18 June 2015
EMA/201512/2015

EU Telematics Strategy and Implementation Roadmap 2015-2017

Submission of comments

Comments from:

Name of organisation
ACRO (Association of Clinical Research Organizations)

Comments should be sent to the Telematics Secretariat at telematics-secretariat@ema.europa.eu and must arrive by 24 May 2015.

General comments

General comment (if any)
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 draft of the "EU Telematics Strategy and Implementation Roadmap 2015 – 2017, version 2.0", and for extending the deadline for submission on comments to 21st June 2015. ACRO fully supports this EMA and HMA initiative for the common alignment of IT deliverables to support the work of both the both the EMA and the national competent authorities. ACRO agrees that a modern IT infrastructure to enable the smooth functioning of the complex EU regulatory system is needed and congratulates the European Medicines Regulatory Network on producing a comprehensive strategy to achieve this. In ACRO's view, the strategy will be successful only if driven by operational excellence and close Network-industry collaboration. Many of the programmes and projects that will deliver the strategy's goals will require significant resource and investment from industry (including CROs and other third party vendors) as well as from the Network. To facilitate this, we therefore believe it will be necessary for the Network to maintain a continuous dialogue and partner with industry stakeholders on strategic decisions and expectations for both technical requirements and milestones for new IT systems and content.

Specific comments on text

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Page 3 1. Executive Summary	Paragraph1 notes that “The EU Telematics strategy provides a high-level ambition for a variety of IT solutions to be delivered.” We recommend replacing the word “ambition” with “goal”.	Use of the word “ambition” implies that the EU Telematics strategy sets out an aspiration rather than a specific goal (or set of goals) that the European Medicines Regulatory Network will deliver.
Page 7 4.1 Addressing Telematics Strategic Objectives	We recommend that this section should additionally address the interactions between the 7 key programmes that will maximise efficiencies in the development of the IT technologies and standards that will underpin the different programmes. In addition, ACRO believes it would be helpful to describe these objectives in tabular form.	ACRO supports the 10 key objectives and the 7 key programmes established to deliver the strategy, and understands the need to identify the P2 Clinical Trials Programme (which will often, but not always, relate to unauthorised medicinal products) separately from those programmes relating exclusively to authorised medicines (e.g., the P3 eCollaboration, and P7 Pharmacovigilance programmes). However, there are many commonalities in the needs of these programmes. One example would be the underlying technology and requirements for the EU portal and database in P2, which are similar to those for the single submission portal and repository for centralised procedure eCTD submissions in P3. Another example would be the upgraded EudraVigilance clinical trial module and central repository for electronic annual safety reports in P2, which will have similar requirements to those of the EudraVigilance Auditable Requirements and PSUR repository in P7. Additionally, the P4 Data Integration Programme will establish common standards, referentials and terminologies applicable to

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		both unauthorised medicines in P2 and authorised medicinal products in the other programmes. Currently, the strategy does not address how the programmes will be managed to ensure that synergies and cross-learnings between them will be maximised to create cost-effective solutions for both the Network and stakeholders.
Page 20 5.2.2 Programme 2: Clinical Trials	We recommend that this section should include references to (1) the ability for information to be submitted once only and referenced/accessed in relation to further clinical trial applications without resubmission, and (2) the use of an electronic application form (eAF) for clinical trials, and the benefits and impacts that these will have for users.	A key requirement and benefit for clinical trial applicants is the ability to submit information once only for use across multiple clinical trial applications. It is disappointing that this is not clearly stated in the strategy and we recommend that this is addressed. Additionally, a key feature of the EU portal will be the use of an eAF for submission of standardised data. While the benefits and impacts of eAF use are summarised in section 5.2.3, no reference is made under 5.2.2, where similar benefits and impacts will apply.
	One of the benefits of the P2 programme stated for industry is “simplifies CT application submission procedures and reuses master product and substance data captured by the regulators in other contexts (Art. 57)”. The impact on industry should also be addressed in addition to the benefits.	For the clinical research organization (CRO) sector of industry, this may be of less benefit than for sponsor organizations and will almost certainly have an impact in that small sponsor organisations who use a CRO to prepare and submit a clinical trial application will also require the CRO to file ISO IDMP information on their behalf when that becomes a necessary precursor for the clinical trial application. Typically, this task has not been contracted to CROs previously and will require additional procedures and training for CRO staff.
	In relation to EudraCT & EU-CTR Legacy, we recommend clarifying that there will be no impact for industry and that the EMA will ensure that data from EudraCT and EU-CTR will be	As all relevant information will be included in current EudraCT and EU-CTR systems maintained by the EMA, there should be no need for industry to be involved in ensuring the

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	preserved and made available.	preservation and maintenance of the information.
	The draft strategy contains no reference to the need to ensure interoperability between the clinical trial database for medicinal product trials established by the Clinical Trials Regulation (EU) No. 536/2014 and the database for medical device investigations that will be required under the forthcoming EU Medical Devices Regulation. We recommend that this is added.	Article 53 of the current text of the proposed EU Medical Devices Regulation states that "When setting up the electronic system referred to in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No [Ref. of future Regulation on clinical trials]." This statement is included in both the original European Commission proposal for a Regulation on medical devices and in the text adopted by the European Parliament on 22 October 2013.
Pages 21/22 5.2.3 Programme 3: eCollaboration	We recommend that the stated benefits of eAF additionally include the ability to populate eAFs with data directly from sponsor/CRO systems and databases.	Over the last several years, many operations in industry have transitioned to the use of structured data, which brings both operational and quality benefits. Efficiency and the highest data quality is achieved when data can be inputted to an eAF directly from the relevant sponsor/CRO system so that the potential for transcription errors is removed.
	We also recommend that the document confirms the electronic signature component of eAFs will be legally accepted by all members of the European Medicines Regulatory Network.	Use of an electronic signature capability will be an integral component of each eAF. However, experience indicates that member states differ in their willingness to accept advanced eSignatures as described in Article 2(2) of Directive 2011/115/EC, and in their adoption of the optional requirement in the Directive for the electronic signature to be based on a qualified certificate created through means of a secure-

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		signature creation device
Pages 24/25 5.2.4 Programme 4: Data Integration	The MDM SPOR section of the document refers to the need for interfaces to be ISO IDMP compliant. Additionally, we recommend that a clearly stated benefit is that controlled terminology standards, study data standards and exchange formats will use internationally recognised standards	Efficiencies for both industry and regulators operating in a global context will be facilitated only by the use of internationally recognised standards, which we consider should be used in all cases unless there is a clear absence of a specific internationally recognised standard.
Pages 26/27 5.2.4 Programme 4: Data Integration	We note that it is planned under the Identity and Access Management (IAM) initiative that user administration will be delegated to designated 'Super Users' of national competent authorities and industry to improve process efficiency, better management and control of user accesses. We recommend that a statement is added to clarify that super-users will have the ability to delegate tasks and access for those tasks to third parties contracted to undertake them on their behalf.	Many tasks that are the responsibility of industry, and possibly some which are the responsibility of the European Medicines Regulatory Network, may be contracted to third parties. To ensure the benefits of the EU Telematics Strategy are fully realised, it is important that access to the required IT systems, databases, repositories and portals can be delegated to these third parties in order to allow them to complete the tasks contracted to them. We also recommend that the process and requirements for authenticating access requests is made as simple as possible, consistent with the level of security required.
Page 35 6.Critical Success Factors	The document acknowledges that "Ongoing collaboration and effective communication is essential to the implementation of this strategy. Communication channels and access to information for relevant stakeholders must continue to be made available." We recommend that this statement should begin with "Ongoing collaboration and timely and effective communication are essential….."	ACRO fully supports the vision of the EU Telematics Strategy to deliver a broad range of cost-effective, efficient and interoperable services to the European Medicines Regulatory Network and its stakeholders, ultimately improving the quality and effectiveness of their business activities. In ACRO's view, the strategy will be successful only if driven by operational excellence and close Network-industry collaboration. Many of the programmes and projects that will deliver the strategy's goals will require significant resource and investment from industry (including CROs and other third party vendors) as well as from the Network. We consider it essential, therefore, that

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		the Network's communications with the industry must take account not only of start-up times for the adaptation of biopharma, CRO and other third party vendor IT systems but also of the budgeting cycles and timelines that must be completed before such work can be progressed. To facilitate this, we believe it will be necessary for the Network to maintain a continuous dialogue and partner with industry stakeholders on strategic decisions and expectations for both technical requirements and milestones for new IT systems and content.
Page 37 Annex 1 – EU Telematics Implementation Roadmap 2015-2017	The first line of the draft Roadmap, relating to Clinical Trials, shows "Transparency Addendum to FS adopted" in March 2015. This step has already been delayed to October 2015 and the Roadmap should reflect this. We also recommend that it would be helpful for all parties involved in the European Medicines Regulatory Network to reaffirm their commitment to maintaining the timelines set out in the Roadmap as far as is technically possible (recognising that technical matters in the design and implementation of IT systems may result in delay), and that a statement of this commitment should accompany the Roadmap. Finally, ACRO recommends publishing any future delays on the agencies' web sites and/or as a newsletter update.	We acknowledge that, as noted on page 36 of the document, the timelines provided in the Roadmap may be subject to change. However, we also note the statement that "Milestones in 2015 are of higher certainty than milestones from 2016 onwards" and therefore it is disconcerting to see that one of the first 2015 timelines described in the Roadmap has already been delayed. Additionally, no reason for this delay has been published and, in the interests of transparency and the commitment to ongoing communication with stakeholders, we urge the Network to ensure that the rationale for any delay to a key milestone identified in the strategy is fully explained to stakeholders and the wider public.
ACRO thanks the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) for the opportunity to submit comments on the draft of the "EU Telematics Strategy and Implementation Roadmap 2015 – 2017, version 2.0." Please do not hesitate to contact us if we can provide additional information (knoonan@acrohealth.org or +1 202 464 9340).		