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Continuous Glucose Monitoring in Clinical Research: Trends and Challenges

Glycated hemogolbin (HbA1c) has been the traditional gold standard for assessing glycemic control in clinical trials, but it does not capture short-term glucose fluctuations. Continuous glucose monitoring (CGM) provides a more comprehensive assessment through metrics like time-in-range (TIR) and mean amplitude of glycemic excursion (MAGE). Time-in-tight range (TITR) (glucose levels between 70 and 140 mg/dL) is emerging as an important endpoint in pediatric populations, where levels above 140 mg/dL predict diabetes progression in children with autoantibodies. Despite CGM's rapid incorporation into routine diabetes management, its adoption in clinical trials has been slow due to a lack of consensus on CGM metrics and regulatory acceptance. Since December 2017, international standardization efforts have aimed to address these issues, and we hypothesized that these efforts would lead to an increase in clinical studies incorporating CGM endpoints. Our analysis of CGM studies in large clinical trials register from 2012 to 2023 showed a significant increase in the past six years, driven largely by non-industry funded research, though industry-funded studies also increased significantly. TIR emerged as the most common CGM endpoint in the last six years, replacing MAGE. Studies involving pediatric populations also increased significantly. These findings suggest international guidelines have positively impacted clinical research and underscore CGM's growing importance in pediatric diabetes studies. However, integrating CGM into clinical trials presents challenges, including data loss and regulatory compliance. Device compliance evaluation during screening and providing replacement sensors can mitigate data loss, and a multi-tier data architecture can support compliant data handling. Future advancements in CGM technology, artificial intelligence, and standardization efforts are expected to further enhance its research applications, though regulatory acceptance remains essential for broader adoption.

Keywords: Continuous glucose monitoring, clinical research, pediatrics, trends

Biography

Andrew Bevan is a Chartered Scientist and an Executive Director of Integrated Project Solutions at PPD, Part of Thermo Fisher Scientific. He has more than 25 years' experience in clinical research developing and managing solutions primarily for large international Phase II-IV cardiovascular and metabolic studies and studies in pediatric and rare disease populations. He has published 19 articles and scientific abstracts covering a diverse range of topics in the clinical research field.

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