

## World's largest study of real-world digital mobility outcomes



## Mobilise-D Conference 20th March 2024

**Royal College of Physicians of Edinburgh** 

Connecting digital mobility assessment to clinical outcomes for regulatory and clinical endorsement.

# **Mobilise-D**

### Nobilise-D

## Welcome to the **Mobilise-D Conference!**

Until recently, accurately assessing mobility in the real-world as people go about their daily activities has been difficult. Mobilise-D was funded to address this important knowledge gap and unmet need.

Mobilise-D is a large academic-industry collaboration funded through the European Innovative Medicines Initiative 2 Joint Undertaking. The consortium brought together experts from 22 academic institutions, 12 industry partners from pharmaceutical, technology, and clinical research organisations, and people with diverse health conditions and mobility impairments. We are approaching the end of our 5 year project, with plans to continue the journey towards reliable, clinically meaningful digital mobility assessment. We are therefore delighted that you can join us today to celebrate our achievements as we share early findings and lessons learned, discuss current and future advances in the field and help us shape the next chapter in the evolution of digital mobility assessment!

Walking (a central feature of mobility) is important to carrying out key activities of daily living and independence. Considered an additional vital sign, aspects of walking and gait are markers of health associated with beneficial and adverse health outcomes. In addition, walking is a fundamental aspect of daily life that is important to people irrespective of health status. Reliably assessing change in one's mobility in the realworld environment provides a novel measure of health and function that would drive therapeutic innovation.

Today you will hear about our journey to provide a comprehensive solution for real-world mobility assessment that is accurate, valid, and acceptable and advances the field towards regulatory approval and application in clinical care of the future.

**Connecting digital mobility assessment to clinical** outcomes for regulatory and clinical endorsement. The Mobilise-D Consortium

Reaching this goal requires a collective effort. Therefore, we are issuing a 'Call to Action' to take the next steps so that mobility – 'the way we walk' - becomes a priority to be measured, monitored and targeted therapeutically to enable people to live healthier independent lives and age well. As you listen to the speakers and interact with the presenters, attendees, and consortium members, we invite you to consider ways you can contribute to the goal of identifying and implementing digital mobility outcomes!



Lynn Rochester Mobilise-D Academic Lead Newcastle University



**Daniel Rooks** Mobilise-D Industry Co-Lead Novartis

On behalf of the Mobilise-D Consortium

### **Mobilise-D Key Facts**

## **Mobilise-D Partners**



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Mobilise-D is funded by the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No. 820820. This JU receives support from the European Union's Horizon 2020 research and innovation program and the European Federation of Pharmaceutical Industries and Associations (EFPIA).





### Newcastle University **U**NOVARTIS



## **Mobilise-D Objectives**, **Achievements and Impact**

### **Mobilise-D Objectives**

The ultimate goal of Mobilise-D is to provide a robust, validated set of algorithms to measure digital mobility outcomes that inform drug and technology development, clinical practice, precision medicine, and stakeholder approval.

#### **Overarching objectives:**

- (i) Deliver a robust, validated, technology-independent set of algorithms, within a standards-based framework, for digital mobility assessment.
- (ii) Provide evidence that the digital outcomes accurately measure and monitor disability and predict clinical outcomes in four of the most common mobility-limiting conditions: chronic obstructive pulmonary disease, Parkinson's disease, multiple sclerosis and hip fracture.
- (iii) Obtain regulatory approval of identified digital mobility outcomes. In addition, EFPIA partners will conduct exploratory studies in congestive heart failure (CHF) using Mobilise-D technology to measure digital mobility outcomes and will employ the validated algorithms to further assess this approach.

#### **Mobilise-D** Achievements

The Mobilise-D achievements are widespread and diverse:

- Established a framework to describe the impact of living with walking impairments and provided evidence that mobility and walking are fundamentally important aspects of health to people with a wide range of health conditions.
- Delivered a systematic approach to mobility assessment that is standardised, validated and freely available.
- Delivered legacy algorithms, data sets and protocols that are freely available to drive uptake and further innovation.
- Demonstrated that digital mobility assessment is feasible, scalable and acceptable in a wide range of health conditions.
- Generated evidence that digital mobility outcomes are clinically valid and provide important insights for research and patient care.
- Educated and trained the next generation of researchers across multiple sectors in the digital assessment of mobility.
- Demonstrated it is feasible to integrate patient involvement in all phases of clinical research, which has a fundamental impact on improving fit-forpurpose studies.

### **Mobilise-D Impact**

Collectively, our achievements will continue to deliver widespread impact across: drug and other therapeutic development; technology improvement; patients and healthcare providers; research and sustainability; regulatory standards; and society.

#### Including:

- Established the importance of mobility as a core concept of health to be identified, monitored and targeted therapeutically so that people can live healthier independent lives and age well.
- Driven innovation in clinical trial design and treatment development that allows for a more diverse population, as well as more precise, sensitive, patient-centric outcome measures.
- Technical standards and algorithms for mobility assessment will stimulate innovation from digital health device companies, making accurate mobility assessment more widely available, accessible and standardised.
- Contributed towards a digital outcome development roadmap to shape a regulatory pathway for mobility assessment in the evaluation of new therapies.
- Built and enhanced knowledge and skills to prepare the workforce of the future across all sectors to deliver sustainable digital health solutions.
- Removed barriers to adoption of mobility assessment through generic solutions for wide implementation that are standardised, acceptable, feasible and scalable to enable cost effective, wide access for clinical management and personalised healthcare.











## **Conference Agenda**

Introduction			Theme 2: Translating Digital Mobility Assess	
08:30 - 09:00	Registration and coffee			
09:00 - 09:20	<b>Conference Opening and Overview</b> Lynn Rochester & Daniel Rooks, Mobilise-D Co-Leads	14:45 - 15:00	Theme 2 Keynote: Bringing digital outcome f qualified endpoint: The long and winding roa Laurent Servais, University of Oxford	
09:20 - 09:30	Welcome Keynote: From Diamond to Mobilise-D: How and Why We're Here Ronenn Roubenoff, Former Mobilise-D Industry Co-Lead			
Theme 1: Real-world Digital Mobility Assessment			<ul> <li>Public and Patient Involvement and Engager</li> <li>How patient input informed Mobilise-D project</li> </ul>	
09:30 - 09:45	Theme 1 Keynote: From what we could measure, to what we should measure: changing perspectives in digital measure development leuan Clay, VivoSense	15:00 – 15:30	<ul> <li>Alison Keogh, Mobilise-D PPIE Lead</li> <li>The patient's perspective Tova Gur Arieh, Public and Patient Advisory (</li> </ul>	
09:45 - 10:25	<ul> <li>Knowledge Gap 1: Can real-world mobility be measured accurately, reliably and is it valid? - everything you need to know!</li> <li>Challenges and solutions for the estimation of technically valid real-world digital mobility outcomes (DMOs) Andrea Cereatti, Mobilise-D Technical Validation Study Academic Lead</li> <li>Future perspectives and legacy of the Technical Validation Study (TVS) Arne Muller, Mobilise-D Technical Validation Study Industry Co-Lead</li> </ul>	15:30 - 15:55	<ul> <li>Regulatory Path &amp; Clinical Implementation</li> <li>The Mobilise-D regulatory journey: key achieve Wim Dartee, Mobilise-D Regulatory Industry</li> <li>The certification of software as a medical devi Giorgio Davico, Mobilise-D Regulatory Acade</li> </ul>	
10:25 - 10:55	Morning break in Interactive Area	15:55 - 16:25	Afternoon break in Interactive Area	
10:55 - 12:30	<ul> <li>Knowledge Gap 2: What do the Digital Mobility Outcomes tell us clinically? Insights from the Clinical Validation Study</li> <li>The Mobilise-D Clinical Validation Study (CVS) Clemens Becker, Mobilise-D Clinical Validation Study Academic Lead</li> <li>The Mobilise-D CVS - A significant data management challenge Brian Caulfield, Mobilise-D Data Management Academic Lead</li> <li>Early insights from the CVS Judith Garcia-Aymerich, Mobilise-D Statistical Analysis Academic Lead</li> <li>Clinical relevance of CVS findings Walter Maetzler and Alison Yarnall, Parkinson's disease Thierry Troosters and Heleen Demeyer, COPD Basil Sharrack, Multiple Sclerosis Beatrix Vereijken, Hip Fracture</li> </ul>	16:25 - 17:10	<ul> <li>Theme 2 Expert Panel Discussion</li> <li>Chair: Camille Carroll, University of Newcastl</li> <li>Panellists:         <ul> <li>Diane Stephenson, Critical Path Institute</li> <li>Dalia Dawoud, National Institute for Health a Ger Quinn, ICON</li> <li>Lis Boulton, Age UK</li> <li>Pippa Powell, European Lung Foundation</li> <li>Keith Park, MS Society</li> <li>David Dexter, Parkinson's UK</li> </ul> </li> </ul>	
12:30 - 13:10	<ul> <li>Theme 1 Expert Panel Discussion</li> <li>Chair: Claudia Mazzà, Biogen, Former Mobilise-D TVS Academic Lead</li> <li>Panellists:</li> </ul>	17:10 - 17:15	Theme 2 Audience Polling Session	
	Jessilyn Dunn, Duke University Sallie Lamb, University of Exeter Alda Marques, University of Aveiro Paolo Bonato, Harvard Medical School	17:15 -	Summary and Legacy	
13:10 - 13:15	Theme 1 Audience Polling Session	17:30	Lynn Rochester & Daniel Rooks, Mobilise-D Co-L	
13:15 - 14:45	Lunch in Interactive Area			



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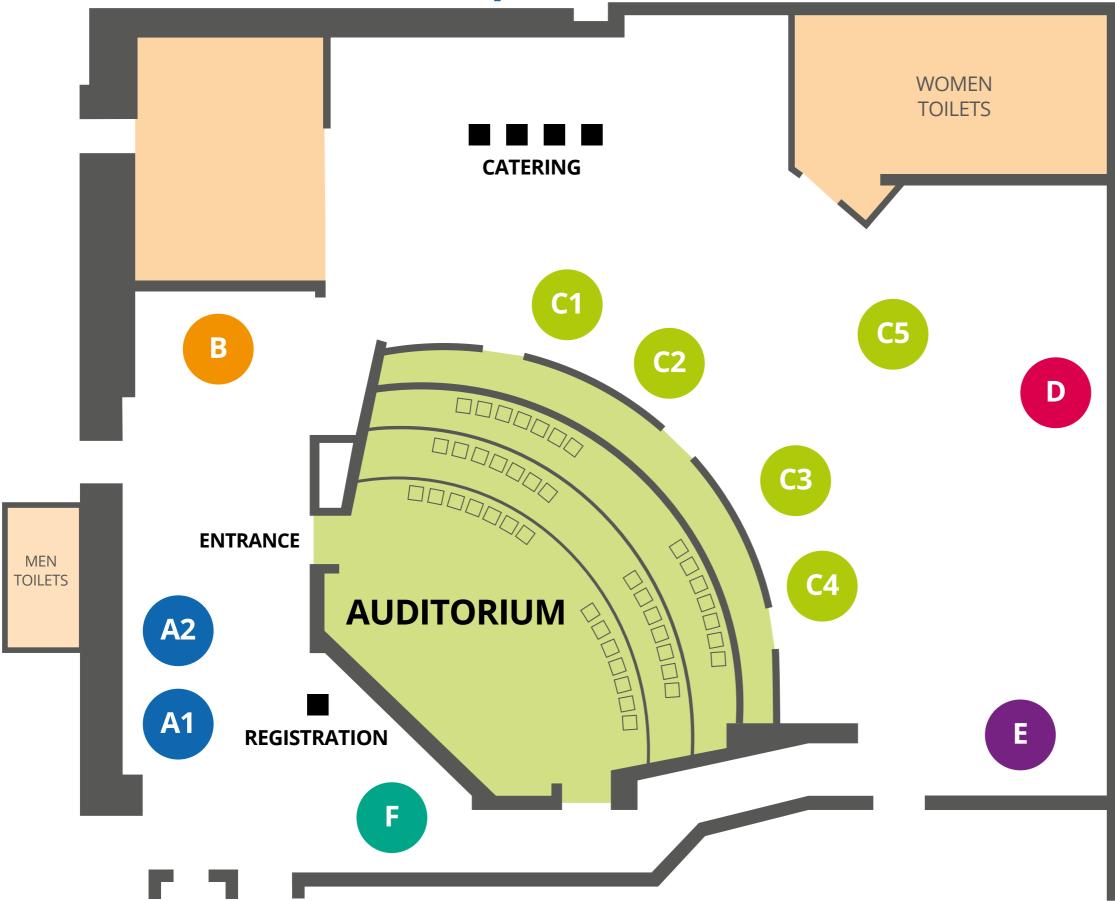
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## **Interactive Area Map**





#### Area A: Mobilise-D Technical Companies

- 1. McRoberts
- 2. Clario

Area B: Technical Validation Study

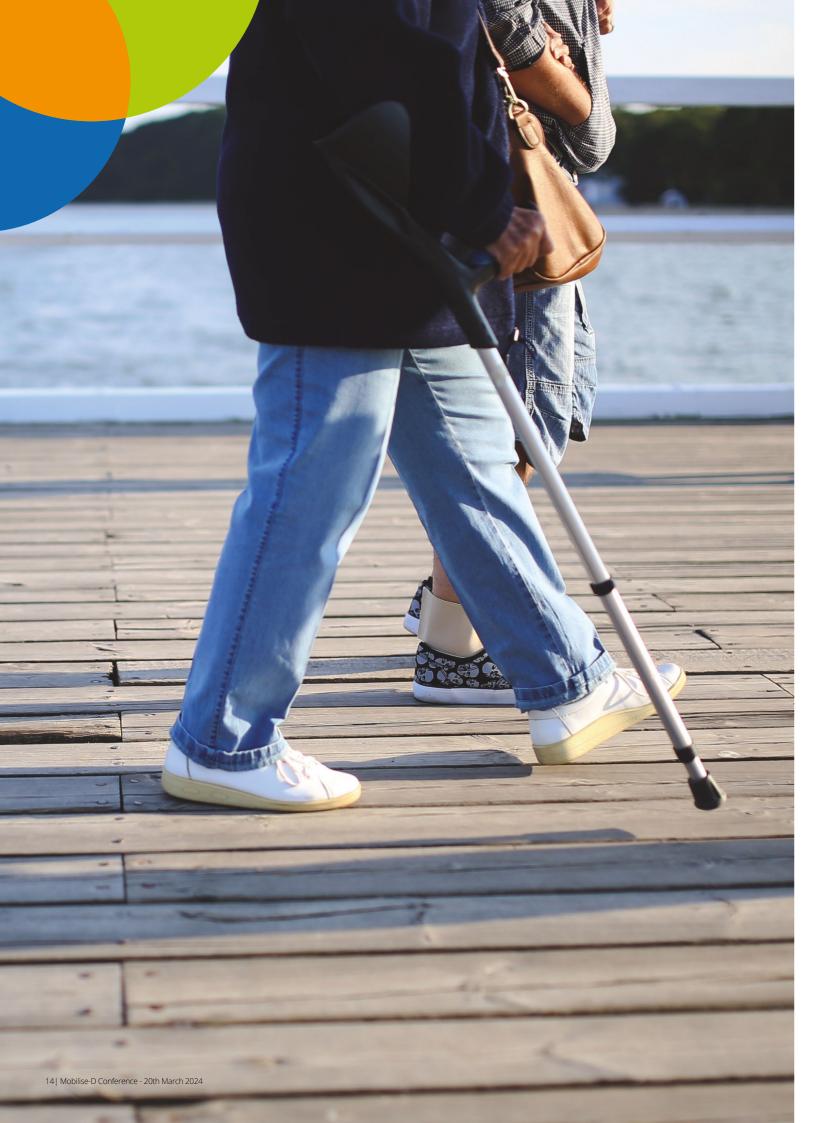
#### Area C: Clinical Validation Study

- 1. Parkinson's disease
- 2. Multiple Sclerosis
- 3. Chronic obstructive pulmonary disease
- 4. Hip Fracture
- 5. Data Management and Statistical Analysis

#### Area D: Regulatory

#### Area E: Public and Patient Involvement and Engagement

#### Area F: Mobilise-D Achievements



## **Interactive Area Information**

We hope that you will make full use of the Mobilise-D Conference Interactive Area through the practical demonstrations, videos, posters of recent project research, and most importantly by speaking to the Mobilise-D experts.

#### Interactive Area timings

10:25 - 10.55 **Morning break** 13:15 - 14:45 **Lunch break** 15:55 - 16:25 **Afternoon break** 

#### Area A: Mobilise-D Technical Companies

#### 1: McRoberts

Demo:

• *Stand-to-sit digital assessment* (Jordi Evers) Demonstration of an in-lab mobility assessment used in the Mobilise-D clinical studies using a single wearable sensor.

#### Meet the Experts:

- Martijn Niessen
- Jordi Evers

#### 2: Clario

#### Demos:

- *Opal Lumbar Sensor Technology* (Kristen Sowalsky and Sonia Ortner) Opal Lumbar Sensor Technology demonstration of future capabilities to capture real-world Mobilise-D DMO data in clinical studies.
- eCOA demo of the EDSS used in MS clinical trials (Valdo Arnera)
   Demonstration of the electronic data capture system

used to measure disability in multiple sclerosis in the Mobilise-D clinical studies.

#### Poster

1. Clario's Opal® Sensor & eCOA support for Mobilise-D DMO Deployment in Clinical Trials (Kristen Sowalsky and Valdo Arnera)

#### Meet the Experts:

- Kristen Sowalsky
- Sonia Ortner
- Valdo Arnera
- Bryan McDowell



#### Area B: Technical Validation Study

#### Demo:

• Hands-on with TVS measurement technology (Paolo Tasca, Lisa Alcock, Andrea Cereatti) Demonstration of the INDIP system and single sensor devices used in Mobilise-D clinical studies -McRoberts and Axivity.

#### Posters:

- 1. Is the Mobilise-D method sensor agnostic? Results of the validation study (Kirsty Scott)
- 2. Real-world gait detection from wrist worn devices (Felix Kluge)
- 3. Mastering the Mobilise-D pipeline for real-world mobility measurement (Anisoara Ionescu, Cameron Kirk and Arne Kuderle)
- 4. Data standardization for Mobilise-D data and external datasets: procedures and guidelines (Ilaria D'Ascanio)
- 5. The number of days required for a reliable estimate of diverse digital mobility outcomes from various gait domains, derived from a 1-week worn lower back sensor (Eran Gazit)

#### Meet the Experts:

- Arne Mueller (Novartis)
- Andrea Cereatti (Polytechnic University of Turin)
- Paolo Tasca (Polytechnic University of Turin)
- Lisa Alcock (Newcastle University)
- Felix Kluge (Novartis)

#### **Area C: Clinical Validation Study**

#### 1: Parkinson's disease

#### **Posters:**

- 1. Baseline data of the Mobilise-D Parkinson's cohort (Walter Maetzler and Alison Yarnall)
- 2. Construct Validity of Digital Mobility Outcomes in people with Parkinson's disease (Mike Long)
- 3. Daily fluctuations of mobility at home: does it relate to FOG? (Christian Schlenstedt and Walter Maetzler)
- 4. Digital mobility outcomes derived from different wearable sensors and their link to clinically relevant scores in Parkinson's disease (Laura Engelgeh and Heiko Gaßner)
- 5. Free-living gait and mobility in freezers and nonfreezers: what can digital mobility outcome tell us? (Pieter Ginis and Jeff Hausdorff)
- 6. Associations of sarcopenia in Parkinson's disease: clinical, functional and digital mobility outcomes (Laura Cordova-Rivera and Alison Yarnall)
- 7. The validity of determining freezing status with objective markers of turning. (Maaike Goris and Moran Gilat)
- 8. The number of days required for a reliable estimate of diverse digital mobility outcomes from various gait domains, derived from a 1-week worn lower back sensor (Jeff Hausdorff and Eran Gazit)

#### Meet the Experts:

- Alison Yarnall (Newcastle University)
- Walter Maetzler (University of Kiel)
- Christian Schlenstedt (University of Kiel)
- Alice Nieuwboer (KU Leuven)
- Heiko Gaßner (University Hospital Erlangen)

#### 2: Multiple Sclerosis Posters:

- 1. Recruitment of the MS cohort, summary and challenges (Gavin Brittain)
- Construct validity of DMOs in MS (Gavin Brittain and Mike Long)
- 3. Telephone EDSS, a widely used clinical tool, is not a reliable alternative to in person EDSS (Gavin Brittain)
- 4. Is a 2-minute walk a valid alternative to the 6-minute walk in MS (Letizia Leocani)
- 5. How do digital mobility outcomes reflect the patient experience of mobility (Ellen Buckley)
- 6. Validity of LLFDI in people with MS (Ellen Buckley)
- 7. Mobility disability importance to people with MS (Ellen Buckley)
- 8. Exploring fatigue measures in MS (Letizia Leocani)

#### Meet the Experts:

- Basil Sharrack (University of Sheffield)
- Ellen Buckley (University of Sheffield)
- Gavin Brittain (University of Sheffield)
- Giancarlo Comi (Vita-Salute San Raffaele University)
- Letizia Leocani (Vita-Salute San Raffaele University)

### 3: Chronic obstructive pulmonary disease Posters:

- 1. Real-world walking in COPD (Laura Delgado)
- *2. Social isolation and loneliness and their associations with physical activity in COPD* (Sara Buttery)
- 3. Validation of the Late-Life Function and Disability Instrument (LLFDI) in people with COPD (Astrid Blondeel)
- 4. Construct Validity Assessment of Digital Mobility Outcomes in COPD: Exploring Convergence, Divergence and Known Group Differences (Mike Long)

#### Meet the Experts:

- Thierry Troosters (KU Leuven)
- Heleen Demeyer (KU Leuven)
- Anja Frei (University of Zurich)
- Nick Hopkinson (Imperial College London)
- · Ioannis Vogiatzis (Northumbria University)

#### **Area C: Clinical Validation Study**

#### 4: Hip Fracture Posters:

- 1. Construct validity in the PFF cohort: comparing DMOs and COAs (Tobias Eckert and Mike Long)
- 2. DMOs during certain phases of hip fracture recovery (Jochen Klenk)
- 3. Walking towards recovery: Investigating real-world Digital Mobility Outcomes in hip fracture patients (Martin Berge)
- 4. Evaluation of real-world mobility recovery after hip fracture (Monika Engdal)

#### Meet the Experts:

- · Clemens Becker (Robert Bosch Medical Foundation)
- Monica Engdal (Norwegian University of Science and Technology
- Lars Gunnar Johnsen (Norwegian University of Science and Technology)

#### 5: Data Management and Statistical Analysis

#### Demo:

Data Management Platform: e-Science Central and Data Visualisation Tools (Hugo Hiden & Alma Cantu)

Demonstration of the data platform used to integrate and process the multiple sources of data in the Clinical Validation Study, as well as some of the tools developed to visualise data.

#### **Posters:**

- 1. The Mobilise Data Management Platform: Architecture, Development and Experiences (Hugo Hiden)
- 1. Parallel Assemblies Plot: Data Visualization Dashboard to Explore Digital Mobility Outcomes (Alma Cantu)
- 2. How many hours and days are needed? Digital assessment of walking activity and gait in adults with walking impairment (Joren Buekers)
- 3. From high-resolution time series to a single, clinicallyinterpretable value – Data aggregation framework and application to walking activity and gait in individuals with mobility-impairment (Sarah Koch)
- 4. QA /Data Cleaning Processes (Brian Caulfield, David Singleton and Lou Sutcliffe)

#### Meet the Experts:

- Dave Singleton (University College Dublin)
- Brian Caulfield (University College Dublin)
- Judith Garcia-Aymerich (IS Global)



#### Area D: Regulatory

#### Poster:

 Regulatory qualification of digital mobility outcomes what regulators (may) ask and what you need to know (Giorgio Davico)

#### Meet the Experts:

- · Giorgio Davico (UNIBO)
- Wim Dartee (Novartis)

#### Area E: Public and Patient Involvement and Engagement

#### Demos:

• The importance of real-world walking to patients (Alison Keogh)

Animation created with patients to explain the importance of walking from their perspective. An infographic of this material will be available to take-away. We will also be showing individual videos of what walking means to some of the patients who have advised us in Mobilise-D.

• What does walking mean to you? (Alison Keogh) Come and share what walking means to you!

#### **Posters:**

- 1. Conceptual framework of walking (Laura Delgado)
- 2. How to recruit under-served patients (Results from MJFF PPIE workshops) (Riona McArdle, Megan Hanrahan and Jack Lumsdon)
- 3. Mobilising patient and public involvement in the development of real-world digital technology solutions: insights from the Mobilise-D consortium (Alison Keogh)
- 4. PPIE reporting recommendations (Megan Hanrahan and Jack Lumsdon)
- 5. How do people want their mobility data over time visualised? Ongoing adapted Delphi study with patients (Jack Lumsdon and Alma Cantu)

#### Meet the Experts:

- Alison Keogh (University College Dublin)
- Riona McArdle (Newcastle University)
- Megan Hanrahan (Newcastle University)
- Jack Lumsdon (Newcastle University

#### Area F: Mobilise-D Achievements

Highlights of Mobilise-D achievements over the last five years.

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### **Mobilise-D Leads**

### Lynn Rochester – Mobilise-D Academic Lead

Lynn Rochester is Professor of Human Movement Science in the Translational and Clinical Research Institute, Newcastle University and an academic physiotherapist. She holds an NIHR Senior Investigators Award.

Lynn set up and leads the Brain and Movement Research Group (BAM) **(http://bam-ncl.co.uk/)**, a multidisciplinary group with a focus on age related gait and mobility disorders. She has an international track record in early translational (experimental medicine) research related to mobility and gait in neurodegenerative disease.

This includes a significant portfolio in digital health. For example, she is Co-ordinator for Mobilise-D (www.mobilise-d.eu); a collaborator on IDEA-FAST (https://idea-fast.eu/) (both funded through European Innovative Medicines Initiative 2 Joint Undertaking); and, is deputy Director of EPSRC funded programme grant TORUS (Transforming the Objective Real-world Measurement of Symptoms) (https://torus.ac.uk/). She also co-leads the Digital Health Theme lead for the NIHR Biomedical Research Centre in Newcastle (https://www.newcastlebrc.nihr.ac.uk/).

### Daniel Rooks - Mobilise-D Industry Co-Lead

### Daniel Rooks is Head of Endpoint Management in Translational Medicine Discovery and Profiling at Novartis, Cambridge, MA, USA.

Dan's work focuses on developing and applying ways to reduce variability and improve data quality in clinical outcome assessments of patient function in drug development clinical trials. Prior to his current role, he led the Muscle Diseases and Neuromuscular Diseases groups and was the Early Clinical Lead of the bimagrumab program. His work with assessments in clinical trials at Novartis and before that at Harvard Medical School include traditional pen, paper, and stopwatch and digital measures.

Dan co-developed the SPPB Guide mobile phone app that standardizes administration of the Short Physical Performance Battery. He is a fellow of the American College of Sports Medicine.



## Welcome Keynote Speaker

### Ronenn Roubenoff, Former Mobilise-D Industry Co-Lead

Ronenn Roubenoff is retired from Global Head of Translational Medicine Discovery & Profiling at Novartis, Cambridge, MA, USA and Basel, CH, and Adjunct Professor of Medicine and Nutrition at Tufts University.

An international authority on sarcopenia, translational medicine, and the use of biomarkers in drug development, he has published >280 papers (h-index 104). Awards include AOA and Delta Omega honor societies; Fellow of the American Colleges of Physicians and of Rheumatology; and the Robert H. Herman Award, American Society for Nutrition.

#### Welcome Keynote Abstract: From what we could measure, to what we should measure: changing perspectives in digital measure development.

As we reach the end of the project duration for MOBILISE-D, we can celebrate many achievements, and look forward to even greater ones in the post-project period. In this talk, Ronenn looks back on the origins of MOBILISE-D, and just how far we've come.





## **Theme Keynote Speakers**

### Theme 1 Keynote: leuan Clay, VivoSense

### Ieuan Clay is Director of Science at Vivosense, where his work focuses on development and qualification of digital measures.

leuan lectures at ETHZ and FHNW in Digital Health, and is an Editorial Board Member at Karger Digital Biomarkers. Following his PhD at the University of Cambridge which focused on technology and analytics development, he joined Novartis Research in 2010, where he built and led the Digital Endpoints group within Translational Medicine (early clinical portfolio), implementing new digital measures into trials and advancing qualification of real-world gait speed with the EMA. He has worked at Evidation Health, focusing on research strategy and helping build their Heart Health patient engagement platform, and at the Digital Medicine (DiMe) society as Chief Scientific Officer, responsible for scientific strategy and output.

#### Theme 1 Keynote Abstract: From what we could measure, to what we should measure: changing perspectives in digital measure development

Digital health, and digital measures, is still a young field and what we think of as "best practice" has evolved significantly. While our motivations, and the belief in the value of radically expanding the range of novel evidence tools, has not changed, we are going through a paradigm shift from an engineeringdriven "what can we measure?" approach to a patient-centric "what should we measure?" way of thinking. This change in thinking takes inspiration from many other fields, and will be the key to unlocking regulatory acceptance and qualification. Challenges remain, but we are on our way to finally seeing digital measures as more than just nice to have.



### Theme 2 Keynote: Laurent Servais, University of Oxford

### Laurent Servais is Professor of Paediatric Neuromuscular Diseases at the University of Oxford in the UK, and invited Professor at the University of Liège in Belgium.

Laurent has been working on innovative and digital outcomes since 2009. He has been instrumental in creating then validating the Actimyo then the Syde. He has led the effort of the identification-validation-gualification of the SV95C- the first digital outcome ever qualified by a regulatory agency. He currently works on the identification and validation of a portfolio of digital outcomes adapted to diseases as diverse as Angelman syndrome-Multiple sclerosis-CMT-ALS or osteoarthritis.

#### Theme 2 Keynote Abstract: Bringing digital outcome from an idea to a regulatory gualified endpoint: The long and winding road of SV95C in Duchenne

Digital outcome measures are increasingly used in clinical research- but this does not translate yet in regulatory qualification or use as primary endpoints in pivotal trials. We will review the qualification process of the SV95C- the first digital endpoint qualified by a regulatory agency- EMA- and explore the opportunities that this first qualification opens in the field of digital outcomes.



### **Theme 1 Presenters:**

#### Andrea Cereatti - Mobilise-D Technical Validation Study Academic Lead

Andrea Cereatti has earned the M.S. degree in mechanical engineering cum laude (2002) and a Ph.D. in Bioengineering in 2006. He is currently full professor in Bioengineering at the Politecnico di Torino (Italy). His research interests focus on methods for motion capture, wearable and smart sensors for mobility performance assessment, and innovative technologies for neuro-muscular rehabilitation. He is currently president of the Italian Society of Clinical Movement Analysis and he has been in the board of directors of the 3-D Analysis of Human Movement Technical Group of the ISB (2014-2018) and founder member of the Italian National Group of Bioengineering. He co-authored more than 130 publications and inventors of three patents.

#### Arne Muller - Mobilise-D Technical Validation Study Industry Co-Lead

Dr. Arne Mueller, a biologist by training, obtained his PhD in Bioinformatics from the University College London, specializing in protein folding prediction. He gained industry experience through a Marie-Curie fellowship at Aventis Pharma, focusing on Toxicogenomics. Dr. Mueller's career progressed at Sanofi and Novartis, where he transitioned from pre-clinical to clinical research, with a particular focus on digital mobility endpoints.

#### Clemens Becker - Mobilise-D Clinical Validation Study Academic Lead

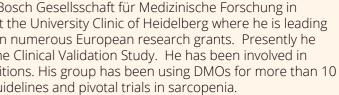
Clemens Becker is the lead of clinical gerontology at Robert Bosch Gesellsschaft für Medizinische Forschung in Stuttgart, Germany. He is a Professor of Geriatric Medicine at the University Clinic of Heidelberg where he is leading the Unit "Digitale Geriatrie". Prof. Becker has been involved in numerous European research grants. Presently he is working with the Mobilise-D consortium, where he leads the Clinical Validation Study. He has been involved in intervention trials in hip fracture and other age-related conditions. His group has been using DMOs for more than 10 years. He has been co-authoring the global fall prevention guidelines and pivotal trials in sarcopenia.

#### Brian Caulfield - Mobilise-D Data Management Academic Lead

Professor Brian Caulfield is a Principal Investigator in the SFI INSIGHT Centre for Data Analytics (www.insight-centre. org). A physiotherapist (physical therapist) by training, Brian is also Chair of Physiotherapy at University College Dublin. He was the Academic Director of the TRIL Centre from 2009-2013 and led the establishment of the ARCH Technology Centre for Connected Health in 2014. He was a Founding Director of the Insight Centre, and served as Director of Insight@UCD from 2013 to 2023. Brian's research programme is focussed on leveraging data from wearable and mobile sensing and actuation platforms to deliver better measurement, understanding and enhancement of human performance in health and sport. He is co-lead for WP3 (Data Management Platform) in Mobilise-D.











## **Theme 1 Presenters:**

Judith Garcia-Aymerich - Mobilise-D Statistical Analysis Academic Lead



Judith Garcia-Aymerich is a respiratory epidemiologist focused in the role of physical activity in the development and prognosis of chronic obstructive pulmonary disease COPD, and the impact of socioenvironmental factors in this relation. Her work also expands to the broader characterization of gait and mobility, to related health determinants such as diet and body weight and composition, and to other allergic, respiratory and chronic diseases. Central to her research is a robust emphasis on methodological rigor. This encompasses the development and validation of assessment tools (e.g., activity monitors, patient-reported outcomes), the use of hypothesis free methods to define and characterise diseases, the use of counterfactual-based methods to estimate causal effects, and the life course approach.

Walter Maetzler - Mobilise-D Parkinson's disease Lead



Walter Maetzler is Professor of Neurogeriatrics at the University of Kiel. He has been working on the diagnosis and treatment of motor and cognitive disorders for 20 years. As part of his research in this field, he has investigated various forms of movement disorders, including Parkinson's disease. In addition to Mobilise-D, he is also involved in other European networks investigating the potential of wearable digital technology for the assessment of activities of daily living, such as IDEA-FAST and StepUp. The focus is on the assessment and validation and pathomechanistic understanding of clinical features using novel digital and mobile technologies.

Alison Yarnall - Mobilise-D Parkinson's disease Co-lead



Professor Alison Yarnall completed her PhD in 2013 at Newcastle University looking at biomarkers of cognitive impairment in Parkinson's disease. She is now a Professor of Geriatric Medicine at the Translational and Clinical Research Institute, Newcastle University; Deputy Director of the Clinical Ageing Research Unit; Honorary Consultant in Older People's Medicine at Newcastle upon Tyne Hospitals NHS Foundation Trust; and DeNDRON Subspecialty Clinical Research Lead for Parkinson's disease in the North East of England. She has a particular interest in mobility (including digital mobility), cognition, gait and falls in people with Parkinson's and other neurodegenerative diseases and has published more than 100 articles in this topic area. She runs a specialist clinic for older adults with Parkinson's and complex health needs, in addition to a general medical memory clinic.

#### Thierry Troosters - Mobilise-D COPD Lead



Professor Thierry Troosters (ISI H-index 73) is a physiotherapist and professor of Rehabilitation Sciences. He heads the department of Rehabilitation Sciences at the KU Leuven (Leuven, Belgium). Along with the Respiratory Division at the University Hospitals in Leuven, he investigates the devastating non-respiratory consequences of lung diseases, often induced by physical inactivity or exacerbations. With his group he is also looking at optimizing and modernizing exercise training strategies for patients with lung disease as well as strategies to measure and enhance physical activity. With their group they pioneered on investigating the impact of physical inactivity patients with COPD and other respiratory conditions including cystic fibrosis and lung transplantation. Thierry is past president of the European Respiratory Society. He led the Society in 2019-2020.

#### Heleen Demeyer - Mobilise-D COPD Co-Lead

Professor Heleen Demeyer (ISI H-index 25) is a physiotherapist performing research at the Department of Rehabilitation Sciences at KU Leuven (Leuven, Belgium) and Ghent University (Ghent, Belgium). Her research focuses on rehabilitation and physical activity in patients with chronic respiratory diseases. She is an expert in the design and evaluation of coaching interventions targeting physical activity and she was involved in an international task force aiming to standardize the measurement of physical activity in patients with COPD. Within the Mobilise-D project she is co-lead of the COPD cohort in the clinical validation study. Heleen Demeyer is currently the representative of the early career members of the assembly of allied respiratory professionals within the European Respiratory society.

#### **Basil Sharrack - Mobilise-D Multiple Sclerosis Lead**

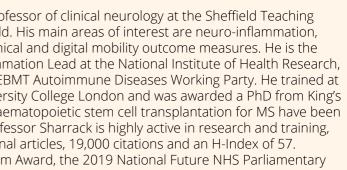
Professor Basil Sharrack is a consultant neurologist and a professor of clinical neurology at the Sheffield Teaching Hospitals NHS foundation Trust and the University of Sheffield. His main areas of interest are neuro-inflammation, autologous haematopoietic stem cell transplantation and clinical and digital mobility outcome measures. He is the director of the Sheffield MS Research Clinic, the neuro-inflammation Lead at the National Institute of Health Research, Sheffield Biomedical Research Centre and a member of the EBMT Autoimmune Diseases Working Party. He trained at the National Hospital for Neurology and Neurosurgery, University College London and was awarded a PhD from King's College, London. His research contributions in autologous haematopoietic stem cell transplantation for MS have been key to the development of this treatment internationally. Professor Sharrack is highly active in research and training, resulting in 15 PhDs being awarded, 160 peer-reviewed original articles, 19,000 citations and an H-Index of 57. Professor Sharrack was rewarded the 2018 EMBT Van Bekkum Award, the 2019 National Future NHS Parliamentary Award and the 2020 Queen Anniversary Award.

#### Beatrix Vereijken - Mobilise-D Communication and Dissemination Academic Lead

Dr. Beatrix Vereijken is Professor at the Department of Neuromedicine and Movement Science, Norwegian University of Science and Technology (NTNU), Trondheim, Norway. She is the Academic Director of NeXt Move, the medical faculty's core facilities for neurophysiology, exercise physiology, movement and elite sports at NTNU. She is NTNU's PI in Mobilise-D and the Academic Lead for the work on communication, dissemination and exploitation of results. She also co-coordinated the EU project PreventIT, a personalised health and ICT project aimed at preventing functional decline at older age. She holds an MSc in Experimental Psychology from the Radboud University Nijmegen and a doctorate in Human Movement Science from the Vrije Universiteit Amsterdam. Her research focuses on mobility across the lifespan, active ageing, activity monitoring, and the development and implementation of health technology.









### **Theme 1 Expert Discussion Panel**

#### Chair: Claudia Mazzà Biogen



#### Former Mobilise-D TVS Academic Lead

Dr Claudia Mazzà is currently employed by Biogen, where she leads the development of Digital Biomarkers of Gait and Posture. Before Joining Biogen, Claudia was a Professor of Biomechanics at the University of Sheffield. Claudia was part of the core team of Mobilise-D right from the project design and she led the activities of WP2 and the technical validation study between 2019 and 2022.

Panellist: Jessilyn Dunn



#### Duke University

Dr. Jessilyn Dunn is Assistant Professor of Biomedical Engineering and Biostatistics & Bioinformatics at Duke University, and Director of the BIG IDEAs Laboratory whose goal is to detect, treat, and prevent chronic and acute diseases through digital health innovation. She is currently PI of the BARDA-funded CovIdentify study to detect and monitor respiratory infections like COVID-19 using mobile health technologies, and an NIHfunded study to develop digital biomarkers of pre- and type 2 diabetes. She also leads the DBDP, an open-source software platform for digital biomarker development. Dr. Dunn was an NIH Big Data to Knowledge (BD2K) Postdoctoral Fellow at Stanford and an NSF Graduate Research Fellow at Georgia Tech and Emory, as well as a visiting scholar at the US Centers for Disease Control and Prevention and the National Cardiovascular Research Institute in Madrid, Spain. Her work has been internationally recognized with media coverage from the NIH Director's Blog to Wired, Time, and US News and World Report.

#### Panellist: Sallie Lamb

#### **University of Exeter**

Sallie Lamb is Pro-Vice-Chancellor and Executive Dean of the Faculty of Health and Life Sciences, and Mireille Gillings Professor of Health Innovation at the University of Exeter. An internationally recognised scholar in ageing, disability, and rehabilitation, she is also an experienced methodologist in the area of clinical trials and high-quality evaluation of health care practice. Sallie is Director of the recently established NIHR Exeter Biomedical Research Centre (BRC) she has a strong commitment to improving the lives of older people through excellent research that answers difficult questions and can inform policy making and commissioning.

#### Panellist: Alda Marques

#### **University of Aveiro**

Alda Marques is a Physiotherapist, Professor at the School of Health Sciences, Researcher at the Institute of Biomedicine, University of Aveiro (UA), and Coordinator of the Lab3R-Respiratory Research and Rehabilitation Laboratory, at UA, in Portugal. Her research focus on understanding how respiratory diseases affect people's life and in developing personalised non-pharmacological interventions (pulmonary rehabilitation, physical activity) based on comprehensive assessments of people with chronic respiratory diseases and their loved ones, to achieve their maximum level of independence and functioning in the community with minimal resources.

#### **Panellist: Paolo Bonato**

#### Harvard Medical School

Paolo Bonato, Ph.D., serves as the Director of the Motion Analysis Laboratory at Spaulding Rehabilitation Hospital, Boston MA. He is an Associate Professor of Physical Medicine and Rehabilitation at Harvard Medical School. He holds Adjunct Faculty appointments at Massachusetts Institute of Technology, the MGH Institute of Health Professions, and Boston University College of Health & Rehabilitation Sciences. He has held Adjunct Faculty positions at the Wyss Institute, Northeastern University, the University of Ireland Galway, and the University of Melbourne. His research work is focused on the development of rehabilitation technologies with special emphasis on wearable technology and robotics.





## **Theme 2 Presenters:**

#### **Alison Keogh - Mobilise-D PPIE Lead**

Alison is the Patient and Public Involvement and Engagement lead for Mobilise-D, facilitating interactions between the patient advisory group and the research activities. Alison is currently an Assistant Prof in Healthcare Innovation in Trinity College Dublin, and a research physiotherapist with the Insight Centre for Data Analytics, in University College Dublin.

Tova Gur Arieh - Mobilise-D Patient and Public Advisory Group member

Tova Gur Arieh is a member of the Mobilise-D Patient and Public Advisory Group since 2021. She is a mother of two, Noa – Her Daughter, 40 years old, is a family practitioner (MD). Nadav – Her son, 37 years old, is a programmer (BSc) and graduated from Tel-Hai College in Israel. She is also a grandmother of five beautiful grandchildren. She was born and raised in Israel. In 1989, Tova and her husband relocated to the United States. During their years there, she studied art history and education. She also taught Hebrew for several years in several Jewish schools. They returned to Israel in 1998. Since 2004, she worked at NITZAN – The Israeli Association for the Advancement of Children and Adults with Learning Disabilities and ADHD, as the Resource Development Director, she recently retired. She was diagnosed with Parkinson's in 2018. However, she probably started to experience different signs about a decade earlier.

Wim Dartee - Mobilise-D Regulatory Industry Co-Lead

Wim Dartee is Global Lead Regulatory Affairs, Devices/Sensors in Clinical Development at Novartis and has over 20 years' experience in Regulatory Affairs and Pharmaceutical Industry. He has local (3 years NL), European, US and Global regulatory affairs experience, direct interactions with all major Regulatory agencies (EMA, key EU national health authorities, FDA, PMDA, Swissmedic), and Notified Bodies BSI, TüvSüd. He has worked across a variety of therapeutic areas, both specialized (Oncology, Tropical Medicine) as well as primary care (Respiratory, CNS and Infectious Diseases) and enjoys finding ways to optimize opportunities within the ever-changing regulatory framework. His role at Novartis has focused on medical devices and combination products to prepare organization regulatorywise, capitalizing on opportunities in combining pharma development projects with innovative devices and digital, and with particular focus on enabling the development of digital endpoints in drug clinical development.

Giorgio Davico - Mobilise-D Regulatory Academic Representative

Giorgio Davico is a researcher at the University of Bologna (Italy), biomedical engineer by training with a PhD in computational biomechanics and musculoskeletal modelling. His research focuses on the development and use of personalized musculoskeletal models to investigate how the aging process and/or ongoing pathologies may affect the way we move, thus supporting clinical management and clinical decision making. Recognising the need for regulatory approval to advance the use of such methodologies in the clinics, within the Mobilise-D project Giorgio acted as academic co-lead of the regulatory work package and was involved in various interactions with European and American regulatory agencies.









### **Theme 2 Expert Discussion Panel**

#### **Chair: Camille Carroll**



#### **University of Newcastle**

Prof. Camille Carroll is Professor of Clinical Neuroscience at Newcastle University and Honorary Consultant Neurologist at University Hospitals Plymouth. Her research is focused on disease modification and the use of digital health technologies for monitoring and personalised care in Parkinson's. Prof. Carroll co-leads the Edmond J Safra ACT-PD initiative, developing a multi-arm, multi-stage trial platform for disease modifying interventions in Parkinson's. She is developing digital tools to support patient self-management and digitally-enabled care. She is NIHR Clinical Research Network National Specialty Lead for Neurodegenerative Diseases and joint Clinical Director of the Parkinson's Excellence Network in the UK.



#### Panellist: Diane Stephenson

#### **Critical Path Institute**

Diane Stephenson is a neuroscientist by training with 30 years combined experience in academic neuroscience and drug discovery. She is passionate about translational science and has a long-time dedication to the discovery of therapies to treat diseases of the nervous system. Dr. Stephenson received her undergraduate degree in Biochemistry at University of California and her Ph.D. in Medical Neurobiology from Indiana University. She spent the majority of her career as a translational neuroscientist at the largest pharmaceutical companies focusing on disease areas including Alzheimer's, Parkinson's, Stroke, ALS and Autism Spectrum Disorders. Dr Stephenson joined Critical Path Institute in 2011 and has led several programs including the Huntington's Disease and Alzheimer's Disease consortia. She presently leads Critical Path for Parkinson's (CPP), a multinational consortium comprised of academic experts, industry scientists, patient advocacy groups and regulatory experts collectively aimed at accelerating drug development tools for Parkinson's disease. The CPP digital drug development tool 3DT project led by CPP includes industry, regulators, academic experts and people with lived experience. Dr. Stephenson focuses on highlighting the voice of people living with Parkinson's in all CPP's efforts.

#### Panellist: Dalia Dawoud

#### National Institute for Health and Care Excellence

Prof. Dalia Dawoud, PhD, is Associate Director (Research) at the National Institute for Health and Care Excellence (NICE). She has over 20 years experience as health economist and researcher. Her current work is focused on advancing HTA and clinical guideline development methods through research. Dalia leads NICE newly established HTA Innovation Laboratory (HTA Lab) as well as NICE's portfolio of European Commission funded projects, such as IMI NEURONET and IHI PREDICTOM and AD-RIDDLE, with cumulative funding of over 5 Million Euros. She is widely published in the area of health economics and outcomes research and serves as Associate Editor of ISPOR journal Value in Health and as Director on ISPOR Board of Directors (2023-2026).

#### **Panellist: Lis Boulton**

#### Age UK

Dr Lis Boulton is Health & Care Policy Manager, in the Charity Influencing Division at Age UK. She has 29 years' experience in health and social care, including 14 years as an academic researcher, working in the Healthy Ageing Research Group at the University of Manchester. She has published extensively on falls prevention and the importance of physical activity for healthy ageing, as well as on social isolation and loneliness, digital access to services, frailty, and end of life. Lis joined Age UK in October 2021, but remains active in healthy ageing research.







## **Theme 2 Expert Discussion Panel**

#### Panellist: Gerard Quinn



#### Mobilise-D Data Management Industry Co-Lead

Gerard Quinn has worked at ICON for over 8 years and currently holds the role of VP, Innovation & Informatics and heads up the ICON AI Centre of Excellence. He has over 25 years' in the life science industry, in both human and animal health, with experience in innovation, strategy, and project portfolio management, process improvement and IT. He holds an MSc in Strategic Quality Management –Lean Six Sigma, BSc is Technology Management and a Lean Six Sigma Master Black belt. He applies his experience to all areas of e-clinical innovation and the nurturing of the enterprise innovation mindset. His team at ICON leads the innovative activities in technology and data science. They identify and build key partnerships with life science and technology leaders to co-develop services and capabilities by evaluating joint capabilities with the aim of driving efficient clinical trials for our sponsors and patients. They also lead the development of ML/AI solutions through the ICON AI Centre of Excellence, that improve cycle times across the clinical research value chain, that provide new intelligence and insight for key decision makers and that in general improve the speed and quality of clinical research.

#### Panellist: Pippa Powell



#### **European Lung Foundation**

Pippa Powell has headed up the European Lung Foundation (ELF) since 2005 and been in the role of General Secretary of Lungs Europe since 2018. In addition to her background and PhD in biomedical science, Pippa has more than 20 years' experience working in respiratory health. First as a journal editor and a medical writer. Then providing evidence-based information for patients, working with the press and media to ensure accurate reporting of respiratory science, and awareness campaigns for the general public. Pippa has championed the role of the patient within science and has been working with professionals to find best practice for patient and public input into respiratory healthcare. Working together with >200 European patient orgs and >300 individuals living daily with lung conditions helps to ensure that the patient voice can be heard via ELF in European Respiratory Society (ERS) activities and wider in the lung health arena.

#### Panellist: Keith Park

#### **MS Society**

Keith Park is the Policy, Public Affairs and Campaigns Manager at MS Society Scotland. He has been at the MS Society in a number of roles over the past thirteen years. These roles have include service and community development roles before taking up his current position three years ago. Keith originally qualified as a Physiotherapist and gained valuable experience working in a range of neurology services in Glasgow.

#### **Panellist: David Dexter**

#### Parkinson's UK

David Dexter was awarded a PhD in Neuropharmacology in 1991. David was awarded a lectureship in Pharmacology at Imperial College in 1994, progressing to Professor of NeuroPharmacology in 2012 and then Deputy Head of the Division of Brain Sciences in 2014. He has pioneered research into understanding the neurodegenerative mechanisms that cause Parkinson's, identifying novel drug targets which he has translated through in vitro and in vivo pharmacological models into drugs which have entered Parkinson's clinical trials. In 2002 David established the Parkinson's UK Brain Bank at Imperial. In 2017 he joined Parkinson's UK as the associate Research Director, then Research Director in 2023. David is also the pharmacology lead on the Parkinson's UK Virtual Biotech, a pioneering programme developing better treatment for Parkinson's.





## **Mobilise-D**

## **Evening Networking Event at the Scottish National Gallery**

### 19:00 - 22:30 The Mound, EH2 2EL

We hope you will join us for our networking and celebratory evening event at the Scottish National Gallery. This stunning neoclasical building is home to world class Scottish and International works of art, and offers iconic views of the Princes Street Gardens.



#### 19:00 - 19:30 **Piped welcome with arrival fizz and canapés**

#### 19:30 - 20:30

Art expert introduction to the newly opened Scottish Galleries. This will cover the building extension and architecture, the methodology of the hang, and some key artworks to look out for. This will be followed by an exclusive opportunity to privately view the collection and ask any questions.

#### 20:00 - 22:30

Contemporary Scottish dining including Taste of Scotland stations showcasing the best of Scottish produce. There will also be mini bowl options of classic Scottish dishes including haggis, neeps and tatties!

**PLEASE** use main entrance via East Princes Street Gardens

## **Mobilise-D**

## Photos and videos at the conference

Please note that throughout the duration of the conference, we will be taking photographs and videos for promotional and documentation purposes. By attending the conference, you grant permission to be included in these materials.

We fully respect your privacy and understand that some attendees may prefer not to be featured in such content. If you do not wish to be photographed or recorded during the event, please inform us by sending an email to **Isabel.neatrour@newcastle.ac.uk.** We will make every effort to accommodate your request and ensure your privacy is respected.

### **Stay connected:**

- Want to know more about Mobilise-D?
- Keep updated on our achievements?
- Find out about data releases?

The Mobilise-D website will continue to be updated after the project ends, so stay tuned for further results and publications.



Visit www.mobilise-d.eu or scan the QR code.

### Please also visit our YouTube channel to watch project content we have created over the last five years.

This includes short videos explaining Mobilise-D and mobility, as well as project webinars and presentations. All presentations from this conference will also be filmed and uploaded to our channel. Please also follow our progress on LinkedIn.



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