



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## EMA framework of collaboration with academia

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## Why did we need a framework of collaboration with academia?

- **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 2016

*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*
- *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

Site-wide search  [▶ Advanced document search](#)[Home](#) [Find medicine](#) [Human regulatory](#) [Veterinary regulatory](#) [Committees](#) [News & events](#) [Partners & networks](#) [About us](#)

## Academia

   

### 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**

### Information for:

#### ▶ Academia

#### Find information for...

- ▶ Patients and carers
- ▶ Healthcare professionals
- ▶ Animal health professionals
- ▶ Pharmaceutical industry
- ▶ Media

#### Search for medicines

Or search across all medicine types

 

#### Innovation in medicines

#### Advanced therapy medicinal products

#### Medicines for rare diseases

#### PRIME

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### EU partners

Regulators outside the EU

Patients and consumers

Healthcare professionals

▶ **Academia**

Resources

Pharmaceutical industry

International organisations

Networks

Health technology assessment bodies

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## Academia

   

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 (ENCaPP)
- ▶ 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.



# Thank you for your attention

## Further information

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