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GlucoseReady™ 2024 Galien Award Application - Innovation

Why this drug or device is innovative, the brand implications for future research and/or how it will improve the human condition (500 words)

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+[1] principles, with a robust audit trail that provides the ability to completely reconstruct source data collection activities. These factors ensure the integrity of the data set, an essential requirement when managing the rigors of an FDA inspection.

From a regulatory standpoint, GlucoseReady™ can standardize and document lifestyle adherence as required by FDA [FDA, 2023b]. 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, particularly those in the critical 'responder' group, 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.

There are also disease-specific benefits from GlucoseReady™. In diabetes it aligns with FDA guidance on detecting both symptomatic and asymptomatic hypoglycemic events. In weight management and MASH/MASLD a suite of eCOA tools can be combined with digital weight and other measuring devices, as well as other disease specific eCOA triggers as needed, ensuring adherence and potentially adaptive dose adjustment.

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 (see Figure 3). 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.

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[1] ALCOA+ references the FDA's principles of data integrity: Attributable, Legible, Contemporaneous, Original, Accurate (+ includes Complete, Consistent, Enduring, Available)

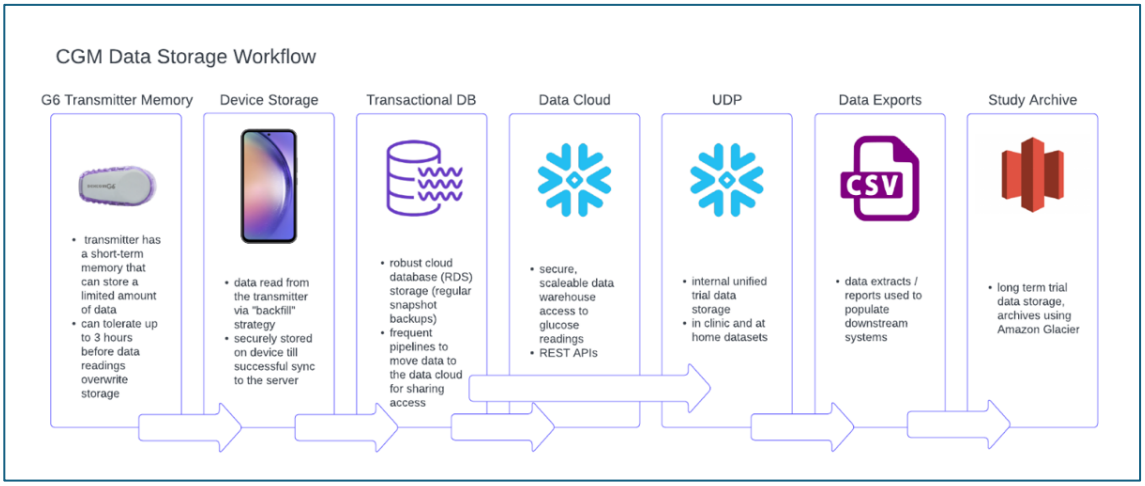

Figure 3 - CGM Data Workflow

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 (see Figure 4). The additional important operational benefit in clinical trials of weight management and MASH/MASLD is behavior prediction and non-adherence tracking to improve retention.

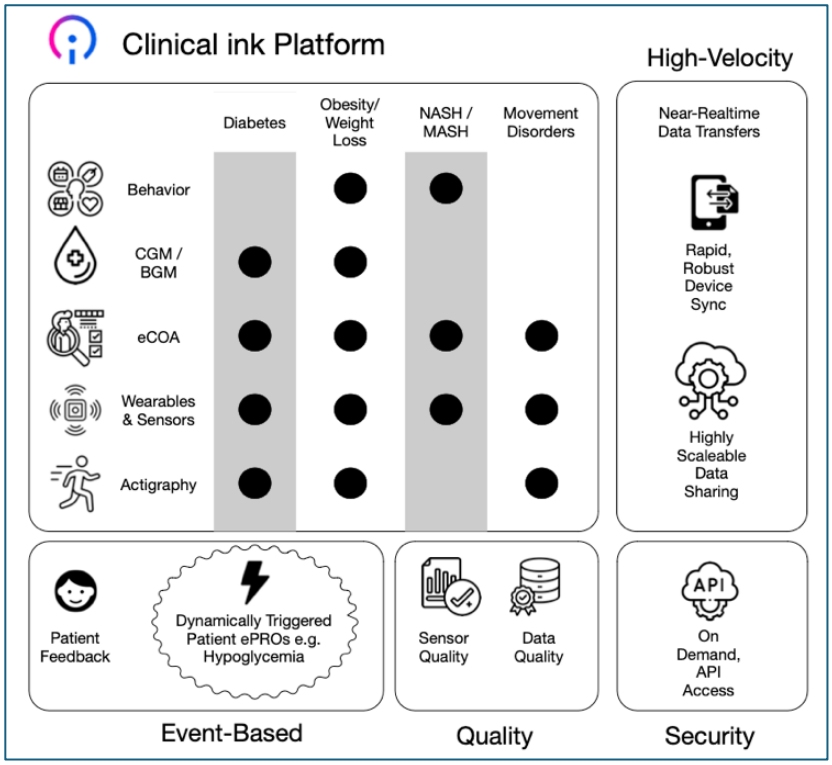

Figure 4 - High Velocity Data Collection and Delivery

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.

Finally, there are significant quality benefits of a single system to ensure the integrity and audit trails of multiple simultaneous sources of data, given the decentralized nature of many trials.

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.

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Please provide appropriate references (PubMed, Abstract, Website)

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