June 2017

Greetings friends of Dose Safety! We've had an exciting last 6 months. I want to share some of our company's great news, as we get closer to reaching our dream of being part of a commercially available automated insulin delivery system that helps people with diabetes live more independent lives. We are now in the third year of our NIH SBIR grant.

New FDA approved iPhone-based automated insulin delivery (AID) investigational device
In April the FDA approved the device to be used in our next clinical study, see below. The device incorporating a Dexcom CGM and Insulet OmniPod insulin pump, serves to reduce the high cognitive load on people with diabetes through automated insulin delivery. The device has three principle capabilities:

1) Automated transitions between hybrid closed loop (HCL) and fully automated closed loop (FACL) - with no premeal bolus required - and open loop operating modes
2) Closed loop basal between meals
3) CGM and pump fault tolerance safety features

Basically the controller is a hybrid closed loop algorithm with fully automated closed loop control as a safety backup. The fully automated control capability is designed to augment hybrid closed loop mode in various circumstances such as, missed pre-meal bolus, incorrect carbohydrate counting, variations in G-I motility, limited mental capacity, unanticipated exercise, etc. If the patient chooses to not manually bolus pre-meal then the fully automated closed loop capability will control blood glucose 24/7.

Upcoming clinical studies
In May the Benaroya IRB approved the protocol for our next CRC study. The studies will be conducted in two phases:

1) CRC study to evaluate hybrid closed loop (HCL) mode using FL dosing algorithm version 2.3. This study will evaluate FL dosing algorithm version 2.3 to handle 75-gram meal in fully automated closed loop (FACL) mode. Validate closed loop basal between meals. Evaluate insulin delivery safety under CGM and pump fault conditions

   The study will start in June. We expect to enroll from 20 to 30 subjects in the study.

2) Three days in a hotel to assess the safety and efficacy of the Dose Safety Controller (DSC) among patients with Type 1 Diabetes (T1D) and its ability to prevent or decrease the risk of hypoglycemia. The system's ability to work under all circumstances and conditions will also be assessed..

Two (2) clinical paper manuscripts in progress
One manuscript documents the clinical results of our previous NIH grant funded ad lib, daily living study, the other will address the clinical study, which will start this month.

Dose Safety software runs on three (3) computing targets
Our dosing algorithm currently runs on Android and iOS smartphones and a Kinetis K22 32-bit ARM Cortex-M4 MCU ultra low-power microcontroller MCU.

If you are attending the ADA conference I will look forward to seeing you in San Diego.

Richard Mauseth, MD, CEO, Dose Safety Inc.