Narrative summary of findings.

Protocol no: YODA Project # 2018-2801

1. Objective
   (1) Apply these approaches to detect safety signals of different drugs based on drug clinical trial data.
   
   (2) Develop and test subgroup (and benefit-risk) analyses approaches to identify subgroups who are vulnerable
to certain AEs, and subgroups who might benefit from the study drug without excessive toxicity.

2. Methods Used
   We use the YODA data set as a real example to compare a few safety data analysis methods. Our analyses were
   not completed, because we found the preliminary results were not promising (our proposed methods did not
   show superiority over other methods) and we decided to try other real examples.

3. Results
   We tested our method (removing dependence among AEs and then conduct hierarchical multiple tests), against
   with other methods (DFDR, MiST), and these methods gave similar findings of signal AEs. We don’t have good
   explanation of why findings from this real example analysis are not consistent with our findings from simulation
   studies, we thus stop using the YODA real example.

4. Conclusions
   N/A.