Academia

Highlights of academia interaction 2017–2019
Overview of the involvement of academics in the work of EMA since the implementation of the Academic Framework

Academic framework and action plan

In March 2017, the European Medicines Agency (EMA) adopted a framework of collaboration with academia, aiming to:

1. To **raise awareness** of the work of the European medicines regulatory network
2. Support timely and effective evidence generation, regulatory **advice and guidance**
3. **Promote** and further develop **the regulatory support** to academic research
4. Work in **collaboration** with the regulatory network in developing regulatory science

The Agency has also developed an action plan which included, among other activities, initiatives for mutual education and training, staff exchange programmes to promote mutual learning, contributing to a strategic research agenda for regulatory science and the creation of an EMA entry point for academia to receive information on available support within the EU regulatory network.

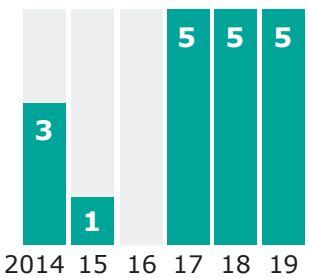
Innovation Task Force (ITF)

ITF briefing meetings provide a forum for early dialogue with drug developers, in particular academic sponsors and SMEs, to proactively identify scientific, legal and regulatory issues linked to innovative therapies and technologies.

31
ITF briefing meetings with academia (36.9% of total)

Innovative Medicines Initiative (IMI)/ Horizon 2020 (H2020):

Since the implementation of the academic framework, the ITF saw an increased in the number of IMI/ H2020 consortia applying for an ITF briefing meeting.



Targeted engagement with academia

The Agency has targeted **engagement** with academia, learned societies and research groups in a range of areas, where they enable the Agency to move forward with its mission. These areas include:

- providing a forum for discussion and debate in the EMA scientific committees and working parties;
- organising and participating in scientific workshops and conferences;
- providing experts to steering committees of research projects and boards of learned societies;
- establishing and supporting networks of excellence;
- engaging in research initiatives of European or international health bodies;
- performing in-house data analysis, literature reviews and database studies in relation to the evaluation of medicines;
- providing regulatory and scientific support to foster development of new and innovative medicines.

More details on these interactions are depicted below.

Externally funded projects

The Agency is involved in and supports a number of research projects with academia, learned societies and research groups.

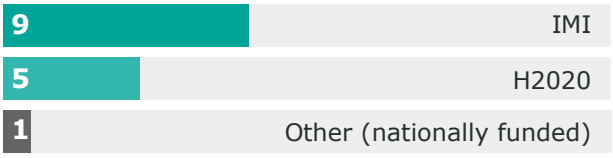
Types of involvement:

11 Consortium member

3 Advisory role

1 Hosting students

Funding scheme:



Projects the Agency is involved in:

VALUE-Dx, PARADIGM, ECRAID, European Joint Programme Rare Diseases, prefer. Patient Preferences, conect 4children, VAC4EU, VITAL Vaccinating Elderly for Healthy Ageing, STARS, FLUCOP, EHDEN, PEARRL, conception, EU-PEARL

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Traineeship and placements

The Agency runs a yearly traineeship programme covering the areas of medicine regulation, life sciences, healthcare, chemistry, information technology, pharmaceutical law, human resources, finance, communications, public relations and library and information science.

Number of traineeships/ National experts on secondment (SNEs) over a period of 3 years (2017 -2019):

154 Traineeships

89 SNEs

The Agency also offers the opportunity for staff from other European public-sector bodies to work at EMA for short periods through its seconded national expert programme (SNE).
Currently 36 staff members who were previously SNEs are still with the Agency.

Testimonial: 'EMA is a fantastic organisation to undertake the traineeship. My team was very supportive and helped motivate me towards my goals'.

Key events

EMA Veterinary Info Day provided first-hand information on the latest developments in the scientific review, regulation and marketing authorisation procedure in the field of veterinary medicine regulation, including the services provided by the Innovation Task Force (ITF).

Regulatory awareness session aimed at academics, Non Government Organisation (NGO) staff and regulators and provided insight into the functioning of the EU regulatory network, the role and work of EMA.

European Reference Networks (ERN) explored reinforcement of EMA and ERN efforts to encourage and facilitate research into new treatments for rare and low-prevalence complex diseases and to foster engagement of ERN in EMA activities.

EU-Innovation network of regulators engaged in the interaction with Academia to boost the success of development programmes (e.g. STARS). The workshop aimed at finding ways to work together to support new medicines and innovative healthcare solutions as well to increase visibility of the network.

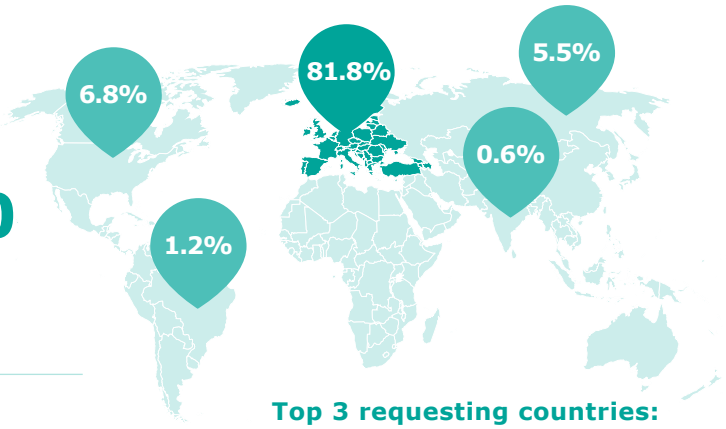
'Regulatory Science to 2025': A multi-stakeholder workshop was held after a public consultation on the 'Regulatory Science to 2025' strategy. The strategy is a plan for advancing EMA's engagement with regulatory science over the next years and aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine.

Queries received by EMA from academia 2017–2019

1,993 Queries (8% of total queries)

200 Access to documents

>30,000 EMA document pages requested



Topic of queries:

Top 3 requesting countries:

UK **20%**

Germany **11%**

The Netherlands **9%**