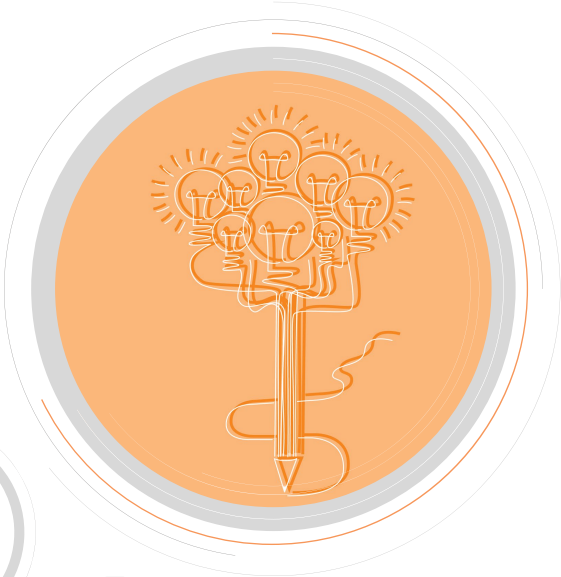
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Optimise capabilities in modelling, simulation and extrapolation



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Bruno Sepodes, CHMP, Anja Schiel, SAWP on 19 November 2019
Presented by Efthymios Manolis, Scientific Advice, EMA

Disclaimer

Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

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Optimise capabilities in modelling and simulation and extrapolation

- Enhance modelling and simulation and extrapolation use across the product lifecycle and leverage the outcome of EU projects
- Promote development and international harmonisation of methods and standards via a multi-stakeholder platform
- Increase capability and redesign the operations of relevant working parties to ensure wider knowledge exchange

Enhance modelling and simulation and extrapolation use across the product lifecycle and leverage the outcome of EU projects

- The CMC / Quality arena is a rich field of scientific and innovative approaches using modelling, simulation and prediction that could be utilised, for example:
  - Stability modelling and prediction of degradation.
  - Process modelling (e.g. development of a digital twin) of a manufacturing process to support development and scale up and control strategy development.
  - Models built from prior knowledge that can support post-approval and the setting of clinically-relevant specifications.
  - Modelling to support bioequivalence evaluation.
- Predictive and modelled approaches to safety evaluation (for active substances, impurities and manufacturing intermediates) that minimise animal utilisation is a current field of interest that demands further investment and acceptance.

Enhance modelling and simulation and extrapolation use across the product lifecycle and leverage the outcome of EU projects

- In Silico Trials should be at the core of the EMA strategy.
- If computer models can guide the diagnostic, prognostic, or therapeutic decision for individual patients, why should they not be able to advise on the safety and efficacy of new medical products?
- Increasing acceptance of predictive approaches, based on modelling, simulation and extrapolation will advance the clinical development of medicines.
- Accepting modelling (and surrogate) endpoints for clinically relevant outcomes measures.

Enhance modelling and simulation and extrapolation use across the product lifecycle and leverage the outcome of EU projects

- Extrapolation in a paediatric patient population in CNS.
- M&S in longitudinal dose response analyses in Phase 2 trials; use within adaptive designs.
- Disease modelling to support clinical relevance of treatment and long-term value demonstration in brain disorders.

Promote development and international harmonisation of methods and standards via a multi-stakeholder platform

- EMA must provide guidance for the inclusion of advanced models into drug development.
- Collaborating more with other regulatory authorities regarding acceptance of innovative approaches.

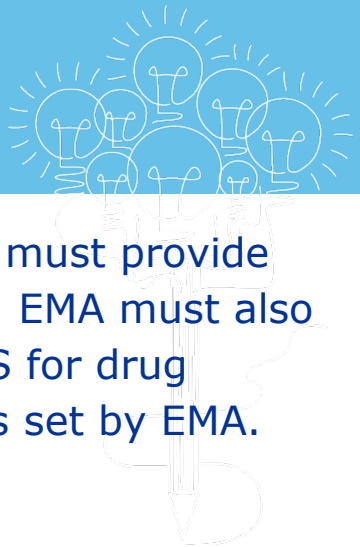
Increase capability and redesign the operations of relevant working parties to ensure wider knowledge exchange

- Modelling/Simulation and Extrapolation require a culture change and a new interdisciplinary operational model.
- Having quantitative experts in all the EMA committees and their respective EMA teams to bridge with the quantitative working parties would be already a great asset. Otherwise quantitative tools will never be integrated in regulatory decision to their full potential.
- Invest in Centres of Excellence in Regulatory science at an EU level, to work with regulatory agencies to provide training and research on Modelling & Simulation tools.
- Collaborating more with other partners e.g. IMI.

Data sharing

- Off-patent medicines could be a learning opportunity on gathering evidence through real-life use data and modelling, simulation and extrapolation.

Artificial Intelligence (AI)



- As advances in MS, including machine learning and AI, continue, EMA must provide guidance for the inclusion of advanced models into drug development. EMA must also effectively educate industry and academic stakeholders engaged in MS for drug development to ensure tools are developed according to the standards set by EMA.

Any questions?

Further information

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