EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Academia Collaboration Matrix Action Plan

Coordinating Group & networks meeting

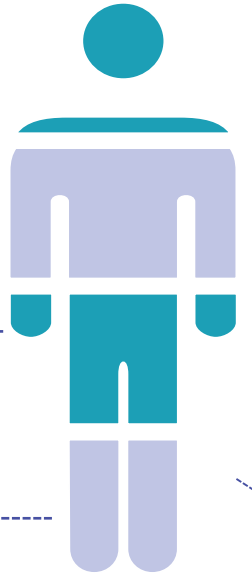
Presented by Lifang Liu, on June 29 2021
Public Engagement Officer, Taskforce Regulatory Science and Innovation

Framework of collaboration with academia *Stakeholders*

Individuals (ESR, scientist, PIs, Experts, KOLs)

Academic groups developing medicines and methodologies

European research consortia
funded under public research programmes



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

European research infrastructures, learned/scientific societies, federations and networks

Principles and Rationale

- raising awareness of EMA's role
- 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.

EMA Regulatory Science to 2025

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Five goals for human medicines regulation

Goal 5

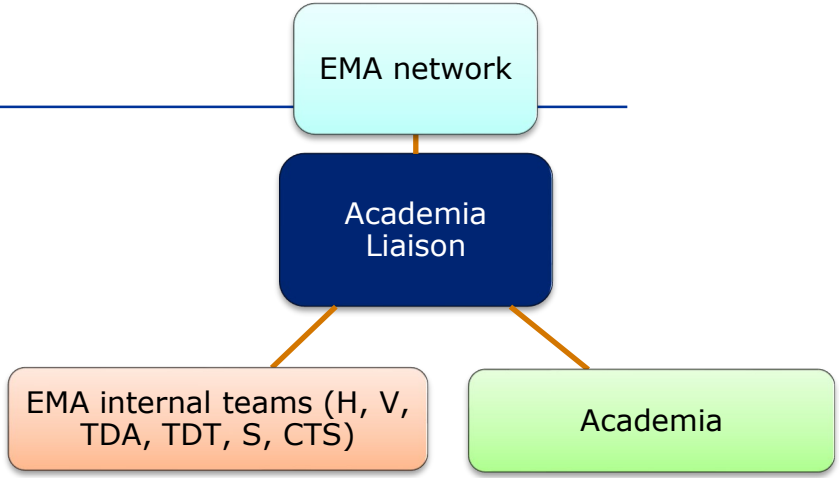
28. Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science

29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

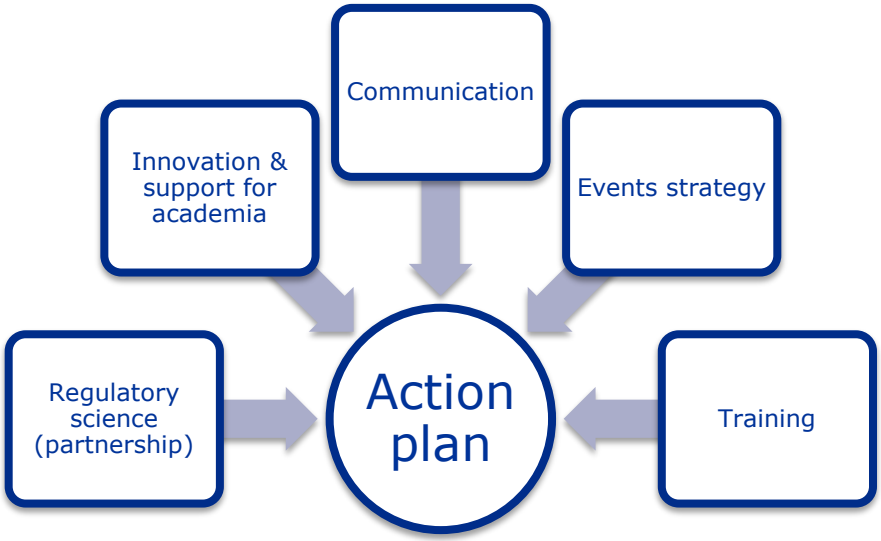
30. Identify and enable access to the best expertise across Europe and internationally

31. Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

The EMA Academia Liaison and tools to support academia



Academia Action Plan 2021-2023



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2021
EMA/159144/2021
Research and Innovation (TRS-RNI)

Academia Collaboration Matrix action plan (2021 – 2023)

Introduction

The European Medicines Agency (EMA) is committed to maintaining a strong working relationship with European academics and researchers. Collaboration with academia is necessary for the Agency to be prepared for future challenges as well as opportunities offered by advances in science and technology. The Agency has targeted engagement with academia, learned societies and research groups in a range of areas.

This Academia Collaboration Matrix action plan was conceived as a tool to deliver on activities identified in EMA strategic plans while giving due consideration to the environment in which the Agency operates, including resources availability.

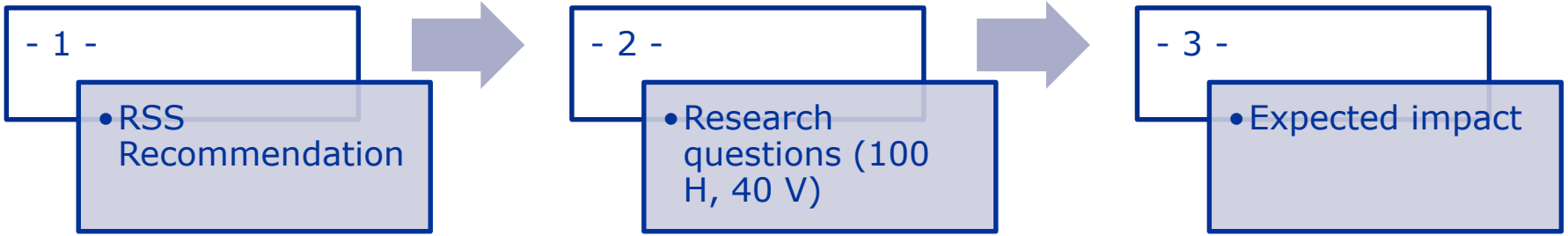
The EMA programming document 2021-2023 states as an objective for the Regulatory Science and Innovation (TRS) Task Force to "Leverage collaborations between academia and network scientists to prepare for engagement with Horizon Europe and Innovative Health Initiative (IHI), define EMA's regulatory science research agenda and enable exchange of knowledge and expertise." Specifically the programming document refers to "an Agency-wide plan for interaction with academia is being developed, which aims (1) to support governance and oversight of interactions with externally funded research and networks; (2) identify academic disciplines/research topics; (3) support the establishment of staff-exchange programmes and placements; (4) create academia-targeted materials to promote existing regulatory tools; (5) set up a communication strategy."

This action plan is in line with the EMA programming document 2021-2023 and the Regulatory Science Strategy to 2025 (RSS 2025), and captures the objectives the Agency must pursue in order to achieve an optimal collaboration with Academia:

- Develop network-led partnerships with Academia / research centres to undertake research in strategic areas of regulatory science;
- Leverage collaborations between Academia and network scientists to address rapidly emerging regulatory science research questions;
- Identify and enable access to the best expertise across Europe and internationally;
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

EMA's Research Agenda Structure



EMA's Regulatory Science Research Agenda (oncology questions)

EUROPEAN MEDICINES AGENCY

1. Contribute to HTAs' preparedness and downstream decision-making for innovative medicines

- Q1: Early share confidential information relating to benefit-risk assessment with HTAs?
- Q2: How to use multi-criteria decision analysis as a common tool for regulatory and HTA decision-making?

2. Expand benefit-risk assessment and communication

- Q1: How can the SMOP be optimised to ensure a wider and simplified benefit-risk communication?
- Q2:How to optimize benefit-risk assessment be optimized to adequately inform HTA bodies?
- Q3: Implement quantitative benefit-risk methodologies in marketing authorisation application?

3. Foster innovation in clinical trials (efficient design, biomarkers, endpoints)

- Q1:what are the standards for validation of surrogate endpoints and biomarkers?
- Q2:What challenges for umbrella trials that involve multiple companies and products within the same trial?
- Q3: Is there a role for regulatory procedures and guidelines?

4. Reinforce patient relevance in evidence generation

- Q1: Treatment optimization for to improve clinical practice
- Q2:Setting standard to collect, analyse, use and report patient-reported outcome data
- Q3: What are optimal approaches to seek patient input for benefit-risk assessment in decision making?
- Q4:Explore patient preferences to weigh the individual outcomes for regulatory and HTA decisions.

5. Support developments in precision medicine, biomarkers and 'omics'

- Q1: What are the valid standards for both regulators and HTAs regarding biomarkers and surrogate endpoints?
- Q2:Are there any strong candidates among clinically validated biomarkers for regulatory qualification?

EMA's Research Agenda-Example

RSS Core recommendation 11: Reinforce patient relevance in evidence generation

Q1. What are the practices and standards for validation of patient-reported outcomes (PROs)? What levels of uncertainty are acceptable for PROs?

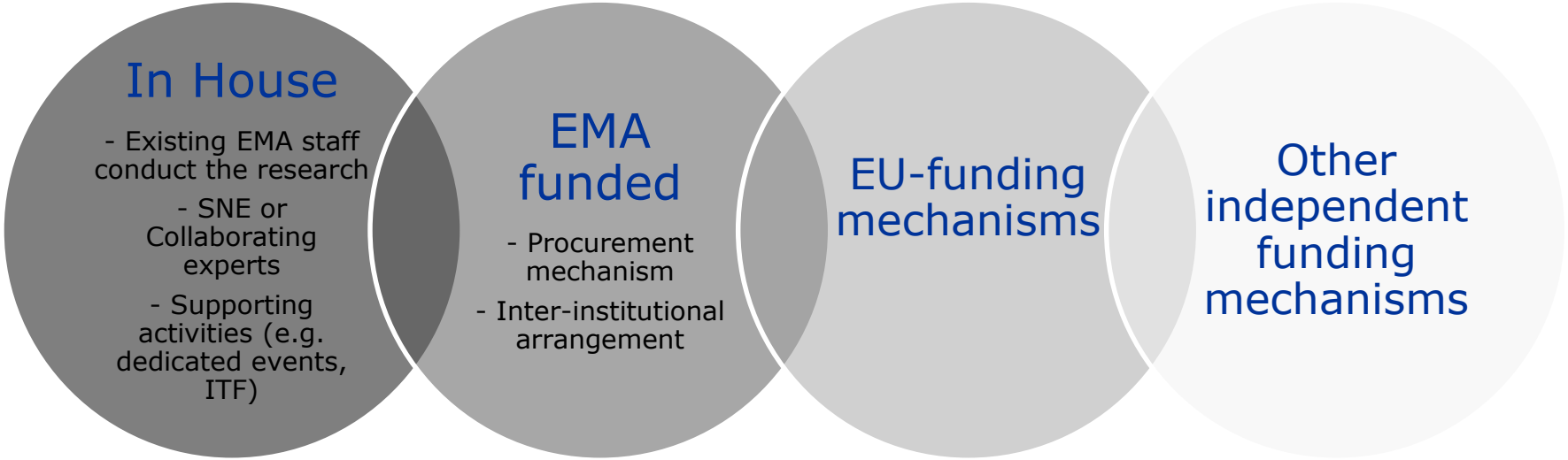
Objective(s)
1. To set regulatory standard to collect, evaluate and validate patient reported outcome data;
2. To consolidate existing expertise in the field.

Need(s)
1. There are no regulatory tools to evaluate whether even a simple PRO is validated.
2. It is unclear what type of uncertainties in PRO assessment is acceptable for regulatory approval.

Potential Impact
The tools and resources developed should ensure accurate capture of PROs on how patients feel or function during the course of disease. This in turn will aid in decision making for regulators, health technology assessment bodies, and, crucially, improve patient satisfaction.

Wish to share your opinions on this topic? Please let us know by emailing academia@ema.europa.eu

Funding opportunities and mechanisms



Communication, event and training

Corporate website
(academia pages)

Stakeholders database
(for targeted communication)

Ask-EMA queries

Events involving academia

- ENCEPP webinar for academia (March 2021)
- European Big Data Forum (March 2021)
- Data standard strategy (May 2021)
- Big Data Workshop for veterinary science (May 2021)
- Health care professional working parties meeting (June 2021)
- **Dedicated discussion with HCPWP on key regulatory scientific questions: clinical trial design, real-world evidence, special populations, medicine shortage (June-Oct 2021)**

Training

(EU-NTC, projects, placements)

- Clinical Trial Information System Training for Academia and SMEs
- Training on oncology-related topics
- ICH guideline training for academia

The Academia Collaboration Network

- 77 academia umbrella organizations, with more than 3500 members
- >100 Top-class scientists, research groups, institutes on Regulatory Science
- >35 EU consortium
- >35 health care professional working groups and learned societies in Europe

Take home messages

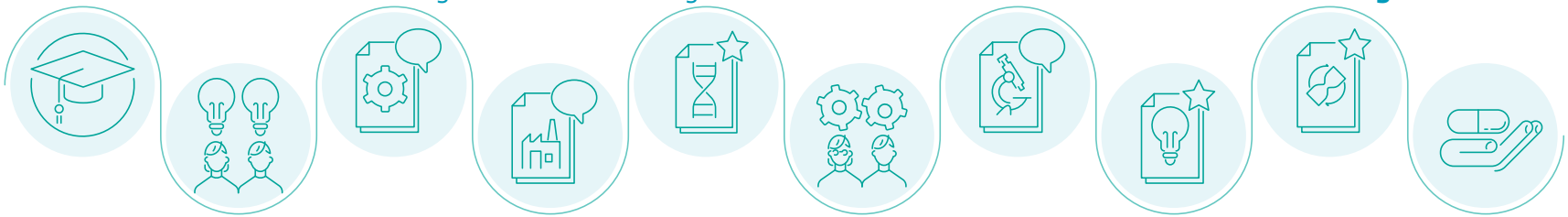
- Enpr-EMA is accessible to EMA services as academia
- Welcome to engage research activities with EMA, thinking of placement opportunities
- Join us during relevant events and trainings
- Join efforts establishing funding streams for research projects
- Regulatory tools, ITF, SA, PRIME, etc, may be useful to you

EMA support to innovation

Dedicated Entry point:

SME office
SME@ema.europa.eu

Academia entry point
Academia@ema.europa.eu



Innovation Task Force (ITF)

Qualification of novel methodologies

SME Office: Reg assistance, SME Briefing Meeting, SME incentives

Orphan Medicine Designation

EU Health Technology Assessment (HTA)

Scientific Advice / Protocol Assistance

ATMP **Classification & Certification**

MAA **Pre-Submission Meeting**

PRIority MEdicines (**PRIME** designation)

Thank you for your attention

Further information: [EMA Supporting medicine developers]

Academia@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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