

# THE INTERNATIONAL DIABETES CLOSED LOOP (IDCL) TRIAL: PLANNED PIVOTAL TRIALS OF CLOSED LOOP CONTROL ON AN EMBEDDED SYSTEM AND A MOBILE SYSTEM

Sue A. Brown, J. Hans DeVries, Boris P. Kovatchev  
on behalf of the IDCL Study Group

## Introduction

A series of planned studies will allow for the initiation of two pivotal trials of closed loop control utilizing an embedded version of an artificial pancreas (AP) on an insulin pump and a mobile version with an implantable sensor, respectively.

## Methods

Both pivotal trials will be multi-center with subjects randomized 2:1 to AP vs. sensor & pump.

Major Eligibility Criteria will include:

- Ages 14-75 years old
- Type 1 Diabetes (US Study: MDI & pump users)
- No A1c restriction (US Study)

Primary Outcome:

% Time in CGM Target Range of 70-180 mg/dL.

Analytical Plan:

Hierarchical Analysis of CGM Metrics including % Time >180 mg/dL, Mean Glucose, % Time <70 mg/dL, %Time <54 mg/dL

Secondary Efficacy Endpoints include HbA1c

## Pilot Results

A pilot study of 5 Adults Subjects using the embedded system was completed in December 2017 at the University of Virginia.

### System Components:

- ✓ Control-IQ algorithm embedded on Tandem t:slim X2 insulin pump
- ✓ G6 CGM (Dexcom): 10 day wear sensor
- ✓ Control IQ: the algorithm is identical to inControl



(TypeZero Technologies) and is intended to be a software update available to t:slim X2 pump users upon PMA approval.

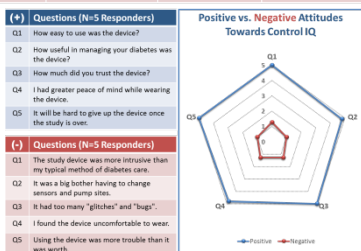
Subject Characteristics (N = 5)	
Mean Age	52.8 years
Gender (M/F)	2 / 3
Mean A1c	6.5%
Mean Daily Insulin Units /kg	0.43

The system maintained closed-loop 98% of the time intended with high system usability scores on patient surveys. Subjects achieved overall 87% time in CGM range between 70-180mg/dL when in closed loop.

System Operation	
Total use (hours)	196.1
CGM availability	94.4%
Closed-loop when CGM available	98.4%

Metric (computed during closed-loop use)	Overall	Daytime	Nighttime
Mean glucose (mg/dl)	129	135	121
Coefficient of variation (median)	27%	27%	21%
% below 54 mg/dL (median)	0.7%	0.0%	0.0%
% below 60 mg/dL (median)	1.1%	2.0%	0.0%
% below 70 mg/dL (median)	2.9%	4.1%	1.0%
Percent in range 70-180 mg/dL (mean)	87%	82%	94%
% above 180 mg/dL (median)	5%	8%	6%
% above 250 mg/dL (median)	0%	0%	0%
% above 300 mg/dL (median)	0%	0%	0%

Subjects answered on a scale 1-5 and results showed subjects strongly agreed with the positive questions and strongly disagreed with negative questions.

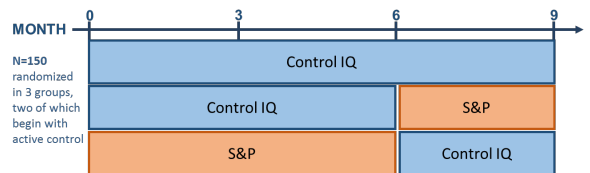


## Embedded AP System

**Objective:** Generate safety and efficacy data satisfying U.S. regulatory requirements; Investigate longer term use of system and transitioning to sensor & pump.

**Enrollment:** Anticipated N=150 subjects randomized 2:1 to closed-loop vs sensor & pump at 7 US Sites

**Design:** 6-month active treatment followed by 3-month cross-over extension:



## Mobile AP System

**Objective:** Generate safety and efficacy data satisfying E.U. regulatory requirements

**Enrollment:** Anticipated N=72 subjects randomized 2:1 to closed-loop vs. sensor & pump at 3 EU Sites

**Design:** 3-month parallel group RCT

### System Configuration:

- ✓ Mobile platform running TypeZero inControl algorithm and inControl Cloud;
- ✓ Senseonics Eversense hybrid implantable and wearable CGM intended for long-term continuous use sensor (up to 180 days);
- ✓ Accu-Chek Insight – a small, discreet pump with pre-filled insulin cartridge (Roche Diagnostics).



## Conclusions

Two pivotal trials will be underway in 2018 with the objective to achieve 1) FDA regulatory approval of the G6-Control IQ system (Tandem) in the US and 2) CE mark for the Eversense-inControl-Insight system in Europe. These studies share the same control algorithm which makes possible the post-hoc comparison of the effectiveness on embedded closed-loop control (Control-IQ) vs. mobile closed-loop (inControl).

## IDCL Study Group

- **University of Virginia:** S.Brown, S.Anderson, B.Kovatchev
- **Profil:** J.H.DeVries
- **Barbara Davis Center:** P.Wadwa, G.Forlenza
- **Stanford University:** B.Buckingham
- **Joslin Diabetes Center, Harvard University:** L.Laffel, E.Isganaitis, E.Dassau, F.Doyle
- **Mount Sinai Medical Center:** C.Levy, D.Lam
- **Sansum Diabetes Research Institute:** J.Pinsker
- **Mayo Clinic, Rochester:** Y.Kudva
- **CHRU Montpellier:** E.Renard
- **University of Padova:** C.Cobelli, D.Bruttomesso, S.Del Favero
- **JAEB Center for Health Research:** J.Lum, D.Raghinaru

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