

## **Breakthrough Studies on Automated Insulin Delivery and CGM for Type 2 Diabetes Unveiled at ADA Scientific Sessions**

*Results Demonstrate Enhanced Diabetes Management and Quality of Life with Advanced Technology*

**ORLANDO, FL, JUNE 22, 2024** – New data focused on advanced technology innovations for managing type 2 diabetes (T2D) highlight the positive impact of automated insulin delivery systems (AID) and continuous glucose monitoring (CGM) in improving glycemic control and overall diabetes management. Three studies showing advancements for type 2 diabetes were presented at the American Diabetes Association's® (ADA) 84th Scientific Sessions in Orlando, FL.

Of the nearly [40 million](#) Americans with diabetes, more than [90% have type 2](#) diabetes. As the prevalence continues to rise globally, effective management strategies are more critical than ever. The studies showcased at the ADA Scientific Sessions emphasize the transformative potential of integrating advanced technologies into diabetes care, particularly for under-resourced populations.

"These studies represent a significant advancement in diabetes management technologies, showing substantial improvements in glycemic control and quality of life for people with type 2 diabetes," said Robert Gabbay, MD, PhD, ADA chief scientific and medical officer. "By leveraging these innovations, we can empower patients with more effective and manageable treatment options, ultimately transforming the landscape of diabetes care."

### **SECURE-T2D Pivotal Trial Demonstrates Significant Benefits of Omnipod® 5 Automated Insulin Delivery System in Adults with Type 2 Diabetes**

Findings from the SECURE-T2D pivotal trial, the first large-scale, multicenter study evaluating the Omnipod® 5 AID System, a novel insulin pump, in a racially diverse group of adults with type 2 diabetes were presented as a late-breaking poster.

The Omnipod 5 AID System is a tubeless insulin pump that automatically adjusts insulin delivery based on CGM data. This system aims to improve glycemic control by responding to glucose levels in real-time, reducing the burden of manual insulin dosing for people with diabetes.

The multicenter pivotal clinical trial included 305 adults aged 18-75 years with type 2 diabetes who were using various insulin regimens (basal-bolus, premix, or basal-only) and had a baseline HbA1c of less than 12.0%. After a 14-day standard therapy phase to establish baseline glycemic control, participants transitioned to 13 weeks of using the Omnipod 5 AID System. The primary endpoint was the change in HbA1c from baseline to 13 weeks. The study population was also notably diverse, with 24% Black and 22% Hispanic/Latino participants.

Key findings from the trial showed that the use of the Omnipod® 5 AID System led to a significant reduction in HbA1c levels, from a baseline average of  $8.2 \pm 1.3\%$  to  $7.4 \pm 0.9\%$  at the end of the study (treatment effect:  $-0.8\%$ , 95% CI:  $-1.0$  to  $-0.7$ ,  $p < 0.001$ ). The greatest improvements were observed in participants with the highest baseline HbA1c.

"The results from the SECURE-T2D trial underscore the potential of the Omnipod 5 AID System to transform diabetes management for adults with type 2 diabetes," said Francisco J. Pasquel, MD, MPH, Associate Professor of Medicine and Global Health at Emory University, and lead author of the study. "The substantial improvements in glycemic control and quality of life, particularly among minority populations, are promising steps toward more equitable diabetes care."

Future research will focus on long-term outcomes and the potential of a new solution to address other aspects of diabetes management. The authors also note that studies may explore its effectiveness in different populations and its impact on quality of life for people with type 2 diabetes. Additionally, ongoing analyses will aim to refine and enhance the system's algorithms to maximize its benefits for users.

### **Improved Glycemic Outcomes with Continuous Glucose Monitoring (CGM) in Type 2 Diabetes Patients: Real-World Analysis Reveals Significant Benefits**

Findings from an oral presentation, *Glycemic Outcomes with CGM Use in Patients with Type 2 Diabetes—Real-World Analysis*, showcase the significant impact of continuous glucose monitoring on patients with type 2 diabetes, revealing the use of CGM substantially improves glucose control in type 2 diabetes patients across all therapeutic treatments.

The study evaluated the impact of CGM on adults with type 2 diabetes using non-insulin therapies (NIT), basal insulin (BIT), and prandial insulin (PIT). This 12-month retrospective analysis used data from a large claims database of over 7.1 million type 2 diabetes patients and compared HbA1c levels before and after CGM use, focusing on the change closest to 12 months post-CGM acquisition.

Among the 6,030 adults with type 2 diabetes (NIT: 1,533; BIT: 1,375; PIT: 3,122), with a mean baseline HbA1c of 8.8% and a mean age of 59 years, significant HbA1c improvements (by 1% across all therapies) were observed across all therapy groups

after 12 months. The study underscores CGM's potential to enhance glycemic control and reduce healthcare costs in both insulin and non-insulin-treated type 2 diabetes patients.

"These results suggest that CGM can play a crucial role in enhancing health outcomes for all diabetes patients, regardless of their treatment regimen," said Satish K. Garg, MD, University of Colorado Denver, and lead author of the study. "The real-world analysis underscores the potential of CGM to not only improve glycemic outcomes but also reduce healthcare resource utilization and overall healthcare costs."

Looking ahead, longer-term studies and randomized controlled trials are recommended to further validate these results and explore the broader implications of CGM use in diabetes care. Future research will focus on confirming the sustained benefits of CGM and understanding its impact on various patient subgroups to tailor diabetes management strategies effectively.

Using the same database, findings from a related late-breaking abstract reveal that CGM use in type 2 diabetes results in more than a 50% reduction in all-cause hospitalizations and acute diabetes-related hospitalizations. Dr. Garg presented the results of the late-breaking abstract, *Impact of Continuous Glucose Monitoring Use on Hospitalizations in People with Type 2 Diabetes—Real-World Analysis*, as an e-theatre poster on Sunday, June 23, 2024.

### **Continuous Glucose Monitoring (CGM) Improves Glycemic Control in Adults with Type 2 Diabetes Not Using Insulin**

Findings from a new study demonstrate that CGM significantly enhances glycemic control in adults with type 2 diabetes who are not using insulin. These results, presented during the general poster session and simultaneously published in *Diabetes Technology and Therapeutics*, underscore the potential of CGM to improve diabetes management and support expanding CGM access for adults with type 2 diabetes not using insulin.

The real-world study analyzed data from over 3,800 adults using Dexcom G6 and G7 sensors. The participants, initially not meeting their glycemic targets, showed significant improvements after six months of CGM use, with further progress at one year.

Key findings include a 0.5% reduction in the glucose management indicator, a CGM approximation of A1C, and a 17% increase in Time in Range (TIR), which translates to an additional four hours per day spent within the target glucose range. The study also highlighted the advantages of the Dexcom High Alert feature, which notifies users when glucose levels exceed their selected targets. Participants who used this feature showed the greatest improvements in their glucose levels. The consistent CGM use over the year suggests sustained benefits and a positive impact on long-term diabetes care.

“We are encouraged by the significant long-term improvements in glycemic control observed in our study,” said Jennifer E. Layne, PhD, Dexcom. “These findings highlight the importance of CGM for managing non-insulin treated type 2 diabetes for clinicians and for patient self-management.”

Looking ahead, the authors plan to continue studying this cohort and other CGM users not taking insulin to explore ongoing patterns of glycemic improvement and real-world behavior change enabled by CGM. The team also intends to evaluate the impact of other Dexcom system features on glycemic control.

### **Research presentation details:**

Dr. Pasquel will present the findings at the late-breaking poster session presentation sessions:

- *Glycemic Improvement with Use of the Omnipod 5 Automated Insulin Delivery System in Adults with Type 2 Diabetes—Results of the SECURE-T2D Pivotal Trial*
- Presented on Saturday, June 22, 2024 at 12:30 PM EDT
- *ePoster Theater - Type 2 Diabetes—Prevention, Treatment, and Technology*
  - Presented on Sunday, June 24, 2024 at 1:50 PM EDT

Dr. Garg will present the findings at the following oral presentation session:

- Oral Presentations - New Technology—Continuous Glucose Monitoring
  - *Glycemic Outcomes with CGM Use in Patients with Type 2 Diabetes—Real-World Analysis*
- Presented on Monday, June 24, 2024 at 8:00 AM EDT

Dr. Layne will present the findings at the general poster session:

- *Long-Term Improvement in CGM-Measured Glycemic Control in Adults with Type 2 Diabetes Not Treated with Insulin—Real-World*
- Presented on Saturday, June 22, 2024 at 12:30 PM EDT

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### **About the ADA's Scientific Sessions**

The ADA's 84th Scientific Sessions, the world's largest scientific meeting focused on diabetes research, prevention, and care, will be held in Orlando, FL on June 21-24. More than 11,000 leading physicians, scientists, and health care professionals from around the world are expected to convene both in person and virtually to unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes. Attendees will receive exclusive access to thousands of original research presentations

and take part in provocative and engaging exchanges with leading diabetes experts. Join the Scientific Sessions conversation on social media using #ADAScientificSessions.

### **About the American Diabetes Association**

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 83 years, the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we aim to improve the quality of life for the over 136 million Americans living with diabetes or prediabetes. Diabetes has brought us together. What we do next will make us Connected for Life®. To learn more or to get involved,

visit us at [diabetes.org](http://diabetes.org) or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook ([American Diabetes Association](#)), Spanish Facebook ([Asociación Americana de la Diabetes](#)), LinkedIn ([American Diabetes Association](#)), Twitter ([@AmDiabetesAssn](#)), and Instagram ([@AmDiabetesAssn](#)).