Welcome to the pitching session on:

Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Presentation order	First Name	Last Name	Job position	Organization	Country
	1 Nayeli	Schmutz	Chief Medical Officer	PIPRA AG	Switzerland
	2 Esther	Blaimschein	Researcher	Bertha von Suttner Private University	Austria
	3 Iris	Sommer	psychiatrist- researcher	имсс	Netherlands
	4 Jakob	Bardram	Professor	DTU, Department of Health Technology	Denmark
	5Oscar	Mayora	Head of Digital Health Research	Fondazione Bruno Kessler	Italy
	6Gabriela	Perez-Fuentes	Clinical Scientist	Vall d'Hebron Institute of Research (VHIR)	Spain
	7 Françoise	Charbit	Health programme manager	CEA	France
	8 George	Suciu	R&D and Innovation Manager	BEIA	Austria
	9 Jérome	Kalifa	Chairman	Let it Care	France
1	0 Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona SL	Spain

If you want to interact with other participants please use the chat function on the top right corner



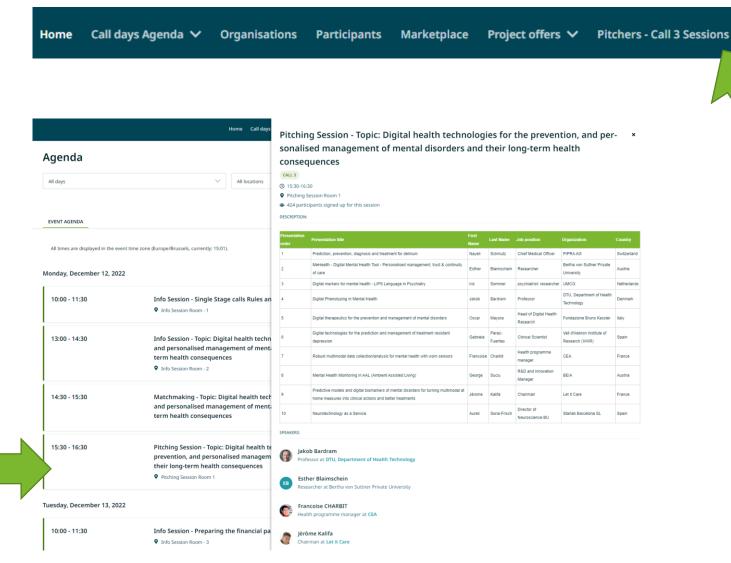


Before we start...

- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.



How to contact the presenters?





IHI Call Days | Call 3

Topic 5: Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Prediction, prevention, diagnosis and treatment for delirium

Contact person name: Dr Nayeli Schmutz

Organisation: PIPRA AG

E-mail: nayeli@pipra.ch

Link to:

- Marketplace opportunity
- Participant profile





Challenges and objectives

Delirium 65+ age

Hospitalized patients

30% affected

Patients in ICU 80% affected







Challenges and objectives



C € APPROVED

predict, prevent, diagnose and treat delirium

- We are seeking partnerships to develop and apply new digital health technologies to delirium
- Our focus perfectly meets the objectives of IHI

Automated Solution:

- Make assessments quicker
- Be easier to integrate into the healthcare pathway
- Allow early clinical intervention and personalized management of patients
- Greatly improve long-term health, economic and social outcomes



Main activities

Develop and refine digital health technologies that address the challenges of prediction, prevention, diagnosis and treatment of delirium

dentification

- PredictiveBiomarkers
- DiagnosticBiomarkers

e.g. Biosensor based **Development**

- Predictive Algorithms
 - Diagnostic Algorithms

Customization

- Customized Software
- Customized Devices

innovativehealthinitiative

Expertise and resources offered



Impactful & highly fundable unmet need (delirium)



Experienced grant writing



Route to commercialization, access to hospitals & KOLs, clinical trial experience



Add us to your consortium without diluting the funding



Expertise requested

We are seeking to partner with a consortium:

- Anyone interested in delirium
- To develop and apply effective digital solutions, wearable devices, biosensor technologies to delirium
- Solutions around patient engagement, soft interventions including prehabilitation, patient empowerment, involvement of family/relatives, carers

We would make a significant contribution to a consortium that has a technology or platform and is still seeking a clinical application



IHI Call Days | Call 3

Topic 5: Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

MeHealth – Digital Mental Health Tool Personalised management, trust & continuity of care

Contact person name: Esther Blaimschein

Organisation: Bertha von Suttner Private University St. Pölten

E-mail: esther.blaimschein@suttneruni.at

Link to:

- Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/202678/opportunities
- Participant profile: https://ihi-call-days.ihi.b2match.io/my



Integrated services, tailored to individual patients' needs





Challenges and objectives

Continuity of care and personalized management

- Integrating EHR, patient summary & other diagnostics (social, psychological)
- Patient-owned DMHT (consent!) operation and maintenance?

O Why IHI?

- Upscale: Multiply pilot, addressing variability across countries
- Contributing to European Health Data Space
- Monitoring of long-term health consequences, co-morbidities

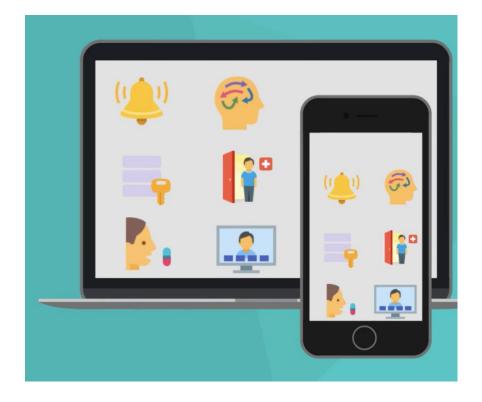
Potential results and expected impact

- Putting patient at the center, improving trust
- Patient empowerment, across numerous conditions and scenarios
- Bridging the gap between in- and outpatient services
- Gain of knowledge through transnational collaboration



Main activities

- Prototyping pilot
- Pilot phase in multiple locations and countries
- Iterative process prototyping
- Long-term transdisciplinary scientific monitoring





Expertise and resources offered

- Clinical Partner
- Social Sciences
- Health Geographies
- Psychotherapy Sciences
- eHealth, standardisation
- Interoperability
- Integrating IT systems
- User experience











Expertise requested

- Industry, IT and technology partners (SME's or large companies)
- Clinical partners (in- and outpatient)
- Patient representatives, caregivers and families
- Research institutes
 - Comorbidities
 - Long-term health consequences
 - Health economics





Digital markers for mental health LIPS Language in Psychiatry

Contact person name: Iris Sommer

Organisation: UMCG

E-mail: i.e.c.sommer@umcg.nl

Link to: https://discourseinpsychosis.org/

https://ihi-call-days.ihi.b2match.io/participations/197425



Challenges and objectives

- To develop acceptable and accurate speech markers to improve diagnosis, treatment monitoring, prognosis and relapse prediction for people with major depression (MDD), bipolar disorder (BD) and schizophrenia (Sz).
 - To line up with service users and clinicians
 - To develop reliable outcome markers
 - To set up a clinical network for MDD, BP and Sz
 - To improve diagnosis, relapse prediction and treatment monitoring



Main activities

- 1. To develop data processing, analysis [and deployment] pipelines/platforms, including benchmarking datasets and tasks, **identifying speech markers** for clinically relevant features of the disorders and their co-morbidity.
- 2. Investigating preferences and needs of service users, their family, social workers and clinicians and collaborate with them to define guidelines for the implementation of speech markers in mental health care.
- 3. To apply digital language markers in a transdiagnostic clinical framework: invite a large cohort of individuals with MDD, BPD, or SZ, and followed up for 2 years in a real-world setting
- 4. Validate the potential of speech markers for differential diagnosis, treatment monitoring prognosis and relapse prediction in multicenter proof-of-concept trials including multiple languages to define acceptability, accuracy and (cost)effectiveness.



Expertise and resources offered

- A strong global network of 190 researchers and psychiatric hospitals assembled under the **Discourse in Psychosis** Consortium
- Existing databases of speech samples of patients recorded under the same protocol from >20 countries in >10 languages
- Expertise in speech and language analyses
- Patient and family associations, networks of clinicians and social workers
- SME providing platform as IKOP
- Industry providing expertise and services IKOP



Expertise requested

- Expertise and data regarding speech of people with depression
- Industry partners who can reinforce our consortium with contributions in legal expertise, management or coordination, data or other in kind contribution.



IHI Call Days | Call 3

Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Digital Phenotyping in Mental Health

Contact person name: Jakob E. Bardram

Organisation: Technical University of Denmark

E-mail: jakba@dtu.dk

- Marketplace opportunity > https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjUyMDg1
- Participant profile > https://www.bardram.net & https://carp.cachet.dk



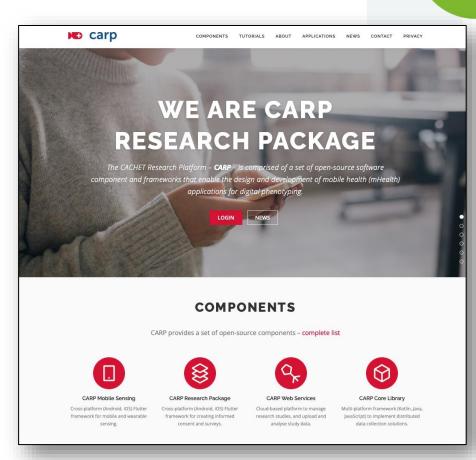
A flexible, interoperable, and reusable digital platform that can be used across numerous conditions and

- scenarios (various mental disorders, comorbidities, long-term health consequences and other disease areas) to collect, analyse and integrate diverse multimodal clinical and patient data, including patient and outcome measures (PROMs) and patient reported experience measures (PREMs), with an ust had developes may differ. Mapping of the specific links between digital scenarios (various mensures and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be additionable to collect, analyse and integrate unvolved across countries should be added to collect, analyse and integrate unvolved across countries should be added to collect, analyse and integrate unvolved across countries should be added to collect, analyse and integrate unvolved across countries should be added to collect, analyse and integrate unvolved across countries should be added to collect, analyse and integrate unvolved across countries should be added to collect. A collection of the specific links between across countries should be added to collect the collection of the specific links between across countries should be added to collection across countries and collection across countries across countries and collection across countries and collection across countries and collection across countries and collection across countries across countries across countries across countries across countries across countries across countr
- with mental disorders, caregivers and other relevant actors (healthcare professionals, social workers etc.) adapted to the needs of the patient population and age-specific needs, tackling the issues of stigma, mbarability, lack of treatment seeking and overall poor adherence to treatment (including lifestyle
- Enhanced and more reliable tools and methods (e.g. analytical tools and algorithms) able to provide he given to providing intuitive equipment and user interfaces and easy (near) real time feedback on the DHT, including on the usability, efficacy/effectiveness, and long-term safety. Together, these enable healthcare professionals and providers to make more inclusive and efficient patient-centred decisions in collaboration with the people with mental disorders and their families.

ative tive

Expertise and resources offered

- We have a loooooong track record in digital health technologies for mental health
 - MONARCA
 - RADMIS
 - <u>Digital Phenotyping in Mental Health</u>
 - Behavioral Activation Technology
- CARP An open platform for Digital Phenotyping
 - https://carp.cachet.dk
 - mobile/wearable sensing & intervention
- Close network of **clinical partners** in Copenhagen
- Scientific basis in
 - Al for Mental Health
 - UX Design for Mental Health
 - Software Architecture for Digital Phenotyping



Expertise requested

- Coordinator / Project Management
- Clinical Partners outside DK
- Research Labs or SMEs using CARP to build real systems
- Large pharma companies interested in RWE





IHI Call Days | Call 3

Topic: Digital technologies for Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Digital therapeutics for the prevention and management of mental disorders

Oscar Mayora

Fondazione Bruno Kessler - Digital Health Lab (Italy)

omayora@fbk.eu / gmezzanotte@fbk.eu

Marketplace opportunity
FBK profile on IHI



Challenges and objectives

- The objective of the project is to investigate how DHT might positively impact the healthcare pathway for people with mental disorders Specific objectives are:
- To define Value-Based Care solutions, enabled by Integrative AI and Digital Therapeutics through:
 - 1) Knowledge-based tools sustained on evidence-based medicine for mental health treatment
 - 2) Trustworthy machine-learning, data-driven models for therapypaths prediction and users engagement
- Implementing the Dtx approach in the project foresees the certification of the mental health solutions

Main activities

- To design a step-care approach towards mental health treatment supported by digital coaching technologies
- To build mental health therapy predictive models from existing registry data to define possible therapy paths
- To conduct a prospective RCT to prove effectiveness of the DTx solutions in treatment of mental health
- To bootstrap the process of certification of the proposed DTx solutions



Expertise and resources offered

- Fondazione Bruno Kessler Digital Health Lab (research body)
 - The Lab develops cutting-edge user-centered design solutions in the digital health area, with a long experience of european projects.
 - Virtual coaching semantic-enabled platform for supporting management of well-being and chronic conditions
 - Strong link with local regulators and healthcare provider through our Trentino Salute 4.0 competence center for enhancing solutions acceptance in real-world scenarios
- In-Kind contributions: To be agreed with private IHI members interested in the proposal.



Expertise requested

- IHI Private members interested on delivery of Digital Therapeutic mental health services
- Psychological clinical expertise on mental disorders and/or comorbidities of mental disorders
- Technological expertise to work on the digital platform and data analytics aspects
- Ethical/legal data management aspects for compliance with FAIR principles and ensure the project contributes to the European health Data Space
- Partner with links with school and social workers that help the evidence generation on how the solution influences patient behaviour
- Partner that can help engaging the regulators to prepare the ground for future acceptance and usability of the result

IHI industry

Research institution

Large industry

Research or SME

any

any



IHI Call Days | Call 3

Topic 5: Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

Digital technologies for the prediction and management of treatment resistant depression

Contact person name: Gabriela Pérez-Fuentes

Organisation: Vall d'Hebron Institute of Research (VHIR)

E-mail: gabriela.perez_fuentes@vhir.org

Link to:

- Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/192310/opportunities
- Participant profile: https://ihi-call-days.ihi.b2match.io/participations/192310



Challenges and objectives

Key problem tackled by our proposal

- Major depressive disorder (MDD) is among the top 2 leading causes of global burden of disease
- Bidirectional association of MDD with a wide range of physical illnesses, contributing to increased morbidity and higher mortality
- Substantial proportion of MDD patients do not benefit sufficiently from available treatment options, often leading to chronification of mental and physical health problems
- Prediction of treatment outcome and tailored management options remain challenging

IHI suitability

- Core team of private (pharmaceutical industry) and public (academic hospitals) partners
- ➤ Established track record from previous IMI2 projects that tackled areas of unmet public need that cause significant patient and society burden → from planning to execution
- Established core network of clinical sites, patient community advisors, regulators, ethics committees

Potential results and expected impact

- Reduce chronification of MDD, predict and prevent relapses and treatment non-response
- Validation of digital phenotyping tools for predicting treatment response and management of comorbidities
- Improve well-being of the population and reduce disease burden



Main activities

- Establish and monitor mental and physical health in large European observational cohorts of patients with MDD
- 2-year follow-up (core study protocol and clinical site network established from previous IMI grant)
- Data collection, harmonisation and standardization
- To assess and monitor treatment response and the longitudinal course of MDD and its physical comorbidities with standard clinical measures and advanced digital phenotyping tools



Expertise and resources offered

- Describe the partners and expertise you already have.
- Academia and industry consortium
 - ✓ Clinical experience focused on observational studies and randomised trials in mental health
 - Expertise in design of observational and interventional studies (incl operational and statistics)
 - ✓ Track record of building clinical site networks and corresponding operational plans
 - ✓ Experience developing consensus guidelines (e.g. disease definitions)
 - ✓ Liaising and actively collaborating with different stakeholders: patient and community representatives, industry, ethics and regulators



Expertise requested

- Profiles for potential partners may include:
- Tech companies (SMEs or large companies): Digital technology expertise in the assessment and monitoring of mental and physical health
- Additional clinical investigators (with expertise in comorbidity)
- Academic or industry partners with expertise in assessment of (socio)economic outcomes
- > Any entity that can add expertise to design, operation or implementation



IHI Call Days | Call 3

Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Cooperation offer

Robust multimodal data collection/analysis for mental health with worn sensors

Contact person name: Françoise CHARBIT

Organisation: CEA-Leti

E-mail: francoise.charbit@cea.fr

Link to:

- Marketplace opportunity
- Participant profile







Challenges and objectives

Identify and measure digital biomarkers of mental states (signature) with combination of synchronised multimodal wearable devices

Neuronal activity (EEG) + Cerebral hemodynamics / neurovascular (fNIRS) + physiological parameters (PPG,EDA, ECG)

USPs

- Address moments in the patient's life that are currently inaccessible outside the hospital
- Find and validate the **relevant signatures** of importance for mental disorders
- Towards Real-time and Non-invasive monitoring
- Data collection of physiological digital biomarkers for comorbidities (e.g. CVD)

Benefits for IHI: an additional opportunity to evaluate the role of wearable devices to collect and exploit data for secondary prevention and monitoring

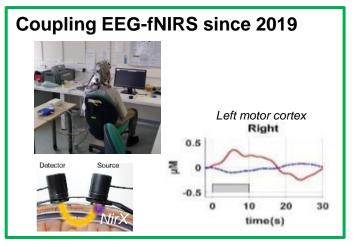


Expertise and resources offered

Mobile EEG

20 years experience in electrophysiology / EEG systems development Pioneer of the Riemannian geometry based approach for EEG classification

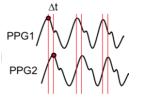
Mobile fNIRS



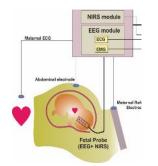
Physiological monitoring

Our internal technology platform to assess reliability, robustness, connectivity and security of wearables (simulates real-life conditions)









Neurovascular coupling of EEG-fNIRs

IFCON - Intrapartum Fetal Cerebral Oximetry and Neuronal Activity INSERM/CHU Amiens Seenel Imaging



We propose to integrate data collected from various modalities (commercial devices) to identify and define relevant digital biomarkers for ambulatory monitoring of mental disorders





Expertise requested

- We provide a potential mean to create a link between hospital-based observations, real-life situations, home-based measurements: we need clinical expertise and a strict reference framework to identify and validate digital biomarkers. The clinician will have access to new information to which he/she does not have access today.
- We need industrial partners to define the ideal case of application and make the future integrated device easy to use and MDR compliant.
- Mobile EEG/fNIRS/PPG-EDA-ECG could be integrated with other biomarkers (vocal, cortisol from sweat /skin)
- Not specific to mental disorders can be implemented also in neurodegenerative diseases





IHI Call Days | Call 3

Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Mental Health Monitoring in AAL (Ambient Assisted Living)

Contact person name: George Suciu

Organisation: BEIA

E-mail: george@beia.eu

Link to:

- Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR50jU0MTA1

Participant profile https://ihi-call-days.ihi.b2match.io/participations/192864







Challenges and objectives

Challenges

- WHO statistics show that **mental disorders** such as depression and anxiety **affect more than one in six EU citizens** representing a significant personal and societal burden.
- The healthcare costs for poor mental health treatments are estimated to cost Europe over €200 billion/year.
- Existing **healthcare innovation** that has changed mental health care, such as Al applications and smartphones, wearabels, Internet of Things sensors, third-party cloud services, and other technologies related to Ambient or Active Assisted Living have proven useful in automated information gathering regarding the patients' vital conditions.

Objectives

- The project's goal is to investigate to which degree technological approaches could support the early identification of signs of mental health conditions and deteriorations thereof.
- This will, in a long run, ease the work of caregivers, help patients in particular in situations due to COVID-related isolation and enable the initiation of countermeasures.
- The project's structure logically flows from a review of the various **exposure determinants** (psychological, social, lifestyle factors, and environmental) of mental health towards the possible solutions and mitigating actions via care ecosystem services and technologies.





Main activities

- The project follows a three-step process, starting with:
 - (1) Identification of information required to assess mental health conditions (use cases) in the elderly using established frameworks.
 - (2) Identify relevant data sources for replacing current manual procedures, such as from wearables or from textual input.
 - (3) In a last step, we compile and aggregate the collected knowledge and condense it into recommendations, for example in the shape of guidelines for stakeholders from industry and health care to facilitate implementation of optimized methods.





Expertise and resources offered





1. ResearchStudio Austria, AT

 Data Circles, Cloud, GaiaX, Data Management, Priv Security

2. BEIA, RÓ

focuses on hardware(IoT) and go-to-market

4. Samariterbund, AT,

End-user

5. Austrian Institute of Technology, AT

Safety&Security, Standardization

6. University Politehnica of Bucharest, RO
 Specification of AAL—Questionnaires, Sensor data from IoT and 3rd Party Cloud Services

• 7. VTT, FI



 O – Other infections, Coxsackie virus, siphilis, varicella, HIV, parvovirus B19, and hepatitis B

C – cytomegalovirus

H - herpes simplex virus-2











Expertise requested

- SME/Large companies
 - Impact & recommendation
- SME/Research institutes/Universities
 - Clinical trials
 - End user evaluation by focus groups of technical feasibility individual components







Topic: digital health technologies for the prevention and personalized management of mental disorders and their long-term health consequences

Predictive models and digital biomarkers of mental disorders for turning multimodal at home measures into clinical actions and better treatments

Contact person name: Jérôme Kalifa

Organisation: Let it Care

E-mail: Jerome.Kalifa@letitcare.com



- Opportunity https://ihi-call-days.ihi.b2match.io/participations/193072/opportunities
- Participant profile: https://ihi-call-days.ihi.b2match.io/participations/193072



Proposed project objectives

Let it Care is a data science and software SME (Paris, France)

 Primary objective for IHI call: harness DHTs for collecting multimodal data in order to identify digital biomarkers predictive of mental disorders-related events (ex: psychotic decompensation, hospitalization risks, relapse, etc.)

Expected results:

- Complete platform including data collection, patient smartphone app, data analysis, and clinical dashboard
- New datasets of multimodal patient data collected at home and in activities of daily living
- Knowledge for improved care pathway and treatments
 - Focus on the patient quality of daily living
 - Better communication of patient experience
 - New digital biomarkers and endpoints as predictive models
 - Continuous monitoring providing more granularity, objectivity and sensitivity to real-time change
 - Improved patient stratification tools for clinical study recruitments



Proposed project activities

- Design and conduct of clinical studies:
 - Patient acceptance and clinical feasibility
 - Technology selection (wearables, software infrastructure)
 - Identification of predictive models, digital markers and endpoints – performance assessment
 - Treatment effects modelling and individualization
- Datasets identification and generation
- Collaboration with regulatory bodies (EMA innovation task force, FDA and Critical Path Institute)



Let it Care brings expertise in:

- Selection of DHTs for decentralized clinical studies;
- Statistical analysis and clinical study modeling;
- Advanced signal processing and machine learning/deep learning methods for integrating heterogeneous data, including time series and longitudinal observations of highly different nature;
- Building digital biomarkers with high predictive performance on disease evolution and on treatment effects;
- Software development: smartphone app, data processing and analysis, visualization dashboard

NB: Let it Care is leading the analytics Work Package in IMI project Idea-Fast (digital endpoints for neurodegenerative and immune-mediated diseases).



Expertise requested

- Clinical partners with clinical knowledge and insight
- Clinical partners for clinical operations and management
- EFPIA partners for model selection, endpoints guidance and priorities, regulatory interactions
- Data management SMEs or academics
- Ethics and legal experts



IHI Call Days | Call 3

Topic: Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Neurotechnology as a Service

Contact person name: Aureli Soria-Frisch (PhD)

Organisation: Starlab Barcelona

E-mail: aureli.soria-frisch@starlab.es

Link to:

Participant profile – https://www.starlab.es/neuroscience





Brain Health needs a new approach

- Lack of modern decision tools for mental health and diseases
- Large misdiagnosis rates
- Large development costs on CNS drug development
- Difficult to find data on efficacy to support regulatory processes
- Lack of user-centric design in brain data services

CNS HIGH RISK



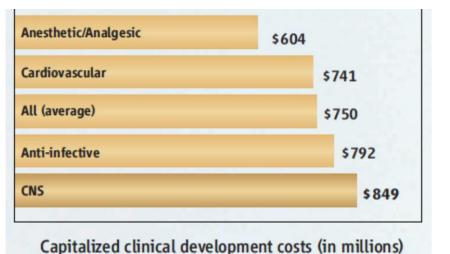
YOUR NEIGHBOR WITH EPILEPSY

GRANDMA WITH ALZHEIMER'S FRIEND WITH DEPRESSION YOUR
DAD
WITH
PARKINSONS

(50M PATIENTS WORLDWIDE)

(90M PATIENTS WORLDWIDE) (240M PATIENTS WORLDWIDE)

(5M PATIENTS WORLDWIDE)



20% PEOPLE
MENTAL HEALTH
PROBLEMS



Neurotechnology as a Service Starlab



 Wireless dry EEG plus non-invasive stim (tCS) 8, 20, 33 channels Medical Grade Hardware (CE, FDA)





Dry electrodes



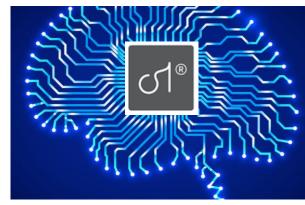




Neurotechnology as a Service



 Wireless dry EEG plus non-invasive stim (tCS) 8, 20, 33 channels Medical Grade Hardware (CE, FDA)



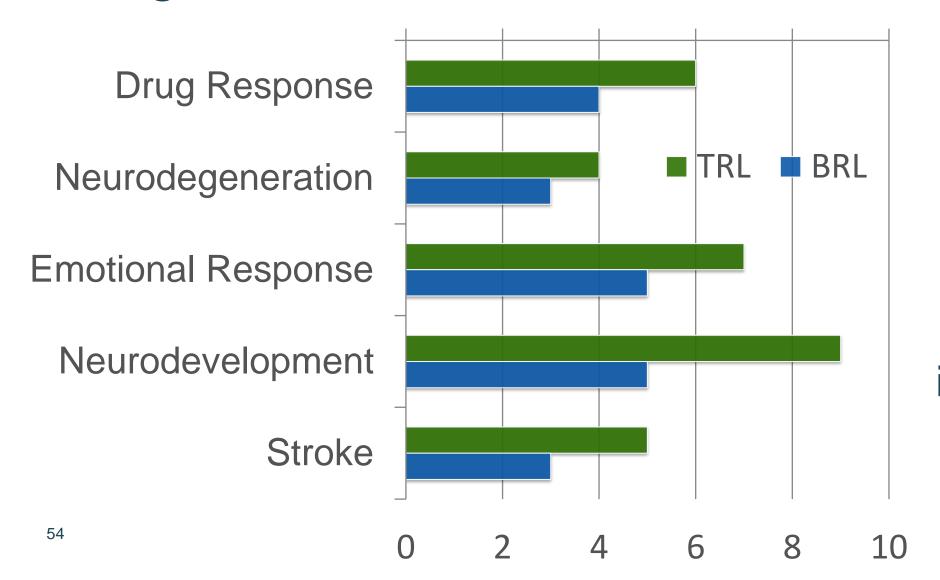
- Machine learning platform for EEG, developed over 10 years
- Proprietary KAI framework

- Protocol preparation
- Data collection
- Advanced Signal Processing
- Machine learning for brain health, trial recruitment, and drug response



Digital Biomarkers Portfolio





Looking for building consortium

info@starlab.es







Thank you for your attention











