Certara Launches Trial Simulator 2.3 to Improve Clinical Trial Success

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Certara's clinical trial simulator enables drug developers to test ideas and evaluate relevant and effective trials for every phase of clinical drug development

PRINCETON, NJ – Nov. 28, 2018 – Certara®, the global leader in model-informed drug development, regulatory science, real-world evidence and market access, today announced the launch of version 2.3 of its Trial Simulator software to help drug developers improve clinical trial design, resulting in greater likelihood of trial success. By allowing users to model and simulate different clinical trial scenarios, Certara's Trial Simulator ® allows them to identify and assess risks and preview the range of expected results before millions of R&D dollars are spent and human subjects are exposed to experimental therapies.

Today, nine out of 10 drugs in development fail to make it to market, costing pharmaceutical companies billions of dollars every year.[1] Even the majority of drugs that get to Phase 3, do not get approved.[2] One reason for trial failures is suboptimal trial design.[1,2]

"Certara's Trial Simulator is a trusted solution that has been used by leading pharmaceutical companies for more than a decade to optimize their clinical trial design and maximize their probability of trial success. But as these trial failure rates testify, we need to increase awareness of trial simulation's capabilities and broaden its adoption. Meanwhile, we continue to enhance Trial Simulator both to support our loyal customers and ensure that the platform continues to meet their evolving needs," said Thomas Kerbusch, PhD, president of Certara Strategic Consulting Services.

Trial Simulator provides an easy-to-use and highly efficient approach to computer-assisted clinical trial design. Drug development teams can use Trial Simulator, together with existing drug knowledge, to answer highly pertinent questions such as: How likely is this trial to succeed? What is the optimal dosing and treatment schedule for a particular indication? What is the expected range of responses across doses? How will a change in patient inclusion/exclusion criteria affect outcomes? Can we shorten the trials or reduce the number of patients in the trials?

With Trial Simulator, drug development teams can define study design attributes, conduct statistical and sensitivity analyses, and create graphical summaries of their work. They gain access to Certara's extensive library of pre-built pharmacokinetic, and pharmacokinetic/pharmacodynamic (PK/PD) models, which allows them to rapidly build population-based drug and disease models that describe drug actions over time in specific subjects. They can even create novel study designs and compare different development strategies. With Trial Simulator, users can share their scientific knowledge, test ideas, and plan the most relevant, effective clinical trials.

Furthermore, Certara's Trial Simulator v2.3 is highly intuitive and easy to use. It combines comprehensive modeling of drug action with an easy-to-use graphical interface and seamless connection to R for custom plotting capabilities. The debugging tool creates real-time plots of any variable in the drug model, including concentration and effects over time. Trial Simulator 2.3 also supports a wide variety of trial designs, including parallel, n-by-n Latin square, and crossover designs. To make the entire process as efficient as possible, Trial Simulator includes built-in analysis routines such as descriptive statistics, ANOVA, ANCOVA, bioequivalence analysis, and the Kaplan-Meier survival analysis.

Interested parties, who would like to see Trial Simulator in action, can access a one-hour archived webinar entitled "Using Realistic Covariates with New Trial Simulator to Optimize Meropenem Dosing in Renally-impaired Children" at https://www.certara.com/webinar-archive/using-realistic-covariates-with-new-trial-simulator-to-optimize-meropenem-dosing-in-renally-impaired-children.

This webinar was co-presented by Dr. Edward Nehus, a pediatric nephrologist in the Division of Nephrology at the Cincinnati Children's Hospital Medical Center and an assistant professor at the University of Cincinnati, Department of Pediatrics, and Dr. Mark Lovern, vice president of Integrated Drug Development at Certara.

References

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2. Grignolo A & Pretorius S. (2016, August 1). Phase III trial failures: Costly, but preventable. Retrieved from http://www.appliedclinicaltrialsonline.com/phase-iii-trial-failures-costly-preventable.

About Certara

Certara enables superior drug development and patient care decision-making through model-informed drug development, regulatory science, real-world evidence solutions and knowledge integration. As a result, it optimizes R&D productivity, commercial value and patient outcomes. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions,

and key regulatory agencies across 60 countries. For more information, visit www.certara.com.

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