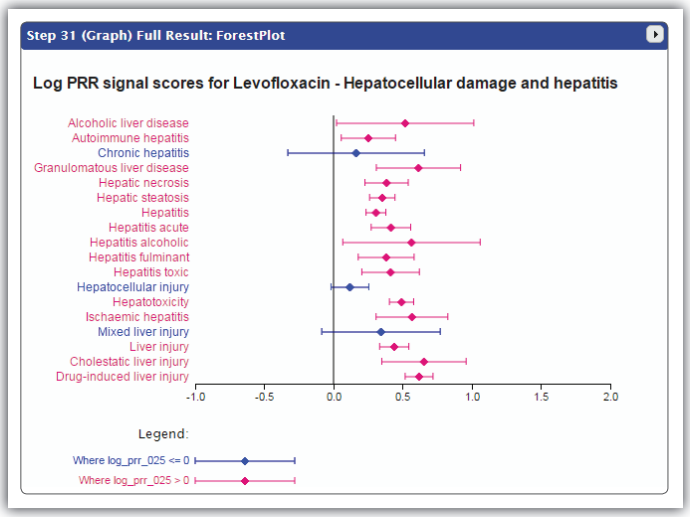
Commonwealth Informatics

Quantitative Signal Detection Services

Commonwealth Quantitative Signal Detection Services: Helping Safety Teams Avoid Surprises

Commonwealth Informatics offers simple, turn-key Quantitative Signal Detection Services to support drug safety reviewers in the detection of safety signals from the FDA Adverse Event Reporting System (FAERS) and WHO VigiBase public spontaneous adverse event databases.

Quantitative Signal Detection (QSD) methods are used systematically by regulators and by large life science and pharmaceutical companies to identify emerging safety issues in therapeutic products. QSD can be applied either to in-house databases or to large publicly available data sources such as FAERS and VigiBase. QSD identifies drug-event pairs that occur disproportionately more frequently in the data than would be expected by chance, alerting safety evaluators to potential issues for further investigation and enabling an organization to be proactive in advance of regulatory communication or action.



Example forest plot graphical display of PRR signal scores for a therapy and event combination available in Commonwealth QSD Reports

Signal detection based on large public databases such as FAERS and VigiBase takes into account all reports that mention a given drug. This includes reports sent directly to the regulator (bypassing the marketing authorization holder), and reports in which the drug is reported as concomitant to a different suspect drug, in addition to reports sent to the marketing authorization holder. Taking into account the full set of reports may strengthen an emerging signal, allowing an organization to identify an issue, and take action on it, before it becomes visible based only on directly received reports. Access to the signal scores from the full public dataset may also enable meaningful subgroup or interaction analysis, or cross comparison of the signals for similar or competing therapies, helping to further clarify or prioritize the significance of an emerging issue.

Historically, due to resource constraints, safety reviewers in smaller organizations have not had access to these capabilities, and were limited to manual review of the subset of reports that they received directly, leaving them exposed to the risk of learning about an emerging safety issue from a regulator. Commonwealth Quantitative Signal Detection Services coupled with the Commonwealth team's experience and expertise enables smaller safety groups to more proactively and effectively manage risk.

Preparing & Informing Pharmacovigilance Leaders

The Commonwealth service offering includes:

- Access to the latest available, cleaned, versions of FAERS and VigiBase data.
- Scheduled quarterly data mining reports from target databases for a set of identified drugs of interest with statistics of disproportional reporting highlighting drug-event combinations for further investigation.
- Scores for MedDRA Preferred Terms organized according to the MedDRA hierarchy.
- Access to graphical and tabular results in PDF and Excel formats.
- Collaboration with the experienced Commonwealth team to design the optimal configuration for your organization and product needs.

Clean Data, Reliable Results

While many vendors can offer adverse event data from public sources, it is critical for safety reviewers to have confidence that the data provides accurate and reliable results. Commonwealth's extensive experience in cleaning spontaneous report data for optimized data mining includes:

- Recoding adverse event reports, captured with then-current MedDRA terms, to a consistent MedDRA version.
- Drug name harmonization, cleaning verbatim drug names and mapping trade and generic names.
- Quality assurance of the updated data prior to release for use.

Proven Statistical Methods

The statistical methods and data visualization techniques used by the Commonwealth team have been developed over many years in collaboration with safety scientists in regulatory and sponsor organizations in the USA and Europe.

Key Benefits

1. **Reduced Costs** Access to industry-standard signal detection techniques and experts without the standing costs of internal expertise and infrastructure.
2. **Easy Startup** Simple standard contract agreement, nothing to install, ready to go.
3. **Transparent Process** Intermediate analysis results available for review and auditing.
4. **Reliable Results** With validated reports designed and delivered by safety industry leaders, you can be confident in the accuracy of the data you receive.
5. **Assistance in Interpreting Results** Your clinical experts can discuss how best to interpret data mining results with our subject-matter experts and data scientists.

Learn More

To learn more or schedule a demonstration, contact us at sales@commoninf.com.

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