EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cancer medicine development and use – EMA Regulatory Science Strategy 2025

Cancer Drug Development Forum Spring conference
Noordwijk aan Zee, The Netherlands

2020-02-12 Ralf Herold; Oncology, Haematology and Diagnostics office

Disclaimer

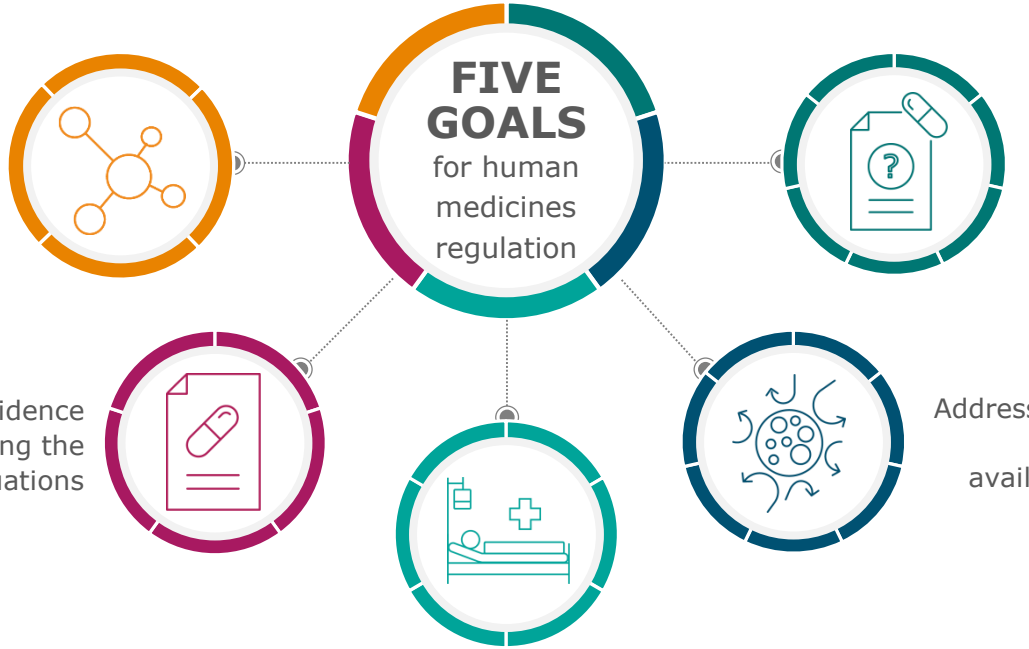
The views expressed in this presentation are the personal views of the author(s) and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

Vision for Human medicines

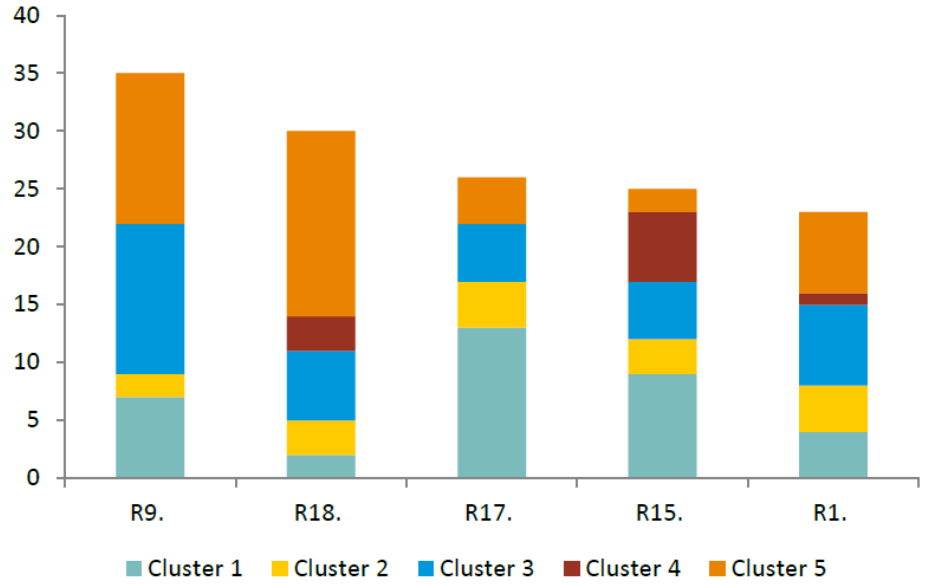
"To underpin its mission of protecting human health, EMA must catalyse and enable regulatory science and innovation to be translated into patient access to medicines in evolving healthcare systems."

https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-2025

EMA Regulatory Science to 2025



Overall aggregate ranking of core recommendations – Top 5



9. Foster innovation in clinical trials

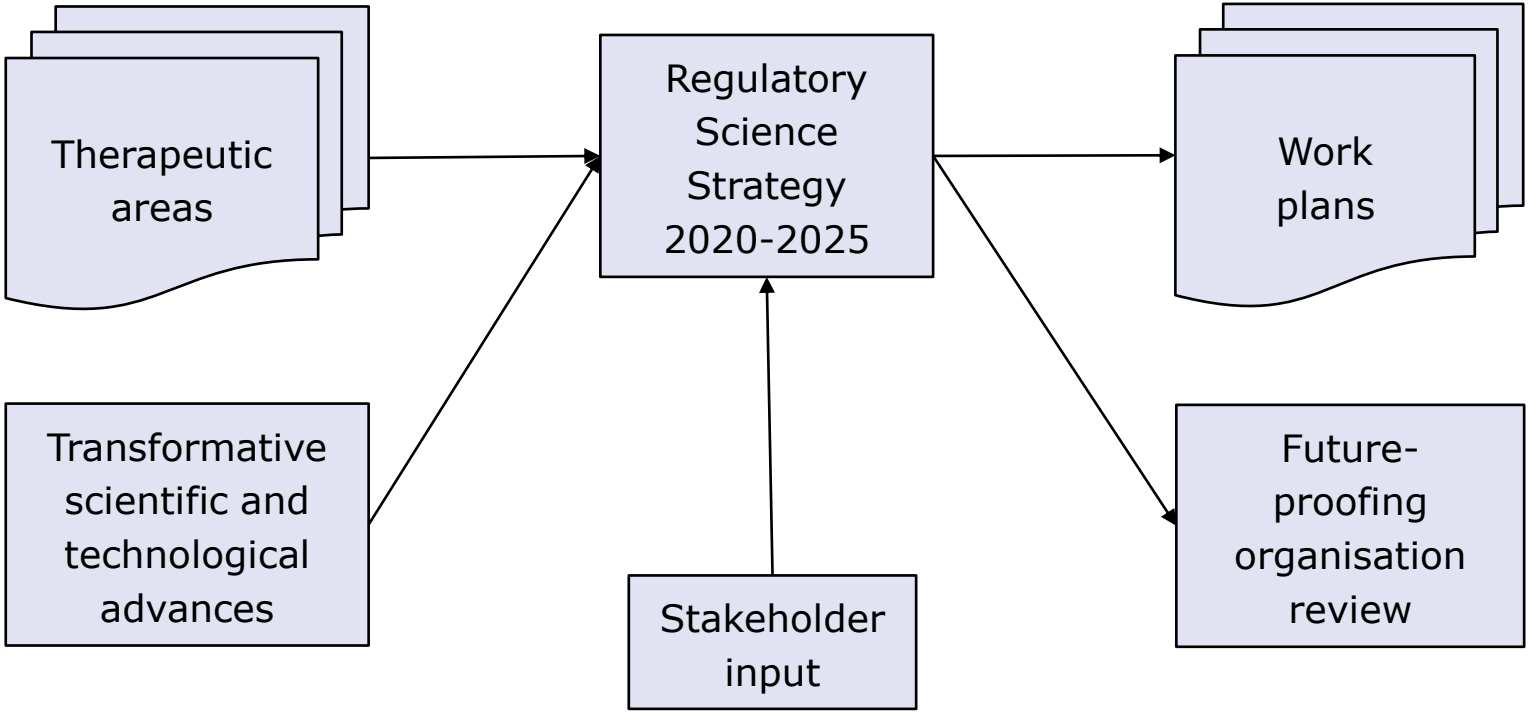
18. Promote use of high-quality real-world data (RWD) in decision making

17. Reinforce patient relevance in evidence generation

15. Contribute to HTA's preparedness and downstream decision making for innovative medicines

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

https://www.ema.europa.eu/en/documents/presentation/presentation-ema-regulatory-science-2025-overview-outcome-publication-consultation_en.pdf#page=14



Examples of underlying actions relevant for oncology

- Expand the B/R assessment by incorporating patient preferences and PROs
- Apply structured B/R assessment to improve communication to the public
- Improve communication with HTA and payers (context, comparators, patient perspective)
- Progress implementing paediatric medicines action plan and geriatric strategic plan
- Assess clinical value of new endpoints and role in patients' access to new medicines
- Promote more integrated development aligning Scientific Advice, Clinical Trial approval, GCP oversight
- Support developments in precision medicine, biomarkers and 'omics'
- …

Based on workshop November 2019 https://www.ema.europa.eu/en/events/multi-stakeholder-workshop-draft-regulatory-science-2025-strategy-stakeholders-human-medicines

Summary

EMA Regulatory science strategy 2020-2025

- Is a motor for improving oncology drug development
- Is the framework for improving oversight and support to activities in oncology
- Enables to focus on the value of cancer medicines to patients and to improve the quality of decisions from oncology discovery to access
- Broad support from stakeholders for many types of actions important for cancer patient
- Needs continued stakeholders engagement in delivering actionable areas
- Need to leverage NCAs and International Regulators' regulatory science programmes
- Need collaboration to deliver: EC, EP, NCAs, HTA, Payers, Medical Device Authorities

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- Francesco Pignatti
- Philip Hines

Thank you for your attention

Further information

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