Category

Best Digital Health Solution

General Information

Company Name *

Clinical ink

Number of employees *

201-500

Turnover and/or Funding

Private company, majority owned by GI Partners, a San Francisco-based private equity firm

words remaining :

487

Product/Solution Name *

GlucoseReady (TM)

Corporate Name *

Clinical ink

Date of Approval *

2023-12-31

Indications *

Type I, II Diabetes Mellitus
Weight Management / Obesity
MASH/Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)
Adherence and Retention

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482

Therapeutic Areas *

Diabetes Mellitus
Cardiovascular
Cardiometabolic
Endocrinology

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495

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Attached Files:

- GlucoseReadyGalien2024Product.pdf

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

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.

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Attached Files:

- GlucoseReadyGalien2024Background.pdf

**History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)**

Clinical Ink has more than 10 years of experience developing a GCP compliant electronic data capture platform, BrainBaseline, that integrates eCOA with various sensors and digital biomarkers. This platform has been audited and validated by numerous large pharma and academic collaborators. It has been used to assess endpoints in neurodegeneration, COVID-19, and bleeding disorders, incorporating a broad range of consumer devices like the iPhone and Apple Watch, and advanced APIs to passively detect disease symptoms.

The emergence of new FDA regulations in cardiometabolic disease and the rise in trials for weight loss, diabetes, and MASH/MASLD led to the development of GlucoseReady™ in April 2023. This platform leveraged the core code and validation of BrainBaseline and the expertise of the same product design and engineering team. The mobile platform seamlessly integrates 'bring your own device' (BYOD) or provisioned device data collection from wearables and sensors supporting continuous passive data capture along with management of data derived from active tasks driven by the study protocol.

GlucoseReady's initial objectives were threefold: (1) establish a library of diabetes-specific eCOA on various devices; (2) offer sensor integration to capture data from continuous and standalone glucose monitoring devices; and (3) trigger eCOA for symptomatic and asymptomatic hypoglycemia. Collaboration with key sponsors revealed a broader demand, extending GlucoseReady's application to chronic weight management, obesity, and MASH/MASLD. Objectives expanded to include the development of disease-specific eCOA libraries, connected weight scales and actigraphy solutions, and the ability to trigger specific eCOA based on digital biomarker data.

The product's scope was developed with senior clinical and technology executives from leading drug developers. These experts emphasized the importance of the ability to predict, track, and prevent non-adherence. To address the known high dropout and low adherence rates in cardiometabolic trials, a digital behavior tool was required. Accordingly, Clinical ink has established an exclusive clinical trial partnership with Observia, a specialist provider of predictive behavioral digital tools and patient reported adherence measures (PRAMs). This tool, SPUR™, has been integrated into the GlucoseReady™ suite to ensure seamless provision of a best-in-class solution for adherence and retention. Developed over a 13 year period, the SPUR™ tool has been validated in seven publications covering multiple chronic disorders including diabetes. The SPUR™ tool has been validated across different demographics and is used by over 15 biopharma companies in 50 thousand patients and 20 different approved medications as an adherence tool.

Data science advancements have added numerous data transfer and visualization elements to GlucoseReady™. Using an API, GlucoseReady™ also leverages Cyntegrity's SOC 2 (Type II) Compliant Risk-Based Quality Management (RBQM) solution to identify protocol non-compliance, provide study site-to-site comparisons, create action lists for sponsor companies or CROs, and provide insights into key risk indicators (KRIs). These issue streams are audited and tracked within the embedded ticketing system.

As of May 2024, GlucoseReady™ has been audited, validated, released, and contracted with several sponsors, initially focusing on type 2 diabetes and weight management. To date, 8 GLP-1 biopharma companies have requested RFI/RFPs and 68 have requested information.

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Attached Files:

- GlucoseReadyGalien2024History.pdf

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

GlucoseReady™ is unique due to its integrated modular components, real-time data flows, and operation under a comprehensive quality management system. It is used by investigators to accurately assess the clinical efficacy and safety of cardiometabolic innovator medicines, whilst improving clinical trial retention. The benefits include improved participant safety and more robust efficacy assessments from continuous data collection. GlucoseReady™ has been developed to ensure electronic source data is captured in compliance with ALCOA+ principles, with a robust audit trail that provides the ability to completely reconstruct source data collection activities.

From a regulatory standpoint, GlucoseReady™ can standardize and document lifestyle adherence as required by FDA. However, a novel approach to the prediction and prevention of low adherence (using SPUR™) is enabled by site level alerts triggering personalized scripts for the investigator to use with individual patients in real-time. This ensures that more patients remain in the trial, avoiding the cost and time implications from managing the missing data from dropouts. Furthermore, data solutions to support adherence have significant health-quality and commercial benefits once the drug is approved.

From an operational standpoint, GlucoseReady™ is intended to create a new standard of digital support. These include connected device inventory status and workflows for alerts/site actions. The speed of data transfer is novel and important. GlucoseReady™ moves data in near real-time from CGM transmitter readings (EGV) or connected BGM to the app on the patient's own smartphone or a provisioned device (via connected device/Bluetooth) and from the app to the study database and out to data sharing tools. This allows for near real-time hypoglycemia triggering and is a major advance from legacy solutions where data are collected from a CGM or BGM transmitter onto a separate physical device/receiver, and eventually transferred for episodic batch delivery of data that might be weeks old.

This same pattern of high velocity collection and delivery extends to weight management and MASH/MASLD, where the patient's own smartphone serves as the hub for digital biomarker connected devices. The additional important operational benefit in clinical trials of weight management and MASH/MASLD is behavior prediction and non-adherence tracking to improve retention.

From a data perspective, GlucoseReady™ provides novel dashboards with real-time access to personalized drivers of behavior and adherence, a range of disease specific eCOAs, and disease specific digital endpoints (quantum and quality of weight loss, lean vs. non-lean, glycemia dynamics, activity, sleep, liver imaging). The solution offers integration by API into the Cyntegrity RBQM as well as other enabled systems such as CTMS, EDC and central lab.

In summary, GlucoseReady™ is a novel, fully integrated GCP eClinical platform designed to optimize patient engagement and retention. It includes a full suite of eCOA capabilities that can address capture of both active patient diaries and passive wearables and complex sensor data. The implementation of AI algorithms are designed to improve patient outcomes and enhance safety surveillance. We believe this unique tool represents the new gold standard for retention and data capture in the new era of GLP-1 cardiometabolic clinical trials.

words remaining :

3

*Kindly clearly label your files with company name and asset name.

Attached Files:

- GlucoseReadyGalien2024Innovation.pdf

Please provide appropriate references (PubMed, Abstract, Website) *

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https://www.clinicalink.com/clinical-ink-announces-new-continuous-glucose-monitoring-solution/
https://www.clinicalink.com/clinical-ink-expands-patient-engagement-solutions-with-behavioral-diagnostic-tool-spur/
https://www.clinicalink.com/therapeutic-areas/diabetes/

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- ,GlucoseReadyGalien2024References.pdf