30 June 2015
EMA/201512/2015

EU Medicines Agencies Network Strategy to 2020 - Working together to improve health

Submission of comments

Comments from:

Name of organisation or individual
ACRO (Association of Clinical Research Organizations)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received. In your reply please indicate whether you are replying as a citizen, organisation or public authority.

Comments should be sent to the European Medicines Agency electronically and in Word format (not pdf).

Comments should be sent to EUnetworkstrategy@ema.europa.eu and must arrive by 30 June 2015.

General comments

General comment (if any)	Outcome (if applicable) *<to be completed by the EMA/HMA>*
The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities around the world (including 30,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries. On average, each of our member companies works with more than 500 research sponsors annually. ACRO thanks the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) for the opportunity to submit comments on the "EU Medicines Agencies Network Strategy to 2020". ACRO fully supports this EMA and HMA initiative to establish a single coordinated strategy for the network, reflecting the need for a coordinated approach by the EMA and the national competent authorities to support biomedical innovation and ensure timely access to safe and effective medicines for EU patients. ACRO welcomes this and future opportunities to provide to the network the expertise available within its member companies for consultation and comment on relevant issues in the field of human medicines.	

General comment (if any)	Outcome (if applicable) *<to be completed by the EMA/HMA>*

Specific comments on text

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
Lines 53 - 128	The Introduction to the document defines the role of the EU Medicines Agencies Network as ensuring that "patients and animals in Europe have access to medicines that are safe, effective and of good quality and that patients, healthcare professionals and citizens are provided with adequate information about medicines." Understandably, the Introduction focuses on regulatory activities to support the availability and use of safe and effective medicines in the EU. However, we consider that this section of the document would be strengthened significantly by also highlighting the activities undertaken by the network to discharge its regulatory responsibilities while at the same time promoting and supporting biomedical innovation and the improvement of public health in the EU. We also note that the document makes no statement about accountability for delivery of the strategy, and consider that the document would be much more forceful if specific accountabilities were defined.	
Lines 186 – 239	ACRO supports the focus on preparedness to address key public health emergencies and priorities. The document	

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	identifies some key priorities as antimicrobial resistance, and the availability of medicines for treating dementia and for use in special populations such as children and the elderly. ACRO recommends that a formal list of public health priorities is developed in consultation with a broad range of stakeholders in order to ensure that agreement is reached on the most urgent priorities, and to ensure that effort is directed to these by the development of an action plan, also developed in conjunction with a broad range of stakeholders, for each priority identified.	
Lines 240 - 274	ACRO supports the objective of ensuring timely access to new beneficial and safe medicines for patients. However, ACRO notes that the network plans to achieve this by ensuring that existing flexibilities to get appropriate medicines to patients more quickly are used to their maximum potential, by taking forward the concept of adaptive pathways and strengthening the collaboration with Health Technology Assessment (HTA)/ pricing and reimbursement bodies and healthcare professionals and patient representative bodies. While we agree that all of this should form part of the approach, we recommend that EMA and HMA does not rely solely on the flexibilities within existing regulatory pathways but also looks more widely to consider new approaches and pathways that would further facilitate timely access to beneficial and safe medicines. ACRO was disappointed to see that a proportionate risk-based approach to medicines regulation was not highlighted as an element of this objective, as we consider that this is a	

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	fundamental principle of effective and efficient regulation. We also note that the collaborative bodies identified in this section are (implicitly) within the EU. We acknowledge that a separate section of the document (Theme 4) addresses international collaboration, but consider that international cooperation between regulators is such an essential element in ensuring the timely access of EU patients to safe and effective medicines that we recommend this is also highlighted in the current section of the document.	
Lines 275 - 318	ACRO is pleased that the document identifies support for patient focused innovation and contribution to a vibrant life science sector in Europe as a key objective for the network. As noted above, we are concerned that some other parts of the document do not adequately highlight the role of the network in facilitating biomedical innovation and improving public health. We are especially pleased that the document commits the network to ensure optimal implementation of the new Clinical Trial Regulation (536/2014) and acknowledges that the decline in EU clinical trial activity over recent years has resulted from an unfavourable regulatory environment. Line 288 recognises that the success of the Clinical Trial Regulation will depend on its implementation across the EU, and ACRO fully endorses this statement. To this end, and to help reverse the global perception of the EU as an unfavourable regulatory environment for clinical trials, ACRO recommends that the network consults widely with stakeholder groups to consider how the Clinical Trial Regulation can be implemented	

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	successfully across the EU, and develops and publishes a detailed plan of the steps that it will take to ensure this is achieved. In order to regain global competitiveness in clinical research, particular stakeholder concerns that would need to be addressed include a clear statement from the network that review timelines stated in the Regulation will be considered as maxima and that everything possible will be done to work to shorter timelines, sponsor concerns about the publication of detailed information about specific clinical trials prior to marketing authorisation, the Annex VI labelling requirements that may adversely impact EU competitiveness by limiting innovation and increasing administrative burden and cost, and the planned "gentleman's agreement" for a clock-stop over the Christmas/Epiphany period, which will create the impression to the rest of the world that Europe's regulators are closed for business as far as clinical trials are concerned during this period.	
Lines 319 - 361	ACRO fully supports the network's stated objective to ensure that it has the capability to regulate novel products of the future, develop regulatory science, consider greater use of real-world databases and increase transparency about the data that underpin regulatory decisions. These are all important developments that will significantly improve the timely access of safe and effective medicines to patients. As noted in the text, however, many of these developments have implications for data privacy and the protection of personal data. Currently, there is no harmonised EU position on requirements for the protection of personal information collected during health research, leading to significant	

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	administrative burden and expense for those conducting such research across the EU. It is unlikely that the forthcoming EU Data Protection Regulation will include the required level of granularity to address this, and so ACRO recommends that an important, additional element of the network strategy should be to work with Data Privacy Commissioners across the EU to develop a harmonised EU position on requirements for the protection of personal data collected in biomedical research. Additionally, as noted earlier, we acknowledge that a separate section of the document (Theme 4) addresses international collaboration, but consider that international cooperation between regulators is essential in the development of regulatory science, and recommend that this is also highlighted in the current section of the document.	
Lines 513 - 539	ACRO supports both the objective to reinforce the scientific and regulatory capacity and capability of the network, and the actions identified.	
Lines 540 - 579	ACRO agrees with the objective to optimise scientific and operational procedures and continuously improve the quality of the (scientific) output within the current regulatory framework. We note that this will be underpinned by adequate and inter-operable IT systems and therefore strongly recommend early and continuing consultation with stakeholder groups representing organisations that will be required to submit data to the IT systems as new systems and standards are developed.	

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	The text rightly emphasises the need for robust quality systems within the network. However, the document does not address the need for accountability and stewardship to ensure appropriate cost controls and streamlining of operations. While recognising the complexity of this in a network comprising national competent authorities funded by EU Member State governments and the centrally (EU)-funded European Medicines Agency and European Commission, ACRO considers that an important element in optimising the operation of the network is to ensure that EU tax payers and user fee payers can be assured that they receive value for money from the operation of the network, and this aspect appears to be missing from the document.	
Lines 580 - 612	ACRO supports both the objective to ensure effective communication of and within the network, and the actions identified.	
Lines 613 - 639	ACRO supports both the objective to strengthen the links with other authorities and with stakeholders, and the actions identified. ACRO welcomes the opportunity to provide to the network the expertise available within its member companies for consultation and comment on relevant issues. We note that the network plans to put in place more streamlined mechanisms to obtain regular feedback from key stakeholders on the operation of its activities and the quality of its output, and recommend that these mechanisms allow for stakeholders to raise and discuss concerns prospectively with the network and are not confined to providing feedback on specific topics requested by the network.	

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Lines 672 - 697	ACRO supports both the objective to assure product supply chain and data integrity, and the actions identified.	
Lines 698 - 734	ACRO is greatly encouraged that the network will take a lead role in convergence of global standards assuring appropriate representation in international fora and will put in place mechanisms to strengthen cooperation with non-EU regulators in a consistent and integrated manner. In ACRO's view, such activities are key to facilitating timely access to safe and effective medicines for patients worldwide. We were surprised to note that the examples of new cooperative mechanisms between international regulators did not include the Global Coalition of Regulatory Science Research, as the European Medicines Agency has participated in this coalition, which has the potential to make a significant contribution to the development of regulatory science and facilitate innovation in biomedical research.	
Lines 735 - 761	ACRO supports both the objective to ensure best use of resources through promoting mutual reliance and work-sharing with regulators in other territories, and the actions identified.	
Lines 762 - 775	ACRO supports both the objective to support training and capacity building and promote the EU regulatory model, and the actions identified. ACRO thanks the European Medicines Agency (EMA) for the opportunity to submit comments on the "EU Medicines Agencies Network Strategy to 2020."	

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	Please do not hesitate to contact us if we can provide additional information (knoonan@acrohealth.org or +1 202 464 9340).	