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# Public consultation on European Medicines Agencies Network Strategy to 2025

Fields marked with * are mandatory.

## Introduction

The purpose of this public consultation is to seek views from EMA's and HMA's stakeholders, partners and the general public on the proposed joint **European Medicines Agencies Network Strategy to 2025** and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, there is an opportunity to help shape the strategy for the coming years, 2021-2025.

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

The strategy will be aligned with the broader **Pharmaceutical Strategy for Europe** being developed by the European Commission and its actions will seek to provide synergies with actions developed under the Pharmaceutical Strategy where their subject matter overlaps. Wherever matters of policy or potential legislative change are referred to, these should be understood as supporting the development and implementation of the broader Pharmaceutical Strategy, where the ultimate responsibility for such matters will lie.

The questionnaire has been launched on 6 July 2020, to enable stakeholder feedback to be collected on the draft network strategy and will remain open throughout the consultation period until **4 September 2020**. In case of any queries, please contact: EMRN2025strategy@ema.europa.eu.

## Completing the questionnaire

This questionnaire should be completed once you have read **the draft joint strategy document**. The survey is divided into a general section on the whole document and then focuses on each strategic theme area. You are invited to complete the sections which are most relevant to your areas of interest.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise the future objectives of the European Medicines Agencies Network.

## Data Protection

By participating in this survey, your submission will be assessed by EMA and HMA. EMA collects and stores your personal data for the purpose of this survey. Requests for contributions to be published in an anonymised form, can be sent to the data controller (S-DataController@ema.europa.eu).

* Name

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## Stakeholder Information

* **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: Press/media/NGO/Not-for profit organisation/other scientific organisations/policy maker, etc.***

Not-for profit organisation

* ***Name of organisation (if applicable):***

If not applicable, please insert "n/a"

Avicenna Alliance

# Overall strategy

* **Question 2: Please indicate which area is relevant to your area of interest?**

Please select one or both options, as applicable

- ☑ Human
- ☐ Veterinary

**Question 3: Having read the proposed strategy, how would you rate it in general terms?**

*Answer the following question on a scale of 1-5, where 5 indicates highly satisfied and 1 highly dissatisfied*

| | 1. Highly Dissatisfied | 2. Dissatisfied | 3. Neutral | 4. Satisfied | 5. Highly satisfied |
|---|---|---|---|---|---|
| * What are your overall impressions of the EMAN Strategy to 2025? | ○ | ○ | ○ | ◉ | ○ |

* **Question 4: Are there any significant elements missing in this strategy?**

*Please note that the strategy aims to focus on major areas of interest for the next five years and it is not intended to cover all activities undertaken by the Network.*

- ◉ Yes
- ○ No

## If yes, please provide further details.

In the section related to data analytics, digital tools and digital transformation, the Strategy does not mention the impact of data produced by Computer Modelling and Simulation (CM&S) on public health. However, the Strategy does mention the need to maximize the capabilities of modelling and simulation in the section related to innovation. A link needs to be made as the two are complementary to each other.

Furthemore, the strategy is missing public education. At times of rapid change, communication and comprehension are essential to successful implementation. The Avicenna Alliance believes this needs to be a dedicated focus topic of the strategy.

## Question 5: The following is to allow more detailed feedback on prioritisation of the joint EMA/HMA goals for each strategic theme, 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 goals and their underlying objectives, there is an option to do so.*

**Strategic Theme area 1: Availability and accessibility of medicines**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| 1) Strengthen the availability of medicines to protect the health of European citizens, via: efficient and targeted regulatory measures, made possible through an in-depth understanding the root causes of unavailability of patented and off-patent products; identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including stakeholders and increased transparency are the essential steps towards this goal. | ◉ | ○ | ○ | ○ | ○ |
| 2) Optimise the path from development, evaluation through to access for innovative and beneficial medicines through collaboration between medicines regulators and other decision makers in the areas of: evidence planning, including post-licensing evidence; engagement in review of evidence and methodologies, respecting remits of the various players; collaboration on horizon scanning. As a result of this work, medicines that address unmet medical needs should have broader and earlier access coverage. | ◉ | ○ | ○ | ○ | ○ |

**Strategic Theme area 2: Data analytics, digital tools and digital transformation**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Enable access to and analysis of routine healthcare data and promote standardisation of targeted data | ◉ | ○ | ○ | ○ | ○ |
| 2) Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics | ◉ | ○ | ○ | ○ | ○ |
| 3) Promote dynamic regulation and policy learning in current regulatory framework | ◉ | ○ | ○ | ○ | ○ |
| 4) Ensure that data security and ethical considerations are embedded in the governance of data within the Network | ◉ | ○ | ○ | ○ | ○ |
| 5) Map the use and needs of data analytics for veterinary medicines and support a streamlined approach across borders within the EEA | ◉ | ○ | ○ | ○ | ○ |

**Strategic Theme area 3: Innovation**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| 1) Catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovators in various phases of medicines development. | ◉ | ○ | ○ | ○ | ○ |
| 2) Foster collaborative evidence generation - improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTAs, and pricing and reimbursement authorities. | ◉ | ○ | ○ | ○ | ○ |
| 3) Enable and leverage research and innovation in regulatory science | ◉ | ○ | ○ | ○ | ○ |
| 4) Enhance collaboration with medical device experts, notified bodies and academic groups | ◉ | ○ | ○ | ○ | ○ |

**Strategic Theme area 4: Antimicrobial resistance and other emerging health threats**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance in animals and humans in support of policy development. | ◉ | ○ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 2) Contribute to responsible use of antibacterial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities | ◉ | ○ | ○ | ○ | ○ |
| 3) Ensure regulatory tools are available that guarantee therapeutic options (with a focus on veterinary medicines) while minimising impact of antimicrobial resistance on public health and the environment | ◉ | ○ | ○ | ○ | ○ |
| 4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development | ◉ | ○ | ○ | ○ | ○ |
| 5) Foster dialogue with developers of new antibacterial agents and alternatives to traditional antimicrobials, to streamline their development and provide adequate guidance in both human and veterinary medicine | ◉ | ○ | ○ | ○ | ○ |
| 6) Improve regulatory preparedness for emerging health threats | ◉ | ○ | ○ | ○ | ○ |

**Strategic Theme area 5: Supply chain challenges**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) | ◉ | ○ | ○ | ○ | ○ |
| 2) Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing | ◉ | ○ | ○ | ○ | ○ |
| 3) Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries | ◉ | ○ | ○ | ○ | ○ |
| 4) Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites, to ensure continuity of supply and availability of medicinal products. | ◉ | ○ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 5) Analyse the possible implications of new manufacturing technologies in order to regulate the new supply chains needed to manufacture and distribute new types of medicinal products for human and veterinary use. | ◉ | ○ | ○ | ○ | ○ |

**Strategic Theme area 6: Sustainability of the Network and operational excellence**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Reinforce scientific and regulatory capacity and capability of the network | ◉ | ○ | ○ | ○ | ○ |
| 2) Strive for operational excellence, building on the work done in the current strategy | ◉ | ○ | ○ | ○ | ○ |
| 3) Achieve a sustainable financial and governance model for the network | ◉ | ○ | ○ | ○ | ○ |
| 4) Develop a digital strategy to drive digital business transformation | ◉ | ○ | ○ | ○ | ○ |
| 5) Enable quick, consistent and adequate response to public and animal health challenges | ◉ | ○ | ○ | ○ | ○ |

# Strategic focus areas

## * Please indicate which Strategic Theme area(s) you would like provide input

Please select as many choices as applicable.

- ☐ 1. Availability and accessibility of medicines
- ☑ 2. Data analytics, digital tools and digital transformation
- ☑ 3. Innovation
- ☐ 4. Antimicrobial resistance and other emerging health threats

- [ ] 5. Supply chain challenges
- [ ] 6. Sustainability of the Network and operational excellence

## Strategic Theme area 2: Data analytics, digital tools and digital transformation

### Question 6: Do the objectives adequately address the challenges ahead?

- ( ) Yes
- (•) No

Comments on objectives of the strategic theme area:

The suggested set of objectives aiming to enable the access to healthcare data are not detailed enough. Issues related to data availability is not overwhimgly addressed in the strategy. Alongside the establishment of a new platform aiming to foster cooperation and build confidence among stakeholders, the EMA/HMA network also needs to establish a framework for data availability. New set of rules and incentives would ease the acess to healthcare data and empower stakeholders in exploiting Real World Evidence and data.

The Strategy also needs to establish minimum data entry portals for all stakeholders whether they are EMA / National Competent Authorities. We recommend to have a mapping of the existing portals in the EU as well as proposals to reduce them.

### Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- (•) Yes
- ( ) No

### If yes, please specify

*Please remember to specify if a particular comment relates specifically to the human or veterinary part.*

1. EMA/HMA network should guarantee a better use of Real World Evidence and of data produced by computer modelling and simulation (CM&S). A new and dynamic EU policy framework is necessary to support and drive the exploitation of Real World Evidence and data produced by CM&S. Moreover, developing a regulatory system for assessing and shaping the use of modelling and simulation data is required to bring healthcare into the digital era.

This new policy framework shall enhance data sharing among all stakeholders. Data sharing will only be possible if a significant level of harmonization and acceptance is reached among all stakeholders. The process will also require standardization in data recording practices.

Moreover, developing a regulatory system for assessing and shaping the use of modelling and simulation data is required to bring healthcare into the digital era. This should include definition of the role of Ethics Committees in the new regulatory framework for in silico trials, so they can be involved in the in silico trial.

2. The need to recognize the added-value of digital evidence generated by CM&S is necessary to enable the development of treatments for specific conditions, especially for paediatric, geriatric and rare diseases, whereby evidence cannot be generated by in vitro, ex vivo and in vivo models.

3. The affordability of data used for clinical trials, especially for in silico trials. Industry stakeholders and researchers should be able to have access to data and Real World Evidence at a lesser cost.

4. Facilitate clinical data sharing to develop in silico trials.

5. The availability of data and mechanism for data sharing to support investigation for problems that can be solved using CM&S including AI.

6. Support and emphasize the use of in silico data for combination products.

7. The development of public databases of digital twins of people, products and healthcare in general.

8. Ethics Committee should solely review the in silico trial protocol in view of the future clinical protocol and/or intended clinical use to ensure representativity of target population(s). This is important for vulnerable patients in order to ensure inclusion of relevant virtual patients into in silico trials.

Please see below a reference for virtual patient cohort libraries:

"In silico clinical trials: concepts and early adoptions":

Francesco Pappalardo, Giulia Russo, Flora Musuamba Tshinanu, Marco Viceconti

Briefings in Bioinformatics, Volume 20, Issue 5, September 2019, Pages 1699–1708

## Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- (●) Yes
- ( ) No

### If yes, please elaborate which ones and provide details on how these could be considered.

The Avicenna Alliance is working alongside EMA and FDA towards harmonization for the use of digital evidence. Furthermore, the Alliance works towards a consistent unified approach to the credibility assessment of in silico methods through Good Simulation Practices.

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- ○ Yes
- ○ No

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## Strategic Theme area 3: Innovation

### Question 6: Do the objectives adequately address the challenges ahead?

- ◉ Yes
- ○ No

Comments on objectives of the strategic theme area:

/

### Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- ◉ Yes
- ○ No

### If yes, please specify

*Please remember to specify if a particular comment relates specifically to the human or veterinary part.*

1. The absence of a policy framework for CM&S remains a challenge for seizing the uptake of in silico trials in the field of health. In order for the in silico market to grow and for research in this field to be encouraged, a

policy framework for in silico medicine needs to be developed. The lack of incentives for enhancing the role of computer modelling and simulation (CM&S) in core medicinal product legislation needs to be addressed by the EMA/HMA Network.

Even the most advanced and predictive model has little value to industry if it cannot be submitted as evidence of the effectiveness or safety of their product:

- Manufacturers of medical devices who use in silico technologies must be provided with a framework for submitting this data to notified bodies, health authorities and evaluators of health technologies.

- Similarly for pharmaceuticals, a framework for admissibility of in silico clinical trial data needs to be developed so that we can move from exploratory clinical trials in humans, to a scenario where we seek to confirm what we know from in silico methods.

- Joint review by EMA /HMA and Notified Bodies should be implemented to facilitate and harmonize clinical study protocol review, including in silico trials

New incentives in policy need to be provided for industries that pioneer this research which has the potential to drastically decrease overall research costs and greatly improve patient safety.

This strategy should be part of the plan of the EMA/HMA to optimize the capabilities in modelling and simulation.

2. Even though EMA/HMA acknowledges the need to foster innovation in clinical trial, the strategy should encourage and promote in particular the adoption of in silico clinical trials to accelerate the development process of orphan drug development and customise treatment to paediatric patients.

3. The link between innovation and patient safety is not addressed in the strategy. The role of CM&S should be enhanced as a means to redefine our current models of healthcare by bringing guarantees towards patient safety.

4. The need to promote the use of CM&S towards the adoption of personalised medicine.

5. Allowing the use of in silico trials to dramatically reduce the time and cost linked to development process and to the performance of clinical trials.

6. The need to bridge the gap between the scientific community, industry and policymakers by advocating for policy changes that take scientific and market developments into account. This would result in fostering collaboration among key players active in promoting new innovative tools in the field of health, especially for CM&S.

## Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- (●) Yes
- ( ) No

## If yes, please elaborate which ones and provide details on how these could be considered.

The Avicenna Alliance is calling for Good Simulation Practices in the EU. The Alliance recommends that the European Commission works to develop Good Simulation Practices, to be used when deploying CM&S solutions in healthcare, especially in nonclinical activities and in clinical trials.

The Alliance is also working on AI and Data. We have released a brand-new position paper on “AI and Big Data effective readiness, a privacy-enhancing pathway to data access”. This position paper applies both to the Public Consultation on a European Strategy for Data and the White Paper on Artificial Intelligence and constitutes the starting point for a much-needed discussion on how should be the policy framework governing AI & Data in the healthcare sector.

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- ○ Yes
- ○ No

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### Any other comments

*Please feel free to provide any other additional comments not provided in the previous questions*

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

EU Medicines Agencies Network Strategy (https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy)

European Medicines Agencies Network Strategy to 2025 (https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf)

Pharmaceutical Strategy for Europe (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1242-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation)

### Background Documents

european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

### Contact

EMRN2025strategy@ema.europa.eu