



Identifying **D**igital **E**ndpoints to **A**ssess  
**F**atigue, **S**leep and **a**c**T**ivities of daily living  
in neurodegenerative disorders and  
immune-mediated inflammatory diseases

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# Overall aims

1. To define **digital endpoints** for the evaluation of **fatigue** and **sleep** disturbances and to explore digital correlates of **selected ADLs** in patients with Immune Mediated Inflammatory Diseases and Neurodegenerative Diseases and to **seek scientific/qualification advice** of such digital endpoints from the EMA/FDA.
2. To ensure **lasting impact** through the creation of **a large, real-world digital dataset** of biophysiological, neurocognitive, behavioural, personal, environmental and socialization observations coupled with **comprehensive clinical data** and **data analytics** to support future research and drug development.

# Conditions of interest

## ■ IMID

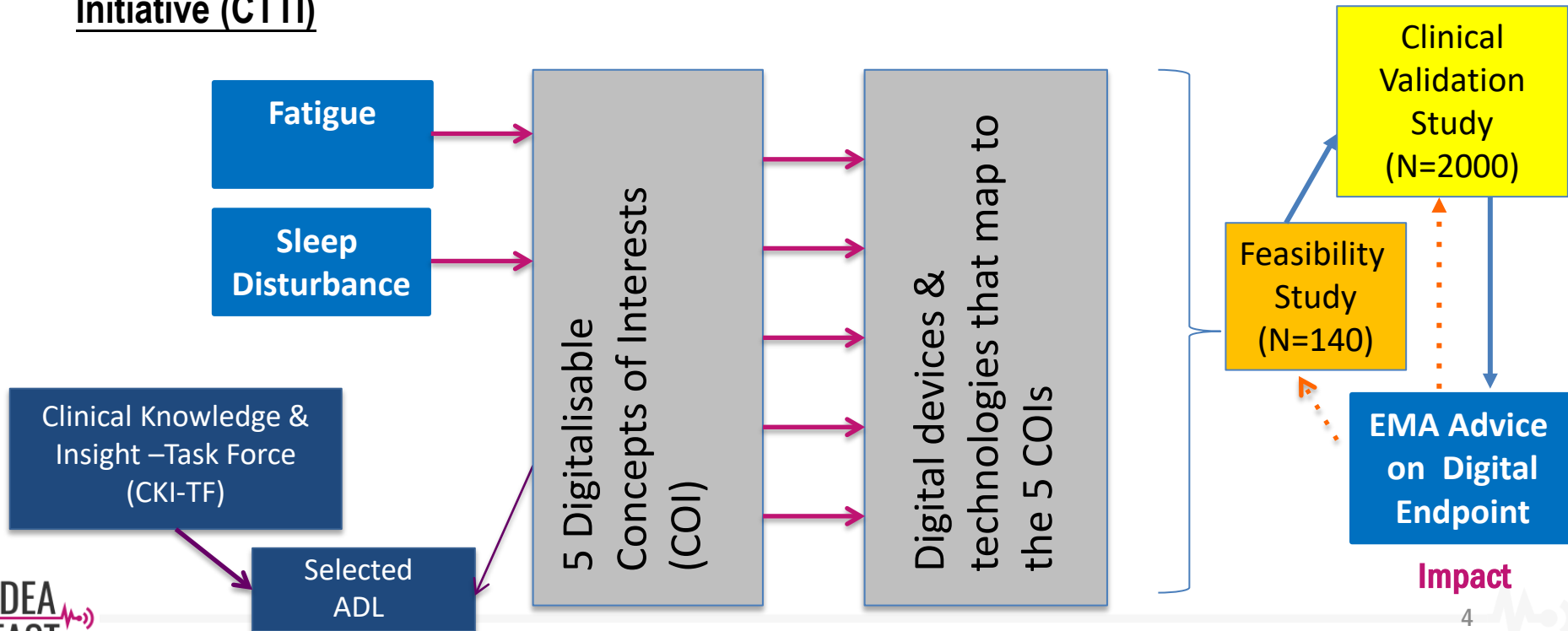
- Inflammatory Bowel Disease
- Sjogren's syndrome
- Lupus
- Rheumatoid Arthritis

## ■ Neurodegenerative disease

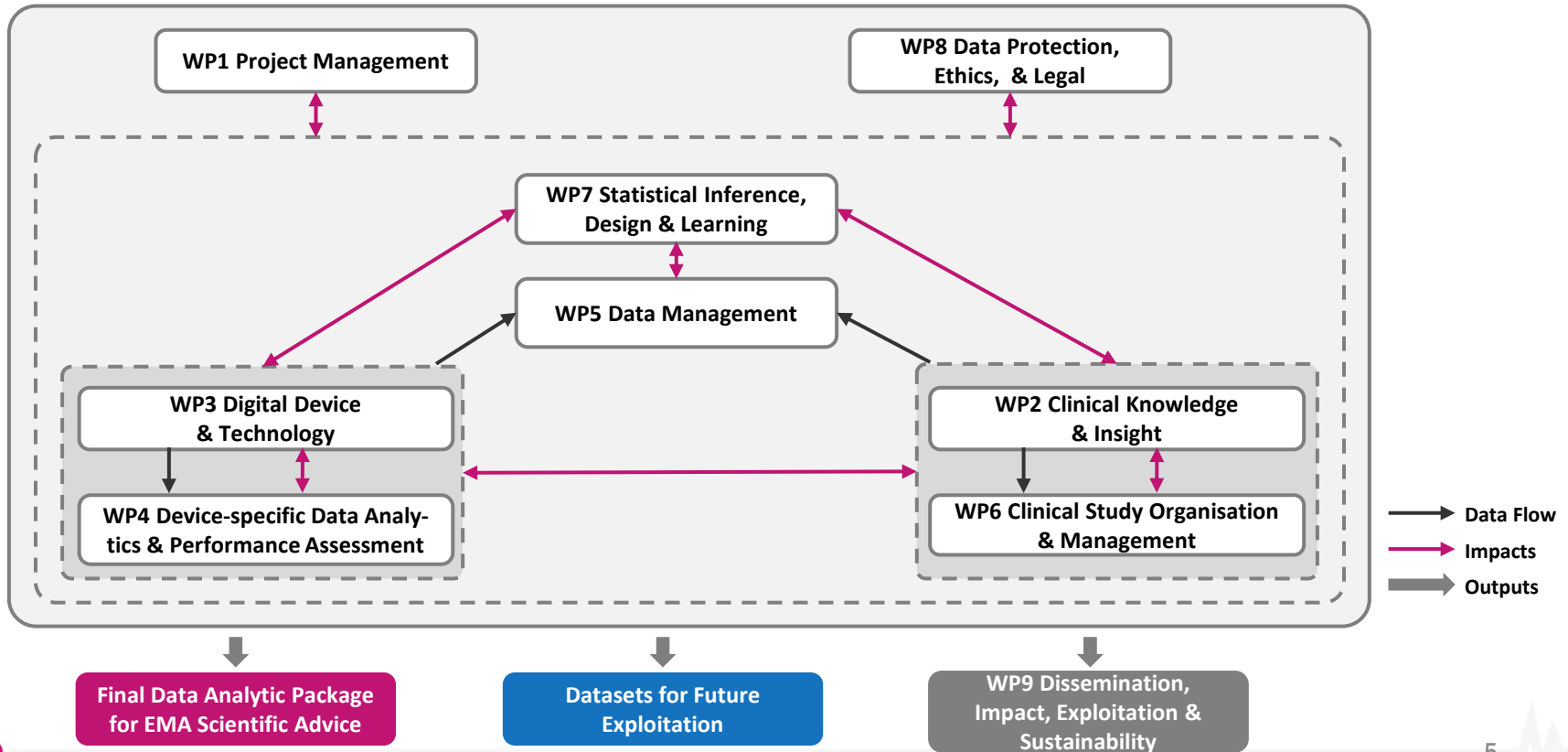
- Parkinson's disease
- Huntington's disease

# Concept and Approach

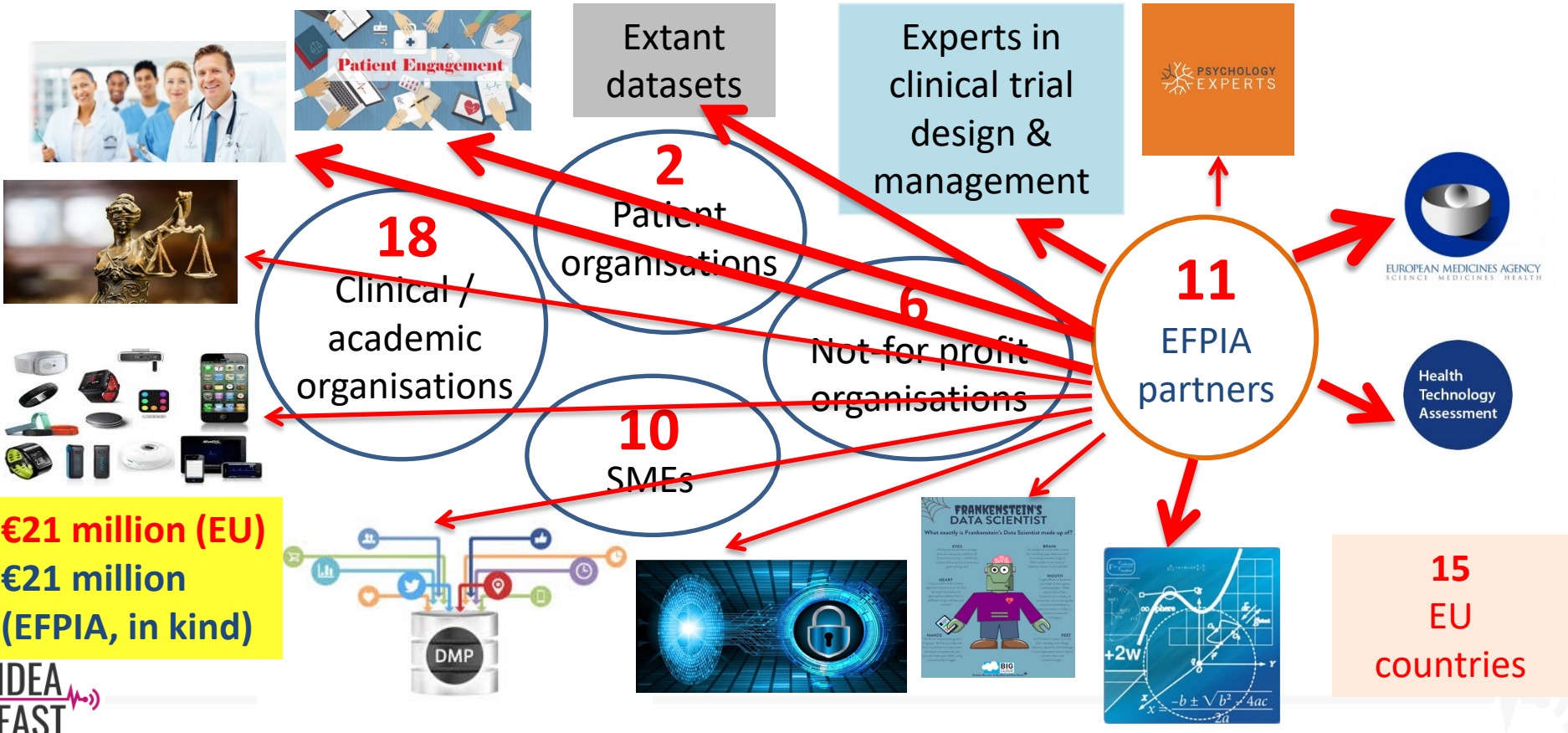
## Clinical Trials Transformation Initiative (CTTI)



# Work Package Relationship



# IDEA-FAST Consortium partners



**€21 million (EU)**  
**€21 million**  
**(EFPIA, in kind)**

| Participant Organisation  | Country        |
|---|----------------|
| <b>University of Newcastle upon Tyne</b>  | <b>UK</b>      |
| <b>Universtätsklinikum Schleswig-Holstein (Kiel)</b>                            | <b>Germany</b> |
| Universita Degli Studi di Brescia   | Italy          |
| Erasmus Universitair Medisch Centrum Rotterdam                                  | Netherlands    |
| University of Glasgow   | UK             |
| University of Limerick  | Ireland        |
| European Clinical Research Infrastructure Network                               | France         |
| Queen Mary University of London   | UK             |
| Imperial College of Science Technology and Medicine                             | UK             |
| Byteflies NV  | Belgium        |
| Dreem   | France         |
| University of Cambridge   | UK             |
| Lixoft SAS  | France         |
| Asociación Parkinson Madrid   | Spain          |
| Stichting MLC Foundation  | Netherlands    |
| Technologie und Methodenplattform für die Vernetzte Medizinische Forschung e.V. | Germany        |
| Medibiosense Ltd  | UK             |
| empirica Gesellschaft für Kommunikations und Technologieforschung mbH mbH       | Germany        |
| FCiências.ID – Associação para a Investigação e Desenvolvimento de Ciências     | Portugal       |
| Pluribus One S.r.l  | Italy          |
| Instituto de Medicina Molecular Joao Lobo Antunes                               | Portugal       |
| VTT Technical Research Centre of Finland Ltd                                    | Finland        |
| Cambridge Cognition Ltd   | UK             |

| Participant Organisation  | Country            |
|---|--------------------|
| Universidad Autonoma de Madrid                                  | Spain              |
| Institut Mines- Télécom   | France             |
| McRoberts BV  | Netherlands        |
| George-Huntington-Institut GmbH                                 | Germany            |
| Institute of Psychiatry and Neurology                           | Poland             |
| Medical University of Innsbruck                                 | Austria            |
| Stavanger University Hospital                                   | Norway             |
| iXscient Ltd  | UK                 |
| European Federation of Crohn's & Ulcerative Colitis Association | Belgium            |
| Leiden University Medical Centre                                | Netherlands        |
| University of Manchester  | UK                 |
| <b>EFFPIA and Associated Partners</b>                           |                    |
| <b>Janssen Pharmaceutica NV</b>                                 | <b>Belgium</b>     |
| <b>Takeda Pharmaceuticals International AG</b>                  | <b>Switzerland</b> |
| Abbvie Inc.   | USA                |
| AstraZeneca AB  | Sweden             |
| Biogen IDEC Ltd   | UK                 |
| Eli Lilly & Co. Ltd.  | UK                 |
| Orion OYJ   | Finland            |
| Parkinson's Disease Society of the United Kingdom               | UK                 |
| Pfizer Ltd.   | UK                 |
| F. Hoffmann-La Roche AG   | Switzerland        |
| Sanofi Aventis Recherche et Développement                       | France             |
| UCB Biopharma SPRL  | Belgium            |
| CHDI Foundation   | USA                |

Coordinator, Co-coordinator, Project leader and co-Project leader are denoted in bold



# Thank you for your attention!

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## Disclaimer

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