EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA framework of collaboration with academia

Presented by Melanie Carr
Head of Stakeholders and Communication Division (ad-interim)

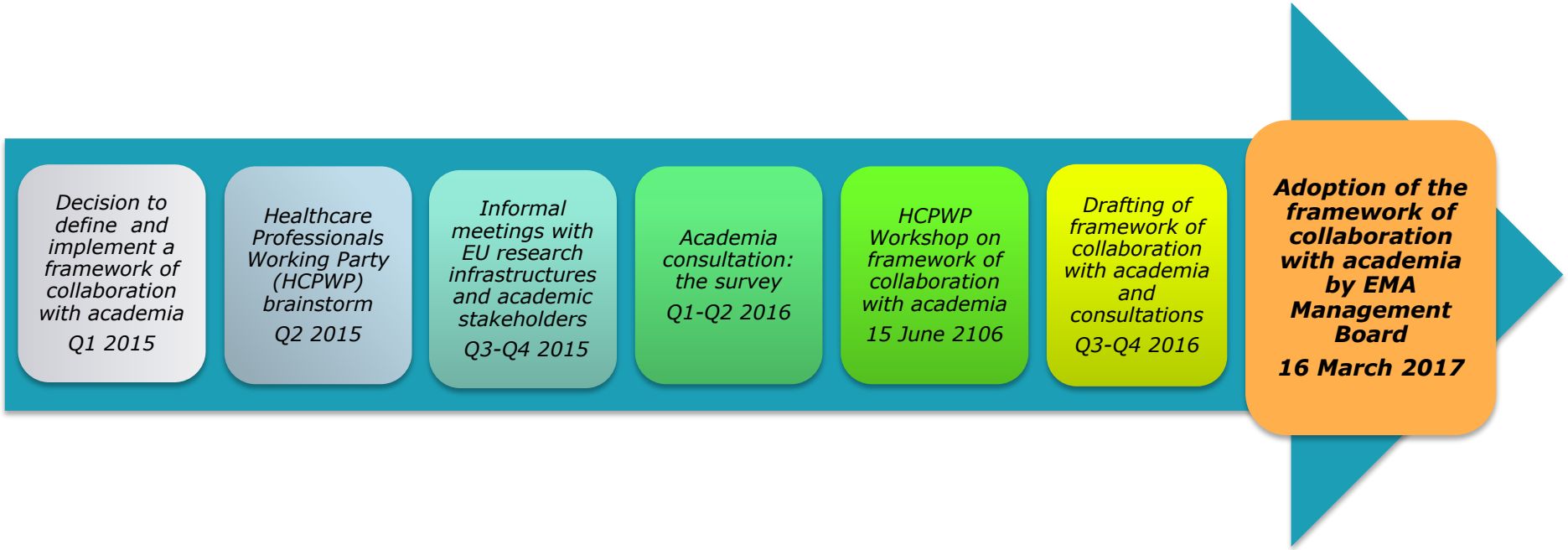
Why did we need a framework of collaboration with academia?

- ***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



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

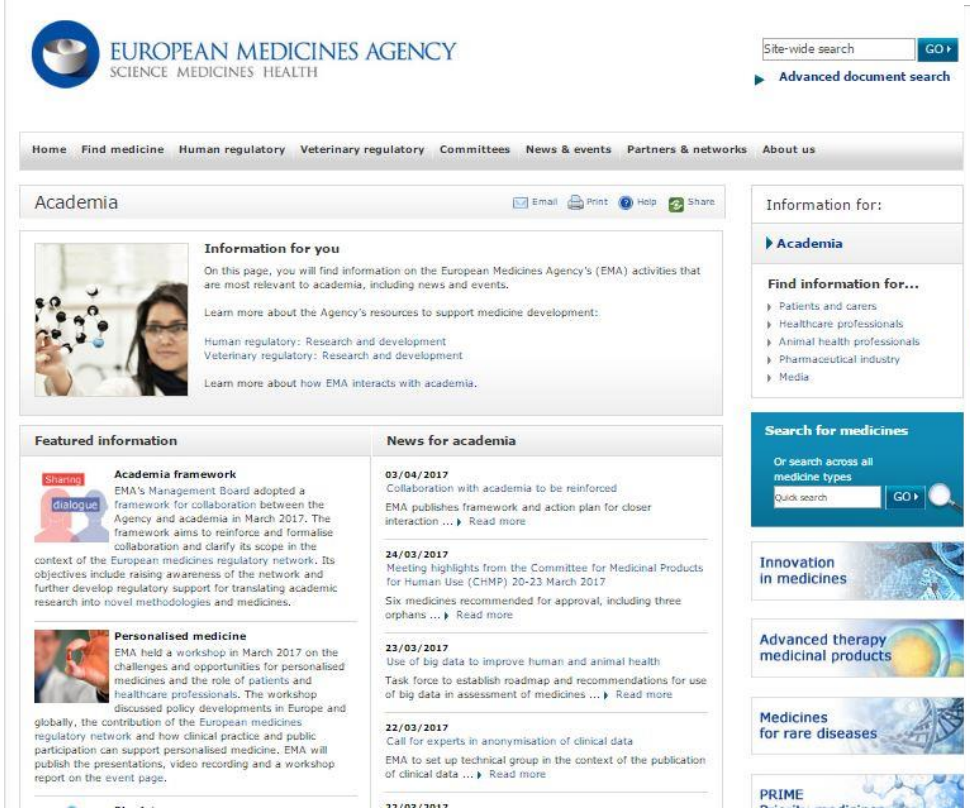
- *Identification of academia contacts points of the EU National Competent Authorities*
- *Implement the criteria for EMA involvement in externally funded regulatory science projects*
- *Include academic stakeholders in the EMA Stakeholder Database for targeted communication and monitoring of interactions*
- *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*

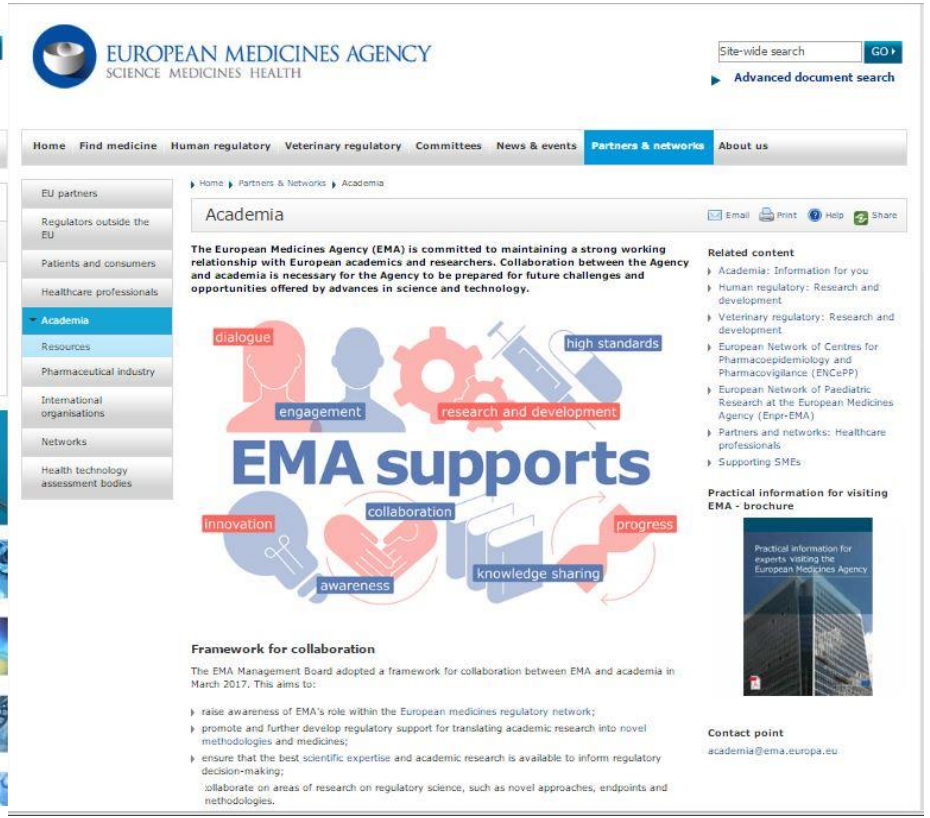
Framework of collaboration with academia

Action plan highlights

- *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





Thank you for your attention

Further information

academia@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**