Customer Story

Ferring Pharmaceuticals & NNE

Challenge

High costs, changing regulatory guidelines and an increasingly competitive marketplace pose a serious hurdle to pharmaceutical companies aiming to get new therapies from the development pipeline to market.

New statistical monitoring tools optimize the drug development pipeline

NNE and Ferring Pharmaceuticals partner to develop innovative statistical monitoring solutions

To facilitate the transition away from traditional monitoring, many pharmaceutical companies have sought partnerships with experts in this growing field who can tailor solutions to their exact needs. Ferring Pharmaceuticals is one such company; Ferring's biostatistics group has developed a partnership with NNE, a leading pharmaceutical engineering consultancy, with vast experience in the drug development process both through manufacturing optimization and statistical support for clinical trials.

"Our core competence is building factories in the pharmaceutical industry – alongside this we have a team of 200 consultants working to optimize and drive the best production, products, quality levels and, for clinical trials, GCP (good clinical practice) levels," explains Kasper Munck, Principal Consultant at NNE and an expert in statistical monitoring and operations research. "I'm called in when [our clients] have a need for either automation or clinical trial analysis," he says. With the highly specific data collection requirements set forth by regulatory authorities in markets around the world, having targeted statistical support at all phases of development is essential, particularly at companies that lack high-level statistical systems infrastructure in-house.

Implementing centralized monitoring in compliance with regulatory guidelines

Because much of their clinical trial collaboration is on products in Phases 2 and 3 – which are large, expensive and essential to gaining regulatory approvals – ensuring high-quality data and regulatory compliance is of utmost importance. To that end, Munck and his team work with Ferring's biostatisticians to develop central and risk-based monitoring approaches, tailoring analyses to any areas deemed critical by the study team in view of regulatory standards. This includes scripting specific dashboards to allow users to monitor study progress and assess ongoing trends including fraud detection, giving them tools to inform decision making.

In contrast to traditional, full monitoring – whereby all data collected for each patient is reviewed – a risk-based approach identifies the key data points to the study and lets study teams focus primarily on this data. "[By instituting a risk-based approach,] we can free up so much time, enabling people to actually perform real tasks instead of just looking at data," explains Munck.

When Ferring initially approached NNE, the company's clinical trial managers had an urgent need to automate their system for constructing patient profiles and narratives. Munck demonstrated how JMP® Clinical could easily address this need, and although Ferring's existing software was adept at distributing results, it lacked the statistical robustness that JMP Clinical offered. "That really got them hooked," he recalls.

With the arrival of a series of new study opportunities shortly thereafter, Ferring was primed to take full advantage of JMP Clinical. NNE was tasked with building a centralized monitoring tool that incorporated the parameters set forth by Ferring and that allowed for flexible, on-the-fly statistical evaluations. "The tool needed to be dynamic because each therapeutic area could have a very different [target endpoint]," explains Munck. While Ferring had worked with experienced coders before, NNE's statistical expertise allowed them to go beyond simply coding what Ferring's monitors dictated; instead NNE engaged with its client to develop the ideal model collaboratively. "We had the capability of understanding both how to code, and the purpose and requirements for the right statistical model," he says.

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> Egbert A. Van Der Meulen, Senior Director of Biostatistics, Ferring Pharmaceuticals

Working with a dedicated specialist from NNE was a great experience, says Egbert A. Van Der Meulen, Senior Director of Biostatistics at Ferring Pharmaceuticals. "We started from two basic requirements: first, being able to perform site performance using statistical inference and clinically relevant endpoint metrics. And second, recruitment quality as opposed to recruitment speed. All of course based on a dynamic click-and-play, slice-and-dice JMP Clinical interface."

Relying on trusted software

Like many experienced consultancies, NNE remains officially software-agnostic. However, with the freedom to use the tools best suited to their clients' specific challenges, Munck says he has found that JMP Clinical serves his portfolio of pharmaceutical R&D clients particularly well. "JMP Clinical has definitely been the easiest tool to both teach and learn," Munck affirms. "That is why we tell our customers that if you don't already have another preference, you should use JMP."

"JMP Clinical is fully based on CDISC ADaM and SDTM data, which Ferring has had in place for over a decade," adds Van Der Meulen. "As such, it has the potential to, frankly, do anything we need in terms of conducting and reporting clinical trials, whether it is central statistical monitoring, signal detection, narrative creation, building clinical data warehouses or, indeed, full-blown clinical trial reporting with close to a single push on a button. This great potential is not fully realized yet, but it will make room for statistical programmers to move on to the next, likely more challenging level of adding value to clinical trial reporting and data explorations."

Saving time in a time-sensitive process

With a combination of standard functionalities, like the data quality and fraud applications, and customized scripts in JMP Clinical, NNE and Ferring can assess variation in critical variables within and between sites to pinpoint risks and determine where additional monitoring or oversight is required, all within a shorter timeframe than before. "What we've done is adapted some of the filtering options in JMP Clinical, implementing JMP scripting on top of the existing customer functionality," explains Munck. Working together over the last year and a half, NNE and Ferring have honed the central monitoring model and now can integrate new trials into the framework within just a week.

Data analysis and review are ongoing throughout each trial, and using JMP Clinical, project teams can review data, quickly evaluate study progress and respond to stakeholder questions immediately by using the adjustable statistical interface. "They have weekly meetings where they look at the trial," Munck says. "You don't need to prepare analyses, you don't need to print anything, you just bring in the data, put it into the tool, and you can answer all the questions directly at the meeting." In the past, Ferring's teams would spend a day or two before each meeting running ad hoc analyses and preparing slides, and even that didn't guarantee that they could answer all potential questions. Having the right tool and the right statistical approach have not only saved time in the analysis and preparation stage, but made meetings more productive.

As they implement their central monitoring approach on a wider array of projects, NNE and Ferring continue to explore new ways to streamline study operations and stay on the leading edge of statistical innovation. For Ferring, Van Der Meulen adds, "we are presently exploring the possibility of auto-generating statistical reports and further down the line, building clinical data warehouses using JMP Clinical and our AdaM-based repository databases. We also plan to explore how JMP Clinical can be put to use in the DOE applications of more complex adaptive and possibly Bayesian Seamless Phase IIa/IIb or II/III trial designs. JMP Clinical would be preferred over a stand-alone special purpose software package – which would likely be rather more expensive. Having a wonderful tool in place for central statistical monitoring is not the end of our collaboration with NNE – far from it."

Solution

Pharmaceutical consultancy NNE partners with leading clients like Ferring Pharmaceuticals to design and implement custom centralized statistical monitoring programs that meet the unique requirements of each of the company's new Phase 2 or 3 drugs. JMP® Clinical enables NNE to roll out scripted applications and dashboards that streamline workflows.

Results

By instituting a sophisticated statistical approach that systematizes data quality improvements, NNE has helped clients like Ferring to navigate compliance and regulatory processes and ultimately, bring new products to market more efficiently.

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