



NEWSLETTER

September 2023

idea-fast.eu



innovative
medicines
initiative



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COS PROJECT RECRUITMENT

As the IDEA-FAST Clinical Observation Study (COS) goes forward, the consortium's main goal is to keep the study running smoothly and successfully. Here's a short update of what has been going on so far:

The COS recruitment is going forward in 18 sites, and will start soon in 2 pending sites waiting for a fully signed site agreement. With 10.5 months left in the recruitment process, we have currently recruited 696 patients in total, and are expecting more across all sites. For now, the main goal is accelerated recruitment of patients, especially of underrepresented diseases, such as Inflammatory Bowel Disease, Rheumatoid Arthritis, and Systemic Lupus Erythematosus.

We thank everybody who has been working hard towards making this COS possible! For a more in-depth look at our sites, you can visit the [Meet the Sites](#) section on our website.

PEOPLE OF IDEA-FAST

The people of IDEA-FAST are the driving force behind the project, and we aim to introduce as many of our collaborators to the general public. Here are some of our recent news:

CLINICAL DELIVERY STAFF INTERVIEW

Clinical staff members play a pivotal role in the delivery of the ongoing Clinical Observational Study. We have engaged in a conversation with Ms. Lauren John, a research practitioner affiliated with the Royal Devon and Exeter Hospital.



CLINICAL DELIVERY STAFF

LAUREN JOHN
RESEARCH PRACTITIONER

Read Here: emp.onl/MkhhW

PEOPLE OF IDEA-FAST

DR. CHRIS LAMB OF NEWCASTLE UNIVERSITY IS AWARDED THE 2023 SIR FRANCIS AVERY JONES MEDAL

Dr. Chris Lamb, the IDEA-FAST cohort co-lead for Inflammatory Bowel Disease, has been awarded the 2023 Sir Francis Avery Jones Medal. His continuous efforts in translational gastroenterology research won him the prestigious Sir Francis Avery Jones (FAJ) BSG Research Award, which is awarded to exceptional gastroenterologists' research in the UK and Republic of Ireland.



Image courtesy of the Newcastle Biomedical Research Centre

Read Here: emp.onl/KrVQF

PEOPLE OF IDEA-FAST

DR. CHLOE HINCHLIFFE - BEST POSTDOC PRESENTATION AT THE ISPGR CONFERENCE

Dr. Chloe Hinchliffe of Newcastle University has been awarded the best oral presentation by a post-doctoral fellow for her presentation “Are measures of gait variability associated with sleepiness and fatigue in immune and neurodegenerative disorders? Insights from the IDEA-FAST feasibility study” at International Society of Posture and Gait Research (ISPGR) World Congress in Brisbane.



Image courtesy of Chloe Hinchliffe

DELIVERABLES

DELIVERABLES SUBMITTED

DELIVERABLE 8.3 AND 8.4 - Report on the challenges of sharing of digital device data from legal and IPR perspectives in the context of a learning healthcare system

The Deliverable discusses the legal possibilities to open up device raw data for research outside the scope of a collaborative research project such as IDEA-FAST.



IDEA-FAST

Identifying Digital Endpoints to Assess FATigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

Grant Agreement No. 853981

**WP 8 – Data Protection,
Ethics and Legal challenges**

D8.4: Report on the challenges of sharing of digital device data from legal and IPR perspectives in the context of a learning healthcare system

Read the Public Deliverable 8.4 Here:
emp.onl/V8o1k

PUBLICATIONS

PAPERS

New publications are continuously on the way. From papers to posters and presentations, there are a couple new publications where the IDEA-FAST consortium contributed:

Paper - Reverse Engineering of Digital Measures: Inviting Patients to the Conversation by **Clay et al.**

“Reverse engineering of Digital Measures” was the second in a series of meetings examining paths forward for enhancing the utility of digital measures. These meetings were organised by the Foundation for the National Institutes of Health ETH Zürich, European Medicines Agency, and VivoSense. The findings show a blueprint for how and why the patient voice can be thoughtfully integrated into digital measure development and that continued multistakeholder engagement is critical for further progress.

Digital Biomarkers

Viewpoint

Digit Biomark 2023;7:28–44
DOI: 10.1159/000530413

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Accepted: March 7, 2023
Published online: May 12, 2023

Reverse Engineering of Digital Measures: Inviting Patients to the Conversation

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Alison Keogh^{d,e} Katarzyna Wac^f Tova Gur-Arie^e Justin Baker^g
Christopher Bull^{h,i} Andrea Cereatti^{e,j} Francesca Cormack^{i,k}
Damien Eggenpieler^l Luca Foschini^m Raluca Ganeaⁿ
Peter M.A. Groenen^o Nicole Gusset^p Elena Izmailova^q
Christoph M. Kanzler^r Lada Leyens^s Kate Lyden^a Arne Mueller^{e,t}
Julian Nam^s Wan-Fai Ng^{h,i} David Nobbs^{i,s} Foteini Orfaniotou^s
Thanneer Malai Perumal^s Wojciech Piwko^u Anja Ries^s Alf Scotland^r
Nick Taptiklis^{i,k} John Torous^g Beatrix Vereijken^{e,v} Shuai Xu^w
Laurenz Baltzer^x Thorsten Vetter^y Jörg Goldhahn^x Steven C. Hoffmann^b

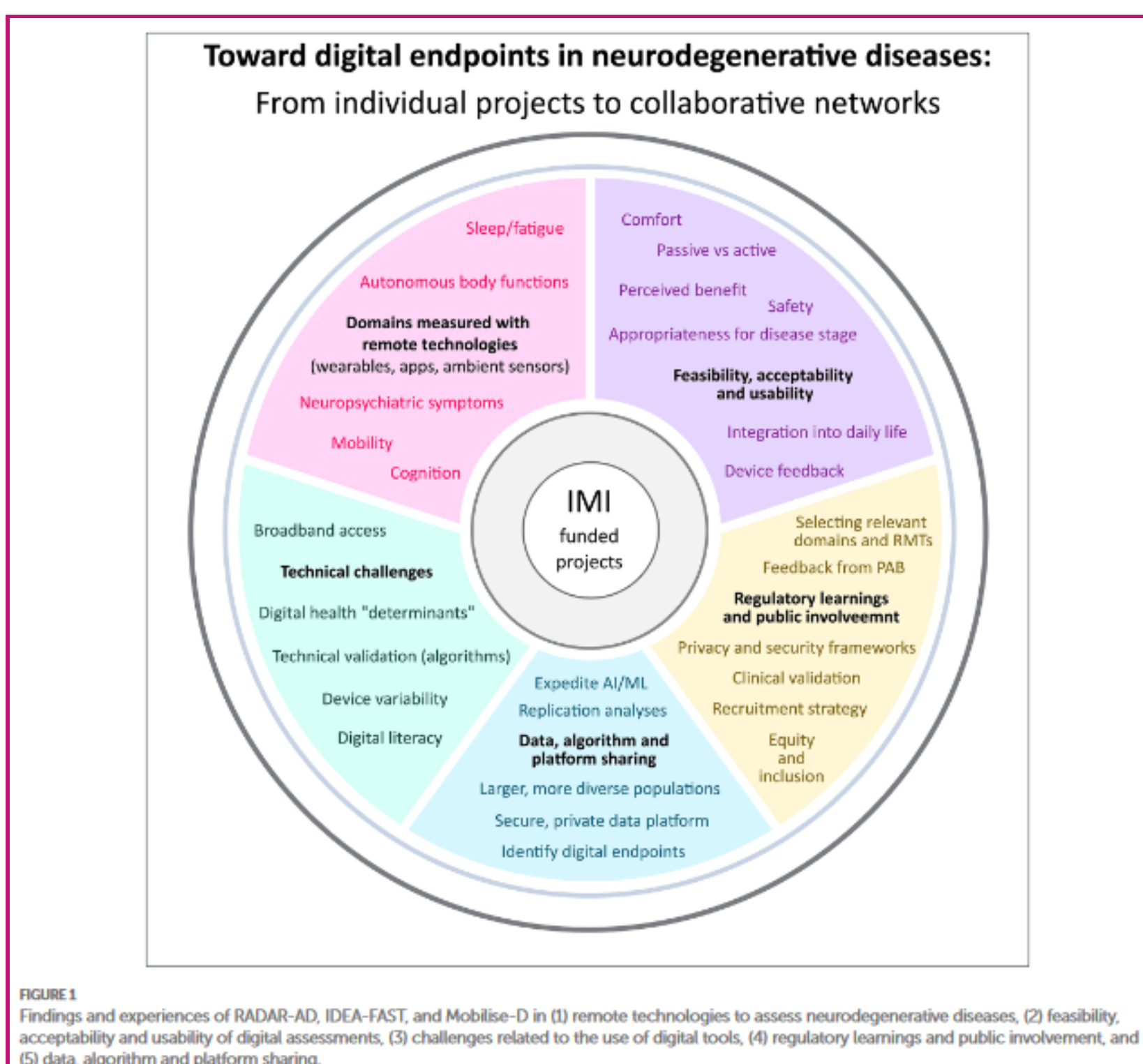
Downloaded from <http://karger.com/dib/article-pdf/7/1/28/3900093>

Read the Paper: emp.onl/giVVs

Paper - Digital endpoints in clinical trials of Alzheimer's disease and other neurodegenerative diseases: challenges and opportunities by **Brem et al.**

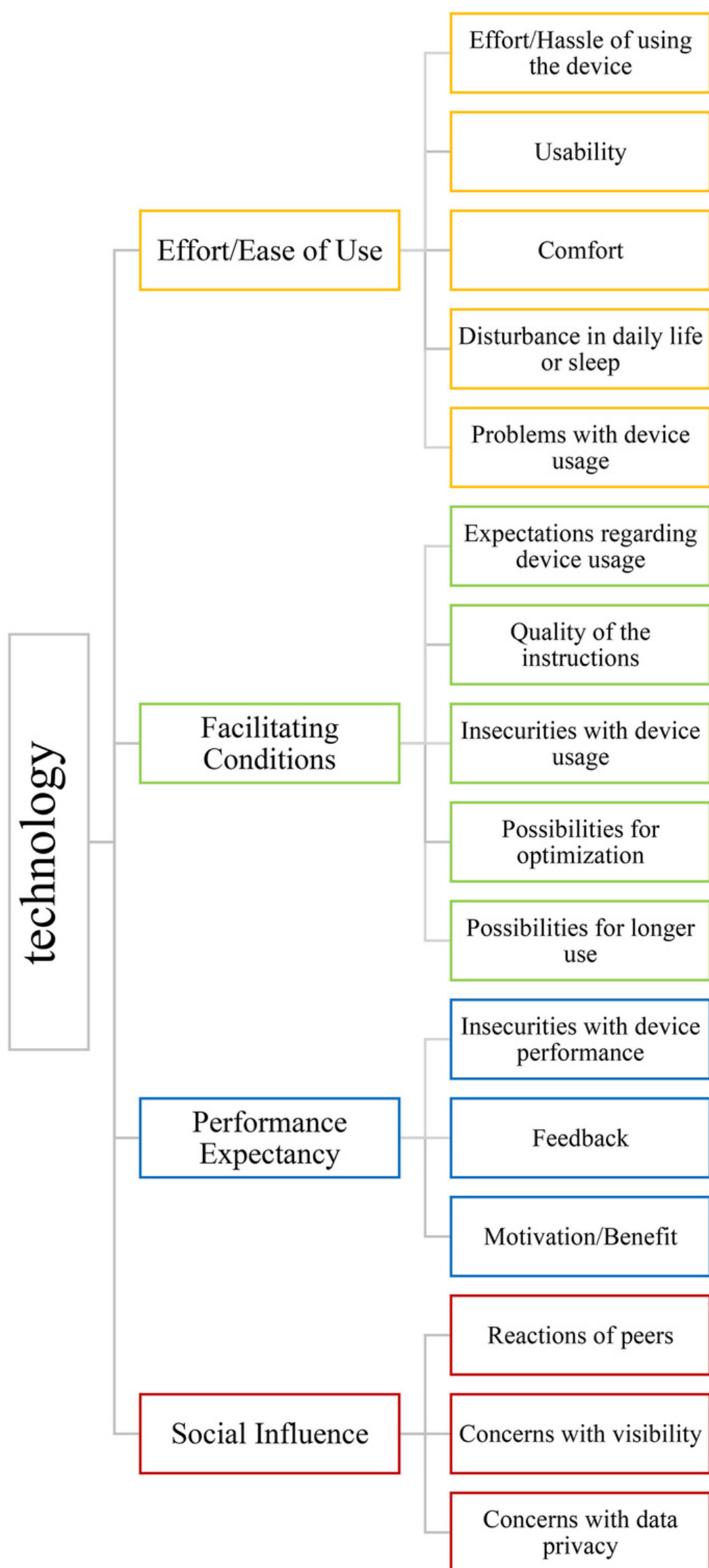
The publication draws on findings and lessons learned from three Innovative Medicine Initiatives (IMI) initiatives, RADAR-AD, IDEA-FAST and Mobilise-D to discuss:

- The value of remote technologies to assess neurodegenerative diseases
- Feasibility, acceptability and usability of digital assessments
- Challenges related to the use of digital tools
- The significance of inter-project exchange and data- and algorithm-sharing



Read the Paper: emp.onl/SHDbz

Paper - Technology acceptance of digital devices for home use: Qualitative results of a mixed methods study by **Graeber et al.**



Digital devices have demonstrated benefits to patients with chronic and neurodegenerative diseases. But when patients use medical devices in their homes, the technologies have to fit into their lives. The authors investigated the technology acceptance of seven digital devices for home use to further explore usability in real-time monitoring of patients.

Read the Paper:
emp.onl/G9EXR

Paper - Regulatory qualification of a cross-disease digital measure: benefits and challenges from the perspective of IMI consortium IDEA-FAST, by **David Nobbs et al.**

IDEA-FAST is developing novel digital endpoints to assess fatigue, sleep quality, and impact of sleep disturbances in patients with neurodegenerative diseases and immune-mediated inflammatory diseases. In 2022, the project's consortium met with the European Medicines Agency (EMA) to get advice on its plans for regulatory qualification of the measures. This paper reviews the IDEA-FAST view on developing digital measures for multiple diseases and the advice provided by the EMA.

Digital
Biomarkers

Viewpoint – Review Article

Digit Biomark 2023;7:132–138
DOI: 10.1159/000533189

Received: May 30, 2023
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Published online: September 19, 2023

Regulatory Qualification of a Cross-Disease Digital Measure: Benefits and Challenges from the Perspective of IMI Consortium IDEA-FAST

David Nobbs^a Wojciech Piwko^b Christopher Bull^c Francesca Cormack^d
Teemu Ahmaniemi^e Sebastian C. Holst^a Meenakshi Chatterjee^f
Walter Maetzler^g Stefan Avey^h Wan Fai Ngⁱ IDEA-FAST Consortium

Read the Paper: emp.onl/QIERA

PUBLICATIONS

POSTERS

Poster presentation - ISCTM App-based cognitive assessment and monitoring, Francesca Cormack, Cambridge Cognition

The IDEA-FAST consortium aims to further develop the measurement of fatigue by capturing multiple physiological and behavioural measures from patients in their free-living setting using digital technology. This poster gives an overview of the performance of three brief cognitive assessments, which have been previously shown to be sensitive to fatigue, sleep or daily activities, deployed as part of the IDEA-FAST feasibility study.



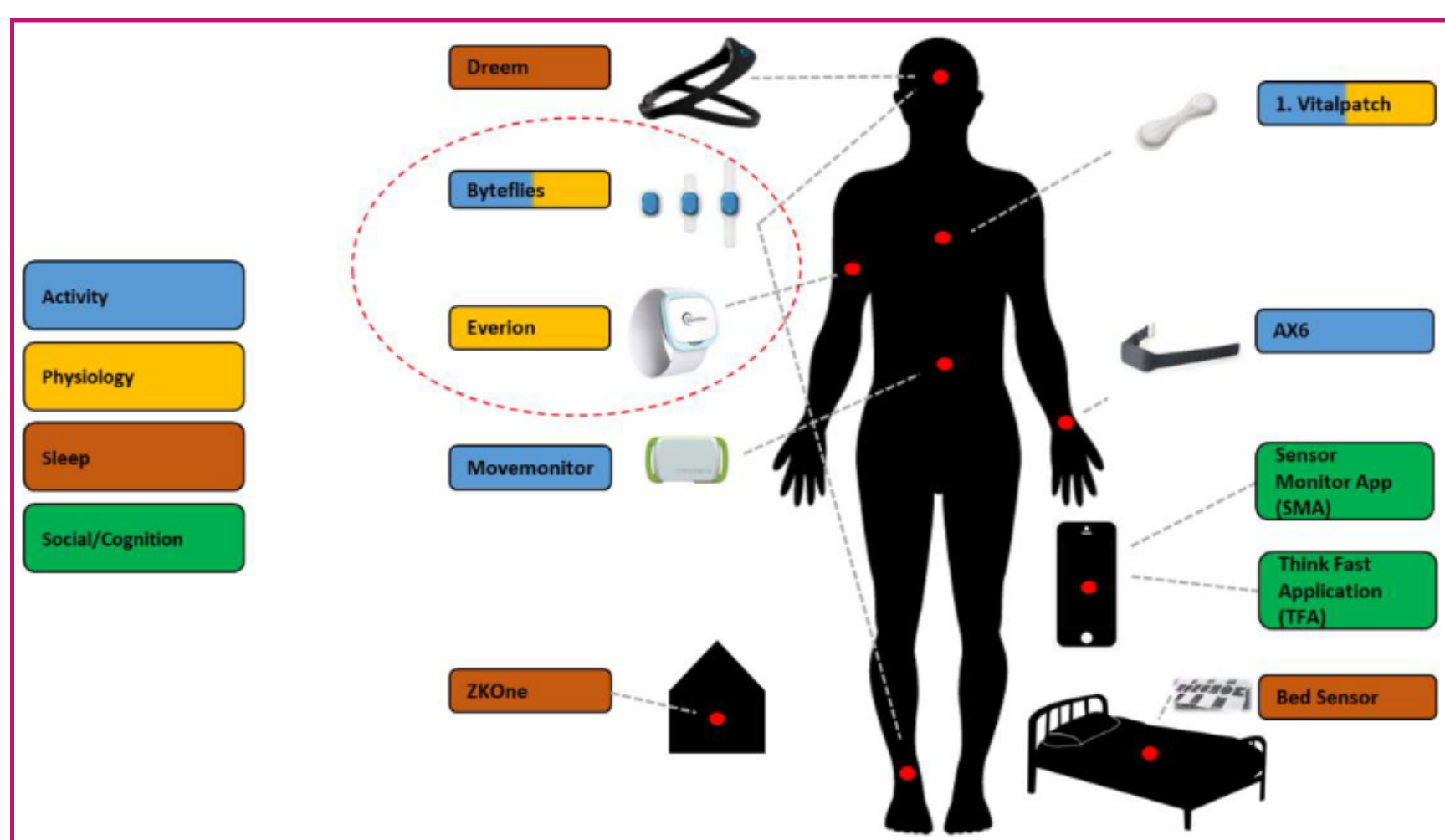
Access the Poster Here: emp.onl/2x5io

Poster presentation - Associations between activity digital measures with sleep and fatigue PROs assessed in the real world, **Rana Zia Ur Rehman, Janssen**

The performance of four activity monitoring devices was evaluated to assess feasibility of capturing digital measures of fatigue and sleep in the feasibility study of the IDEA-FAST project from six different disease groups and healthy controls.

Participants completed sleep-, fatigue- and pain-related Patient reported Outcomes up to 4 times a day, using a mobile phone application.

Performance of different activity monitors was assessed by evaluating the coverage, data quality of the derived features, and their association with PROs in all participants and in individual disease cohorts



Access the Poster Here: emp.onl/5vSmC

RECENT EVENTS

Throughout the year various facets of IDEA-FAST's goals and achievements are presented in summits, congresses, and workshops.

Digital Biomarkers Summit - May 10th, 2023

Tarrytown, New York

Stefan Avey (Jannsen), our WP7 Co-lead, represented IDEA-FAST at the US Digital Biomarkers Summit, with a presentation on developing cross-disease multicomponent digital biomarkers of fatigue.

Read More: emp.onl/ukwUZ

ISPGR World Congress 2023 - July 9th, 2023

Brisbane, Australia

The International Society of Posture and Gait Research (ISPGR) World Congress brings together posture and gait experts from around the world for discussion and exchange of the most cutting edge knowledge, insights, issues and ideas. IDEA-FAST was represented by Dr. Chloe Hinchliffe, postdoctoral researcher at Newcastle University.



Image courtesy of Chloe Hinchliffe

Read More: emp.onl/r9GCP

EMBC 2023 - July 24th - 27th, 2023

Sydney, Australia

EMBC 2023 is the 45th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. This conference, themed “Engineering Better and More Resilient Healthcare for All”, is focused on highlighting the fragilities and responses of healthcare systems worldwide.

Dr. Chloe Hinchliffe of Newcastle University held a talk for EMBC 2023 titled “Is there a relationship between gait variability and patient reported fatigue & sleepiness?” where she spoke more about her work with IDEA-FAST.

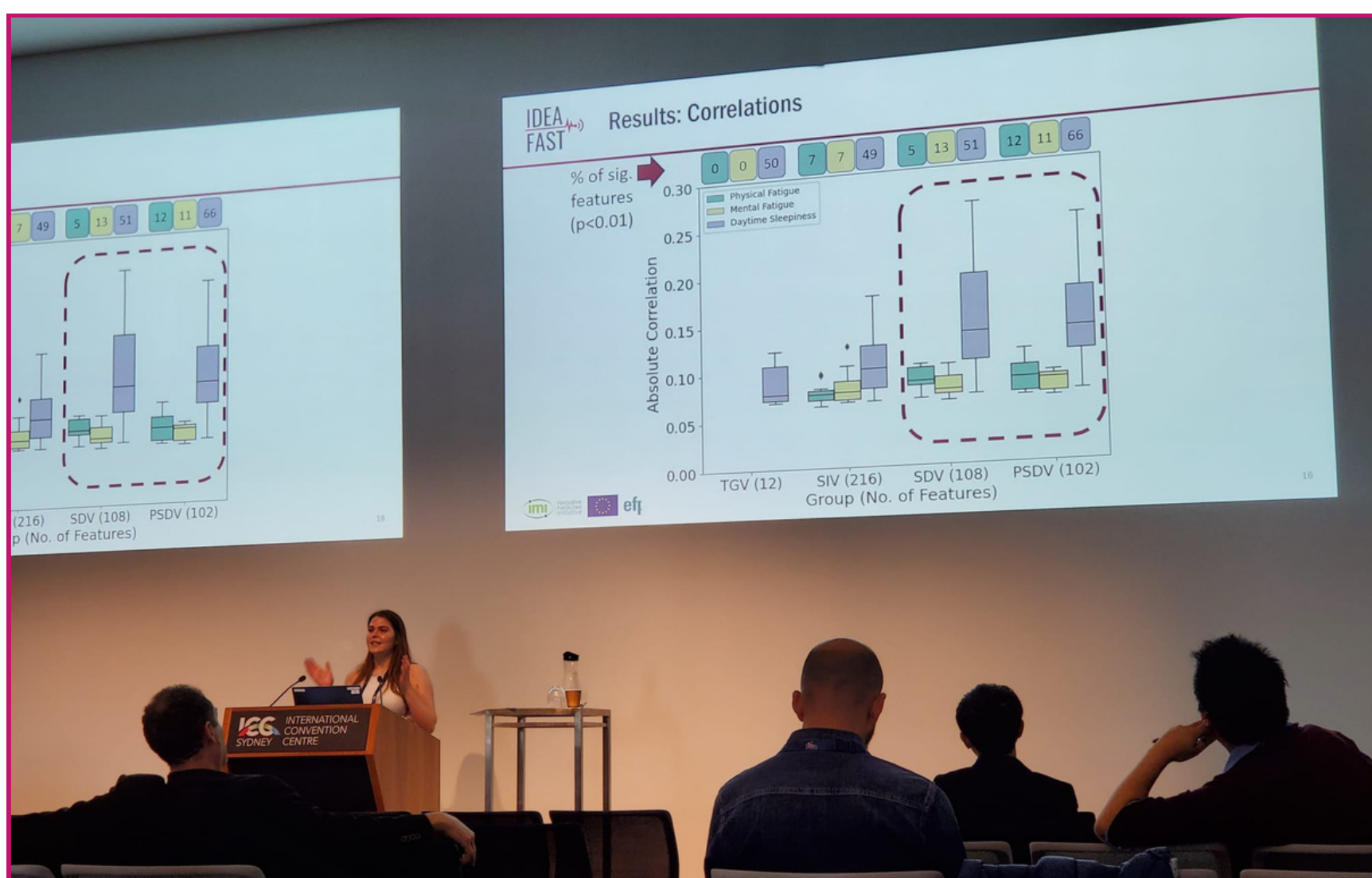


Image courtesy of Chloe Hinchliffe

BioMedEng 23 - September 14, 2023

Swansea University, Swansea, Wales

The BioMedEng23 is the UK's largest gathering of Biomedical Engineers, Medical Engineers, and Bioengineers. Dr. Chloe Hinchliffe held a presentation titled "Impact of weekly gait activity data aggregation methods on associations with fatigue and sleepiness in immune and neurodegenerative disorders" at the conference.



Image courtesy of Chloe Hinchliffe

From BITS to BETTER Workshop - September 22, 2023

Beatrixgebouw, Utrecht, the Netherlands/ Online

Workshop on meaningful patient involvement in developing digital endpoints in research and disease management. A recording of this session will be made available soon.

Read More: emp.onl/A7GQu

IDEA-FAST WEBINAR

New Ways of Measuring Fatigue and Sleep Disturbances in Chronic Diseases June 7th, 2023

Online Session

Our IDEA-FAST webinar on “New Ways of Measuring Fatigue and Sleep Disturbances in Chronic Diseases” witnessed active participation from a diverse group of attendees, including representatives from patient advocacy organizations, industry professionals, researchers, and healthcare providers. The session focused on discussing the latest advancements in research and the potential benefits that digital endpoints can bring to current treatment opportunities.

Our panel of speakers shared their expertise on chronic illnesses, and the challenges of fatigue and sleep disturbances faced by patients, further elaborated by two patient testimonials.

The screenshot shows a webinar slide with the following content:

- IDEA-FAST** Challenges and pitfalls in measuring fatigue using PROs
- A multi-faceted phenomenon including physical, cognitive, emotional and psychosocial aspects
 - Highly variable & unpredictable
 - Fatigue is currently measured using Patient-reported outcome (PROs)
 - Recall periods (typically 1-4 weeks) of PROs poorly capture variability and prone to recall bias
 - Subjectivity of PROs could also reduce sensitivity of the tools to capture change
 - Unmet need for additional measurement tools
- Figure:** Four line graphs showing 'Fatigue level (VAS 0-10)' over 'Time (7 days)'. The x-axis is labeled 'Time (7 days). M=Morning, A=Afternoon, E=Evening, N=Night'. The graphs show highly variable and unpredictable fatigue levels across different days and times.
- Logos:** imi, European Union, efpia, and others.
- Webinar Interface:** On the right side, there are video thumbnails for participants: Fai Ng, Shahan Tariq, Redder, W.J.M. (Is...), Monique Devillers, and Alex... with a '+40' button.

Read More: emp.onl/Du1Ro

UPCOMING EVENTS

ISCTM 2023 Autumn Conference - October 5, 2023
Barcelona, Spain

The ISCTM brings together international stakeholders representing academia, government, policymakers, industry, and the public to address strategic clinical, regulatory, methodological and policy challenges in clinical research.



Read More: emp.onl/Og9BX



STAY UPDATED!

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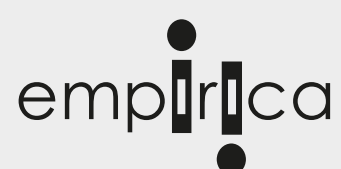
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