

Public consultation on EMA Regulatory Science to 2025

Fields marked with * are mandatory.

* Name

* Email



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction

The purpose of this public consultation is to seek views from EMA's stakeholders, partners and the general public on EMA's proposed strategy on Regulatory Science to 2025 and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, you have the opportunity to jointly shape a vision for regulatory science that will in turn feed into the wider EU network strategy in the period 2020-25.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic goals and core recommendations. We also seek your views on whether the specific underlying actions proposed are the most appropriate to achieve these goals.

The questionnaire will remain open until June 30, 2019. In case of any queries, please contact: RegulatoryScience2025@ema.europa.eu.

Completing the questionnaire

This questionnaire should be completed once you have read the draft strategy document. The survey is divided into two areas: proposals for human regulatory science and proposals for veterinary regulatory science. You are invited to complete the section which is most relevant to your area of interest or both areas as you prefer.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise our future actions in the field of regulatory science.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission will be made publicly available.

For more information about the processing of personal data by EMA, please read the [privacy statement](#).

Questionnaire

Question 1: What stakeholder, partner or group do you represent:

- Individual member of the public
- Patient or Consumer Organisation
- Healthcare professional organisation
- Learned society
- Farming and animal owner organisation
- Academic researcher
- Healthcare professional
- Veterinarian
- European research infrastructure
- Research funder
- Other scientific organisation
- EU Regulatory partner / EU Institution
- Health technology assessment body
- Payer
- Pharmaceutical industry
- Non-EU regulator / Non-EU regulatory body
- Other

*** Please specify:**

between 1 and 1 choices

- Individual company
- Trade association
- SME

Name of organisation (if applicable):

ACRO (Association of Clinical Research Organizations)

Question 2: Which part of the proposed strategy document are you commenting upon:

- Human
- Veterinary
- Both

Question 3 (human): What are your overall views about the strategy proposed in EMA's Regulatory Science to 2025?

Please note you will be asked to comment on the core recommendations and underlying actions in the subsequent questions.

Question 4 (human): Do you consider the strategic goals appropriate?

Strategic goal 1: Catalysing the integration of science and technology in medicines development (h)

- Yes
- No

Strategic goal 2: Driving collaborative evidence generation – improving the scientific quality of evaluations (h)

- Yes
- No

Strategic goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems (h)

- Yes
- No

Strategic goal 4: Addressing emerging health threats and availability/therapeutic challenges (h)

- Yes
- No

Strategic goal 5: Enabling and leveraging research and innovation in regulatory science (h)

- Yes
- No

Question 5 (human): Please identify the top three core recommendations (in order of importance) that you believe will deliver the most significant change in the regulatory system over the next five years and why.

First choice(h)

9. Foster innovation in clinical trials

1st choice (h): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

ACRO agrees with the Underlying Actions in the EMA Strategy document. In order to effect these changes, ensure appropriate industry input from stakeholders who are actively engaged in clinical trial innovation to develop appropriate guidance for sponsors, CROs, and competent authorities. We note that the document mentions AI (and an AI test laboratory) regarding the EU Regulatory Network. We believe the potential of AI within clinical research should also be explored.

Second choice (h)

10. Develop the regulatory framework for emerging digital clinical data generation

2nd choice (h): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

ACRO agrees with all of the Underlying Actions in the Strategy document. ACRO strongly agrees with the action to modernise GCP regulatory oversight. Modernisation of GCP regulatory oversight must consider technological advancements. For instance, a truly virtual or decentralized trial would require use of technologies such digital signatures, which are currently inconsistently accepted by Member States. ACRO strongly agrees with developing the capability to assess complex datasets captured by technology such as wearables. And, we believe ACRO's expanding membership -- which includes technology companies such as Bioclinica, Oracle, Medidata, ERT, and Veeva -- could be a helpful resource to the Agency.

Third choice (h)

19. Develop network competence and specialist collaborations to engage with big data

3rd choice (h): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

ACRO agrees with the Underlying Actions. The harmonisation of data standards, characterisation of data quality, and provision regulatory guidance as to acceptability of evidence are essential and urgently needed to progress the use of Big Data.

Question 6 (human): Are there any significant elements missing in this strategy. Please elaborate which ones (h)

Innovative trial designs often result in the inclusion of small trial populations or sub-populations. ACRO believes guidance on clinical trials in small populations would complement recent guidance on innovative trial designs.

Question 7 (human): The following is to allow more detailed feedback on prioritisation, which will also help shape the future application of resources. Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas outside your interest or experience, please leave blank.

Should you wish to comment on any of the core recommendations (and their underlying actions) there is an option to do so.

Strategic goal 1: Catalysing the integration of science and technology in medicines development (h)

| | Very important | Important | Moderately important | Less important | Not important |
|---|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| 1. Support developments in precision medicine, biomarkers and 'omics' | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. Promote and invest in the Priority Medicines scheme (PRIME) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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|--|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| 4. Facilitate the implementation of novel manufacturing technologies | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. Diversify and integrate the provision of regulatory advice along the development continuum | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation** you are commenting on:

Strategic goal 2: Driving collaborative evidence generation – improving the scientific quality of evaluations (h)

| | Very important | Important | Moderately important | Less important | Not important |
|--|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 8. Leverage novel non-clinical models and 3Rs | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. Foster innovation in clinical trials | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. Develop the regulatory framework for emerging digital clinical data generation | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11. Expand benefit-risk assessment and communication | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12. Invest in special populations initiatives | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13. Optimise capabilities in modelling and simulation and extrapolation | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 14. Exploit digital technology and artificial intelligence in decision-making | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on:**

Strategic goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems (h)

| | Very important | Important | Moderately important | Less important | Not important |
|--|----------------------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| 15. Contribute to HTAs' preparedness and downstream decision-making for innovative medicines | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 16. Bridge from evaluation to access through collaboration with Payers | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 17. Reinforce patient relevance in evidence generation | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 18. Promote use of high-quality real world data (RWD) in decision-making | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | | | | |

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|---|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 19. Develop network competence and specialist collaborations to engage with big data | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 20. Deliver real-time electronic Product Information (ePI) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 21. Promote the availability and uptake of biosimilars in healthcare systems | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 22. Further develop external communications to promote trust and confidence in the EU regulatory system | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on:**

Strategic goal 4: Addressing emerging health threats and availability/therapeutic challenges (h)

| | Very important | Important | Moderately important | Less important | Not important |
|--|----------------------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| 23. Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 24. Continue to support development of new antimicrobials and their alternatives | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 25. Promote global cooperation to anticipate and address supply challenges | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 26. Support innovative approaches to the development and post-authorisation monitoring of vaccines | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 27. Support the development and implementation of a repurposing framework | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on:**



Strategic goal 5: Enabling and leveraging research and innovation in regulatory science (h)

| | Very important | Important | Moderately important | Less important | Not important |
|---|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| 28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 30. Identify and enable access to the best expertise across Europe and internationally | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on:**

Strategic Goal #5 contains excellent proposals which should not be limited to academia. ACRO recommends consulting the Agency's registered industry associations.

Thank you very much for completing the survey. We value your opinion and encourage you to inform others who you know would be interested.

Useful links

EMA website: Public consultation page (<https://www.ema.europa.eu/en/regulatory-science-strategy-2025>)

Background Documents

[EMA Regulatory Science to 2025.pdf](#)

Contact

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