EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory Science Research Needs

2025 update

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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14 July 2025
EMA/510633/2024

Regulatory Science Research Needs

2025 update

Executive summary

Gaps exist in regulatory science that need to be addressed to improve medicine development and evaluation, to ultimately enable access to medicines that address patients' needs. Regulatory science applies scientific disciplines to developing and evaluating medicines and medical devices as well as to advancing regulatory tools, standards and the regulatory system's evolution. Research into regulatory science aims to address repeat issues in development and evaluation as well as gaps that hinder regulatory advancement.

The Regulatory Science Research Needs (RSRN) are organised currently into four sections to encompass a wide range of priority topics related to improving clinical research; improving regulatory system evolution; leveraging technologies for development of specific types of medicines; and advancing animal health and the regulation of veterinary medicines. This update resulted from a cross-Agency process and an external consultation collecting topics that will benefit from engaging external researchers.

By highlighting these research needs, the goals are to stimulate academic and multi-stakeholder research in these fields; to encourage researchers to consider in their area of work the regulatory and public health challenges and opportunities; to help researchers identify topics of common interest for interactions such as in the EMA/HMA European Platform for Regulatory science research[1] and for exploring with researchers pathways for translating results into solutions; and to offer the research needs for the awareness of funders so as to support their scoping of funding calls. The list of needs will be further evolved into a living document, updated periodically to ensure ongoing engagement as new topics are identified.

[1] European Platform for Regulatory Science Research, https://doi.org/10.1038/d41573-025-00024-y

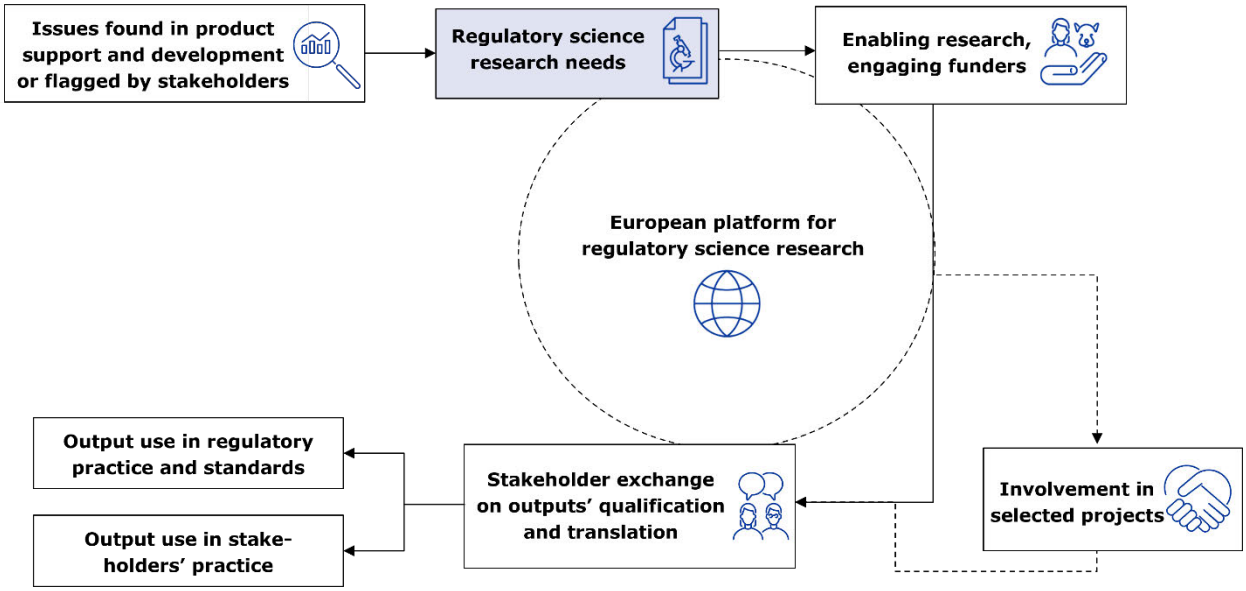
1. Introduction

1.1. EMA advancing regulatory science

In 2020, the EMA Regulatory Science Strategy to 2025[2] set the foundation for several initiatives and actions aiming at ensuring that the EU Medicines regulatory network has the regulatory tools to fulfil its mission in face of new scientific challenges. The emergence of new types of medicines, innovations in research and development (R&D), novel methods to perform clinical trials and experiments are examples of opportunities but also of challenges from a regulatory perspective.

The Regulatory Science Research Needs (RSRN) initiative aims to identify such challenges and opportunities in order to formulate them as needs for research that could help fill gaps in the regulator's ability to assess medicinal products and deliver public health benefits. The RSRN initiative is part of EMA's activities to systematically advance regulatory science through research (Figure 1).

Figure 1: EMA activities to advance regulatory science research



Issues found in product support and development, or flagged by stakeholders. Challenges in medicine development and regulation are identified from several sources, e.g. by screening internal reports, from questions that arise in interactions with medicine and methodology developers, from publications, by horizon scanning activities and from interviews with internal experts, as described in section 3.

Regulatory Science Research Needs. The identified challenges are formulated as research questions which if addressed will help fill the gaps in regulatory science. As part of the systematic approach to formulate the research questions, the type of research gaps[3] and concerned scientific disciplines[4] are presented in section 2.

[2] https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy
[3] Research gaps in, e.g., problem evidence, theory, concept, knowledge, methodology, empirical data, population
[4] Type of disciplines, e.g., natural, social, formal or applied sciences; wet- or dry-lab research; desk-based research

The research needs are mainly for researchers and funders to support them in delivering research outputs that have relevance also for filling gaps in regulatory science. Researchers and scientists mainly work in the academic sector, and some work in the for-profit-sector and at regulatory agencies; the RSRNs will mostly benefit from research that includes collaborations between groups, disciplines and stakeholders.

Enabling research, engaging funders. Enabling research on the identified topics involves different lines of activities:

1. Researchers working on RSRN topics or interested in working on RSRN can engage with EMA, present their research and explore areas of common interest via direct contact with the Regulatory Science and Academia Workstream at regulatory.science@ema.europa.eu;
2. EMA provides technical information on regulatory science upon request to European funders and has raised awareness internationally about the RSRN to support the uptake of relevant topics in considerations for funding calls;
3. EMA invites regularly tenderers for a framework contract on quality, efficacy and safety studies on medicines[5] which can cover a variety of research in RSRN focus areas to support the delivery of relevant research outputs, such as on translational questions, medicine use in pregnancy and breast-feeding, decision-making in public health and animal health, methodology and statistics, experience of patients and healthcare professionals, risk minimisation measures, non-interventional studies, innovative technologies for manufacturing and quality control, computational methods for comparison of molecular structural features.

Involvement in selected projects. EMA is involved in selected publicly-funded research projects, with different roles.[6] The aim is to contribute to, and closely monitor, relevant research outputs that might directly impact the EU regulatory system by facilitating the adoption of practical solutions that benefit public and animal health.

Exchanging with stakeholders on the qualification and translation of outputs. To ensure that the output of regulatory science research is translated into impactful solutions in regulators' or stakeholders' practices that ultimately support public and animal health, several activities are required to stimulate meaningful changes in the long term:

1. EMA is involved in selected research projects or is exposed to outputs and potential solutions at an early stage, so that EMA can stimulate internal discussions on topics of relevance.
2. EMA maintains a dynamic exchange with trade associations and academic developers on RSRN topics. These discussions allow the development of principles, recommendations, priorities and approaches that can help the translation of research output into practical applications in R&D and improved regulatory standards and practices.
3. To support the relevance of solutions, EMA welcomes developers of regulatory science solutions at an early stage, e.g. via EMA's contact for regulatory science and regulatory science research

[5] Procurement | European Medicines Agency (EMA)
[6] https://doi.org/10.3389/fmed.2023.1181702

(regulatory.science@ema.europa.eu), in Academia briefing[7] or Innovation Task Force briefings,[8] and scientific and qualification advice.[9]

4. EMA is building collaborations on regulatory science research topics with experts from academia and the not-for-profit sector via the Collaborating Experts programme[10].

European Platform for Regulatory Science Research. EMA and the Heads of Medicines Agencies (HMA) will launch in early 2025 the European Platform for Regulatory Science Research. The platform aims to advance and accelerate regulatory science research, to increase the quality and impact of research and outcomes, thereby improving regulatory practices, standards, medicines development and use. This includes contributing to research needs identification, exchanging experience on methodology and best practices, and fostering translation of results into practical solutions. The platform is also intended to promote dialogue and foster collaboration between regulatory science researchers and regulators across Europe and beyond.[1]

Integrated presentation of research needs.
This document seeks to provide an integrated presentation of regulatory science research needs. To this end, it details the updated research needs that have resulted from the cross-Agency process outlined above, in section 2.
In addition, research in specific areas, such as arising from multistakeholder interactions indicating regulatory challenges in areas such as artificial intelligence and pharmacovigilance impact research,[11] is carried out by EMA internally, within the EU Medicines regulatory network or with individual collaborating experts.[10]

Overall, the research needs therefore comprise:

- Section 2 (on page 9) research regulatory science research needs
- Vaccine Monitoring Platform (VMP) research agenda
- AI network research priorities roadmap[12]
- ACT EU PA5 Clinical trial analytics research priorities

It should be noted that the EMA as member of the EU Agencies Network on Scientific Advice (EU ANSA) is working with other agencies such as EFSA[13] and ECHA[14] that have published respective research needs, and analogies with this regulatory science research needs concerning medicinal products in this document are being explored.

[7] https://www.ema.europa.eu/en/partners-networks/academia
[8] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/supporting-innovation
[9] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance
[10] See PRAC impact strategy, https://www.ema.europa.eu/en/human-regulatory-overview/pharmacovigilance-overview
[11] https://careers.ema.europa.eu/content/Collaborating-Expert/?locale=en_GB
[12] Which will be based on the AI Action plan (see Artificial intelligence workplan to guide use of AI in medicines regulation)
[13] EFSA https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2025.e220401
[14] ECHA https://echa.europa.eu/research-to-enhance-protection-of-our-health-and-environment

1.2. RSRN opportunities for researchers

The opportunities for researchers are based on the proactive dialogue that EMA is establishing with researchers. These interactions are mutually beneficial, since researchers can receive regulatory orientation and can hear about optimising their case, while EMA gains early exposure to tools, methods and developments that can help future-proof the regulatory environment beyond the case at hand. By engaging with EMA, researchers can more easily translate their outputs into concrete applications and public and animal health solutions, particularly when the application impacts a medicine's lifecycle or requires regulatory assessment.

Researchers working on specific RSRN and with results mature enough to benefit from discussion with EMA topic experts can write to regulatory.science@ema.europa.eu to request such a discussion, referring to the specific topic and research question. Such topic and research question can potentially be brought for discussion to a European Platform for Regulatory Science Research[1] meeting.

1.3. Developments in relation to the RSRN v1 (2021)

Since first published on 15 December 2021, the RSRN v1 list has stimulated interactions with EMA and has allowed various activities to be identified and undertaken in relation to the specific topics.

Examples of RSRN v1-related developments include activities conducted as part of:

- EU projects and public-private consortia, such as funded under Horizon Europe and IHI (with or without involvement of regulatory scientists from the EMA or National Competent Authorities);
- Projects delivered through EMA's Collaborating Experts Programme[15];
- Activities funded through EMA's Framework contract for tenderers of studies into quality, efficacy and safety of medicines.

Examples of EU or global activities that have been informed by the RSRN v1 include:

- Calls for funding proposals;
- EMA focus groups that contribute to leveraging research outcomes (e.g., Focus Group on the Qualification Procedure and the Focus Group on Regulatory Science Research Translation);[16]

[15] https://careers.ema.europa.eu/content/Collaborating-Expert/, whose outputs are among the scientific publications listed here: https://www.ema.europa.eu/en/news-and-events/publications/scientific-publications
[16] https://www.ema.europa.eu/en/events/tenth-industry-standing-group-isg-meeting

- Scientific publications or monographs such as on research management,[17,18] on regulatory support pathways,[19,20,21] on setting priorities[22,23] and on improving methods[24,25] for regulatory research, and on results,[26] each referencing the RSRN v1;

The work in relation to RSRN is conducted in concertation with other EMA initiatives and pilots, such as the ATMP pilot, real-world evidence studies, Emergency Task Force activities.

[17] Arnouts S et al. Technology Readiness Levels for vaccine and drug development in animal health: From discovery to life cycle management. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9811140/
[18] Berkner S et al. Too advanced for assessment? Advanced materials, nanomedicine and the environment. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9378259/
[19] Kallio MJ et al. Translating Academic Drug Discovery Into Clinical Development: A Survey of the Awareness of Regulatory Support and Requirements Among Stakeholders in Europe. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10099080/
[20] Massella M et al. Regulatory Considerations on the use of Machine Learning based tools in Clinical Trials. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9638313/
[21] Saesen R et al. Advancing academia-driven treatment optimisation in oncology: Launch of the EMA Cancer Medicines Forum. https://www.ejcancer.com/article/S0959-8049(22)00169-1/fulltext
[22] Pasmooij AMG et al. The Evolution of Drug Regulatory Sciences in the Netherlands: More than a Country Report. https://onlinelibrary.wiley.com/doi/abs/10.1002/cpt.3275
[23] Reddy N et al. Regulatory landscape of alternatives to animal testing in food safety evaluations with a focus on the western world. https://www.sciencedirect.com/science/article/pii/S0273230023001381
[24] Stevens ER et al. Enhancing the quality and efficiency of regulatory science literature reviews through innovation and collaboration with library and information science experts. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2024.1434427/full
[25] Barrett JS et al. Generation and interpretation of big data in pediatric drug development. In: Essentials of Translational Pediatric Drug Development. https://www.sciencedirect.com/science/article/pii/B9780323884594000122
[26] Whittaker HR et al. Eligibility of patients with chronic obstructive pulmonary disease for inclusion in randomised control trials investigating triple therapy: a study using routinely collected data. https://doi.org/10.1186/s12931-024-02672-x

2. List of regulatory science research needs: 2025 update

2.1. Structure and overview on research needs and types of research

This part of the document details the regulatory science research needs in sections with those needs that 1) improve clinical research; 2) improve regulatory system evolution; 3) foster technologies for development of specific novel medicines; and 4) advance specifically animal health and the regulation of veterinary medicines. In line with the One Health approach, some of these topics also reflect a holistic perspective that recognises the interconnection of human, animal and environmental health.

Each **section** has several **focus areas** with several **research needs** encompassing several **priority topics**. Specific identifiers such as **RSRN-2025-CT1-1** indicate the version update (2025), the research need (CT1) and the priority topic (1).

Each **research need** is associated with keywords and domains of impact of the research, which can help to navigate the list and find topics of interest.

Additionally, each **priority topic** is associated with letters that define the **type of research** that is thought relevant for addressing the topic. Multiple letters mean that the topic touches different or overlapping research fields, or that it might benefit from complementary or synergistic research approaches. The types of research are categorised as follows:

- **(A) Natural sciences**: disciplines such as biology, chemistry, physics, which make use of rigorous scientific methods, including observation, controlled experiments, analysis, mathematical models and empirical evidence.
- **(B) Social sciences**: fields such as sociology, political science, economics, policy science, which mainly employ qualitative methods (such as interviews, focus groups, etc.), and analyse policy and social dynamics, societal patterns and matters relating to decision-making.
- **(C) Formal sciences**: fields such as logic and mathematics, which make use of language tools and abstract structures.
- **(D) Applied sciences**: disciplines such as medicine, biomedical engineering and genetic epidemiology, where scientific knowledge and research are applied to achieve tangible goals, solve real-world problems and improve systems and technologies.
- **(E) Wet-lab research**: experimentation in laboratory settings.
- **(F) Dry-lab research**: computational and theoretical research, in other words by using computer systems, coding and data analysis to generate new information and data outputs.
- **(G) Desk-based research**: literature reviews, synthesis of relevant existing data and analysis of existing information, often from published sources or retrievable under request.

The following Table 1 provides an overview as counts of research needs and their priority topics within the respective needs section.

Table 1: Overview of 2025 updated RSRNs

Sections with Research needs to ...	Number of research needs	Number of priority topics
2.2. …improve clinical research	9	25
2.3. …improve regulatory system evolution	11	35
2.4. … foster technologies for development of specific types of medicines	14	35
2.5. … advance specifically animal health and the regulation of veterinary medicines	15	27
Total	49	122

The following Figure 2 indicates the relative frequencies of keywords that characterise the research needs in this 2025 update.

Figure 2: Word cloud of priority topics

2.2. Research needs to improve clinical research

This section includes 9 research needs and 25 priority topics to develop clinical trial methodologies and advance clinical trial design, thereby enhancing the flexibility, speed, and quality of clinical trials.

The needs in this list touch upon statistical analysis in clinical trials, innovative approaches in clinical trial design and the optimisation of clinical trials in specific therapeutic areas.

Researchers working on these RSRN topics or interested in working on RSRN can engage with EMA via direct contact with the Regulatory Science and Academia Workstream at regulatory.science@ema.europa.eu.

RSRN ID	Research need	Priority topic	Keywords	Impacted domain
Focus area: Statistical analysis in clinical trials				
CT1	Research on use of the estimand framework ICH E9(R1)	1. Develop principles for aligning estimation methods with targeted estimands for intercurrent event strategies, including hypothetical scenarios (C; D; F) 2. Develop principles for applying causal inference approaches to clinical trials in the estimand framework (C; D; F) 3. Identify commonalities between the estimand framework and frameworks for HTA assessment (e.g., PICO) and generate recommendations on how they could be aligned based on methodological principles (C; D; G)	• Study design • Statistical analysis • Estimands	Human and Veterinary medicines Health technology assessment
CT2	Research to enhance robustness of non-randomised studies	1. Develop a framework of multiple dimensions and criteria for the rigor and quality of non-randomised clinical trials including contextual considerations (e.g. challenges with rare diseases or certain technologies) (C; D; G)	• Statistical analysis • non-randomised clinical trials • Clinical trials	Human medicine
CT3	Research on analytical methods for clinical trials	1. Perform a review of elicitation and data-driven methods for priors for Bayesian analyses of clinical trial results to inform clinical and regulatory decision-making, and identify use-cases that would particularly benefit from using such priors (focus on rare and ultra-rare diseases, special populations and other areas of high unmet medical needs) (B; C; G) 2. Research multiple bias modelling in evidence synthesis and analysis, to inform regulatory decisions (C; G)	• Statistical design • Statistical analysis • Rare diseases • Several therapeutics areas • Orphan medicines • Clinical trials	Human medicine

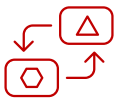
Focus area: Innovative approaches in clinical trial design				
CT4	Research on methods to improve efficiency of design and analysis methodologies for trials	1. Perform a comparison of methods to use non-concurrent arms, including handling time trends, in platform trials (G) 2. Research hierarchical / multi-level modelling approaches for analyses of efficacy endpoints in complex or personalised treatment trials (C; D; G) 3. Conduct a review of features of medicines and of trial participants that are relevant for expressing their independency with respect to considerations for "type 1 error control" (e.g., when included in arms, periods, groups or other elements of platform trials) (G) 4. Develop with stakeholders a protocol for, and prepare the conduct of a multi-stage or platform trial that establishes a new early efficacy endpoint(s) and uses this endpoint in future participants in the trial to investigate the efficacy of an investigational product(s) (e.g. vaccines targeting low incidence, high risk nosocomial infections) (G) 5. Research ways of constructing ordinal endpoints that include functional improvements or impairments and favourable or detrimental events, and simulate its impact on trial efficiency using past trials (F; G) 6. Perform an analytical and simulation-based comparison of designs for first-in-man oncology studies in terms of efficiency and patient benefit-risk (A; C; F; G) 7. Review stakeholder positions and arguments (covering ethics, policies, pharma-cology, medicine) concerning diversity, equity and inclusion, analyse the impact and implications for various activities in particular clinical research and medicine development (B; G)	• Clinical trials • Platform trial • Complex trials • Oncology • First-in-man studies	Human medicine

CT5	Research on EU capacity and operational aspects of clinical trials	1. Develop a mapping and quantification of key challenges for sponsors (commercial and non-commercial) to efficiently plan, resource, set-up and conduct multinational clinical trials in the EU (and beyond) (B; G) 2. Perform gap analysis and quantify capacities and competencies (e.g., researchers, organisations, infrastructure) in the EU for carrying out master protocol-based trials, large, simple pragmatic or low interventional clinical trials in the EU (and beyond; to include aspects of health care systems, health professionals formation etc.) (B; G) 3. Map clinical trials with decentralised elements (e.g., over time, geography, therapeutic area, types of elements) and perform trend analyses to describe challenges and opportunities (if possible, including the impact of the EU DCT recommendations[27]; B; G) 4. Research including a survey and interviews into the local, regional and country-specific availability and usability of existing electronic health care record, hospital and medical practice IT systems for screening persons and recruiting subjects into clinical trials (B; G)	• Clinical trials • Network capacity • Decentralised clinical trials	Human medicine
Focus area: Clinical trials optimisation in specific therapeutic areas				
CT6	Research on innovative clinical trial designs to support medicines development	1. Review complex clinical trials in rare diseases and perform analyses to evaluate design choices, opportunities and avenues to address challenges of drawing conclusions from them (B; G) 2. Research into efficiency of broader options for clinical trial design, broader inclusion of study populations, stratification approaches and analyses, e.g. in obesity and diabetes (G) 3. Research into efficient options for organising and designing clinical research in pre-symptomatic stages of neuro-degenerative diseases for documenting clinical benefits (B; D; F; G) 4. Research to develop non-invasive markers for MASH	• Clinical trials • Advanced therapy medicinal products • Rare disease • Platform trials • Complex trials • Obesity • Neurology	Human medicine

[27] Facilitating Decentralised Clinical Trials in the EU | European Medicines Agency (EMA)

		suitable for clinical trials for regulatory purposes (D; E; G)		
CT7	Research on safety documentation in clinical trials	1. Perform an analysis of clinical trials to inform principles and requirements for collecting and reporting cardiovascular toxicities ensuring scientific strength while reducing burden on clinical trial sites and patients, by using case studies from the following therapeutic areas: 1) oncology; 2) neurology; 3) psychiatry (B; D; G)	• Clinical trials • Side effects • Cardiovascular toxicity	Human medicine
CT8	Research on natural history studies to support medicines development for rare diseases	1. Design protocols and conduct natural history studies to 1) propose and define endpoints for clinical trials in rare diseases lacking authorised medicines and 2) explore their use as comparative groups for clinical trials in understudied rare diseases without internal control, exploring options to handle changes over time in aspects of endpoint definition or documentation (D) 2. Develop approaches that model measurement uncertainty, random and systematic fluctuation (C; F)	• Clinical trials • Natural history • Rare diseases • Orphan medicines	Human medicine
CT9	Research to optimise evidence generation	1. Review clinical trials conducted to support marketing authorisation of medicines to treat solid cancers or malignant haematological conditions to gauge inclusiveness of the concerned populations and identify approaches for effective inclusiveness (including but not limited to factors such as age, ethnicity, sex; B; G)	• Clinical trials • Age • Haemato-oncology • Representation	Human medicine

2.3. Research needs to improve regulatory system evolution



This section includes 11 research needs and 35 priority topics that aim to improve the Agency's regulatory methodologies, standards and practices, thereby optimising the processes and oversight needed to ensure efficiency of the medicines regulatory system. This is expected to help maintain an adaptive and dynamic regulatory system that fosters growth and innovation, while ensuring public trust and reliability.

The needs in this list touch upon research that goes beyond current regulatory pathways, as well as research into the handling of shortages of medicines and medical devices, communication strategies and data management.

Researchers working on these RSRN topics or interested in working on RSRN can engage with EMA via direct contact with the Regulatory Science and Academia Workstream at regulatory.science@ema.europa.eu.

RSRN ID	Research need	Priority topic	Keywords	Domain of impact
Focus area: Going beyond current regulatory pathways				
RP1	Research on the impact of medical devices and medicinal product / medical devices combinations on the medicine's lifecycle and the regulatory system	1. Review and describe the evidence framework and methodological principles for generating scientific evidence underpinning medical devices, medicines and their combination (G)	• Medical device/drug combination • Combination product • Clinical trials • Regulatory framework	Human medicine
RP2	Research on regulatory pathways for medicines and drug development tools	1. Investigate the needs and opportunities for new drug development tools (and technologies) to be supported through new expressions of regulatory endorsement (B; G) 2. Research to develop criteria to inform the regulatory evaluation and assessment of transmission-blocking agents (D; G) 3. Conduct research to identify parameters that influence regulators' reliance on others' assessments globally (B; G) 4. Deepen the research on methodologies, including Bayesian, for indirect comparisons of effects on clinically relevant endpoints between medicines, including use cases in the field of rare diseases (D; F)	• Drug development tool • Regulatory science • Reliance • Rare diseases	Human and Veterinary medicine
RP3	Research on impact of classifications / definitions on regulatory environment	1. Perform a mapping and review of international classifications and assessment frameworks of borderline products to describe their impact on different stakeholders (B; G) 2. Perform a review of criteria used globally for biosimilar assessment, including clinical development (type and amount of data) and critical quality attributes (G) 3. Perform a global, quantitative, geographic and time-related analysis of types of health-related clinical research, covering and going beyond regional regulatory definitions (e.g., "studies", "trials", "low-intervention trials", trials in the health system) to provide a landscape of research, a synopsis of research classifications /	• Clinical trials • Clinical research • International harmonisation • Classifications • Borderline products	Human medicine

RSRN ID	Research need	Priority topic	Keywords	Domain of impact
		terminology, and an overview of types of designs and links with the health system (A; D; G)		
RP4	Research on pharmacological commonalities and the potential for leveraging mechanism of action for studying interventions	1. Perform a descriptive analysis of pharmacological commonalities across diseases and subtypes to leverage a mechanism-of-action approach for investigating therapeutic interventions (G) 2. Perform a scoping review to explore how the mechanism of action-approach can be developed from oncology to other therapeutic areas (in particular neurology, unmet medical needs), taking into account experience with paediatric medicine development (e.g., EU paediatric investigation plans, U.S. required paediatric assessments and written requests) (G)	• Mechanism of action • Paediatric investigation plan • Neurology • Unmet medical needs	Human medicine
Focus area: Shortages				
RP5	Research on shortages of medicines and medical devices globally	1. Perform comparative analysis of different jurisdictions globally in terms of handling shortages of medicines and medical devices (B; G) 2. Perform a qualitative and quantitative analysis of the clinical use patterns of the most used critical medicines in hospital settings across the EU (D; G) 3. Perform quantitative analysis of the rate of export of critical medicines outside the EU (G)	• Shortages	Human and veterinary medicine
RP6	Research on availability of critical medicines and medicines for unmet medical needs	1. Research to update 'white spots'[28] in pharmaceutical development pipelines of unmet medical needs with a particular focus on rare metabolic diseases (B; G) 2. Develop methodologies and perform an analysis of the impact of social media on key medicines' availability, identify factors determining the impact and develop suggestions for suitable interventions or best practices of prevention (B; G)	• Shortages • Social media • Rare disease • Unmet medical needs • Communication	Human and veterinary medicine

[28] https://doi.org/10.1586/17512433.2015.1028918

Focus area: Medicines information and communication				
RP7	Research on approaches to improve communication and engagement on medicines to better address public needs	1. Develop criteria and measurable parameters for credibility and for public trust relevant for EMA (B; G) 2. Develop methods and approaches relevant for EMA to identify and address fake news and misinformation (B; D; F; G) 3. Perform an in-depth analysis of how misinformation on vaccines and population hesitancy is impacting public health (B; G) 4. Perform an analysis of stakeholders' knowledge, needs and perceptions on antimicrobial resistance (AMR)/One Health (B; G) 5. Perform an analysis of stakeholders' knowledge, information needs and perceptions implications concerning gene therapies and other advanced therapy medicinal products (ATMPs) (B; G) 6. Perform an analysis of stakeholders' needs for biosimilar uptake, such as educational needs, in particular on interchangeability (B; G) 7. Perform an analysis of EMA communication output on vaccines (including any new communication materials), including through user testing (G) 8. Develop criteria and measurable parameters to address and assess efficacious communication on benefit/risk information in the package leaflet and medicines' overviews (G) 9. Perform comparative analysis and develop methodological approaches to optimise the use of ePI data and improve medication literacy (G).	• Communication • Public trust • Misinformation	Human and Veterinary medicine
Focus area: Data management				
RP8	Research to improve understanding of data processing opportunities	1. Perform a comparative analysis to inform the development of principles for harmonisation of data protection strategies across regulators and stakeholders (B; G)	• Data management	Human medicine

RP9	Research on tools to improve the use of scientific data	1. Review the most used and impactful models/tools to link and optimise use of heterogeneously structured scientific data, identifying limitations and needs (G) 2. Explore best methodological practices for data management and analysis of regulatory metadata (i.e., information about medicines, development tools, clinical trials, application of standards such as OMOP and ISO), covering descriptive and inferential uses, visualisation and prediction (C; F; G) 3. Explore use of modelling and simulation methods for the analysis of historical data from regulatory submissions for cross-product meta-analyses, including disease progression models to support scientific advice/marketing authorisation applications and regulatory guidance (C; F)	• Data management • Scientific data • Regulatory metadata • Modelling and simulation	Human and Veterinary medicine
Focus area: Pharmacovigilance				
RP10	Research on implementability and implementation of risk minimisation measures (RMM) required as part of the marketing authorisation	1. Perform qualitative or mixed methods studies to understand how typical clinical actions for risk minimisation demanded by RMM are systematically integrated in healthcare processes (e.g. teratogenic risk counselling, annual medication reviews, regular lab testing) and identify en-/disabling factors for RMM integration, including human factors impacting on behaviour change (B; G) 2. Perform qualitative or mixed methods studies to understand dissemination of RMM messages and tools across healthcare and to patients beyond the dissemination required from marketing authorisation holders (e.g. through scientific literature/newsletters, continued medical education, media/digital tools) (B;G) 3. Perform qualitative or mixed methods studies to understand the perception of RMM messages in terms of clinical utility as	• Risk management • Risk minimisation • Patient safety • Healthcare interventions • Patient-centred care • Pharmacovigilance	Human medicine

		discussed in the scientific literature and professional forums (B;G)		
RP11	Research on the applicability and reliability of the use of artificial intelligence in pharmacovigilance processes	1. Perform studies to explore the use of AI approaches to optimise the use of EudraVigilance data in signal management activities (F; G) 2. Perform studies to explore the use of AI approaches to improve knowledge mining of regulatory and public documents routinely used in signal management activities (F;G) 3. Perform studies to explore the use of AI approaches to leverage other data sources rather than strictly regulatory data (e.g., real-world data, genomics data) to contextualise signal findings (F; G) 4. Perform studies to explore the use of AI approaches to improve communication with the public on safety signals (F; G)	• Data management • Scientific data • Regulatory metadata • Modelling and simulation • Pharmacovigilance	Human and Veterinary medicine

2.4. Research needs to foster technologies for development of specific types of medicines

This section includes 14 research needs and 35 priority topics that aim to generate scientific evidence to improve efficacy, safety and protocol optimisation related to development of novel technologies or tools used across medicine lifecycle.

The needs in this list touch upon research on platform technologies and vaccines, tackling antimicrobial resistance, non-animal models and 3Rs-related developments, advanced therapeutic medicinal products (ATMPs), real world data/real world evidence and biomarkers.

Researchers working on these RSRN topics or interested in working on RSRN can engage with EMA via direct contact with the Regulatory Science and Academia Workstream at regulatory.science@ema.europa.eu.

RSRN ID	Research need	Priority topic	Keywords	Domain
Focus area: Platform technologies and vaccines				
NT1	Research on mRNA-based medicines across therapeutic areas with a focus on oncology and rare diseases	1. Generate scientific evidence on efficacy and safety as determined by the type of mRNA (e.g., self-amplifying, trans-amplifying, circular) considered for future medicines in comparison to mRNA types used in authorised medicines (A; D; E) 2. Generate scientific evidence on how molecular	• Platform technologies • mRNA • Oncology • Rare diseases	Human and Veterinary Medicine

RSRN ID	Research need	Priority topic	Keywords	Domain
		features (e.g., coding sequence, backbone, structure), chemical modifications and synthesis pathways are related to clinical safety and efficacy of mRNA-based medicines and can be used for comparing authorised with investigational medicines (A; D; E) 3. Generate scientific evidence on the safety and efficacy as determined by different delivery systems and routes of administration of mRNA-based investigational or authorised medicines (D; E; F)		
NT2	Research on reactogenicity and immunogenicity for novel vaccines combining an increasing number of antigens for different pathogens using the same platform technology (e.g., mRNA-based)	1. Perform studies to define best administration approaches with respect to immunogenicity and reactogenicity in consideration of regulatory assessment requirements (E; G) 2. Comparative studies of the impact of different numbers and types of combined antigens on immunogenicity and reactogenicity and their relation (E; F)	• Vaccines • Immunogenicity • Platform technologies	Human and Veterinary medicine
NT3	Research to inform regulatory assessment of platform technologies	1. Perform a quantitative analysis of how and which changes in platform technologies and point of care manufacturing could impact results of quality, non-clinical and clinical testing of medicinal products (E; G) 2. Explore opportunities and challenges of platform technology approaches for monoclonal antibodies or ATMPs and analyse their potential impacts on regulatory assessment (G) 3. Develop scientific methods to simulate and predict the impact of changes in a platform technology on clinical safety and efficacy (C; D; F; G)	• Platform technologies • Active substance • Monoclonal antibodies • Computational modelling • Machine learning	Human and Veterinary medicine
NT4	Research to strengthen scientific evidence in the field of mRNA vaccines and novel vaccines technologies	1. For a broader set of rare adverse events, perform studies to describe mechanistic, pharmacodynamic and pathophysiological pathways and causal aspects 2. Perform studies to characterise aetiology and pathophysiology of rare	• Vaccines • Immunisation • Adverse drug reaction	Human and Veterinary medicine

RSRN ID	Research need	Priority topic	Keywords	Domain
		adverse events for mRNA vaccines and novel vaccines technologies (A; D; E)		
NT5	Research on potential modifiers of treatment effects	1. Perform appropriately designed clinical trial(s) using different types of vaccines to robustly evaluate and quantitively estimate if and how their treatment effect on immunogenicity depends on and varies with potential factors such as: 1) gut microbiome; 2) time of the day for administration; 3) age; 4) ethnicity; 5) pharmacogenomics; 6) epidemiology of circulating pathogens (A; D; E)	• Vaccines • Immunogenicity	Human medicine
NT6	Research on optimisation of post-authorisation study design	1. Perform a comparison of a set of possible vaccine study designs in the post-authorisation setting with respect to efficiency and robustness (G)	• Vaccines • Post-authorisation studies • Infectious diseases	Human and veterinary medicine
Focus area: Antimicrobial resistance				
NT7	Research to establish standards for phage-based therapies	1. Perform studies to identify elements that determine the potency of phage-based therapies (A; D; E) 2. Perform studies to develop quality standards for phage-based therapies, including to compare and address fixed mixtures as well as mixtures adapted to different therapeutic targets) (A; D; E; F) 3. Perform studies to define manufacturing standards of phage-based therapies (G)	• Bacteriophages • Antimicrobial resistance	Human and Veterinary medicine

RSRN ID	Research need	Priority topic	Keywords	Domain
NT8	Research on development of novel antibiotics	1. Using a multistakeholder approach, develop standards for assays to allow high-throughput screening libraries for new antibiotics (E; G) 2. Using a multistakeholder approach, develop methods to identify potential candidate antibiotics from novel sources such as human and animal "microbiomes" (E)	• Antimicrobial resistance • Antibiotics	Human and Veterinary medicine
Focus area: New approach methodologies (NAMs) / Non-animal models / 3Rs				
NT9	Research to improve regulatory acceptance of 3R methods / NAMs	1. Conduct an analytical comparison of approaches and criteria used by regulators (e.g., EDQM, EMA) to evaluate approval for NAMs, and identify key elements that could support regulatory harmonisation in validation and qualification processes. (G) 2. Develop scientific evidence of clinical predictivity of NAMs for *in vivo* pathophysiology (A; E; F)	• 3Rs • Non-clinical models • *In vitro* models • Modelling and simulation	Human and Veterinary medicine EU regulatory system
NT10	Research on impact of medicines in pregnancy, breast-feeding, neonates	1. Develop non-clinical models to predict transfer of medicines to human breast milk and uptake by the neonate (A; D; E; F) 2. Develop modelling approaches including physiologically based pharmacokinetic (PBPK) models to predict transfer of medicines to human breast milk and uptake by the neonate (A; D; E; F) 3. Review and provide an analytical comparison of the available non-animal models that fit the purpose of measuring the impact on pregnancy, breast feeding, neonates (G) 4. Conduct studies to better understand the effects of using HIV anti-retrovirals during pregnancy and breastfeeding on the foetus and newborn (including a better understanding of U=U levels on breastfeeding) (E; F; G) 5. Conduct a scoping review of methods and strength of evidence concerning pharmacological	• 3Rs • Non-clinical models • Pregnancy • Neonatal medicine • Breast-feeding • *In vitro* models • HIV • Modelling and simulation	Human medicine

RSRN ID	Research need	Priority topic	Keywords	Domain
		mechanisms and factors influencing (aggravating or protecting) embryo and foetal impact of exposure to selected classes of medicines during pregnancy (B; G)		
NT11	Research on modelling and simulation methods to support regulatory decisions	1. Develop models and designs for characterisation of exposure response throughout drug development to support dose selection and posology claims in SmPC, with a focus on special populations (F; G) 2. Perform studies to develop optimal PK (and PD) designs in children to support extrapolation from adults (A; D; E; F) 3. Develop modelling approaches including PBPK for renal/hepatic impairment in elderly patients (A; D; E; F) 4. Develop methods to quantify and report uncertainties in complex models, such as diagnostic and reporting tools to facilitate regulatory decision based on these models (D; F)	• Modelling and simulation • Dose selection • Posology • Special populations	Human medicine
Focus area: Non-clinical models / ATMPs				
NT12	Research on methods to improve regulatory acceptance of ATMPs	1. Perform studies to develop non-clinical efficacy models for therapies based on genome editing (A; E; F) 2. Develop methods to validate predicted or observed off-target effects of genome editing, especially effects on regions with unknown functions (A; E; F)	• 3Rs • Non-clinical models • ATMPs • Genome editing • Side effects	Human and veterinary medicine
Focus area: Real-world data (RWD) / Real-world evidence (RWE)				
NT13	Research on methods to improve use of RWE in decision-making	1. Perform studies on the application of causal inference methods to RWE for medicines, contributing to effective and efficient decision-making (C; D; F; G) 2. Develop/explore methods to assess the robustness of RWE-derived claims for centrally authorised medicinal products and in consideration of products authorised by other regulators (F)	• RWD, RWE • Causal inference	Human and Veterinary medicine

RSRN ID	Research need	Priority topic	Keywords	Domain
		3. Develop methods to understand and possibly mitigate the impact of heterogeneity between RWD sources on the choice of analytical approaches and designs used to take into account this heterogeneity, with a focus on: sample composition; prognostic / risk factors specific to therapeutic areas; nature / type of the data source (C; D; F; G) 4. Perform mapping of medical ontologies and develop cross-dictionary phenotyping to assess the impact of their differences on RWE use and value (G)		
Focus area: Biomarkers				
NT14	Research on predictive biomarkers for patient-tailored treatment of frequent diseases	1. Develop studies for discovering, confirming and validating biomarkers (including multi-modal biomarkers, and AI-based predictive biomarkers) that may predict response to a medicine, with a focus on frequent or chronic diseases such as cardiovascular diseases (A; E; F)	• Biomarkers • Personalised medicine • Cardiovascular diseases	Human medicine

2.5. Research needs to advance specifically animal health and the regulation of veterinary medicines

This section includes 15 research needs and 27 priority topics that aim to ensure the safety and efficacy of veterinary medicines, safeguarding both animal and public health.

The needs in this list include research on non-animal models and 3Rs-related developments, environmental risk assessment, antiparasitic and antimicrobial resistance, pharmacovigilance methods, novel therapies and innovation, vaccines and veterinary big data.

Researchers working on these RSRN topics or interested in working on RSRN can engage with EMA via direct contact with the Regulatory Science and Academia Workstream at regulatory.science@ema.europa.eu.

RSRN ID	Research need	Priority topic	Keywords	Domain of impact
Focus area: New approach methodologies (NAMs) / Non-animal models / 3Rs				
VET1	Research to develop 3Rs-compliant methods for regulatory testing of veterinary medicines and establishment of maximum residue limits	1. Develop methods for quantitative *in vitro/in vivo* extrapolation modelling (A; E; F) 2. Develop *in silico* models specifically for	• 3Rs • Non-clinical models • *In vitro* models • Maximum residue limit • Computational biology • Nanoparticles	Veterinary medicine

RSRN ID	Research need	Priority topic	Keywords	Domain of impact
		veterinary medicines (F) 3. Develop microphysio-logical / cellular models specifically for veterinary medicines (A; E; F) 4. Develop *in vitro* models for the assessment of toxicity and potency of novel therapies, particularly nanoparticles and RNA-based veterinary medicinal products (A; E; F)		
Focus area: Environmental risk assessment				
VET2	Research to generate data for regulatory decisions on environmental safety of veterinary medicinal products	1. Develop methods to reliably estimate, measure and analyse environmental concentrations of substances used in veterinary medicinal products (A; D; E; F) 2. Develop methods/ produce data to inform the assessment of public health risks related to antimicrobial resistance acquired via the environment resulting from the use of a veterinary medicinal product (A; D; E; F; G) 3. Conduct a gap analysis of the availability of environmental risk assessment (ERA) data for veterinary medicinal products and propose new models to update ERAs (e.g., addressing water pollution effects of veterinary products) (G)	• Environmental risk assessment • Veterinary medicinal products	Veterinary medicine
VET3	Research on approaches to monitor environmental risk	1. Develop tools and strategies to monitor environmental risks arising from the release of bacteriophages used to treat food-producing animals (including in aquaculture). This includes validation of methods to detect interactions between antibiotics and bacteriophages that might affect antibiotic activity (C; D; F; G)	• Environmental risk assessment • Bacteriophages • Antibiotics • Antimicrobial resistance	Veterinary medicine

Focus area: Antiparasitic resistance				
VET4	Research to increase scientific knowledge on antiparasitic resistance	1. Perform studies to identify the mechanisms of antiparasitic resistance development and transmission (A; E) 2. Develop methods to estimate and accurately predict the level of antiparasitic resistance depending on parasite and antiparasitic substance class (A; C; E; F)	• Antiparasitic resistance • Risk assessment	Veterinary medicine
VET5	Research to ensure control and prevention of antiparasitic resistance	1. Perform studies to determine the types of data and the minimum level of evidence necessary to ensure reliable assessment of antiparasitic resistance (F; G) 2. Perform mapping and gap analysis of measures necessary for the control and prevention of antiparasitic resistance globally (G)	• Antiparasitic resistance • Risk assessment	Veterinary medicine
Focus area: Pharmacovigilance				
VET6	Research on approaches to leverage data for improved pharmacovigilance	1. Perform studies to establish the data landscape of pharmacovigilance-related information (including species population, data on treatment) at the level of veterinary practice and husbandry in the different Member States (G) 2. Perform an analysis of data in the union pharmacovigilance database to identify potential biases in terms of product type population that may affect data warehouse analyses and suggest appropriate measures to improve the robustness and consistency for signal management (C; F; G)	• Pharmacovigilance • Data management • Union pharmacovigilance database	Veterinary medicine
VET7	Research on approaches to facilitate and improve reporting of adverse events related to veterinary medicines	1. Perform analysis on the sales data relative to the reporting of adverse event in the different Member States 2. Develop new methods (and review relevant existing methods) to increase the reporting rates of adverse events	• Adverse drug reaction • Adverse event	Veterinary medicine

		for veterinary medicinal products (to cover technologies such as mobile devices and apps) (D; F) 3. Investigate and develop methods to optimise the dissemination of updated safety information to practising veterinarians and animal owners (food-producing animals and companion animals) (B; G)		
Focus area: Novel therapies and innovation				
VET8	Research on identification of regulatory bottlenecks for novel manufacturing	1. Review novel manufacturing methods and delivery approaches (including devices) with a focus on related regulatory limitations and bottlenecks (G) 2. Review and perform an analysis on the approach underpinning novel manufacturing regulation in the devices field, highlighting learnings that could translate into medicine regulation (G)	• Advanced manufacturing	Veterinary medicine
VET9	Research on novel methodologies for quality control of veterinary medicines	1. Develop or optimise methods entailing deep sequencing for testing of contaminants, to inform limit-setting for veterinary use, such as blood products, cell products (D; E; F)	• Quality control • Pharmaceutical quality • Product quality issue • Deep sequencing	Veterinary medicine
Focus area: Vaccines				
VET10	Research on vaccines for priority diseases	1. Perform an analysis to identify challenges, opportunities and potential synergies to foster the development of veterinary vaccines for therapeutic gaps in the market (e.g., specific target species, limited markets, zoonotic and emerging diseases) (G)	• Vaccines • Priority diseases • Limited market • Zoonosis • Emerging diseases	Veterinary medicine

VET11	Research on methods to ensure highest quality of vaccines	1. Perform an analysis to discover opportunities offered by novel methods for the detection of nucleic acids applied to the quality control of veterinary vaccines (e.g., in the detection of contaminating material and vaccine strain characterisation) (G) 2. Develop approaches to investigate process- and product-related impurities in veterinary vaccines (D, E, F)	• Quality control • Vaccines	Veterinary medicine
Focus area: Antimicrobial resistance				
VET12	Research on data generation for regulatory decisions on antimicrobials	1. Develop models to support the initial or the maintained marketing authorisation of antimicrobials of public health relevance. The models might take into account the following elements: 1) off-patent veterinary antimicrobials; 2) modelling and extrapolation using PK/PD; 3) dose optimisation (B; F; G)	• Antimicrobial resistance • Dose optimisation • Pharmacokinetic study • Pharmacodynamic study	Veterinary medicine
VET13	Research on methods for reporting data on antimicrobial use	1. Develop methodologies to establish defined daily dose and defined course dose (DDDvet/DCDvet) for reporting of antimicrobial use in different animal species (A; D; E; F)	• Defined daily dose • Defined course dose • Antimicrobial resistance	
VET14	Research on diagnostics to support prudent use of antimicrobials	1. Develop and establish/validate point-of-care/ companion diagnostics for veterinary antimicrobial sensitivity tests (D)	• Antimicrobial resistance • Point-of-care testing • Diagnostics	Veterinary medicine Notified bodies
Focus area: Veterinary big data				
VET15	Research on big data activities on the veterinary domain	2. Perform a review and highlight differences and opportunities of big data initiatives (e.g., to further explore availability of data sources on animal health, data integration and analytics solutions) to support the Veterinary Big Data strategy (B; G)	• Veterinary Big Data strategy	Veterinary medicine

2.6. Topics prioritization and stakeholder input

The EMA does not seek to rank regulatory science research needs in order of priority, because each topic contributes uniquely to the advancement of regulatory science within its respective domain, and the topics concern complementary groups of researchers (and regulatory issues).

During the public consultation on the draft research needs, several stakeholders expressed their views on the relative importance of various research needs and topics.

The following list was compiled from comments that addressed several research needs and expressed the priorities for the commenting stakeholder within the sections of research needs.

CT2 - Research to enhance robustness of non-randomised studies

CT3 - Research on analytical methods for clinical trials

CT4 - Research on methods to improve efficiency of design and analysis methodologies for trials

CT5 - Research on EU capacity and operational aspects of clinical trials

CT6 - Research on innovative clinical trial designs to support medicines development

RP2 - Research on regulatory pathways for medicines and drug development tools

RP9 - Research on tools to improve the use of scientific data

NT2 - Research on reactogenicity and immunogenicity for novel vaccines combining an increasing number of antigens for different pathogens using the same platform technology (e.g., mRNA-based)

NT3 - Research to inform regulatory assessment of platform technologies

NT4 - Research to strengthen scientific evidence in the field of mRNA vaccines and novel vaccines technologies.

NT9 - Research to improve regulatory acceptance of 3R methods / NAMs

NT11 - Research on modelling and simulation methods to support regulatory decisions

NT13 - Research on methods to improve use of RWE in decision-making

3. Methods

3.1. Identification and formulation of new research needs

Between February and May 2024, more than 20 interviews were conducted with internal experts across various EMA departments and workstreams to obtain relevant input and feedback on challenges in their area of work. The interviews identified over 90 critical topics relating to daily operations, handling of assessment procedures and feedback from scientific committees and working parties. These topics were evaluated and used to inform the updated RSRN list.

Regulatory challenges that might benefit from further research were also identified through screening of different sources:

- Procedure reviews. Selected procedures were reviewed and gaps were identified across different therapeutic areas and quality, non-clinical and clinical domains (e.g., CHMP initial marketing authorisation day 120 overview reports). The procedure reviews were so far exploratory to inform and complement the expert interviews.
- Horizon scanning activities. To enable EMA and the EU regulatory network to proactively respond to forthcoming challenges and opportunities, EMA conducts horizon scanning activities in collaboration with experts and groups such as the EU-IN. The horizon scanning reports include recommendations how to adapt the network, minimise regulatory bottlenecks, support developers and facilitate innovation reaching patients. Challenges and recommendations found in the reports were analysed to inform the updated RSRN list.
- Regulatory interactions at early stages. EMA provides developers with opportunities for interaction, to create a supportive environment for anticipating regulatory aspects while exploring opportunities related to new developments. Academia briefings, Innovation Task Force briefings and Portfolio & Technology Meetings of recent years have been used to collect relevant non-product-specific questions and to inform the updated RSRN list.
- Enquiries from academia. EMA interacts with academic developers in several ways, including through direct interaction facilitated by EMA's academia liaison and enquiries sent via AskEMA or to academia@ema.europa.eu. While providing answers to requesters, EMA takes the opportunity to flag and identify recurrent topics that might benefit from regulatory science research.

The identification of RSRNs showed some priority topics were recurrent, across interviews or several information sources. A small number of the identified challenges were not suitable to be formulated as priority topics for the attention of external researchers. The research needs and opportunities were further divided into sections that represent major clusters of research with several focus areas.

3.2. Investigating and tracking progress on research needs

The documentation of progress of activities addressing research needs is highly work intensive, and it could not yet be done systematically and continually by any stakeholder. Efforts to document progresses were made mainly to explore methods, given limited resources.

- A manual literature search was performed to find relevant studies in specific RSRN fields. Additionally, for each specific RSRN, a set of keywords has been tested. Sequential searches were run to first isolate topic-specific publications and to subsequently isolate those reporting on solutions from a regulatory perspective. A manual literature search was only conducted on a subset of research needs according to upcoming priorities and specific interactions with relevant developers.

- EMA also started to explore automating search strategies to track outcomes of regulatory science research. The aim was to explore text mining and AI approaches for the retrieval of publications that likely address questions expressed in the RSRN list.
- EU-funded projects (with or without involvement of EMA) have been screened to identify relevant research on RSRN. Several have progressed to in-depth interactions with EMA to leverage research outputs.