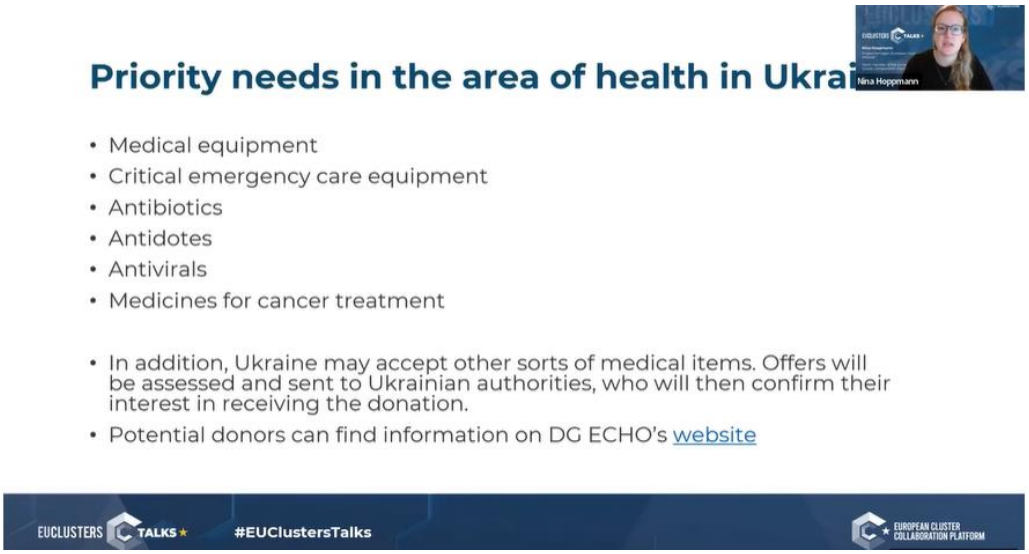
Watch online HERE

The presenter of the EU Clusters Talks is **Jennifer Baker**

Nina Hoppmann starts with the ECCP news



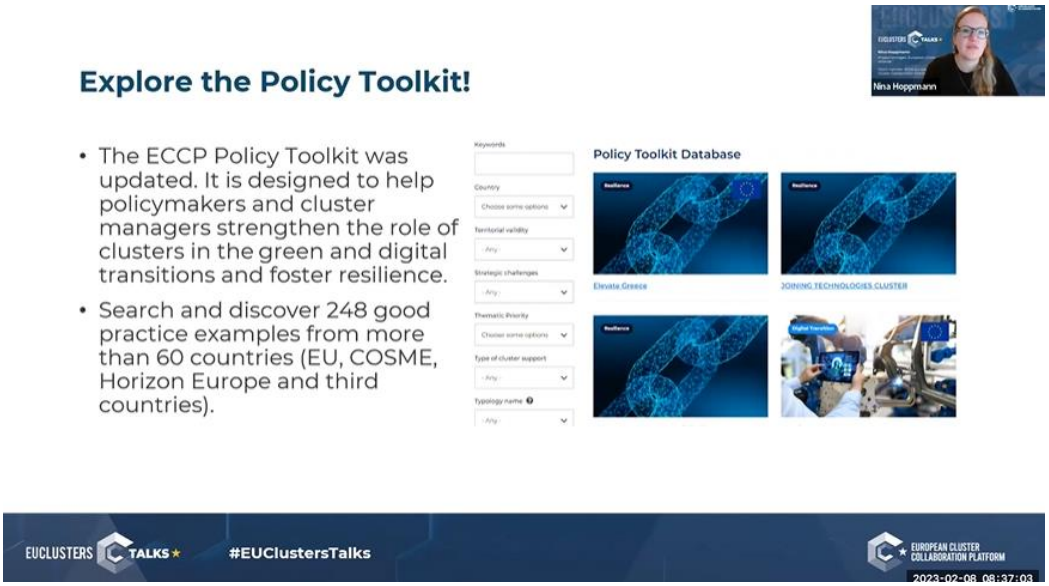
More information and Registration for C2Lab HERE.

More information about the EU single market HERE.

REGISTER YOUR LOCAL EVENT HERE

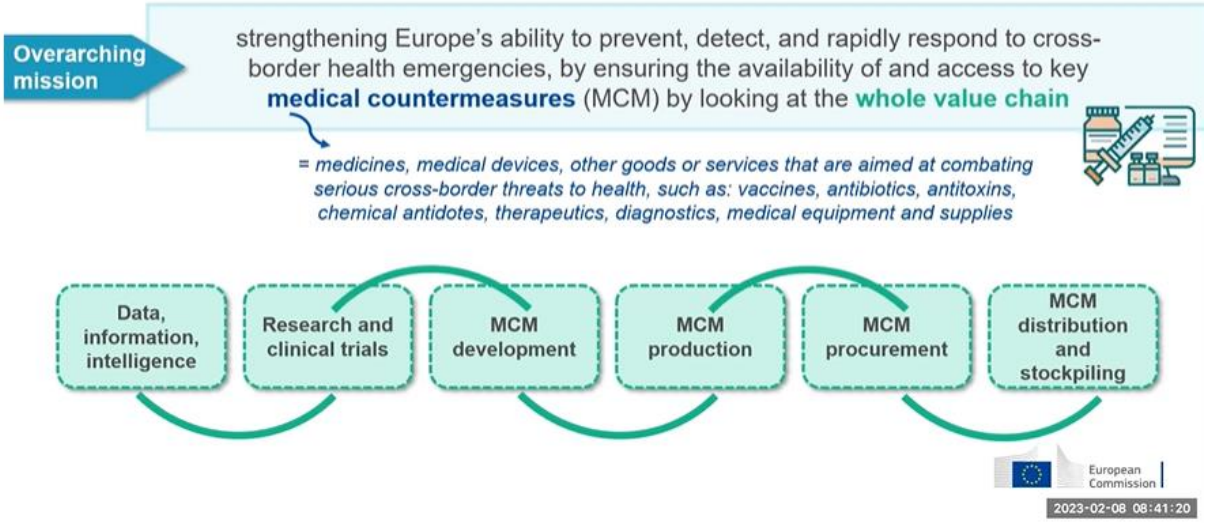
Online matchmaking event for entities related to pharmaceutical manufacturing. More information HERE

Explore the Policy Toolkit HERE

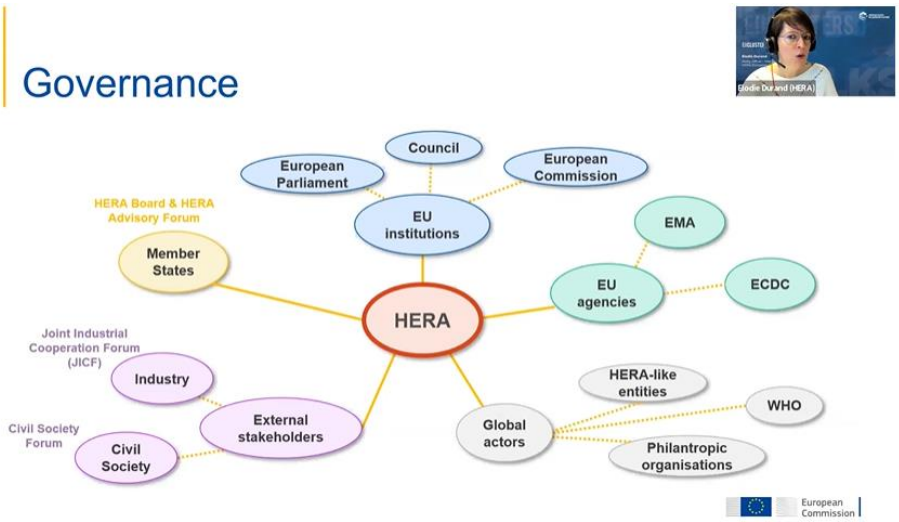


Follows the video about Hera and the first speaker is Elodie Durand, Policy Officer – Medical Counter Measures from HERA.

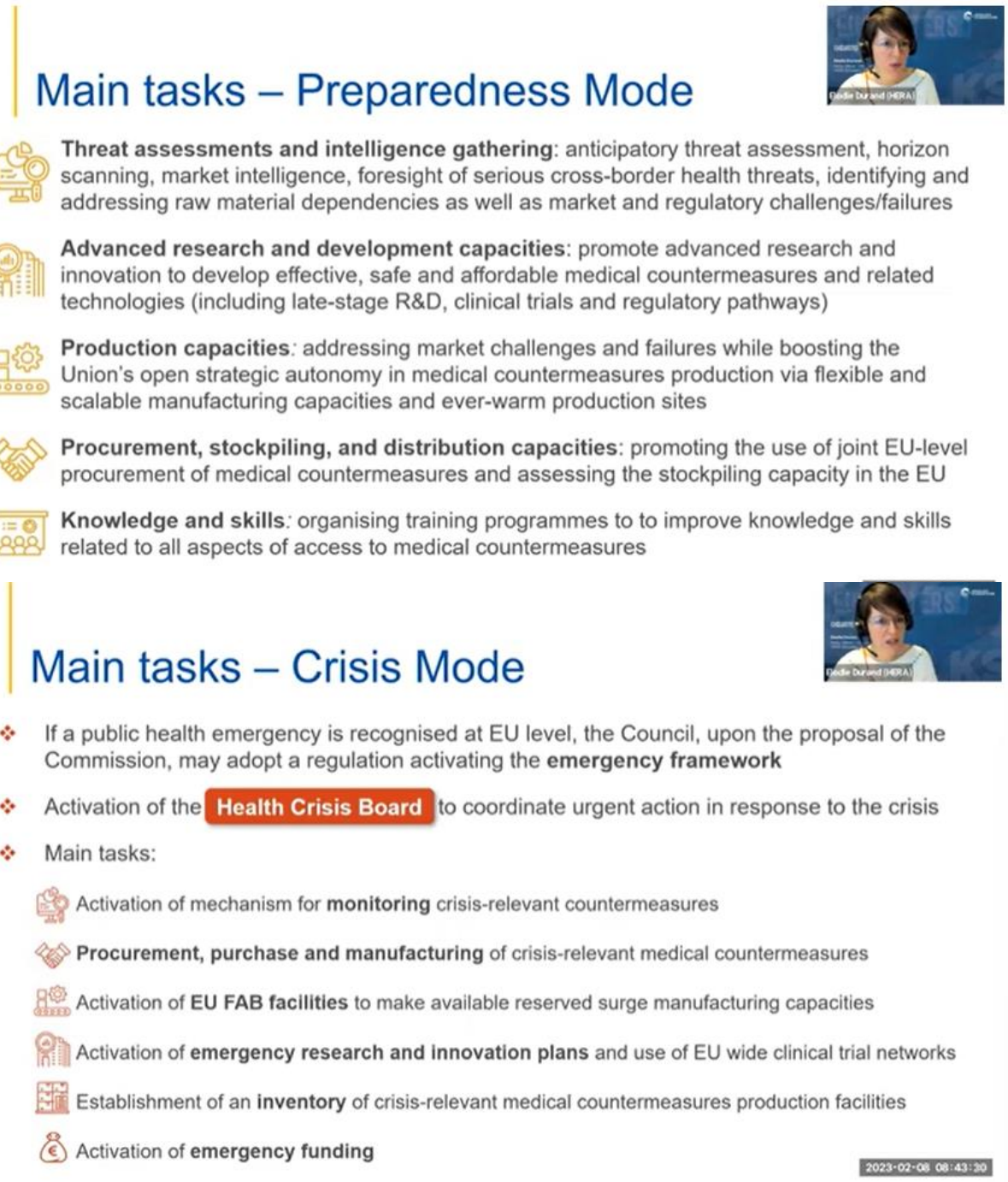
Elodie will cover where HERA is right now and what they are doing.



HERA was established in 2021, and they have made plenty of achievements. One of the biggest ones is the vaccine for Covid-19 and Monkeypox. HERA covers various medical countermeasures – from vaccines to therapeutics, PPE (personal protective equipment) and much more. They cover medical countermeasures (MCM) within the whole value chain. Both medicines and therapeutics are authorised on the EU market.



HERA is proud of its extensive network. They have been working very closely with other EU institutions and agencies (national and international), and they have other actors. They have dedicated forums for essential stakeholders, such as Civil Society and Industry forums. The European Cluster Alliance (ECA) is a member of the Joint Industrial Cooperation Forum (JICF). It is an essential forum where they can share their work and get feedback.



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://health.ec.europa.eu/health-emergency-preparedness-and-response-hera_en

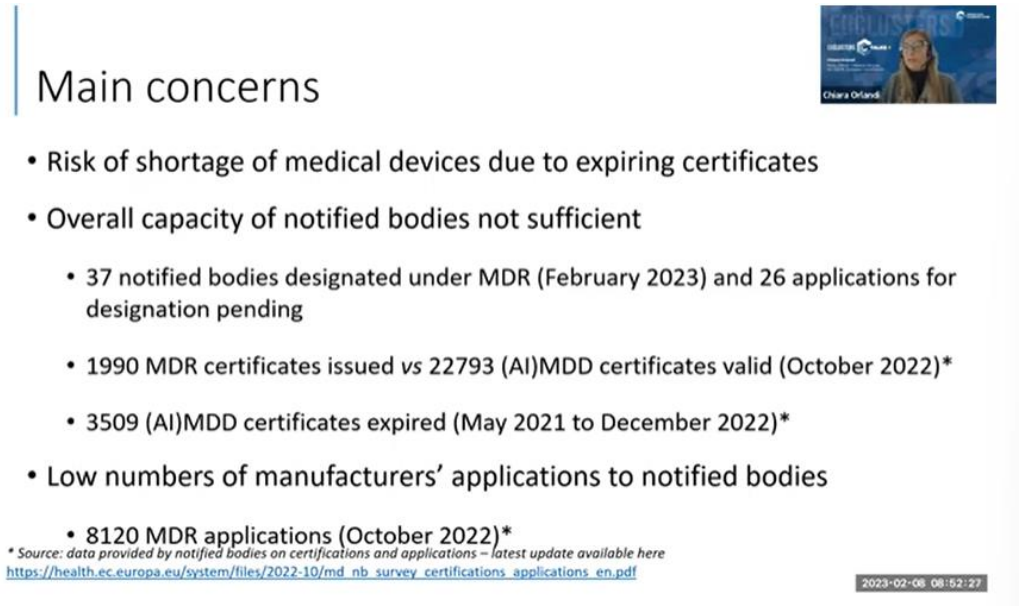
HERA work plan 2023: https://health.ec.europa.eu/system/files/2022-11/hera_2003_wp_en.pdf

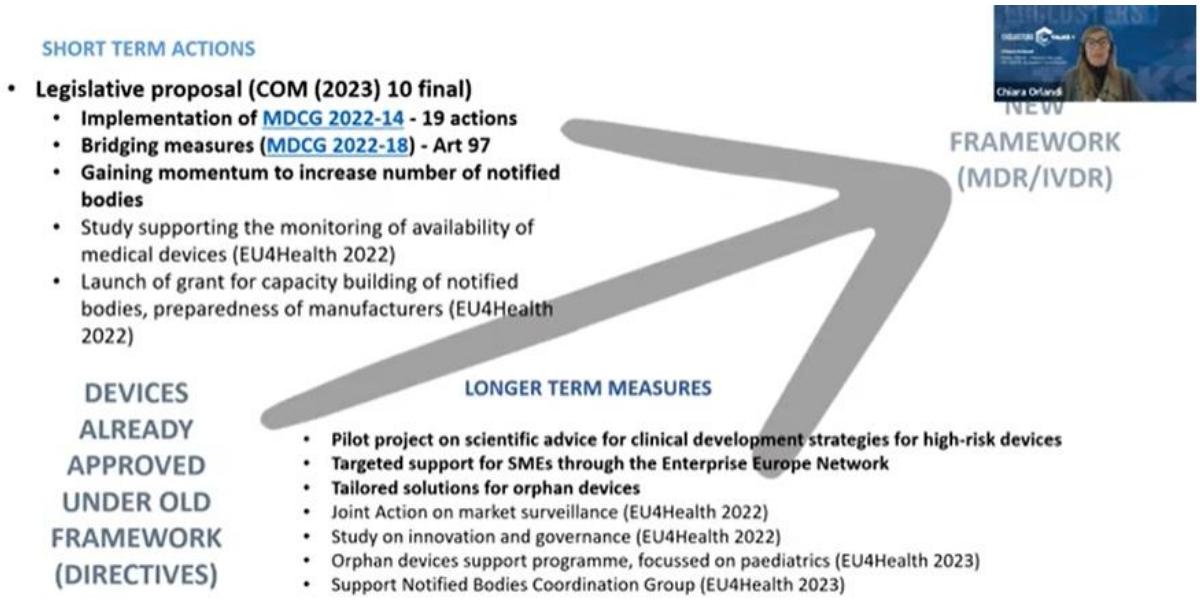
Contact: HERA-01@ec.europa.eu

The next speaker is Chiara Orlandi, Policy Officer – Medical Devices, DG SANTE.

Chiara talks about policies and initiatives in the area of medical devices. Firstly, she talks about the European Commission, and she says that European Commission is not working alone but also with the member states and the key stakeholders.

Two regulations for medical devices are already applicable.





Follows panel debate

Max Pöhlmann gives us their assessment of how successful HERA is within the agenda that it set for itself.

HERA is a very new entity with much to cover that must be established. From his point of view, based on what is happening in Germany, a lot of framework needs to be set to make HERA successful. It is necessary to have higher production capacity, development and availability of drugs and medical devices. He believes plenty of things have to be done correctly so they can have an effective and efficient response to any health threats that might be there in the future. There is much debate, talks, and preparation for legal entities, companies, and clusters. They always try to bridge the gap between industry, politics, and cluster members. Companies don´t work for free, and the legal framework needs to reflect and empower them to make money and develop innovative good medicine. Right now, there are a lot of political movements going on. Politicians realised that we need to be active and active our strengths to develop our drugs ourselves. We will get there eventually, but much work must be done.

Similar question to Michael Kerschbaumer, do you agree with Max?

Michael says they are dealing with a different type of client than Max. The Enterprise Europe Network focuses on small and medium-sized enterprises and startups. They are facing other challenges. He says many highly innovative SMEs and startups in the health tech sector are trying to reach the market, but they need more instruments to scale up. For example, look at the European Innovation Council accelerator. Half the companies are applying for funding, but only 5% - 7% can get into the program. The only possibility for these highly innovative solutions from these SMEs from all over Europe to reach market readiness is to find the solution for them. Otherwise, their great ideas will never reach the market. Otherwise, we will remain in the old structures of devices and solutions. These new ideas could actually solve many problems. There isn´t enough funding to support these ideas. And if there are investors, they are impatient. They instead invest in fast-growing companies. But in health tech companies, it takes time to develop something new. We are talking about years of development.

Jennifer adds that market readiness in the medical sector differs from other market readiness sectors. It is different from putting out a new mobile phone. We are talking about medicines, lives and medical devices that could majorly impact people's lives.

Michael adds that the regulations for the medical industry are necessary, but this means that the projects last much longer than the app or phone development. It also needs more funding in later years. Let´s say the project lasts seven years, but in the fourth year, they don´t have funding and investors prefer to invest in something faster. Of course, we cannot rely only on financing, but there is not enough initiative to support SMEs in later years.

Michael also says that Montserrat Daban will have much more to add to such a topic.

Montserrat Daban, Cluster Director of Science Policy and Internationalisation, Biocat

She would like to react to things which were already mentioned.

Firstly, what HERA means for Biocat? For them, it is a transition pathway for the health ecosystem. The health ecosystem differs from the other ecosystems, as mentioned already. This means that the transition pathway tools are under HERA. Biocat is a part of the HERA´s Joint Industrial Cooperation Forum, which helps them to connect with industrial players. It is

also about alerts on cross-border threats. It is necessary to mention that Covid-19 brought more research and innovations, preparedness and stockpiling. All mentioned are part of HERA, and being part of HERA is essential for cluster organisations. Not only innovations come from HERA but also the transformation of the industry. Because of Covid-19, we had the opportunity to see the sector's transformation, especially in digital health.

Montse mentions that her experience is different to other panellists too. She represents the whole regional ecosystem involving hospitals, research organisations, universities, startups, scale-ups, and more.

The best tools for support:

- Cluster organisations ask stakeholders what they need from clusters in case of growth (financial support, support to reach national and international markets, new talents...).
- Help with stakeholders' challenges (business, crisis, climate crisis, transitions, and business models...).

Michael adds that we must also talk about the gatekeepers of the health system. We have two main Gatekeepers that are still, in his opinion, reluctant when it comes to embracing innovations in the health industry. The users in the hospital, like the administrators, are reluctant to new technologies and reimbursement of the public health insurance system. These things must go hand in hand for new technologies and ideas to enter the market.

Enterprise Europa Network organises events to support companies on the way to get together with large corporates and get funding. But the systemic changes need to come from policy, from the commission, and to be discussed with the cluster collaboration platform. Michael says many innovations must be led through to the system, which will change the situation.

Max also adds to the topic. He entirely agrees with what Michael said. Many good ideas and innovations are ready to be translated into a stadium of readiness. He mentioned that he attended meetings between the hospital and a company where they discussed the best conduct of clinical trials, how to get their drugs, and their innovative therapeutics into the clinic. It took a lot of work to reach the point where everyone agreed. Translation is one of the fundamental problems that we must solve to become quicker and leaner. He thinks many companies need help with the bureaucracy around getting drugs to the market. Once they hit a point where they can get to a clinic (a clinical-stage trial), it is difficult for them to start. They need money to keep going, and the framework is complicated. He believes this is something we need to improve. Also, sharing data would be beneficial too. Many companies would benefit massively from the availability of Health Data. It is also tricky because, in Germany, there is strict data protection. Lots of data is there already and could be used by smaller companies, especially those that need help to afford massive data analysis.

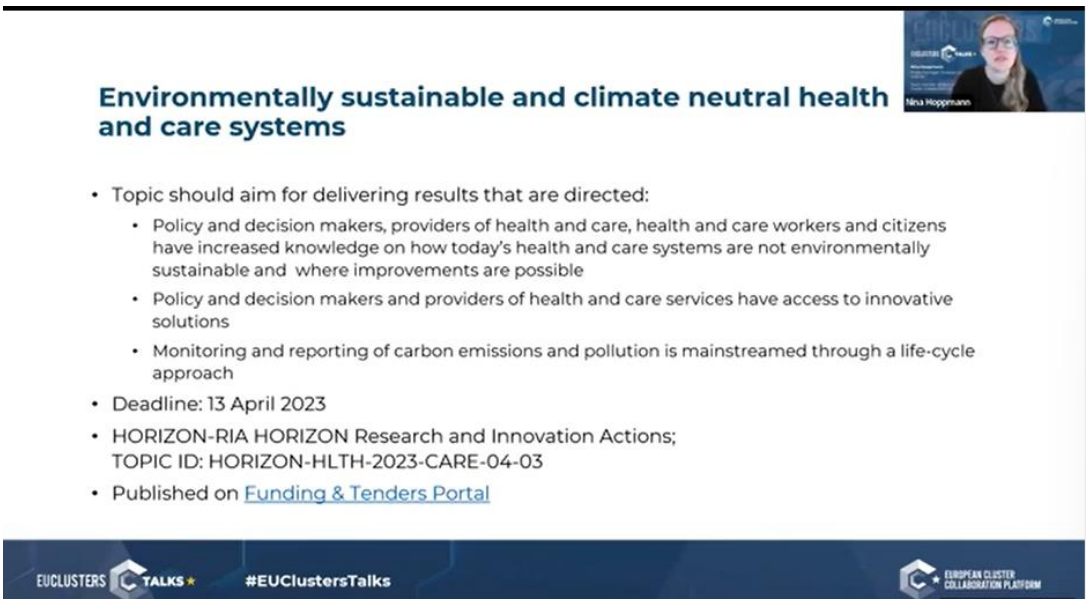
Montse adds her thoughts. She believes good ideas need to fill the market needs. Not all good ideas can fit the market needs. Many needs could be met. It is necessary to identify these needs. She also mentions that the process of implementing these ideas should be faster.

Chiara says that innovations are one of the aspects they are looking at. They want to foster innovations; they want to retain these innovations. She also mentions a study they are about to lunch. It addresses governance and innovations in the medical device sector. Chiara also says the access of innovations to the market. These innovations need to access the market in a reasonable time. Timing for certifications of medical devices, especially high-risk devices, can take too long (18 months to 2 years).

Michael goes back to the data. There are a lot of KI applications in the stage of development when it comes to diagnostics. What do these KI need? They need a vast amount of data with diagnostics attached to them. For companies, it's impossible to get the data. They have to produce the data themselves. What would help would be some open data approach of anonymised companies. An initiative like this from the European Commission is needed.

Max adds that it would be essential to have available data on the European level so that large pharmaceutical companies would not work only with data generated in different parts of the world and might not be 100% applicable to the population in Europe. It would be essential to have a European generating these health data. All of these points we need to communicate positively. It is a very sensitive but important topic. We need to be discreet about this topic but also be focused. Creating a space where we could share European data is a good idea, but we have to be careful that we do it right and are quick enough so that not every country or region creates their framework.

Back to Nina Hoppmann and funding opportunities.




Nina Hoppmann
Pandemic preparedness and response: Sustaining establ
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
EUCLUSTERS TALKS
#EUClustersTalks
EUROPEAN CLUSTER COLLABORATION PLATFORM


Nina Hoppmann
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
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