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With Covid-19 halting clinical trials, wearables could be key — but data 'wild west' gets in the way

By Jordan Brayanov, Jen Goldsack, *and* Bill Byrom Aug. 11, 2020

With better data standards, clinical trials could more easily use home health devices like pulse oximeters. *Adobe*

The biotech and pharma industries are at a pivotal moment, facing a pandemic that's caused three out of every four clinical trials worldwide to be suspended or delayed[2]. At the same time that hundreds of companies are racing to move forward with trials for Covid-19 treatments and vaccines, thousands more are worrying about how they'll be able to conduct other trials[3] in the midst of a global lockdown.

This is bad for business, and far worse for the patients afflicted by diseases and conditions whose drug trials have been sidelined for months.

Some companies are exploring remote clinical trials that rely on participants using digital devices like smartwatches and pulse oximeters at home. The approach makes sense, but there's a major issue with it: Health tech is the modern equivalent of the wild west. Both the technologies and the data they collect are wildly inconsistent across platforms.

To overcome this, pharmaceutical and technology companies must develop and adopt common standards, create new protocols, and, most importantly, do something they tend to avoid: work together.

When competing companies band together to rally behind technology standards, they can achieve big things. In 1998, five of the world's biggest telecom providers established an interest group for a new communications protocol called "Bluetooth."[5] Today, the consortium has grown to more than 36,000 companies[6] and is the reason that Bluetooth now works on virtually every computer and smartphone on the planet.

The Bluetooth group found success because it had market share — as do the biotech, pharma, and tech industries. By setting aside our competitive instincts and coming together to embrace standard protocols, we could ensure that patients have access to clinical trials and encourage Silicon Valley to come to the table as collaborators.

Even before Covid-19, the challenges to leveraging digital technologies in medical product development seemed insurmountable in an industry plagued by sluggish patient recruitment, protracted timelines, and low success rates. The promise of a new era of decentralized trials has taunted the industry since Pfizer first tried them out[7] nearly a decade ago. But now that millions of consumers use fitness trackers and smartphones, and many trial participants have had positive experiences with telehealth during the pandemic, the clarion call to digitize clinical trials may finally be heard.

That said, challenges remain in scaling remote trials.

A top priority for standardization efforts should be to create mechanisms for seamless data and information exchange across hardware and software tools. Take a measurement like heart rate. You'd think that monitoring heart rate remotely would be easy. But wearables from technology giants like Apple and Samsung measure it in different and proprietary ways. One device may record the number of beats over 10 seconds and multiply by six; another may communicate an "instant" heart rate reported after every single heartbeat. This means the two platforms' data aren't consistent and so can't easily be used simultaneously in clinical trials.

Such incompatibilities happen all over the industry, even with tools being used to contain Covid-19. TempTraq[8] and Vivalink[9] both have FDA-cleared wireless patches for remotely monitoring body temperature, but because the data output for the two devices is completely different, they can't both be readily used in a clinical trial, in clinical care, or even as part of aggregated public health data without adding additional layers of software. The same challenges are inhibiting global efforts[10] to combat Covid-19 using a wearable electrocardiogram that connects to a smartphone.

Pivotal trials of new medical products — the phase of research that provides the final evidence of safety and efficacy — typically take three years[12]. There are currently few guarantees to trial sponsors that software updates will be done in ways that the data

output at the end of a trial is equivalent to the data output at the beginning of it. This is inhibiting the use of high-performing, low-cost, user-friendly commercial technologies, despite studies showing that they can be as accurate as wearables designed for research[13]. This challenge also makes it impossible for clinical trials to take a "bring your own device" approach.

Hand-wringing over the lack of common standards often leads to nothing more than another new standard[14]. That's not our intent here. We offer an opportunity for the biotech, pharma, and tech sectors to come together and leverage their collective purchasing power to establish the bare minimum requirements for specific measurements to be embraced for research at scale. For example, if a technology claims to provide "continuous heart rate monitoring," at the very least it must provide one heart rate measurement every minute. If the device claims to provide an electrocardiogram, then it must deliver the raw output from the ECG tracing. This would build on the digital health standards work of organizations such as HL7[15], IEEE[16], ISO[17], the Consumer Technology Association[18], Open mHealth[19], and Continua[20].

Many key players in the life sciences have already signed on[21] for what we're proposing. But this kind of effort needs more collaboration, in the same way that happened with Bluetooth. The entry of several of the biggest names in technology — Ericsson, IBM, Intel, Nokia, and Toshiba — helped rope in 3Com, Lucent, Microsoft, and Motorola[22], creating a tipping point that spurred thousands of other organizations to join.

While it's understandable that Covid-19 is the world's top concern right now, the focus of efforts in its direction has downstream effects, particularly on diseases like Alzheimer's that are still so far from a cure. By adopting digital standards, important clinical trials can continue remotely for Covid-19 as well as a host of other health conditions.

Consider the possibilities if the $1.2 trillion global pharma industry[23] could come together in the same way to make it as easy for people to use home-health technologies as it is to connect a phone to a speaker.

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