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

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.

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.

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.

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.

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.

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.