An initiative of the European Union

EUCLUSTERS TALKS ★

Health in Europe: Where does our ecosystem stand?

8 February 2023

online

08:30-09:45 CET

EUROPEAN CLUSTER COLLABORATION PLATFORM

Agenda

1. News from the European Cluster Collaboration Platform
2. Video: About HERA
3. Perspectives from the European Commission
   ***Elodie Durand**, Policy Officer - Medical Counter Measures, HERA, European Commission*
   ***Chiara Orlandi**, Policy Officer – Medical Devices, DG SANTE, European Commission*
4. Panel debate
   ***Max Pöhlmann,** Project & Cluster Manager, BioM Biotech Cluster Development*
   ***Michael Kerschbaumer**, Project Manager "Innovation", SFG Steirische Wirtschaftsförderungsgesellschaft*
   ***Montse Daban**, Director of Science Policy and Internationalisation, Biocat*
5. Open round with the audience
6. Funding opportunities

Housekeeping rules

Jennifer Baker, presenter

- Please use the **Q&A function to ask questions,** and the **chat function** to comment or share links
- We invite you to **join the debate**: Please **raise your hand** and we will give you the floor.
- Please **unmute yourself** and **activate your camera** when you take the floor.
- Please note that the session is being **recorded**.

NEWS FROM THE EUROPEAN CLUSTER COLLABORATION PLATFORM

EUCLUSTERS TALKS

EUROPEAN CLUSTER COLLABORATION PLATFORM

Priority needs in the area of health in Ukraine

- Medical equipment
- Critical emergency care equipment
- Antibiotics
- Antidotes
- Antivirals
- Medicines for cancer treatment

- In addition, Ukraine may accept other sorts of medical items. Offers will be assessed and sent to Ukrainian authorities, who will then confirm their interest in receiving the donation.
- Potential donors can find information on DG ECHO's website

Europe’s single market turns 30!

- 2023 marks the 30th anniversary of the European single market.
  It is one of the EU’s greatest achievements.
- You’re invited to join us at many events, talks and exhibitions organised by the Commission.
- DG GROW can support you in organising local events and initiatives.
  Register your local event!

Come to the next C2Lab!

- **Registration is open for Lund, Sweden, on 21-22 March 2023**
- Interactive workshop to bring and find collaboration partners, mature your project idea, and build the business case for your idea
- Focus on energy transition and circular economy + 1 open strand
- For cluster organisations, companies, research organisations, actors from the civil society, and other interested entities
- Join the C2Lab Discussion Group on LinkedIn

Matchmaking event and high-level pharmaceutical forum between the EU and Latin America and the Caribbean (LAC)

- Marketplace and matchmaking event on pharmaceuticals from 2 February to beginning of April 2023
- High-level forum on 21 March 2023
- Entities related to pharmaceutical manufacturing from Latin America and the Caribbean or the European Economic Area
- Registration until 24 February on B2Match

Explore the Policy Toolkit!

- The ECCP Policy Toolkit was updated. It is designed to help policymakers and cluster managers strengthen the role of clusters in the green and digital transitions and foster resilience.
- Search and discover 248 good practice examples from more than 60 countries (EU, COSME, Horizon Europe and third countries).

ABOUT HERA

Elodie Durand

Policy Officer - Medical Counter Measures, HERA

European Commission

HERA activities

EU Clusters Talk – Health in Europe: Where does our ecosystem stand?

Elodie Durand – Unit HERA.3 – Medical Countermeasures

8 February 2022

HERA'S mission and mandate

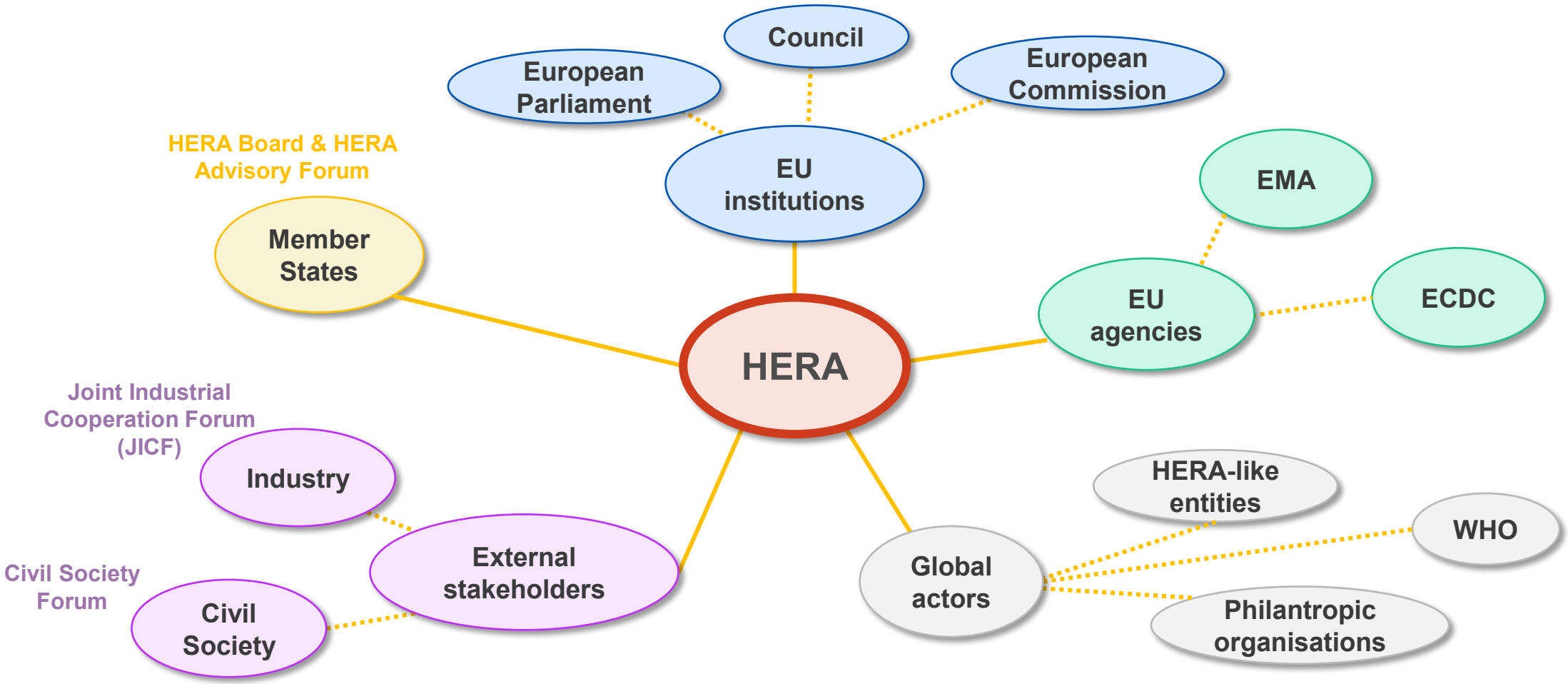
Overarching mission

strengthening Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the availability of and access to key **medical countermeasures** (MCM) by looking at the **whole value chain**

= medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, such as: vaccines, antibiotics, antitoxins, chemical antidotes, therapeutics, diagnostics, medical equipment and supplies

Data, information, intelligence → **Research and clinical trials** → **MCM development** → **MCM production** → **MCM procurement** → **MCM distribution and stockpiling**

Governance


Council
European Parliament
European Commission
HERA Board & HERA Advisory Forum
EU institutions
EMA
Member States
EU agencies
ECDC
HERA
Joint Industrial Cooperation Forum (JICF)
Industry
HERA-like entities
WHO
External stakeholders
Global actors
Civil Society Forum
Civil Society
Philantropic organisations

Main tasks – Preparedness Mode

Threat assessments and intelligence gathering: anticipatory threat assessment, horizon scanning, market intelligence, foresight of serious cross-border health threats, identifying and addressing raw material dependencies as well as market and regulatory challenges/failures

Advanced research and development capacities: promote advanced research and innovation to develop effective, safe and affordable medical countermeasures and related technologies (including late-stage R&D, clinical trials and regulatory pathways)

Production capacities*:* addressing market challenges and failures while boosting the Union's open strategic autonomy in medical countermeasures production via flexible and scalable manufacturing capacities and ever-warm production sites

Procurement, stockpiling, and distribution capacities: promoting the use of joint EU-level procurement of medical countermeasures and assessing the stockpiling capacity in the EU

Knowledge and skills*:* organising training programmes to to improve knowledge and skills related to all aspects of access to medical countermeasures

Main tasks – Crisis Mode

- If a public health emergency is recognised at EU level, the Council, upon the proposal of the Commission, may adopt a regulation activating the **emergency framework**
- Activation of the **Health Crisis Board** to coordinate urgent action in response to the crisis
- Main tasks:


Activation of mechanism for **monitoring** crisis-relevant countermeasures


Procurement, purchase and manufacturing of crisis-relevant medical countermeasures


Activation of **EU FAB facilities** to make available reserved surge manufacturing capacities


Activation of **emergency research and innovation plans** and use of EU wide clinical trial networks


Establishment of an **inventory** of crisis-relevant medical countermeasures production facilities


Activation of **emergency funding**

Budget

- Operational budget: **EUR 6 bn** over 2022-2027
- Contributing programmes: *HERA's activities shall respect the governance of contributing programmes*
  - **EU4Health:** EUR 2.8 billion
  - **Horizon Europe:** EUR 1.7 billion
  - **UCPM/rescEU:** EUR 1.3 billion
- Crisis operations: **Emergency Support Instrument**

HERA WORK PLAN 2023 priorities

- State-of-art IT system
- Further development of medical countermeasures for epidemic and pandemic preparedness
- Reservation of manufacturing capabilities for vaccines (EU FAB)
- Financing mechanism referred to as “HERA INVEST”
- Strategy on EU-level stockpiling
- DURABLE laboratory network

Useful links

- https://ec.europa.eu/health/health-emergency-preparedness-and-response-hera_en
- HERA Workplan 2023 https://health.ec.europa.eu/system/files/2022-11/hera_2003_wp_en.pdf
- Contact: HERA-01@ec.europa.eu

Thank you

European Commission

Chiara Orlandi

Policy Officer – Medical Devices, DG SANTE

European Commission

EU Clusters Talks Health in Europe
Where does our ecosystem stand?

DG SANTE

Unit D3 - Medical Devices

Wednesday 8 February 2023

EU regulatory framework for medical devices

Directive 90/385/EEC on active implantable medical devices (AIMDD)

Directive 93/42/EEC on medical devices (MDD)

Regulation (EU) 2017/745 on medical devices (MDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2021**

Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD)

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2022**

Specific transitional provisions → Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

Main concerns

- Risk of shortage of medical devices due to expiring certificates
- Overall capacity of notified bodies not sufficient
  - 37 notified bodies designated under MDR (February 2023) and 26 applications for designation pending
  - 1990 MDR certificates issued *vs* 22793 (AI)MDD certificates valid (October 2022)*
  - 3509 (AI)MDD certificates expired (May 2021 to December 2022)*
- Low numbers of manufacturers' applications to notified bodies
  - 8120 MDR applications (October 2022)*

** Source: data provided by notified bodies on certifications and applications – latest update available here*
https://health.ec.europa.eu/system/files/2022-10/md_nb_survey_certifications_applications_en.pdf

SHORT TERM ACTIONS

- **Legislative proposal (COM (2023) 10 final)**
  - **Implementation of MDCG 2022-14 - 19 actions**
  - **Bridging measures (MDCG 2022-18) - Art 97**
  - **Gaining momentum to increase number of notified bodies**
  - Study supporting the monitoring of availability of medical devices (EU4Health 2022)
  - Launch of grant for capacity building of notified bodies, preparedness of manufacturers (EU4Health 2022)

NEW FRAMEWORK (MDR/IVDR)

DEVICES ALREADY APPROVED UNDER OLD FRAMEWORK (DIRECTIVES)

LONGER TERM MEASURES

- **Pilot project on scientific advice for clinical development strategies for high-risk devices**
- **Targeted support for SMEs through the Enterprise Europe Network**
- **Tailored solutions for orphan devices**
- Joint Action on market surveillance (EU4Health 2022)
- Study on innovation and governance (EU4Health 2022)
- Orphan devices support programme, focussed on paediatrics (EU4Health 2023)
- Support Notified Bodies Coordination Group (EU4Health 2023)

International activities

- International cooperation in the field of medical devices: https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_en
- Multi-lateral cooperation: International Medical Device Regulators Forum (IMDRF)

EU Chair of the IMDRF management committee in 2023
https://audiovisual.ec.europa.eu/en/video/I-235965?&lg=EN

References and information sources – horizontal

- EUR-Lex and *Official Journal of the European Union*: https://eur-lex.europa.eu/homepage.html?locale=hu
- "New Legislative Framework": https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en
  - Conformity assessment: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/conformity-assessment_en
  - Notified bodies: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies_en
  - NANDO information system: https://ec.europa.eu/growth/tools-databases/nando/
  - European standards: https://single-market-economy.ec.europa.eu/single-market/european-standards_en
  - Market surveillance for products: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance_en
- CE marking: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en
- The 'Blue Guide' on the implementation of EU product rules 2022: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG

References and information sources – sectorial (I)

- Medical Devices - Sector: https://health.ec.europa.eu/medical-devices-sector_en
  - New Regulations: https://health.ec.europa.eu/medical-devices-new-regulations_en, https://health.ec.europa.eu/medical-devices-sector/new-regulations_en, https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations_en
  - *In Vitro* Diagnostics: https://health.ec.europa.eu/vitro-diagnostics_en
  - Harmonised standards: https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
  - Notified bodies: https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies_en
  - Unique Device Identifier (UDI): https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en, https://eu-udi.zendesk.com/hc/en-150
  - Expert panels: https://health.ec.europa.eu/medical-devices-expert-panels_en
  - European Medical Device Nomenclature (EMDN): https://webgate.ec.europa.eu/dyna2/emdn/A
  - Eudamed: https://health.ec.europa.eu/medical-devices-eudamed_en, https://ec.europa.eu/tools/eudamed/eudamed, https://webgate.ec.europa.eu/eudamed-help/
  - Medical Device Coordination Group (MDCG): https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/overview_en#medical-device-coordination-group---mdcg, https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565
  - International cooperation: https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_en
  - Contacts: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en
  - Publications, factsheets: https://health.ec.europa.eu/medical-devices-sector/publications_en

References and information sources – sectorial (II)

- Guidance - MDCG endorsed documents and other guidance: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_hu
  - MDCG 2021-25 Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC: https://ec.europa.eu/health/system/files/2021-10/md_mdcg_2021_25_en_0.pdf
  - MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD: https://ec.europa.eu/health/system/files/2020-09/md_mdcg_guidance_significant_changes_annexes_en_0.pdf
  - MDCG 2022-4 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD: https://ec.europa.eu/health/system/files/2022-02/mdcg_2022-4_en.pdf
  - MDCG 2021-24 Guidance on classification of medical devices: https://ec.europa.eu/health/system/files/2021-10/mdcg_2021-24_en_0.pdf
  - MDCG 2021-27 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746: https://ec.europa.eu/health/system/files/2021-12/mdcg_2021-27_en.pdf
  - MDCG 2021-5 Guidance on standardisation for medical devices: https://ec.europa.eu/health/system/files/2021-04/md_mdcg_2021_5_en_0.pdf
  - How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used – also in the COVID-19 context: https://ec.europa.eu/health/system/files/2020-09/md_mdcg_qa_conformity_documents_en_0.pdf
  - and much more …

Thank you

Contacts:

DG SANTE - *Unit D.3 Medical Devices*
Maria-Chiara.ORLANDI@ec.europa.eu
SANTE-MED-DEV@ec.europa.eu

Panel debate

Max Pöhlmann, Project & Cluster Manager, BioM Biotech Cluster Development

Michael Kerschbaumer, Project Manager “Innovation“, SFG Steirische Wirtschaftsförderungsgesellschaft; Enterprise Europe Network

Montse Daban, Director of Science Policy and Internationalisation, Biocat

What are your thoughts?

FUNDING OPPORTUNITIES

Environmentally sustainable and climate neutral health and care systems

- Topic should aim for delivering results that are directed:
  - Policy and decision makers, providers of health and care, health and care workers and citizens have increased knowledge on how today's health and care systems are not environmentally sustainable and where improvements are possible
  - Policy and decision makers and providers of health and care services have access to innovative solutions
  - Monitoring and reporting of carbon emissions and pollution is mainstreamed through a life-cycle approach
- Deadline: 13 April 2023
- HORIZON-RIA HORIZON Research and Innovation Actions;
  TOPIC ID: HORIZON-HLTH-2023-CARE-04-03
- Published on Funding & Tenders Portal

Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks

- This topic aims at maintaining and strengthening existing strategic coordination mechanisms across adaptive platform trials and across cohort studies.
- Proposals should describe a coordination mechanism for adaptive platform trials and/or for cohort research.
- Deadline: 13 April 2023
- HORIZON-CSA HORIZON Coordination and Support Actions;
  TOPIC ID: HORIZON-HLTH-2023-DISEASE-03-05
- Published on Funding & Tenders Portal

Maintaining access to regular health and care services in case of cross-border emergencies

- Topic should aim for delivering results that are directed:
  - Decision- and policymakers have access to modelling tools and foresight studies
  - Decision- and policymakers and health and care providers can better facilitate and manage access to regular health and care delivery during cross-border emergencies
  - Health and care professionals have access to training
  - Health and care professionals, citizens and patients access advanced digital tools enabling managed access to regular health and care services
  - Patients can be involved in the co-design and co-production of health and care delivery models
  - Health and care providers and health and care professionals have access to knowledge and data
- Deadline: 13 April 2023
- HORIZON-RIA HORIZON Research and Innovation Actions;
  TOPIC ID: HORIZON-HLTH-2023-CARE-04-01
- Published on Funding & Tenders Portal

Development and harmonisation of methodologies for assessing digital health technologies in Europe

- Topic should aim for delivering results that are directed:
  - Policymakers in the EU have at their disposal a methodological framework and standardised approaches for assessing digital health technologies
  - Regulators have access to robust, scientifically underpinned evaluation methodologies
  - EU citizens gain faster access to safe and well-performing person-centred digital technologies
  - (Digital) Health Industry/digital health technology developers and HTA bodies can contribute to the development of EU harmonised Health Technology Assessment
  - Improved cross-border use and interoperability of digital health tools and services
  - Increased trust in digital health technologies and better integration of digital health tools and services in health and care systems
- Deadline: 13 April 2023
- HORIZON-RIA HORIZON Research and Innovation Actions;
  TOPIC ID: HORIZON-HLTH-2023-IND-06-07
- Published on Funding & Tenders Portal

Call from Ventures Thrive: Investment in deep-tech start-ups

- Ventures Thrive is one of the first pan-European deep-tech venture builders, committed to helping start-ups quickly scale their development.
- Funded by the European Innovation Council (EIC), the 1,500,000 EUR grant will be deployed over two years to invest in up to 32 deep-tech startups focused on addressing some of the world's most pressing problems.
- Each accepted start-up is eligible for up to 100,000 EUR in cash and services – equity free.
- Deadline: 16 March 2023
- More info: www.venturesthrive.eu

Register for the next Talks

22 February 2023: Transition Pathway for Mobility

8 March 2023: Euroclusters

22 March 2023: Interregional Collaboration

5 April 2023: Raw Materials and Circular Economy

Register on the European Cluster Collaboration Platform!

https://clustercollaboration.eu/

Strengthening the European economy through collaboration

The European online hub for industry clusters

Strengthening the European economy through collaboration

Find partners per country, region, sector or industrial ecosystem

THANK YOU

EUCLUSTERS TALKS

EUROPEAN CLUSTER COLLABORATION PLATFORM