

## **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.