STARS
STRENGTHENING
REGULATORY
SCIENCE

Breakout Session 4 Outcomes

18 November 2021

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

STARS
STRENGTHENING
REGULATORY
SCIENCE

Recommendations

#4 Low threshold access to regulatory authorities.

#8 Expanding and promoting existing structures within NCAs.

#12 Early communication with regulators and HTA before starting research project.

#16 Support of research of regulatory processes by specific funding

#19/#20 Continuous regulatory training of academia and regulators.

Initial poll results

12- Early communication with regulators and HTA before starting research project

4- Low threshold access to regulatory authorities

16- Support of research of regulatory processes by specific funding measures

19/20- Continuous education and training of regulators and academia

8- Expanding and promoting existing structures within NCAs

Guiding elements

- Speed of change of regulatory framework and of innovation – timeliness of communication
- Two-way communication (multi-lateral) (Pilot II)
- Proactive communication from all sides
- Common language, mutual understanding
- Multidisciplinary approaches

#4 Low threshold access to regulatory authorities

- Importance of informal advice - does not replace, but does facilitate formal advice
  - Building trust
  - Demonstrating openness and accessibility – removing notion of “hurdle”
  - Gaining time in further stages and optimizing use of resources
- Flexibility of solutions, tools and methods to be applied – no “one-size fits all”

#8 Expanding and promoting existing structures within NCAs.

- Strengthening and promoting innovation offices
- Ensuring sufficient resources and staff are available at NCAs

#12 Early communication with regulators and HTA before starting research project.

- Essential to initiate communication as early as possible
- Gain efficiency, avoid delays and hurdles
- Potentially integrate patient communities to the same early dialogue
- Culture of early communication needs to be stimulated by ALL stakeholders

#16 Support of research of regulatory processes by specific funding

- Ensure this is a priority area for funding
- Involve academia in defining research priorities within regulatory research

#19/#20 Continuous regulatory training of academia and regulators.

- Promote Core curriculum – harmonization and common starting point
- Regulatory training from undergraduate onwards, for all – sustained access to training

Additional recommendations

- Funders → include consultation of regulatory bodies as a requisite (when relevant) in grant proposals, provide links to relevant regulatory tools in call text + ensure consultation fees and other expenses related to the consultation process are eligible
- Knowledge exchange or “two-way training” established between regulators and academia, where not only academia is trained on regulatory aspects, but regulators also benefit from academia, learning about the most recent methodologies, tools and technologies from academia
- NCAs should be provided with sufficient staff and funds to provide the necessary support to academia. Funding could be complemented with EU funding.
- Research institutions and/or academic sponsors should establish a regulatory support office, with a formally recognized role of “regulatory expert”. This office could:
  - Provide regulatory support to multiple projects
  - Interact with regulatory agencies
  - Promote training and education on regulatory aspects

Overarching conclusions

- Big picture: implementing the recommendations should have a positive impact on: economy, jobs, public health
  - Optimal use of monetary and human resources
  - Best public health outcomes
  - Key incentive for policy makers

Final polling results

- 12- Early communication with regulators and HTA before starting research project
- 19/20- Continuous education and training of regulators and academia
- 4- Low threshold access to regulatory authorities
- 8- Expanding and promoting existing structures within NCAs
- 16- Support of research of regulatory processes by specific funding measures

- 12- Early communication with regulators and HTA before starting research project
- 4- Low threshold access to regulatory authorities
- 16- Support of research of regulatory processes by specific funding measures
- 19/20- Continuous education and training of regulators and academia
- 8- Expanding and promoting existing structures within NCAs