BCG Analyses for Primary Endpoint: Ajudicated GRA Exact Conditional Test(ECT) - Adjusted for Clinical Center Output from Proc-StatXact 4 (v4.0.1) on SUN SOLARIS_ (C) Cytel Software Corporation ESTIMATION AND TESTING OF COMMON ODDS RATIO Data file name : < ADJ > Population Variable Name : ARM Outcome Variable Name : responder Strata Variable Name : CCID Weight Variable Name : . [10 2x2 informative tables] Summary of Exact Distribution of S [sum of counts in cell(1,2)]: Min Max Mean Std-dev Observed Standardized 0.0000 43.0000 21.9955 2.9617 16.0000 -2.0244 Exact p-values for testing that the Common odds Ratio is 1: One-sided: Pr { S .LE. 16.0000 } = 0.0312

 Pr { S .EQ. 16.0000 }
 =
 0.0175

 Method 1: 2 * One-sided
 =
 0.0612

 Method 2: (Sum of Probs .LE. 0.0175)
 =
 0.0619

 Method 3: Pr{|S-Mean| .GE. |
 16.0000-Mean|}
 =
 0.0619

Pr { S .EQ. Two-sided: Method 1: 2 * One-sided 0.0623 Exact Estimation of Common Odds Ratio: Conditional maximum likelihood estimate: 0.4979 95.00% Conf. Intervals: Exact : (0.2329 , 1.0326) Mid-p corrected : (0.2460, 0.9842) Mantel-Haenszel Inference: Common Odds Ratio estimate: 0.5069 Two-sided p-value: 0.0469(with RBG variance) 0.0429 (M-H variance) 95.00% CI with RBG variance: (0.2594 , 0.9906)