

HOW CONTEXT & CONNECTIVITY CONTRIBUTE TO A FULL PICTURE OF HEALTH

In this article, Erika Vazquez, Marketing Associate, MC10, shows how recent technological advances make it possible to gather detailed contextual data about patients and gain true insights into whether their treatments are genuinely improving their quality of life, using examples of recent industry collaborations to highlight how pharma companies are already moving rapidly in this direction.

In a study evaluating the effectiveness of a drug designed to control heart rate, monitoring a subject's pulse over a period of time will undoubtedly help answer the primary question: is the drug effective at controlling the patient's heart rate?

While the answer to that primary question may be yes, researchers must consider what else happened while the patient was being treated with the drug. Perhaps the subject's heart rate was well controlled, but the subject became more sedentary and less active. Or perhaps the subject experienced increased restlessness during sleep. The heart rate might be controlled, but that doesn't mean the treatment is successful. Without the surrounding contextual data, comprehension of a subject's response to treatment is incomplete.

As the US healthcare system becomes increasingly outcomes based and accountable, evaluating therapeutic efficacy requires researchers to consider the bigger picture of a subject's health. In the past, the data available to a physician was limited to the information that could be gathered through a patient history, physical exam, and lab tests. An evaluation of health was limited to a snapshot of one tiny moment in time. For example, a cardiogram takes six seconds to acquire, but there are 86,400 seconds in a day.

Today's technology provides the opportunity to examine those other 85,394 seconds to find the problem. With the help of wearables and novel data-capture tools, we can now look at efficacy over time as we observe the

patient in their daily life (Figure 1). These healthcare data collection devices provide a much more accurate and complete assessment of compliance and medication efficacy. The modern day ability to look at a patient's data within the context of their own natural habitat, for example their work, school or home settings, provides a level of validity that simply is not attainable in the artificial environment of the doctor's office.

From academia to pharma, wearables are providing robust physiological data to reach study conclusions. As Validic (Durham, NC, US), a provider of digital health data analysis solutions, points out, activity and sleep data collected by wearables¹ can help trial sponsors to "uncover important patterns such as a participant being less active on days that a medication dose is missed or a participant sleeping more after taking the medication, indicating drowsiness as a possible side effect". This contextual data also serves as a "useful indicator of behavioural health, providing researchers with a more objective means to understand how a participant may be feeling while taking a drug".

In Pfizer and IBM's Project Blue Sky Initiative to study Parkinson's disease progression with wearables,² multiple metrics matter. "IBM and Pfizer aim to get a more holistic view of the patient by measuring a number of health metrics, including motor function, dyskinesia, cognition, sleep, and various daily activities," MobiHealth News reported.

Ms Erika Vázquez
Marketing Associate
E: evazquez@mc10inc.com

MC10, Inc
10 Maguire Rd
Building 3, 1st Floor
Lexington
MA 02421
United States

www.mc10inc.com

"A cardiogram takes six seconds to acquire, but there are 86,400 seconds in a day. Today's technology provides the opportunity to examine those other 85,394 seconds."

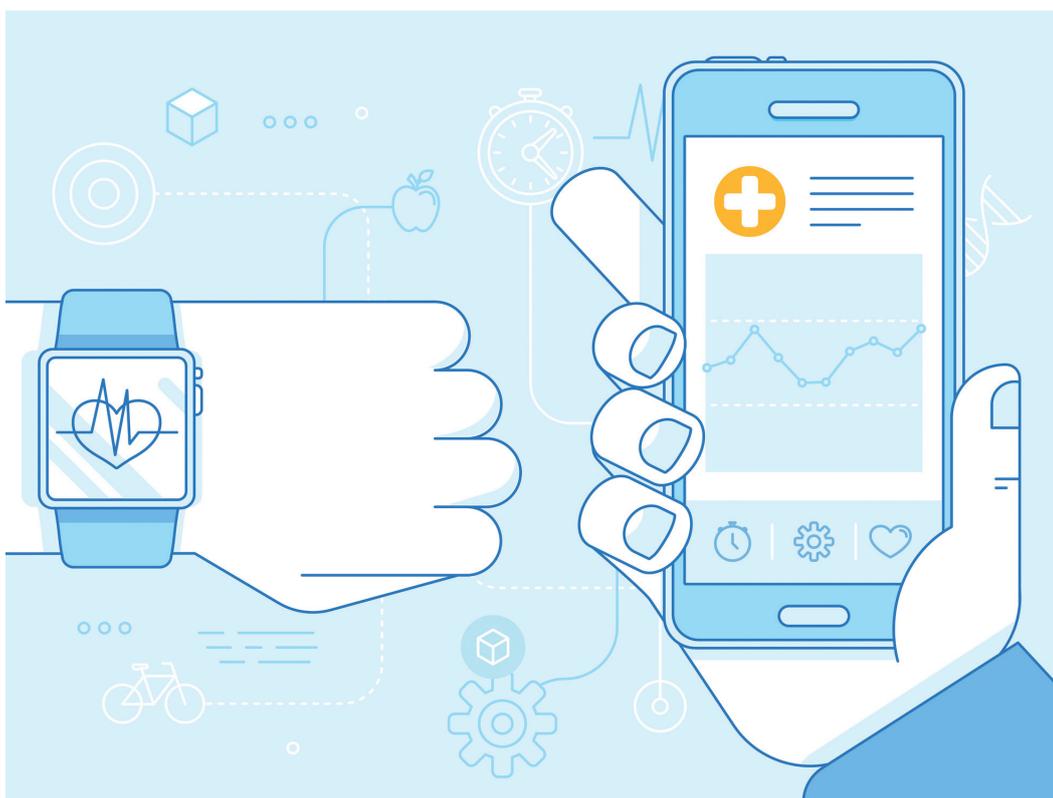


Figure 1: With the help of wearables and novel data capture tools, we can now look at efficacy over time as we observe the patient in their daily life.

“Activity and sleep data collected by wearables can help trial sponsors to “uncover important patterns such as a participant being less active on days that a medication dose is missed or a participant sleeping more after taking the medication, indicating drowsiness as a possible side effect.”

When mobile apps and wearables are used as complementary tools in research studies, the full potential of connectivity and context becomes attainable. Apps encourage compliance through reminders and can easily collect subjective data from study participants, providing the context to understand fully the targeted and accurate physiological data wearables capture.

Oklahoma State University (Stillwater, OK, US) researchers evaluated the feasibility of a novel methodology for

assessing “physiology, behaviour, and psychosocial variables”. The study used two objective sensors (a BioHarness (Zephyr, Annapolis, MD, US) and a wActiSleep-BT monitor (ActiGraph, Pensacola, FL, US)) and a mobile app to monitor each subject’s daily routine over a 20-day period.³ The results suggested that wearable sensors combined with ecological momentary assessment technologies (in this case, app questionnaires) are capable data-generating tools for developing “dynamical systems models of high value health behaviours such as sedentary activity, moderate to vigorous physical activity, sleep, and diet”. Additionally, results indicated that “a wearable sensor holds promise for linking subjective feeling states with physiological data and has the potential for informing intervention development”.

Takeda USA (Deerfield, IL, US) and Cognition Kit (a joint-venture between Cambridge Cognition (Cambridge, UK) and Ctrl Group (London, UK) are “collaborating on a study to assess whether mobile apps and wearables with continuous monitoring capabilities can be used to glean new insights into major depressive disorder⁴ that could drive better treatment.”

The Cognition Kit app collects physiological data and evaluates cognition. MobiHealth News explained that the study aimed to “use continuous monitoring to catch under-recognised symptoms of major depressive disorder, thereby providing a more holistic view of the user’s mental health”.

For GlaxoSmithKline’s clinical trial leveraging Apple’s ResearchKit to study rheumatoid arthritis,⁵ the company focused on “asking patients the right questions”. GSK Chief Medical Officer Murray Stewart told Clinical Leader, “Carrying that a step further, we also know rheumatoid arthritis patients can be prone to suffer from depression. Designing questions that deal with depression can also be recorded on the app and allow researchers to better understand the patients and data. This will help

researchers to get a more holistic view of the health of a patient.”

By utilising mobile technology and wearables, researchers gain a comprehensive overview of subjective and objective data that was previously unattainable. Success is no longer measured by assessing if drugs and procedures do what they are supposed to, but by measuring whether or not the patient is better for it. Evaluating contextual data helps to measure therapy success through the lens of quality of life.

This article is based on the author’s March 2017 blog item “The Value of Contextual Data in Health Monitoring”.

REFERENCES

1. Plumer J, “Wearables in clinical trials: it’s about correlation and context”. *MobiHealthNews*, October 10, 2016.
2. Pai A, “Pfizer, IBM partner to create wearable sensors system to study disease progression in people with Parkinson’s”. *MobiHealthNews*, April 7, 2016.
3. Brannon E et al, “The Promise of Wearable Sensors and Ecological

Momentary Assessment Measures for Dynamical Systems Modeling in Adolescents: a Feasibility and Acceptability Study". *Transl Behav Med*, 2016, Vol 6(4), pp 558-565.

4. Mack H, "Takeda and Cognition Kit partner for Apple Watch-based study on depression". *MobiHealthNews*, February 27, 2017.
5. Miseta E, "GSK Uses Apple ResearchKit in Rheumatoid Study". *Clinical Leader*, February 21, 2017.

"Success is no longer measured by assessing if drugs and procedures do what they are supposed to, but by measuring whether or not the patient is better for it. Evaluating contextual data helps to measure therapy success through the lens of quality of life."

ABOUT THE COMPANY

MC10 is a private company, backed by a syndicate of financial and strategic investors, that is improving human health through digital healthcare solutions. The company combines its proprietary ultra-thin, flexible body-worn sensors with advanced analytics to unlock health insights from physiological data.

MC10 has received widespread recognition for its revolutionary technology and was recently named in Fast Company's Most Innovative Companies in 2016 as a leader in healthcare.

ABOUT THE AUTHOR

Erika Vázquez joined the MC10 team after graduating from Tufts University (Medford, MA, US). She shares the company's vision of rethinking the boundaries of technology to help improve human health and our understanding of the body.



2017/18 EDITORIAL CALENDAR

Download the
2017/18 Media Pack
for more information!

Publication Month	Issue Topic	Materials Deadline
July 2017	Novel Oral Delivery Systems	DEADLINE PASSED
Sept 2017	Wearable Injectors	July 24th
Oct 2017	Prefilled Syringes	Aug 21st
Nov 2017	Pulmonary & Nasal Drug Delivery	Sept 25th
Jan 2018	Ophthalmic Drug Delivery	Nov 20th
Feb 2018	Prefilled Syringes	Dec 22nd
Mar 2018	Skin Drug Delivery: Dermal, Transdermal Microneedles	Jan 20th
Apr 2018	Pulmonary & Nasal Drug Delivery	Feb 19th
May 2018	Injectable Drug Delivery: Devices Focus	Mar 19th
June 2018	Connecting Drug Delivery	April 23rd
July 2018	Novel Oral Delivery Systems	May 21st