COVID-19 As Catalyst for Precision Medicine/Digital Therapeutics

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Almost overnight businesses across the globe had to rethink their operations, as COVID-19 caused profound disruption; across communities, how we engage, the way we work, our healthcare systems, our economy… The rapidly changing environment has been a catalyst for change as it transformed the global health community's acceptance and use of digital health technologies, such as telemedicine, triage solutions and digital therapeutics (DTx).

Technological innovations are making it easier than ever to get a variety of health information. Digital health adoption is fuelled by communication and collaboration between regulators, companies, researchers, hospitals, patient organisations, etc. in order to break down silos between research and care.

Patients across the world are more empowered than ever to engage in their health and wellbeing. Digital therapeutics is one of the emerging fields in digital health, that is able to fulfil the unmet need for patient-centred care. It has the potential to bring personalised care to everyone.

Patient access to DTx could improve health outcomes, reducing chronic disease related hospitalisations, mitigating additional pressures on healthcare providers during the COVID-19 outbreak, and reducing vulnerable populations' potential coronavirus exposure. The ultimate goal is to integrate DTx into current healthcare infrastructure and individual lifestyles.

The DTx sector as a whole remains still in early development stages as just a handful of solutions have compelling clinical and economic evidence and FDA clearance. Due to the current public health emergency, the FDA issued [a guidance](#) in April. It provides a policy that helps to expand the availability of digital health therapeutic devices for psychiatric disorders to facilitate consumer and patient use while reducing user and healthcare provider contact and potential exposure to COVID-19 during the pandemic.

[Several researchers](#) assume that the outbreak is unlikely to impact the significant commercial barriers that are the main impediment to broader use of DTx:

- distinguishing DTx from more general health and wellbeing applications
- digital inequality
- regulatory preparedness as only DT initiatives entail regulatory approval
- incentivisation and affordability: DT companies need to find ways of working in healthcare ecosystem to align incentives between pharmaceutical companies, beneficiaries and healthcare providers
- education and technology adjustment for the patients to DT when issues of adherence and compliance are widespread in conventional therapeutics
- to promote the development of research programme for DT, it is necessary to offer incentives to researchers for addressing unmet medical needs.

DTx companies, focussed on providing mental health solutions, can apply their existing models to help in COVID-19 detection and monitoring, as they are often software application-based solutions, with multivariate models built into an artificial intelligence (AI) and wearable sensors that allow to measure vital parameters, such as heart rate, body temperature and oxygen saturation.

Measuring these vital parameters allows AI models to predict the infection and can be used to monitor how the disease and the patient health evolves.

Creating new health models by using design of experiment to determine the vital parameters helps us to better understand the disease and its progression and thereby decrease the patient risk.

Furthermore, new COVID-19 health models can be bridged with existing DTx models. The purpose of this integration is to monitor the psychological health of the infected patient. We have found that mental support can help patients coping with the stress of being infected with the virus.

There is a huge challenge to develop this integrated model as there is an overlap in vital signs for COVID-19 and mental health. Adding new parameters, such as blood pressure and sleeping patterns, may facilitate the development of a psychological target profile to understand the source of change in vital parameters. Additionally, a control model can be developed to monitor the healing process of the patient.

All the data that are gathered from the sensors and the associated models can provide us with an in-depth insight in the recovery of the patient's mental health.

Due to the current pandemic, the mental healthcare is being put under severe pressure as we are seeing a spike in people who report struggling with their mental health. For example, a major impact of COVID-19 is the isolation of patients, which results in experiencing the feeling of loneliness and therefore impacts the mental health of the patient. Loneliness can be measured by the sum of all vital parameters and general motion data, but measuring does not suffice to tackle the issue. A DTx company is currently developing a model that copes with loneliness. They are well aware that loneliness cannot be solved by using chatbots or other automated solutions. They have therefore set up a collaboration with an organisation to provide them with support through their team of psychologists.

Through their application they monitor the mental health of patients and when a threshold is reached, one of the psychologists reaches out to the patient and has a therapeutic talk with them. There is nothing as effective as a good human talk.

The recent unprecedented times have shown us that data are paramount. However, one of the biggest limitations is the quality of data, including their meta-data. With advances in technology, there are many tools that organisations can use to improve data quality. Depending on the needs and preferences of the organisations, the choice of technology is made, e.g. cloud-based versus on-premise, compatibility with different sources, integration with other platforms, complexity of data sets, etc.

DTx companies could give pharma companies access to data from millions of patients, during clinical development phases and even when the product has already hit the market, thus generating the unprecedented data flux. It is particularly important for fields with a high volume of good-quality data, which could benefit from AI-enabled platforms provided by DTx companies.

We believe that the way forward is a combination of digital and personalised therapy allowing to heal the patient in the most comfortable way.

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