

CASE STUDY

PharmaPendium®

A Head of Safety Pharmacology at a Market-leading Pharmaceutical Company
Streamlining Drug Development



SUMMARY

A Head of Safety Pharmacology at a market-leading pharmaceutical company discusses the use of PharmaPendium to improve the selection of potential compounds with additional meaningful criteria.

Advances in science and technology are enabling new drug discoveries, but equally important is making these innovations affordable. This demand translates to a continuous drive to streamline drug development and make informed decisions that avoid superfluous work, additional expenses, and late-stage drug failures.

Embedded in Knowledge Systems

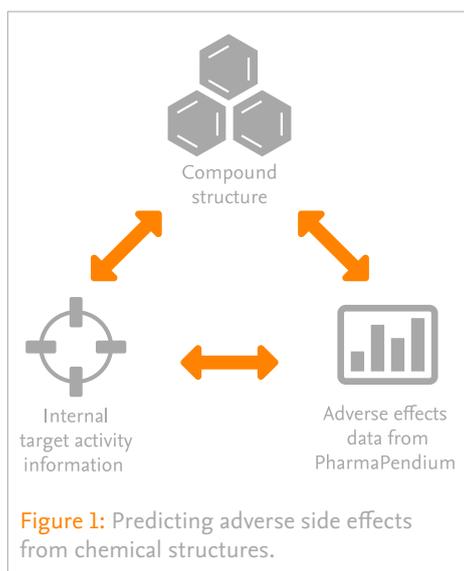
With over 3 million lines of comparative extracted drug safety, pharmacokinetic and metabolizing enzyme precedent data and fully searchable FDA/EMA documents, FDA advisory Committee meetings and AERS, PharmaPendium can enable multifaceted analyses such as:

- Comparative safety profiling of marketed drugs versus internal candidates
- Clinical translatability of pre clinical data on adverse effects
- Predictive modeling based on compound structure

Using Structure to Predict Adverse Side Effects

High-throughput screening of compounds generates a long list of potential drug candidates based on compound-target interactions. Developing each compound that exhibits the sought-after target activity is inefficient and thus, we use other meaningful criteria to narrow down the list of candidates.

Our approach is to examine our in-house data on target activity in light of adverse effects reported for compounds with similar chemical features. For this analysis, we need in-depth data from adverse effects reports in a format that is easily imported and mined in our internal knowledge management platform and visualized with internal graphical tools (Figure 1).



Essential Information at Your Fingertips

The data from adverse effect reports are deeply indexed in PharmaPendium enabling multifaceted analyses that help define the significance of an adverse drug reaction. For example, an analysis by System Organ Class allows us to differentiate an adverse drug reaction from general symptoms of the treated disease. The adverse drug reactions in a particular class can be further teased apart based on diagnosis. Thus, reports under the category “cardiac“, for example, can be broken down into arrhythmias, valve effects, myocardial disorders and more (Figure 2).

In this way, reported adverse drug reactions for tested and marketed compounds that share chemical features with internal candidates can be examined in detail to make predictions about potential target or off-target effects. Armed with insights from these data, our development strategies can emphasize compounds with chemical features that are likely to be the safest and most effective.



Figure 2: The deep data indexing of PharmaPendium enables multifaceted analyses. The indexing of cardiac disorders by adverse effects illustrates the extensive and systematic data structure underlying PharmaPendium. Each indexing category includes number of relevant hits in parenthesis, and additional layers of information can be explored by expanding closed nodes labeled with a (+).

Comprehensive Coverage of Regulatory Decisions

Statements from regulatory and health authorities regarding a drug or class of drugs are equally informative to drug discovery and development efforts. These statements reflect not only the success and safety of a tested compound, they can also serve to guide our development efforts for drug candidates that exert their effects on the same target. That is, regulatory reports do not only document if a drug is approved for use or not. Regulatory decisions also highlight potential targets for the development of a therapeutic, criteria and secondary testing for the approval of a particular drug, drug action mechanisms under scrutiny, and more. PharmaPendium provides access to searchable pages of FDA approval packages, Pharmacology and Toxicology reviews, minutes of the Drug Advisory Committee meetings, European Public Access Reports from the European Medicines Agency, historical data, and pre-clinical studies that we have not found published anywhere else.

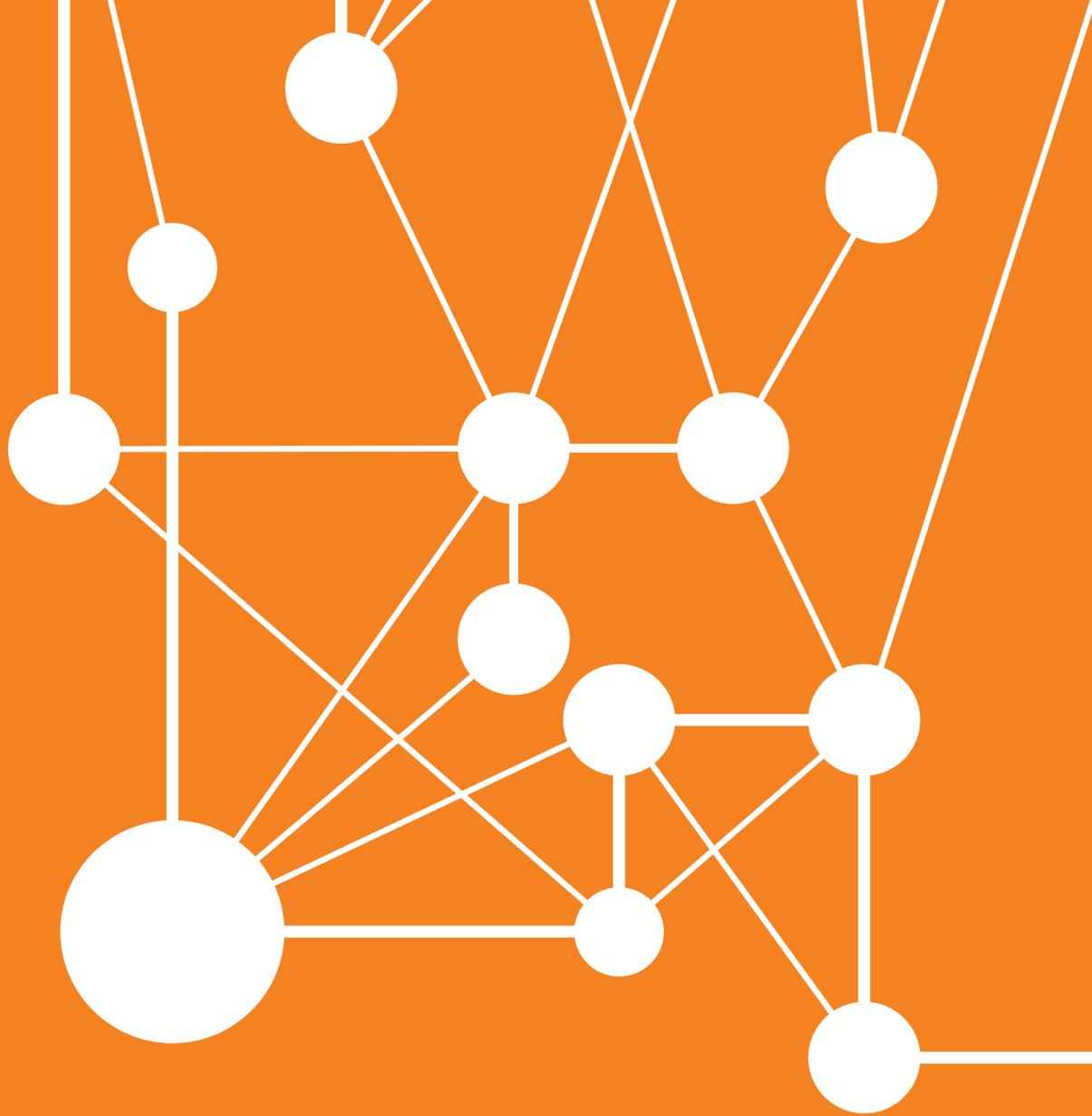
The Bottom Line

With its extensive, longitudinal database of excerpted pre-clinical, clinical and post-release safety data, PharmaPendium is our choice knowledge resource to guide development efforts toward the most promising compound candidates. We use PharmaPendium data to predict effects of candidate compounds, to annotate and interpret experiments in safety pharmacology, to evaluate the relevance of effects observed in pre-clinical studies, and to differentiate compounds under development from marketed drugs. To see how PharmaPendium can help address your drug safety and adverse events tracking needs visit.

PharmaPendium is the only research solution that brings together excerpted preclinical, clinical and post-marketing safety data in a single, longitudinal, database that provides unique insights into regulatory context with over 2.2 million searchable pages of FDA approval packages. This extensive drug development content also includes EMA EPAR's, historical data and unique preclinical study information that has not been published anywhere else, and collectively provides regulatory-based evidence to help support critical drug safety decisions.

The Pharmacokinetics Module includes detailed exposure data (C_{max}, T_{max}, T_{1/2}, AUC, and 91 more parameters) as well as critical data on drug efficacy, dosage, safety and PK studies; all extracted from FDA and EMA regulatory documents.

The Metabolizing Enzymes and Transported Module provides reported data that can help assess possible drug : drug interactions based on similarities with drug targets, drug classes, common adverse events and chemical structures. Leverage this data to help with risk assessments such as drug induced toxicity and CYP interaction- induced changes in bioavailability.



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