GlucoseReady™ 2024 Galien Award Application - Background

Various new treatment options, including glucagon-like peptide-1 (GLP1) agents, are under investigation for treating cardiometabolic diseases such as diabetes, weight management/obesity and metabolic dysfunction-associated steatohepatitis (MASH)/metabolic dysfunction-associated steatotic liver disease (MASLD) [Abdelmalek, 2024]. These drugs are intended to achieve different endpoints: in some cases, weight loss, in others change in blood glucose, liver inflammation, and ultimately reduction in clinical event outcomes such as major cardiovascular events, cirrhosis, and death [Gomes, 2024].

However, clinical trials in these chronic disease states are complicated by the difficulty in standardizing lifestyle and maintaining adherence [Burgess, 2017]. Clinical trial sponsors and their CRO partners must therefore address the regulatory challenges of capturing symptoms (electronic clinical outcome assessment [eCOA], including hypoglycemia) and digital biomarkers (weight, activity, heart rate, sleep, and glucose levels), in addition to the necessity of predicting, tracking and ensuring adherence and retention to avoid dropouts.

Recent US Food and Drug Administration (FDA) guidance has underscored these issues by mandating lifestyle standardization for obesity and diabetes clinical trials [FDA, 2024a]. FDA is also requiring hypoglycemia (either symptomatic or triggered by continuous glucose monitoring (CGM) devices) to be incorporated as a novel endpoint in some diabetes trials [FDA, 2024b].

We recognized that there was an unmet need for a system able to address these challenges. Firstly, we designed an FDA-compliant approach to capture, display and export all of these endpoints in a single GCP-compliant data environment. Secondly, we realized it was important to digitize behavioral traits to capture disease specific lifestyle information and create tailored adherence advice. This advice must be provided in real-time to participants and sites with appropriate feedback loops captured within the system. Thirdly, artificial intelligence driven algorithms were needed to leverage the advantage of eCOA connected to sensors. For example, hypoglycemia observed on continuous glucose monitoring (CGM) or blood glucose monitoring (BGM) is needed to trigger an e-diary, and all data should be available in real-time. Finally, it was essential to visualize these data in a system that allowed for timely and efficient decision making by key stakeholders including patients, sites and sponsors.

Clinical ink has developed GlucoseReady™, a single integrated GCP-compliant digital platform [Anderson et al, 2024]. The suite of tools includes disease specific eCOAs, behavioral assessments by the SPUR™ tool, lifestyle standardization, BGM / CGM, digital weight scale and actigraphy. We also required the ability to use a risk-based quality management system to visualize data, identify anomalies and quantify risk. The key risks included non-adherence particularly in responder patients.

Clinical ink

Please provide appropriate references (PubMed, Abstract, Website)

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