

Regulatory science in Horizon Europe and the Innovative Health Initiative

EMA REGULATORY SCIENCES RESEARCH NEEDS
LAUNCH EVENT – 18 JANUARY 2022



LAPLAZA SANTOS Carmen
HEAD OF UNIT HEALTH INNOVATIONS &
ECOSYSTEMS
DG RESEARCH & INNOVATION

Horizon Europe

The ambitious EU research and innovation framework programme (2021-2027)



fuel EU's **scientific and technological excellence** and the strengthen the European Research Area (ERA)

**Science
& technology**



tackle policy priorities, including **green and digital transitions** and Sustainable Development Goals

Society



boost Europe's **innovation uptake, competitiveness** and **jobs**

Economy

Horizon Europe is impact driven

R&I as
a **compass**
for the **future** we want

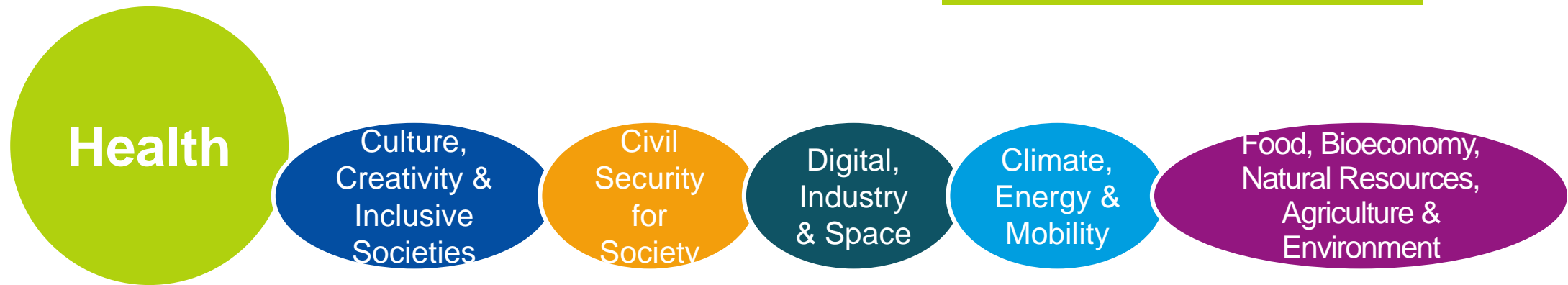


Pillar II

GLOBAL CHALLENGES & EUROPEAN INDUSTRIAL COMPETITIVENESS

6 clusters

€53.5 billion



Innovation in health technologies requires a parallel advancement in regulatory science

Regulatory science research

- The health sector is subjected to strict regulatory requirements. Providing evidence and guidelines for stakeholders and regulators is crucial to ensure uptake of innovations.
- Innovation in health technologies development raises new regulatory questions that require adaptation and the support of regulatory science.
- Support to regulatory science is foreseen in Horizon Europe and is part of the pharmaceutical strategy
- Essential to engage with regulators

Horizon Europe – Cluster 1 „Health“

Strategic Plan 2021-24 → 6 Expected Impacts

Work Programmes → 6 “Destinations”

1. Staying healthy in a rapidly changing society
2. Living and working in a health-promoting environment
3. Tackling diseases & reducing disease burden
4. Ensuring access to innovative, sustainable & high-quality healthcare
5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society
6. Maintaining an innovative, sustainable & globally competitive health industry

Horizon Europe – funding modalities

Support to regulatory science can be provided mainly through:

- **Grants to collaborative projects** (Pillar 2, incl. Cluster 1 ‘Health’)
→ top-down open competition by multi/international consortia proposing projects on specific topics in response to calls for proposals

For example, Destination 6 of the health work programme: Maintaining an innovative, sustainable and globally competitive health industry

- **Partnerships** between R&I investors and funders (Pillar 2 and Pillar 3, incl. Cluster 1 ‘Health’)

For example, Innovative Health Initiative (IHI)

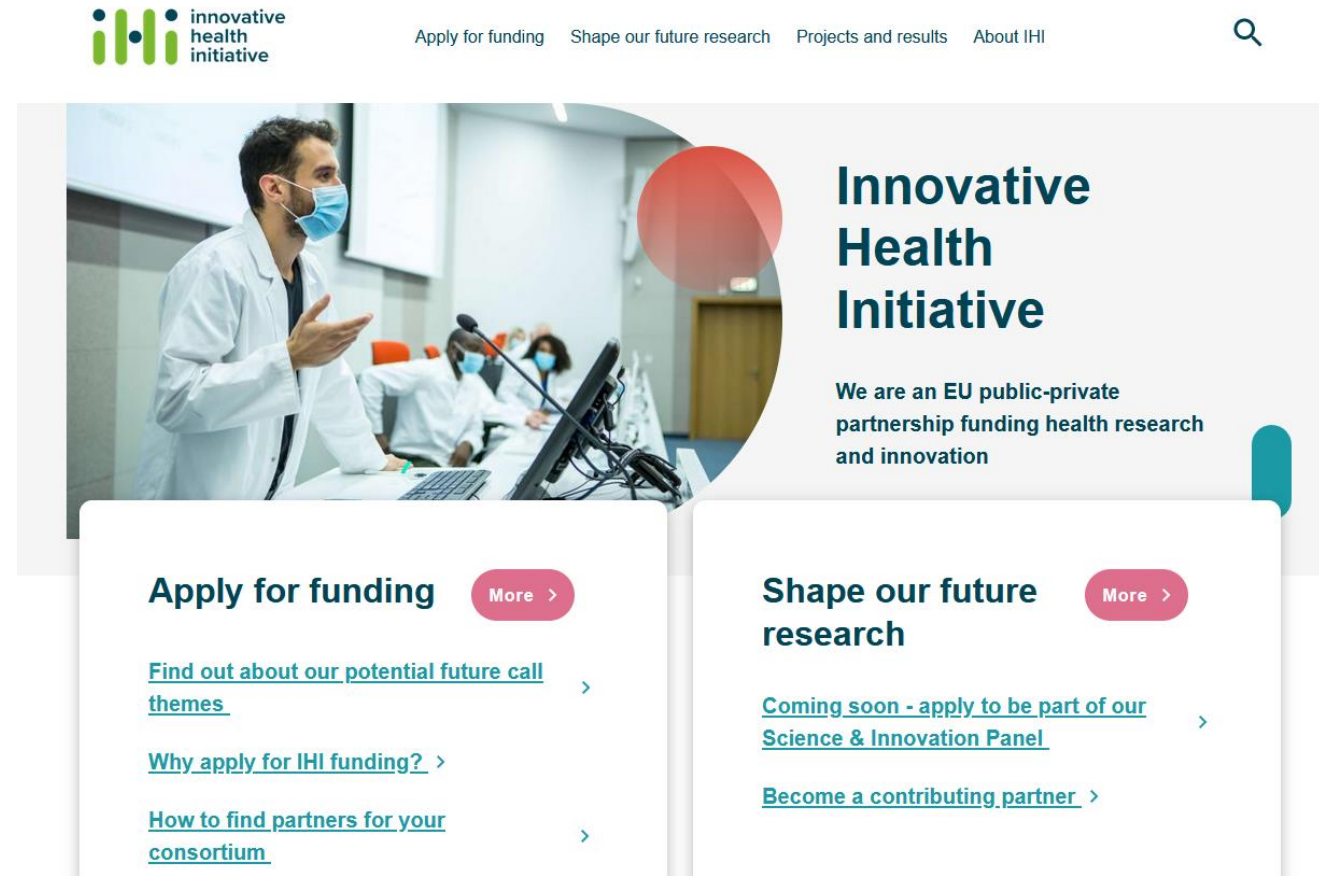
Examples of topics addressing regulatory science in the Work Programme 21- 22

HORIZON-HLTH-2022-TOOL-11-02: *New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment* [Research and Innovation Action]

HORIZON-HLTH-2021-ENVHLTH-03-01: *European partnership for the assessment of risks from chemicals (PARC)* [Programme Co-fund Action]

Innovative Health Initiative (IHI)

- European public-private partnership in precompetitive R&I between the EU and several health industry sectors (pharmaceuticals, vaccines, biotech, medical devices, imaging, diagnostics...)
- Flexible as regards disease areas, as long as addressing an unmet public health need
- Covers prevention, diagnosis, treatment, disease management...
- Total budget EUR 2.4 billion over 7 years



Regulatory aspects in IHI



- The development of cross-sectoral integrated solutions requires the establishment of a constructive, trusted, and continued dialogue between industry sectors and regulators
- IHI intends to contribute to regulatory science, e.g. helping to address regulatory challenges related to products that combine different types of technologies and services
- Focus on integrating the perspectives of various stakeholders (patients, carers, health care providers, health care professionals, industry, HTA bodies, regulators & NBs, policy makers and payers)
- Regulators will provide early input into IHI activities via one of its advisory bodies, the Science & Innovation Panel
- For more details, see the Strategic Research & Innovation Agenda planned for publication still in January



IHI first call for proposals – draft ideas



Single stage calls

- Innovative patient-facing care pathways for patients with neurodegenerative diseases and comorbidities
- Next generation imaging and image-guided diagnosis and therapy for cancer
- Precision oncology: Innovative patient-centric, multi-modal therapies against cancer
- Access and integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need.

Two stage calls

- New tools for prediction, prevention and monitoring of cardio-metabolic diseases including secondary manifestations to enable timely intervention
- Strengthening EU clinical development excellence and innovation attractiveness: Harmonised methodology to promote the uptake of early feasibility studies (EFS)

The research supported by this partnership should remain at pre-competitive level, not aiming at delivering products or services directly in health care systems or on the market.

Classified as internal/staff & contractors by the European Medicines Agency





Thank you!

#HorizonEU

<http://ec.europa.eu/horizon-europe>



© European Union 2021

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.
Image credits: © ivector #249868181, #251163013, #273480523, #241215668, #245719946, #251163053, #252508849, #241215668, #244690530, #222596698, #235536634, #263530636, #66009682, #273480523, #362422833; © petovarga #366009967; © shooarts # 121467308, 2020. Source: Stock.Adobe.com. Icons © Flaticon – all rights reserved.