BIOBUSINESS BRIEFS

DEAL WATCH

‘Big data’ deal for diabetes clinical trial modelling

Data analytics company GNS Healthcare and the contract research organization Covance have entered into a deal to develop predictive models of clinical trials.

“There are many advantages to clinical trial modelling, such as reduced cost and time savings in situations where the use of existing data can accurately simulate a trial and its potential outcome without the need for an actual trial,” says Felix Frueh, an executive partner at Opus Three (a consulting firm that focuses on personalized medicine), Gaithersburg, Maryland, USA. “Modelling and simulation is not a new approach to drug development — for example, it has been explored in situations where data are sparse, such as in paediatrics and other populations with a limited number of patients,” he continues.

The collaboration is set to model clinical trials of several diseases, beginning with type 2 diabetes (T2D). Clifford Bailey, Head of Diabetes Research at Aston University, Birmingham, UK, notes that it is challenging to conduct actual T2D clinical trials for many reasons. “For example, T2D is a heterogeneous disease, so there is a broad spectrum of patient responses seen in clinical trials. In addition, T2D is a progressive disease, so individuals experience different rates of disease progression, and this will affect their response to a drug in a clinical trial.” So modelling could prove to be useful for T2D clinical trials: “These between-patient differences could be captured in a model to predict the trajectory of a patient’s progress or response to a drug,” he says.

The modelling collaboration will use data that Covance has gained from its role as a contract research organization supporting preclinical and clinical drug development, together with GNS Healthcare’s so-called reverse engineering and forward simulation platform. This super-computer-powered tool is designed to automate the extraction and identification of causal network models from so-called ‘big data’ — large complex data sets that are not amenable to simple statistical analyses. Financial terms of the agreement have not been disclosed.

“Of course, the quality of the output is dependent on the quality of the data used to feed the model and run the simulation,” cautions Frueh. “Therefore, novel ways to get access to, as well as manage and process, high-quality data assets is crucial. The partnership between GNS Healthcare and Covance is an attempt to address this critical need.”

But some aspects of T2D clinical trials might be difficult to model, such as patient responses that are not captured by biomarker end points. “Biomarkers — such as HbA1c (glycosylated haemoglobin) to determine glycaemic control — only measure the totality of the therapeutic effect and do not inform about fluctuations in blood glucose throughout the day and night. Such effects would be difficult to include in a model.”

Bailey highlights another limitation of modelling: “What happens to a patient before they are recruited to a clinical trial (such as the health status of the patient before recruitment: for example, blood pressure and levels of blood glucose and lipids) can influence what happens during a trial (including a patient’s response to therapy), and it is very difficult to factor this into a model.”

Indeed, Frueh notes that a model of clinical trial outcomes only provides indirect evidence of the potential outcome that needs to be confirmed. “But that said, modelling and simulation provides a powerful alternative to actual clinical trials, especially for early decision making. It may be particularly useful for the development of personalized medicines, where it would be difficult to recruit a statistically significant number of patients from distinct subpopulations into a clinical trial,” he concludes.

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