



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](mailto:DataController@ema.europa.eu)).

* Name

Karen Noonan

* Email

knoonan@acrohealth.org

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"

Association of Clinical Research Organizations (ACRO)

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?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

*** 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

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
<p>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.</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>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.</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
---	----------------------------------	-----------------------	-----------------------	-----------------------	-----------------------

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

	Very important	Important	Moderately important	Less important	Not important
<p>1) Enable access to and analysis of routine healthcare data and promote standardisation of targeted data</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>2) Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>3) Promote dynamic regulation and policy learning in current regulatory framework</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Ensure that data security and ethical considerations are embedded in the governance of data within the Network	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Map the use and needs of data analytics for veterinary medicines and support a streamlined approach across borders within the EEA	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) Enable and leverage research and innovation in regulatory science	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Enhance collaboration with medical device experts, notified bodies and academic groups	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
---	----------------------------------	-----------------------	-----------------------	-----------------------	-----------------------

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.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6) Improve regulatory preparedness for emerging health threats	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3) Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Strive for operational excellence, building on the work done in the current strategy	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3) Achieve a sustainable financial and governance model for the network	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) Develop a digital strategy to drive digital business transformation	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Enable quick, consistent and adequate response to public and animal health challenges	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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:

ACRO agrees that the goals and objectives proposed in this strategic theme area are appropriate. ACRO is concerned that current healthcare systems in the EU sometimes hinder innovation, and this is especially notable in the development of real-world data (RWD), real-world evidence (RWE) and artificial intelligence (AI) solutions. I must note that ACRO is pleased to see EMA's planned meeting on AI in clinical trials in September 2020. AI is necessary to maximise the opportunities offered by RWD/RWE and is essential to using large volumes of these data effectively. Unlocking RWD/RWE using predictive AI models and analytics tools can accelerate the understanding of diseases, identify suitable patients and investigators to inform investigator site selection, and support novel clinical study designs. When combined with an effective digital infrastructure, AI can also support process automation, enabling the continuous stream of clinical trial data to be harvested, cleaned, aggregated, coded, stored and managed. The use of improved electronic data capture technology can also reduce the impact of human error in data collection and facilitate seamless integration with other databases. ACRO acknowledges that effective AI implementation will raise concerns related to individual privacy and confidentiality, informed consent, and patient autonomy and recommends that, to facilitate clinical research and innovation, there is a need to ensure a standardised EU approach is taken to address these concerns. However, the biggest block to the effective use of AI is that the algorithms need to be applied to large quantities of standardised data, and the current lack of standardisation, especially within the various electronic medical record systems currently used in clinical practice across the EU, hinders successful deployment. The lack of curated data sets, which helps in training the technology to perform as requested, is a major block to widespread adoption. ACRO is hopeful that these issues will be addressed through the European Commission's Digital Health Agenda and the planned EU Digital Health Space, with the support of the EMA.

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.

ACRO notes that the proposed strategy includes specific objectives to strengthen EU Network processes for Big Data submissions and to build an EU Network capability to analyse Big Data. In the clinical trial context, submissions will in future be made via the Clinical Trial Information System (CTIS). However, with the exception of specific standardized substance, product, organisation and referential (SPOR) data, CTIS is structured for the submission of traditional study reports and does not reflect the increased digitalisation of clinical research and submission of data rather than of reports. ACRO acknowledges the intensive effort that has been put into the development of CTIS but recommends that, as part of the overall strategy, consideration should be given to its adaptation to/replacement by a system that is sufficiently flexible to readily accommodate data submissions (and other innovations in clinical trials – see below).

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.

ACRO has recently established a specialized committee focused on technological innovation and the increasing digitization of clinical trials. This expert group is called the “ACRO Technology Innovation Working Group.”

The EMA Network Strategy Document devotes significant attention to the important role of RWD/RWE as complementary to clinical trial data and also as a tool to generate evidence for regulatory decision-making. The ACRO Technology Innovation Working Group can be a valuable resource to the EMA and HMA as they analyze how to optimize RWD/RWE.

This ACRO expert group focuses on the increasing digitization and modernization of the drug development process and is composed of technology experts from across ACRO’s membership. ACRO member companies include both global clinical research companies (Covance, ICON, IQVIA, PAREXEL, PPD, Syneos Health, PRA Health Sciences) and global technology companies (Bioclinica, ERT, Medidata, Oracle, Signant Health, Veeva Systems, and Science 37).

This ACRO expert committee analyzes a wide variety of technology issues related to clinical trials – including, but not limited to: RWD/RWE, AI/machine learning, cloud solutions, Big Data, advanced analytics, and technology validation.

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

- Yes
- No

If yes, please provide details of the ongoing or planned initiatives.

ACRO has two other specialized committees of interest to EMA -- (1) a Risk-Based Quality Management (RBQM) Group and (2) a Decentralized Clinical Trials Working Party. These ACRO Committees are discussed below in the "Innovation" section of this survey.

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:

ACRO notes the helpful focus on applying innovation specifically to clinical trials that appears in several sections of the Network Strategy to 2025:

- The document notes that a key focus of Innovation is “supporting innovation and digitalisation in clinical trials by strengthening the Network’s expertise in handling more complex designs, including the use of data analytics and real-world data”
- In addition, the Innovation section notes that “new and innovative clinical trial designs and methodologies are already challenging the system”
- Moreover, the Appendix notes that one of the formal Objectives of Innovation is to “Foster innovation in clinical trials”

ACRO is concerned, however, that current approaches within the EU Network work against these objectives. For instance, the application of the EU Clinical Trial Regulation is dependent on the successful development of the Clinical Trial Information System (CTIS) that will facilitate the submission of a single application dossier, coordinated assessment by the competent authorities of the member states, and public transparency of the clinical trial and its results. While the European Commission and EMA are seeking to address concerns as CTIS is developed, there remain concerns that it is structured in such a way as to hamper innovation, for example (a) its inability to handle novel trial designs (e.g., platform trials) appropriately, and (b) the lack of flexibility around submission and processing of substantial modifications, which will likely lead to delays in implementation of significant changes required to clinical trials. It is also notable that, as stated earlier, with the exception of specific standardized substance, product, organisation and referential (SPOR) data, CTIS is structured for the submission of traditional study reports and does not reflect the increased digitalisation of clinical research and the trend towards submission of data rather than of reports. ACRO acknowledges the intensive effort that has been put into the development of CTIS but recommends that, as part of the overall strategy, consideration should be given to its adaptation to /replacement by a system that is sufficiently flexible to readily accommodate future innovations in clinical research and the regulation of clinical trials.

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.

Under the topic of innovative trial design, the Agency enumerates various examples of innovative trial design. ACRO asks the Agency to consider explicit recognition of the need to decentralised clinical trials (or appropriate elements within a clinical trial) in order to reflect trial participant needs and reduce the inconvenience associated with participation in a clinical trial.

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.

ACRO notes the helpful focus on applying innovation specifically to clinical trials that appears in several sections of the Network Strategy to 2025:

The document notes that a key focus of Innovation is “supporting innovation and digitalisation in clinical trials by strengthening the Network’s expertise in handling more complex designs, including the use of data analytics and real-world data”

In addition, the Innovation section notes that “new and innovative clinical trial designs and methodologies are already challenging the system”

Moreover, the Appendix notes that one of the formal Objectives of Innovation is to “Foster innovation in clinical trials”

In addition to ACRO’s “European Scientific & Regulatory Committee,” which is composed of ACRO members who are seasoned experts with deep and broad knowledge of overall regulatory policy and legislation in Europe, ACRO is also undertaking several very specific, narrowly targeted activities in the field of Innovation that could support and complement EMA/HMA network activities.

Three of these ACRO activities dedicated to Innovation are relevant here:

1—The ACRO “Decentralised Clinical Trials Working Party (ACRO DCT WP)”

In October 2019, ACRO established a Working Party targeted on facilitating the greater consideration and adoption of decentralised clinical trials. The Working Party focused their work on examining the brand new, unique and distinctive considerations and challenges that emerge under a decentralised trial model (versus a conventional or traditional clinical trial). The ACRO DCT WP determined that the most effective way to help mitigate the uncertainties and hesitance surrounding the DCT model – and thereby foster greater adoption – was by developing a Quality by Design Manual for Decentralised Clinical Trials and a companion Risk Assessment Tool for Decentralised Clinical Trials. The ACRO DCT WP has finalized this Decentralized Clinical Trials Toolkit, which is now available on the ACRO website (acrohealth.org). The ACRO DCT Working Party has had informal discussions and conversations with the UK MHRA about its work, and the Working Party is eager to meet with other regulators to share and discuss these tools.

2—The ACRO “Risk Based Quality Management (RBQM) Working Group”

ACRO has a committee made up of expert members dedicated to gathering data from ACRO member companies to provide a historical landscape of the use of risk-based monitoring and risk-based quality management to provide both data and argumentation to support RBM as a Best Practice, as outlined in three separate papers available on ACRO’s website:

“Establishing Risk-Based Monitoring within a Quality-Based System as “Best Practice” for Clinical Studies”

“Risk-Based Quality Management(RBQM) -A Collaborative Approach to Holistic Clinical Trial Oversight”

“Considerations to Support Clinical Trial Monitoring Oversight During COVID-19”

3—ACRO “Technology Innovation Working Group”

(Please Note:

This content is repeated from “Data Analytics” Section of Survey as it is applicable to both sections of this Survey)

The EMA Network Strategy Document devotes significant attention to the important role of RWD/RWE as

complementary to clinical trial data and also as a tool to generate evidence for regulatory decision-making. The ACRO Technology Innovation Working Group can be a valuable resource to the EMA and HMA as they analyze how to optimize RWD/RWE.

This ACRO expert group focuses on the increasing digitization and modernization of the drug development process and is composed of technology experts from across ACRO's membership. ACRO member companies include both global clinical research companies (Covance, ICON, IQVIA, PAREXEL, PPD, Syneos Health, PRA Health Sciences) and global technology companies (Bioclinica, ERT, Medidata, Oracle, Signant Health, Veeva Systems, and Science 37).

This group is examining RWD/RWE, AI/machine learning, cloud solutions, Big Data, advanced analytics, and technology validation.

A final note on how ACRO can be an expert resource to EMA and HMA:

We believe there are two possible ways in which ACRO's numerous expert committees and working groups might be expert resources for the Agency.

ACRO would be happy for any of its expert committees to be a resource to the EMA and HMA.

We are available to meet with the Agencies for targeted, issue-specific conversations on single topics (such as RWD/RWE or DCTs). In addition, we would also be available for recurring, annual "bilateral meetings" with EMA (similar to EMA meetings with Sponsor associations) at which a variety of topics could be discussed in a single meeting.

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

- Yes
- No

Any other comments

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

The Association of Clinical Research Organizations (ACRO) and its clinical research and technology company members stand ready to be an expert resource to the Agency wherever this would be helpful. And, we thank the Agency for this opportunity to provide feedback.

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 \(https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy\)](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 \(https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf\)](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 \(https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation\)](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-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