

Insulet initiates EVOLVE pivotal trial or fully closed-loop AID in T2D – May 4, 2026

Study to enroll up to 350 adults with T2D using insulin, evaluating glycemic outcomes without meal announcements or bolusing

Insulet [announced](#) that it has enrolled the first participant in EVOLVE (Evaluation of the Fully Closed Loop Omnipod System in Type 2 Diabetes), the company's pivotal RCT (randomized controlled trial) evaluating its fully closed-loop (FCL) AID system in adults with T2D using insulin. The study is expected to enroll up to 350 participants across a maximum of 40 US sites. It follows the FDA Investigational Device Exemption (IDE) approval of the FCL system in [March 2026](#).

Unlike current hybrid closed-loop (HCL) AID systems, Insulet's investigational FCL system is designed to function without any user-initiated meal announcements or bolusing. It also eliminates the input of settings to get started through its novel auto titration design.

Insulet plans to [submit](#) the system to the FDA in 2027 for use in T2D, with a potential commercial launch in 2028. We imagine that the absence of "mealtime" boluses is perceived as less risky in T2D than T1D due to some insulin production and imagine that is part of the strategy of "T2D first" with this approach.

Table of Contents

1. [EVOLVE pivotal trial focuses on real-world usability and outcomes, building on encouraging feasibility data](#)
2. [Fully closed-loop AID aims to eliminate user burden, but remains limited by underlying physiology](#)
3. [Patient variability and benefits of system engagement raise questions on whether FCL systems can deliver consistent outcomes without user input](#)
4. [Close Concerns' Questions](#)

EVOLVE pivotal trial focuses on real-world usability and outcomes, building on encouraging feasibility data

While EVOLVE will evaluate glycemic outcomes, the trial will also focus on whether FCL systems can maintain performance in real-world settings without user input or start-up settings. This trial builds on prior feasibility studies, including Insulet's EVOLUTION 2 study (n=24), [presented at ATTD 2026](#) by Prof. Martin de Bock (University of Otago, New Zealand).

In this study, participants with T2D [achieved](#) a mean Time in Range (TIR) of ~68%, an approximately 24% improvement over standard insulin (mostly MDI) therapy, without meal bolusing and with minimal hypoglycemia. He noted that [91% of participants](#) (22 out of 24) in EVOLUTION 2 chose to continue in the extension study as patients felt "safer with this system than injections," and that the system "continues to be life changing" – wow!

There is a growing body of evidence that automation can improve glycemic outcomes compared to standard MDI management. The pivotal EVOLVE trial should address this question in a larger-scale, randomized evaluation across a broader population.

Fully closed-loop AID aims to eliminate user burden, but remains limited by underlying physiology

FCL systems represent a meaningful step beyond current HCL AID systems, removing the need for carbohydrate counting and manual bolusing, two of what are described as "the most persistent sources of burden in diabetes management". While from our view, the carb counting burden is overstated compared, for example, to the high number of people without insulin access at all or with access to only the least stable insulins, it would obviously be incredible

from a diabetes management perspective for both patients and clinicians for far more people to have access to pump therapy and related algorithms as they stand as well as more advanced algorithms (and pumps!) in the future.

At [ATTD 2026](#), we heard from several researchers who emphasized that algorithmic advances such as these must take into consideration physiological limitations:

- **Dr. Marc Breton (University of Virginia)** [discussed](#) how the rapid rise in glucose following meals remains difficult to match with the slower pharmacokinetics of subcutaneous insulin, often resulting in postprandial hyperglycemia, even in automated systems.
- **Dr. Gregory Forlenza (University of Colorado Anschutz)** [said](#) that current insulin formulations, while improving, are still not fast enough to fully eliminate the need for anticipatory dosing. Ultra-rapid-acting insulins would offer some potential to mitigate this barrier.
- **Dr. Rayhan Lal (Stanford University)** [noted](#) that while removing meal announcements is an important step toward automation, FCL systems must also reflect real-world variability, including exercise, stress, and hormonal shifts. He said that even highly optimized systems today often perform best with some degree of user input, and that access, cost, and data transparency will be critical factors influencing real-world impact and adoption.

Patient variability and benefits of system engagement raise questions on whether FCL systems can deliver consistent outcomes without user input

We see patient heterogeneity, both in people with T1D and T2D, as a challenge for FCL systems. Insulin requirements vary widely across individuals (and for the same individual from day to day) based on multiple factors, such as diet, exercise, degree of insulin resistance, and behavioral factors (e.g., sleep). This raises the bar for the adaptability of fully automated algorithms.

Data from Medtronic's [Viverra](#) feasibility studies in T1D [presented at ATTD 2026](#) showed that TIR results are not as strong without meal announcement. While users maintained strong glycemic outcomes with FCL (TIR of 74%), outcomes were highest when some degree of user engagement was maintained (TIR of 78%-79% with optional bolusing). Similarly, FCL systems such as the University of Virginia's [AIDANET](#) (Adaptive NETWORK) have demonstrated non-inferior outcomes compared to hybrid systems, but improvements were most relevant for individuals with higher baseline A1c.

Speaking for the [CamAPS Liberty](#) FCL system, Prof. Roman Hovorka (University of Cambridge) recently [suggested](#) that FCL may be particularly valuable to reduce user burden (especially during periods when individuals want to step back from intensive self-management), improve glycemic management among those with poor outcomes at baseline, and expand overall access to AID. Data from the system showed that FCL use led to meaningful improvements in glycemia from open-loop insulin pump use, though not yet to the target level of TIR >70%.

Collectively, these findings suggest that fully automated systems may deliver the greatest benefit in populations struggling with traditional management. While the best glycemic outcomes currently depend on user interaction, manufacturers have a clear goal of reducing user interaction while optimizing TIR.

FCL for T2D may expand AID into broader populations

Insulet's tubeless (e.g., no sets) Omnipod platform may further differentiate its FCL development approach by simplifying the experience and reducing clinicians workloads, thus lowering barriers to adoption beyond traditional pump users. The combination of tubeless design^[1] and fully automated insulin delivery could enable broader uptake among individuals who may not otherwise consider pump therapy. Although this is a shift in how AID is positioned, real-world adoption will depend on provider familiarity, reimbursement, and user trust in automation.

Competitive landscape: FCL development accelerates across AID systems

Momentum toward FCL systems is building across the field, with multiple companies advancing next-generation algorithms alongside Insulet:

- **MiniMed:** The [Viverra FCL algorithm](#) can detect unannounced meals and deliver automated boluses. Feasibility data show TIR ~74% without meal announcements, increasing to ~78%-79% when users retain

optional engagement.

- **Tandem:** The company is [developing](#) an FCL system with the University of Virginia, with a pivotal study also expected in 2026 and an FDA submission targeted for 2027.

[1] The terminology used to describe AID systems (“tubeless” vs. “tubed,” “durable” vs. “disposable”) has varied over the years by industry, clinicians, and patients. A tubeless design has great appeal to many patients who prioritize discretion, though some concerns remain around minimizing diabetes waste generated by disposable medical technologies.

Close Concerns’ Questions

1. In Insulet’s feasibility studies, how challenging were the meals and other lifestyle factors, given the strong TIR results?
2. How effectively can FCL algorithms manage postprandial excursions in real-world settings? Pizza, anyone?
3. What other real-world dynamics, such as exercise, is Insulet’s algorithm able to handle?
4. What will we learn about the differences in FCL between people with type 1 and type 2 diabetes?
5. To what degree will FCL systems meaningfully expand AID adoption across the diabetes landscape?

-- by Riya Chatterjee, Jeremy Alkire, Kat Moon, and Kelly Close