

# PharmaPendium®

## Fact Sheet



### PHARMACOKINETICS (PK) MODULE

Planning a successful regulatory approval strategy requires understanding pharmacokinetic properties of a drug candidate within the context of the complete landscape of approved drugs.



## PharmaPendium® Fact Sheet

### Introduction

Planning a successful regulatory approval strategy requires understanding pharmacokinetic properties of a drug candidate within the context of the complete landscape of approved drugs. Essential data are contained in FDA, EMA and AERS documentation but accessing and sifting through millions of lines of comparative data is resource intensive. The PK Module does the work helping researchers find critical data from successful drug approvals in minutes.

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### APPLICATIONS

- Define the therapeutic window of new drugs earlier and more effectively.
- Model the impact of different pharmacophores on exposure properties.
- Compare internally generated pharmacokinetic data with drugs that share similarities in terms of their class, chemistry and targets.
- Perform risk assessments to answer key questions about safe dosing.

### FEATURES

#### COMPREHENSIVE AND HISTORICAL COVERAGE OF RELEVANT DATA

The PK Module enables retrieval of data extracted from more than 2.1 million pages of FDA Approval Packages (1938 to present), EMA EPARs (1995 to present) and 6 million AERS files. FDA documentation dating back to 1938 means complete historical coverage to complement the latest drug approval data that can lead to new insights and help find new repurposing opportunities.

#### CONSOLIDATED ACCESS TO HARD TO FIND DATA

The PK Module contains 1.4 million lines of data that is difficult to find. This includes detailed exposure data ( $C_{max}$ ,  $T_{max}$ ,  $T_{1/2}$ , AUC, etc.) that is almost never published, and data on absorption, biotransformation, distribution, and elimination not available from any other commercial research tool. All data is linked back to the regulatory documents from which it was extracted making it easy to cite page and documents for internal and external reviews. This high quality reference data can be exported and used in existing PK and PK/PD models to help verify initial results.

#### CONNECTING CRITICAL INFORMATION

Complementing information from regulatory documents are extracted metabolite, preclinical and clinical toxicity data, and target information from over 3,000 journals and FDA/EMA drug approval documents. The PK Module also contains Meyler's definitive work Side Effects of Drugs (15<sup>th</sup> edition), which has over 40,000 references providing researchers an even broader overview of this essential aspect of drug development.

#### INSIGHT ON A GLOBAL SCALE

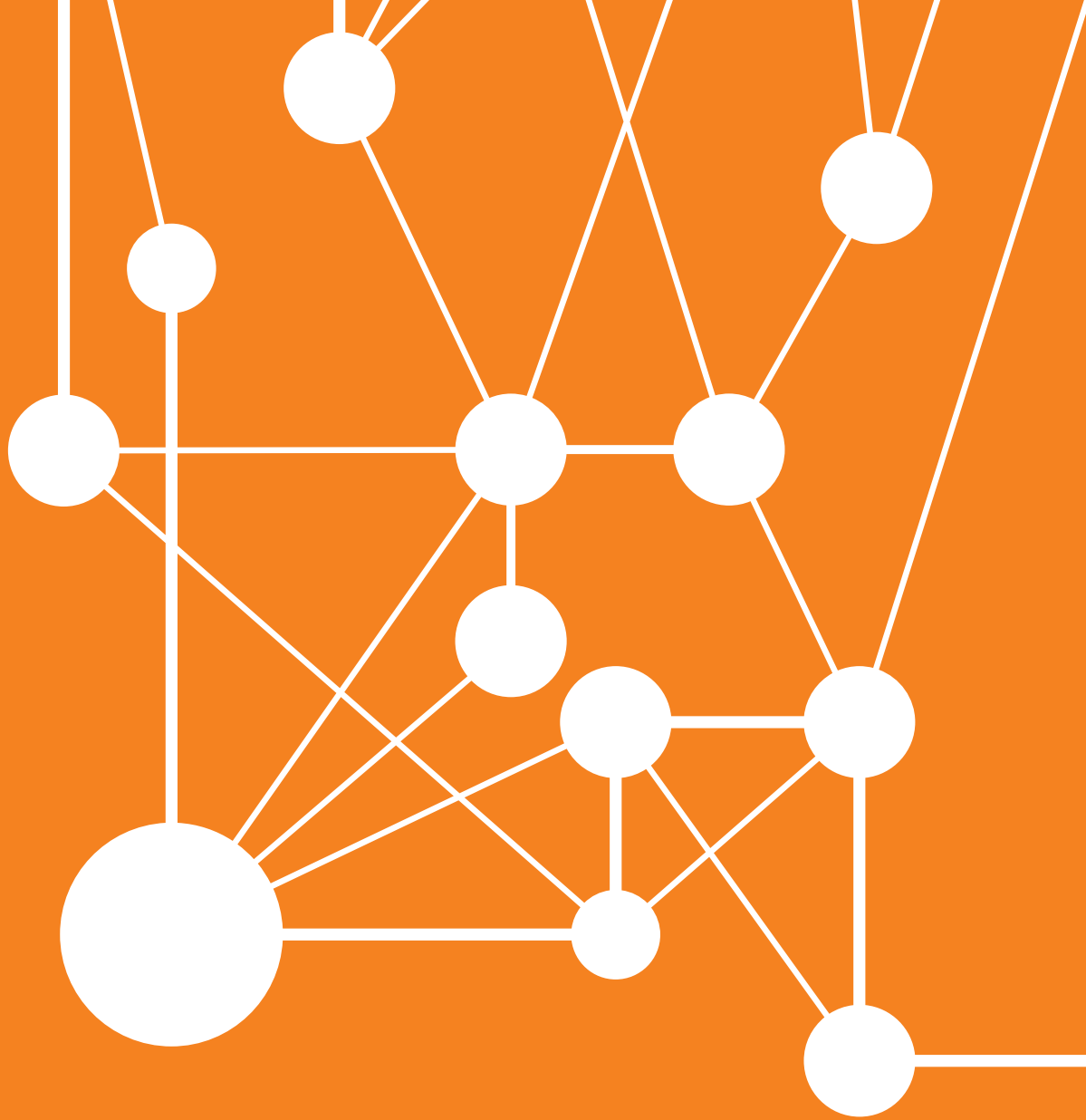
Gain insight into the differences between the FDA and EMA decision-making processes. The database contains information about over 50 drugs and active ingredients approved in Europe but not in the US. Understanding such differences helps to target new regulatory submissions, gain competitive advantages on the global market and improve communication with regulatory agencies.

#### INTELLIGENT SEARCH FUNCTIONS AND INTERCONNECTED REFERENCES

The PK Module is designed to enable advanced queries that focus on what is most important for ADME research with access to data from 95 key parameters. Search for the parameter of interest and experimental conditions and apply filters to refine and sort results based on:

- Drug name
- Concomitant drugs
- Dose or standard dosagee
- Route
- Value (normalized in searching)
- Disease states
- Demographic differences
- Species
- Study group (population)
- Enantiomers
- Metabolites
- Tissue-specific studies

A number of more recent FDA documents cite documents from pre-1992. In the Pharmacokinetics Module, every citation of a previous FDA document is now traceable, searchable and viewable so you can capture the complete context of a review decision, issue, or requirement.



## Futher Information

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### ASIA AND AUSTRALIA

Tel: + 65 6349 0222

Email: [sginfo@elsevier.com](mailto:sginfo@elsevier.com)

### JAPAN

Tel: + 81 3 5561 5034

Email: [jpinfo@elsevier.com](mailto:jpinfo@elsevier.com)

### KOREA AND TAIWAN

Tel: +82 2 6714 3000

Email: [krinfo.corp@elsevier.com](mailto:krinfo.corp@elsevier.com)

### EUROPE, MIDDLE EAST AND AFRICA

Tel: +31 20 485 3767

Email: [nlinfo@elsevier.com](mailto:nlinfo@elsevier.com)

### NORTH AMERICA, CENTRAL AMERICA AND CANADA

Tel: +1 888 615 4500

Email: [usinfo@elsevier.com](mailto:usinfo@elsevier.com)

### SOUTH AMERICA

Tel: +55 21 3970 9300

Email: [brinfo@elsevier.com](mailto:brinfo@elsevier.com)