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# Quest for a new measure of mental health

Novartis researchers are searching for more effective ways to discover drugs for neurological and psychiatric diseases.

By Elizabeth Dougherty | Jul 30, 2018

There's no blood or spinal fluid test for depression, schizophrenia or bipolar disorder. Rather, these disorders are evaluated the old-fashioned way: using pencil and paper.

For over half a century, questionnaires have been used to assess the mental state of patients. But it isn't just the diagnostic tools that have stagnated. Medicines for neuropsychiatric disorders haven't changed much either. In fact, the field of neuroscience has the worst track record in pharma when it comes to turning new drug leads in the research lab into medicines that improve patients' lives.

It may be that these outdated measurement tools are contributing to the slow progress of neuroscience therapeutics. "Questionnaires aren't sensitive enough or reliable enough to measure changes in response to an experimental drug, so they may let ineffective drugs through the clinical evaluation process or rule promising therapeutics out," says Jang-Ho Cha, Global Head of Translational Medicine for Neuroscience at the Novartis Institutes for BioMedical Research. "If we had a better detector, it might change the game."

So Novartis researchers are tapping into a stream of emerging digital measurement tools for neuroscience to see if any of them improve upon the gold-standard written questionnaire. Their hope is that more sensitive and reliable measurement tools will weed out ineffective drugs as early as possible in the drug discovery process, when trials are small and patients are few. At a time when many pharmaceutical companies have dropped their neuroscience research and drug discovery programs, Novartis is moving full steam ahead and has taken on the task of modernizing early-stage clinical trials using digital technologies.

"There's nothing in your life that you still use from the 1960s," says Cha. "Yet we're using these outdated tools to navigate clinical trials that cost tens of millions of dollars to run. We can do better."

The first step for Novartis will be to run a clinical trial that does not involve any experimental drugs. Rather, it will test a set of novel digital measurement tools against the standard questionnaire for major depressive disorder. Any of the new digital tools that provide assessments as good as or better than the questionnaire will be considered to evaluate patients in future trials to test experimental drugs for depression.

"We want to know how these digital technologies stack up against the gold standard. Some will be worse. Some will be hard to use. We'll let those go," says Cha. "But others may be better. We want to use those in our trials."

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>
> **Jang-Ho Cha**, Global Head of Translational Medicine for Neuroscience

## Measurement matters

Doctors use the MADRS (Montgomery-Asberg Depression Rating Scale) questionnaire to assess a patient's depression on a scale of 0 to 60. Once a month, the doctor and patient meet. The doctor asks the patient a series of questions – a bit like the quizzes found in magazines and on social media sites that assess a person's stress level or personality type, though backed with more clinical muscle. The patient answers with self-assessments of his or her symptoms such as sadness, sleep quality and negative thoughts while the doctor assesses the patient's demeanor.

Digital tools take a different approach. Rather than relying on the doctor's impressions and patient's reflections at that moment, they objectively and frequently measure some aspect of the patient's behavior, such as speech patterns, social interactions or facial expressions.

Some measure passively, such as the tool that measures social interaction. Over time, it tracks the patient's social activity, drawing on email and social media exchanges as well as tracking the patient's movements using GPS. Steps are taken to protect the patient's anonymity and privacy.

Others take measurements periodically, such as tools that record and analyze speech and facial expressions. These tools are based on research that has shown that certain vowels or syllables may be elongated during depression and that subtle facial expressions, such as the slight turn-down of the lips or eyes, are also more common during depression.

What these tools have in common is that they are backed by machine learning algorithms trained to analyze the social behaviors, facial features and voices of both depressed and healthy individuals. Machine learning algorithms are a form of artificial intelligence that can detect subtle differences in photos, video, audio and GPS data that might escape the notice of a clinician, not only because the cues may be slight, but also because machines are rarely distracted by other concerns.

What the machines have in common with clinicians, however, is the ability to internalize profiles of patients. Over years, doctors build up an intuition about depression. Machines do the same – only much faster – and they also create even more precise categories, in part because the data they rely on can be collected continuously or daily, with minimal effort on the part of the patient. As a result, the machine's assessments could more reliably reveal how a patient is responding to a new therapy.

## Track records

To determine exactly how reliable these tools are in clinical trials, they need to be tested. "We need to see if these devices work in a clinical setting and to find out if patients are OK with using them," says Kristin Hannesdottir, an expert at NIBR in neuroscience disease measurement who will run the trial.

The Novartis research team plans to run a head-to-head test of these digital tools alongside the MADRS questionnaire. They will recruit a small number of people who are not depressed as well as people with major depressive disorder to participate in a trial that will determine if these tools are as good as or better than MADRS at detecting and assessing levels of depression.

The trial will provide guidance to clinical researchers both in and outside Novartis about which digital technologies could potentially be used in future trials of novel drugs for depression. "A patient's reality cannot be assessed during a 15-minute visit to the clinic. We are looking for a battery of measures that are more precise, less subjective, and that provide data that enables us to gather meaningful insights at numerous touchpoints during the patient's day," says Danny Bar-Zohar, who as Global Head of Neuroscience Development in Global Drug Development at Novartis tests leads from mid-stage clinical research in late-stage clinical trials. "Once you have more reliable data points to work with, then you have a more informative

analysis of your early-stage clinical data and can make more tailored drug development decisions.”

*Main image: Stock photo by wigglestick/Adobe. Adapted by PJ Kaszas.*

Novartis researchers are testing digital measurement tools that could improve #neuroscience #drugdevelopment.

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