



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Developing research partnerships with academia

Feedback from breakout session 5D

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

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Disclaimer

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Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science: **summary of written comments**



Pre-consultation

Supported

- Identify, in consultation with academia and relevant stakeholders, fundamental research topics in strategic areas of regulatory science
- Proactively engage with DG Research & Innovation, DG-SANTE, IMI and MS funding agencies to propose and issue calls to establish research collaborations

Consultation feedback

More ambition

- Collaboration with academic research centres
- Role of industry in network-led partnerships
- Funders - innovative funding models; explaining incentive models; opportunities for collaborative regulatory science initiatives
- Global consortia
- Regulatory science priorities - incorporated into national and European translational calls
- Training/education – pipeline of talent to support long-term future of regulatory science



Given 'the vision', in support of delivering for patients, create a Roadmap to develop Network-led partnerships with academia

1. **Identify the gaps** foreseen from RSS2025 – how to address & take forward?
2. **Key elements to be delivered:** a Network-led partnership to address the following
 - Support for academics developing medicines
 - Regulator has a question – where to take this?
 - 'Wet lab' related
 - Clinical trials related
 - Epidemiology / RWD related
 - Translation & methods - how to work together to define priorities, co-design modelling & simulation / CT / QoL methods, agree PROs, and so on?
3. **Associated education & training needs**





Enablers & barriers:

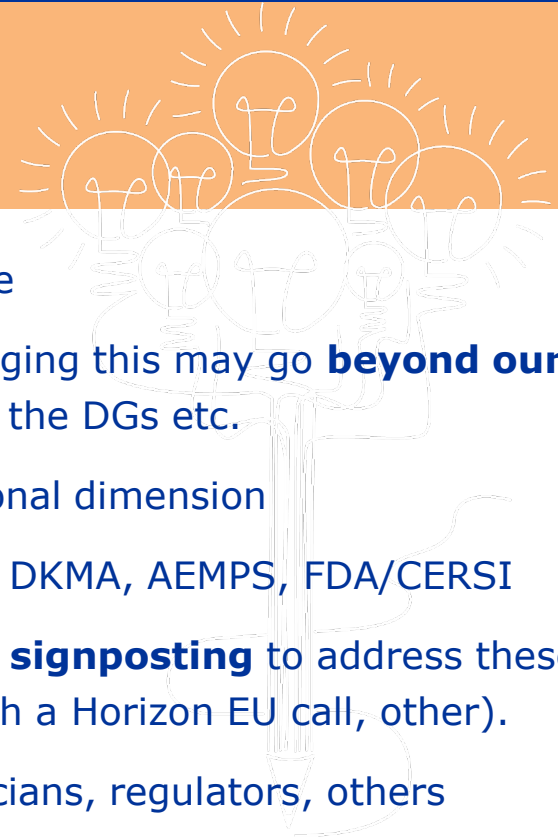
- Clear **willingness** of stakeholders **to work with us & together**, globally, transparently & for patient benefit
- **Build on existing** networks, platforms, infrastructures (EU-Innovation Network, JRC, ERN, EU lead factory, C4C)
- Use opportunities @DG R&I and others to **voice research needs** translated into funding
- Sustainable infrastructure & project based **funding** - consider 'wheel & spokes' funding model
 - Horizon EU incl. Innovative Health Initiative, Marie Curie
 - A budget line for EMA, EU-innovation network & National Competent Authorities
- **Education & training** from BSc to continuing professional development – building on the work in STARS for the identification of training needs & existing offerings





The foreseen Network-led partnership with academia:

- benefits from a **clear vision** for EU public health and therefore
- has relevant stakeholders and funders at the table, acknowledging this may go **beyond our usual Network** and bringing in other decentralised Agencies, the DGs etc.
- is **co-created** with HMA / NCAs and includes a clear international dimension
- is developed **learning from existing models** e.g. from MEB, DKMA, AEMPS, FDA/CERSI
- identifies the **questions relevant to patients** & provides the **signposting** to address these (e.g. at national level, through the infrastructure itself, through a Horizon EU call, other).
- identifies the **training needs** – of medicines developers, clinicians, regulators, others
- delivers on the above in a **continuous dialogue**, not as a one-way communication





Any questions?

Further information

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