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Hypo-METRICS case study

Innovative diabetes hypoglycemia study achieves high patient engagement and quality data volume with uMotif eCOA / ePRO platform

Hypo-METRICS study engaged patients – using uMotif's eCOA / ePRO platform along with continuous glucose monitoring (CGM) sensors – to capture high volumes of quality data and deliver valuable new insights into hypoglycaemic events.

Need: Expanded insight into the impact of hypoglycemia in people living with Type 1 and Type 2 Diabetes

Hypoglycemia, characterized by low levels of blood glucose, is a frequent complication of diabetes that can lead to cognitive impairment and serious cardiovascular outcomes. While a common event that can significantly affect a patient's quality of life, the real-world impact of 'hypos' on people living with diabetes remains poorly understood.

The Hypo-METRICS study is part of the Hypo-RESOLVE project [www.hypo-resolve.eu] funded through the EU - Innovative Medicines Initiative (IMI) and the study is led by King's College London. It is designed to capture Ecological Momentary Assessments (EMAs) using the innovative uMotif platform to understand the impact of symptomatic and asymptomatic low sensor detected hypoglycemia on clinical, patient-related, and health economic outcomes; including mood, quality of sleep, and productivity on people living with diabetes.

Researchers will use these data to optimize the current definition of hypoglycemia in the age of CGM.

The 10-week study – with 600 participants across nine sites in the United Kingdom, Austria, The Netherlands, and France – matched patient reported hypoglycemia recorded on the uMotif platform to episodes of sensor detected hypoglycemia captured by CGM to better reflect the persons living with diabetes' own experience.

Challenge: Accurate and timely symptom tracking

Historically, understanding the prevalence and effect of hypoglycemia events has been challenging due to the lack of proven, real-time and easy-to-use tools to measure the day-to-day occurrence and impact of symptoms. Though diabetes studies often track hypoglycemia incidence, typical monitoring approaches gather PRH information retrospectively – which impacts both data quantity and reliability. The Hypo-METRICS study used EMAs, which capture real-world data close to the time of an event. While EMAs can provide more accurate data for researchers, the need for frequent data capture can place a high burden on patients – potentially leading to lower levels of participation and higher levels of attrition. The Hypo-METRICS study team needed to ensure an easy, enjoyable and engaging EMAs data capture experience for patients.

Ecological Momentary Assessments

A method of collecting data in real-world environments ('ecological'), addressing a current or very recent state ('momentary'), measured either randomly, at specific times, or in relation to specific events, with multiple assessments, to follow variation over time and across situations.

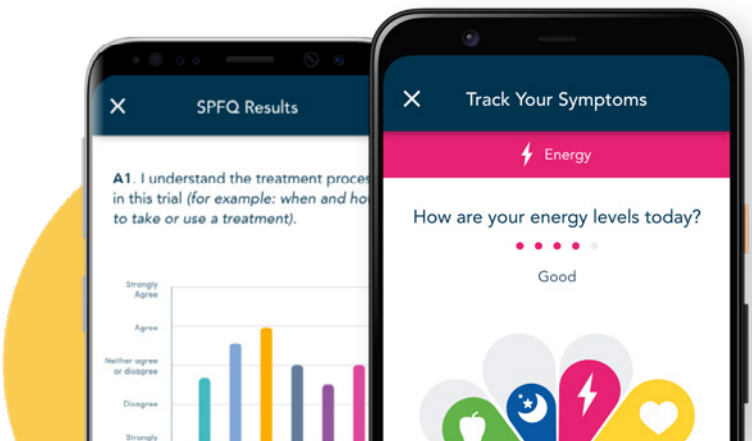
Why uMotif?

King's College London conducted an extensive search for a solution and chose uMotif based on its reputation for providing a highly engaging eCOA / ePRO application that can support high volumes of data, across multiple countries.

uMotif's demonstrated experience in achieving high rates of patient data capture, by bringing consumer-grade technology to the life sciences industry, was particularly important in the selection process.

Collaborative Approach

uMotif worked with the Hypo-METRICS team, and patient advocates, to design novel questionnaires in multiple languages – delivered through the uMotif eCOA / ePRO platform – to evaluate various hypoglycemia symptoms. The Hypo-METRICS app also tracks intensity levels of common hypo symptoms; including sweating, heart palpitations, shaking, hunger, confusion, headache, movement, coordination, and speaking difficulties.



Patients recorded all hypoglycaemic events at or near the time of occurrence using uMotif's unique data tracking interface (seen in Image 1). Every day, patients completed three subjective EMAs questionnaires and the EQ-5D-5L questionnaire.

Each week, patients also completed the Patient-Reported Outcomes Measurement Information System (PROMIS) and the Work Productivity and Activity Impairment Questionnaire (WPAI). In total, participants were asked to complete over 300 questionnaires over a 10-week period.

In addition to completing the subjective questionnaires, patients wore a blinded CGM device (the Freestyle Libre 2 provided by Abbott Diabetes) that continuously tracked participants' glucose ranges. Sleep data was collected using Fitbit Charge 4.

Impact: High data quality and volume, extremely low dropout and research innovation

High engagement:

- PRH was higher than in previously reported studies of diabetes, which attests to the benefit of real-time reporting
- Most study participants had >90% questionnaire compliance

Low attrition:

- Only 1% of people dropped out after the first week of the study
- Compelling onboarding engaged participants to continue in the study

Faster data capture: improves quality and drives new insights:

- Daily eCOA / ePRO questionnaires, captured alongside CGM data, drove new insights
- 250,000 total subjective data points were captured by study participants
- Linking subjective patient data captured via the app, with CGM data, yielded insight that can drive new discoveries about the relationship between CGM and PRH events

Research innovation:

- First-ever combination of PROs and CGM data at scale introduced a powerful new methodology to assess the impact of hypos

> **We needed an easy-to-use solution, that can be used across multiple countries, to manage a high volume of data capture – uMotif's platform provides the opportunity to engage our patients**

Professor Pratik Choudhary Project Lead, King's College London

Published Research

Investigating the day-to-day impact of hypoglycemia in adults with type 1 or type 2 diabetes: design and validation protocol of the Hypo-METRICS application. ***Source: BMJ Open***

Hypo-METRICS: Hypoglycemia—Measurement, Thresholds and Impacts—A multi-country clinical study to define the optimal threshold and duration of sensor-detected hypoglycemia that impact the experience of hypoglycemia, quality of life and health economic outcomes: The study protocol. ***Source: Diabetic Medicine***

Find out more about how uMotif can help drive unparalleled patient engagement and data capture in your next study.

Contact us