IHI Call 11 – topic 1 Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction

Elisabetta Vaudano IHI JU
24.06.2025 • Online

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Before we start…

- We are recording this webinar and it will be published on the IHI website.
- We will also publish the presentation slides.
- IHI call 11 was launched on 17.06.2025 and the final call texts and details of how to apply can be found at: https://www.ihi.europa.eu/apply-funding/ihi-call-11
- Ask questions by using the Q&A function (bottom right on your screen)

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Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 11 topic 1 presented by lead of the pre-identified industry consortium
  - Proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover**
  - rules and procedures

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Innovative Health Initiative

EU **partnership in health** between:

- the **European Union** represented by the European Commission

&

- **Healthcare industry associations:**
  - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
  - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
  - **EuropaBio** (biotechnology industry)
  - **MedTech Europe** (medical technology industry)

COCIR Advancing Healthcare
efpia
EuropaBio The European Association for Bioindustries
MedTech Europe from diagnosis to cure
Vaccines Europe
Co-funded by the European Union

IHI’s general objectives

- Turn health research and innovation into **real benefits for patients and society**

- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need

- Make Europe’s health industries globally **competitive**.

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IHI projects are…

Created via open and competitive calls for proposals

Cross sectorial public private partnerships leveraging:

- Contributions from industrial partners from the IHI industry associations (COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTechEurope)
- if relevant, contributions from contributing partners (must be approved by IHI GB)

and

- Public funding via European Commission (Horizon Europe)

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Strategic Research & Innovation Agenda

Focus

- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

Goal

- Lay foundations for development **of safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level

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https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

Eligibility for Funding: UK, Canada, Switzerland, South Korea

In IHI Call 11, legal entities from the following countries are Eligible/Not Eligible to receive funding as follows:

Country	Call 11, Topic 01	Call 11, Topics 02 - 05
United Kingdom ('UK')	Eligible to receive funding	Not Eligible to receive funding
Canada ('CA')	Eligible to receive funding	Not Eligible to receive funding
Switzerland ('CH')	Not Eligible to receive funding	
South Korea ('KR')	Not Eligible to receive funding	

Alternative Funding: legal entities from UK, CA, CH, and KR may be able to receive funding from their own governments, Potential applicants should contact their National Contact Point ('NCP') or relevant representative**.** IHI JU takes no role or responsibility in the application for, or granting of, such funding.

UK applicants: Are requested to contact the UK National Contact Point Ms Jo Frost **(**ncp-health@iuk.ukri.org**)** as soon as possible to register for updates, and for advice and assistance regarding UK participation in IHI Call 11.

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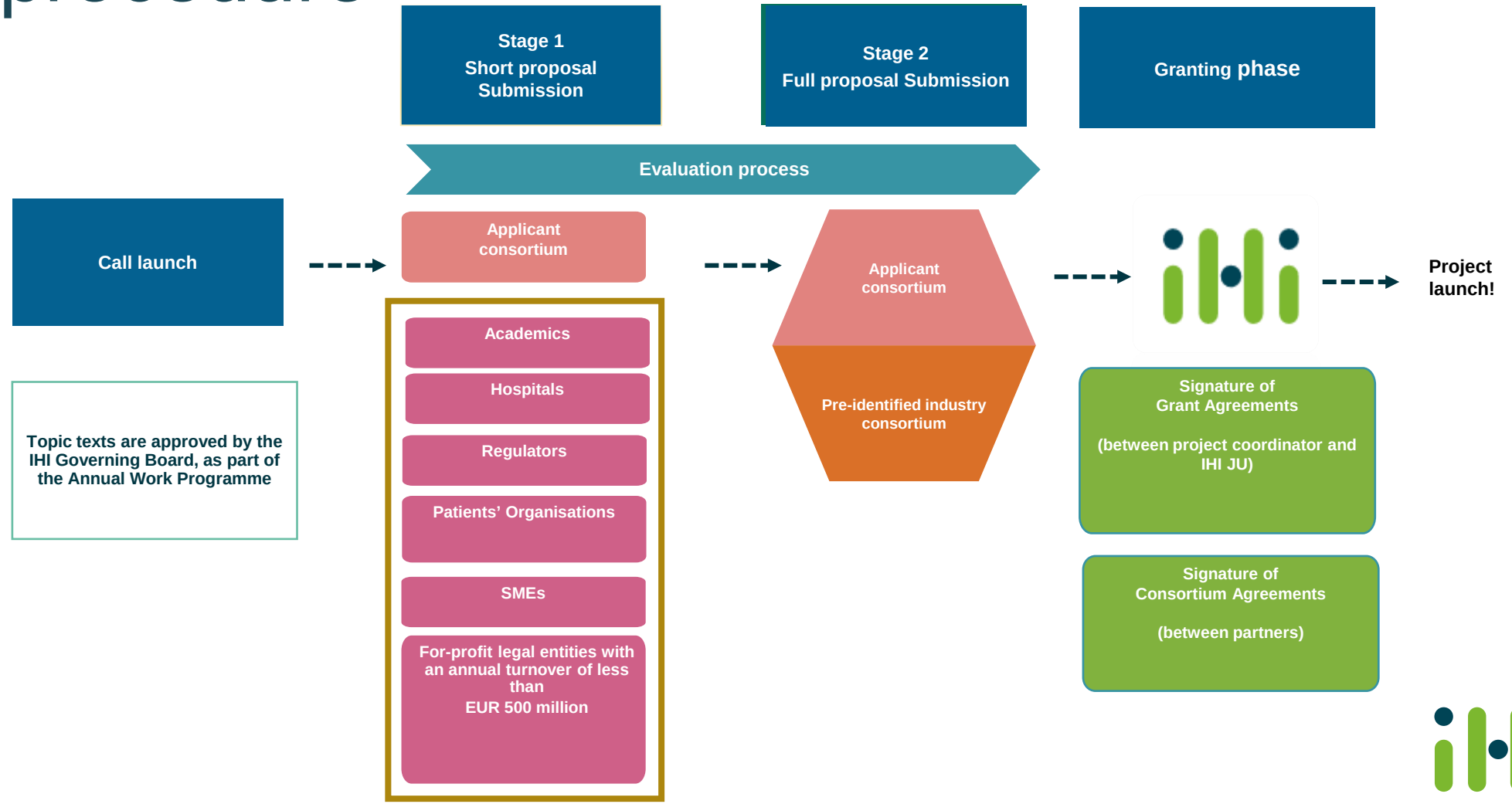
How does IHI work? Two-stage procedure



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Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction

IHI call 11 – topic 1

Hugh Marston, Thorsten Laux (Boehringer Ingelheim)
24.06.2025 • Online

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The challenge

- **Current diagnosis and patient stratification in health disorders with CNS driven symptoms** are based on DSM-5 / ICD-11 codes, which are **not aligned with underlying biological processes and mechanisms**.
- Subsequent **suboptimal disease classification and patient stratification** is a key reason for the **low Probability of Success (PoS) of clinical development** and the **historical lack of new and more efficacious treatments**.
- The **transdiagnostic approach** bases disease definition and patient stratification on **overarching symptom domains** and their underlying neuronal circuitry and processes irrespective of conventional definitions.
- This holds the promise of **more meaningful markers and endpoints which will improve the PoS** of clinical development and patient access to much needed therapies in this space.
- The symptom domains of **reward/motivation** and **impulsivity (RM&I)** have been selected for this topic as they are relevant for many classes of disorders with a particularly **high unmet patient need** and have **biological tractability**. They span transdiagnostically across a broad spectrum of disorders including but not limited to **Alzheimer's Disease (AD), major depressive disorder (MDD**), **obesity**, substance abuse disorders, schizophrenia, bipolar disorder, borderline personality disorder, obesity, Parkinson's Disease.

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Need for public-private, cross-sector collaboration

- The topic aims to address this complex challenge by:
  - adopting a holistic, **transdiagnostic approach** focused on the common underlying biology of RM&I symptom domains across the relevant disorders
  - building on an existing **federated data platform** to consolidate, curate, link and analyse **large, robust, multimodal datasets** from relevant patient populations and **identify related marker and endpoints hypotheses**
  - **prospectively testing such hypotheses in clinical case studies** focusing on but not limited to AD, MDD, and obesity
  - **fostering collaboration in multi-stakeholder network**, including people with lived experience (LE), carers, HCPs, providers, regulators, industry, HTA bodies and payers, to prepare the healthcare system for this transformative shift
- **Acquisition and harmonisation and collaboration at this scale and across multiple disorder classes is beyond the capacity of a single organisation.**
- IHI provides an ideal model for creating such an initiative, integrating all relevant and diverse stakeholder groups in a focussed and collaborative framework.

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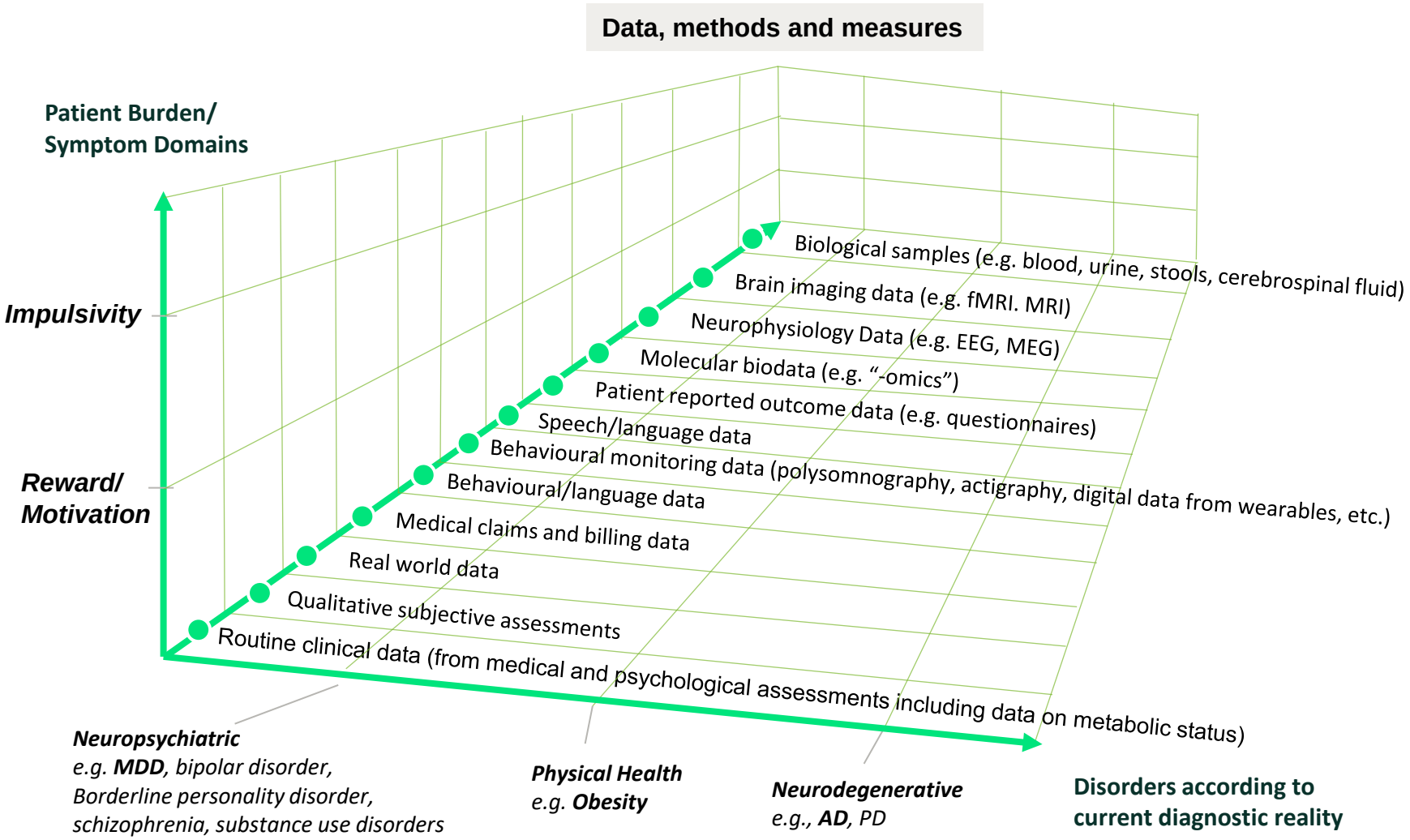
Topic aims at collecting large amount of high-quality, multimodal data and biological samples from historic and future clinical trials and RWE ...

for subsequent application of advanced analytics, modelling, and simulation to identify ...

and subsequently test hypotheses for novel transdiagnostic markers and endpoints ...

which will be prepared via a multi-stakeholder platform for health care system readiness



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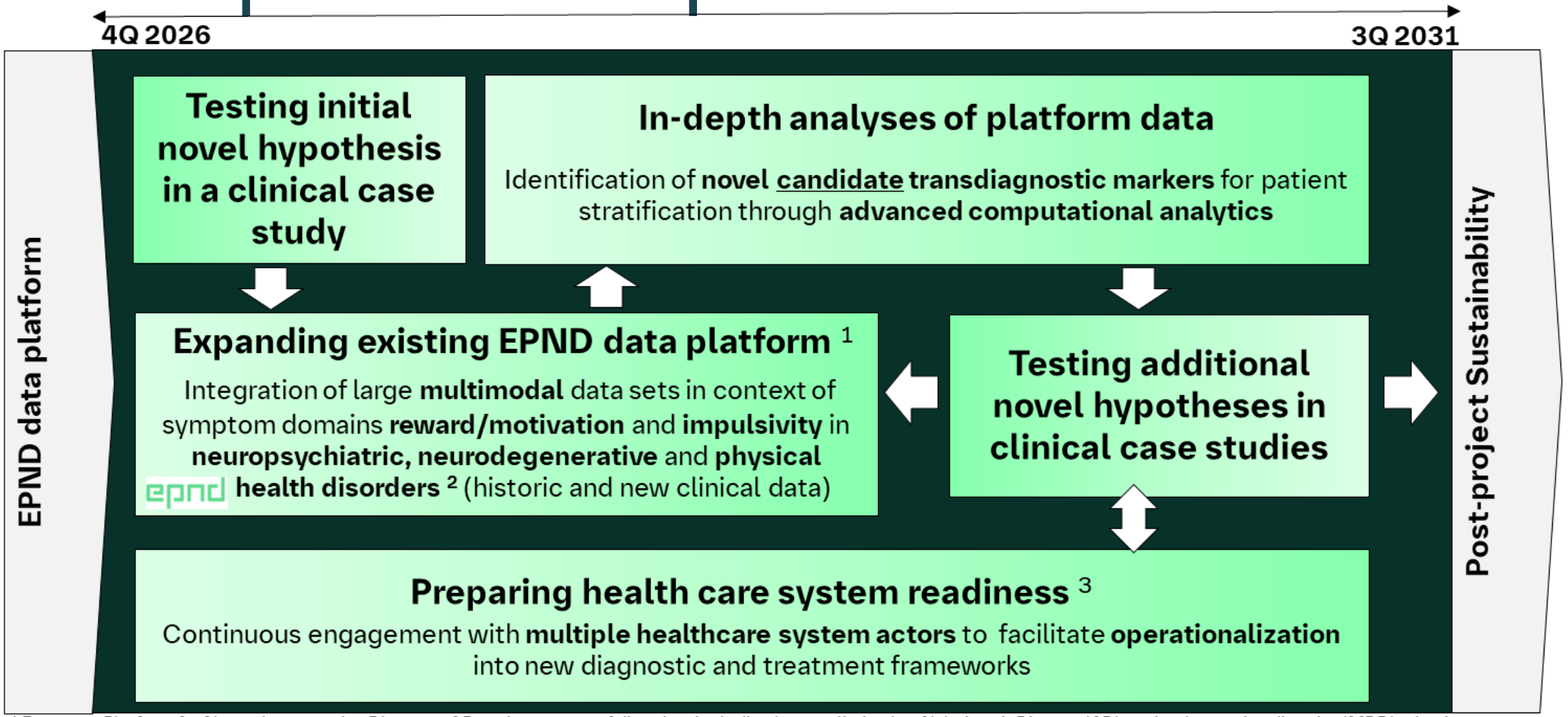
Scope of the topic



[1] European Platform for Neurodegenerative Diseases; [2] Broad spectrum of disorders including but not limited to Alzheimer's Disease (AD), major depressive disorder (MDD), obesity, substance abuse disorders, schizophrenia, bipolar disorder, borderline personality disorder, obesity, Parkinson's Disease.;
[3] Disclaimer: No full validation toward qualification and registration of new marker/endpoints at EMA is intended

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Expected outcomes

1. **A sustainable and collaborative large, multimodal data platform** that can **identify novel transdiagnostic candidate markers and endpoints for the symptom domains of RM&I in neuropsychiatric, neurodegenerative, and physical health disorders***
2. **Novel transdiagnostic candidate markers and endpoints** are identified and progressed towards validation. **Learnings are applied in drug discovery** to increase **PoS**
3. **Clear roadmap to achieve full validation of candidate markers and endpoints** by regulatory and HTA bodies. **Clinical best-practice guidelines** are developed, and **recommendations are made to the current diagnostic classifications** to expedite the adoption of precision medicine
4. **Greater understanding of the biological foundations of RM&I symptom domains** and their role in AD, MDD, obesity and other relevant disorders, enabling the generation of novel therapeutic approaches by industry
5. **Closer alignment between psychiatry, neurology, and physical health disciplines** to enable dialogue between HCPs and other medical specialists to optimise outcomes, particularly for individuals with complex healthcare needs and comorbidities

* Relevant disorders include **Alzheimer's disease** (AD), **major depressive disorder** (MDD) and **obesity** (priority areas). Other relevant disorders/diseases include but are not limited to substance use and associated disorders, schizophrenia, bipolar disorder, borderline personality disorder and Parkinson's disease. **For a disorder/disease to be relevant, there must be evidence to show that reward/motivation and/or impulsivity are clinically significant symptom domains.**

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Expected impact

Data platform for precision medicine:

- A comprehensive, sustainable data-driven health platform linking behaviours and symptoms to quantitative biological markers
- Much-needed refinements to existing diagnostic frameworks and treatment paradigms, providing a clear step towards personalised healthcare for CNS-driven symptoms
- Model for other disease areas where there is need for more biology-driven precision medicine

Advancing mechanistic understanding:

- Clarification of the biological basis of CNS transdiagnostic symptoms expediting the identification of novel and more effective precision therapies across the relevant disorders, boosting the competitiveness of European industry and beyond
- Advanced mechanistic understanding will also galvanise innovation in diagnostics

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Expected impact

Patient outcomes and stigma:

- A significant improvement in care quality (more integrated and personalised care) and in health outcomes for people within the RM&I driven relevant disorders
- This includes healthcare innovations arising from improved understanding of the relationship between psychiatric and physical health and their underlying biology with far-reaching implications for patient health beyond psychiatry and neurology
- Reduction of stigma and provision of opportunities for early intervention

Efficiency in the healthcare system:

- Precision treatments reduce avoidable waste in healthcare resources, leading to overall cost reduction, higher productivity, and a positive economic impact on the European health care budget.
- Overall, a transformative shift towards a more integrated and personalised approach to healthcare will benefit patients across Europe and beyond

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Expected contributions of the industry consortium

Members of the pre-identified **industry** consortium:

- AbbVie
- Boehringer Ingelheim (Lead)
- Gates Ventures LLC (Co-lead)
- iFAB
- Novo Nordisk
- Roche

In addition, the following **contributing partner** will participate in the IHI JU action:

- Wellcome Trust

Expected contributions of the industry consortium

- The **AD Workbench** as facilitation of access to EPND hub infrastructure including the EPND catalogue
- Expertise and capabilities for **data management, biostatistics and data science;**
- Contributions to systematic literature reviews
- Activities to make available **multimodal datasets and (if possible) samples** collected from **historical clinical trials** and activities to collect data in **prospective clinical trials** (e.g. placebo and potentially comparator data)
- **Clinical trial, translational, digital health, and medical expertise and guidance** related to clinical protocol design, clinical operations, clinical and real-world data collection and analysis
- Expertise in **legal, ethics, compliance, and representativeness in research/study design**
- Expertise in **regulatory strategy, policy and decision making, HTA assessment and reimbursement**, involvement of **LE expertise**
- Contribution to the elaboration of **educational and training programmes** for HCPs, people with LE and carers

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Expected contributions of the applicants

- **Project management** expertise and capabilities in running multi-stakeholder cross-sector projects
- **Data platform** expertise and capabilities to leverage the AD Workbench to establish an extended version of the EPND platform
- **Data capture / data management and analysis** expertise and capabilities to import, curate and integrate existing and prospective datasets and ideally samples from public and private sources into the data platform
- Expertise and capabilities in **data science**, to develop and apply advanced AI supported analytics, modelling and simulation, and bias mitigation, and conduct multimodal analyses at scale to develop hypotheses of new candidate markers and endpoints
- Proven expertise and capabilities in the **conduct of transdiagnostic pilot clinical case studies**: i) expertise in RM&I symptom domains, translational, digital and clinical science, development and validation of new markers/endpoints; ii) systematic literature reviews of potential transdiagnostic markers and endpoints and hypotheses generation; iii) design and conduct of all pilot studies including regulatory and ethics approvals, setting up sites, recruitment in AD, MDD and obesity, collection and storage of data and samples, and measurement of all parameters described in the topic text
- **Involvement of LE and patient advocacy groups/organisations** as consortium members
- Resources to **engage with people with LE, carers, HCPs** to prepare training programmes and educational materials
- Expertise and capabilities in **interacting with regulatory authorities, HTA bodies, payers, policy makers, medical societies, organisations of people with LE, and patient advocacy groups**
- **Regional health care centres** with a centre of excellence in the relevant disorders

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Key Facts

- **Budget:**
  - The maximum financial contribution from the IHI JU is up to **EUR 20 202 000**.
  - The indicative in-kind contribution from industry beneficiaries is **EUR 13 987 940**.
  - The indicative in-kind and financial contribution from IHI JU contributing partners is **EUR 6 642 533.**
  - Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated with the Horizon Europe program.

- **Duration:**
  - The indicative duration of the action is **60 months**.
  - This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

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Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

Proposal submission & evaluation

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Proposal Template - Parts A, B & Annexes

- **Part A** of the proposal is **administrative data** that is entered in webforms through the Funding & Tenders Portal.

- **Part B** of the proposal is the **narrative part** that includes three sections:
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**

- **Annex:**
  - Participant type

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Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
  - Soundness of the proposed methodology
- **Impact**
  - Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.

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Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the outline of the work plan
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

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Tips for applicants

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Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - https://www.ihi.europa.eu/apply-funding/ihi-call-11
  - https://www.ihi.europa.eu/sites/default/files/uploads/Documents/Calls/IHI_Call11_CallText.pdf
- Form your consortium **early**
  - Already think “public-private partnership“
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results (see also our guide)

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Finding project partners

You'll need to build or join a consortium!

- Use EU Funding & Tenders portal **partner search tool:**
  - https://europa.eu/!QU87Nx
- Get in touch with your **IHI national contact point**:
  - https://europa.eu/!D7jyMy
- Network on social media:
  - https://bsky.app/profile/ihieurope.bsky.social
  - be.linkedin.com/company/innovative-health-initiative

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