

# Making more informed drug development decisions

Comparative extracted data on approved drugs provide valuable insights into drug development programs and decisions

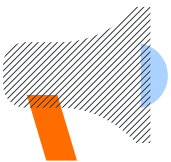






“With PharmaPendium, I can find information that I can’t retrieve anywhere else. That’s a major benefit for me.”

— Laura Newman, DMPK scientist



## The information generation challenge

Meet Laura Newman, a scientist in metabolism, drug interaction and genetics. As part of the compound development team, Laura manages clinical pharmacology studies such as pharmacokinetics, special population, metabolism and drug interaction.

“These are performed at clinical research organizations, mainly in Europe but also in the US,” explains Laura. “I’ve also been a part of late-stage projects like filing processes; writing up a NDA and a MMA.”

Laura reports that in the past, she and her team weren’t able to generate as much information early in the drug development process as would be ideal. “I think that’s starting to change. Now we include more biomarkers and exploratory measurements than we did previously because we have new technologies like EEG and genotyping and because the organization has learned that you might benefit from that at a later stage.”

More information means more informed choices and more intelligent programs. PharmaPendium helps us to make better, more informed decisions.

— Laura Newman, DMPK scientist



## Finding valuable information with ease

Laura is responsible for writing the protocol and managing collaboration with the clinic, dealing with many of the practical aspects of running a study. “All of this is based on a development plan for the compound so that’s mainly where I’ve used PharmaPendium, to figure out information on registered, drugs where they’re comparable, the target profiles and when we do comparisons to our own product. If I don’t find what I want on the FDA web page, then I quickly move to PharmaPendium.”

PharmaPendium helps researchers like Laura find information that isn’t readily available anywhere else. “For example, with the FDA, if a compound has a certain H-filing then the documents are not available online. If you need to go further back than the last seven years, then they were filed in paper and it has not been scanned and put on the web page. So that information is not available there.”

“We were using a marketed compound in one of our studies as base medication and we were looking to find the original file to see the pharmacokinetics information the company had given the FDA in the filing. But the file was submitted before 1992 and so the original document was not available on the FDA’s web page,” recalls Laura. “But the original file from 1990, was available in PharmaPendium. So, I found what I needed.”



## Saving time in research

“PharmaPendium saves me a lot of time. If I don’t find things immediately on the authority’s web page, then I would start digging in other places. Now I just go to PharmaPendium,” says Laura.

Because PharmaPendium is meticulously indexed and hierarchically structured, users like Laura can search for comparative data on candidates sharing the similarities they specify. “I typically search on the specific compound that I want information on. Then I look through my findings to see if the documents have the information that I was looking for. If they have, then I can use it in the context that I need.”

Laura reports that she typically uses the advanced search functionality so she can apply limiters to her results set. That’s not to say that she won’t use the quick search when appropriate. “Of course, one could start with the big picture and then if the mountain of resources is too overwhelming, you could do some filtering. On the other hand, if you only have a few hits on a quick search, you don’t need to do more limiting.”



## Progressing with confidence

PharmaPendium supports Laura in her quest to make the best decisions possible because she can find information not readily available anywhere else: “Now we can make comparisons with older, competing compounds in the same indication area. We can cross reference our search results with other resources we have found ourselves and that helps us with our development plans,” observes Laura. “With PharmaPendium, I can find information that I can’t retrieve anywhere else. That’s a major benefit for me.”

“You can have better risk mitigation strategies if you can depend on the information that you’ve found. More information means more informed choices and more intelligent programs. PharmaPendium helps us to make better, more informed decisions.”

# 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.

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November 2020