One step closer: digital readouts of walking as a measure of health

Mobilise-D's letter of support from the EMA is not only a nod to the promise of their research – it shows how important it is to connect with regulators early

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Reduced walking speed is a sign of many health conditions. The Mobilise-D project wants to make continuous digital measurements of the way a person walks, gathered using wearable sensor technology, accepted as valid indicators of their state of health, much in the same way as blood pressure readings or oxygen levels are. This undertaking is probably the most comprehensive and ambitious work in this busy and fast-moving field. That's why there's a lot of interest in the recent news that the project has received an early public nod of support for their working methods and plans from the European regulator, the European Medicines Agency (EMA).

The use of wearable sensor technology to monitor how a person walks is more objective and reliable than, say, self-reporting or snap-shot observations made during clinic visits. It holds a lot of promise in particular for clinical trials, and while digital technologies like smartphones and wearables are increasingly used in drug development, it's early days yet. We don't yet know how

well these digital mobility measurements can predict bad clinical outcomes like falls, hospitalisations, deaths, loss of independence, and worsening disease status. As such, very few digital mobility outcomes have been 'qualified' for use as a mobility performance biomarker in regulatory drug trials.

Mobilise-D's mission is to get these digital mobility outcomes, or DMOs, 'qualified' to be used as biomarkers in clinical trials. It's an ambitious goal and they are using five different diseases as test cases (**read more about project**). The letter of support – an intermediary sign of encouragement from the EMA on the way to full qualification - is important because it demonstrates not only the promise of the innovation, but also how important it is to build rapport with the regulating authorities early, something IMI encourages in all our funded research.

Support, qualification, authorisation

The regulator doesn't only recommend marketing authorisation for medicines – they also facilitate and support their development, for instance relating to the way clinical trials are run, establishing what 'qualifies' as acceptable clinical endpoints (outcomes like disease, symptoms or signs), new imaging methods, or new methods of doing things - like measuring mobility using devices and apps (read more about the EMA'S qualification process).

Before full qualification, a letter of support may be issued, meaning the EMA considers the data not yet sufficient for qualification but the novel methodology is promising and has potential value.

When the EMA does qualify one of these things, it means they consider them acceptable to be used in medicines development, and that anyone else can use this qualified method under the same defined condition (so-called 'context of use') without having to go through the process of re-demonstrating its validity all over again.

Proceed confidently with their work

To increase their chances of getting their results accepted and their methods qualified, IMI encourages our research projects to interact early using the opportunity offered by the qualification advice procedure, in order to find out what kind of data the regulator needs and expects. At the very start of Mobilise-D, the consortium made a strategic plan on how to get regulatory acceptance for DMOs. They decided to interact with the EMA very early on by submitting a request for qualification advice, and to take an incremental approach, starting with qualification advice of monitoring biomarkers in Parkinson's disease.

Early interactions with regulators are particularly valuable in young and evolving fields like digital health technologies, where the regulatory framework is still under development and many things are still uncertain. The consortium's step-by-step approach is also critical for maximising the chances of success, because it allows them to refine their plans as they gain more knowledge. With this positive feedback, Mobilise-D can progress confidently with their work.

The letter of support is beneficial beyond the bounds of the project: others in the scientific community, as well as pharmaceutical companies, can use the feedback to help them develop their own regulatory strategies around the use of digital health technologies. These letters include a high-level summary of the novel methodology, context of use, available data and ongoing and future investigations, and they can also enhance the visibility of the methodology, encourage data sharing and stimulate other studies.

As debates about regulatory approval for these new technologies are ongoing, Mobilise-D have set up a discussion channel on Slack called #dHealth4Trials to help these discussions along. Request to join here http://www.insilico.world/digitaltechnologies/

Read more

Publication: Toward a Regulatory Qualification of Real-World Mobility Performance Biomarkers in PD Patients Using DMOs

Regulators need solid evidence that new technologies are reliable. IMI can provide it

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