

EMA framework of collaboration with academia

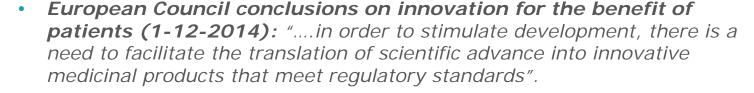
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Why did we need a framework of collaboration with academia?







 EU Medicines Agencies Network strategy to 2020 "...support for patient focused innovation and contribute to a vibrant life science sector in Europe."



European Medicine Agency work plan 2016-2017 "...the Agency will support a strengthening of the collaboration and integration across the network and with academia..."



Horizon 2020 framework programme: Health, demographic change and well-being, work programme 2016-2017 "... Engagement with regulators and consideration of the regulatory framework issues are highly recommended."



In a nutshell



"EMA wants to move to a new level of collaboration with academia. Science is progressing fast and we see an unprecedented level of complexity in the development and evaluation of new medicine. Academia play an important role in helping the EU medicines **regulatory network** to keep abreast of the opportunities and challenges brought by science and to have access to the right expertise to evaluate these innovative medicines. Interaction with EU regulators and a **better** understanding of the regulatory environment can help academia translate their discoveries into patientfocused medicines. I believe that working more closely together will bring great benefits to public health". Guido Rasi, EMA Executive Director



Process leading to the framework of collaboration with academia

Decision to define and implement a framework of collaboration with academia Q1 2015

Healthcare Professionals Working Party (HCPWP) brainstorm Q2 2015 Informal meetings with EU research infrastructures and academic stakeholders Q3-Q4 2015

Academia consultation: the survey Q1-Q2 2016

HCPWP Workshop on framework of collaboration with academia 15 June 2106 Drafting of framework of collaboration with academia and consultations Q3-Q4 2016 Adoption of the framework of collaboration with academia by EMA Management Board

16 March 2017



Framework of collaboration with academia

Purpose

Aims to formalise and structure the collaboration between the Agency and Academia in the wider context of the European Regulatory System for Medicines

Scope

Framework will cover collaboration between Agency and academia, covering areas of common interest in relation to medicines for human and veterinary use. Queries relating to a specific product and/or regulatory procedure fall outside the scope of this framework

Implementation

Action plan, monitoring and reporting

Key elements

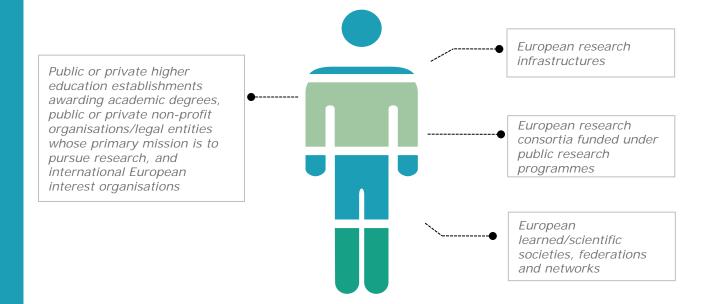
- Mapping of academic entities with an interest in the regulatory activities
- Evolution of available expertise to keep pace with advances in scientific knowledge
- Identifying opportunities to promote research and knowledge generation
- Promoting and reinforcing dialogue through effective communication
- Monitoring progress and output of the cooperation with academia







Framework of collaboration with academia Scope (stakeholder mapping)





Framework of collaboration with academia **Objectives**

- 1. To raise awareness of the mandate and work of the European medicines regulatory network as a means to increase academia's engagement and trust in the regulatory system that addresses society's needs
- 2. To promote and further develop the regulatory support to foster the translation of academic research into novel methodologies and medicinal products which meet the regulatory standards required to address patients' and public and animal health's needs;
- 3. To ensure that the **best scientific** expertise and academic research are available to support timely and effectively evidence generation, regulatory advice and guidance, and decision making in regulatory processes;
- 4. To collaborate on relevant areas of research relating to regulatory science (e.g. novel approaches, novel endpoints, methodologies), adapting to scientific progress whilst affording appropriate patient safety.



Framework of collaboration with academia
 Methodology



INFORM

e.g. dedicated web pages, relevant news items,Q&As, information days, information materials



CONSULT

e.g. e.g. public consultation on policies or guidance, surveys



CONSULT & INVOLVE

e.g. multi-stakeholder meetings, workshops, conferences, development of regulatory guidelines



COOPERATE

e.g. participation to research projects, cooperation in activities of education and training, participation in scientific advisory groups, cooperation with established EMA stakeholders and networks

Co-ordination cross-agency through matrix model





Framework of collaboration with academia Action plan highlights

- Identification of academia contacts points of the EU National Competent Authorities
- Implement the criteria for EMA involvement in externally funded regulatory science projects
- Include academic stakeholders in the EMA Stakeholder Database for targeted communication and monitoring of interactions
- Gap analysis of expertise in the European expert database
- Identify priority areas where regulatory requirements pose a challenge for academia and their networks
- Create a dedicated space for academia on the Agency website and develop a communication plan

- Initiate, within the EMA Scientific Coordination Board, a process to develop a regulatory science strategic research agenda
- Define a scientific event strategy for EMA fora, meetings, workshops, focus groups with the participation of academia as well as for the participation of EMA staff in external events organised by academia to discuss issues of common interest
- Create an EMA entry point for academia to receive information on available support within the EU Regulatory Network
- Map possibilities for staff exchange programmes to promote learning between academia and the Agency and define the criteria for implementation
- Investigate opportunities for mutual education and training

GO F

Academia web pages

are most relevant to academia, including news and events.

Human regulatory: Research and development

Veterinary regulatory: Research and development

Learn more about how EMA interacts with academia

Learn more about the Agency's resources to support medicine development:

News for academia

interaction ... > Read more

orphans ... > Read more

of clinical data ...) Read more

Collaboration with academia to be reinforced

for Human Use (CHMP) 20-23 March 2017

EMA to set up technical group in the context of the publication

03/04/2017

23/03/2017

22/03/2017

22/02/2017



Information for you





pllaborate on areas of research on regulatory science, such as novel approaches, endpoints and

nethodologies.

report on the event page.

Academia

Featured information

Academia framework

objectives include raising awareness of the network and

Personalised medicine

globally, the contribution of the European medicines

regulatory network and how clinical practice and public

participation can support personalised medicine. EMA will

publish the presentations, video recording and a workshop

further develop regulatory support for translating academic research into novel methodologies and medicines.

EMA's Management Board adopted a

framework for collaboration between the

Agency and academia in March 2017. The

framework aims to reinforce and formalise collaboration and clarify its scope in the context of the European medicines regulatory network. Its

EMA held a workshop in March 2017 on the

medicines and the role of patients and

nealthcare professionals. The workshop

challenges and opportunities for personalised

discussed policy developments in Europe and



Embrace the framework

Share your knowledge

Be imaginative



Thank you

Further information

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