

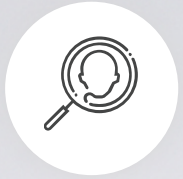
# **ONLINE DIABETES SUPPORT**

**ROBERT H. SLOVER, MD**

**EPIC CONFERENCE**

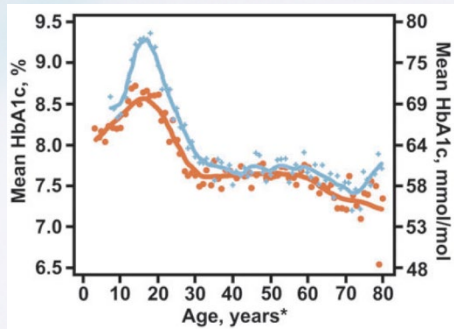
**MAY 22, 2021**

# Managing Diabetes is a Challenge for Persons with Diabetes (Families), Providers, and Health Systems



## The Data Paradox

The amount of clinical data (glucose, insulin, and more) available per each person increased dramatically due to new technologies



Foster et al. *DTT*:22, 2019



## Imbalance and complications

This caused high complexity and uncertainty when transforming this vast amount of data into treatment decisions. Thus, still a majority of the patients are not meeting the ADA glucose target.

60% of the expenditures are on complications



## Workforce shortage

In addition, 46,000 persons (PWD) with diabetes for every endocrinologist in the USA.

More than 60% of PWD get their Insulin treatment from GP and not from endocrinologist



## A burden on the system

6-month wait times for an appointment

**Diabetes: a 'ticking time bomb' for the NHS**

Lack of specialist support and rising numbers of people living with the condition will create huge complications, say experts

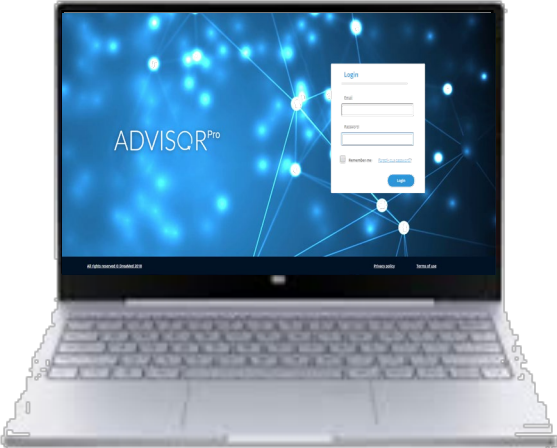
**The Guardian**  
Wed 24 Oct 2018



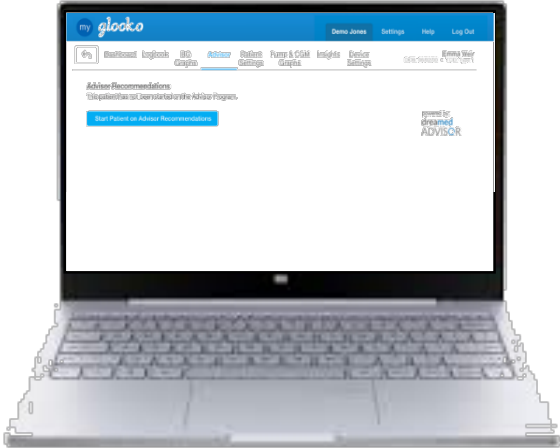


# How DreaMed Advisor™ Pro Works

1 Patient downloads data, data is sent to the diabetes management platform



Standalone with Advisor Report



Advisor Report Integrated into

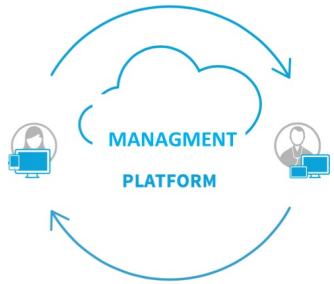
TIDEPOOL

glooko



# How DreaMed Advisor™ Pro Works

2

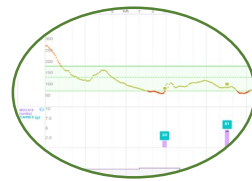
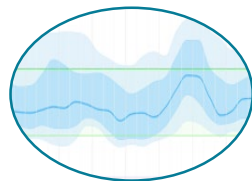


DreaMed Advisor pulls data



3

Process & Analyzes Data Detecting



**Glucose Patterns    Insulin Dosing Events**

4

Aggregate all recommendations into one advice and provide:

**Recommendations on how to change the pump settings: Basal Rate, Carbohydrate Ratio, Correction Factor**

**Discussion notes on behavioral issues related to insulin dosing**



# How DreaMed Advisor™ Pro Works

## 5 Advisor Recommendations are Presented to the HCP

Insulin Pump  
Setting  
Recommendations

Personalized  
Diabetes  
Management Tips

ADVISOR Pro Patients Help Dr. Smith Richard

Patients > Jenny Bell > Recommendations List > Recommendation - 01/28/2019

JENNY BELL 01/18/2018 - 02/08/2018

CURRENT ADVISOR RECOMMENDATION [Advisor help](#)

Basal Rate — 2 Carb Ratio — 3 Correction Factor [Prev](#) [Next](#)

CARB RATIO - CURRENT

Time	Carb ratio (g/U)
12:00 am	40
07:00 am	25
09:00 pm	40

RECOMMENDED CARB RATIO [Edit](#)

Time	Carb ratio (g/U)
12:00 am	32
07:00 am	24
11:00 am	18
03:00 pm	22
09:00 pm	40

Updated values in bold

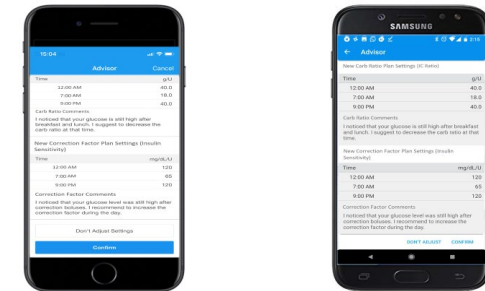
[View Active Insulin Time](#) [View BG Target](#)

Comments

- When you have high episode in the evening, remember to use the bolus calculator to give a correction bolus.
- You are over treating your lows. Eat moderately when treating your lows.
- I noticed that many of your lows come after a manual bolus. Using your bolus calculator may help you



## 6 HCP share results



# Advisor™ Pro Clinical Experience

Oct-Dec  
2016

## Pilot 1 RCT, 6 weeks

Presented at ATTD, Paris, Feb 2017

 N=15  
Patients



vs.

ADVISOR<sup>Pro</sup>

Jan - May  
2017

## Pilot 2 RCT, 3 months

Presented at ATTD, Vienna, Feb 2018

 N=13  
Patients



vs.

ADVISOR<sup>Pro</sup>

Feb - Nov  
2017

## Expert Survey Study

*Nimri R et al, Diabetes Obes Metab. June 8, 2018*

 N=15  
Patients



N=26  
Experts



vs.



vs.

ADVISOR<sup>Pro</sup>

“Physicians provide **different insulin dose recommendations**

based on the same data sets.

The automated advice of the

DreaMed Advisor Pro **didn't**

**differ significantly** from the

advice given by the physicians

in the direction or magnitude

of the insulin dosing.”

ADVISOR<sup>Pro</sup>



# Insulin dose optimization using an automated artificial intelligence-based decision support system in youths with type 1 diabetes

Revital Nimri 1, Tadej Battelino 2, Lori M. Laffel<sup>3</sup>, Robert H. Slover<sup>4</sup>, Desmond Schatz<sup>5</sup>, Stuart A. Weinzimer<sup>6</sup>, Klemen Dovc 2, Thomas Danne<sup>7</sup>, Moshe Phillip 1,8 ✉ and NextDREAM Consortium\*

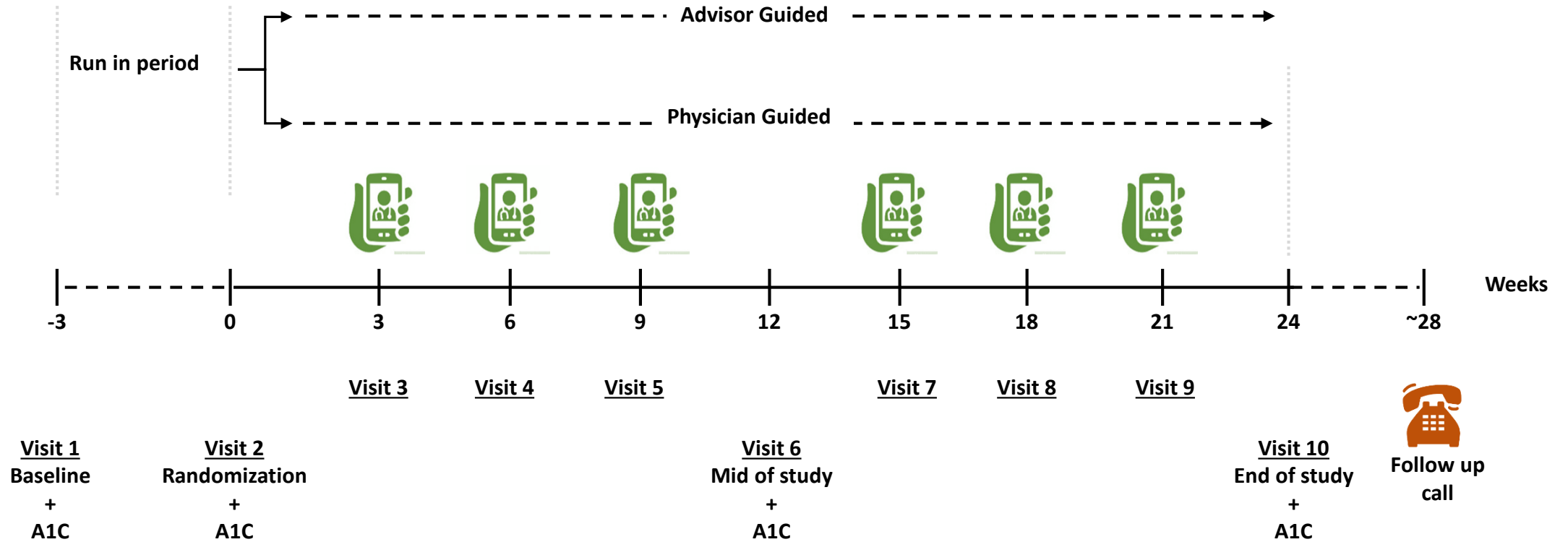
# The Advice4U Study: Hypothesis /Objective



Frequent optimization of insulin pump therapy based on continuous glucose monitoring readings using the **Advisor would result in statistically non-inferior glycemic control compared with dose adjustments done by physicians** from specialized academic diabetes centers



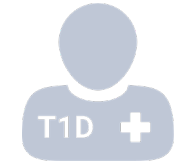
# The Advice4U Study: Design





# The Advice4U Study: Population

## Key Inclusion Criteria



**Age**  
10-21y

**HbA1c**  
7-10%  
53-86 mmol/mol



For at least 4 months

**Willingness to use CGM**

## Key Exclusion Criteria



Within the month  
prior to  
enrollment



Within 6  
months prior to  
enrollment





Any medical condition that  
would negatively impact  
participation in the study





# The Advice4U Study: Randomization

Participants were randomized within Age and A1c as follows:

			mmol/mol
	Age 10-14yr	A1c 7 to 8%	(53-<64)
	Age 15-18yr	& A1c 8.1 to 9%	(64-<75)
	Age 19-21yr	A1c 9.1 to 10%	(75-86)



ADVISOR<sup>Pro</sup>







# The Advice4U Study: Endpoints

## Primary Endpoints

- Efficacy            % of readings within range 70-180 mg/dL (3.9-10 mmol/l)
- Safety             % of readings below 54 mg/dL (3 mmol/l)

## Secondary Endpoints

HbA1c change from baseline to end of study & Adverse Events


## Exploratory Endpoints

CGM metrics & Insulin Doses

Device Satisfaction            -            Healthcare Professional Post-Intervention Survey

---

# The Advice4U Study Results: Participant's Baseline Characteristics

Characteristic*	ADVISOR Arm (n=60)	 Physician Arm (n=62)
Gender (F/M)	32/28	32/30
Age (yr)	15.5 ± 3.0	15.8 ± 3.0
Weight (Kg)	61.7 ± 13.8	63.4 ± 13.1
Height (cm)	164.3 ± 11.0	167.0 ± 11.0
BMI ‡	22.6 ± 3.4	22.5 ± 3.1
BMI-SDS§	0.5 ± 0.9	0.7 ± 0.7
Glycated hemoglobin (%)	8.4 ± 0.8	8.4 ± 0.8
Glycated hemoglobin (mmol/mol)	68.4 ± 8.5	68.0 ± 8.8
Total Daily Insulin (U/kg/day) †	0.9 ± 0.2	0.8 ± 0.2
Diabetes duration (yr)	6.6 ± 4.1	7.7 ± 4.2
Pump-therapy duration (yr)	4.9 ± 3.8	5.4 ± 3.7
Sensor use duration (yr)	1.9 ± 1.9	2.6 ± 2.5

‡ The body-mass index

§ The BMI-SDS was calc

† Baseline insulin infor

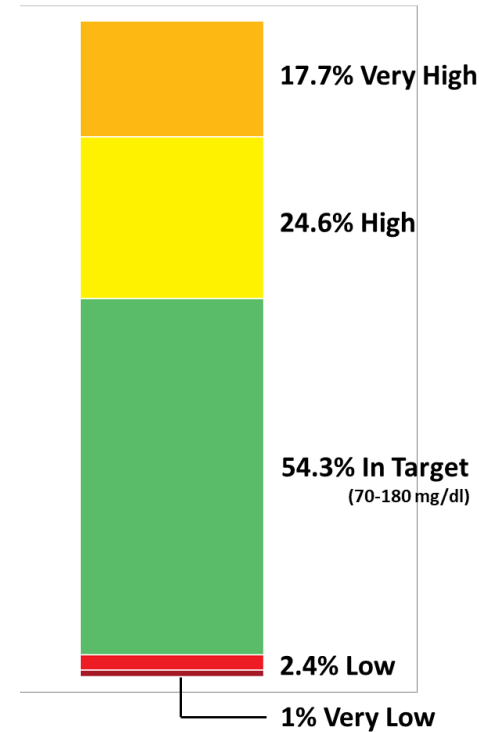
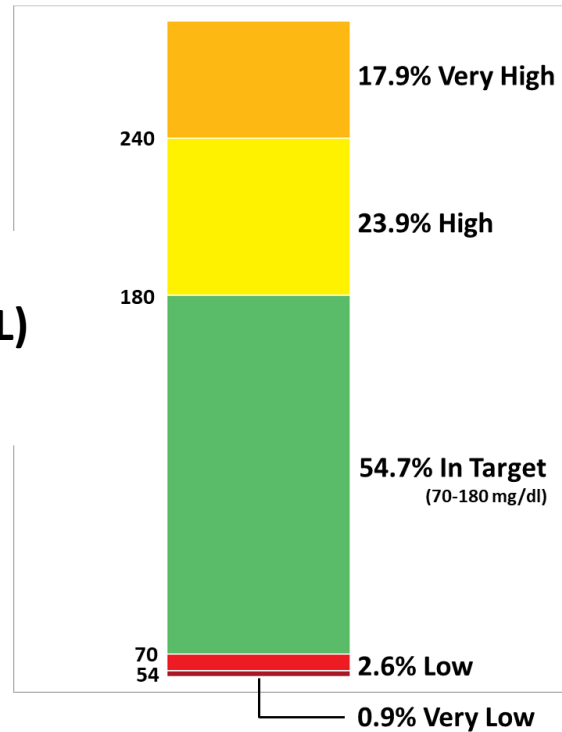
# The Advice4U Per-Protocol Study Results: Time within Range



Arm (N=30)

ADVISOR Arm (N=30)

Time in Ranges (mg/dL)



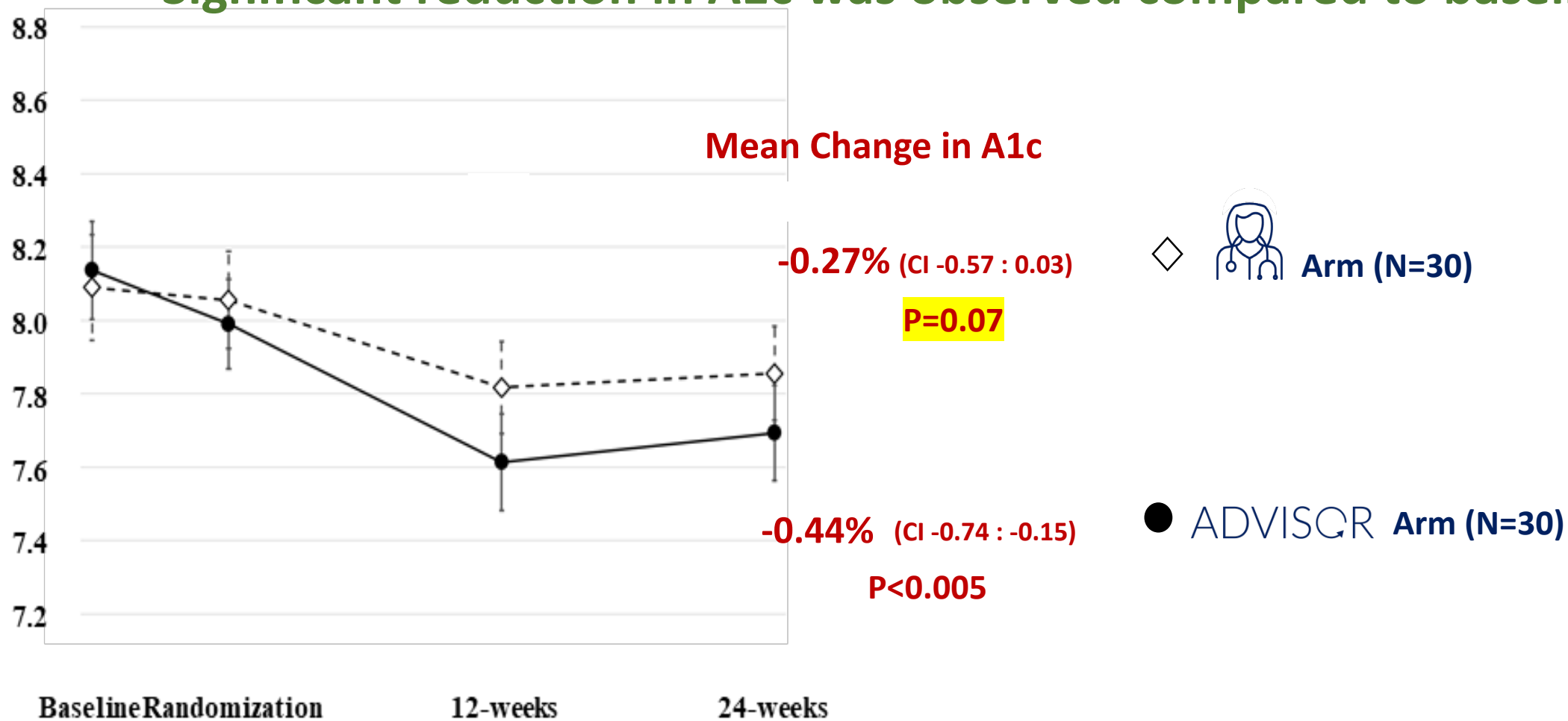
**Primary Outcome:** For non-inferiority comparison of time within 70-180 mg/dl (margin 7.5%)  $P < 0.0001$  (ANCOVA model)

**Exploratory Outcomes:** Comparison for other metrics:  $P = N.S$  (a two-sided t-test)



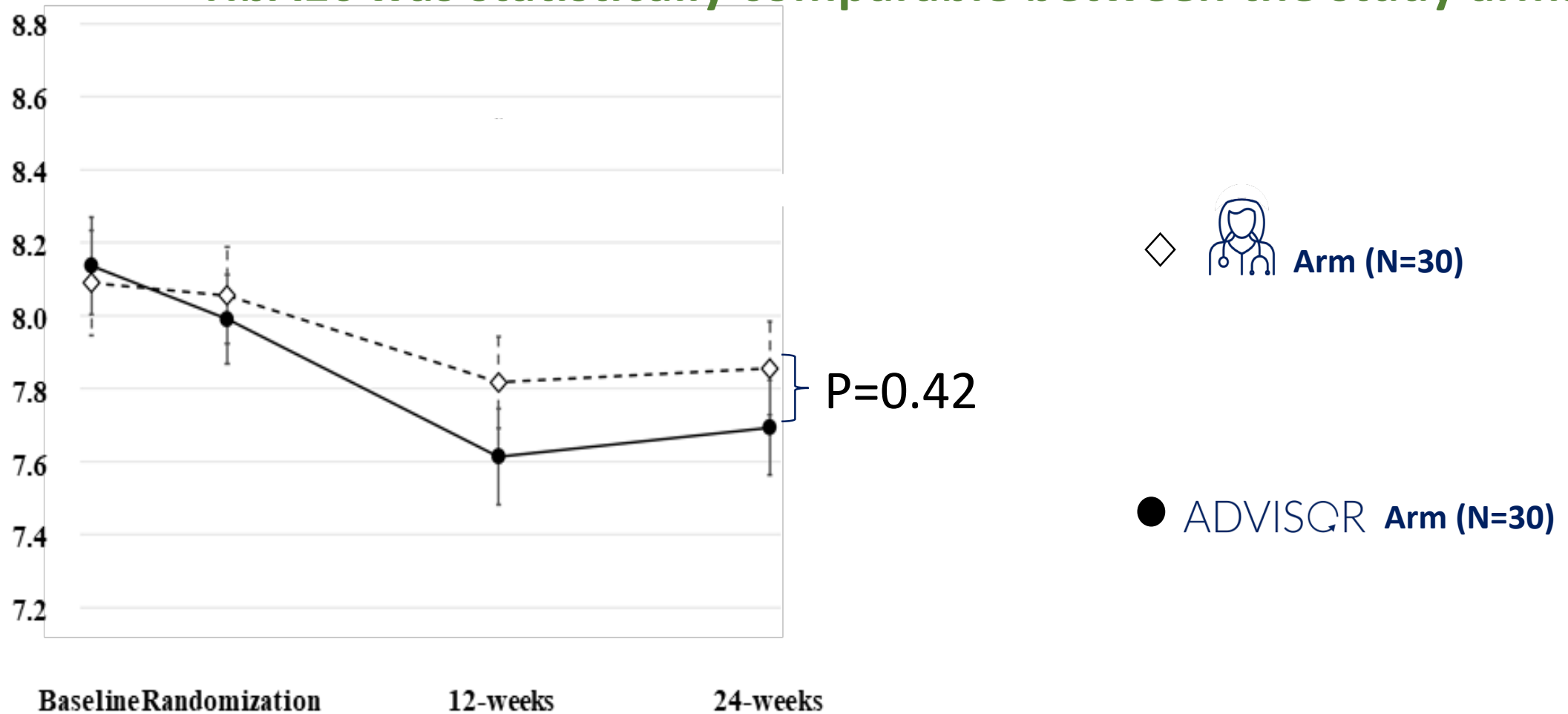
# The Advice4U Per-Protocol Study Results: Secondary Outcome - HbA1c

Significant reduction in A1c was observed compared to baseline



# The Advice4U Per-Protocol Study Results: Secondary Outcome - HbA1c

**HbA1c was statistically comparable between the study arms**






# The Advice4U Study Results: Exploratory Outcomes

ADVISQR




Outcome	ADVISQR Arm (n=30)	 Physician Arm (n=30)	P value
Mean total daily insulin dose (U)	60.5 ± 22.1	54.4 ± 10	0.185
Basal insulin dose (U)	27 ± 12.4	25.2 ± 7.05	0.468
Bolus insulin dose (U)	33.5 ± 12.4	29.4 ± 6.95	0.143

No significant difference in the TDD between arms



# The Advice4U Study Results: Adverse Events

	ADVISOR Arm (n=60)	 Physician Arm (n=62)
No. of severe hypoglycemic events	0	2
No. of severe hyperglycemic events (DKA)	0	1
No. of severe AE unrelated to diabetes	2	1
Significant Hyperglycemia (pump occlusion)	2 (1)	8 (4)
Ketonuria	0	2
Significant hypoglycemia	3	2
Sensor related contact allergic	1	0
Insulin pump site infection	0	4
No. of AE not related to study intervention (sum)	44	55

AE – Adverse Events

Significant hypoglycemia/hyperglycemia

# Participants pair Example, Data From Advice4U Study

**P-007-011**

ADVISOR<sup>Pro</sup>

## DIABETES DIAGNOSIS

Gender:	Female
Age[yr]:	14
BMI [Kg/m <sup>2</sup> ]:	24.8
HT[cm]:	172
WT[kg]:	73.5
Diagnosis of T1D [yr]:	5.2

## INSULIN THERAPY

Insulin pump [yr]:	4.4
TDD[U]:	70.5
U/kg/day:	0.96
# Bolus/day:	12.3

**P-007-001**



## DIABETES DIAGNOSIS

Gender:	Female
Age[yr]:	14
BMI [Kg/m <sup>2</sup> ]:	18.8
HT[cm]:	174
WT[kg]:	57
Diagnosis of T1D [yr]:	5.1

## INSULIN THERAPY

Insulin pump [yr]:	3.2
TDD[U]:	58.7
U/kg/day:	1.03
# Bolus/day:	4

# Participants pair Example Data: Compare Glucose Control Over Time

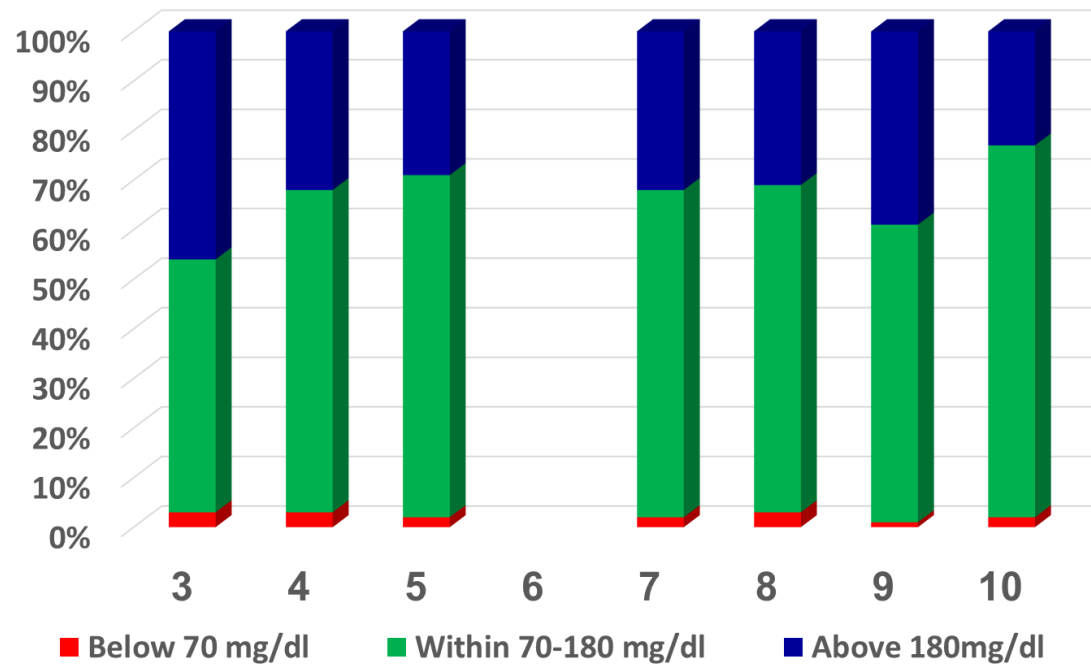
**P-007-011**

ADVISOR<sup>Pro</sup>

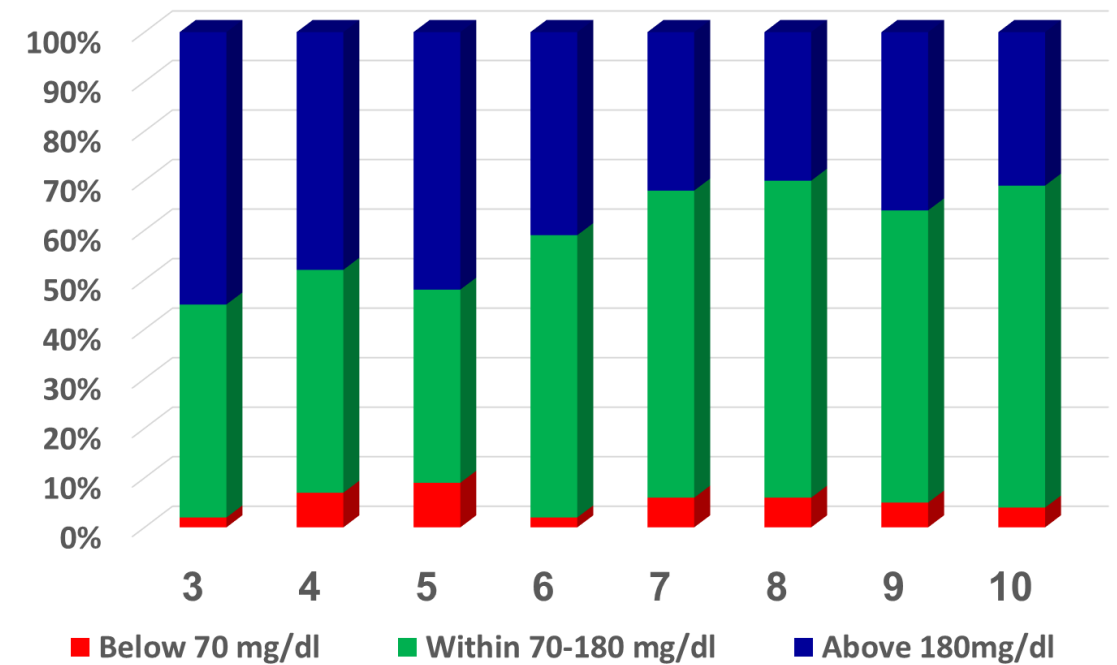


**P-007-001**

Percentage Glucose Readings in Range per Visit #



Percentage Glucose Readings in Range per Visit #



# Participants pair Example Data: Compare Glucose Control Over Time

**P-007-011**

ADVISOR<sup>Pro</sup>

Data Point	HbA1c [%]
Baseline	8.1
Randomization	7.5
12-Weeks	6.4
24-Weeks	6.5

**P-007-001**



Data Point	HbA1c [%]
Baseline	8.1
Randomization	7.8
12-Weeks	7.3
24-Weeks	6.9



# The Advice4U Study Results: The Healthcare Professional Post-Intervention Survey

The Healthcare Professional Post-Intervention Survey, is a 50-item questionnaire

Completed by physicians randomized to Advisor arm at 12-weeks and 24-weeks

Section A	Section B	Section C	Section D
16 statements about <b>general experience</b> with Advisor	12 statements about <b>experience with Advisor recommendations</b>	12 open questions about benefits and updates	10 Yes/No questions about integrating Advisor into routine daily practice
Answers in scale from “Strongly Disagree”(=1) to “Strongly Agree” (=5)			

Developed by **Professor Katharine Barnard**, Bournemouth University, Bournemouth, UK BHR Ltd., Portsmouth, UK with contribution from Lorri Laffel & Revital Nimri

---

# The Advice4U Study Key Results: The HCP Post-Intervention Survey

Answers in scale from “Strongly Disagree”(=1) to “Strongly Agree” (=5)

Section A: General experience with Advisor		
Statement (results presented as average)	12-weeks (n=8/13)	24-weeks (n=13/13)
Using the Advisor Pro was <b>intuitive and simple</b>	<b>4.8</b>	<b>4.8</b>
I found the Advisor Pro to be <b>reliable</b>	<b>4.1</b>	<b>4.5</b>
I believe the Advisor Pro was <b>safe</b>	<b>4.5</b>	<b>4.4</b>
The Advisor Pro <b>saved me time</b>	<b>4.3</b>	<b>4.3</b>
The Advisor Pro was <b>useful</b> in helping me communicate insulin dosing decisions to my patients	<b>4.6</b>	<b>4.5</b>
The Advisor Pro was sufficiently dynamic to provide <b>accurate advice in different situations</b>	<b>4.3</b>	<b>4.2</b>
The Advisor Pro was <b>similar to therapy adjustments I would have done</b> clinically	<b>3.3</b>	<b>3.5</b>



# In Summary

- DreaMed Advisor Pro, provided similar level of glycemic outcomes as physicians from academic centers experienced with technology use
- AI based decision support system can provide safe and efficient automated insulin dose adjustments and management insights tips
- 11/13 of the physicians participated in the Advisor Arm stated they would be interested to continue to use Advisor Pro in their clinic



Get Advice from  
anywhere, anytime



Whenever a  
change is needed



Too far and busy  
to see HCP



In between visits  
Titration



Lack access to  
medical services



Telemedicine



Clinical Visit