# Optimising eDiary Design for Diabetes Clinical Trials Using Real World Usage Data

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**Figure 1:** Distribution of days based on the number of measurements made on that day.

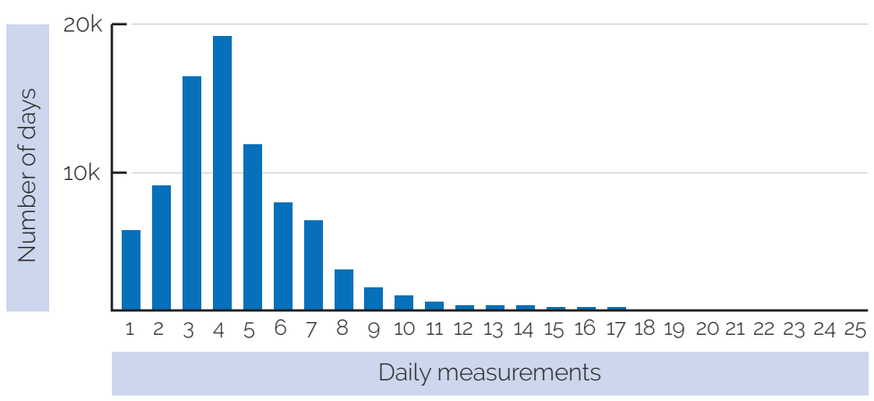



**Figure 2:** Most active study days for patients shown based on the number of measurements made on that day.

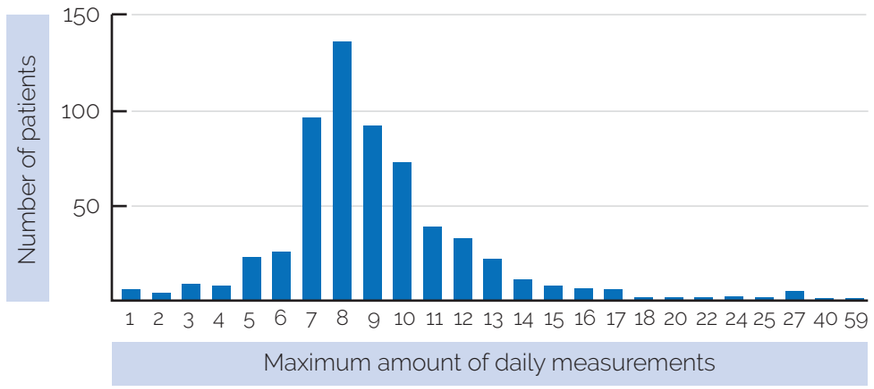
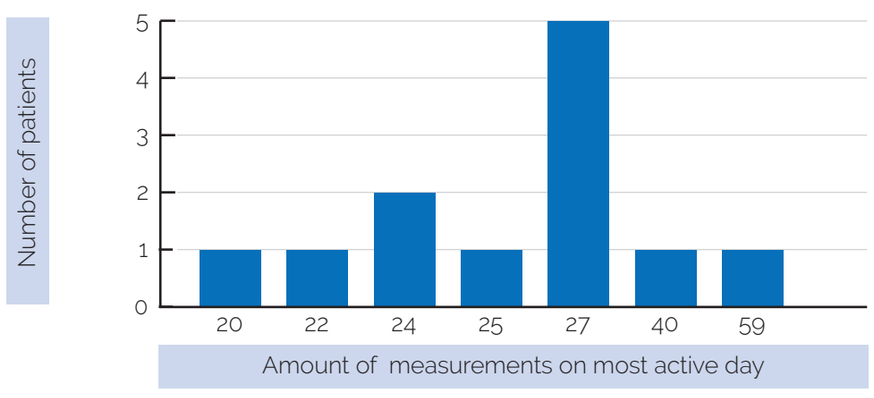



**Figure 3:** Patients who recorded 20 or more measurements on their most active day.




## Background and Aims:

It is expected that in 15 years diabetes will be in the top ten causes of death across the globe. Diabetes clinical trials often look to capture a vast amount of patient data including blood glucose measurements, nutritional value of meals and insulin intake. Historically paper collection of this data led to high patient burden and low patient compliance, something which electronic clinical outcome assessments (eCOA) have shown to improve. By studying real world usage data, we set out to optimise our eCOA design to enhance user experience and reduce burden. The purpose of the research was to find a reasonable estimate for the maximum amount of daily blood glucose measurements. This information could be used to refine both the user interface of our eCOA diary device and to minimise the software handling times during use.

## Methods:

In a typical clinical diabetes trial patients are asked to record their blood glucose levels several times a day and transfer them wirelessly via Bluetooth to a diary device collecting eCOAs. The number of measurements varies from one subject to another and from day to day. The software handling times of these measurements depend on the largest possible number of measurements recorded per day. Without knowing the actual limits to the number of measurements, the largest number must be assumed to be high, thus leading to a sub-optimal solution. Our TrialMax® platform was used in a global diabetes study to gather eCOA data. We collected real time blood glucose measurements from 613 individual subjects participating in the study, which gave us a good statistical sample of the behaviour of the subjects. We were then able to analyse distributions of the amount of blood glucose measurements over time and gain knowledge of the typical patterns in the data. First we explored how many blood glucose measurements were reported by patients per day on average. By doing so, we learned that there was significant variation on the number of reported measurements between patients and also between days for the same patient. We then plotted out what was the maximum number of blood glucose measurements a patient had reported on a single day. Looking at the distribution of these values we could then choose an approximate value for the maximum number of daily blood glucose readings and handle the outlier cases separately.

## Results:

On average around 4 measurements a day were recorded by the patients (Fig 1). The day during which each patient recorded the most measurements was considered the patient's most active day. Most patients recorded 7 to 10 measurements on their most active day (Fig 2). Only 12 patients out of the total of 613 patients had recorded more than 20 measurements on their most active day. It is noteworthy that a single outlier had recorded 59 measurements within a single day. (Fig 3)

## Conclusions:

The information that the vast majority of diabetes patients in clinical trials never record more than 20 measurements during one day was enough to optimise the software for the majority of users and handle the outlier cases separately. The usability of the solution didn't need to be sacrificed because of a very small group of users while still being able to take the outliers into account. By analysing real world data, more optimised eCOA solutions can be developed to improve the patient experience.

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