SOFTWARE FOR EVALUATING DRUG INDUCED HEPATOTOXICITY

Technology Summary

The detection and assessment of drug induced liver disease has emerged as a challenging task due to the low incidence of findings and the burdensome work of searching through massive quantities of data sets. A method to assist medical diagnosis to identify sometimes rare but serious cases of drug induced liver disease is of interest.

To address this issue, FDA researchers have created a software tool for assisting differential medical diagnosis of drug-induced liver injury (hepatotoxicity) using clinical trial data. The software can identify a small subset of patients at risk for hepatotoxicity out of a pool of thousands of clinical trial participants. This software tool is the only one of its kind developed using SAS/IntrNet®.

Potential Commercial Applications

- Hepatotoxicity detection
- Drug interactions

Competitive Advantages

- Personalized prediction
- SAS/IntrNet® compatible

Development Stage: Software Tool - Patent protection is not being pursued for this technology.

Inventors: Ted Guo

Publications:

- Guo T, et al. A Tool to Help You Decide [detect potentially serious liver injury]. Silver Spring, Maryland: Presentation at the Annual Conference of the American Association for the Study of Liver Diseases, 2008. PMID 21332248

- Guo T, et al. How a SAS/IntrNet tool was created at the FDA for the detection of potential drug-induced liver injury using data with CDISC standard. San Diego, California: Proceedings of the Western Users of SAS Software Annual Conference, 2009.

Product Area: Software

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