Collaboration with academia on regulatory science activities

EMA Veterinary Awareness Day 2023

Presented by Ralf Herold on 13 September 2023
Regulatory Science and Innovation Task Force, EMA

Content

- Academia and EMA
- Strategic purpose of engagement
- Regulatory science and innovation
- Opportunities

EMA’s mission and main activities

- Foster scientific excellence in the evaluation and supervision of medicines, for the
- Benefit of public and animal health in the European Union (EU)

- Support research & innovation of medicines
- Facilitate development of medicines
- Enable timely access to new medicines
- Evaluate marketing authorisations
- Monitor medicines along their life cycle
- Provide reliable information on medicines
- Advance regulatory science and practices

EMA engaging stakeholders

Patients, healthcare professionals, academia, industry

Inform
(announcement of review of policy or guidance; information days)

Consult
(written—public consultation on policies or guidance, surveys)

Consult and involve
(direct interactions—stakeholder meetings, workshops, conferences, public hearings)

Cooperate/participate
(direct interactions—technical expert groups, focus groups)

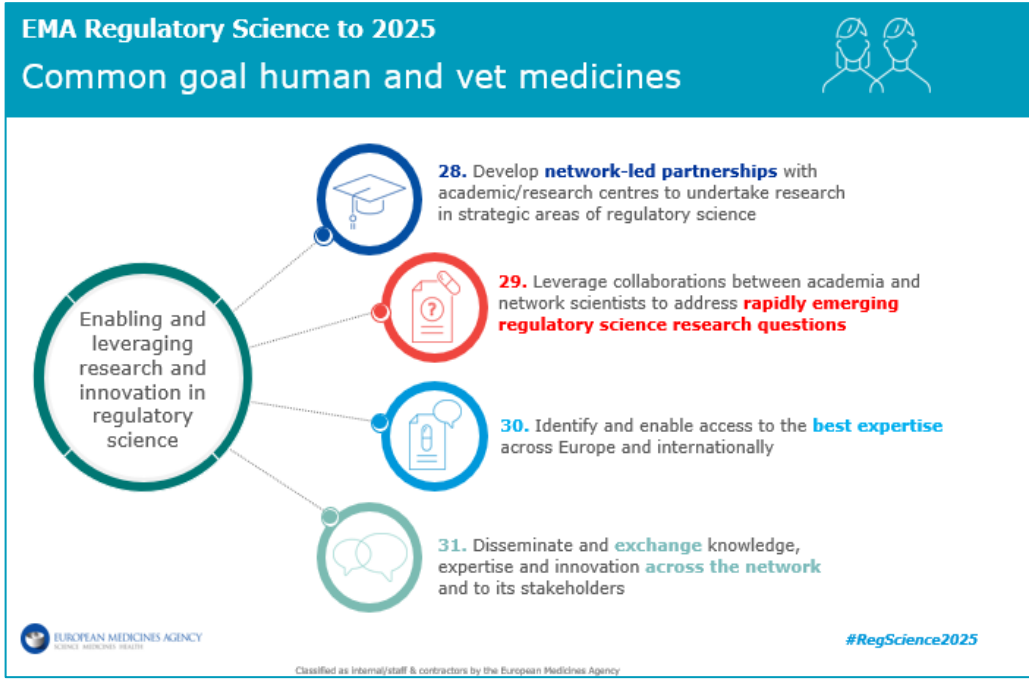
Academia as strategic partner for EMA

Framework for collaboration between EMA and academia

Promote and further develop regulatory support for translating academic research into novel methodologies and medicines

Ensure 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

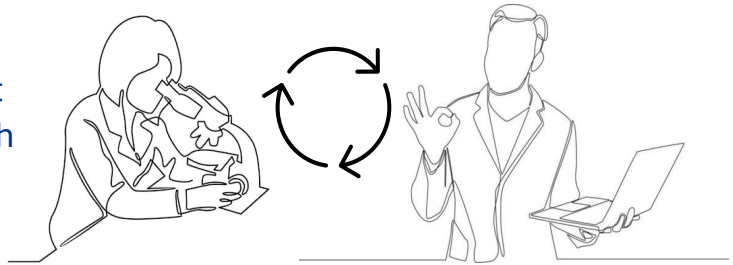


https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/framework-collaboration-between-european-medicines-agency-academia_en.pdf

Academia as strategic partner for EMA

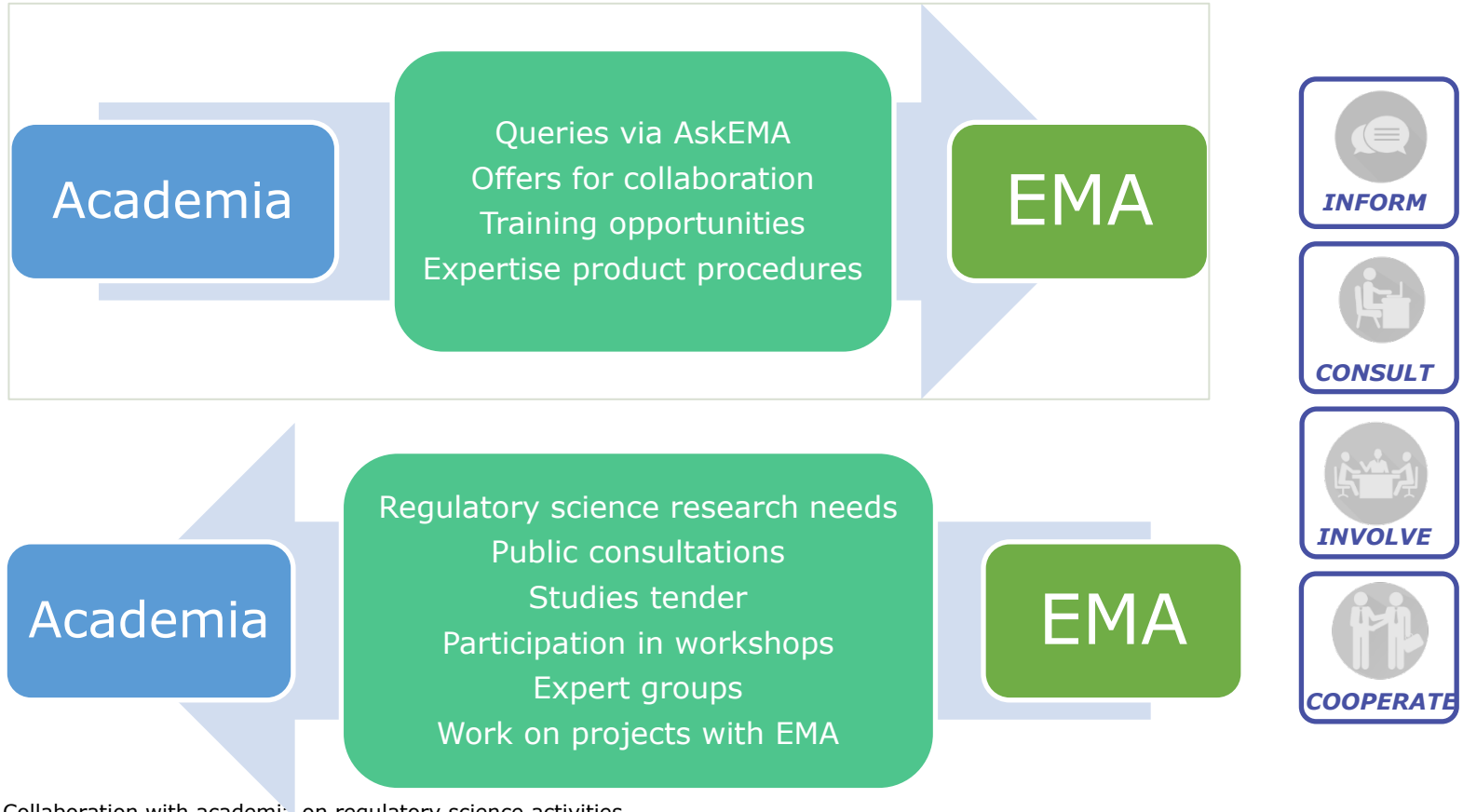
Virtuous cycle

Academic developers:
EMA provides regulatory support for translating academic research into novel methodologies and medicines

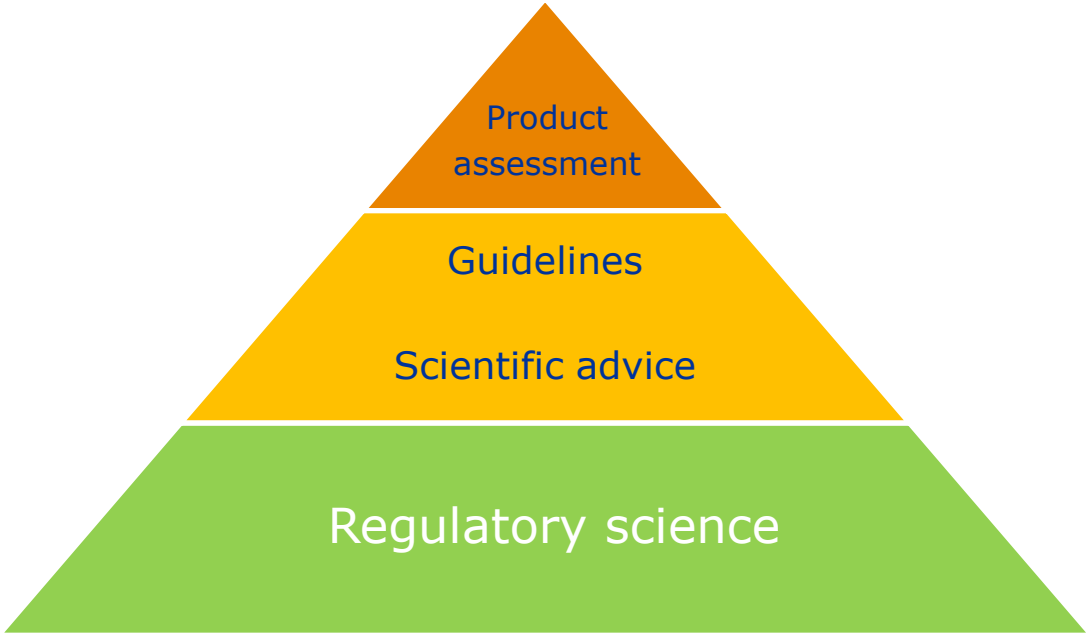


Knowledge gaps:
Contribute best scientific expertise and research to support regulators in advising & decision-making

Regulatory science research needs: Collaborate on areas of research on regulatory science



The role of regulatory science at EMA



"the data supporting the efficacy in the proposed indication for guinea pigs are rather limited; however, there are no recognised models to investigate this indication in the target species,"

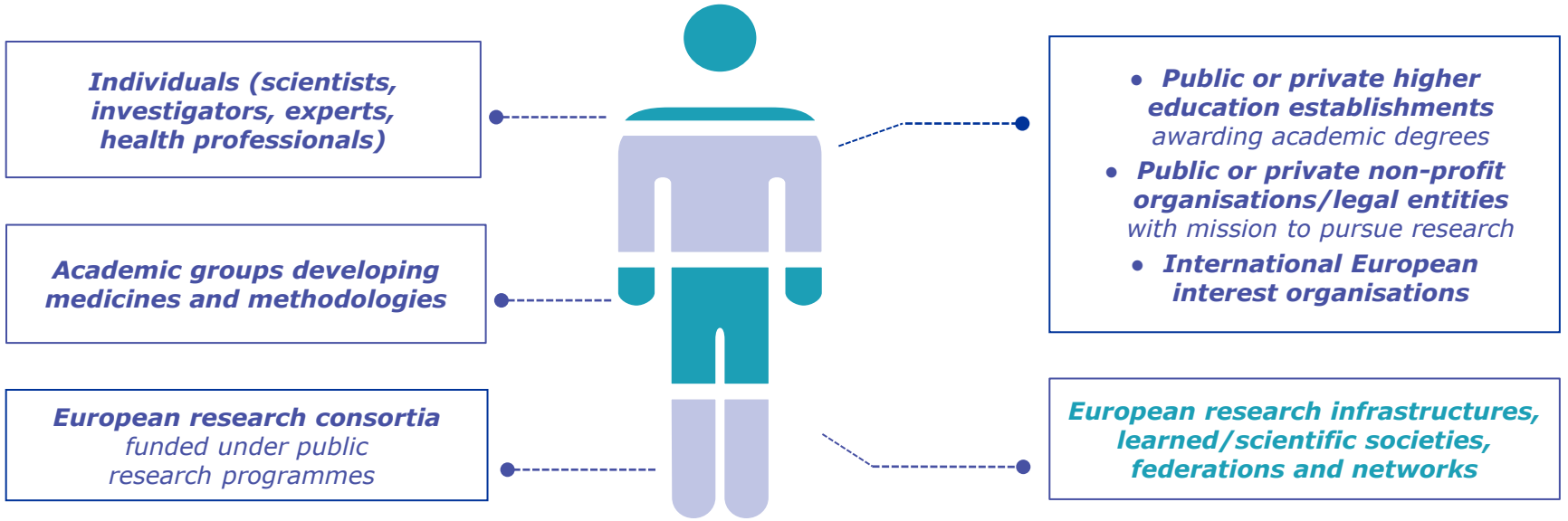
Guideline on potency tests for cell therapies, e.g. "The assay variability has to be taken into account, whether it is method- or product related."

Does the CVMP (SAWP-V) agree to the use of X for treatment of Y without additional studies of Z, given the experience and available data?

Research is needed on the relationship between sales data, veterinary medicinal product types and species, to adverse event data in Eudra-Vigilance, to establish baseline data and identify potential sources of bias

Framework of collaboration with academia

Stakeholders



https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/framework-collaboration-between-european-medicines-agency-academia_en.pdf

Invitation to register as academic stakeholder

- Registration benefit: to be kept in the loop and be approached for opportunities to participate in EMA activities, e.g., exchange or collaboration on general regulatory science matters

- If your organisation is not-for-profit and active in the field of medicines or regulatory science, please contact academia@ema.europa.eu: EMA will send a link to register your organisation
- Individuals can register here: https://fmapps.ema.europa.eu/stakeholders/signup.php

- Background: https://www.ema.europa.eu/en/documents/other/emas-individual-stakeholder-database-patients-consumers-healthcare-professionals-academia-frequently_en.pdf

Working at EMA on regulatory science…

EMA Careers portal

Seconded national expert at EMA

- EMA regularly publishes vacancy notes
- SNEs are sought for their high level of professional knowledge and experience
- Contribute expertise and work practically on EMA initiatives and larger projects
- Typical duration is 2-4 years at EMA in Amsterdam
- Experts (have to) remain in their contract with employer from academic sector; employer will be reimbursed and SNE can benefit from subsistence allowance

- https://careers.ema.europa.eu/content/Seconded-National-Experts/?locale=en_GB
- https://www.ema.europa.eu/en/documents/other/decision-executive-director-rules-governing-secondment-national-experts-ema_en.pdf

EMA Careers portal

Collaboration expert at EMA

- EMA publishes vacancy notes around May and intermittently
- CEs are sought for collaborative research activities of public and animal health interest
- CEs can work remotely and on site as needed, variable duration
- CEs remain in contract with their employer
- Typical output is a presentation, report or joined scientific publication

- https://careers.ema.europa.eu/content/Collaborating-Expert/?locale=en_GB
- https://www.ema.europa.eu/en/documents/other/policy-80-european-medicines-agency-policy-use-expertise-specific-tasks-be-undertaken-agency_en.pdf

EMA Careers portal

Traineeship at EMA

- 1 Oct to 31 July. EMA invites applications annually around August
- 10 months at EMA in Amsterdam, work on specific projects, integrated in core activities
- Trainees gain experience relevant to their professional background and career
- Monthly stipend, travel contribution, mentor, progress monitoring, structured competency development, networking, make an impact

- https://careers.ema.europa.eu/content/Traineeship/?locale=en_GB
- https://www.ema.europa.eu/en/documents/recruitment/decision-executive-director-rules-governing-traineeship-programme-ema_en.pdf

EMA Careers portal

…and contributing to advances in regulatory science

2023

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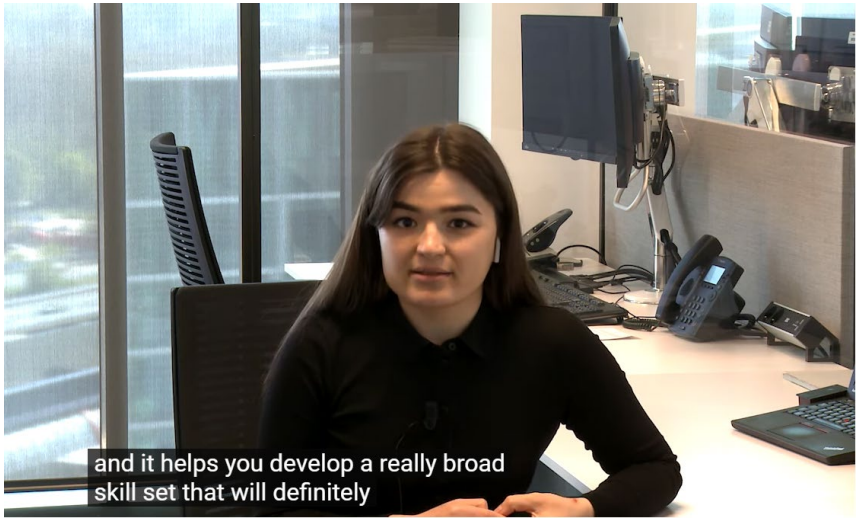

https://www.ema.europa.eu/en/news-events/publications/scientific-publications

https://www.youtube.com/watch?v=TpXz7seHOiw

What is EMA’s Regulatory Science Strategy to 2025

Collaboration with academia on regulatory science activities

The Regulatory Science Strategy to 2025 is a plan for advancing EMA's engagement with regulatory science over the next five to ten years, covering both human and veterinary medicines.

The strategy aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine.

Key points about academia collaborating with EMA

- Academia are important stakeholders for EMA, across ways of engagement
- EMA offers not-for-profit developers a comprehensive set of support options

- EMA is increasing engagement with academia for regulatory science, on a broad range: from tackling difficult regulatory issues with the scientific method to providing training

- Academia involvement benefits regulatory science and thus public and veterinary health
- Advancing regulatory science will accelerate novel developments
- Multi-stakeholder collaboration is needed for many regulatory science topics

Acknowledgements

- Tony Humphreys, Regulatory Science and Innovation Task Force
- Maribel Rico-Salas, Academia liaison
- Helene Casaert, SME office

Thank you for your invitation

Further information

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