PharmaPendium®

Fact Sheet

Drug safety and risk assessment in focus

Drug safety considerations impact the entire drug lifecycle, from preclinical safety assessments through clinical trials to post-market monitoring. PharmaPendium provides fully searchable, deeply extracted information from FDA and EMA regulatory documents, unique FAERS search capabilities, and a powerful tool for predicting multiple drug–drug interactions (DDIs) simultaneously. It is an essential resource for supporting more informed decisions about drug safety and risk mitigation.

ELSEVIER

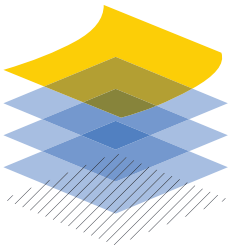
Informed decisions in drug safety

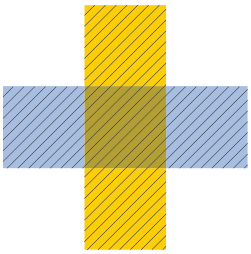
PharmaPendium provides comparative regulatory-based evidence in a single database, helping users to inform critical pre- and post-market drug safety activities.

Alongside dedicated and innovative drug safety-focused tools like its Drug–Drug Interaction Risk Calculator (DDIRC) and FDA Adverse Event Reporting System (FAERS) search functionality, PharmaPendium includes fully searchable FDA and EMA regulatory documents, adverse event reports, and FDA Advisory Committee meetings. It also delivers extracted pharmacokinetic, efficacy, safety, and metabolizing enzyme and transporter data for a comprehensive overview of potential drug safety concerns.

PharmaPendium helps users:

- Anticipate potential safety risks in clinical studies and beyond
- Improve the speed and success of regulatory submissions
- Identify safety signal and DDI concerns early
- Predict and assess potential DDIs to define risk mitigation strategies
- Prioritize drug candidates with the best chance of success in clinical trials
- Improve preclinical and clinical study design to optimize translational insights and clinical outcomes





>2.5 million
pages of FDA approval documents

>235K
pages of EMA approval documents

>11.8 million
reports from FAERS

>711K
pages of FDA Advisory Committee Meetings

4,550
fully indexed and searchable drugs

>1.81 million
safety data lines

>333K
metabolizing enzyme & transporter data lines

>1.69 million
efficacy data lines

>2.89 million
activity data lines

Drug Safety module

Fully text searchable FDA and EMA regulatory documents contain a wealth of comparative safety information on marketed drugs. For deeper, more precise searching, PharmaPendium includes detailed extracted safety information on parameters like adverse effect, toxicity, dose and species, with links to the sources to reveal the context of the extracted data.

The post-market safety data in PharmaPendium comes from the FAERS and can be searched through the Drug Safety module or the FAERS search form. All adverse effects in PharmaPendium are normalized to MedDRA by experts, enabling a unique translational view of data across the drug life cycle.

FAERS search form

Spontaneous adverse event reporting systems like FAERS allow rapid signal detection and support an epidemiological approach to identifying adverse events that occur with low frequency, in populations not tested in clinical trials or over longer periods, and those resulting from drug–drug or drug–food interactions.

The FAERS search form (Figure 1) makes it much easier to detect emerging post-market safety concerns by supporting searches for specific drug combinations or specific conditions. Changes in the number of FAERS reports are revealed with the Heatmap and percentage calculations.

This type of detailed searching can provide:

- Additional insights into drugs suspected in adverse events, including information on drugs reported as a primary suspect drug and also as a secondary suspect drug
- Better insights into the prevalence of comorbidities not evident during clinical trials
- Information on drug–drug interactions to help mitigate risk for new drugs under development

The DMPK Solution

Drug–drug interactions account for ~3–5% of all reported adverse drug reactions and, with an aging population and trend towards polypharmacy, they are an increasingly urgent concern. With its powerful DDIRC (Figure 2), comprehensive drug metabolizing enzyme and transporter data, and in-depth pharmacokinetic parameters, the PharmaPendium DMPK Solution helps scientists to identify potential interactions for multiple drugs simultaneously, providing a full risk profile against marketed drugs

It enables users to answer critical questions, including:

- Is a drug candidate likely to interact with marketed drugs?
- Could transporters affect the disposition of the new drug?
- Might the new drug affect the metabolism of other drugs?
- What studies were conducted to assess DDI risks?
- What concomitants interact with marketed drugs?
- How might interactions affect pharmacokinetic properties?

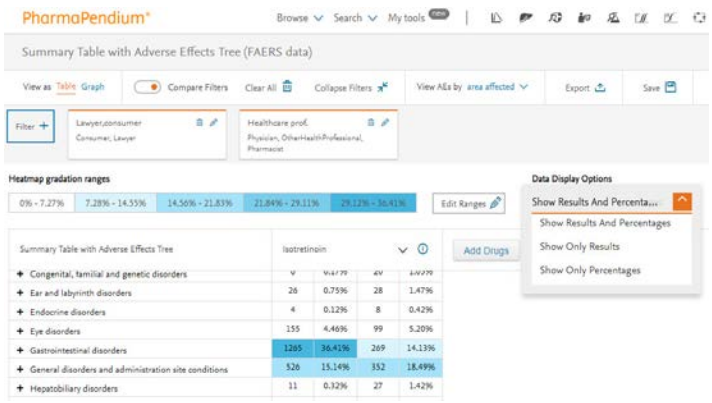


Figure 1. The FAERS search form enables deep searching of adverse event reports.

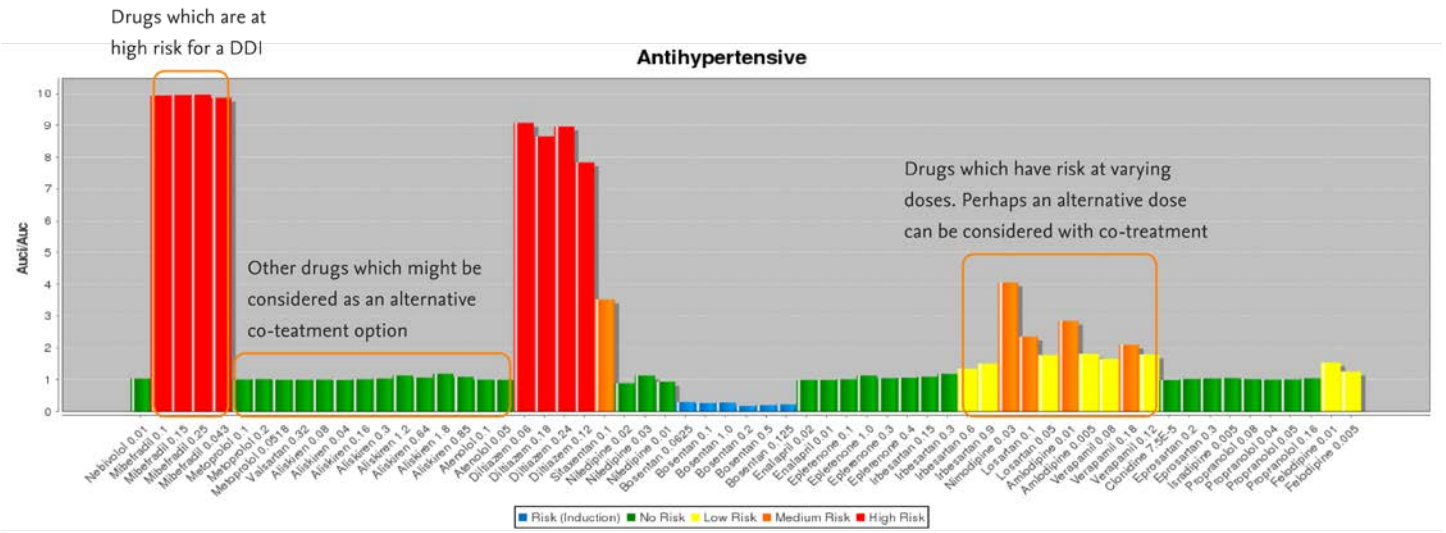


Figure 2. The DDIRC helps users see the risk of interactions between proprietary and marketed drugs.

PharmaPendium

PharmaPendium helps drug developers make more informed decisions about drug safety and efficacy, risk mitigation and study design by providing searchable FDA and EMA drug approval documents and drug safety data..

For more information about PharmaPendium, visit elsevier.com/pharmapendium.