Development of regulatory science strategy to 2025

01 Baseline review and horizon scan: 2017–2018

A baseline review and horizon scan was conducted across 60 areas of science, technology and health, including regulatory science.

02 Stakeholder interviews: 2017–2018

To validate these internal findings, 55 semi-structured and 15 open interviews were conducted with external experts and opinion leaders from EMA's key stakeholder groups.

03 Analysis phase I: 2018

Interviews were analysed using open and axial coding. The resulting themes and sub-themes were then mapped onto the outputs of the baseline review and horizon-scanning, and formed the basis of a draft set of regulatory science strategic goals, each comprising a series of core recommendations and underlying actions.

04 Agreement of Strategic Reflection: 2018

Goals, recommendations and actions were then reviewed and refined by EMA's scientific leads and the Scientific Coordination Board, to form the Regulatory Science to 2025 strategic reflection document.

05 EMA multi-stakeholder workshops: 2018

The draft reflection paper was presented and discussed at a multi-stakeholder workshop for human medicines (Nov 2018) and at another workshop dedicated to veterinary medicines (Dec 2018).

06 Public consultation: 2019

The strategic reflection paper was launched for a six-month public consultation. Responses were captured using an online survey tool, eliciting both qualitative and quantitative feedback.

07 Analysis phase II: 2019

A total of 150 responses to the survey were received. The qualitative results underwent framework analysis, whilst the quantitative results were used to produce ranking and descriptive statistics. The preliminary data analysis was used to prioritise core recommendations.

08 EMA multi-stakeholder workshops: 2019

The prioritised core recommendations were discussed with academia, patients, healthcare professionals, consumers, industry and EU regulatory partners and institutions at two workshops, for human and veterinary medicines, respectively. Feedback on these priorities, and their implementation, was gathered.

09 Final EMA Regulatory Science Strategic Reflection to 2025

Feedback and analysis from the public consultation and workshops was used to update the draft strategic reflection. This finalisation involved EMA's scientific leads, Scientific Coordination Board and committees.

This image is taken from:
Philip A. Hines, Rosanne Janssens, Rosa Gonzalez-Quevedo, Apolline I.O.M. Lambert, Anthony J. Humphreys; A future for regulatory science in the European Union: the European Medicines Agency's strategy, Nature Review Drug Discovery, Comment 31 March 2020.
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