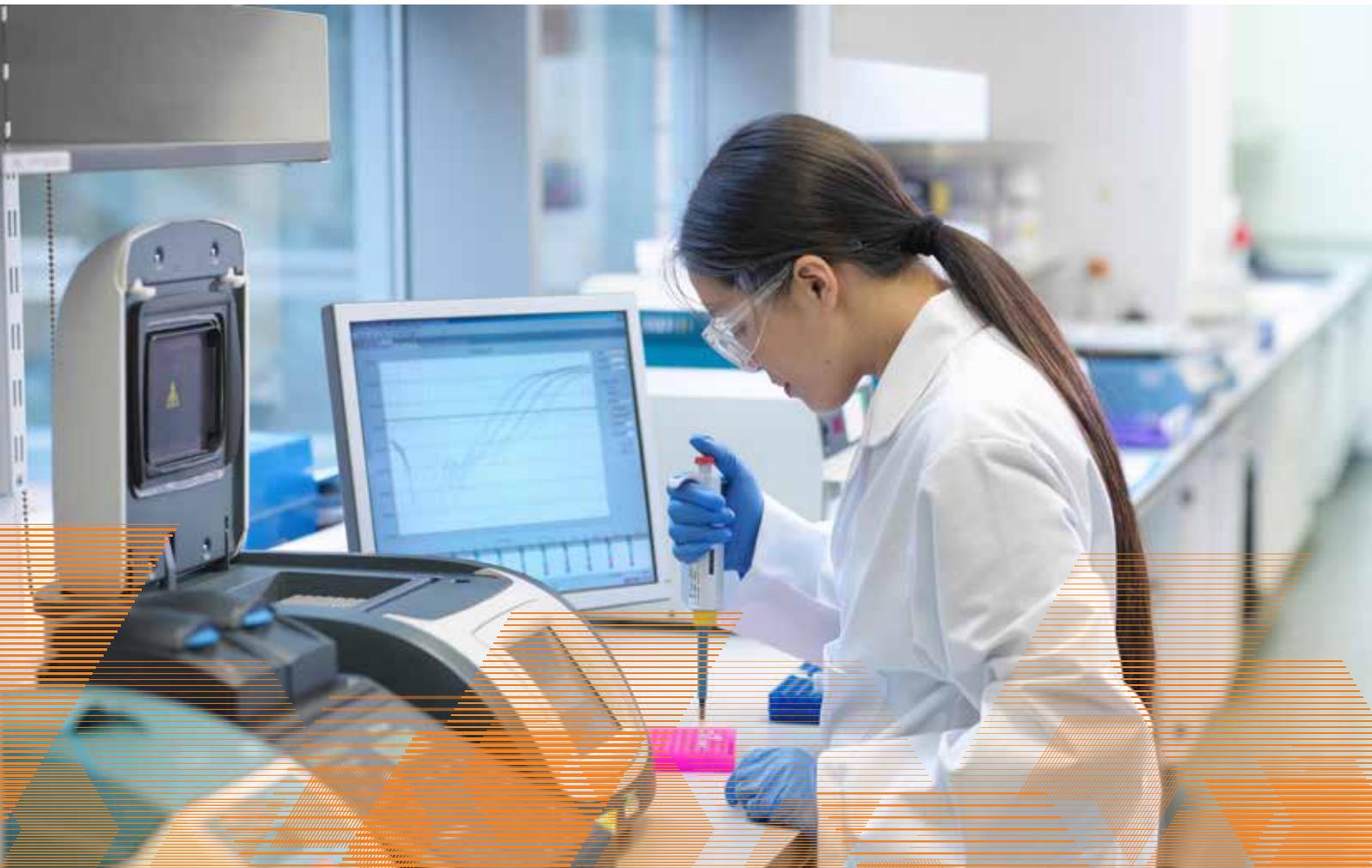


CASE STUDY

PharmaPendium®

A Leading Dermatology Company

Streamlining Workflows



SUMMARY

A single PharmaPendium session could save two to three weeks of work.

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“PharmaPendium offers access to approval packages dating back over 70 years, providing us with information that might otherwise have been missed.”

– **Scientific Information Manager,**
A Leading Dermatology Company

Medical device development — a challenging field

Efficacy, pharmacokinetics and safety data are critical to successful drug development. And FDA drug approval packages provide a rich source of preclinical and clinical intelligence.

The PharmaPendium online database offers searchable access to over 2.0 million pages of FDA approval packages, together with FDA Advisory Committee Documents, EMA Approval documents (EPARS) and the FDA Adverse Event Reporting System (AERS).

Senior Product Manager Philip MacLaughlin explains, “PharmaPendium allows users to quickly track the biological effects of more than 4,250 approved drugs; to seek out existing products sharing similarities - such as, for example, 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 – including toxicologists, pharmacologists and pharmacokineticists, regulatory affairs professionals, discovery modelling and preclinical/clinical development specialists, pharmacoepidemiologists and information professionals.”

For a leading dermatology company, PharmaPendium has eliminated the need for, literally, months of essential research 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 – in particular, clinicians doing phase I, II and III studies and dossier submission – 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 the Drugs@FDA website, amongst other tools, however 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; to determine the questions that the American drug authority posed to other pharmaceutical companies developing similar products.

The company’s Scientific Information Manager explains, “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.”

“Instead of spending weeks gathering data from scientific articles which would then have to be standardized, we now spend a half day working with PharmaPendium; the hard work is all done for us.”

– **Information Manager,**
A Leading Dermatology Company

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

The benefits of PharmaPendium to the latter—pharmacokinetic teams—have, it seems, been particularly remarkable. The Information Manager continues, “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 organisation. 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.”

The greatest impact of the PK module is on our ‘licensing in’ activity—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.

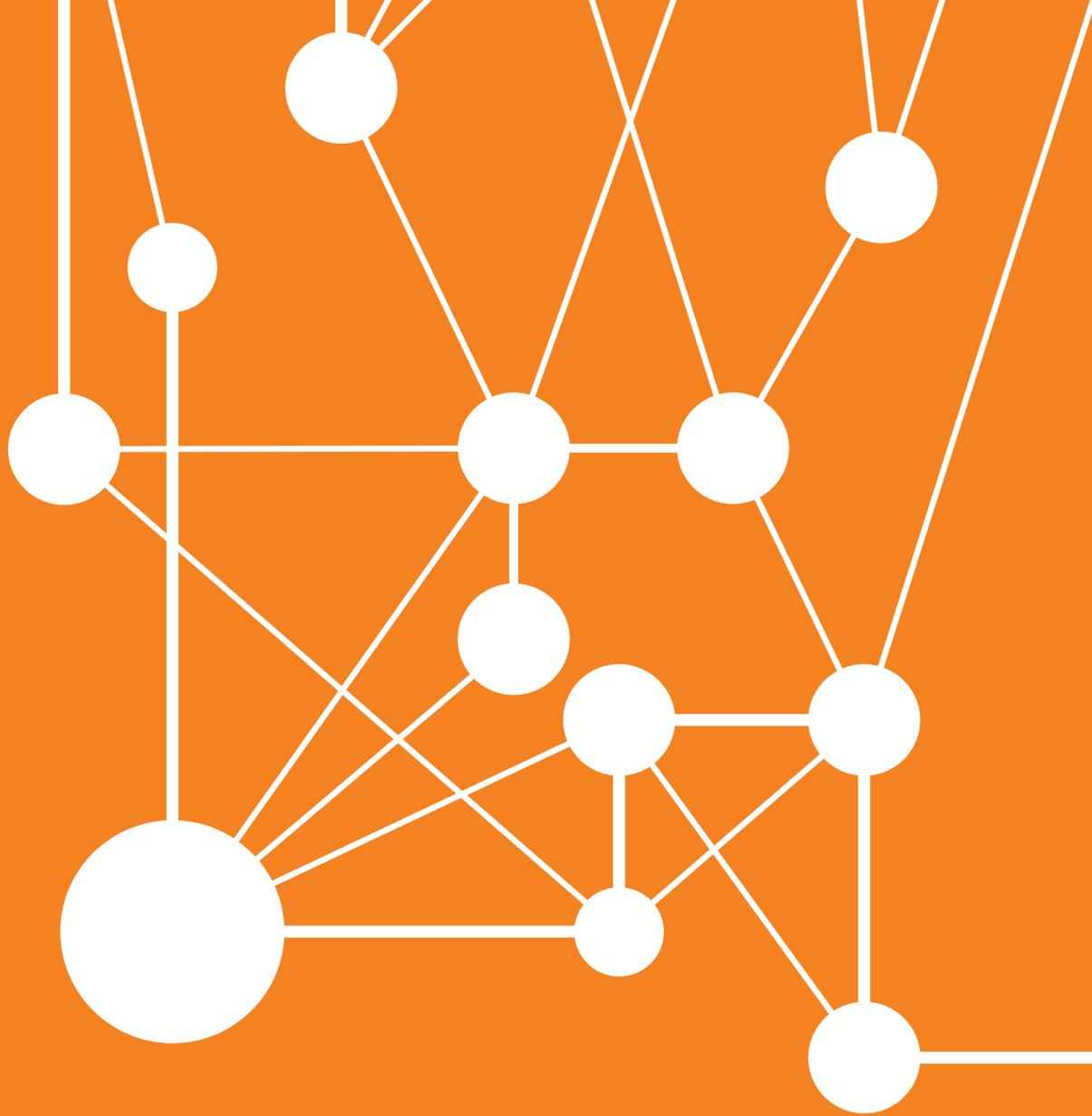
“For a typical project, the PK staff will be told: ‘We would like your advice as a pharmacokinetics specialist regarding this drug molecule.’ They will then simply go into PharmaPendium, enter the name of the drug molecule, and extract the PK data—all in one session.”

“A single PharmaPendium session could save two-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 utilize 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.”

“In short, 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.”



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ASIA AND AUSTRALIA

Tel: + 65 6349 0222

Email: sginfo@elsevier.com

JAPAN

Tel: + 81 3 5561 5034

Email: jpinfo@elsevier.com

KOREA AND TAIWAN

Tel: +82 2 6714 3000

Email: krinfo.corp@elsevier.com

EUROPE, MIDDLE EAST AND AFRICA

Tel: +31 20 485 3767

Email: nlinfo@elsevier.com

NORTH AMERICA, CENTRAL AMERICA AND CANADA

Tel: +1 888 615 4500

Email: usinfo@elsevier.com

SOUTH AMERICA

Tel: +55 21 3970 9300

Email: brinfo@elsevier.com