PharmaPendium®

Fact Sheet

SEARCHABLE FDA/EMA DRUG APPROVAL DOCUMENTS

Searchable FDA/EMA Drug Approval documents and extracted comparative data provides essential information for more informed drug development decisions on critical drug safety, risk assessments and mitigation and study designs.

ELSEVIER

PharmaPendium®
Fact Sheet

Introduction

PharmaPendium is a decision support solution designed to help improve pharmaceutical development by providing unique comparative pre-clinical, clinical and post-release drug information in a single longitudinal database. In addition, PharmaPendium has fully searchable FDA/EMA drug approval documents that helps you find relevant information in minutes. Part of the portfolio of Elsevier R&D Solutions for Pharma & Life Sciences, it answers critical drug development questions.

- Can I find safety, efficacy and DMPK data to support my analysis of in vitro and in vivo test results?
- Can I compare my drug to approved drugs to help optimize my drug safety analyses and trial design?
- How can I assess PK parameters and potential drug-drug interaction risks for my drug candidate?
- What support can I get for making my case to the regulatory authorities?

FEATURES

UNIQUE CONTENT HELPS YOU GET PROMISING DRUG CANDIDATES TO MARKET FASTER

PharmaPendium provides extracted pre-clinical and clinical safety, pharmacokinetic and metabolizing enzyme and transporter data that you cannot find anywhere else. PharmaPendium gives you access to original FDA/EMA drug approval documents and a whole range of medical and drug development journals along with references from Meyler's *Side Effects of Drugs* and Mosby's *Drug Consult*, allowing you to make better drug candidate assessments.

1.99M+ pages of FDA approval documents	**153K+** pages of EMA approval documents	**6.74M+** AERS reports	**617K+** pages from FDA Advisory Committee Meetings
4,277 drugs indexed and fully searchable	**1.45M+** pharmacokinetic data lines	**282K+** metabolizing enzyme and transporter data lines	**1.45M+** safety data lines

Content figures based on February 2015

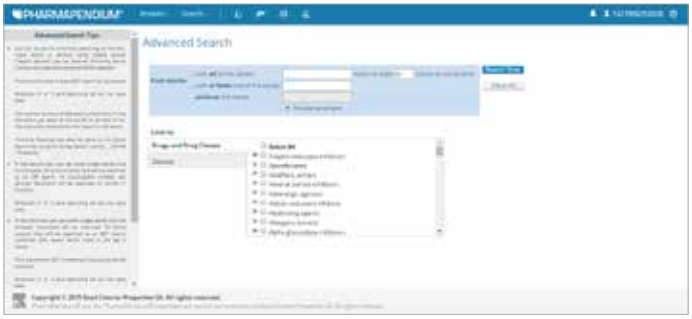


Figure 1. Optimized search query form with filters

FLEXIBLE SEARCH QUERY OPTIONS

PharmaPendium allows text searching with synonym recognition; structure searching with structure similarity and substructure options; and browsing by categories such as drug name, class or target, or adverse effect and toxicity. You choose how you want to search the data and filter your results.

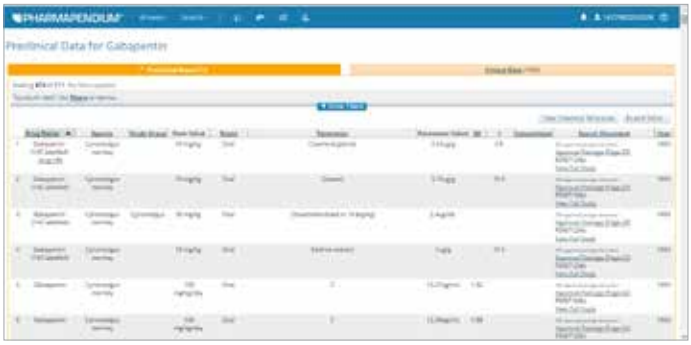


Figure 2. Pharmacokinetics data search results for gabapentin (Neurontin)

INCREASED ACCESS TO REGULATORY DOCUMENTS

FDA, EMA and AERS documents contain vast amounts of crucial pharmacokinetics data that never reach academic publications. The optional Pharmacokinetics Module gives you greater access to study results, including detailed preclinical and clinical exposure data extracted from the entire istory of FDA approval packages and EMA documents. This historical context supports your drug repurposing decisions. Also, by providing deeper insight into differences between FDA and EMA approvals, PharmaPendium helps improve your regulatory submissions.

Figure 3. Results of a metabolizing enzymes and transporters search with carbamazepine as the key word.

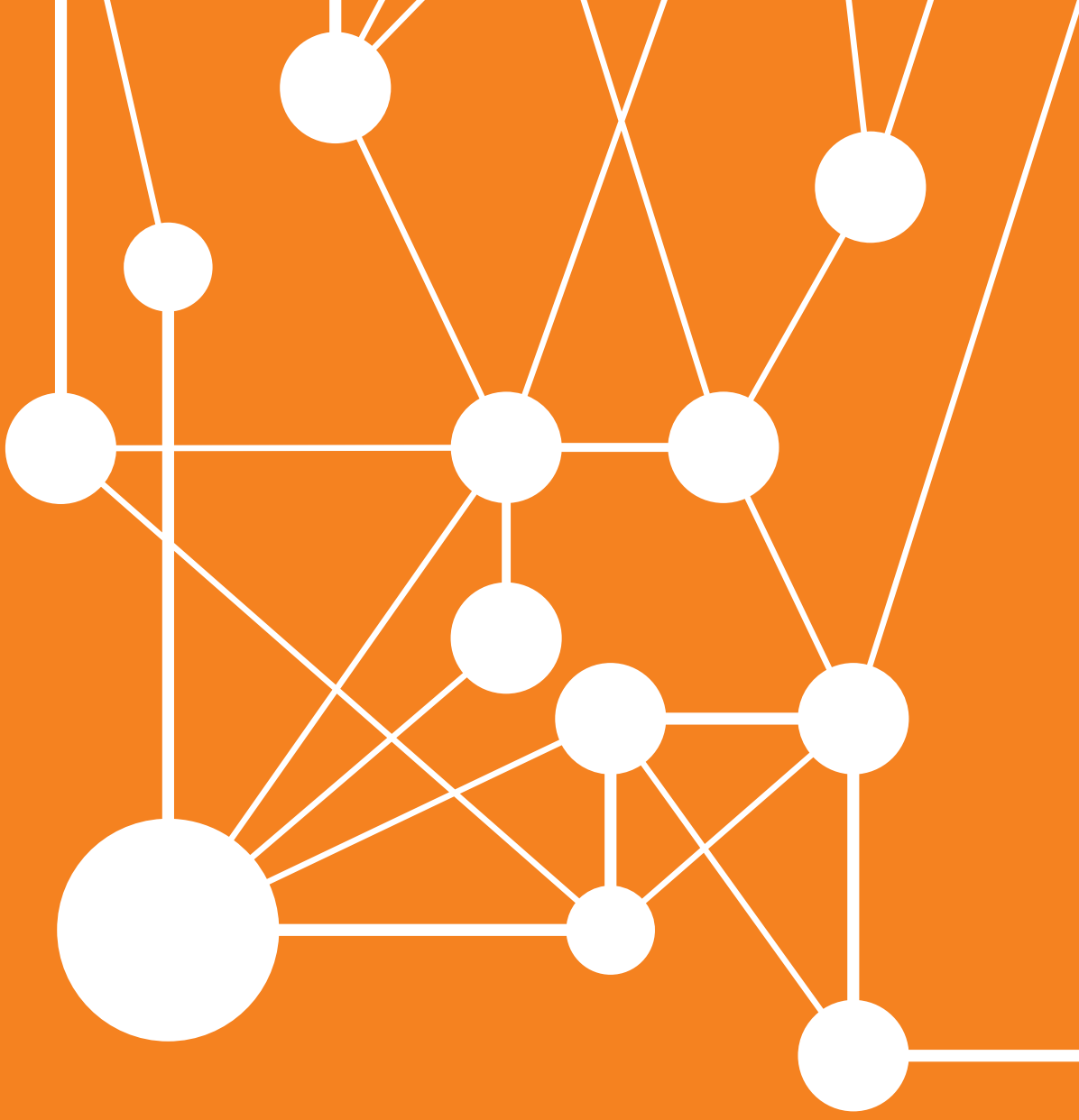
DRUG-ENZYME AND DRUG-DRUG INTERACTIONS REVEALED

With more data on interactions between drugs and enzymes than any other database, the optional Metabolizing Enzymes and Transporters Module lets you accurately make key risk assessments on bioavailability, toxicity and more. Predicting drug-drug interactions and adverse effects early saves research time and resources and drives your research forward. submissions.

KEY BENEFITS

WHAT DOES THIS MEAN FOR YOU?

- Better risk assessment of your drug candidate's toxicity
- Detailed assessments of your drug candidate's PK parameters and properties
- Better assessment of previous pre-clinical experimental design including species selection
- Rapid evaluation of potential drug-drug interaction risks
- Increased chances of successful submissions to regulatory authorities



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