Insulet Corporation: Omnipod® 5 Clinical Results

PRESENTERS
Dr. Trang Ly MBBS FRACP PhD
SVP, Medical Director, Insulet Corporation

Dr. Bruce Bode MD FACE
CEO and President, Atlanta Diabetes Associates
Clinical Associate Professor, Emory University

MODERATOR
Deborah Gordon
VP, Investor Relations, Insulet Corporation

Q&A PANEL
Shacey Petrovic
President & CEO, Insulet Corporation

Eric Benjamin
SVP, Innovation and Strategy, Insulet Corporation

Insulet Investor Webcast
March 20, 2021, 12:30PM EST

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

omnipod simplify life

Forward Looking Statement

This presentation may contain forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs or strategies regarding the future. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission in February 2021 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

Agenda

- Omnipod 5 product overview
- Omnipod 5 pivotal study results presented at ENDO 2021
- Discussion with Dr. Bruce Bode
- Q&A

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Kate

Kate, age 6
Omnipod since 2014

Kate

Kate, age 6
Omnipod since 2014

Kate, age 13
Omnipod 5 pivotal study since 2019

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

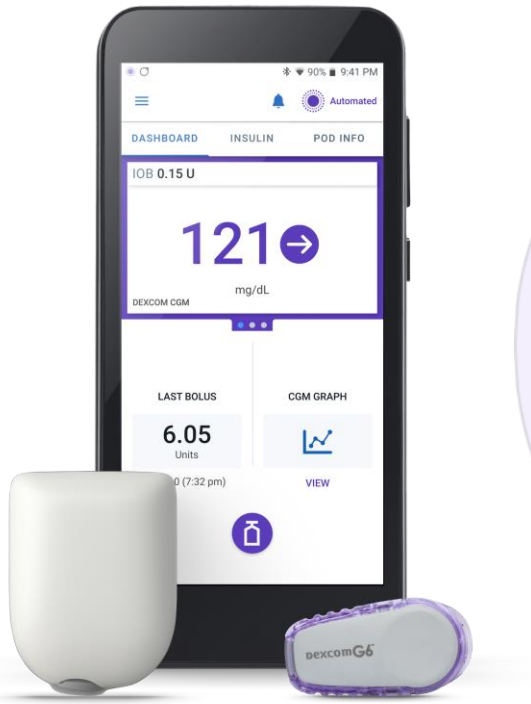
First and Only Wearable, Tubeless Solution
The future of insulin delivery

omnipod 5

Fully On-body Automated Insulin Delivery

- **Wearable Pod** communicates directly with **Dexcom G6** Continuous Glucose Monitoring System
- **Personalized, adaptive, treat to target algorithm** built into the Pod
- **Omnipod® 5 app** allows users to control the system from a compatible personal smartphone

Omnipod 5 App



Pod + Algorithm

dexcomG6®

Novel Features & Function

- Glucose targets from 110-150 mg/dL, adjustable by time of day
- **HypoProtect™** for times of reduced insulin needs
- **SmartBolus calculator** informed by Dexcom G6® CGM value and trend
- **Automatic** cannula insertion & priming

Illustrative purposes only. Final product may or may not be what is represented here.

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

omnipod simplify life

Omnipod 5 Use in Children and Adults with Type 1 Diabetes: Main Results from the 3-month Pivotal Study

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Study Objective

Evaluate the safety and effectiveness of the Omnipod 5 System in people with type 1 diabetes

- In adults and children aged 6-70 years
- With user-selected target glucose ranging from 110-150 mg/dL

Primary Outcomes

Primary effectiveness endpoints:

- Change in HbA1c
- Time in range (TIR) 70-180 mg/dL

Primary safety endpoints:

- Diabetic ketoacidosis
- Severe hypoglycemia

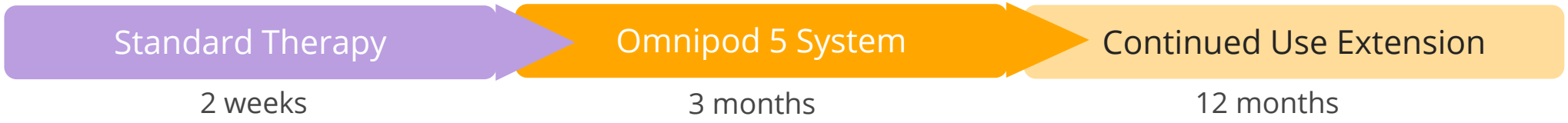
Methods

Study Design

- 241 participants enrolled at 17 institutions across the US
- Multicenter single-arm outpatient study:
  - 14-day standard therapy (ST) phase
  - 3-month automated insulin delivery (AID) phase
- Unrestricted eating and exercise throughout
  - Included missed meal bolus and moderate intensity exercise challenges

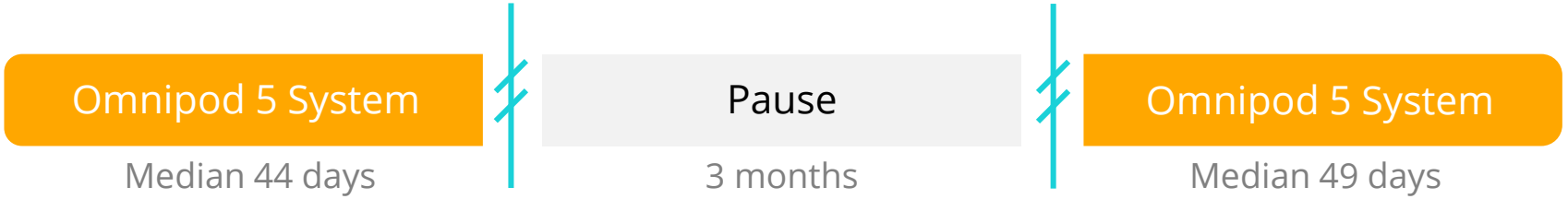
Inclusion Criteria

- Children: Age 6 to 13.9 years
- Adolescents and adults: Age 14 to 70 years
- All participants:
  - Type 1 diabetes for ≥6 months
  - HbA1c <10.0%
  - Any prior insulin therapy (CSII or MDI)



ClinicalTrials.gov Identifier: NCT04196140

Study Pause



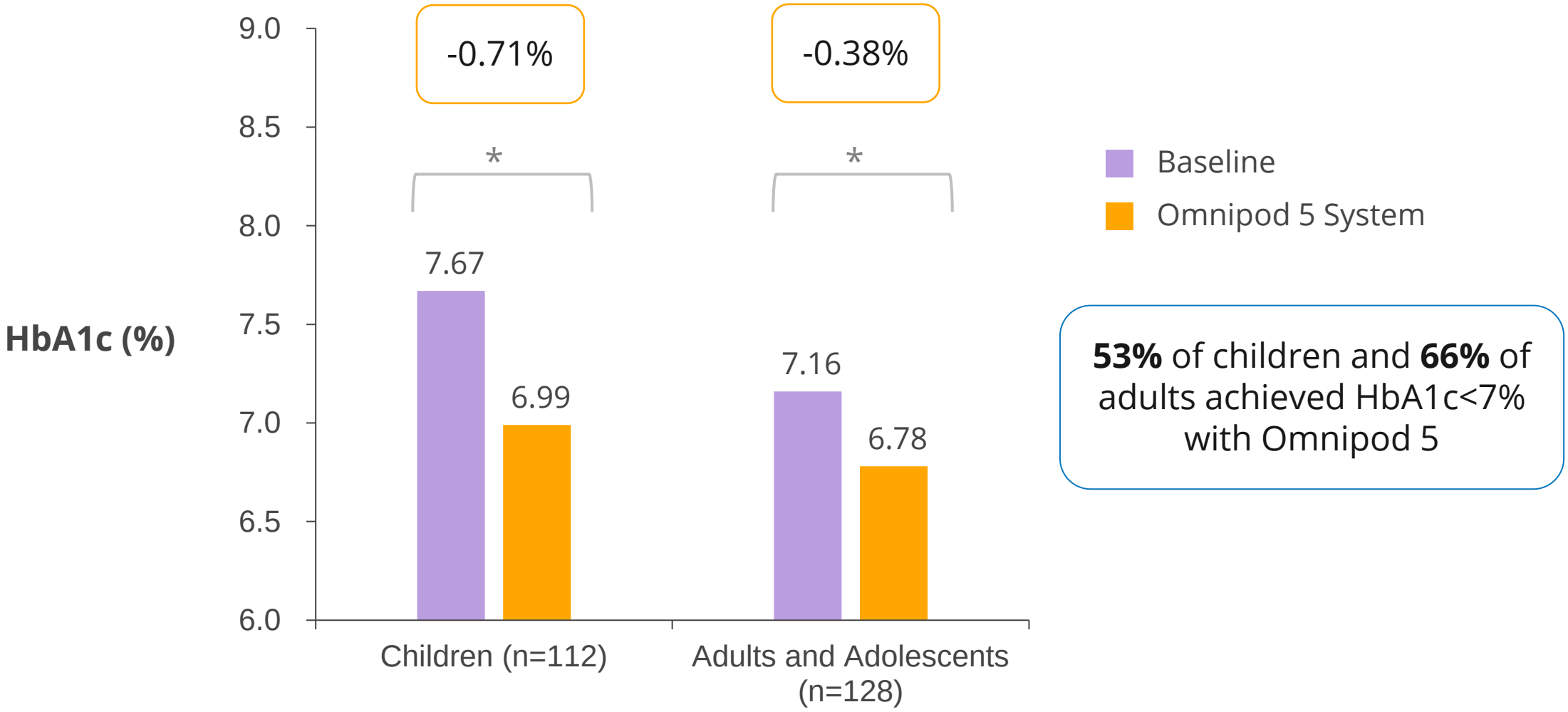
- Pause for 3 months due to software anomaly
- No adverse events occurred as a result of this issue
- During pause, participants could continue study system use without automated insulin delivery, or use another form of therapy
- 99% of participants resumed Omnipod 5 use after the study pause

Participant Characteristics

Characteristic	Children (N=112)	Adults (N=128)
Age, yr	10 ± 2	37 ± 14
Female, n (%)	60 (54)	78 (61)
Weight, kg	39 ± 13	79 ± 17
Diabetes duration, yr	5 ± 3	18 ± 12
HbA1c, %	7.7 ± 0.9	7.2 ± 0.9
Total daily insulin, U/kg	0.85 ± 0.24	0.61 ± 0.22
MDI users, n (%)	13 (11.6)	23 (18.0)

mean±SD [range] or n (%)

Primary Outcome: HbA1c after 3 Months of Omnipod 5 Use

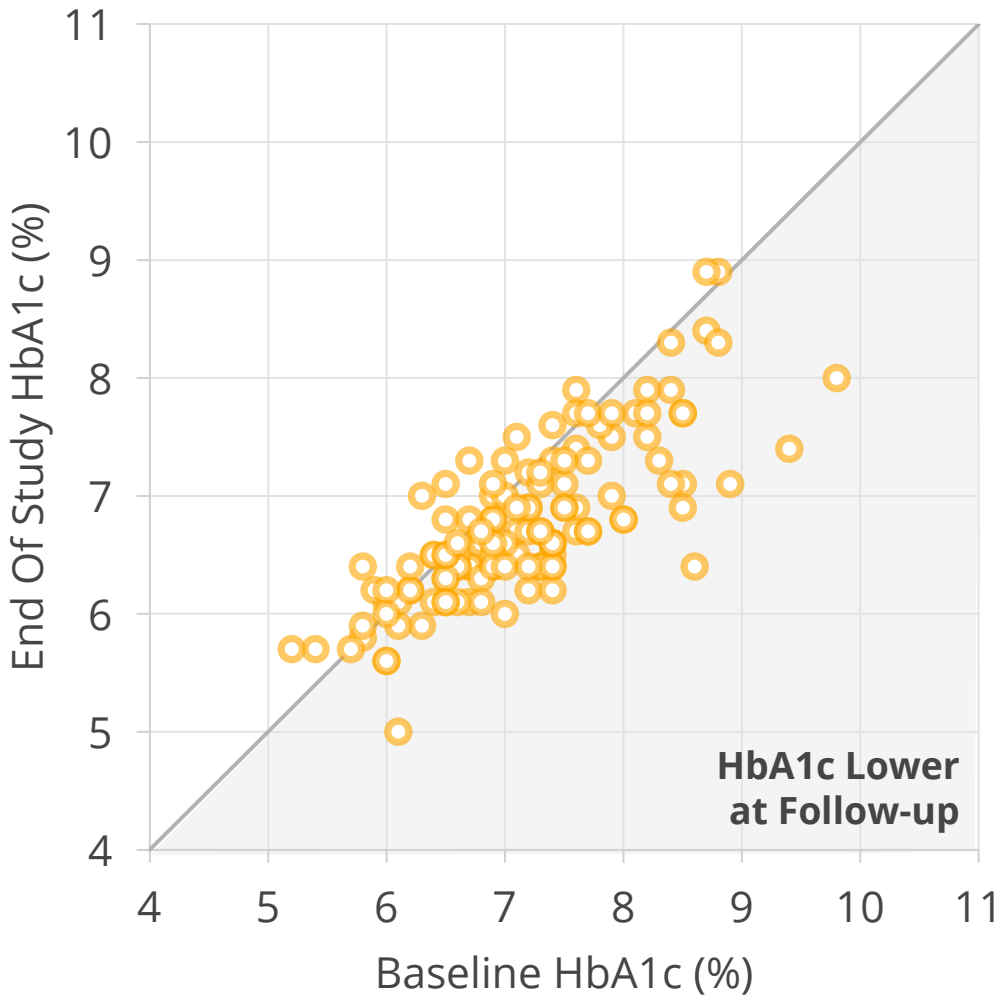


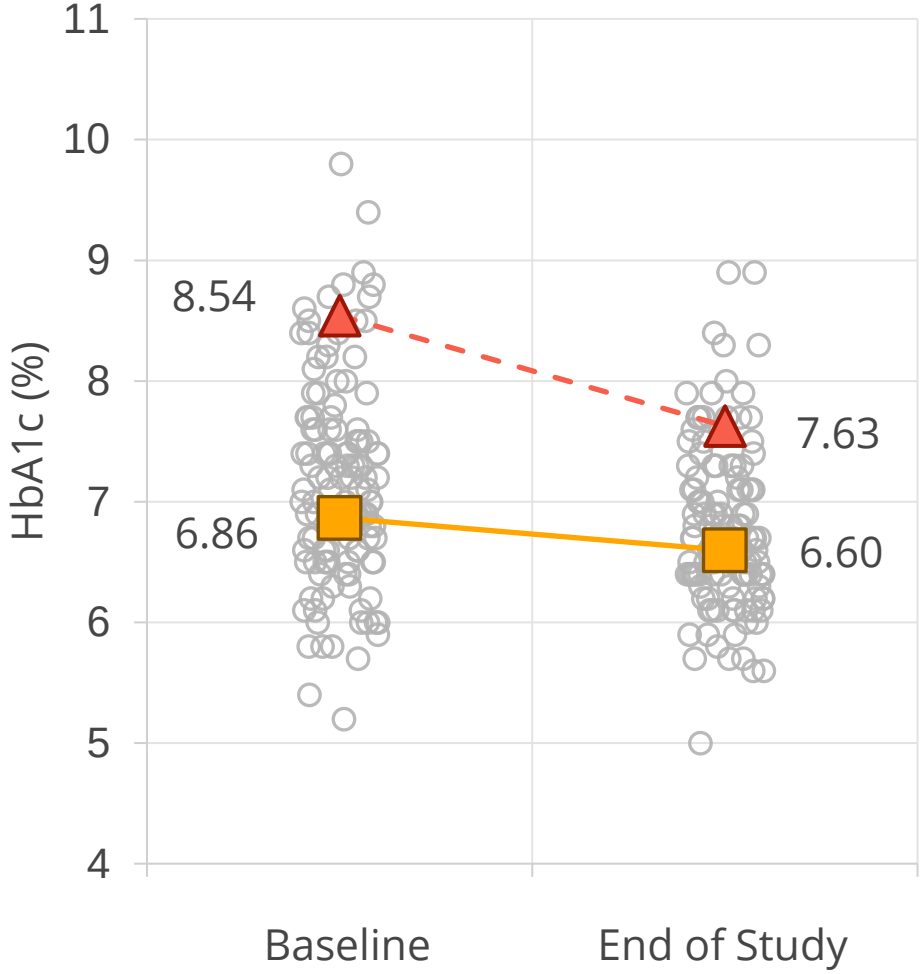
53% of children and **66%** of adults achieved HbA1c<7% with Omnipod 5

*p<0.05; data shown as mean, missing data at follow-up for n=4 in each age group

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Reduced HbA1c with Omnipod 5 System Adults





Baseline HbA1c ≥8%

Baseline HbA1c <8%

Individual Participant

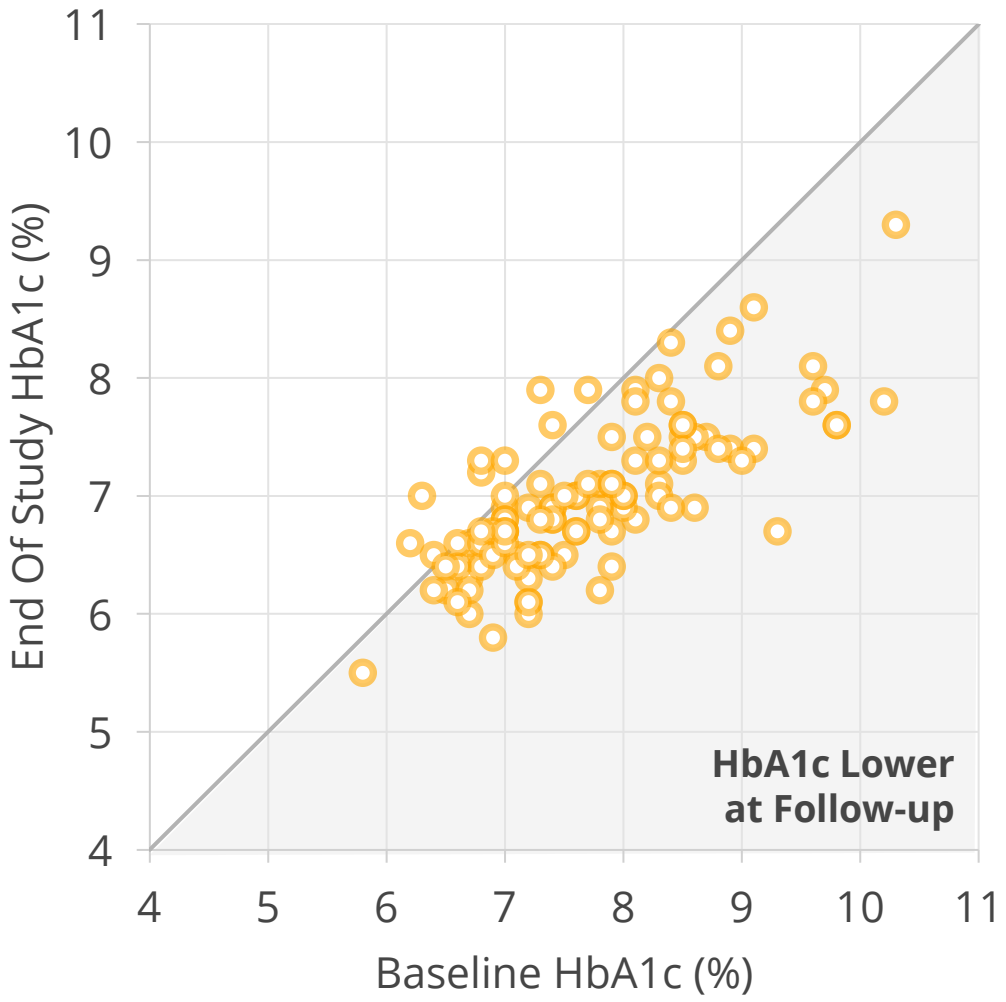
Baseline HbA1c ≥8%
N=22, Change = **-0.91***

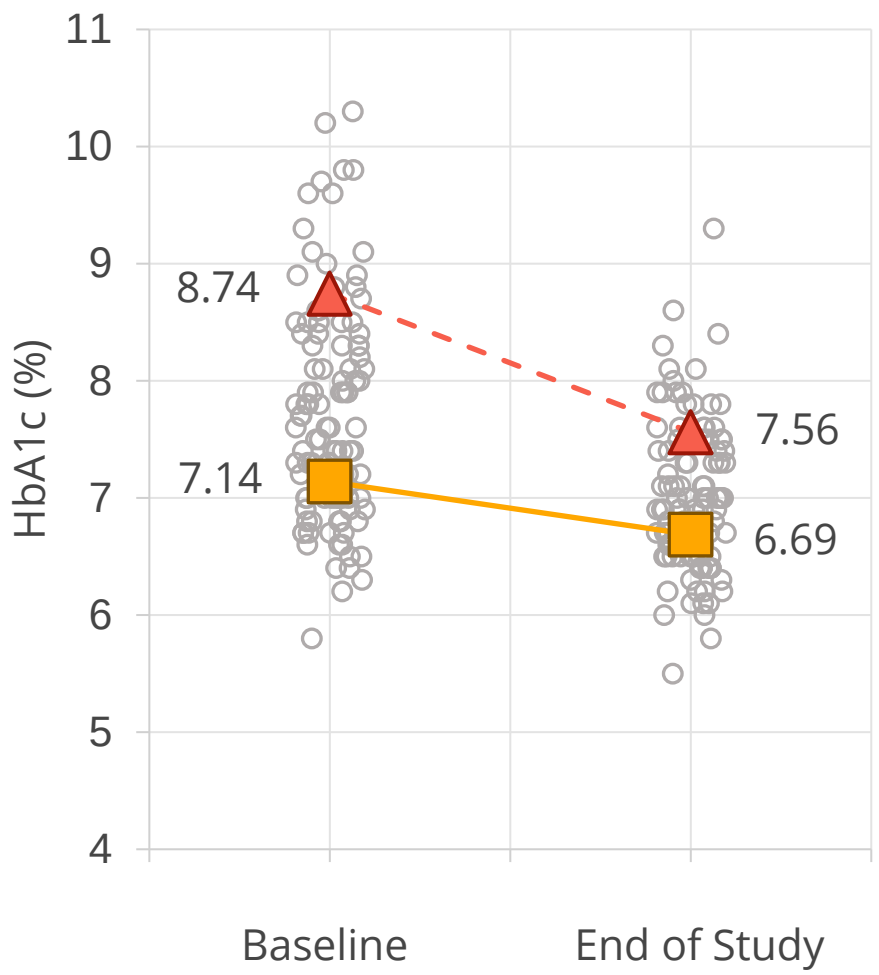
Baseline HbA1c <8%
N=102, Change = **-0.27***

*p<0.05; data shown as mean

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Reduced HbA1c with Omnipod 5 Children





Baseline HbA1c ≥8%

Baseline HbA1c <8%

Individual Participant

Baseline HbA1c ≥8%
N=38, Change = **-1.18***

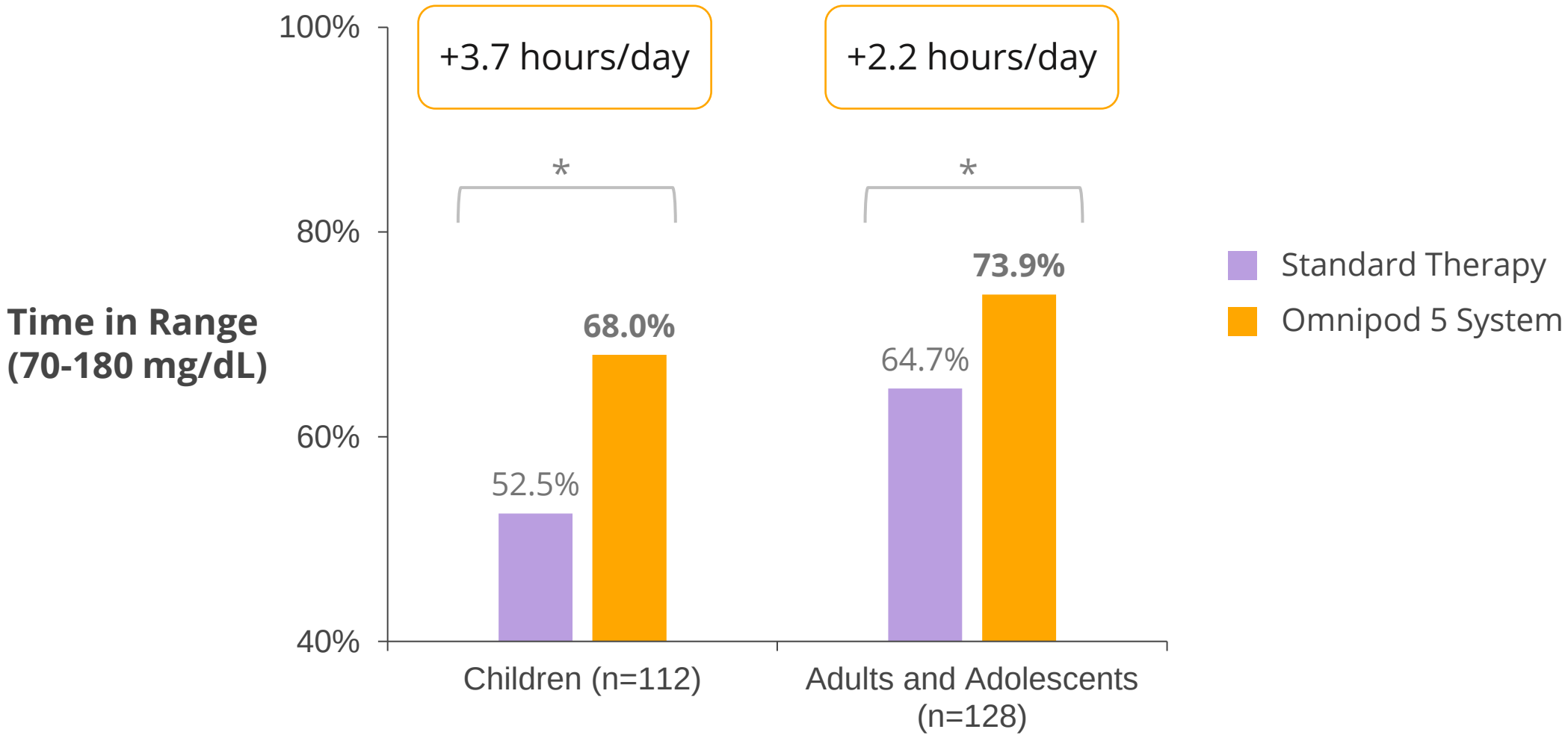
Baseline HbA1c <8%
N=70, Change = **-0.45***

*p<0.05; data shown as mean

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

INS-OHS-03-2021-00012 V1.0

Primary Outcome: Improved Time in Range with Omnipod 5

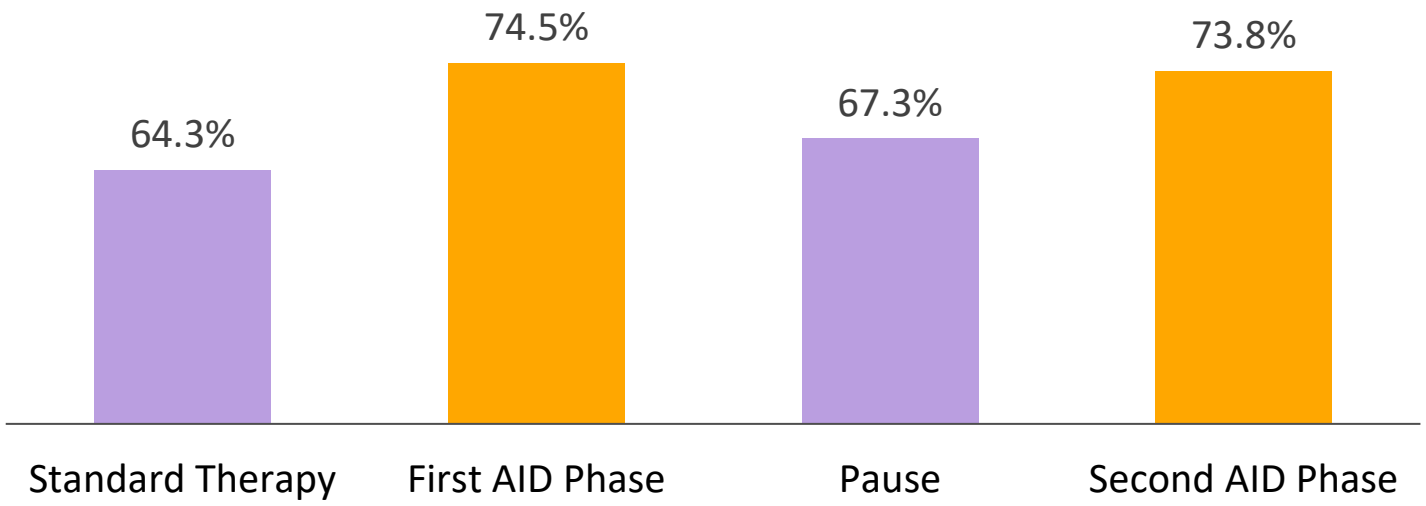


*p<0.05; data shown as mean

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

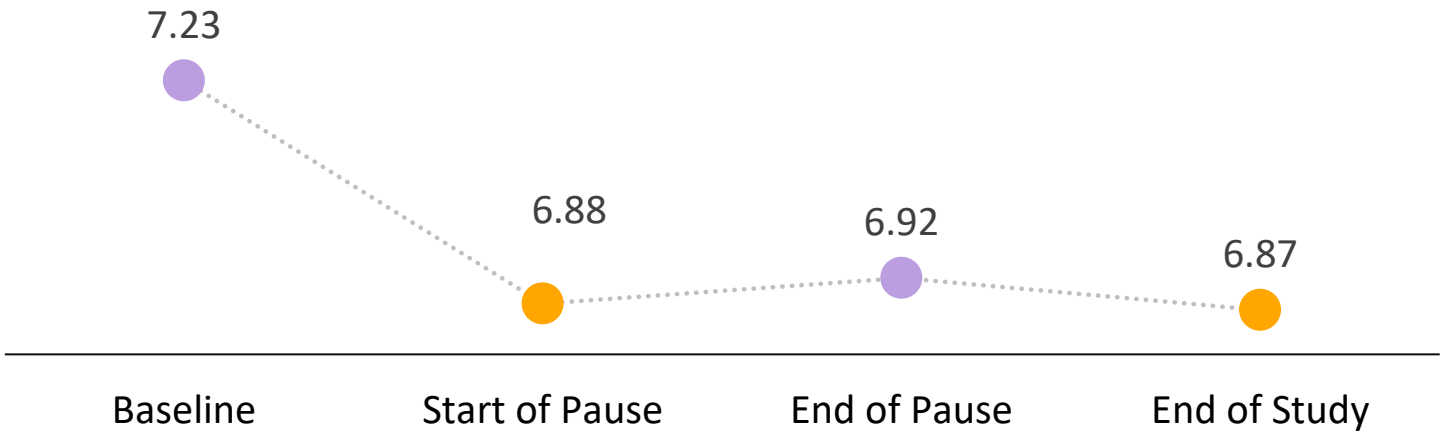
Study Pause Effect on Outcomes Adults

Time in Range (70-180 mg/dL)



For **n=115** participants with CGM data in all 4 phases

HbA1c (%)

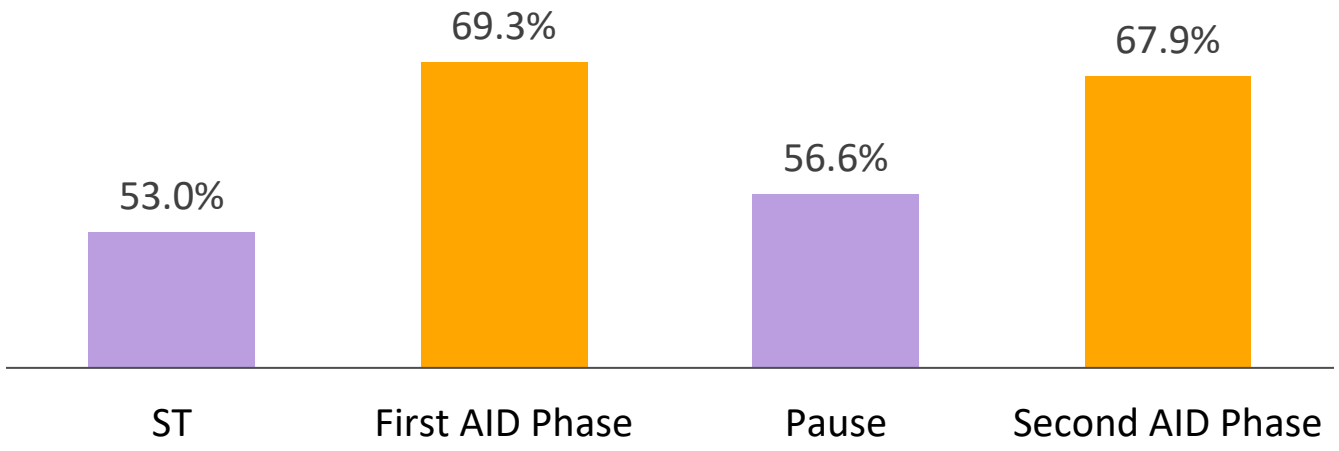


For **n=60** participants with HbA1c at all 4 time points

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

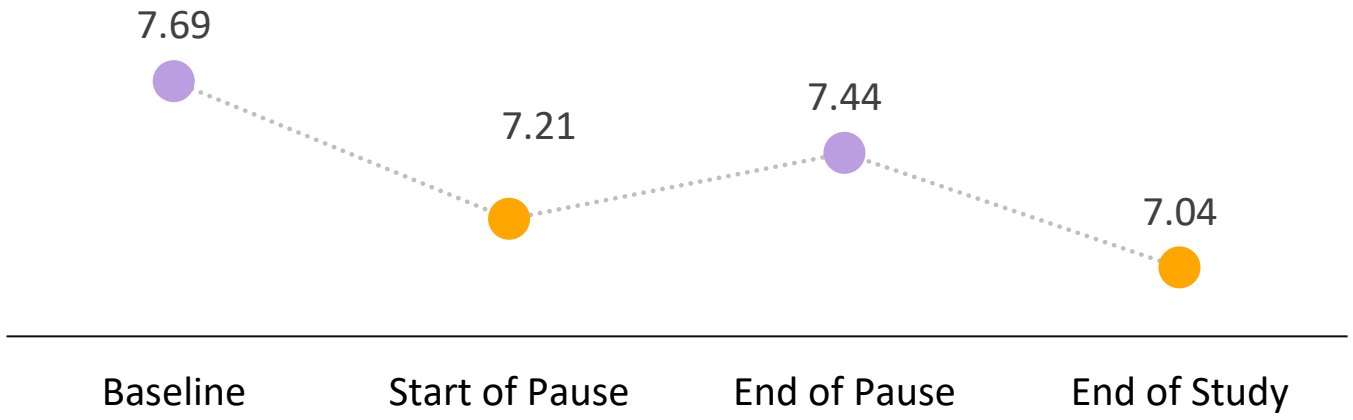
Study Pause Effect on Outcomes Children

Time in Range (70-180 mg/dL)



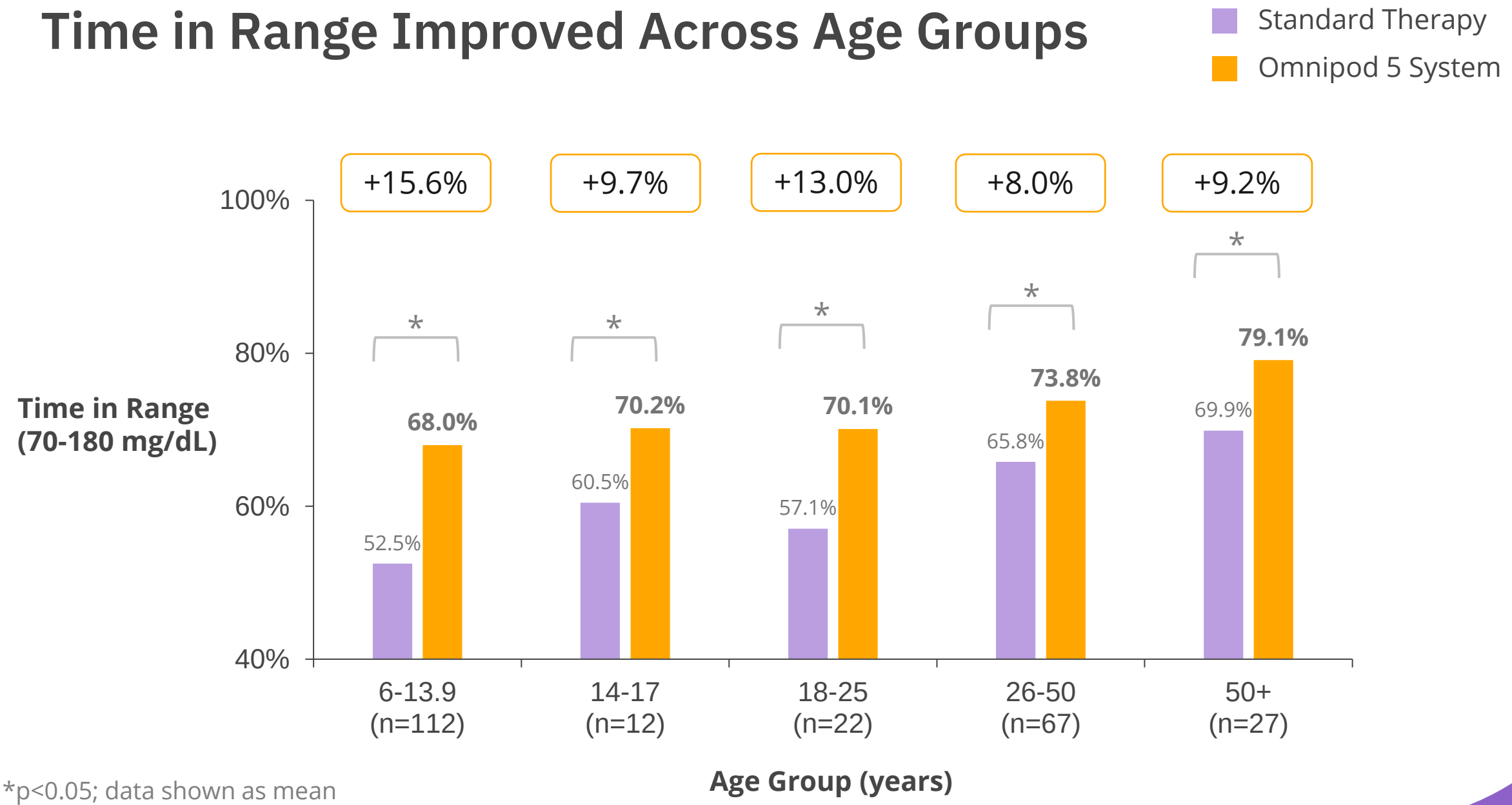
For **n=103** participants with CGM data in all 4 phases

HbA1c (%)



For **n=35** participants with HbA1c at all 4 time points

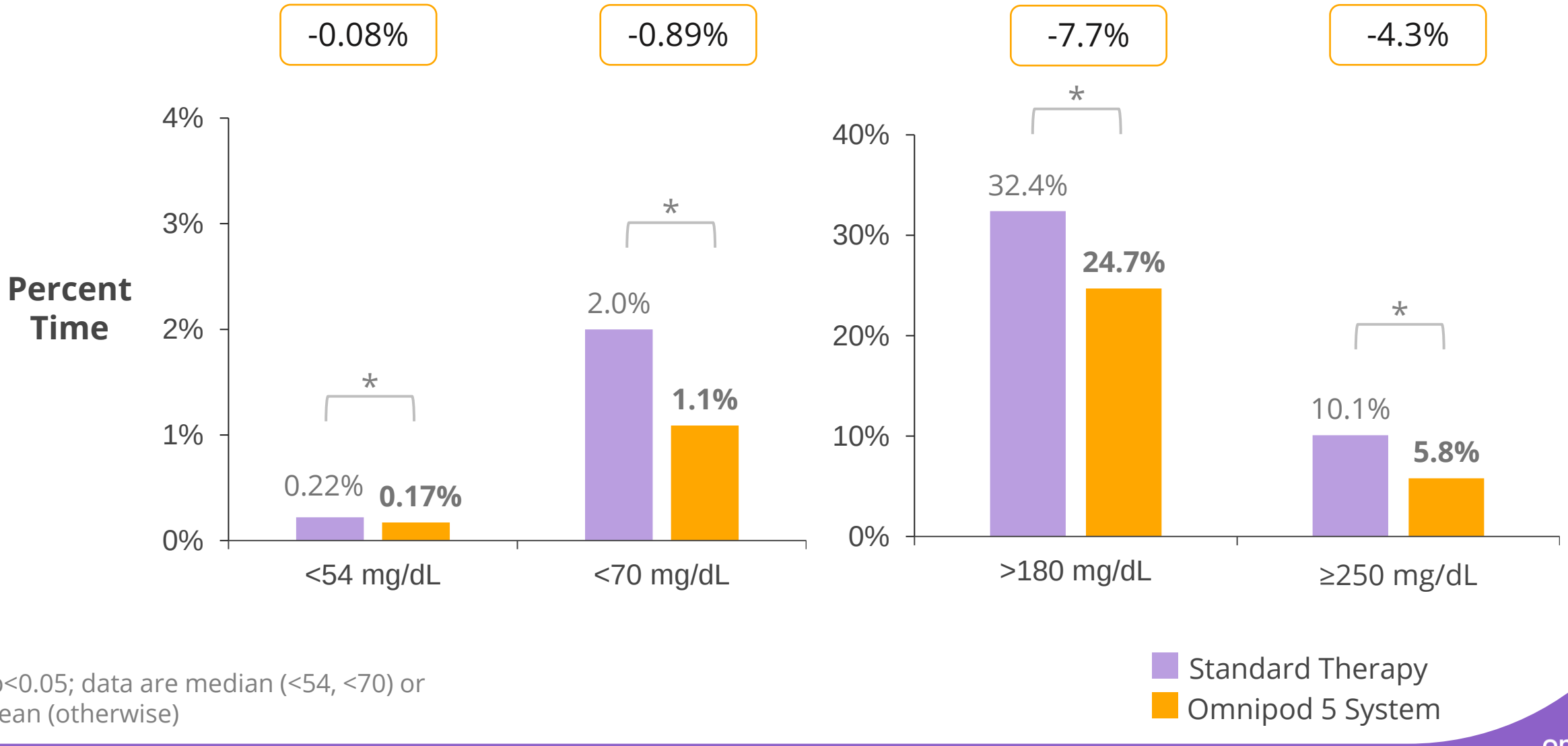
Time in Range Improved Across Age Groups



*p<0.05; data shown as mean

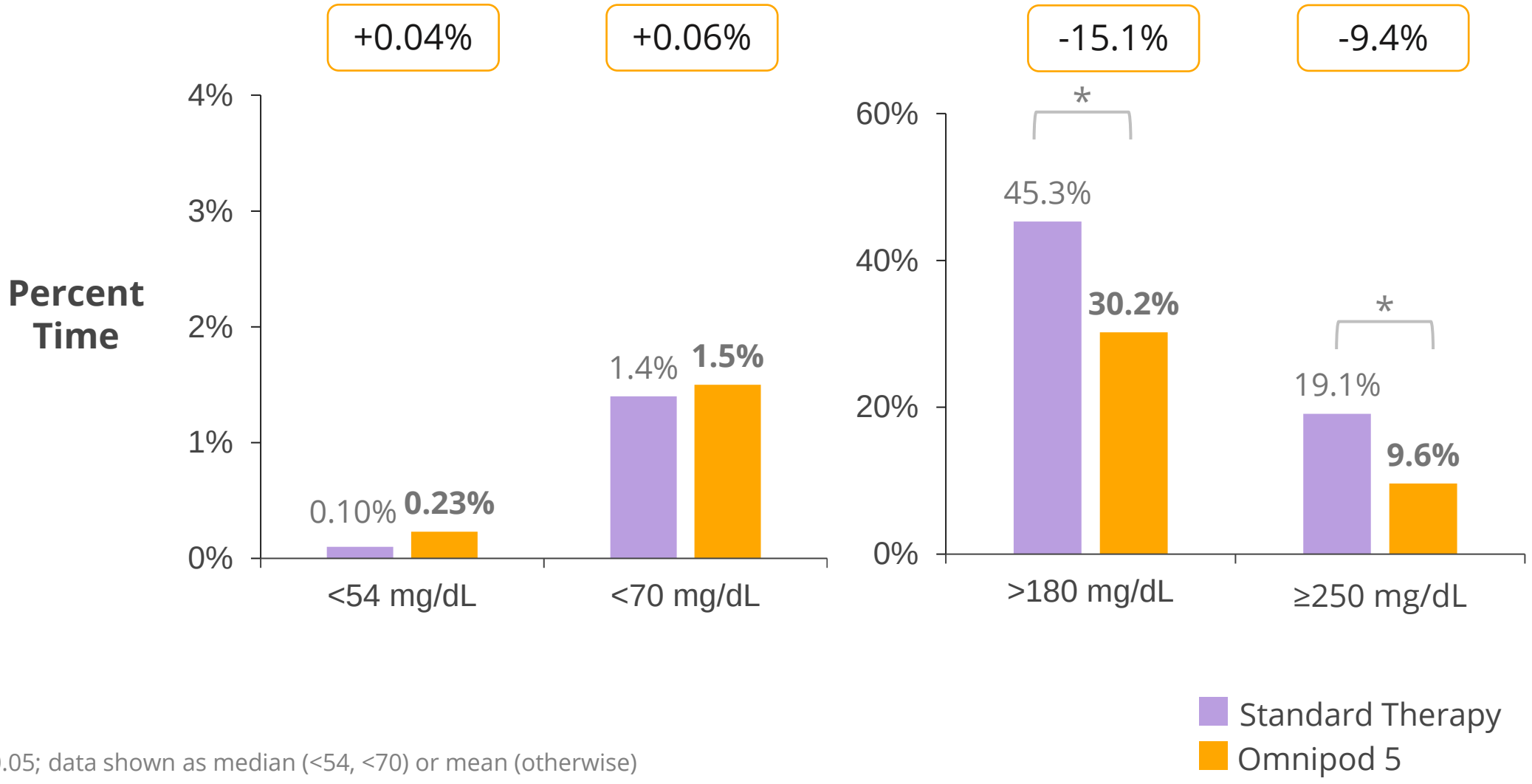
 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Reduced Time in Hypoglycemic and Hyperglycemic Ranges Adults



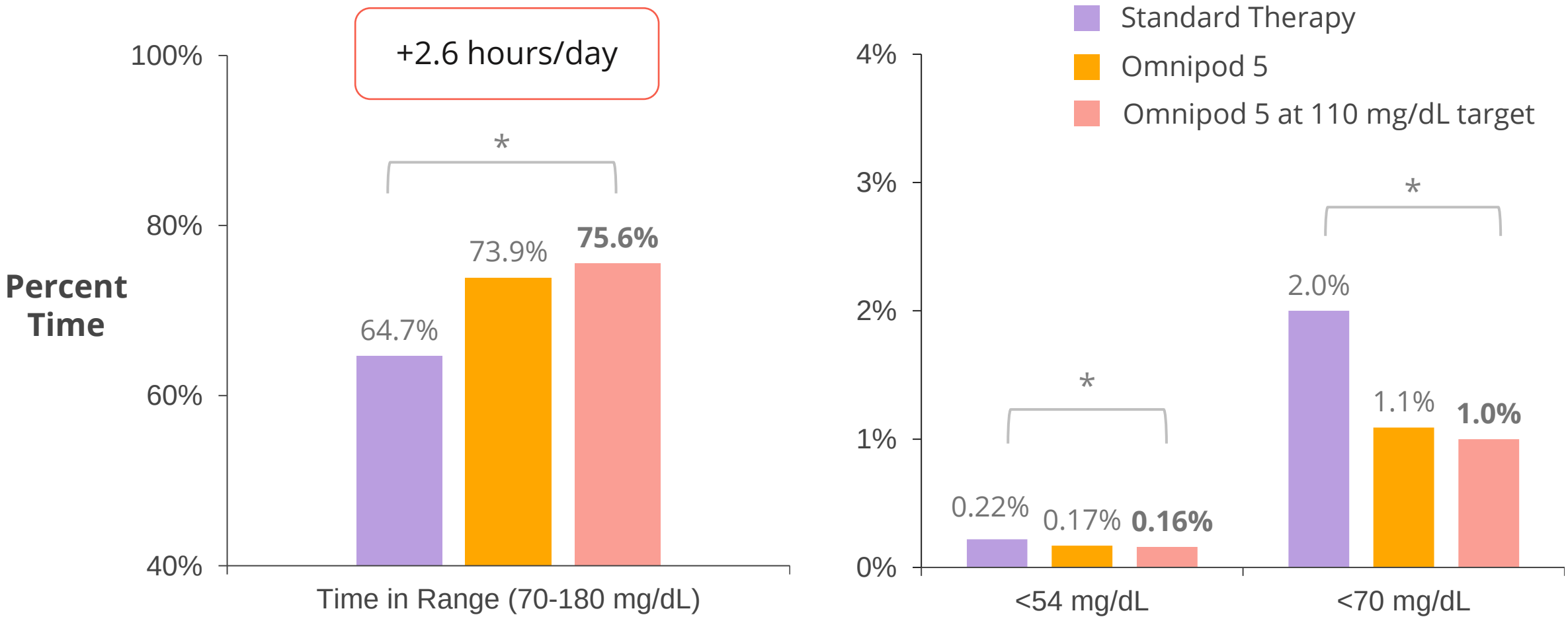
*p<0.05; data are median (<54, <70) or mean (otherwise)

Hypoglycemia Remained Low with Reduced Hyperglycemia Children



*p<0.05; data shown as median (<54, <70) or mean (otherwise)

Optimal Outcomes with Target Glucose of 110 mg/dL Adults



*AID significant compared to ST with p<0.05
n=121 at 110mg/dL target and n=128 for other conditions; 110 mg/dL used for 81% of cumulative study time.

Conclusions

- The Omnipod 5 system was safe and performed well in children and adults with type 1 diabetes when used for 3 months at home:
  - HbA1c was reduced to **6.78%** in adults and **6.99%** in children
  - In adults, TIR increased to **73.9%**, or to **75.6%** when using the 110mg/dL target
  - In children, TIR increased to **68.0%**
  - Time in hypoglycemia was reduced for adults, remained low for children
- The system remained in Automated Mode for 95% of the 3-month study
- The majority of participants continued into the 12-month extension phase

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Discussion with Dr. Bruce Bode

Omnipod 5 Principal Investigator

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.

Q&A

 CAUTION: Investigational Device, Limited by United States Law to Investigational Use.