

## Mobilise-D Patient and Public Information

The purpose of this document is to outline information about the work of the Mobilise-D Consortium and what it hopes to achieve. This document is a short summary of the project and is split into a number of different sections:

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Information about Mobilise-D can also be found online at:

<https://www.mobilise-d.eu>

And on our YouTube Channel:

<https://www.youtube.com/channel/UCZHsEuoUzt1xN4oKNUNbC3A/videos>



Mobilise-D aims to produce validated and accepted digital mobility outcomes to monitor daily life walking of people with different mobility problems, with the goal to improve follow-up and personalized care. Specifically, there are five patient cohorts that have been included in the Mobilise-D work: Chronic Obstructive Pulmonary Disorder (COPD), Congestive Heart Failure (CHF), Hip fracture, Multiple Sclerosis (MS) and Parkinson's Disease (PD).

## Section 1: Mobility

### **What is mobility?**

Mobility, or the ability to move from one place to another, is a key contributor to physical, mental and social well-being. In our daily lives, it allows us to exercise, work, take walks with friends or go grocery shopping. At home, it allows us to engage in self-care activities and move from our bedroom to the toilet, kitchen or living room. In both cases, mobility is essential to living a functional and autonomous life. In Mobilise-D, we are focusing on measuring real-world walking, that is walking during normal, day to day activities. Walking is also referred to as 'gait' - which describes the way someone walks.

### **Why do we want to measure walking?**

As gait reflects our health, measuring it can tell us information that could be helpful to clinicians to guide advice. The way you walk can help us to predict different health conditions which may help clinicians to make an earlier diagnosis. How you move can also help us monitor how your condition changes over time, and how well you respond to treatments. This information can help clinicians tailor treatment plans to your individual needs, and importantly, allows



them to gather information between your regular appointments – allowing more timely and personalised adjustments to treatment.



## Section 2: Measuring mobility

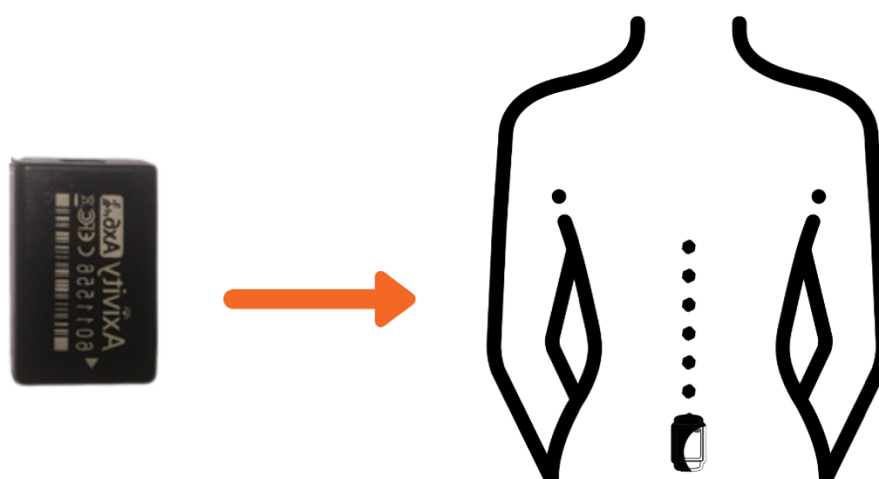
### **What tools can we use to measure mobility?**

Using technology to measure gait can provide more information about how you move and give us confidence about how accurate this information is. The most commonly used methods to measure walking now include wearable technology (or body-worn sensors). Wearable technology – such as small digital devices, can be worn on your body to capture movement. Wearable technology uses sensors to measure movement and the position of your body in space (e.g. if you are standing up or lying down). Wearable technology can capture information about



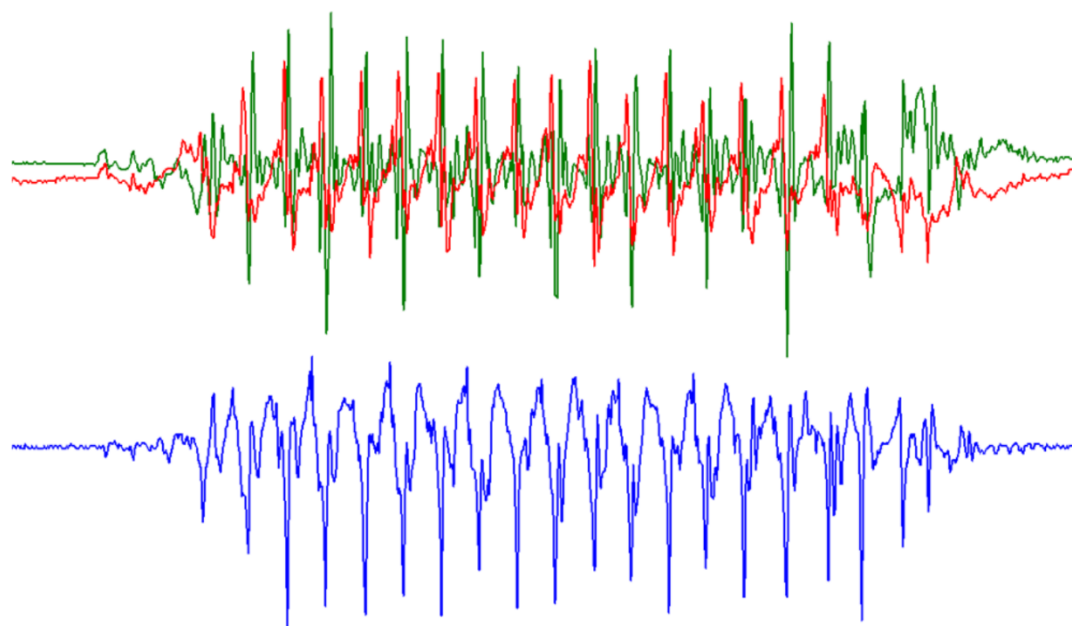
your walking within the clinic and out in the real world, which means that they can give a more detailed picture of a person's mobility.

In Mobilise-D, we are using a small body-worn device worn on the lower back (further information on Page 8). The device used in Mobilise-D will collect high quality data and accurate data, which can be paired with the equations we develop to measure gait. The device used in Mobilise-D does not provide the person who wears it with feedback. Instead, it collects the data as a person moves around, and they don't need to do anything with the device (Figure 1).



**Figure 1: Where the sensor will be placed on the body**

When you wear this device, it captures movement which is transformed into a signal that looks like this (see Figure 2):



**Figure 2: What a sensor signal looks like**

The Mobilise-D consortium will develop methods to extract important information about your walking from this signal using algorithms, or equations. Simply put, algorithms are a sequence of instructions which perform a certain action – in this case, they carry out calculations on the signal to find out information about your walking. We will refer to the information these algorithms provide as “digital mobility outcomes”.

### **What is a digital mobility outcome?**

Digital Mobility Outcomes (DMOs) are aspects of gait that are measured using digital technology. These DMOs can provide important information about health conditions that can support clinicians to make appropriate decisions about diagnosis and treatment. There are many different DMOs measuring different



aspects of walking. They can be grouped in different categories such as pace, rhythm, variability, asymmetry and postural control.

### **How will we use a digital device in Mobilise-D?**

There are two different ways that we will use this body-worn device in Mobilise-D to collect information on people's walking: in the laboratory and the real-world. Both settings provide us with important information that is needed to ensure that the DMOs used in the algorithms are accurate and reflect real-life situations. These settings will be used in the first of two studies to demonstrate the accuracy of the algorithms (more information on the studies can be seen in Section 4).



**Figure 3: The device we will use to measure walking in Mobilise-D**



## **What is the digital device being used in Mobilise-D?**

The device being used in the Mobilise-D study is called the McRoberts (MoveMonitor). This is a medical grade device meaning that it has already gone through a regulatory process to determine its accuracy in measuring mobility. Although this device has already been shown to be accurate, the purpose of the Mobilise-D project is to separate the device from the algorithms so that they are not reliant on each other.

The device is 106.6 x 58 x 11.5mm in size and weighs 55grams. It has more than 7-days of battery life and so it does not need to be charged by the patients who take part in the study. The device collects information about whether a person is moving, and what position they are in. The device can determine, through its sensors, whether a person is walking slowly or fast, or whether they are standing, sitting or lying down. However, the device does not and cannot track where you are as it does not contain any GPS sensor.

The device does not provide any feedback to the person wearing it. It has no lights, no screen and it does not integrate into any outside apps. Therefore, the device simply collects information quietly. The patient simply needs to wear it.



## Section 3: What is Mobilise-D?

### **Aim**

At the end of the project, the Mobilise-D consortium aims to provide a validated set of algorithms to measure digital mobility outcomes. If successful, these algorithms may help with future drug development and treatment plans, support future clinical trials, and help to implement new ways of monitoring patients.

### **Benefit**

Validated digital mobility outcomes will impact both drug development and patient care. The ability to make valid predictions about mortality, rates of hospitalization or nursing home admission, risk of falls, and monitor compliance, treatment response, and mobility associated adverse events is an important step for next-generation care. Table 1 summarizes key benefits of producing validated digital mobility outcomes, such as those proposed in Mobilise-D.

Ultimately, we want to develop DMOs that we will be able to make clinical decisions on treatment from. However, before we get to this point, we need to first prove that mobility can be measured in the real-world, that this measurement is accurate, and that it relates to clinical conditions. Therefore, the current work of Mobilise-D is a piece of a bigger jigsaw puzzle.





**Table 1: Benefits of digital mobility outcomes in Mobilise-D**

<b>1</b>	Develop validated (accurate) outcomes which can predict clinical outcomes
<b>2</b>	Improves personalized health care
<b>3</b>	Allows us to identify people according to their real-life mobility characteristics, which can help to categorise patient groups for various conditions
<b>4</b>	Puts plans in place and lays the groundwork for regulatory approval for assessing mobility
<b>5</b>	The proposed outcome and algorithm pairing allows this tool to be applied across other health conditions
<b>6</b>	Provides continued impact of the research by producing the largest bank of mobility data which can be used in future research to support further and future algorithm development and validation

## **The Consortium**

Mobilise-D is a 5-year, IMI-funded consortium project consisting of more than 300 professionals from 34 universities, hospitals and industry partners across Europe and the USA (Figure 4). Our researchers have expertise in healthcare, data science and engineering amongst other skills. The Consortium works closely with regulators such as the European Medicines Authority and other stakeholders to make sure that DMOs will be approved for use to measure the effectiveness of new pharmaceutical and other therapies.



**Figure 4: Some of the members of the Mobilise-D consortium**

## Section 4: The work of the Mobilise-D Consortium

### **Mobilise-D clinical studies**

The data captured from the devices will be used to validate digital mobility outcomes. This means that it will be explored to determine whether it is accurate. Specifically, Mobilise-D intends to pursue a technical, clinical and regulatory validation (Figure 5).

To prove technical accuracy we need to make sure that the digital mobility outcomes accurately capture walking in the real-world. This is being done through the Technical Validation Study (taking place between April 2019 - July 2021). The aim of the Technical Validation Study is to validate the accurate measurement of Digital Mobility Outcomes and identify that the approach to measurement is acceptable in the people who will be asked to use it. In other words, algorithms that we know can accurately measure different aspects of walking. The key to this is that it is taking place within a real-world situation.



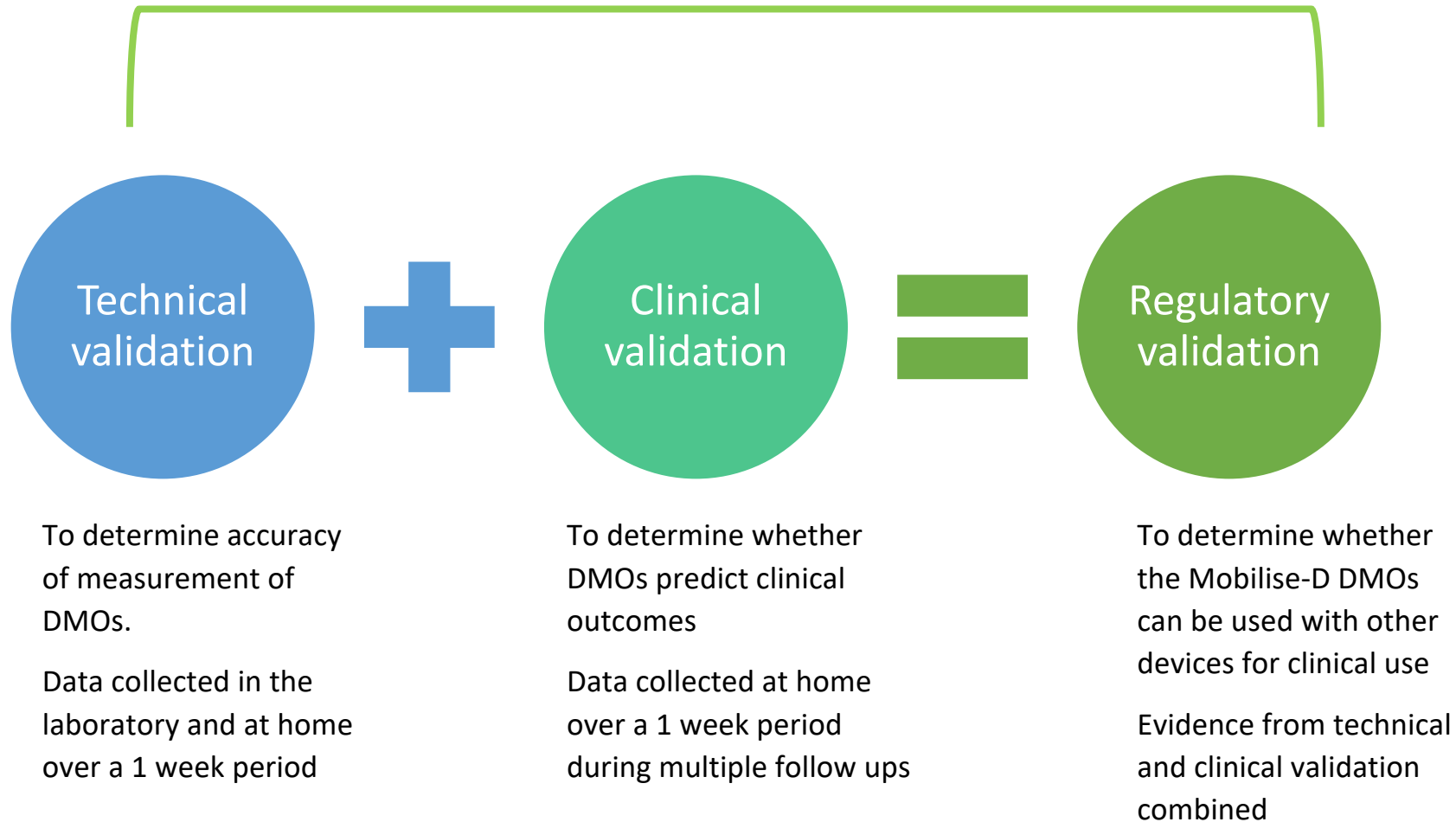
Several previous studies have validated both sensors and digital mobility outcomes in the lab. However, there are no robust validation studies to date that demonstrated that measurement of DMOs in the real world is accurate and acceptable to patients and healthcare professionals. Therefore this Technical Study is needed.

To gain clinical validation we need to make sure that the digital mobility outcome is related to other health outcomes. We will do this through the Clinical Validation Study (taking place between April 2021 and the end of the consortium in April 2023). The Clinical Validation Study takes the algorithms developed in the Technical Validation Study and implements them in over 2,500 patients from four patient groups: Chronic Obstructive Pulmonary Disease, Hip fracture, Parkinson's Disease and Multiple Sclerosis. During this time, participants will have mobility assessments every 6 months for a period of 2 years that will allow us to relate the Digital Mobility Outcomes with clinical characteristics of their conditions.

Finally, for regulatory validation, we will present the Digital Mobility Outcomes, plus all of our supporting evidence, to health authorities (i.e. EMA, FDA) in order to demonstrate that they are accurate and clinically meaningful to patients. Before DMOs can be integrated into clinical care pathways, we need to firstly gain regulatory approval that shows that they are accurate and clinically meaningful.



## Mobilise-D research activities



**Figure 5: The validation process of Mobilise-D**



## Section 5: Patients

### **Patient groups**

Mobility is an important aspect of health, regardless of age or any other factor. However, some conditions may have more symptoms that impact on mobility than others. It is important to make sure that any Digital Mobility Outcome developed in Mobilise-D can be used accurately across a range of conditions. With this in mind, there are five patient cohorts that have been included in the Mobilise-D work: Chronic Obstructive Pulmonary Disorder (COPD), Congestive Heart Failure (CHF), Hip fracture, Multiple Sclerosis (MS) and Parkinson's Disease. These cohorts represent a broad range of people living with chronic conditions of a different nature, that have been related to mobility problems before. Together, the cohorts allow for a robust evaluation of the mobility spectrum resulting from different diseases and injuries and provide a rich and diverse testbed for clinical validity.

### **Benefits of taking part in Mobilise-D**

For the patients who take part in either the Technical or Clinical Validation Study in Mobilise-D, there are no direct benefits to their participation. The McRoberts sensor does not provide them with feedback during the studies. However, by capturing their data with the devices in the study, they are supporting the development of new and innovative ways to monitor their condition.



## **Patient requirements**

The specific tasks undertaken by patients depends on whether they are part of the technical or clinical validation components of the study. The Technical Validation has been completed, however recruitment for the clinical Validation component is ongoing. For this component, patients will be followed up with every six months over a two-year period. At these six-month intervals, patients will be asked to complete a number of questionnaires and outcome measures associated with their condition. This is to track their progress. They will also be asked to wear the sensor for one-week at a time during this follow up. The sensor will be worn at home in their daily lives. Patients do not need to charge the device or interact with it during this time. The sensor can be worn all day and only needs to be taken off for a bath or shower.



## **Patient and Public Advisory Group**

Patients are at the core of Mobilise-D. For the project to be effective, the work undertaken must be meaningful and important to people living with different mobility problems. The consortium can only do this by working closely with the people it aims to benefit. Including the needs and wishes of patients and the public within the research is therefore integral to its success.

In Mobilise-D, a Patient and Public Advisory Group (PPAG) was established in April 2021 with the aim of guiding and supporting researchers in creating research that is clinically meaningful. This PPAG will work alongside the researchers to:

- Design research that tackles questions and needs relevant to people with Parkinson's disease, Multiple Sclerosis, Chronic Obstructive Pulmonary Disorder, Heart Failure and Hip Fracture
- Interpret the results of the research
- Identify the best way to promote and share the research
- Train early career researchers in how to conduct patient and public led research

The group will meet regularly to discuss topics of interest and to provide feedback and direction on work completed. The group will meet a minimum of four times a year to discuss topics of note as a group. At all times in the process, the group will be informed about how their contributions have helped shaped the Mobilise-D research, and the impact that it has made.



## Key take away message

The underlying idea of Mobilise-D is that loss of mobility predicts worsening medical outcomes regardless of underlying condition. Mobilise-D, will first develop a common Digital Mobility Outcome tool across five different patient cohorts and will test this for accuracy in the Technical Validation Study. This will then be tested in over 2500 participants to see if the Digital Mobility Outcome predicts clinical outcomes that we want to avoid such as falls, hospitalizations, deaths, loss of independence, and worsening disease status. The ultimate goal is to bring these data to health authorities and regulators so that digital assessment of mobility can be accepted for use in future clinical research and clinical practice. It is hoped that this will help stimulate therapeutic development to treat mobility loss and improve clinical management in order to improve the lives of people in Europe and beyond.