# Theme 3: Regulatory science, innovation and competitiveness

## Helping improve innovation and competitiveness in the EU healthcare sector

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# Theme 3 – general considerations

## Potential changes to the goals, objectives or narrative of the strategy

- Future proofing of the EU Innovation Ecosystem (goal 1)
- Enable rapid adaptation to scientific and technological developments, development of regulatory tools and approaches and also identify areas where additional expertise is needed (goal 1, objective 2)
- Supporting the competitiveness of the biomanufacturing sector (goal 1, objective 3)
- Supporting the generation of high-quality evidence in quality, non-clinical (including non-animal methods) (goal 2, objective 4)
- Add the integration of RWD (goal 2, objective 5)
- Aligning approaches internationally (goal 2, objective 6)
- Include funders (goal 3, objective 7)
- Foster the dialogue and communication among the different stakeholders (narrative of the strategy)

# Theme 3 – general considerations

## To be considered in implementation actions

- Development/ updating of the guidelines
- Promoting the inclusion of patients e.g. in the scientific advice
- More transparency within the procedures, also in all kinds of public-private cooperation
- Promote the uptake of RWD and patient – reported outcomes (PRO)
- Improvement of CTIS and foster use of RWD – EMA and HMA, ACT EU/ CTCG are already working on these improvements
- Improved mechanisms to prevent ethical and financial waste, e.g. pre-grant advice
- Foster innovation effectively, regulatory guidance and flexible pathways should be made available – included in the EU-IN workplan
- Better alignment among member states e.g. borderline cases

# Theme 3 – Goal 1 (advancing science and technology)

**Promote the integration of advancing science and technology in medicines development and manufacturing**

1. Continue to support innovation and the integration of scientific and technological advancements in the development of human and veterinary medicines
2. In collaboration with other EU bodies, implement a model for efficient, timely and coordinated EU horizon scanning for human and veterinary medicines that addresses the needs of regulators, HTA bodies and payers, supported by digital tools and AI
3. Facilitate the implementation of novel manufacturing technologies and analytical techniques

# Theme 3 – Goal 1 (advancing science and technology)

## To be considered in implementation actions

- Regulatory guidance should be updated timely to reflect innovative technologies and remove ineffective methods.
- Improved mechanisms are needed to stay updated with changes and regulatory updates to prevent ethical and financial waste.
- Regulatory guidance and flexible pathways should support small and mid-sized companies in integrating advancements, ensuring robust and efficient development processes.

# Theme 3 – Goal 2 (generation of evidence)

**Foster generation of high quality and impactful evidence with particular focus on clinical trials**

4. Support the generation of high-quality evidence in quality, non-clinical and clinical domains by researchers and sponsors from early development stages and provide timely scientific and/or regulatory advice
5. Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation
6. Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions e.g. the Joint Research Centre

# Theme 3 – Goal 2 (generation of evidence)

## To be considered in implementation actions

- Several comments request greater support for non-animal models, as they consider the strategy takes a light approach.
- Non-clinical models aligned with the 3Rs are included in objective 6, and specific actions will be considered in alignment with 3Rs WP workplan, etc.
- A progressive/gradual transition is envisaged.
- Comments related to enhancing the CT ecosystem, CTA harmonisation requirements, and CTIS improvements: references made to ACT EU and CTCG.
- A goal and objective focused on CTs are included in this theme, and concrete actions will be discussed.

# Theme 3 – Goal 3 (stakeholder cooperation)

**Promote stakeholder cooperation to accelerate the translation of innovation into therapies, facilitate the repurposing of existing therapies and increase EU competitiveness**

7. Develop network-led partnerships with key stakeholders (e.g. academia, and industry) to deliver impactful progress in regulatory science and provide training

8. Enhance the regulatory competence of researchers and developers from academia, hospitals and small and medium sized enterprises (SMEs) to facilitate the translation of research into innovative medicines through direct support and pre-competitive research collaborations

9. Increase collaboration with medical device experts, notified bodies, ethics and patient communities, HTA bodies and the Substances of Human Origin (SoHO) network in conjunction with the European Commission to support development and authorisation of combination products

# Theme 3 – Goal 3 (stakeholder cooperation)

## To be considered in implementation actions

- More transparency within the procedures, also in all kinds of public-private cooperation.

## Other comments

- Comments on network capacity and capability, already reflected in Theme 6 and ongoing initiatives (IncreaseNET, the EU NTC offer, and ongoing efforts to enhance the network capability, capacity, and the system efficiency).

## Comments outside the remit of medicines agencies

- Highlighting opportunities in the ongoing pharmaceutical legislation revision, with some claiming that certain provisions are not ambitious enough. The strategy could be updated once the legislation comes into force.