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NEWS

MAS-EPSILON Announce Availability of the First FDA-Accepted Type 1 Diabetes Metabolic Simulator

The T1DMS provides a safe, interactive modeling and learning environment for the research/training/education of study investigators, healthcare providers and patients and families managing their disease towards improved glucose control.

June 16, 2011 - Charlottesville, VA - MAS-Epsilon announce the availability of the only diabetes simulation technology accepted by the U.S. Food and Drug Administration (FDA) as a substitute for animal trials in the pre-clinical testing of control strategies in the Type 1 Diabetes Metabolic Simulator (T1DMS).

The T1DMS is designed to simulate early-phase clinical studies on an in-silico population with the glucose dynamics of individuals or a particular person. In collaboration with Drs. Claudio Cobelli and Chiara Dalla Man at the University of Padova (Padova, Italy), Drs. Boris Kovatchev and Marc Breton at the University of Virginia Diabetes Technology Center developed a computer simulator of the human metabolic system based on the previously introduced Meal Model of glucose-insulin dynamics.

This simulator became the first computerized simulation tool accepted by the FDA as a substitute for animal trials in the pre-clinical testing of control strategies in Type 1 Diabetes. In silico testing can produce credible pre-clinical results from testing interventions and management strategies at a fraction of the time and cost of current pre-clinical animal testing methods.

"We are very enthusiastic about the opportunity to build and provide a robust commercial version of the model technology to the diabetes research and disease management community," states Kurt Wassenaar, MAS/Epsilon CEO. "We believe that "in silico" modeling can be a significant factor in improved and accelerated development of new products for diabetes care, as well as central to the development of the artificial pancreas."

The computerized modeling provides a safe, interactive learning environment for the training/education of study investigators, healthcare providers involved in diabetes management using CGM sensors, insulin pumps and controllers and for patients and families managing their disease towards improved glucose control; and provides an important means of standardization of the research and development process of new diabetes management tools and interventions as well as a blueprint for modeling other disease processes.

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The T1DMS is available to the academic/scientific/medical and pharmaceutical communities for research on a training population. As new treatment methods become available, the current version of the T1DMS will be upgraded accordingly for simulations that match and keep pace with new treatments and commercial demand for testing and simulation.

Currently, over 50 academic and 10 industrial sites are using the test version of the simulator worldwide toward development of an artificial pancreas. Additionally, over 100 pharmaceutical and Diabetes device companies are active in developing novel and more effective medications for diabetes and related conditions.

The cost and time savings of metabolic simulation modeling is estimated in the millions of dollars and years of development when compared to current pre-clinical animal testing methods.

In early 2012, plans to have a web-based study, testing and training services to both academic and industrial investigators involved in the R&D of control algorithms, pumps, sensors and novel insulin formulations for the Artificial Pancreas Project (APP) sponsored by the Juvenile Diabetes Research Foundation (JDRF).

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