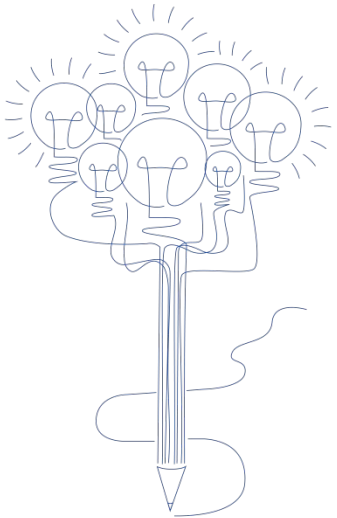
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Responding to the needs of the 21st century patient: Addressing challenges and opportunities across the European Regulatory Framework



EMA's Regulatory Science Response

Human Stakeholders Workshop

Presented by Hans-Georg Eichler on 24 October 2018
Senior Medical Officer, EMA

An agency of the European Union

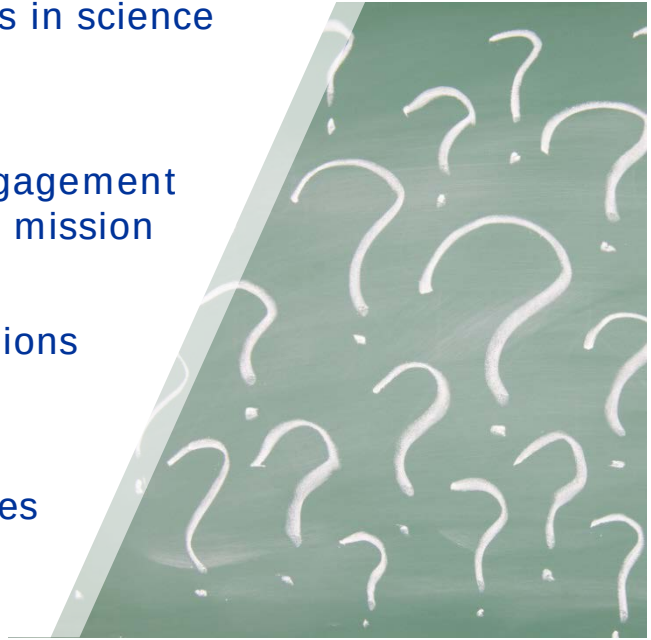
Why now?

To monitor and sign-post emerging and future trends in science and technology

To identify key priorities where new or enhanced engagement is essential to the continued success of the Agency's mission

To prioritise use of resources and external collaborations to strategically advance regulatory science

To shape and influence the vision for the EU Medicines Agencies Network (EMRN) Strategy 2020–25



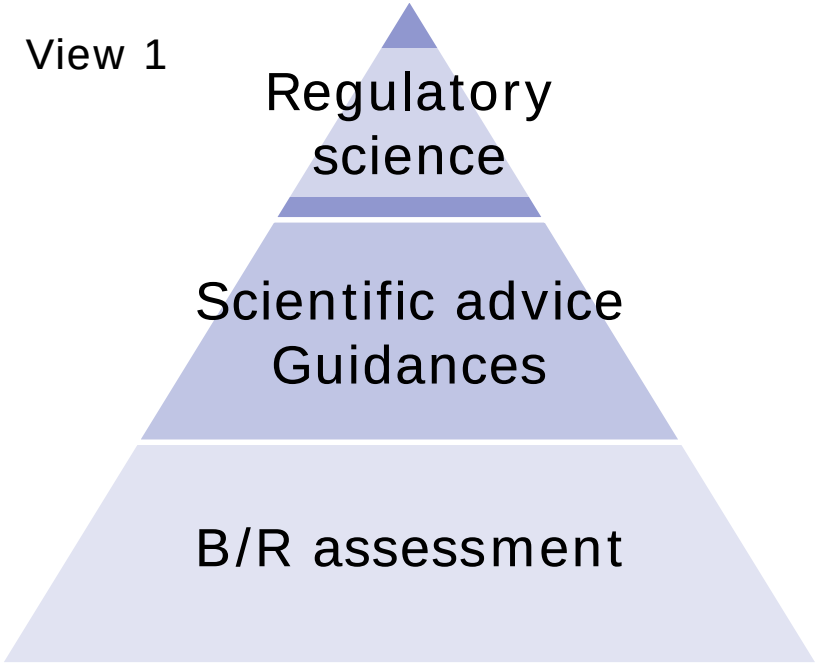
How does EMA define Regulatory Science?

Regulatory science is defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine.

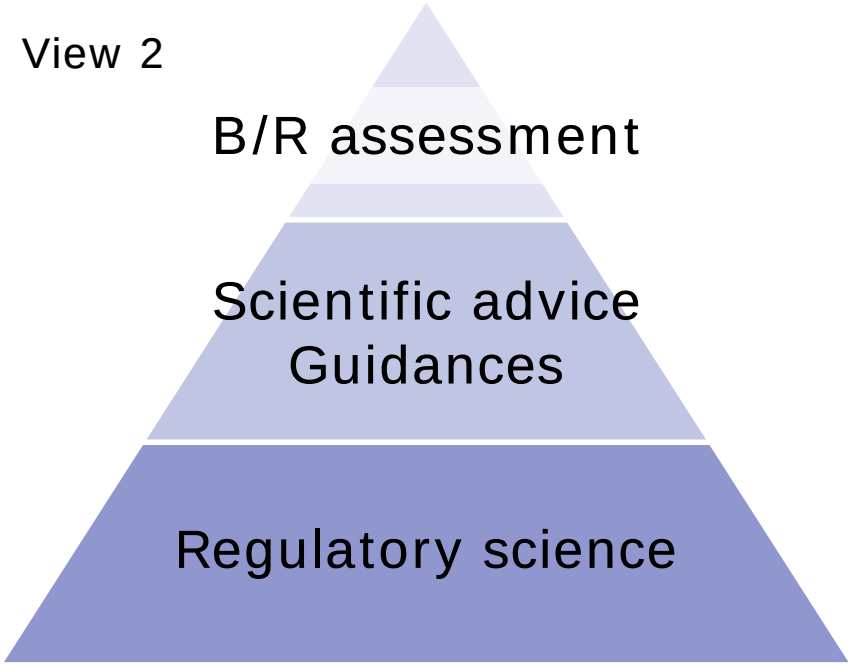
It encompasses basic and applied medicinal science and social sciences, and contributes to the development of regulatory standards and tools.

The role of regulatory science at EMA?

View 1



View 2

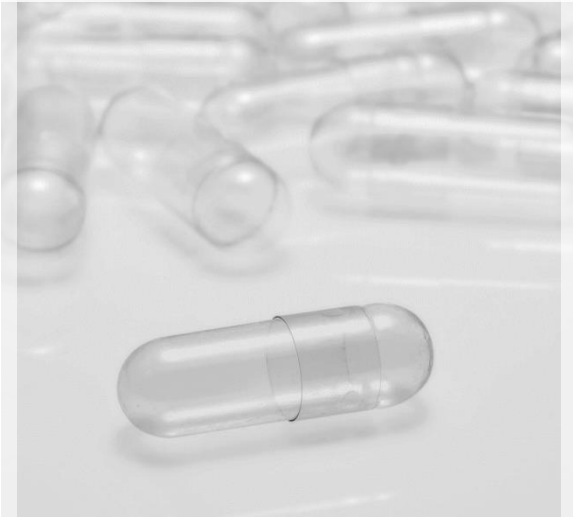


Case studies in regulatory science

Real world data

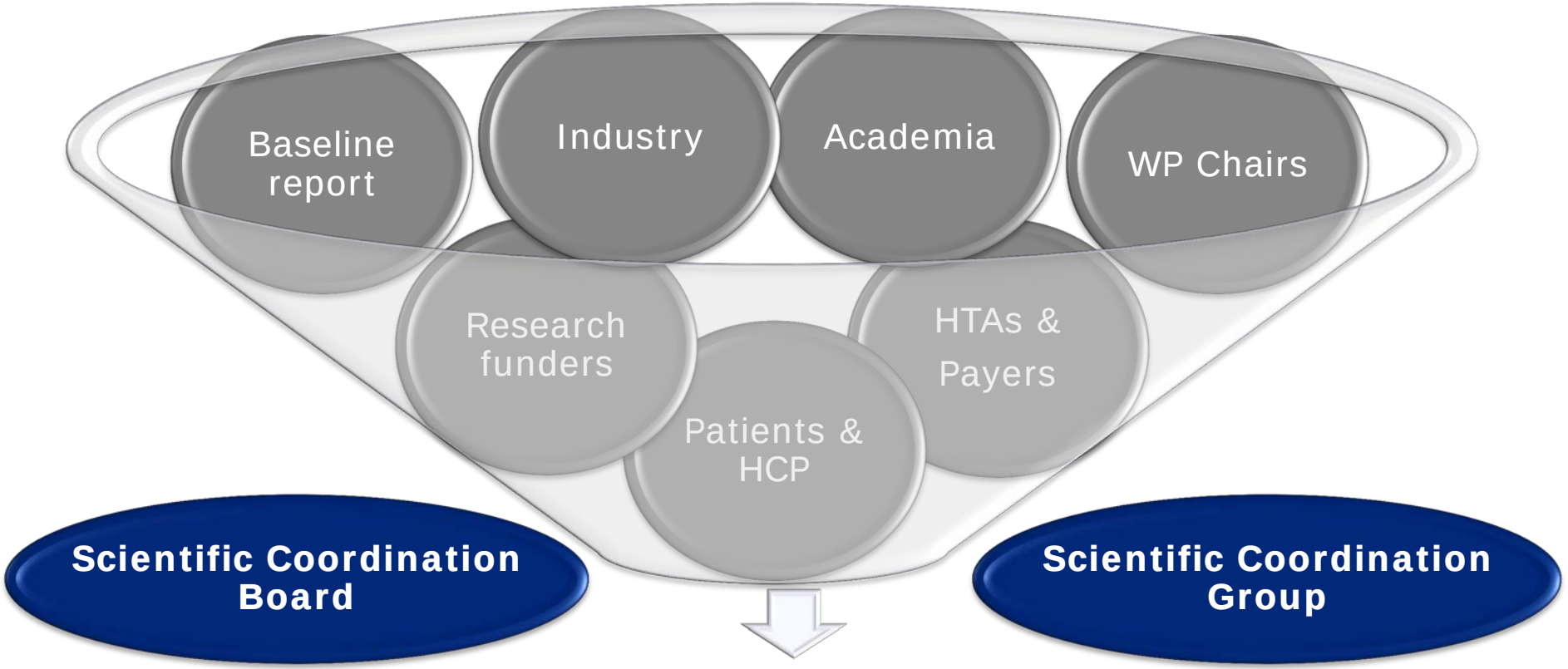
Estimands

Transparency of CT



Vision—EMA Regulatory Science to 2025

> 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.



Regulatory Science to 2025

Strategic goal 1

To catalyse the integration of science and technology in drug development.

Strategic goal 2

To drive collaborative evidence generation to improve the scientific quality of evaluations.

Strategic goal 3

To advance patient-centred access to medicines in partnership with healthcare systems.

Strategic goal 4

To address emerging health threats and availability/therapeutic challenges.

Strategic goal 5

To enable and leverage research and innovation in regulatory science.

EMA Regulatory Science to 2025—Timeline

Legislation follows science, not the other way round: implication for future EU legislation?

Meet the speakers

EUROPEAN MEDICINES AGENCY

Simone Boselli, EURORDIS

Biljana BORZAN, European Parliament

Olga Solomon, European Commission

Karl Broich, HMA Management Group

Alan Morrison, EFPIA