

# Insights from DPHARM: reimagining the future of connected clinical trials

At this year's DPHARM conference in Philadelphia, leaders from across the clinical research community gathered to explore how digital innovation is transforming clinical trials. Carolina Canapè, Business Development Lead Digital Health at Ypsomed, sat down with Shawn James, Communication Expert at Ypsomed, and Gora Touré, Marketing Manager at Ypsomed, to reflect on key themes from the event, the growing role of connected devices in decentralized trials, and how Ypsomed's CliniPilot® solution is helping sponsors enhance data integrity while reducing site and patient burden.



**Carolina Canapè**  
Business Development Lead Digital Health

Carolina Canapè, PhD, MBA, is a commercial leader with over 15 years of experience in MedTech and digital health. She specializes in developing and executing global go-to-market strategies, integrating digital solutions, and driving innovation across clinical and commercial environments.

Dr. Canapè currently serves as Business Development Lead for Digital Health at Ypsomed AG, where she is responsible for advancing strategic partnerships and commercial initiatives focused on connected devices. She previously held senior roles at IQVIA, GenomSys SA, and Bracco Imaging, where she drove global business development efforts in digital health.

She holds a PhD in Molecular Imaging and an MBA. Her combined scientific and commercial expertise positions her at the forefront of digital transformation in healthcare and clinical research.

Hi Carolina. You just got back from DPHARM in Philadelphia. Could you briefly sum up your overall experience, and tell us what some of the key themes were at this year's conference?

The DPHARM conference is where the clinical research industry comes together to challenge the status quo and reimagine the future of clinical trials. This goes beyond discussing the current state of pharma; it's about showcasing how bold thinking, digital innovation, and the right mindset can drive meaningful transformation. As attendees we gain a front-row seat to the industry's push toward end-to-end digitalization in clinical R&D, with real-world case studies that demonstrate measurable operational impact and scalability. DPHARM offers both a strategic roadmap and tangible examples of how we can accelerate progress and deliver better outcomes for patients and stakeholders alike.

One big topic at DPHARM was the transformative impact of decentralized clinical trials (DCT) on clinical research. What did you hear in those conversations about the barriers that still remain?

The discussion moved well beyond theory, as panelists shared compelling data showing that DCTs can deliver substantial return on investment – adding up to tens of millions in value per drug entering Phase II,

with a sevenfold ROI. This reinforced the view that DCTs are no longer experimental, but a strategic necessity for sponsors seeking to accelerate timelines, reduce costs, and expand patient access. While challenges remain – such as the burden on investigative sites, fragmented technology ecosystems, and concerns around data quality from remote collection – these issues also present opportunities to innovate and develop more resilient, inclusive, and efficient clinical trial models.





You told us that data consistency across sites and patients came up several times at DPHARM. Why do you think this issue is so persistent, and what role can new tools or approaches play in addressing it?

The issue remains persistent in clinical trials, especially in decentralized models, because of the inherent variability in how data is collected, interpreted, and integrated across diverse settings. This creates inefficiencies in clinical trial operations: data entry work and digitization of paper-based patient data, as well as increased error rates which result in clinical trial staff burden and additional cost for the sponsor. However, during DPHARM new tools and approaches were showcased which can make a difference. For example, real-time data monitoring, AI-powered anomaly detection, and standardized data capture protocols are helping to harmonize inputs across sites. We were proud to introduce our own CliniPilot® solution, a smart autoinjector add-on enabling automated injection data capture and transfer, with seamless integration into standard electronic data capture systems (EDCs) and existing workflows, allowing sponsors to ensure data integrity without adding burden to patients or sites.

Some participants voiced worries that layering digital solutions onto trials could add complexity or regulatory risk. How do you see it?

While connected devices offer many benefits in clinical trials, the perception is they also come with challenges. Concerns like cybersecurity, regulatory compliance, and managing multiple digital tools can add complexity. That's why it's essential for sponsors and clinical research organizations (CROs) to partner with experienced vendors who understand these risks and can ensure smooth implementation. On the patient side, while many appreciate the convenience of remote monitoring, some may struggle with new technologies or worry about data privacy. Addressing these concerns through thoughtful design, clear communication, and strong data protection measures is key to successful adoption.

However, when digital solutions like CliniPilot® are built to fit effortlessly into existing workflows and comply with data standards they can actually reduce complexity by automating manual tasks, improving data quality, and enabling real-time oversight. Moreover, results recently published in Ypsomed's study *A Human Factors Validation of a Smart Autoinjector Accessory De-*

*signed to Improve Self-Injection Outcomes and User Confidence*<sup>1</sup> showed that intended users could operate a smart autoinjector add-on (e.g. CliniPilot®) successfully, giving strong usability outcomes for participants.

It is worth adding that regulators are increasingly supportive of digital innovation, as long as it enhances patient safety, data integrity, and trial efficiency.

**At DPHARM you also gave a short talk on CliniPilot®. If you had to distill it into two or three key messages, what would you want the audience to remember?**

CliniPilot® addresses a critical gap in clinical trials: the lack of visibility into what happens during at-home treatment. Traditionally, it's been difficult for sponsors to collect reliable and objective data on injection timing, technique, adherence or common injection errors. CliniPilot® transforms Ypsomate® autoinjectors into smart, connected devices that automatically capture and transmit key injection data – such as time, date, outcome, and user errors to an EDC systems. By enabling real-time monitoring and early intervention, CliniPilot® not only improves data quality and trial outcomes, but also provides valuable real-world in-

sights into patient behavior during at-home treatment. This visibility – traditionally difficult to achieve – helps pharma sponsors gain insights into patient behavior post-launch, enabling the design of targeted patient support programs that ensure proper onboarding, correct use, and sustained adherence, ultimately driving better therapeutic outcomes and long-term product success. It supports traditional, hybrid, and decentralized models, embedding effortlessly into existing workflows. CliniPilot® also enhances patient engagement through guided home injections and smart reminders, while linking injection data with electronic Patient Reported Outcome Application (ePRO)/electronic Clinical Outcome Assessment (eCOA) outcomes to unlock deeper insights. For pharma sponsors, this means smarter, more efficient, and more inclusive trials.

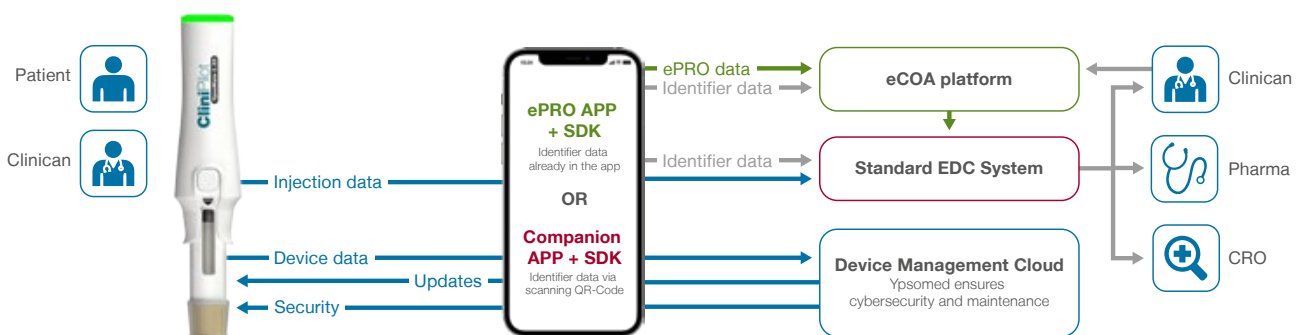
Integration is a conference buzzword, but in practice, trials already rely on multiple platforms and devices. What makes the integration of CliniPilot® with existing systems different?

Great question! Integration is often a buzzword, but CliniPilot®'s integration stands for:

- **Plug-and-play compatibility:** CliniPilot® is designed to integrate seamlessly with existing EDC systems and with eCOA apps, minimizing the need for custom development.
- **Modular and flexible architecture:** It can be tailored to different trial designs – hybrid, decentralized, or traditional – without disrupting existing workflows.
- **Real-time data synchronization:** Injection data and adherence metrics are captured and synced automatically, together with ePROs enabling immediate visibility for trial teams and reducing manual reconciliation.
- **Patient and site-centric design:** Integration isn't just technical, it's operational. CliniPilot® supports workflows that reduce burden for both sites and patients, making adoption smoother and more sustainable.
- **From trials to real-world care:** The same devices can extend beyond studies to support post-trial follow-up, real-world evidence, and patient support programs – bridging research and care.
- **Less burden, more engagement:** By guiding patients and reducing site workload, connected devices improve retention, adherence, and data quality while making trials more accessible.
- **Scaling decentralized models:** As DCTs become standard, connected devices form the backbone for remote monitoring, automated data capture, and patient-centric delivery.

If you think about the next 3–5 years, where do you see the real opportunity for connected devices in clinical development, beyond the buzz?

In 2024, over one-third (36%) of studies used connected devices – a clear sign of their growing value in clinical research. In the next 3–5 years, the real opportunity lies in moving beyond isolated use cases toward fully integrated, insight-driven ecosystems.



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