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Public consultation on EMA Regulatory Science to 2025

Fields marked with * are mandatory.

* Name

on behalf of Academic Institutions in the PEARRL Network (namely School of Pharmacy, University College Cork, Ireland; School of Pharmacy, University of Bath, UK; Faculty of Pharmacy, National and Kapodistrian University of Athens, Greece; University of Applied Sciences & Arts Northwestern Switzerland, Institute of Pharma Technology, Switzerland; Johann Wolfgang Goethe University, Institute of Pharmaceutical Technology, Germany

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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 (/eusurvey/files/709b37da-74ac-4572-912e-e806823d181b/c9ac0d81-b0a4-406b-b69e-506f0476be2d)

Contact

RegulatoryScience2025@ema.europa.eu (mailto:RegulatoryScience2025@ema.europa.eu)

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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 (https://www.ema.europa.eu/en/about-us/legal/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

Name of organisation (if applicable):

PEARRL EU network - A European training network for innovative drug development strategies and regulatory tools tailored to facilitate earlier access to medicines www.pearrl.eu

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.

> We are strongly supportive of the publication of the EMA's strategy for Regulatory science over the coming years, as stated in this strategy document. PEARRL is a European Training Network which brings partners from academia, pharmaceutical industry and regulatory agencies in an EU wide collaborative partnership, with the collective goal of developing new approaches to facilitate earlier access of patients to emerging drug candidates. The network is funded (€ 4 million) under the European Union's Horizon 2020 research and innovation programme (Marie Sklodowska-Curie actions Innovative Training Network 2016-2020).
>
> In PEARRL there are 15 early stage researchers working on research in Regulatory Science domains. We have also developed specialized training for the PhD graduates on tools to support regulatory applications, with training provided by the Regulatory partners involved in PEARRL. In addition the PhD students in PEARRL have all completed 3 month training secondments at Regulatory agencies in Europe. Therefore we have considerable experience in developing an EU network focused on Regulatory Science initiatives and indeed, there are parallels between what we have established in the PEARRL network and some of the core recommendations in the EMA strategy (most notably Goal 1 and Goal 5). We are therefore fully supportive of encouraging wider applications of these recommendations and actions.

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

Comments on strategic goal 3 (h):

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

> We believe what is meant by this strategic goal could be 'advancing access to patient centered medicines in partnership with healthcare systems'. Please consider a text change or a clarification here.

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)

29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions ▼

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.

> We agree completely with all three recommendations 1 (Ring-fence EMA funding...), 2 (Ensure close interaction between network scientists and academia..) & 3 (Actively engage, through these applied projects, in training early-career researchers in regulatory science - here, please add Modelling & Simulation).
>
> We also feel that that 'Modelling & Simulation for regulatory application' should be included as an 'emerging regulatory science research question' as part of recommendation 1.

Second choice (h)

13. Optimise capabilities in modelling and simulation and extrapolation ▼

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.

> We are of the opinion that there are gaps in expertise at the EU regulatory level in Modelling & Simulation tools.
>
> There is a need to invest in Centres of Excellence in Regulatory science at an EU level, to work with regulatory agencies to provide training and and research on Modelling & Simulation tools (i.e. PBPK models). Such centres would additionally provide an opportunity to advance research on the use of these tools in regulatory science and provide a pipeline of of early career graduates (e.g. PhD graduates) with the appropriate skills and expertise to meet these gaps. Also, such Centres of Excellence should be based on a multi-partner networks to leverage expertise and training available across a number of EU academic institutions.

Third choice (h)

8. Leverage novel non-clinical models and 3Rs ▼

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.

> We suggest that the EMA proposal should clarify how the use of pre-clinical models and 3Rs principles are to be supported.
> We specifically suggest greater emphasis on 'non-clinical' models such as in vitro biopharmaceutics tools (e.g. biorelevant conditions) and in silico (Modelling & Simulation) approaches be included to provide more clarity on the 3R approaches can be supported. This would be of particular benefit for the Reduction and Replacement parts of the 3Rs.

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

We believe there is an opportunity for the EMA to further develop expertise in Modelling & Simulation tools in order for regulators to keep abreast of their emerging application in the assessment of human medicines. While we acknowledge that the Modelling and simulation working group (MSWG) has achieved great strides in promoting the use of M&S tools as a regulatory tool, we believe there is a need to develop expertise further across the various EU national agencies. We also see opportunities for greater expertise in advanced characterization and in vitro tools to support a robust evaluation of drug product performance.

Europe is far behind the US in research metrics in Regulatory Science. As an example, looking at statistics for 2018, the FDA co-authored >1,500 PEER reviews research publications (based on Scopus metrics). By comparison the EMA published 90 papers in 2018. Even allowing for publications by national agencies (e.g. MHRA ~150, BfARM ~60, MEB ~44, HPRA ~2), these metrics clearly show that Regulatory science research in the EU is well behind the level in the US. In order to attract the best scientific and clinical experts to work at the EMA, and to advance scientific discussion, a radical change in approach is needed.

To accomplish the necessary changes, we propose that Centres of Excellence in Regulatory Science be established at an EU level. These should provide sustained support to Regulatory Science research initiatives in a similar way to the US FDA funded CERSI model. A key driver of the success of regulatory science research are the FDA funded CERSIs which contribute to FDA's evolving regulatory science agenda https://www.fda.gov/science-research/advancing-regulatory-science/centers-excellence-regulatory-science-and-innovation-cersis. Europe needs comparable, centrally funded Centres of Excellence in Regulatory Science similar to the FDA model in order for the EU to be a global leader and innovator in advancing science and promoting new medicine development.

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'	○	○	○	◉	○
2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments	○	◉	○	○	○
3. Promote and invest in the Priority Medicines scheme (PRIME)	◉	○	○	○	○
4. Facilitate the implementation of novel manufacturing technologies	○	○	○	◉	○
5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products	◉	○	○	○	○
6. Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals	○	○	◉	○	○
7. Diversify and integrate the provision of regulatory advice along the development continuum	○	◉	○	○	○

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:

Comment in relation to '1. Support developments in precision medicine, biomarkers and 'omics'. The regulator plays a role in supporting translation and assessing medicines based on new advances and emerging science. Perhaps instead of referring to directly 'supporting development in precision medicine, biomakers and "omics", the EMA would be better served by supporting the scientific community in its quest to advancing the use of these advances.

Specifcally, we see opportunities for the European Chemical agency (EChA) and the EMA to work closely in assessing toxicity risks associated with nanotechnology and developing understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals.

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	◉	○	○	○	○
9. Foster innovation in clinical trials	◉	○	○	○	○
10. Develop the regulatory framework for emerging digital clinical data generation	○	◉	○	○	○
11. Expand benefit-risk assessment and communication	○	◉	○	○	○
12. Invest in special populations initiatives	◉	○	○	○	○
13. Optimise capabilities in modelling and simulation and extrapolation	◉	○	○	○	○

14(Explpit digital technology and artificial intelligence in decision-making	All public surveys (/eusurvey/home/publicsurveys/runner)	○	●	○	○

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**:

In relation to clinical trials there needs to be an appropriate balancing between compliance, on the one hand, and flexibility to ensure new scientific advances can be explored, on the other hand. This is particularly relevant in the context of regulatory oversight of clinical trials where an excessive focus on a 'regulatory philosophy' is restrictive whereas a focus on 'science and regulatory philosophy' will lead to better overall outcomes in science and quality. Fostering innovation in clinical trials should include greater flexibility in trial design requirements.

Further, there is considerable scope to enhance expertise in the use of Modelling & Simulation in the EU. We feel that partnerships between academia and the regulatory agencies will facilitate greater utilization of modelling in regulatory applications, including the design of clinical trials.

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	○	○	○	●	○
16. Bridge from evaluation to access through collaboration with Payers	○	○	●	○	○
17. Reinforce patient relevance in evidence generation	○	○	●	○	○
18. Promote use of high-quality real world data (RWD) in decision-making	○	○	●	○	○
19. Develop network competence and specialist collaborations to engage with big data	○	●	○	○	○
20. Deliver real-time electronic Product Information (ePI)	○	○	●	○	○
21. Promote the availability and uptake of biosimilars in healthcare systems	○	○	●	○	○
22. Further develop external communications to promote trust and confidence in the EU regulatory system	○	○	●	○	○

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**:

While we feel that the Regulatory agency has a role in promoting awareness among health professionals and patients about availability of new medicines, it is important that the EMA's priorities are focused on science, quality and patient safety. Point 16 'Bridge from evaluation to access through collaboration with Payers' is very broad and it is important that the Payer priorities (which focus on cost and political/societal factors) remain distinct from regulatory decisions, which should be based solely on medical and scientific aspects.

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	○	○	○	○	○
24. Continue to support development of new antimicrobials and their alternatives	◉	○	○	○	○
25. Promote global cooperation to anticipate and address supply challenges	○	○	◉	○	○
26. Support innovative approaches to the development and post-authorisation monitoring of vaccines	○	◉	○	○	○
27. Support the development and implementation of a repurposing framework	○	◉	○	○	○

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	◉	○	○	○	○
29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	◉	○	○	○	○
30. Identify and enable access to the best expertise across Europe and internationally	◉	○	○	○	○
31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	◉	○	○	○	○

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**:

We strongly encourage greater participation of EU regulatory agencies in collaborative research partnerships with academia. We also need to manage perceived conflict of interests to ensure that networks where regulatory-academia and academic-industry partnerships are foreseen can be managed effectively within a single consortium.

We advocate a graduate training model for PhD graduates to pursue careers in Regulatory settings. We currently rely excessively on PhD training programmes focused on 'blue skies' i.e. Basic research and to a limited extent applied research. Graduate programmes that train graduates on developability, and regulatory and assessment tools are currently lacking. So in the EU we are missing out on a valuable talent and skills resource for the Regulatory agencies – who are overly reliant on recruiting early career graduates who have worked in industry for a short number of years and then consider switching to a regulatory career.

We need to prioritize Regulatory science specific PhD training networks to train talented graduates on the regulatory tools and skillset required to develop their career further within a regulatory setting. We could also consider joint academic –regulatory graduate supervision models. There are already some good models in Europe e.g. www.pearrl.eu and https://www.regulatoryscience.nl/editions/2019/08/promovendi but we need to role this out EU wide.

We support the actions proposed to proactively engage with DG Research & Innovation, DG-SANTE, IMI and Member State funding agencies to propose and issue calls to establish research collaborations. We would also highlight that funding grants opportunities for academia in the US for Reg Science are very diverse, and not exclusive for ATMPs, precision medicines etc. As an example the FDA's GDUFA Regulatory Science programme is a generic drug research program aimed at advancing public health by providing access to safe and effective generic drugs. https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-regulatory-science

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

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