When knowledge drives results:
the impact of a winning data strategy

Having an effective clinical trial data strategy in place can make the difference between success and an expensive failure for a pharma company. pharmaphorum's **Richard Staines** spoke to Cytel's global head of data management **Paul Fardy** to find out how.

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Convincing regulators to approve drugs has never been easy, with billions of dollars spent each year to generate the clinical evidence required to clear the multiple safety and effectiveness hurdles.

Many people have hailed the era of big data as a turning point for pharma, with the latest technology allowing for an increasingly granular and detailed read-out of a drug's performance in clinical trials. But with great insights comes great quantities of data and managing the vast amount of information generated by a study can be difficult.

Enter Cytel, a global provider of innovative analytical software and clinical research services that is trying to change the way pharma thinks about its clinical data strategy, an element of planning that all too often is decided too late in development. That, in turn, puts trials and large amounts of investment at risk, along with the time, effort, bravery and sacrifice of the patients involved.

Cytel's Paul Fardy told pharmaphorum that important changes need to be made – including getting down to brass tacks as early as possible and defining what data is being collected and the kind of standards that must be applied.

Without changes to the process, a large trial can all too easily run into difficulties and even fail, putting a pharma company's regulatory filings or business development plans in jeopardy.

He said: “The ultimate risk is failure to get approval of a potentially effective drug that may have benefited patients. If you are in a smaller company, the objective is often to get a drug licensed by a larger company. The risk here is that you are not going to get the opportunity to get that drug taken on by a larger company.”

The lack of a strategically implemented data strategy can also lead to problems with regulators – in many cases scientists working for organisations such as the FDA, or the European Medicines Agency will have queries about the clinical data package.

Poor quality or insufficient data can lead to serious delays with regulators, Fardy said, adding: “You may not be able

to respond to questions that ultimately could decide the future success of your treatment."

Trial data often comes from disparate sources, making it even more important to ensure that there is appropriate documentation of data, and traceability. This can slow the process even further if data diligence is not already in place, as companies find themselves having to fish around for the answers to the regulators' questions.

"I have spent a lot of time trying to collect data that I did not know existed, when a sponsor has started considering the data consistency implications too late in the day" he said. "If you don't have a clear strategy you run the risk of not knowing how to handle your data."

All of this wastes valuable time and could have a knock-on effect on profits – as every pharma exec knows, unnecessary delays during the clinical development process can cost billions if the drug in question is a potential blockbuster.

And the clinical development process itself is usually monetised, with big pharma trial sponsors paying out substantial milestone payments when certain trial targets are met, such as the successful completion of a stage of clinical development.

A poorly defined data strategy "could lead to delays in hitting major milestones in any of the stages", he added. "The end result may mean that patients' access to potentially beneficial new medicine could be slowed or, at worst, never materialise, which would be totally unacceptable."

Centralise and collaborate

So how should companies draw up their global data strategy? Fardy said that a cross-departmental approach is necessary, with a governance committee overseeing the various departments and stakeholders involved. Everyone needs to understand the impact and implications of how the data will be collected, managed and stored.

Data collection and analysis should also be centralised as much as possible, to solve the problem of traceability, and allow sponsors to maximize the value of their data through cross study analyses. The connections between data management, programmers and biostatisticians is crucial, and centralisation enhances these connections.

"The use of electronic data capture allows you to work across global areas but ensures the system can quickly resolve most discrepancies. However, the success of your clinical data strategy is not about the specific products or platforms that are used, the process and the way you manage the data is most important," he stressed.

"There is a lot to gain from centralisation of data, it can definitely reduce the time needed, and training costs needed through adopting technology."

Connecting with patients

Fardy said that the approach also helps companies wishing to engage proactively with patients during the clinical trial process.

Patient centricity is a hot topic that is being discussed more and more in pharma – and a company's global data strategy can play an important role in connecting with the patients on the trial.

Fardy cautioned that careful thought ust be given to data capture devices, which must suit the needs of patients. For example, tablets may be unsuitable for patients with conditions that can affect dexterity.

"The right technology has got to be used for a specific set of patient needs and then set up, so patients and investigators can use it effectively."

Have the right data for health technology assessment (HTA)

Fardy's definition of data does not just include the conventional clinical trial data that is collected to reassure regulators about the safety and efficacy of drugs but goes beyond this into patient reported outcomes (PRO), electronic health records (EHR), social media and more.

Along with many others in the industry, Fardy says that this 'secondary or social' data gathered during the clinical trial phase is increasingly playing a part in health technology assessment.

Whereas in the past HTA studies may have been conducted as an afterthought once the trial process is complete, there is now a trend to use secondary endpoints to gather information about issues such as quality of life that can be invaluable to ensure market access once the trial process is complete.

"What happens at the moment is HTA is considered late in development, but we are looking at ways to bring that discussion much earlier on. The more you plan the better the outcome is."

In the future Fardy said companies must also be prepared to capture data from other sources, which could be used to help adapt trial designs to patients' needs.

"I know that social media usage is something that is being looked at. In itself it is a strong tool for patient engagement," he explained.

He concluded that the end goal of a data strategy is to convert data into knowledge, which can allow companies to make the right decisions both for the project, and the wellbeing of patients.

"Data transforms into information. That turns into knowledge. Data has limited meaning, and by the time you get to knowledge you are making important decisions on the trials, and patients. It can have an effect on their safety, and whether the people you are trying to help are living longer."

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About the interviewee

Paul Fardy is global head of data management at Cytel. Cytel is shaping the future of drug development. Cytel's solutions bring together technology, data science, data analytics, and clinical research services to drive superior outcomes and results for clinical trial sponsors. With operations across North America, Europe, and India, Cytel employs 900 professionals, with strong talent in biostatistics, programming, and data management. For more information about Cytel, visit http://www.cytel.com/.