CASE STUDY

# PharmaPendium®

Laura Newman, Scientist

## Making Better, More Informed Decisions

**SUMMARY**

Comparative extracted data from FDA/EMA drug approval documents provide valuable insights into drug development programs and decisions.

ELSEVIER

# Find information that can't be found anywhere else and save time with better search control functionality.

A clinical scientist specializing in drug metabolism, genetics and drug interactions uses comparative information in PharmaPendium to augment drug candidate characterization earlier in preclinical development and to better anticipate clinical outcomes.

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 latestage 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 bio-markers 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."

To find the baseline information she needs, Laura relies on a number of resources. "For formal information it's the authorities' web pages, looking into the files for registered compounds. Or it's sources like Medline looking up qualifications on various targets or findings. Of course, all of the information on a registered compound is available on the agency's website but for compounds still in development it is up to the company to decide what information they want to publish."

To bridge this gap, they will often conduct preclinical experiments with competitor's compounds. "If the structure is public we do the experiment ourselves to see how our compound acts compared to the competitor's compound on various criteria like pharmacology, safety or otherwise."

For more informal information Laura taps into a number of resources – from posters at conferences to engaging with researchers in other organizations. "We have our antennae out at conferences and things like that if there's any posters or if they know people at various companies," explains Laura.

### Making the best decisions possible

A critical component of Laura's work is finding the information she needs to make the best decisions possible. "It is taking decisions based on limited information because you won't know everything, especially in the early stages. You do what you can to screen compounds, but then also you have to interpret those results and then make decisions on what to do from there. And you have to do that in a way so that your plan has at least some mitigations and strategies to make sure that you're still moving forward."

Laura is quick to point out that it's only with the benefit of hindsight that you know if the decision you made was right. "We've had a discussion about whether you take the best decisions or the right decisions. In a world like ours, I would tend to say that you could only take the best decisions because only looking back will tell you whether it was the right decision," says Laura. "You simply don't have all the information that you might need to take the right decision at a certain point and time."

Is she satisfied that her information needs are met? "I would say we are actually able to make good, realistic plans and also come to a consensus on what's reasonable to do. But that's one of the challenges. Some parts of the organization are more risk willing than others and so the final plan is a compromise. Generally, we get that information both from the early screening stages but also from the pre clinical area before we start."

"You can have better risk mitigation strategies if you can depend on the information that you've found. The more information you have, the more informed choices you can make and most probably the more intelligent programs you can make in your project. PharmaPendium helps us to make better, more informed decisions."

– **Laura Newman,** Scientist

**Finding valuable information that's not available anywhere else**

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 with search functionality to limit and control searches**

"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 let go of it and slide to PharmaPendium. At least before I start digging on the authority's web page," 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 projects with more 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."

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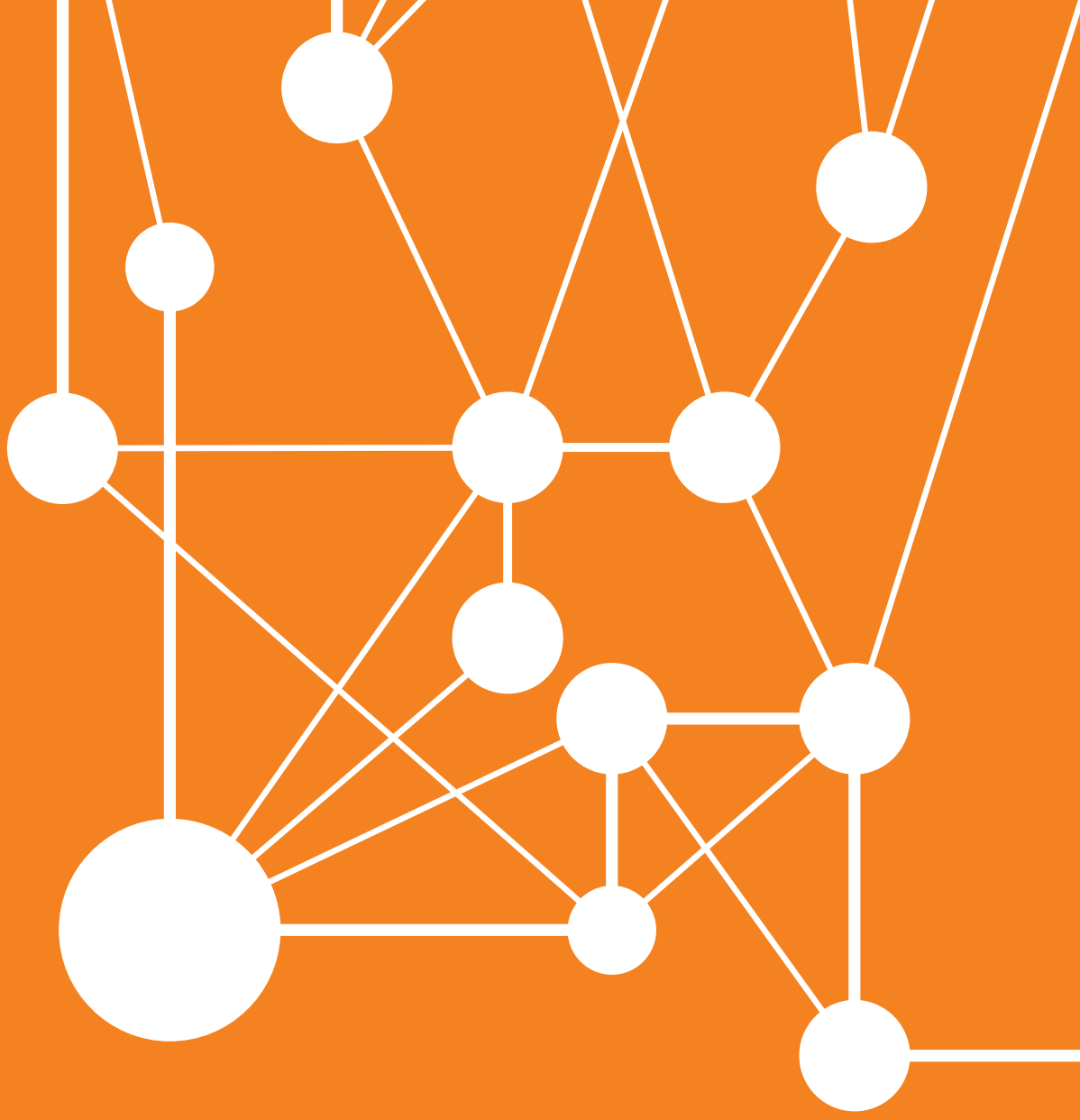

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