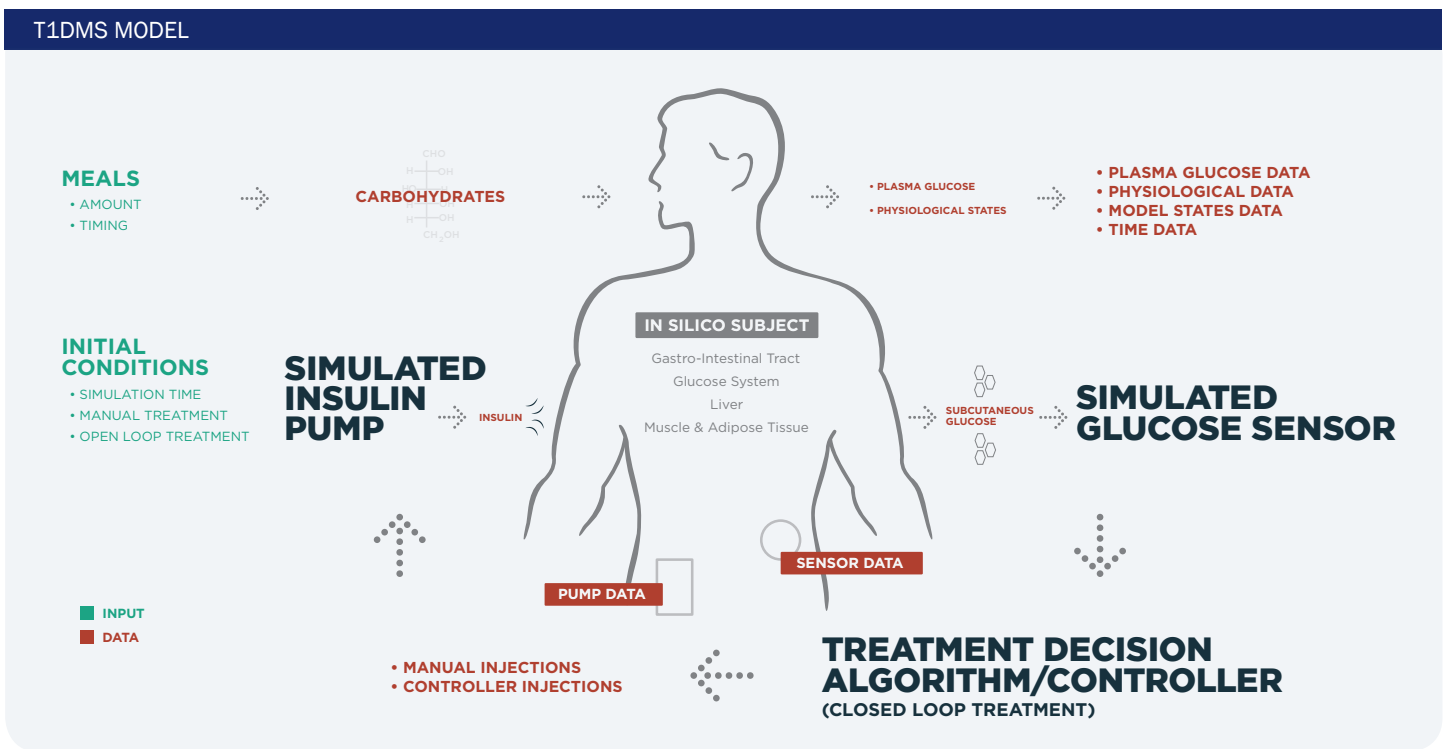


Simulate the treatment of Type 1 Diabetes

The UVA/Padova T1DMS is simulation software that allows users to design and test treatment of in-silico subjects with Type 1 Diabetes Mellitus. The T1DMS improves diabetes research and product development strategies by providing control over the experimental parameters and shorter tuning cycles.



PRIMARY APPLICATIONS

- ▶ Simulate and test treatment protocols identical to proposed clinical studies
- ▶ Measure the impact on diabetes management and treatment

Pre-clinical experiments using the UVA/Padova T1DMS are conducted at the level of individual subjects, which provides insight into the intra- and inter-personal differences seen in humans. Real-life conditions are modeled to include varying meal sizes and timing and variable insulin dosing and timing and hyperglycemia and hypoglycemia are detected and measured.

The UVA/Padova T1DMS has been used by over 40 academic research groups and over 15 prominent commercial research and pharmaceutical groups active in the international diabetes management arena. This software is used by the JDRF Artificial Pancreas Consortium.

Advantages for both industry & academic research and development

The UVA/Padova T1DMS allows the user to design experiments which examine and tune control algorithms for insulin dosing strategies and also guide and focus the emphasis of protocol designs for clinical studies.

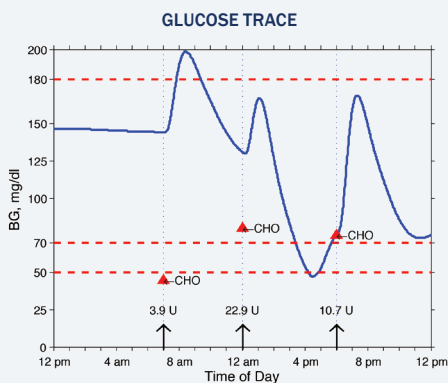
SOFTWARE OVERVIEW

IN SILICO POPULATION

- ▶ Embodies the biophysiological parameters of the FDA accepted in silico population
- ▶ 10 adults, 10 adolescents, 10 children

BASIC USER-DEFINED SIMULATION INPUT

- ▶ Meal profiles (amount, timing and duration of a meal)
- ▶ Insulin treatment (amount and timing of basal/bolus insulin doses)
- ▶ Time of simulation and regulation (length & time of day)
- ▶ Hardware (pump & sensor)
- ▶ Control law definition in control algorithms



SUBJECT-SPECIFIC DATA TO FINE-TUNE TREATMENT

- ▶ Individualized, intra-personal results
- ▶ Inter-personal differences are revealed across the spectrum of human variation
- ▶ Population results are calculated from the individual results as in a clinical trial
- ▶ Age, Body Weight (kg), Subject-specific optimal basal insulin rate (u/hr), individual carbohydrate ratio (CR, g/U), total daily insulin, and insulin sensitivity (maximum drop in glucose mg/dl per unit of insulin[MD])
- ▶ Metabolic testing results may be simulated for individual subjects and incorporated into treatment plans prior to the regulated model run

SIMULATION SERVICES

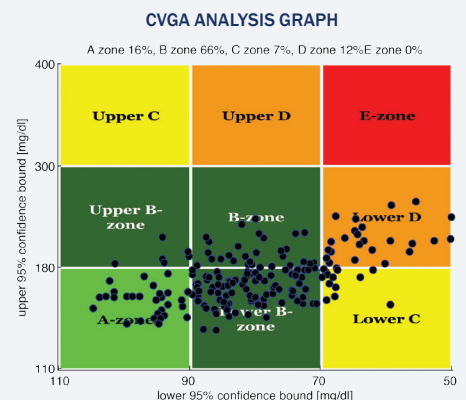
- ▶ Simulation services using the 300 subject FDA-accepted population are available through The Epsilon Group
- ▶ To date, six IDE's have been granted by the FDA based on studies using the T1DMS

SIMULATION RESULTS DATA (PER SUBJECT AND POPULATION)

- ▶ Blood glucose (BG) values and simulated sensor readings (mg/dl per minute)
- ▶ Basal/bolus insulin injections (pmol/minute)
- ▶ User-specified data from controller
- ▶ System states, carbohydrate intake and more...

SIMULATION RESULTS ANALYSIS

- ▶ Real-time glucose traces for visual understanding of insulin-glucose fluctuation
- ▶ Blood glucose excursion analysis
- ▶ Control variability grid analysis



Learn more at www.tegvirginia.com/t1dms

