Welcome to the Innovative Health Initiative kick-off & brokerage event

Brussels, 14/06/2022

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

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Catherine Brett

Moderator

Slido: #IHIbrokerage

Info session

Session 1 - The Innovative Health Initiative: state of play

Hugh Laverty

Head of Scientific Operations, IHI

Anna Chioti

Chair, Science and Innovation Panel, IHI

Session 2 - IHI research priorities and calls for proposal

Call 1

IHI Scientific Officers

- Elisabetta Vaudano responsible for topic 1, Call 1
- Tek-Ang Lim responsible for topic 2, Call 1
- Oussama Karroum responsible for topic 3, Call 1
- Colm Carroll responsible for topic 4, Call 1

Call 2

Industry representatives

- Matthias Müllenborn, Vice President, Novo Nordisk - contributor to topic 1, Call 2
- Andrea Rappagliosi, Senior Vice President, Edwards Lifesciences - contributor to topic 2, Call 2

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IHI call 1 – topic 1

An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities

Elisabetta Vaudano
14.06.2022 • Brussels / Online

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The challenge

- Neurodegenerative disorders represent a high societal burden impacting patients, their families, and the public health care systems.

- Patients with a neurodegenerative disorder frequently display at least one comorbidity, which together with the observed polypharmacy creates a highly complex system that needs better understanding to optimise current care pathways.

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Scope of the topic

Budget: 15 M EUR

What

To develop a decision-support system to enhance medical decisions with targeted clinical knowledge, patient information, and other health information

Address a patient population with a neurodegenerative disease with evidence of the importance of comorbidities.

- The choice of the comorbidity should consider the burden for patients, carers and families, and the availability of medical technology-generated data. Cancer is out of scope.

Why

To achieve a more holistic (breaking silos across medical specialties) approach to managing and treating patients with a neurodegenerative disease and a comorbid condition

- addressing the needs of today,
- creating preparedness for a future paradigm-shift in treatment.

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Expected outcomes

- A **digital platform** to guide patients and healthcare professionals, easy adaptable for re-use in other health areas
- A **sustainable framework for collaboration** across specialties and stakeholders to foster social innovation
- **Standards and guidelines** for data collection and operation of the digital platform enabling medical technology innovation
- Enhanced, more reliable **tools and methods for (near) real time feedback on health interventions**, to support joint patient/doctor decision making
- Enhanced **clinical interpretation of complex data** influencing variations in patient status and required care, for the benefit of patients and healthcare providers

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IHI call 1 – topic 2

Next generation imaging and image-guided diagnosis and therapy for cancer

Tek-Ang Lim
14.06.2022 • Brussels / Online

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The challenge

- Provide **early evidence of improved cancer patient care** when using next-generation imaging technologies and image-guided solutions as part of combined cancer therapies.

- An **optimised image-based care path** from early diagnosis and screening to treatment and follow-up is essential to improve the outcome of cancer patients and help optimise clinical workflows and cancer patients' journey.

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Scope of the topic

Budget: 40 M EUR

- Contributing to the development of high-quality tools, high-quality data, advanced patient imaging and image-guided technologies and processes for improved early diagnosis, prognosis, staging, intervention planning, therapy and management of cancer and long term follow up.

- Enabling the development of improved artificial intelligence (AI) and machine learning (ML) validation and evaluation methodologies for imaging and image guided diagnosis and image-guided therapy for cancer.

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Expected outcomes

Projects should:

- Expand the use of cancer patient imaging data sources, with improved data quality, annotation and computability, contributing to solutions that automatically link images to clinical data to improve diagnostic, staging, predictive and therapeutic tools for clinicians, including image-guided tools.

- Develop robust evaluation and validation frameworks for AI/ML-based algorithms applied to cancer patient images, to improve image-guided diagnosis, prediction of therapy outcome, planning and therapy of cancer patients.

- Propose novel, continuously self-learning, trustworthy, explainable AI/ML-enabled image guided diagnosis, therapy planning, and interventional systems used in clinics/hospitals and possible related benchmarks.

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IHI call 1 – topic 3

Personalised oncology: innovative people centred, multi-modal therapies against cancer

Karroum Oussama
14.06.2022 • Brussels

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The challenge

- Different treatment modalities are available for various cancers
- The differing biology of cancers and the differing efficacy of treatment modalities show the need of patient-specific approaches
- Multi-modal therapies shown to be of high value
- Strong need to increase the therapeutic arsenal of such multi-modal therapies and to tailor the treatment approach to the individual patient

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Scope of the topic

Budget: 40 M EUR

Biomarker-guided multi-modal precision oncology:

- To combine at least **two cancer treating modalities**: Development of new health technologies integrated with current therapy concepts
- Development of **research protocols** for multi-modal therapies to be explored via **early clinical studies**
- To consider the **clinical decision-making process** aspect
- The evaluation of aspects such as the **sequencing, timing and dosing of therapies**
- The use of **prognostic and predictive biomarkers** and the combination of diagnostic tools to plan and adapt treatment
- **Methodologies and standards** for the combination of various technologies into integrated healthcare solutions

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Expected outcomes

Platform, standards and regulatory

- Platform for R&I collaboration across sectors
- Cancer healthcare pathway standards
- Demonstration of the benefits of health technology convergence

Improved multi-modal therapy

- Health innovations in cancer therapy through development, testing and validation of multi-modal therapeutic approaches
- Improved active monitoring and adaptation of therapy through the patient journey, involving early-response biomarkers as well as more involvement of patients in the cancer patient journey

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IHI call 1 – topic 4

Access and integration of heterogeneous health data for improved health care in disease areas of high unmet public health need

Colm Carroll
14.06.2022 • Brussels

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The challenge

- There is a **wealth of data** that could be harnessed for use in healthcare

- **Accessing, integrating & analysing** these data to **maximise the value for patient care** and research is extremely challenging.

- This topic aims to provide a **scalable platform** for the seamless **integration or linkage** of these diverse data and **develop tools** to allow the data to be used in **clinical care**, **patient self-management**

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Scope of the topic

Budget: 40 M EUR

For clearly identified **disease areas of high unmet public health need**, applicants are expected to:

- Develop/ further develop a **scalable, open platform** for the seamless integration or linkage of data from diverse **public and private** data sources
- Develop or further develop **tools focussed on the needs of patients**
- Develop / further develop **clinical (and other) decision support systems.**
- Demonstrate the **added value of the platform** through a use case **(study)**
- Demonstrate the **widespread applicability** and **scalability** of the platform & tools
- Facilitate **long-term access and re-use** of the data

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Need for public-private, cross-sector collaboration

- The data to be integrated in the funded projects are expected to come from diverse **public and private sources.**

- **Cross-sectoral** expertise is needed including from:
  - Patients
  - Health care professionals
  - Healthcare data specialists
  - Academic researchers
  - SMEs
  - Pharmaceutical and medical technology industries.

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IHI call 2 – topic 1

Cardiovascular diseases - improved prediction, prevention, diagnosis & monitoring

Matthias Müllenborn
14.06.2022 • Brussels / Online

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The challenge

- Cardiovascular disease is one of the leading causes of death globally
- 60 mill people in EU live with CVD, annual cost of 210 bill EUR

- Need a better risk classification
- Need a better identification
- Need a better understanding of the
  - natural progression of disease
  - impact of interventions beyond simply ”counting the events”, which invariably comes with delay

- This will ultimately result in:

Smarter design, development, and evaluation of novel therapies

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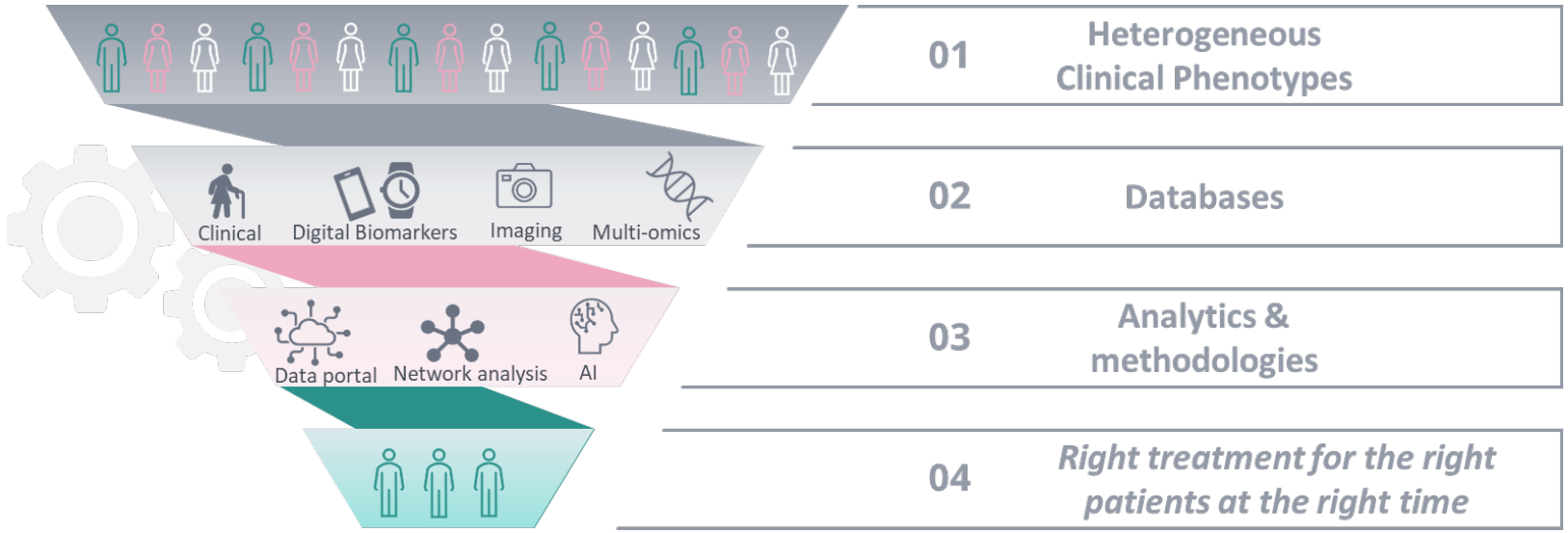
Scope of the topic

- Identify risk factors
- Focus on initial drivers
- Right treatment for the right patient at the right time
- Primary and secondary prevention
- Sustainable models for assessing future interventions
- Patient empowerment (wearables, biometric data)



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Expected outcomes

- Identify hurdles and solutions towards right treatment for the right patient at the right time
- Identify risk factors and predictive/prognostic models
- Build sustainable database (proteomics, genomics, transcriptomics, biometrics, imaging, behaviour)
- Platform for scientific dialogue and educational environment with KOLs, HTAs and regulators
- Support building a CVD patient community in EU
- Increase holistic understanding across drugs, devices, data, digital, diagnostics
- Platform for dialogue with EU politicians, policy makers, and CV interest groups
- Drive prevention of cardiometabolic complications
- Pave the way for more sustainable clinical trials and evidence models for CVD
- Better and earlier treatment options in clinical practice

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Expected contributions of the applicants

- Identification of and access to relevant data sources (devices, intake forms, diagnostic and exploratory tests) for ASCVD and HF
- Plan for data capture, storage, and sharing, e.g. integration into a federated database
- Increase understanding of early disease
- Generate & validate a risk model
- Include social, ethical, regulatory aspects, through real-word evidence and wearables
- Develop model for short- and long-term economic consequences
- Develop decision tool for physicians
- Integrated PROM
- Explore possibilities for novel methods of clinical development and trial execution

IHI funding for applicant consortium: 10 679 000 EUR

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Expected (in-kind) contributions of the industry consortium

- Data: data from clinical trials, biobank data, real world data, wearables and other smart devices, algorithms, identification of risk, sensor technology, telecommunication, data management/hospital information system, AI, mobile technology
- Expertise: medical expertise, bioinformatics, data science, public health, patient input, clinical and regulatory expertise, early identification from wearables
- Technology: such as wearable devices, mobile technology, telecommunication technology and other smart devices that will enable the recording of new data.
- Identify hurdles and solutions towards right treatment for the right patient at the right time

Partners: Novo Nordisk (“Lead”), Becton Dickinson, Evotec, Fresenius, Huawei, Philips, Roche Diagnostics, Astra Zeneca, Lilly, JDRF

In-kind contribution: 10 679 000 EUR

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IHI call 2 – topic 2

Setting up a harmonised methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the EU

Andrea Rappagliosi, Edwards Lifesciences
14.06.2022 • Brussels / Online

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The challenge

Patients with unmet medical needs in Europe experience delay in access to valuable innovation

EU losing attraction for early clinical trials investments

European Clinical Excellence hub struggling to keep the pace of other regions globally

Early Feasibility Studies (EFS) not taken up in the EU

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Scope of the topic

Set a tested and trialed EU methodology to promote the uptake of Early Feasibility Studies in the EU:

Blueprints, guidelines, templates

in line with EU regulations

Stakeholder network

Connected through an EU online portal

Use-cases (pilots)

To test and validate the methodology

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Expected outcomes

The EU methodology for EFS in the EU, stakeholder network and online portal will contribute to:

Patients: engaged from the start

EU-wide and national **regulators**, **HTA bodies**, **Notified Bodies**: Earlier knowledge, better plan, uniform approaches.

Healthcare professionals, medical societies, hospitals and researchers: Improved clinical excellence, stronger disease understanding, earlier quality data.

Health technology developers, incl SMEs: Controlled opportunity to test and assess early on, better informed development phase.

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Expected contributions of the applicants

- **Expertise from:** regulators, healthcare professionals, patients and patient representatives, health technology developers and SMEs, HTA bodies, research organisations, academia, biostatisticians, legal experts, ethicists.

  - To co-create an EU Methodology
  - To facilitate an active and sustainable stakeholder network
  - To develop an online portal with ‘all you need to know and do’ when conducting an EFS in the EU.

IHI funding for applicant consortium: 10.7 Million EUR

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Expected (in-kind) contributions of the industry consortium

- Legal, ethics & compliance, regulatory, R&D, and clinical expertise to feed into the development of the EU Methodology and online portal.
- Propose potentially breakthrough technologies across disease areas to test the EFS methodology and inform any further adaptations.
- Project management, dissemination and communication.

In-kind contribution: 10.7 Million EUR

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Webinars

Register at: webinars-IHI first calls for proposals

- Learn more about the **topic** & get in touch with **potential partners**
- Includes time for **questions and answers**
- **Networking:** list of participants will be published (where permitted)
- Recording and slides will be published

10/06 | 10:30 - IHI rules and procedures – recording available
15/06 | 14:30 - Imaging and cancer (call 1)
16/06 | 14:30 - Early feasibility studies (call 2)
22/06 | 10:30 - Health data for unmet public need (call 1)
22/06 | 14:30 - Cardiovascular diseases (call 2)
23/06 | 10:30 - Multi-modal cancer therapies (call 1)
23/06 | 14:30 - Neurodegenerative diseases (call 1)

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Q&A

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- Elisabetta Vaudano, topic 1 - Call 1
- Tek-Ang Lim, topic 2 - Call 1
- Oussama Karroum, topic 3 - Call 1
- Colm Carroll, topic 4 - Call 1
- Matthias Müllenborn, topic 1 - Call 2
- Andrea Rappagliosi, topic 2 - Call 2

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