

The future of diabetes clinical trials



Continuous glucose monitoring (CGM) for diabetes management and research

Photography by Isy & Leigh Anderson and Alden Chadwick



Introduction

The latest technology in diabetes management – continuous glucose monitoring (CGM) – has been catching the attention of healthcare professionals, patients and big tech companies alike. The time has come for clinical researchers to start paying attention too, as the data that can be gathered using CGM has the potential to transform diabetes clinical trials.

In this article you'll find out how CGM is benefiting diabetes patients, and how it can now be used to deliver clinical trials that are simultaneously smaller and more powerful than ever before.

To summarise, using CGM for your diabetes trials could allow you to:

- Collect 288 blood glucose level readings every 24 hours, as opposed to the typical 6-8 readings you might get from SMBG testing.
- Access a wealth of data that also provides the context to understand exactly how your trial drug is affecting patients' health.
- Drastically improve patient compliance and reduce attrition from trials by making the process much easier for patients.
- Reduce data loss and human error by automatically collecting data through a digital receiver.

Continuous glucose monitors collect 288 blood glucose level readings every 24 hours.

What is continuous glucose monitoring?

An alternative to SMBG

CGM is an alternative to self-monitored blood glucose testing (SMBG); the traditional finger stick tests which take a measurement of blood glucose levels to help patients monitor and manage their diabetes.

Typically, patients meet with a GP at regular intervals, who tests their HbA1c level to provide a guide as to the patient's average glucose levels over the previous few months. The GP then sets a target HbA1c level to help the patient avoid hyper or hypoglycaemia.

Patients must do regular SMBG tests to ensure they can take action if blood glucose levels are too high or low at that moment in time.

A new era

CGM is different. Patients have a small sensor placed under the skin on their abdomen, which takes a glucose reading every five minutes and sends the data back to a receiver – giving 288 measurements every 24 hours. The receiver is about the size of a pager and can be attached to the patient's belt; or, in the most recent models, an app on the patient's iPhone or Apple Watch can act as the receiver.

HbA1c readings taken every few months allow doctors to give patients an approximation of their average glucose levels in the previous time period, while daily SMBG tests give patients a snapshot of their glucose levels at that moment. Patients must use this information to make decisions about insulin dosing, exercising and what they eat.

CGM, on the other hand, gives patients detailed, real time information about their glucose levels over the whole day, and most importantly, provides the context needed to make more informed decisions. Because patients can see whether their levels are going up, down or remaining stable, they're much better equipped to understand what their body needs at any given time. They can also identify patterns that could help them achieve greater stability in blood glucose levels in the future.



CGM has the potential to reduce long term health issues such as heart attacks and strokes.

Real time warnings to keep patients safer

The newest CGM devices can even send warnings when a patient is nearing hyper or hypoglycaemia – particularly useful for patients who experience hypoglycaemia unawareness.

One challenge with the newest Type 2 drugs is the risk of causing hypoglycaemia due to patients overcompensating for their hyperglycaemia, and taking too much insulin¹. A CGM unit featuring alarm based warnings can help patients choose the right dose and avoid this overcompensation.

Patients can also share their real time data with family, friends or carers and send alerts to them in the case of a developing emergency. For example, take the parents of a child with diabetes – with CGM, they no longer have to wake up their child in the night for SMBG tests. CGM offers peace of mind by letting them monitor their child's blood glucose levels through the night, so they needn't disturb their sleep unless some action is required.

Long term health benefits

It's even possible that longer term health issues such as heart attacks and strokes could be reduced for diabetes patients using CGM, as patients are armed with the information needed to help them battle ill-health more effectively². Using CGM may also help to reduce the number of glycaemic episodes a patient experiences, as it allows them to exercise better control over their blood glucose levels³.

What the FDA and EMA say

Following positive feedback from an FDA review panel in July 2016, both the EMA and FDA may soon be labelling CGM for use in place of SMBG testing to inform the administering of insulin doses⁴.

Previously, CGM measurements alone could not be used to manage insulin dosing. SMBG testing had to be carried out alongside CGM to confirm the validity of the data. This latest review in favour of CGM has been welcomed by manufacturers of the devices⁵; and it strongly confirms CGM as a future standard for diabetes care. From this point on, it becomes possible for CGM measurements to be used as the primary end point in diabetes clinical trials.

It's what the regulators want to see, it provides improved patient safety and it will help us to develop better diabetes treatments for the future.



What does CGM mean for clinical trials?

We've already discussed how CGM has the potential to help patients manage their diabetes more effectively. But how can the data available through CGM improve clinical trials to deliver better treatments?

Smaller, more powerful studies

CGM has the potential to let researchers design studies that are simultaneously smaller and more powerful than ever before. Because CGM units collect hundreds of data points per day, and the process is much less reliant on patients for recording data, researchers may be able to recruit fewer subjects for their trials, or run shorter trials, and still collect a significant amount of useful data.

Easier for patients

In a traditional clinical trial for diabetes, researchers may require subjects to carry out up to eight finger stick tests a day. This runs the risk of data loss and high attrition rates from trials due to patient compliance issues. With CGM, data is automatically collected by the receiver, reducing the risk of data loss and minimising the burden on patients.

More and better data

Perhaps the most exciting benefit of CGM for clinical trials is the sheer quantity and value of the data being recorded. Instead of relying on a small number of SMBG tests per day – which record a moment in time and only provide a maximum of around eight data points to compare per day – CGM provides researchers with 288 data points per day, including night time readings, allowing them to analyse the real time effects of the drug being tested.

Using CGM for your diabetes clinical trial

As we've said, the receivers for the latest CGM units include screens displaying visual feedback about how blood glucose levels are changing over the day. For the purposes of a clinical trial, devices must be blinded to ensure the data reflects the effects of the drug being tested, as opposed to changes in patient behaviour as a result of the information they can see on the screen. For this reason, it's essential to work with an equipment partner that can recommend the right unit for your study, and supply equipment configured, blinded and ready for immediate use.

As you might expect, there is a capital investment required to start using CGM for clinical trials. That investment can be partially offset by the potential to recruit fewer participants and run shorter studies, and the reduced risk of data loss due to patient compliance issues and volunteer attrition.

With the FDA and EMA now recommending CGM for diabetes management, clinical trial protocols should follow suit – taking advantage of CGM technology to run more insightful clinical trials that will speed effective drugs to the patients who need them.

Getting started

If you're convinced by the potential of CGM for diabetes clinical trials and you want to make sure your next trial takes advantage of this new technology, we recommend the following next steps:

- Speak to your biostatistician about how the data available through CGM could help meet your study goals more effectively.
- Investigate how CGM could positively impact patient recruitment for your study.
- Select an equipment partner that can support your trial from beginning to end – from reviewing your protocol to enable you to choose the right CGM devices, to providing pre-blinded and configured units, and then removing equipment at the end of the study and supporting you with equipment reporting.



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