Worldwide Clinical Trials

Integration of CGM, ePRO, & Digital Biomarkers in Early Phase Obesity Trials

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Why this Matters in Early Phase Obesity Development

Integrating continuous glucose monitoring (CGM), electronic patient-reported outcomes (ePRO), and digital biomarkers enables a more complete and dynamic characterization of therapeutic effect in early phase obesity trials. Together, these technologies move beyond static endpoints to provide continuous, contextual, and functional insights.

CGM: Captures real-time metabolic impact.
CGM provides high-resolution insight into glycemic variability, postprandial responses, and early metabolic shifts

ePRO: Adds patient-centric context.
ePRO data contextualizes CGM outputs by capturing how patients experience metabolic changes, including appetite, satiety, gastrointestinal tolerability, energy, and overall well-being

Digital biomarkers: Demonstrate functional relevance.
Wearables and digital endpoints quantify whether metabolic improvements translate into meaningful changes in daily functioning, supporting a more holistic assessment of t reatment benefit.

Methods

Structured interviews with multidisciplinary stakeholders in early phase obesity trials explored the use of CGM, ePRO, and digital biomarkers, focusing on their impact on execution, adherence, data quality, and workflows. Qualitative analysis identified key benefits, challenges, and best practices to support effective implementation.

Best Practices

Operational approaches that maximize value and feasibility:

- Align tools with endpoints to ensure data directly informs key program decisions
- Invest in proactive training and support to drive participant adoption and usability
- Continuously monitor adherence and data quality to maintain integrity and interpretability of digital endpoints

Results

Benefits
CGM enabled high-resolution metabolic profiling and dynamic assessment, while ePRO and digital biomarkers enhanced engagement and captured real-time functional outcomes

Challenges
Technology adoption, cross-platform data integration, and participant training requirements

Operational impact
Reduced site burden and enabled more frequent, high-quality data collection

Implementation Enablers

- **Early Planning** to define integration strategy and avoid downstream rework
- **Endpoint Alignment** to ensure digital measures support key study objectives
- **Proactive Participant Support & Training** to drive adoption and usability
- **Continuous Monitoring Of Adherence & Data Quality** to preserve endpoint integrity
- **Robust Data Management frameworks** to enable seamless integration and analysis
- **Cross-functional Collaboration & Operational Infrastructure** to support scalable execution

Conclusions

Integrating CGM, ePRO, and digital biomarkers enhances endpoint sensitivity and operational efficiency in early phase obesity trials. Realizing this value depends on thoughtful technology selection, proactive participant support, and robust data management.

While implementation introduces challenges, these are largely addressable through early planning and disciplined execution, enabling successful and scalable integration of digital approaches across early phase programs.

Operational Factor	Impact on Execution
Technology Adoption	May limit deployment without proactive participant and site support
Data Integration Across Platforms	Introduces operational complexity and challenges in consistent data flow and review
Participant Training Requirements	Requires structured onboarding to ensure adherence and usability
Continuous Adherence + Data Quality Monitoring	Preserves interpretability and maximizes value of digital measures
Alignment of Tools With Endpoints	Essential to ensure collected data directly informs endpoint measurement and key program decisions

Key Takeaways For Early Phase Obesity Programs

Digital integration is feasible and high-value when supported by dedicated infrastructure and cross-functional collaboration

CGM, ePRO, and digital biomarkers provide a more comprehensive, patient-centric view of early treatment effects

Maximized impact requires early planning, endpoint alignment, and continuous monitoring of adherence and data quality

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