Data Visualisation as an Enabler for Nonclinical Safety Signal Detection

Project Scope
The overall objective is to explore how data visualization can be used as a means for enabling safety signal detection within the scope of nonclinical data. To augment this, algorithms for assisting in the identification of safety signals will be identified in the literature (and from the public domain) and considered for investigation as case examples using suitable data, such as may be available from research databases. As an example, analyses of clinical trial safety data have utilized eDISH plots of serum ALT activity and total bilirubin levels for signal identification of hepatotoxicity (based on Hy's Law). Could this and similar approaches be translated to nonclinical data? The intent is for the project to utilize existing software visualization tools (including HistoGraphic which was developed in the team's preceding project) to demonstrate potential safety signal detection using the identified algorithms or visual cues. The project will not expand into the development and/or evaluation of visualization software. A key project deliverable will be to reinforce the importance of promoting standardized nonclinical safety data in SEND format (e.g. LB, MI & MA domain data) as a signal alert enabler. The project will use non-confidential, nonclinical data from the IMI eTOX/eTRANSAFE Consortia (in the European Union) for real-world evaluation of cross-domain algorithms which may identify safety signals in nonclinical studies. The project concluded following presentation of a poster at the June 2019 FDA PHUSE Computational Sciences Symposium. The poster summarizes key presentations and discussions held during project team teleconferences. A copy of the poster can be accessed on this wiki page under "Project Updates" (see below).

Reasources

- Project introduction presentation materials - kick-off-meeting on 21 September 2018
- Data visualization as an enabler for nonclinical safety signal detection - PHUSE Webinar on 26 Sept 2018
- "Evolution of the food and drug administration approach to liver safety assessment for new drugs, current status and challenges" JR Senior, Drug Safety 2014
- "Methodology to assess clinical liver safety data" Merz et al, Drug Safety 2014

Deliverable

- Project team poster presented at the 2019 FDA PHUSE CSS

Archived Content

GSK Safety Visualization Tool Presentation – 2019

Project team questionnaire/survey November 2018

Comparisons between animal tox findings and human therapeutic exposure based on AUC sample HERMAGRAM