PEER REVIEWED

IMI Mobilise-D: The Next Generation of Mobility Research

Mobility represents an important marker of health, and a slow walking speed is associated with a greater risk of disease, cognitive decline, risk of falls and even earlier death. As the population ages, the number of people experiencing mobility issues is expected to rise. However, accurately assessing people's mobility, especially in the real world, is far from easy.

The Innovative Medicines Initiative (IMI) funded Mobilise-D project aims to develop a comprehensive system to analyse people's gait using digital technologies, including sensors worn on the body. The IMI is a public-private partnership aiming to speed up the development of better and safer medicines for patients. The project focuses on conditions that often affect mobility, namely chronic obstructive pulmonary disease, Parkinson's disease, multiple sclerosis, and hip fracture recovery. IMI Mobilise-D plans to work closely with regulators and other stakeholders to ensure that the solutions are accepted. Once validated, the IMI Mobilise-D results will help to improve the accurate assessment of mobility in clinical trials. They will also make it easier for clinicians to monitor patients' mobility and thereby contribute to improved, more personalised care.

IMI Mobilise-D is a five year public-private partnership launched in April 2019 with 34 consortium members consisting of a collaboration between leading universities, hospitals, pharmaceutical and technical companies. ICON is a consortium member of the IMI Mobilise-D project and is a co-lead on the data management workstream and an active member on the communications workstream, Project Executive committee and the Exploitation, Impact and Sustainability Committee.

ICON is also co-lead for Work Package 3, which is responsible for the design and implementation of the end-to-end data storage and management platform, as the principal aim of Work Package 3 is to provide a facility for managing and storing the data generated during Work Packages 2 and 4, which consist of the Technical and Clinical Validation Studies, respectively. ICON is also a significant contributor to Work Package 7, whose main goal is to drive public awareness of the project by disseminating, teaching, and spreading the outcomes and results of the project. To promote access and use of project results, Mobilise-D will create and implement procedures to make data, standards, and software openly accessible. To ensure sustainability after the life of the project, digital mobility assessment modules will be developed and released that will enable external researchers and industry to include real-world mobility assessment in future studies and trials.

Why is Mobility Important?

Walking is an important part of mobility, however almost a third of people over 75 have difficulties walking,[1] with severe societal and personal consequences. Mobility is also an important indicator of health and functional integrity. Even small changes in how we walk, such as how fast or how far, signal underlying problems or worsening health, and provide important insights into multiple health conditions. Additionally, living with long-term diseases further contribute to the burden of mobility loss.

Traditionally, mobility has been assessed through patient reported outcome measures (PROMS) or by testing them in a lab or clinic. These methods have provided physicians with important information about their patient's mobility; however, they have their limitations. PROMs are subjective and rely upon the patient's memory and interpretation of their mobility and, therefore, they can be unreliable. While testing in a lab or clinic is detailed and objective, it is only a snapshot measurement of the patient's mobility under specific circumstances and doesn't give physicians the full picture. Lab and clinic testing also has the potential to be sensitive to the 'white coat' effect, where patients perform differently in healthcare settings because of increased motivation or anxiety associated with doctor's visits.

To successfully assess a patient's mobility, physicians need a way to measure mobility in daily life in an objective, continuous way with high granularity. The road to achieving this level of measurement has been challenging due to real-world conditions being highly variable, with factors such as weather, time of the day, surface textures, and reasons for walking all impacting how people walk. Although the monitoring technology exists (e.g., wearable sensors), only one of the existing algorithms that estimate mobility parameters has been technically and clinically validated and brought to regulatory acceptance, the Stride Velocity 95th centile (SV95C) for Duchenne muscular dystrophy.

How will Mobilise-D improve mobility measurements?

The key goal of Mobilise-D is to provide a validated, robust set of sensor-algorithm solutions to measure multiple real-world digital mobility outcomes (DMOs) in four patient cohorts. These algorithms will inform therapeutic development, clinical practice, precision medicine, industrial development, and stakeholder approval, ultimately facilitating clinical trials and the development of drugs and novel therapies.

Patients involved in this project are given a small wearable device, data from this device coupled with newly developed state-of-the-art algorithms will be used to capture digital mobility outcomes continuously while the patient is at home. To ensure that these have the precision and accuracy required for use in drug development and health, Mobilise-D has conducted a world-first technical validation study on people with multiple health conditions and healthy people. This allowed us to verify device performance, determine the validity and reliability of algorithms in the lab and the real world, and evaluate patient and professional perspectives on the acceptability of the sensors.

To ensure the successful clinical application of digital mobility outcomes measures, Mobilise-D sensor-algorithm solutions should provide reliable, accurate measures of mobility, detect changes over time, relate the change to altered health (e.g., worsening of condition) or the effect of an intervention, and capture changes that are meaningful to patients. Through Mobilise-D, over 2,000 patients will be

monitored every six months for two years with an extensive clinical assessment and a seven-day digital mobility assessment. The results will provide the evidence for clinical validity that is required for regulatory endorsement, as well as unique legacy datasets for future work.

Conclusion

Mobility is undeniably a critical marker of health, and its assessment plays a pivotal role in understanding and improving the wellbeing of individuals. Assessing mobility has previously been reliant on subjective patient reports or controlled in-clinic tests, each with its limitations. However, the IMI Mobilise-D project is pioneering a transformative approach to mobility assessment through the integration of digital technology. By employing wearable sensors and cutting-edge algorithms, Mobilise-D aims to provide a comprehensive and objective evaluation of an individual's mobility in real-world settings, offering a level of granularity and accuracy that was previously unavailable. This ambitious five-year public-private partnership, consisting of a consortium of leading universities, hospitals, pharmaceutical, and technical companies, holds the promise of significantly improving the assessment of mobility across various health conditions.

The IMI Mobilise-D project offers a path to more accurate, continuous, and personalised mobility assessments. This endeavour not only promises to transform the way we understand and manage mobility but also holds the potential to improve the lives of countless individuals affected by mobility issues. As we move forward, we can look to a future where the assessment of mobility is more comprehensive, precise, and impactful than ever before. If you want to know more about Mobilise-D or are interested to become involved, please visit www.mobilise-d.eu.

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Gerard Quinn, VP, IT Innovation & Informatics, has worked at ICON for over nine years and has over 25 years in the life science industry, with experience in innovation, strategy, process improvement and IT. Gerard leads his team's work on the innovative activities in technology and data science. They identify and build key partnerships to co-develop services by evaluating joint capabilities with the aim of driving efficient clinical trials for sponsors and patients.