



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA framework of collaboration with academia

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An agency of the European Union





Why did we need a framework of collaboration with academia?



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



- **European Council conclusions on innovation for the benefit of patients (1-12-2014):** “....in order to stimulate development, there is a need to facilitate the translation of scientific advance into innovative medicinal products that meet regulatory standards”.
- **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 patient-focused 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)*



Public or private higher education establishments awarding academic degrees, public or private non-profit organisations/legal entities whose primary mission is to pursue research, and international European interest organisations



European research infrastructures

European research consortia funded under public research programmes

European learned/scientific societies, federations and networks



• 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*



Academia web pages

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Information for you

On this page, you will find information on the European Medicines Agency's (EMA) activities that are most relevant to academia, including news and events.

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

Human regulatory: Research and development
Veterinary regulatory: Research and development

Learn more about how EMA interacts with academia.



Featured information



Academia framework

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 objectives include raising awareness of the network and further develop regulatory support for translating academic research into novel methodologies and medicines.



Personalised medicine

EMA held a workshop in March 2017 on the challenges and opportunities for personalised medicines and the role of patients and healthcare professionals. The workshop discussed policy developments in Europe and 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 report on the event page.

News for academia

03/04/2017

Collaboration with academia to be reinforced
EMA publishes framework and action plan for closer interaction ... [Read more](#)

24/03/2017

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 March 2017
Six medicines recommended for approval, including three orphans ... [Read more](#)

23/03/2017

Use of big data to improve human and animal health
Task force to establish roadmap and recommendations for use of big data in assessment of medicines ... [Read more](#)

22/03/2017

Call for experts in anonymisation of clinical data
EMA to set up technical group in the context of the publication of clinical data ... [Read more](#)

17/03/2017

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The European Medicines Agency (EMA) is committed to maintaining a strong working relationship with European academics and researchers. Collaboration between the Agency and academia is necessary for the Agency to be prepared for future challenges and opportunities offered by advances in science and technology.

Related content

- Academia: Information for you
- Human regulatory: Research and development
- Veterinary regulatory: Research and development
- European Network of Centres for Pharmacovigilance and Pharmacovigilance (ENCuPP)
- European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
- Partners and networks: Healthcare professionals
- Supporting SMEs

Practical information for visiting EMA - brochure



Contact point
academia@ema.europa.eu



Framework for collaboration

The EMA Management Board adopted a framework for collaboration between EMA and academia in March 2017. This aims to:

- raise awareness of EMA's role within the European medicines regulatory network;
- promote and further develop regulatory support for translating academic research into novel methodologies and medicines;
- ensure that the best scientific expertise and academic research is available to inform regulatory decision-making;
- collaborate on areas of research on regulatory science, such as novel approaches, endpoints and methodologies.



Embrace the framework

Share your knowledge

Be imaginative



Thank you

Further information

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