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Supplementary Information

Regulatory Science and Innovation Programme for Europe (ReSciPE): a proposed model

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Table S1: Areas of regulatory science and innovation subjected to horizon-scanning

Science & technology	Regulatory science tools	Health threats	Environment	International regulatory science cooperation
<ul style="list-style-type: none"> * Major therapeutic areas (oncology, CNS – neurodegeneration, CNS-psychiatry, diabetes, obesity, HIV, vaccines, immunotherapy, etc.) * Gene therapy and regenerative medicine (cells and tissue-based products, novel materials) * Personalised/precision medicine and biomarkers * Methods, technologies, etc. (nanotechnology, ‘omics, disease taxonomy, digital health and wearable technology, novel manufacturing and 3-D printing) 	<ul style="list-style-type: none"> * Access pathways (PRIME, adaptive pathways, biosimilars, synergies with HTAs and payers) * Non-clinical methodology (novel models, application of 3Rs in medicines development) * Clinical methodology (modelling and simulation, extrapolation, patient-reported outcomes, new endpoints, Bayesian methods, co-acting medicinal products, novel clinical trials) * Special populations (paediatric, geriatric, pregnancy) * Risk-benefit evaluation * Big data and e-Health (real world evidence, open science, cognitive computing) * Communications (social and behavioural science) * Pharmacoepidemiology and pharmacovigilance 	<ul style="list-style-type: none"> * AMR * Emerging threats 		