

Streamlining preclinical and clinical drug development

Comprehensive access to extracted data and documents on marketed drugs provide critical insights





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— Scientific information manager, leading dermatology company

Access to comprehensive information is essential to successful drug development

For a leading dermatology company, PharmaPendium has eliminated the need for months of research work each year. The company’s scientific information manager explains “As a company, we probably access PharmaPendium between 60 and 80 times a month to compare products that are currently in development and at the lifecycle management stage. The database provides us with access to regulatory documents, registration dossier documents and entire approval packages. Our staff need simply enter the name of a medicine, or its trade name, to view all the related data.”

Interestingly, at this company, PharmaPendium is used primarily by the company’s development teams. Clinicians doing phase I, II and III studies and dossier submission use it to determine which classes of medicines produce particular effects in given situations.

Prior to the introduction of PharmaPendium, the company’s developmental clinicians would use other tools, but they did not find everything they needed there. By contrast, PharmaPendium enables regulatory affairs staff and clinicians to quickly and easily access historical approval data, which helps them determine the questions that the FDA posed to other pharmaceutical companies developing similar products.

“If we are developing, for example, a topical antibiotic, we will always look at what has been done in the past. PharmaPendium offers access to approval packages dating back over 70 years, providing us with information that might otherwise have been missed.”

He continues: “There are three types of PharmaPendium user in our company: the people from regulatory affairs, who are interested mainly in the FDA approval packages; the staff engaged in clinical development; and the pharmacokinetic teams who utilize the PharmaPendium PK module.”

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The benefits of PharmaPendium to the latter—pharmacokinetic teams—have, it seems, been particularly remarkable. “When we undertook an evaluation of this product, a senior colleague insisted that working for half a day with PharmaPendium PK saved his people several weeks of work. I found this difficult to believe, so I really tried to challenge our PK specialists throughout the organization. But they insisted: it now takes them one morning to extract essential data and import it to our software, where previously it would have taken two or three weeks at the least.”

He continues: “The greatest impact of the PK module is the assessment of new external opportunities. It allows us to quickly extrapolate PK data for potential in licensing products, enabling our specialists to run software models, ensuring more precise estimates. For a typical project, the PK staff will be told: ‘We would like your advice as a pharmacokinetics specialist regarding this drug molecule.’ They will then simply go into PharmaPendium, enter the name of the drug molecule, and extract the PK data, all in one session. A single PharmaPendium session could save two or three weeks of work. When you have five or six projects a year that adds up to a whole lot of time: up to three months or even more.”

Clinicians also use PharmaPendium’s FDA approval package information when designing clinical studies and development plans. The information manager says: “In the past, we lost

valuable time discussing these things with the FDA; our clinicians would often be involved in a series of exchanges, trying to understand what the FDA would ask of us. Instead of spending weeks gathering data from scientific articles which would then have to be standardized, we spend half a day working with PharmaPendium; the hard work is all done for us.”

He concludes: “PharmaPendium saves us a huge amount of time, and therefore money. The return on investment is huge. To any traditional pharmaceutical company, I would say: PharmaPendium is essential.”

How PharmaPendium works

Efficacy, pharmacokinetics and safety data are critical to successful drug development. FDA drug approval packages also provide a rich source of preclinical and clinical intelligence. The PharmaPendium online database offers searchable access to over 2.0 million pages of searchable FDA approval packages, FDA Advisory Committee Documents and EMA Approval documents (EPARS). It also provides a unique means to search the FDA Adverse Event Reporting System (FAERS).

PharmaPendium allows users to quickly track the biological effects of more than 4,250 approved drugs; and to seek out existing products sharing similarities, such as class, structural chemistry, pharmacokinetics or targets, with drug candidates at every stage of development.

By providing comparative preclinical, clinical and post-marketing drug data in regulatory, scientific and commercial contexts, PharmaPendium significantly improves workflows for professionals involved in preclinical assessment. That includes toxicologists, pharmacologists and pharmacokineticists; regulatory and medical affairs professionals; discovery modelling, preclinical and clinical development specialists; pharmacoepidemiologists; and information professionals.

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PharmaPendium®

PharmaPendium informs critical drug development decisions on safety and efficacy, risk assessments and mitigation and study designs with fully searchable FDA and EMA drug approval documents and FAERS data, a drug-drug interaction risk calculator and comparative safety, pharmacokinetic, efficacy, and metabolizing enzyme and transporter data.

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

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November 2020