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PharmaPendium®
PHARMACOVIGILANCE

Fact Sheet: Drug Safety and Risk Assessment in Focus

Supporting informed decisions with the PharmaPendium Drug Safety, FAERS and DMPK Solutions

Supporting informed drug safety decisions

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. Discover more about this essential resource for supporting more informed decisions about drug safety and risk mitigation.

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Drug Safety Fact Sheet

Introduction

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 FAERS search functionality, PharmaPendium includes fully searchable FDA and EMA regulatory documents, adverse events 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 post-market
- 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

>2.32M pages of FDA approval documents	**>200K** pages of EMA approval documents	**>9.75M** FDA AERS reports	**>684K** pages from FDA Advisory Committee Meetings
4466 fully indexed and searchable drugs	**>1.66M** safety data lines	**>310K** metabolizing enzymes & transporter data lines	

*As of June 2017. Note that PharmaPendium contains additional pharmacokinetic, efficacy and activity data not described here.

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 across drugs, drug classes, adverse events and more, PharmaPendium includes detailed extracted safety information on parameters including adverse effect, toxicity, dose and species, with a link directly to the source data so users can understand the context of the extracted data.

The post-market safety data in PharmaPendium comes from the FDA Adverse Event Reporting System (FAERS) and can be searched via the Drug Safety module or through a unique FAERS search page (Figure 1). All adverse effects in PharmaPendium are normalized by an expert content extraction team to MedDRA, enabling a unique translational view of data across the drug life cycle.

FAERS search form

Spontaneous adverse event (AE) reporting systems, such as the U.S. FAERS system, represent a valuable source of real-world evidence for post-market drug safety data. They allow rapid detection of signals and support an epidemiological approach to identifying adverse events that occur with low frequency, in populations not tested in clinical trials or that occur over longer time periods and those resulting from drug–drug or drug–food interactions.

With the PharmaPendium FAERS search form, post-market reports can be specifically searched for instances where a drug is reported as a primary suspect, secondary suspect, concomitant and/or interacting drug and results filtered by (for example) secondary suspect drug or type of adverse event.

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

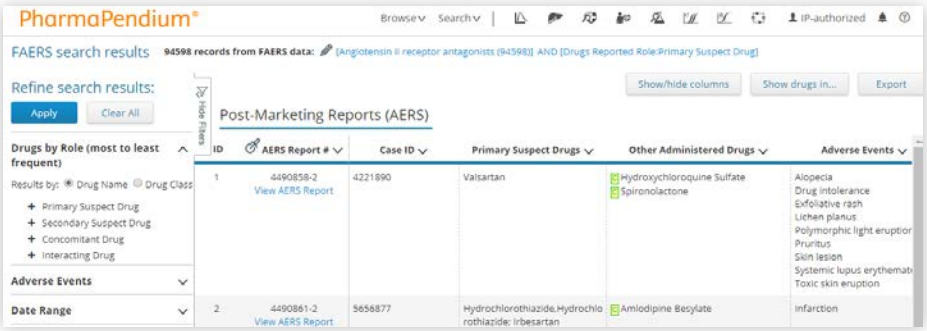


Figure 1 The FAERS search form enables deep searching of adverse event reports.

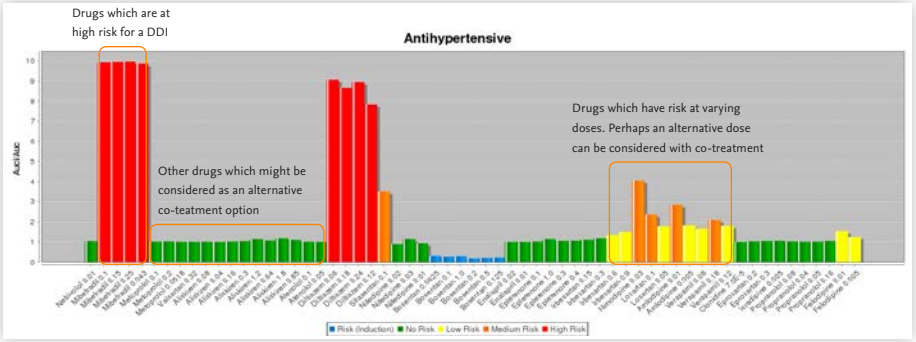


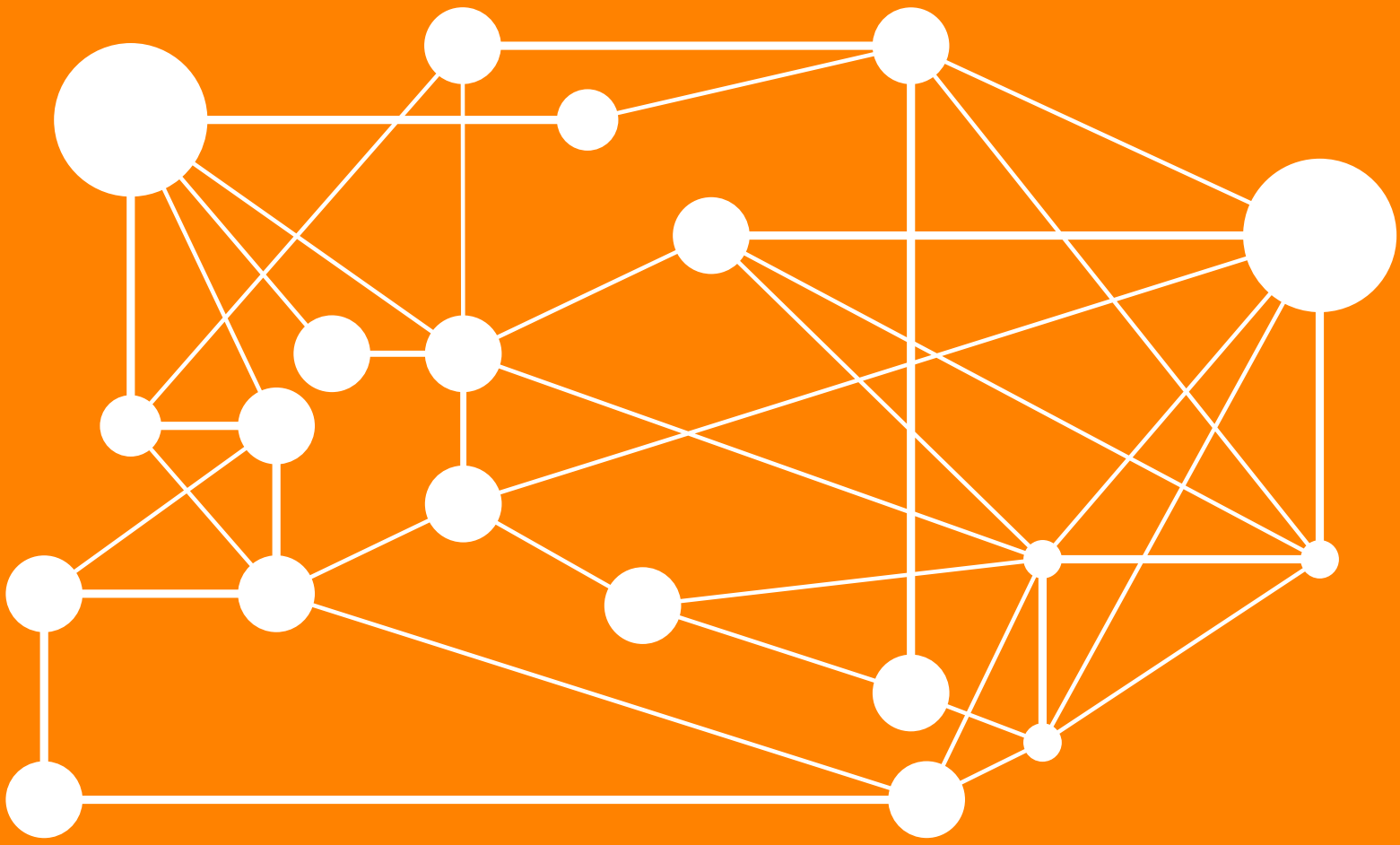
Figure 2 The DDIRC helps users see the risk of interactions between proprietary and marketed drugs.

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 Drug–Drug Interaction Risk Calculator (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:

- What is the risk that a drug candidate will interact with other, marketed drugs?
- Can 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?
- How do potential interactions affect pharmacokinetic properties?



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.

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