Our Most Frequently Asked Question

Is it "Real Time"?

The most frequently asked question we get is "Can you do real-time compliance monitoring?" The simple answer is "yes, but… do you really need it?"

What is Real Time Monitoring?

The term "real-time monitoring" has become a catchphrase without a definitive meaning behind it. Within the context of compliance monitoring, the term must be defined before being able to truly assess the necessity and extent to which "real time" should be happening. There are two aspects of real time:

- the frequency with which the built-in electronic tag checks to see if medication has been removed from the blister package or vial
- the frequency with which the dosage removal data are uploaded from the package to the Med-ic® cloud

Med-ic® and eCAP™ have a built-in electronic tag which "wakes up" and polls the package for medication removal events at regular intervals. The tag polls every 4 seconds. Events are recorded to the nearest minute.

As the following paragraphs show, there is no way a patient can be actively connected without additional devices in their hands or on their desktop. The closest one could come to "real time" data connection is using a GSM subscription separate from any existing data subscription which the patient might already have on their mobile device. This involves a rather expensive and bulky module on the package which would require regular (daily/weekly) battery recharging. Instructing patients to keep their package in range of a mobile connection and recharge the battery regularly is usually not a core competency of clinical study support teams.

How is Compliance Data Collected?

Compliance data about the patient dose taking intervals are stored on the package's electronic tag and those events are then downloaded to a secure cloud using a computer, smartphone, tablet, or other reading device.

- For blister packaged medication, this might involve a standard NFC equipped personal device or reader, which would be done on an intermittent or as-required basis by the patient or caregiver by tapping the package to their handheld device.
- In other cases, where vials are equipped with our CoolBlue™ BlueTooth communications technology, such updates can be sent on an automated basis whenever the package is in proximity with a paired device.

Once event data has been uploaded to the Med-ic cloud, this event history can then be analyzed and displayed on any authorized device or computer. The data can also be used to trigger notifications or interventions. The granularity of this aspect of real-time is determined by the intervals at which the data are downloaded from the tag.

In clinical trials, Med-ic packages are typically scanned at the time the patient visits with the Clinical Research Monitor and the data are uploaded, displayed graphically and used to coach the patient their adherence. In most cases, a granularity of one, two, even four weeks or more is sufficient for the purposes of the study. Although the tag "wakes up" every 4 seconds to see if any medication has been taken, the data become available only at the follow-up visit. Of course, where a patient might have an NFC device, the package data can be uploaded more frequently by prompting the patient to do so between visits to the study center.

If more frequent monitoring of the patient's medication-taking behavior is required, we can pair any of our CoolBlue™ equipped eCAPs to a Bluetooth LE device, which in turn would be connected via WIFI or mobile data connection and download tag data automatically. It is likely that the intervals are not regularly close to "real-time", even with automated BlueTooth pairing and WIFI or GSM (mobile phone) connection, because there is no guarantee that the package is always in proximity with the paired smart phone, for instance. It would be quite a challenge to then determine if a dose was missed or a device connection failed.

What Does Real Time Monitoring Try to Address?

Compliance data are used for coaching and patient management. It is widely accepted that targeted education is more effective than broad stroke education in bringing about behavioural changes. For example, sending an SMS reminder to subjects who have been identified as being non-compliant is more effective than sending SMS reminders routinely to everyone. A weekly or biweekly review of actual adherence data and focusing patient support on an identifiable basis makes more sense, both financially and ethically, than "real-time" monitoring of all subjects all of the time.

In compliance monitoring it is important to remember that we are concerned with non-compliant subjects or patients. We also know that most non-compliance is not deliberate. It follows that anything we do to increase the demands on the patient will exacerbate the situation. For that reason, we prefer Med-ic and eCAP in their simplest form, passively collecting dose taking event data all of the time, but transferring or downloading this event history on an as needed or when-available basis only.

It's not as though a clinician or nurse would be staffing a computer screen awaiting a missed dose from the patient, and even if there were such staffed monitoring center, it wouldn't be reasonable to assume that the patient could be reached at all times to do something about an *allegedly* missed dose.

With our adherence devices, the patient doesn't have to do anything other than take their medication in the usual way and the patient doesn't need any technical expertise, or additional devices. To the patient, the package is indistinguishable from and feels like a regular blister package or medication vial.

The data stored on our packages are indeed collected "real time", and are available for analysis and follow up on as regular a basis as desired or required. But not at the high cost of technological implementations, uncertain data connections, or inconvenience and probably erroneous interventions.