EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Draft framework of collaboration with academia

ENCePP plenary meeting, 22 November 2016

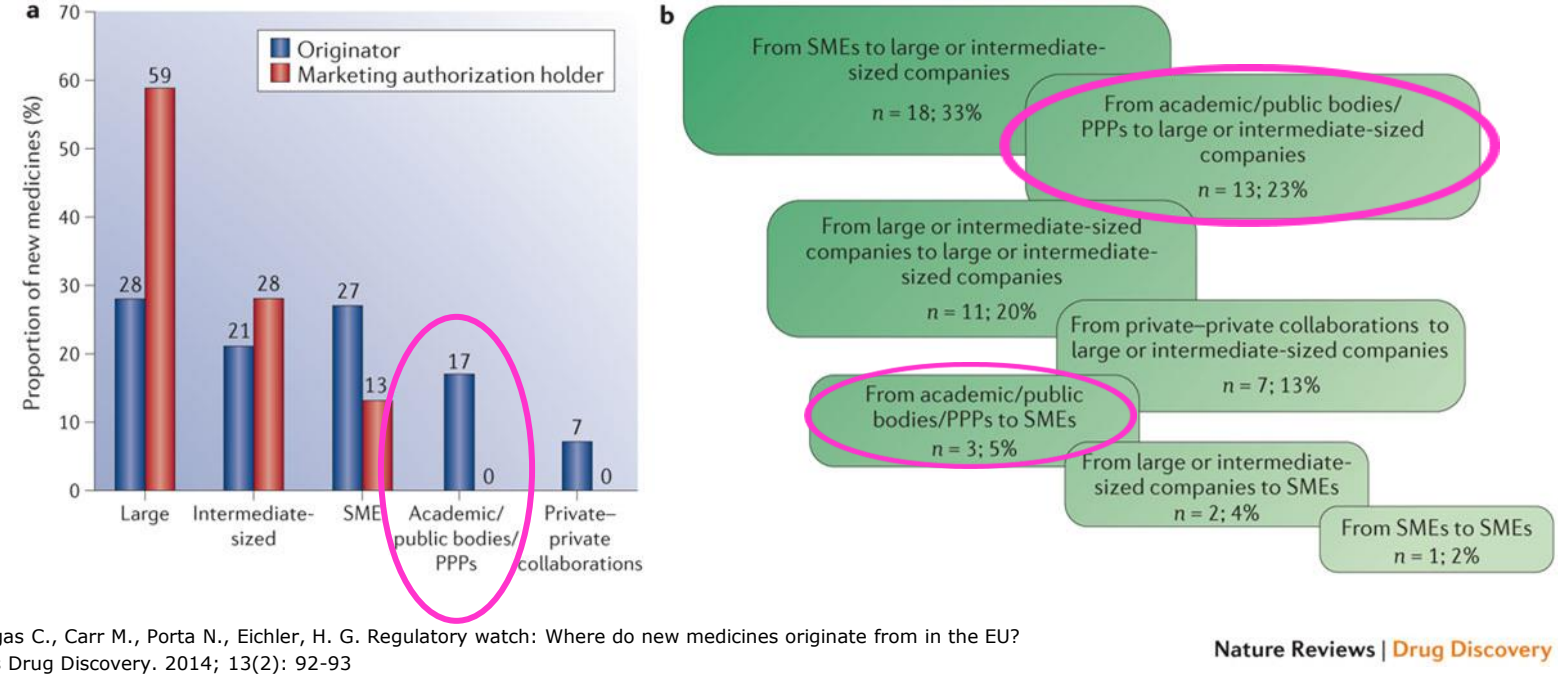
Presented by Isabelle Moulon
Head of Public Engagement Department
Communication and Stakeholders Division

Acknowledgments

- HCPWP Academia Topic Group – co-chairs Rosa Giuliani (ESMO) and Sergio Bonini (EMA)
- Internal EMA Academia Task Force
- Public Engagement Department

Academia: an important source of innovation

Origin of new medicines in the European Union (2010–2012)



Lincker H., Ziogas C., Carr M., Porta N., Eichler, H. G. Regulatory watch: Where do new medicines originate from in the EU? Nature Reviews Drug Discovery. 2014; 13(2): 92-93

Nature Reviews | Drug Discovery

Why 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*."

… and in a nutshell

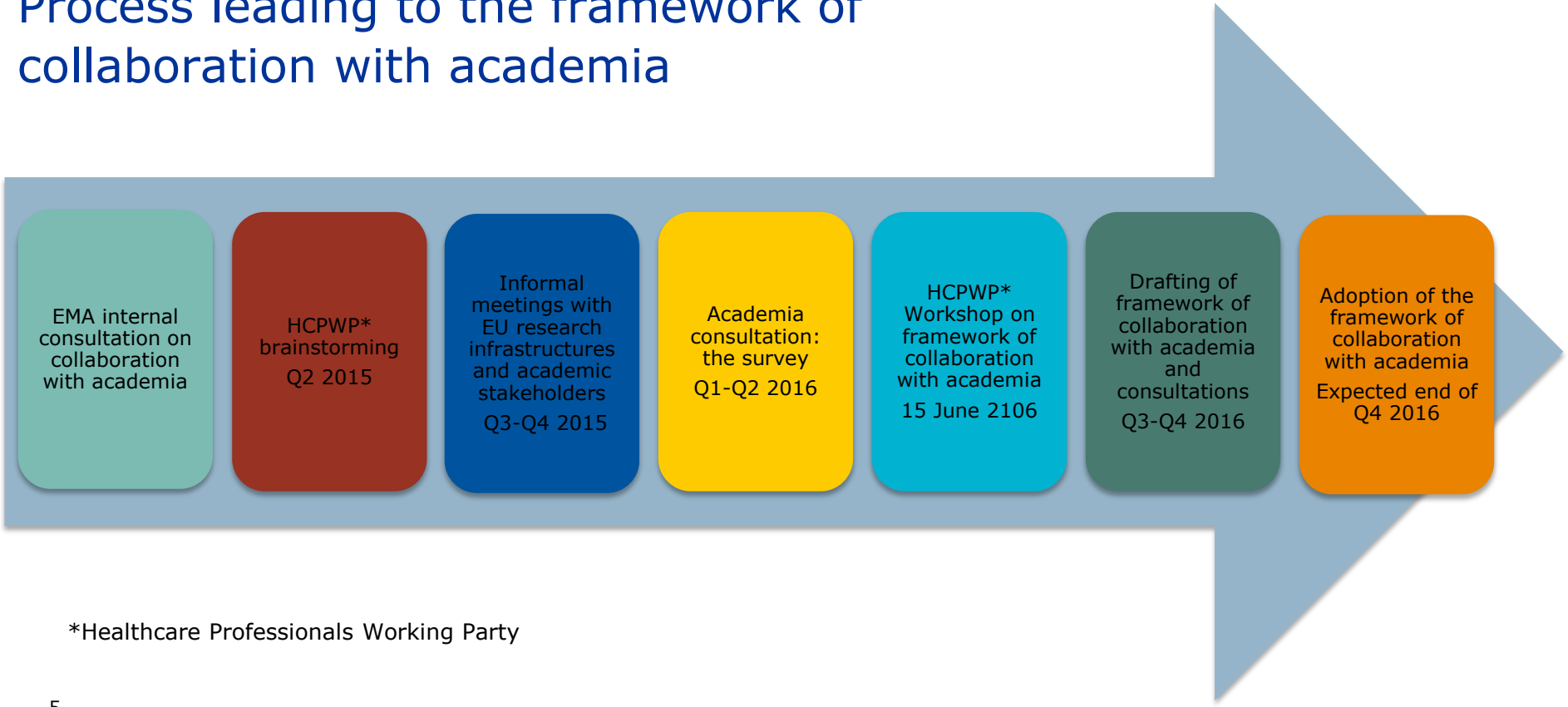
"EMA wants to move to a new level of collaboration with academia. Science is progressing fast and we see an unprecedented level of complexity in the development and evaluation of new medicine.

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



*Healthcare Professionals Working Party

Consultation with academia via survey: objectives

- Take a snapshot of the current interaction between academia and regulators at European level, and collect needs and expectations (survey tool)
- Open a dialogue for laying the foundations of a robust framework of collaboration:
  - To support innovation in the biomedical field
  - To underpin European translational medicine activities
  - To enhance the development of regulatory science
  - To attract leading expertise and enhance mutual understanding

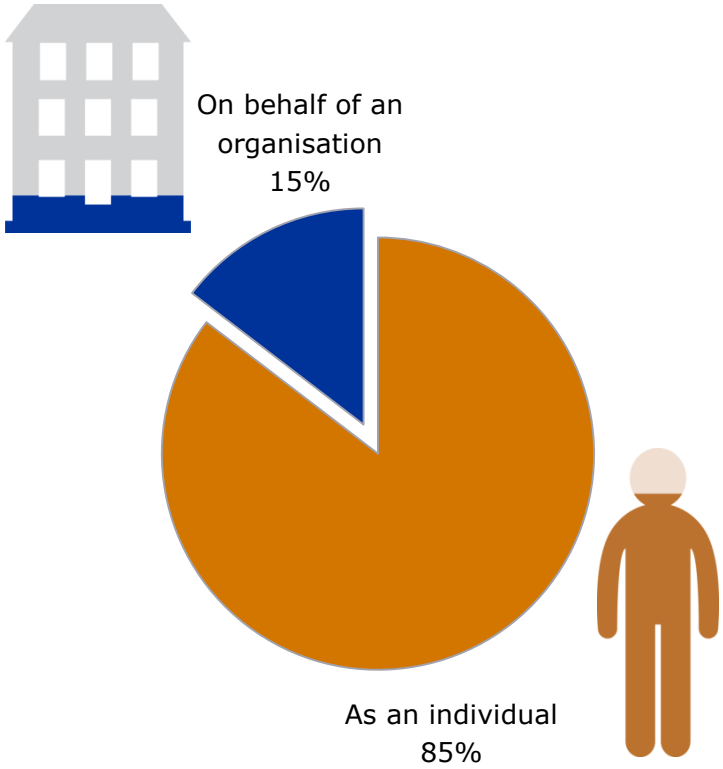
Survey structure and dissemination strategy

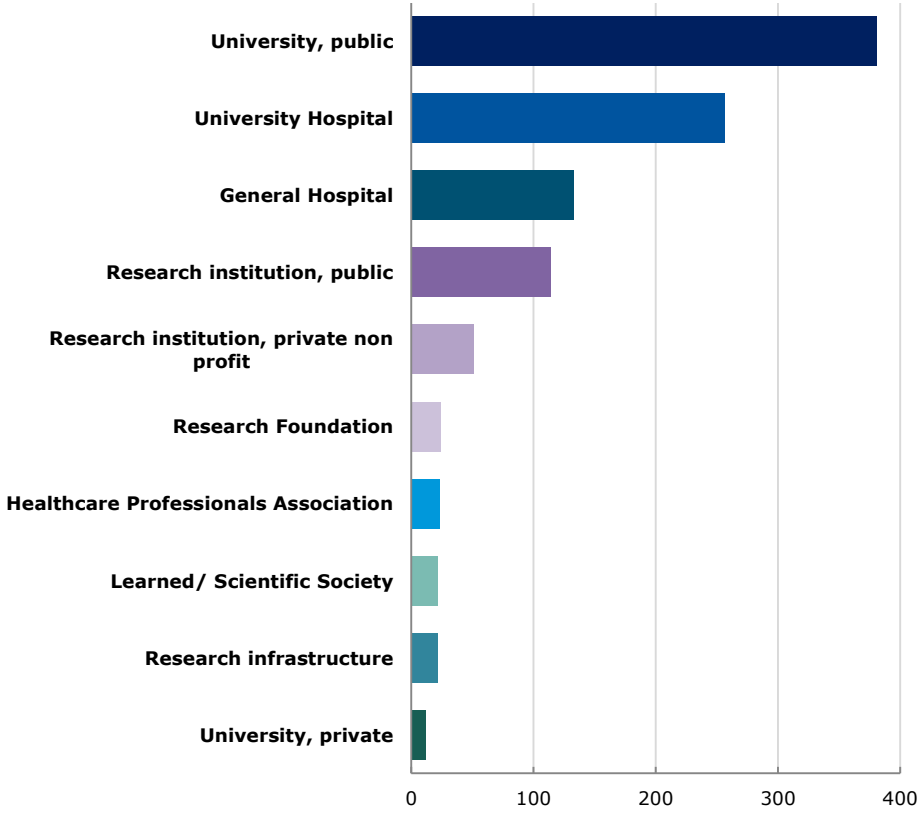
- Online survey using SurveyMonkey®
- Survey consisted of 3 parts: Profiling, Interaction with Regulators and Future Developments (12 questions in total; National Competent Authorities were consulted and their input incorporated into final version)
- Launched 1 February 2016 – closed 18 April 2016
- Published on EMA website and proactively disseminated through academic groups, learned societies and healthcare professional organisations
- 1016 respondents at survey closure (877 responses retained after data cleaning)

Profiling

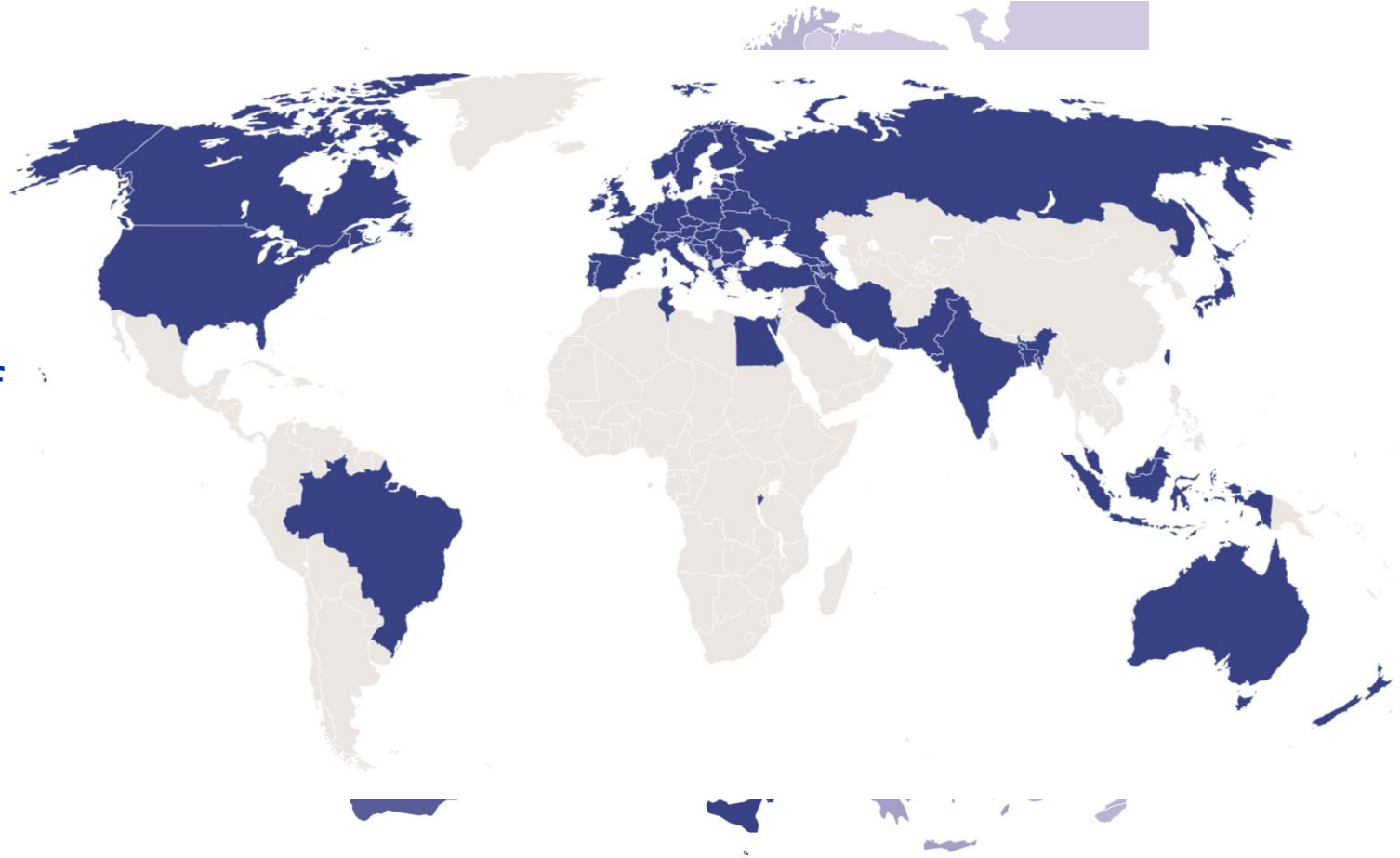

Profiling
5 Questions
Interaction with regulators
5 questions
Future developments
2 questions

Respondents' affiliation





Geographical distribution of respondents



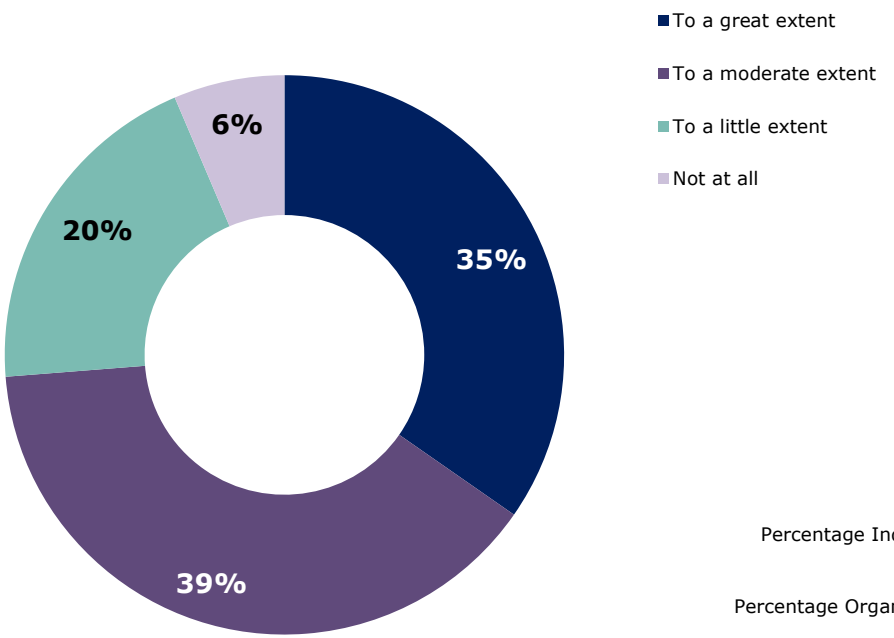
Summary of profiling

- Respondents: 85% individuals (n=749) and 15% organisations (n=128)

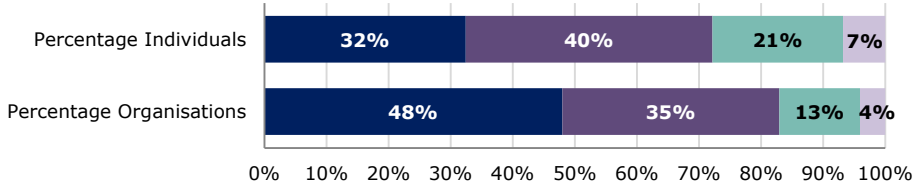
Affiliation	Area of activity	Type of research
• **Public universities (n=381)** • **University hospitals (n=257)** • General hospitals (n=133) • Public research institutes (n=114) • Private research institutes (n=51)	• **Medicine (n=717)** • Pharmaceutical sciences (n=283) • Biology (n=265) • Social sciences and Humanities (n=90) • Chemistry (n=65)	• **Clinical research (n=569)** • Basic research (n=291) • Pre-clinical research (n=289) • Real-world research (n=245)

Interaction with regulators

Awareness of the role and activities of regulatory bodies



Question: To what extent are you aware of the role and activities of regulators?

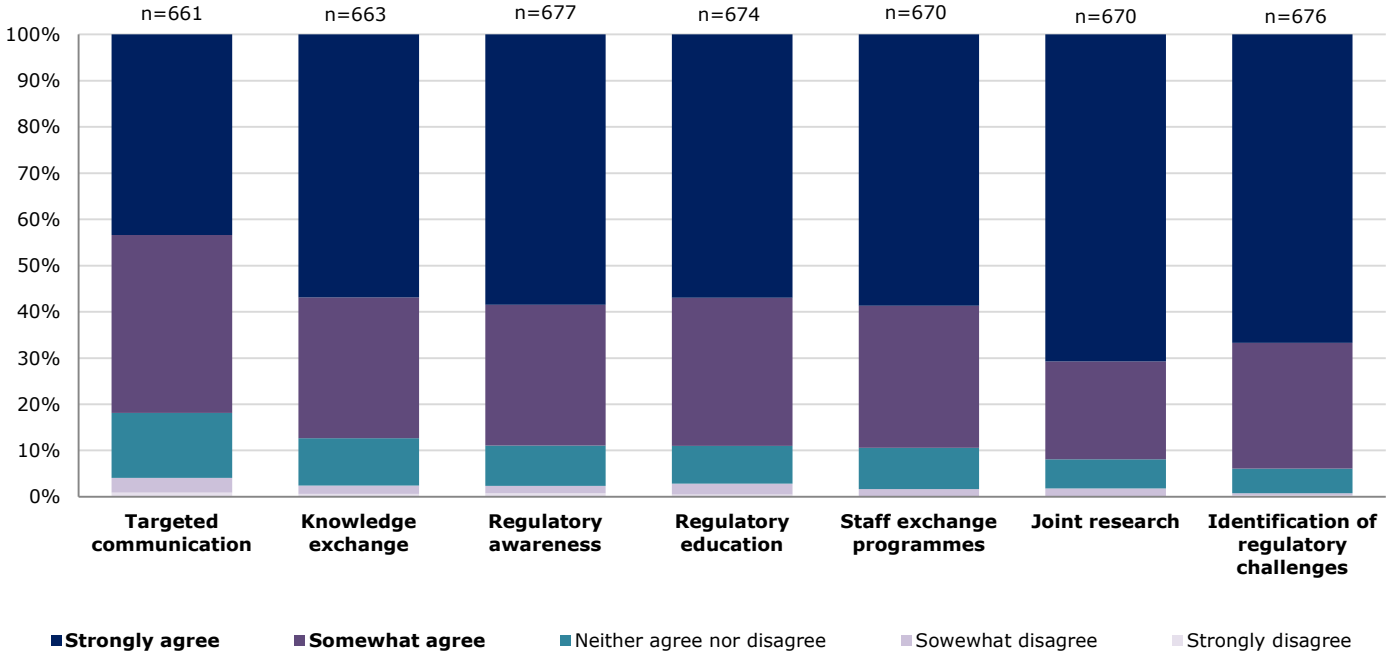


Summary of Interaction with Regulators

- The awareness of regulators' role and activities among academics has space for improvement
- National Competent Authorities (NCAs) represents a robust asset of interaction and contact with academics
- EMA should strengthen its visibility and outreach among academics
- Most of the respondents provided their expert opinion to the regulatory activities

Future developments

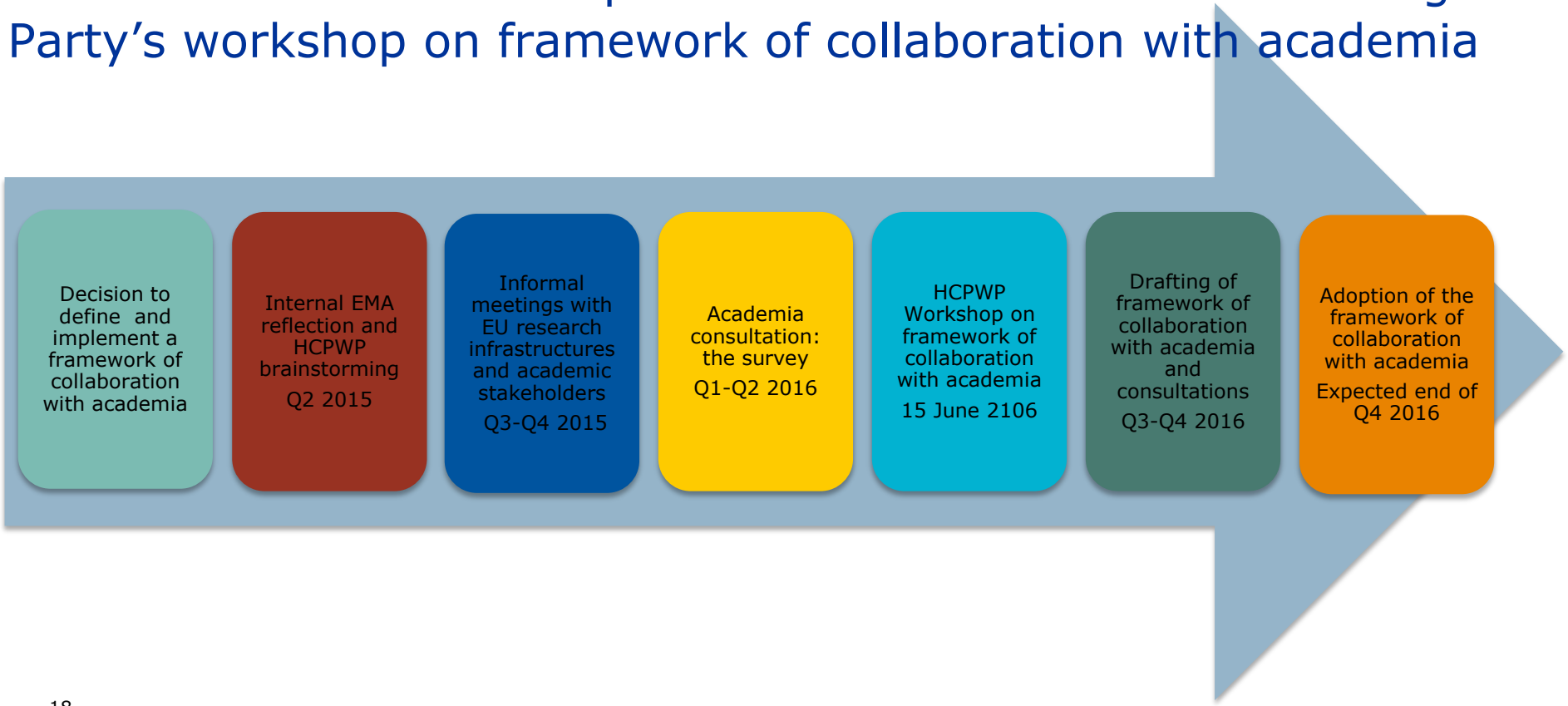
What should be pursued for a closer collaboration between academia and regulators



Overall summary of survey results

- The survey provided an informative snapshot of the current interaction between academic stakeholders and regulatory bodies
- It clearly identified a need for enhancing awareness of the role and activities of regulatory bodies among academic stakeholders
- It helped to identify the key areas of collaboration to be developed within the framework
- Over 900 written comments identifying strengths, weaknesses, opportunities, challenges and further suggestions for enhancing collaboration
- Survey report

A further consultation step: Healthcare Professionals Working Party's workshop on framework of collaboration with academia

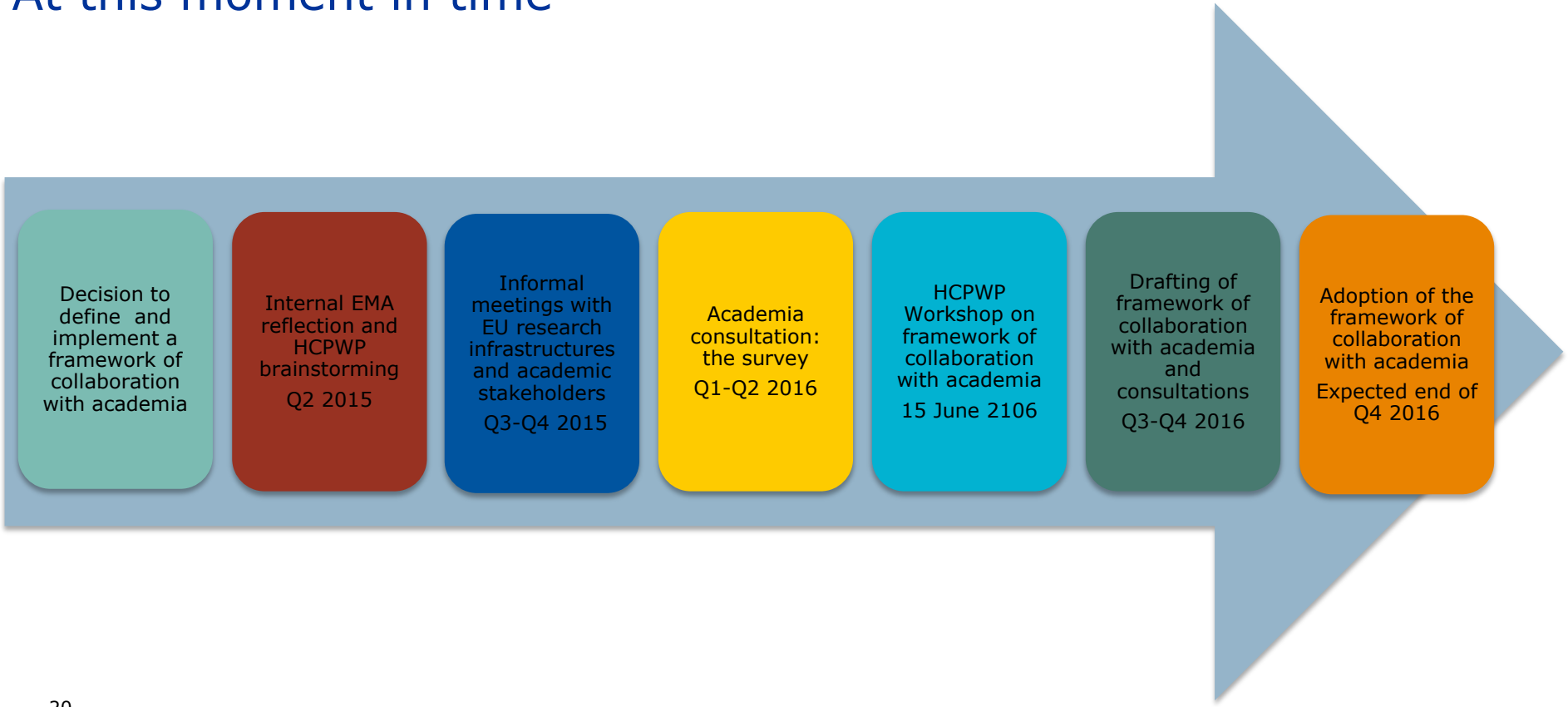


A further consultation step: Healthcare Professionals Working Party's workshop on framework of collaboration with academia

Workshop outcomes:

- Consensus on the opportunities of leveraging and enhancing existing activities in the field of education and training, potentially combined with research endeavours
- Call from academics to the regulators for supporting independent research (i.e. not industry driven) and proactively indicate priorities and a strategic research agenda in regulatory science
- Consensus on the crucial importance of putting in place a communication strategy (in its tools and content) that will allow structured bidirectional exchanges
- Links to workshop webpage and report

At this moment in time



Structure of the framework of collaboration

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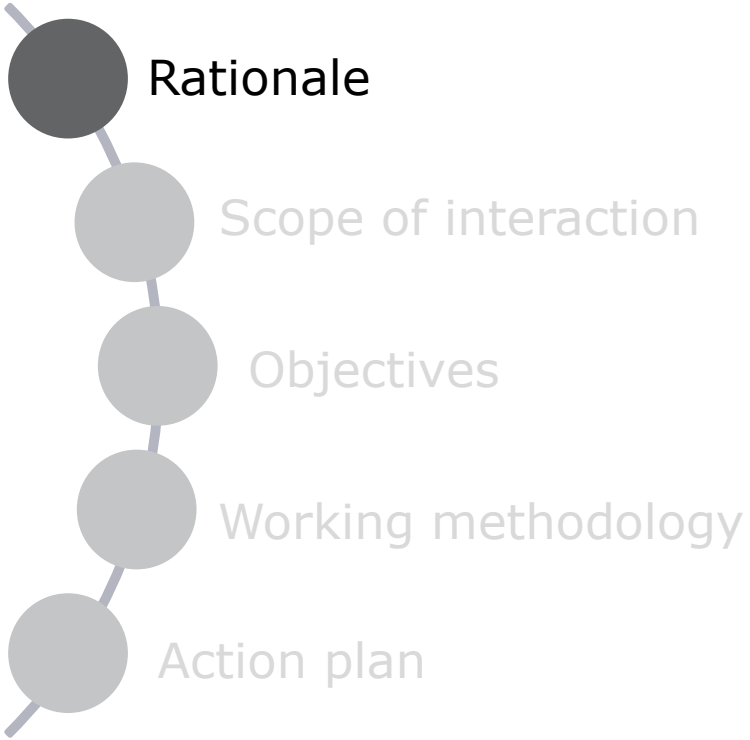

Rationale: why do we need a framework of collaboration with academia?

- **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*."
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Scope of interaction

- 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
- Established European research consortia funded under public research programmes
- European learned/scientific societies, federations and networks

➢ Operating in all fields of research related to the development, manufacturing, assessment, and use of medicines, including health communication and social sciences.

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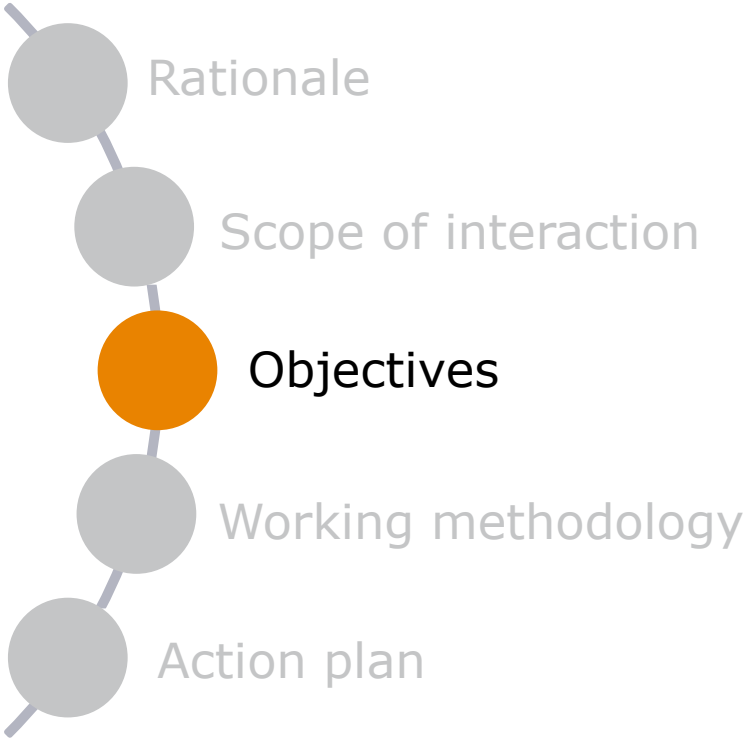

Objectives

- To raise awareness of the mandate and work of the Agency within the European medicines regulatory network as a means to increase academia's engagement and trust in the Agency's activities
- To promote and further develop the support on offer from the EMA within the European medicines regulatory network to foster the translation of academic research into novel methodologies and medicinal products which meet the regulatory standards
- 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

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Working Methodology

Based on 4 elements:

- EMA Stakeholder database
- EMA European Experts database
- Research and knowledge generation
- Communication & Multi-stakeholder dialogue

EMA stakeholder relations management framework	
Inform – to enable feedback	e.g. dedicated web pages, relevant news items, Q&As, information days, information materials including videos and presentations
Consult – via written consultation	e.g. public consultation on policies or guidance, surveys
Consult and Involve – via direct interactions	e.g. multi-stakeholder meetings, workshops, conferences, public hearings, input into the development of regulatory guidelines and other regulatory procedures
Cooperate / participate – via direct interactions	e.g. participation to research projects, cooperation in activities of education and training, participation in scientific advisory groups and ad-hoc expert groups, cooperation with established EMA stakeholders and networks.

Structure of the framework of collaboration

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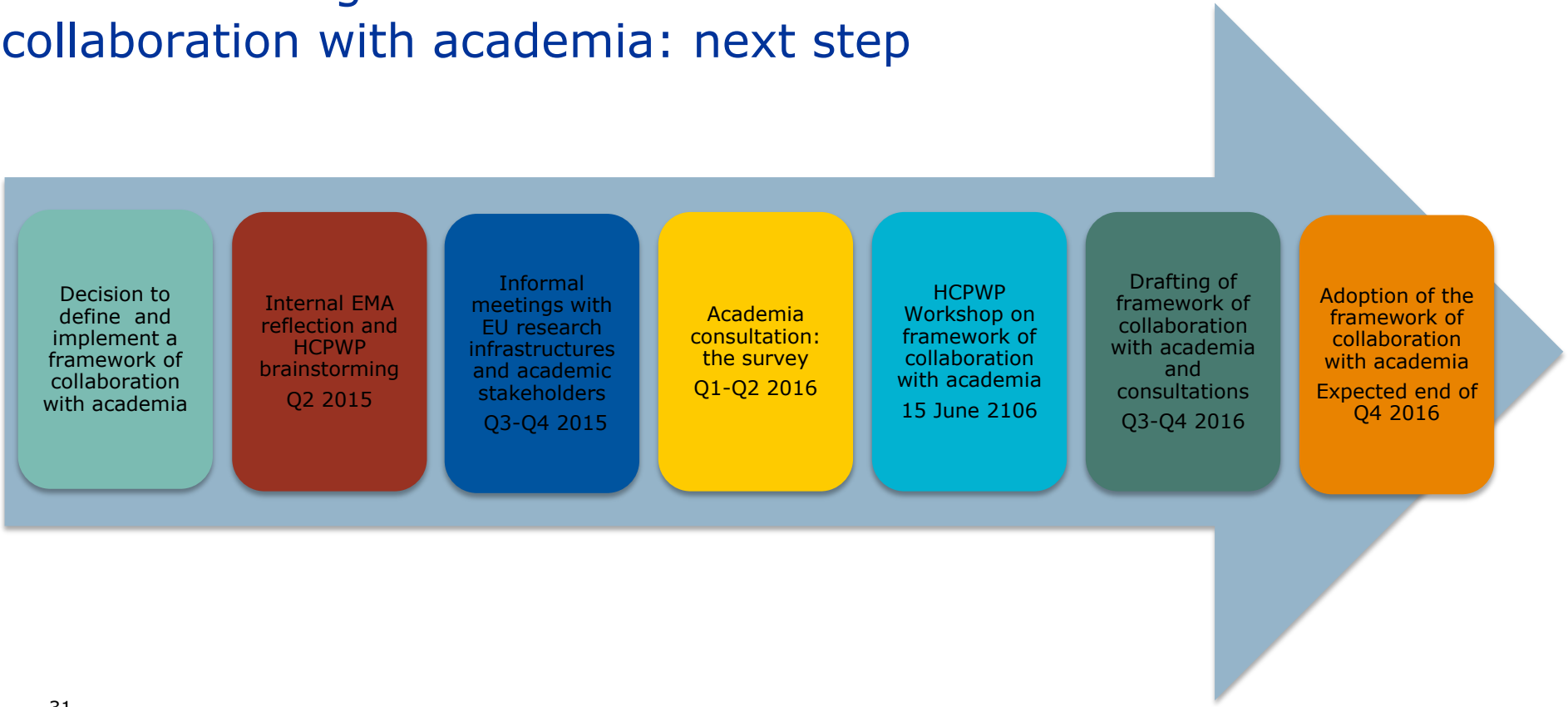
Process leading to the framework of collaboration with academia: next step



Thank you for your attention

Further information

Isabelle.Moulon@ema.europa.eu
Monica.Ensini@ema.europa.eu
Ivana.Silva@ema.europa.eu
Dora.Duarte@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact