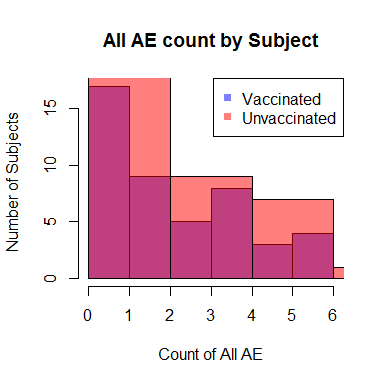
July 27, 2015

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

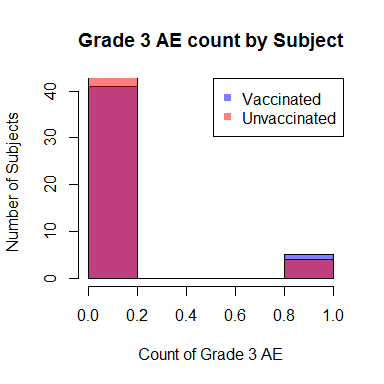
Wilcoxon rank sum test with continuity correction  
  
data: outcount$AEcount[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$AEcount[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 1056, p-value = 0.8505  
alternative hypothesis: true location 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

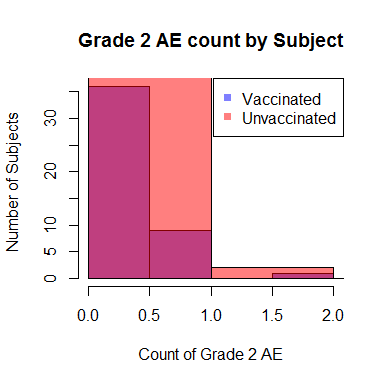
Wilcoxon rank sum test with continuity correction  
  
data: outcount$grade3count[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$grade3count[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 1106, p-value = 0.7136  
alternative hypothesis: true 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

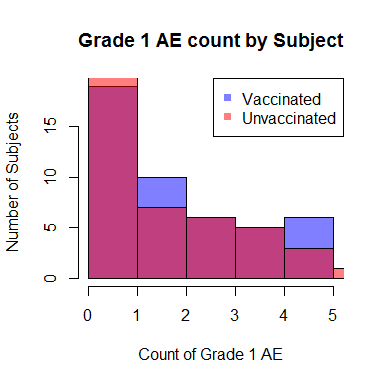
Wilcoxon rank sum test with continuity correction  
  
data: outcount$grade2count[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$grade2count[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 982, p-value = 0.3247  
alternative hypothesis: true 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

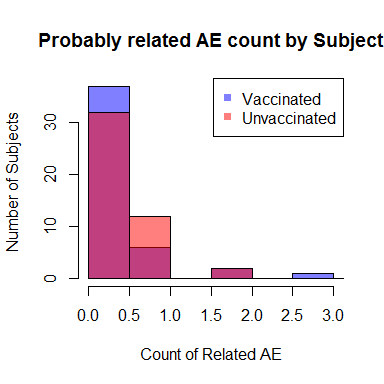
Wilcoxon rank sum test with continuity correction  
  
data: outcount$grade1count[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$grade1count[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 1086.5, p-value = 0.9692  
alternative hypothesis: 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

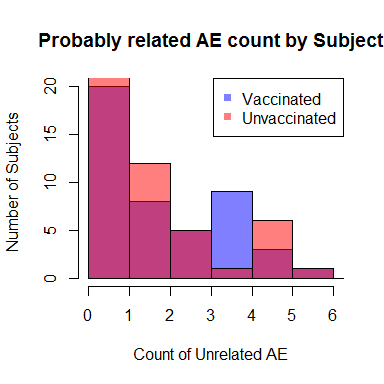
Wilcoxon rank sum test with continuity correction  
  
data: outcount$relatedcount[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$relatedcount[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 960, p-value = 0.2285  
alternative hypothesis: 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



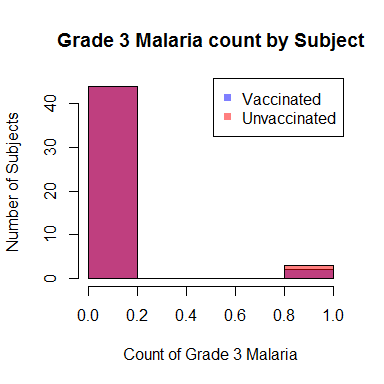
## Malaria

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

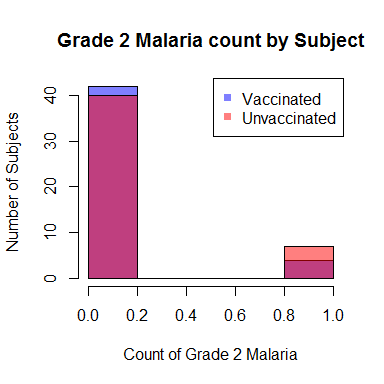
Wilcoxon rank sum test with continuity correction  
  
data: outcount$malaria3[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$malaria3[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 1057, p-value = 0.6441  
alternative hypothesis: true location 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

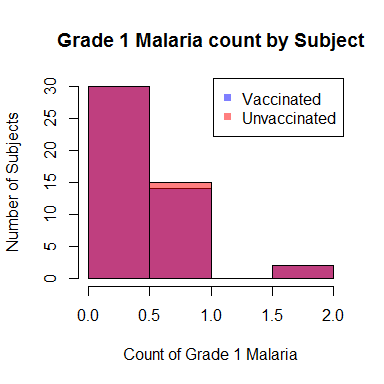
Wilcoxon rank sum test with continuity correction  
  
data: outcount$malaria2[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$malaria2[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 1013, p-value = 0.355  
alternative hypothesis: true location 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

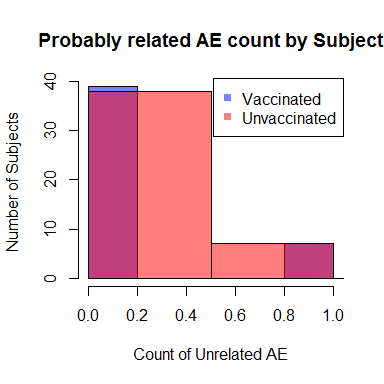
Wilcoxon rank sum test with continuity correction  
  
data: outcount$malaria1[outcount$trtfree == 1]/outcount$timeontrial[outcount$trtfree == and outcount$malaria1[outcount$trtfree == 0]/outcount$timeontrial[outcount$trtfree == 1] and 0]  
W = 1062.5, p-value = 0.8715  
alternative hypothesis: true 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.