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EMA Industry standing group – Focus Group Regulatory Science Research Translation

Output report and recommendations

1. Introduction

Regulatory science applies a range of scientific disciplines to the quality, safety and efficacy evaluation of medicines for decision-making throughout the lifecycle of medicinal products, and regulatory science research informs the progress of regulatory tools, practices and standards.

Research questions in regulatory science are continually being identified by stakeholders (in particular by developers, researchers, funders) and regulators.[1] Translation of research outputs aims to improve the regulatory framework, tools and practices, and it seeks to maximise the outputs' strategic uptake, practical application and further development in the wider health system.

The Focus Group (FG) on Regulatory Science Research Translation (annex) had as main deliverable to identify what is needed to accelerate regulatory science research so that research outputs can be accepted and used by different stakeholders in the health system, with a focus on stakeholders using the outputs for their research and development (R&D) or evaluation of medicinal products.

This report summarises the priorities and approaches for pre-competitive[2] research consortia as well as recommendations that should be widely applicable and useful for regulators and stakeholders involved in funding, conducting and translating research outputs into practical applications, to ultimately obtain benefits for public and animal health, and access to safe and effective medicines.

The FG considered a range of observations (annex) and acknowledges that the recommendations are variably difficult to implement yet may be relevant also for other types of projects.

[1] Examples include Horizon Europe topics including those addressed by the Innovative Health Initiative and other Joint undertakings or European partnerships, and EMA' Regulatory science research needs https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/regulatory-science-research-needs

[2] 'pre-competitive' often refers to collaborative research building knowledge, developing foundational technologies, standards, methods, solutions or tools but not delivering commercial products or services

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2. Priorities and approaches for consortia to accelerate translation of research outputs

Based on in-depth discussions informed by presentations of partners in public-private partnerships (PPPs with academic and industry partners), the Focus Group identified elements that are put forward for consideration at different stages of a research project, from design to dissemination. These elements are reported below as priorities to accelerate translation of research outputs, with a particular focus on aspects related to the regulatory strategy.

As a high-level principle, pre-competitive collaborative projects and consortia seek to provide new solutions and applications in the health system.

Pursuing change management in a well-informed way and with competent resources is foundational for the success of a PPP and for the impact of translation of its outputs.

This includes systematic activities to understand what it would take for the environment and the health systems to integrate and implement a potential output or solution that the consortium envisions. Analyses of what would need to change and what is needed to accelerate such an implementation have to be complemented with activities to anticipate and address concerns and expectations of stakeholders who have to be systematically identified and strategically approached. PPPs will benefit from including change management approaches and resources in their plans and budget.

Medicine and device regulators are but two of typically multiple relevant stakeholders. The regulatory strategy of a pre-competitive collaborative research project or consortium outlines how to generate evidence on the methods and solutions being researched. The strategy should evolve over time in line with project progress and should be based on systematically collecting and analysing previous regulatory outputs, related research, and other relevant information.

Regulatory intelligence activities and functions play a key role in this process. This generally entails monitoring public regulatory information and analysing it for implications concerning expected or required research and development approach; regulatory intelligence is available from for-profit-organisations in PPPs and made more concrete below (section on project deliverables). The regulatory strategy also includes the planning of interactions with regulators and therefore anticipates timepoints, topic areas or questions to inform further works and type(s) of regulator(s) to be involved.

Besides change management activities stressed in other parts of this report, a change management approach should be informed by a structured and updated ("living") regulatory strategy, for which it is fundamental to consider the following elements:

Priorities related to regulatory preparedness

- Start developing a **regulatory strategy** during the project design phase of the pre-competitive collaborative project or consortium. In particular those projects that plan works towards regulatory endpoints (may be underlying or part of a submission to regulators for decision-making) or regulatory methodology (how evidence is generated to inform decision-making) would benefit from submitting a brief strategy in the application, refining their regulatory strategies early during project conduct, from seeking regulatory feedback (see below on opportunities for interaction with regulators) and from making their strategies public. Continually execute, re-assess and update the regulatory strategy based on a full oversight and understanding of the project progress.

- Link the regulatory strategy with the implementation work plan and identify potentially critical paths as well as any potential impediments or blockers for regulatory acceptance of project approaches and outputs with a sufficient level of detail (often more detailed than the project's risk assessment). Both are part of the **change management approach**, which should be pursued as overarching means for developing outputs relevant to stakeholders and preparing to make impact.
- Build into the project the **regulatory expertise** such as available from industry partners. Identify potential gaps and allocate budget for regulatory intelligence services.
- Seek to get into contact with partners in **related ongoing or previous projects** and build on their expertise.[3]
- Involve **technology transfer offices** (TTOs) and regulatory affairs structures as increasingly available at academic partner organisations from the design phase of the project
- Identify the **various different regulators** involved in the translational process of the technology/method in development and the needed interactions, such as:
  - National Competent Authorities for medicines (consider their services and processes such as scientific advice, pre-grant advice, clinical trial authorization, authorisation of studies other than clinical trials),[4]
  - EMA (consider services and processes such as described in the *Insights box* below),[5]
  - EFSA, ECHA, EDQM, Reference Laboratory for alternatives to animal testing (EURL ECVAM),[6]
  - Competent Authorities for Medical Devices (CAMD) in the EU,[7]
  - National competent authorities for the medical devices sector,[8]
  - Notified Bodies including NANDO, Team-NB, NBOG,[9]
  - Health Technology Assessment bodies and payers.[10]
- **Allocate budget for regulatory services** that may be needed as per the strategy (see fees for scientific advice, qualification advice and opinion, national procedures and others)[11]

[3] E.g. as identified from publications, IMI/IHI project fact sheets https://www.ihi.europa.eu/projects-results/project-factsheets, https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/partner-search
[4] https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states
[5] https://www.ema.europa.eu/en/human-regulatory-overview/research-development
[6] https://doi.org/10.2903/j.efsa.2025.e220401, https://echa.europa.eu/support, https://www.edqm.eu/en/faq-helpdesk-reference-standards-rs, https://joint-research-centre.ec.europa.eu/projects-and-activities/reference-and-measurement/european-union-reference-laboratories/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en
[7] https://www.camd-europe.eu/
[8] https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en
[9] https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en#other-contact-points, https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/free-search
[10] https://www.ema.europa.eu/en/partners-networks/health-technology-assessment-bodies, https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment_en, https://www.medev-com.eu/
[11] https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency, https://accelerating-clinical-trials.europa.eu/our-work/support-non-commercial-sponsors/national-initiatives-non-commercial-sponsors_en, https://www.ihi.europa.eu/resources-projects/engaging-regulators

The following points exemplify sources for **regulatory intelligence** on novel methodologies and drug developments tools. The links below can be searched for examples and precedents that are relevant to the area under study or to the research methodology of the consortium. Reviewing documents is instructive for understanding scientific plans and regulatory reviews.

- EMA Novel methodology qualification opinions, public comments and letters of support
- EMA Qualification of novel methodologies for drug development: guidance to applicants
- EMA Expert panel opinions, views and advice on medical devices, *in vitro* diagnostics and at the request of the Medical Device Coordination Group and the European Commission
- European Commission website for the Medical device sector

Internationally, examples of sources include the FDA searchable database on Drug Development Tool (DDT) Qualification Programs and Medical Device Development Tools (MDDT), Qualification Process for Drug Development Tools and Qualification of Medical Device Development Tools guidance as well as information by PMDA on new modalities and novel evaluation technologies and early considerations.

Priorities specific to project deliverables

- **Adopt a comprehensive change management approach** that is related to the activities and evolving outputs of the consortium. Change management goes beyond project management and is an effective approach for accelerating translation and making impact. Identify at an early stage the potential outputs and use them for **stakeholder identification and mapping** to plan engaging them appropriately.
- In-depth preparation for implementing and using consortium outputs broadly, e.g., for regulatory-scientific guidelines, pharmaceutical R&D, and engagement with stakeholders about what they see is needed to establish use of the outputs in the health system.
- Define which outputs will be disease- or product-specific and which will be independent, what is their added value vis-à-vis existing tools or methods (e.g. biomarker, endpoints, *in silico* methods) and how their utility or value can be maximised for relevant stakeholders. The value should be estimated, including in terms of public health interest, e.g., shortening time to access or reducing number of experimental units while maintaining or strengthening evidence.

For a **regulatory strategy document**, this section includes activities and elements based on EMA experience; broader experience is reflected in publications by various projects (see annex).

It will be informative to conduct and maintain a gap analysis comparing current international regulators views (e.g., in scientific guidelines, precedent medicine assessments, qualifications, publications) and current activities (e.g., design of research in the field) with the potential consequences, intentional or unintended, of the consortium's outputs (e.g., for future medicine development, assessment, clinical research aspects such as diagnostic tests, inclusion criteria, observation duration, clinical endpoints, long-term safety documentation, sample sizes, health system change readiness and so forth).

- The strategy would include how gaps will be addressed with new and existing data and scientific reasoning, and how to make a coherent case for the consortium's output. An **evidence generation plan** will bring together the studies planned by the consortium and relevant existing data with an ordered sequence of hypotheses, assumptions, study questions, methodologies, statistical methods, anticipated use of supportive or surprising results and decision points.

- Identify relevant deliverables, draft and refine a **'context of use'** (CoU) which will be a starting point for seeking support and agreement from regulators about establishing and using the output as a favourable alternative to current approaches. Anticipate that researchers, developers and projects often strive for broad application, versatility and generalisation of solutions and that verification so far is typically based on selected use cases, demonstration of specific claims and qualification of narrow CoUs. Strategic approaches can anticipate advancing in awareness of this situation at several levels, as part of the scientific approach, of the regulatory strategy and of the change management.
- Anticipate that regulatory challenges (e.g., unexpected issues and requirements) could arise from the works for the specific project deliverables and anticipate options that could reduce the time until regulatory acceptability
- As detailed in the beginning of the chapter, the regulatory strategy includes timings and topics for seeking specific interactions with regulators

Priorities related to regulatory awareness and engagement

- Pro-actively seek discussions with regulators (see *Insight box*) in Europe and internationally which are concerned by the research and its potential outputs, to find a path for aligning the research with regulatory principles and for minimising blockers in regulatory acceptance
- Review EMA's Regulatory science research needs,[12] which include horizontal questions and issues collected across regulatory areas and which reflect the knowledge gaps as seen from the regulator's perspective
- Ensure engaging with medicine regulators in projects that primarily seek implementation in the health system in addition to engaging payers when solutions might concern the quality, efficacy, safety or benefit-risk of medicines
- Maintain awareness on regulators' activities, initiatives and opportunities (e.g., ACT EU,[13] Quality Innovation Group,[14] Industry stakeholder platform on R&D support,[15] ICH,[16] ICMRA[17] and other global regulatory organisations)
- Maintain awareness on technical guidelines within the working area (e.g., ICH guidelines). Guidelines issued by regulators should be identified for proposing updates and initiating a revision process or for newly drafting, which could be pursued for example through EMA's eligible healthcare professionals' organisations[18] or direct contact with EMA.
- Maintain awareness of contents of workplans of regulatory groups, such as EMA's Committees and Working Parties (for therapeutic areas or cutting across, such as methodology, safety and others)[19]

[12] https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/regulatory-science-research-needs
[13] https://accelerating-clinical-trials.europa.eu/
[14] https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp-working-parties-other-groups/quality-innovation-group
[15] https://www.ema.europa.eu/en/events/14th-industry-stakeholder-platform-research-development-support
[16] https://ich.org/page/news
[17] https://icmra.info/drupal/index.php/en/strategicinitiatives/
[18] https://www.ema.europa.eu/en/partners-networks/healthcare-professionals/eligible-healthcare-professionals-organisations
[19] https://www.ema.europa.eu/en/committees/working-parties-other-groups, https://www.ema.europa.eu/en/search?keywords=anyword&search_api_fulltext=workplan&f%5B0%5D=ema_search_entity_is_document%3ADocument

- Conversely, regulatory guidelines should be tracked to monitor which research outputs from consortia contributed to the scientific evidence, even if not explicitly quoted.
- Ensure that project partners representing different groups of stakeholders including regulators consult and involve their organisations internally on evolving outputs and on challenges experienced by the organisations (e.g., 'failed' methods or developments, regulatory challenges)
- Participate in and follow initiatives and working groups of stakeholders and regulators (e.g., ACT EU, EFPIA's Regulatory support and sustainability workgroup, dare diseases) that could be relevant to best shape the regulatory strategy and anticipate regulatory needs and pathways.

Insight. <u>How to start and continue engaging regulators</u>

To prepare first interactions with regulators, it will be useful for the pre-competitive collaborative project or consortium to have already conducted some regulatory intelligence (above). With a global impact perspective, regulators across different regions of the world should be considered.

Be ready to share the description of action (annex to Grant agreement or similar) to clarify scope and ambitions, involved participants/partners, work approaches, deliverables and time plans.

There are several ways in which a pre-competitive collaborative project or consortium can interact with regulators, including with EU National Competent Authorities.[20] In the case of EMA:

- Consider an EMA Academia or Collaboration management briefing before starting the project or at an early phase of development to express the interest in having regulators involved in the project and explore whether EMA scientists are interested to contribute and be involved. Consider that EMA has limited resources for direct involvement in externally funded projects. To maximize the possibility of EMA involvement consider how the project aligns with strategic focus area of the Agency (EMANS 2028[21]) and monitor research agendas and research needs flagged by EMA[12]
- Consider requesting an Innovation Task Force (ITF) briefing meeting[22] early in the project activities to discuss the development plan with experts from EMA and the regulatory network and raise questions on project's scientific and regulatory aspects
- Make use of the statutory regulatory services, such as Scientific advice in the context of the development of specific medicinal products and Qualification advice on validation of novel methodologies, which provide scientific and regulatory input. This is potentially conducive to clinical trial authorisation, experiment authorisations, attracting partners, sponsors and contributors, supporting the validity of novel tools for evidence generation in a marketing authorisation application. Fees for these services are typically eligible for grant reimbursement; besides, fee waivers are available for certain entities and types of requests[23]
- Consider inviting regulators to participate in project workshops to explore challenges concerning different stakeholders'; EMA cannot contribute to consensus finding but may be invited to review or provide comments.
- Consider participating in regulators' workshops and public initiatives, including consultations on draft documents.[24] Register as stakeholder with the EMA to be informed on initiatives and information related to your field of work.[25]

EMA has also broad experience with direct involvement in public-private-partnerships, consortia and external activities related to regulatory science, which is governed by principles and criteria.[26]

[20] https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/EU-IN/2023_02_EU-IN_Involvement_of_competent_authorities_in_externally_funded_projects.pdf and https://accelerating-clinical-trials.europa.eu/our-work/support-non-commercial-sponsors/national-initiatives-non-commercial-sponsors_en
[21] https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-final_en.pdf
[22] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/innovation-task-force-briefing-meetings
[23] https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency
[24] https://www.ema.europa.eu/en/news-events/open-consultations
[25] https://www.ema.europa.eu/en/partners-networks/academia#exchange-of-expertise-12493
[26] https://www.ema.europa.eu/en/documents/other/european-medicines-agency-process-engaging-externally-funded-regulatory-sciences-and-process-improvement-research-activities-public-and-animal-health_en.pdf

3. Recommendations

The recommendations provided in this report were developed based on in-depth discussions informed by presentations of partners in public-private-partnerships (PPP, academics and industry partners). In addition to the priorities for consideration of a consortium (above chapter), the recommendations in the following go beyond the regulatory remit, target multiple stakeholders and aim to stimulate a systemic adaptation of the environment, in support of better translation of research output into practical application, improved regulatory standards and practices and increased benefit for public and animal health.

3.1. Recommendations for consideration by EMA

- Expand capacities for evaluating and supporting relevant externally funded projects and their outputs.
- Explore how to increase the **visibility** of regulator-supported consortia outputs in submissions to regulatory, in regulatory procedures and discussions and in public-facing documents, and of tracking the use of regulator-accepted outputs in marketing authorisation applications (MAA)
- Consider safe harbours for using outputs that are progressing based on regulatory advice but not yet regulatory accepted or qualified in developments of medicinal products that proceed to MAA
- Support activities to improve the engagement with researchers and scientists from academia and industry, including on the **qualification** of novel methodologies, which is being improved based on input by industry, academia and other stakeholders.[27]
- Develop a framework for formalized and publicised regulatory **reflections** on project activities or evolving outputs (and possibly funding calls and desirable working methods)
- Use the European **Platform** for Regulatory science research[28] launched in 2025 by EMA and HMA to advance understanding of, works on, delivery and translation of regulatory science research needs, by discussing cross-cutting issues such as methods, experience and collaborations.
- Consider drafting guidances for how to develop and evaluate selected, different types of novel tools and methods, and making them well visible.
- Strengthen the EMA-HMA[29] **coordination** of support and involvement of regulatory science experts from EMA and from NCAs in relevant external projects.
- Establish options to continually discuss with stakeholders including industry the translation of outputs of projects, making use as relevant of the a.m. platform, EMA collaboration management briefings and EMA Industry stakeholder platform on research and development support
- Consider options to document which scientific research/literature was used for the drafting of a scientific guideline.

[27] https://www.ema.europa.eu/en/documents/other/future-proofing-qualification-novel-methodologies-qonm-action-plan_en.pdf
[28] https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/european-platform-regulatory-science-research
[29] https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/EU-IN/2023_02_EU-IN_Involvement_of_competent_authorities_in_externally_funded_projects.pdf

3.2. Recommendations for consideration by industry

- Support and **provide regulatory strategic advice** and intelligence proactively and continually in pre-competitive collaborative projects and consortia (based on the priorities highlighted above) with the goal to ensure that all partners within consortia can expand their understanding of the regulatory pathways and can benefit from the acquired knowledge in future projects
- Support the identification and provision of **training** offers such as relevant for academic stakeholders in and beyond specific projects, including on areas of interest of application in product discovery, research and development, regulatory aspects
- **Facilitate alignment** n expectations as regards regulatory acceptability and evidence requirements with academic and other public partners within consortia
- Promoting sharing of deliverables, research outputs and their acceptability for regulatory decision-making within the project and beyond
- Ensure that project participants representing industry consult and **involve their organisations** internally on evolving outputs, on challenges experienced by the organisations (e.g., 'failed' methods or developments, regulatory challenges) and expectations for implementing new or changed methods and approaches

3.3. Recommendations for consideration by academic researchers and their organisations

- Work towards the creation of inclusive academic federation that addresses the intersections between scientific areas-specific learned societies, to reduce fragmentation in best practices and to foster knowledge sharing for intersecting research areas and methods. The federation should also aim to engage researchers via their universities and not-for-profit research organisations for communication, networking, facilitate interactions with stakeholders and regulators.
- Identify and develop pathways to increase communication, collaboration, knowledge-sharing, alignment among researchers working on complementary / related research outcomes to address a more impactful and standardized approach to problems, using dedicated channels and the a.m. platform for regulatory science research
- Create an organisation for representation of academic researchers active in regulatory science
- Share best practices for linking research on regulatory science challenges with university curricula

3.4. Recommendations for consideration by multiple stakeholders

The following recommendations require further discussion, likely across several stakeholders and are further divided into topic categories.

- No less important than project management is **collaboration management**. In pursuit of the agreed collaborative research among potential competitors, people involved need to have the ability to challenge each other to make progress and to generate outputs that benefit the research space rather than individual participants.
- Collaboratives and consortia will benefit from **measuring** how safe participants can challenge others[30] for awareness of and taking action on dysfunctions and behaviours that are in the way of achieving results.[31]

Sharing of technologies, data and other outputs

- Create an accessible, **curated knowledge base and repository of project outputs** that are relevant for developing and evaluating medicines and related interventions for health systems that cuts across research and innovation projects, providing practical applicability and operational references. This should include as resource types amongst others, detailed protocols and experimental considerations, master protocols, information on bottlenecks and negative results, programme code, mathematical specifications of models and values of its parameters, relevant datasets including for testing, infrastructure and architecture as code, templates for information sheets, service level agreements, collaboration, material transfer and other contracts, other 'drug development tools' as well as collaboration facilitation methods and continually collected records of the application / use of the resource. It may be possible to build on existing repositories.[32] Domain-specific meta-data that speak to the stakeholders in the field is needed to increase visibility, findability, re-use and improvement (e.g., using a regulatory science ontology, maturity indicators, drug development areas). The approach should seek integration with a scientific journal for publications on repository content. (Potentially interested stakeholders: European Commission, funders, trade associations, European Research Infrastructures)
- Promote the approach and value for sharing of data sets, algorithms, code, models, protocols and so forth such as through **playbooks** that accommodate the information needs of all relevant stakeholders and various roles in organisations, from technical to executive (potentially interested stakeholders: Industry, Academia, Consortia, trade associations, regulators).
- Ensure that datasets, models and other digital **assets** are properly citable and referenceable,[33] and ensure instructions that stipulate their citation are included within the asset, to facilitate tracking for impact and further development of the asset.
- Update the approach for **critical risk mitigation** to anticipate translation for sustainability and practical availability of materials and resources, such as reagents, assays, software, etc., needed to use and reliably reproduce in vitro models and other experiments. This includes early agreements to ensure the availability of resources for all relevant stakeholders who want to adopt project-related technologies (potentially interested stakeholders: Industry, academia, consortia).

[30] Psychological safety, such as suggested by Edmonson (2019)
[31] Ineffective teams, such as suggested by Lencioni (2002)
[32] The EU Open Research Repository is a Zenodo community https://zenodo.org/communities/eu/; the Horizon Results Platform is https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/horizon-results-platform/; the recently started European Open Science Cloud (EOSC) at https://open-science-cloud.ec.europa.eu/resources/all
[33] See also Digital Services Act (DSA) and the Digital Markets Act (DMA); https://ec-europa-eu.libguides.com/dsa-dma/citing-and-referencing, EU Publication Data citation (2022) A guide to best practice https://op.europa.eu/s/AdMp

- Invest in planning to **align on quality and manufacturing standards** for related types of technologies / deliverables / tools / methods. This includes discussions across regulators, different projects, researchers, and industry to ensure consistency and reduce variability related to different approaches, operators, cell providers, and differences in facilities (potentially interested stakeholders: Industry, academia, consortia, funders, trade associations, relevant regulators).

Access to expertise and training

- Maintain a **pool of experienced participants** from previous projects ('alumni') who are open to be contacted and asked to provide on-demand advice and knowledge transfer to other consortia or projects (potentially interested stakeholders: Funders, Industry, Academia, Consortia)
- Establish a **competence centre to offer hands-on project and regulatory support**, including consulting on contracting, data sharing and stakeholder engagement, building on the experience and expertise of previous and ongoing projects' participants. Additionally, use platforms (e.g. EMA/HMA European Platform for Regulatory science research) to facilitate knowledge transfer, share and maintain expertise available for multiple stakeholders (potentially interested stakeholders: Industry, Consortia, funders, European Commission, regulators).
- Develop learning offerings for researchers in academia to improve regulatory preparedness, focusing on practical aspects of regulatory procedures and the value of regulatory endorsement (potentially interested stakeholders: Industry, trade associations, regulators).
- Support projects in conducting early analyses of impacts, cost-benefit trade-offs and utilities for different stakeholders' perspectives (potentially interested stakeholders: Funders, trade associations).
- Facilitate timely clinical recruitment of patient cohorts and discuss plans for investments that are needed to ensure the efficiency of clinical trial methodologies, in particular when clinical trials are to be performed in multiple countries (potentially interested stakeholders: European Commission, Industry, regulators).

Dissemination and adoption of research output

- In relation to the curated knowledge base and repository mentioned above, create a web portal for a harmonised presentation and narratives for research outputs, applications and use cases from pre-competitive projects and consortia relevant to the biomedical space, where leads of stakeholder types can find information of their interest, which may include information on added value, regulatory procedures and public commentaries. (Potentially interested stakeholders: European Commission, funders)
- Develop a centralized system to track the use, implementation and adoption of methods developed by research consortia; see also above on digital assets. This could include forward and reverse bibliometric analyses with subsequent content analyses to identify references that document any use and further development of project outputs. (Potentially interested stakeholders: Funders, European Commission, regulators).
- Support the funding of implementation projects aiming at optimizing and focus on the adoption of deliverables from terminated projects (potentially interested stakeholders: funders, European Commission).

Annex

Industry Standing Group (ISG) Focus Group (FG) on Regulatory Science Research translation

Objectives and mandate

The objective of this group is to develop recommendations, priorities and approaches for enhancing the translation of regulatory science research outputs into practical application in research and development and in improved regulatory standards and practices.

Translation includes advancing the regulatory framework for the development, evaluation and use of medicines and drug development tools, as well as maximising the uptake and application of research outputs by relevant stakeholders.

In addition to nominated members from industry organisations, a multistakeholder approach will be used by involving relevant academic stakeholders, researchers, funders, and the European Commission.

The following outcomes are expected:

- Define relevant actors for initiating and progressing the translation of regulatory science research outputs.
- Describe relevant existing and any newly required translation approaches, including criteria, governance, milestones and deliverables (e.g., training and competency building, stakeholders needed, type of regulatory endorsement needed, requirements for raising awareness and for availability of tools).
- Define key elements to be considered when establishment and running of private-public partnerships to ensure early embedding of relevant translation approaches to obtain regulatory support and practical application.
- Develop reflections on what is needed to accelerate the process of translation of research outputs, and to maintain speed and efficiency of translation of regulatory science research outputs for the benefit of patients and public health.

Working method

The Focus Group's working method was developed to explore concrete examples of regulatory science research. The starting point for this work was the list of regulatory science research needs identified by EMA, as well as the priorities defined by research consortia and trade associations, who outlined their objectives and the impact they aimed to achieve. The idea of setting up a focus group was discussed during the Sixth Industry Standing Group (ISG) meeting | European Medicines Agency (EMA) on 21 September 2023 followed by EMA's request for nomination of participating members to industry trade associations.

From this foundation, the Focus Group selected a range of case studies from ongoing regulatory science projects carried out by consortia. These were chosen to ensure a broad representation of different focus areas and topics.

The selected case studies were then discussed in monthly meetings. These sessions brought together Focus Group members, EMA representatives, and observers from the European Commission's

Directorate-General for Research and Innovation (DG RTD), along with scientific experts from the consortia behind each case study from both academia and industry.

During the meetings, the research teams presented their projects, explaining their objectives, sharing data and results, and highlighting any challenges they had faced, or anticipated, in implementing or translating their findings into practical or regulatory use. These presentations served as the basis for in-depth discussions, where Focus Group members worked with the research teams to identify factors that could help bridge gaps and overcome challenges in translation of research outputs (see observations in next section).

Insights gained from these discussions were then used to draft the general principles, priorities, and recommendations presented in this report.

A consultation phase followed, involving the research teams who had contributed to the case studies, EMA representatives, and stakeholders from DG RTD and the Innovative Health Initiative (IHI), whose insights and comments enriched the report and are acknowledged with thankfulness.

Summary of observations

The recommendations above were informed by observations reported below made during the ISG FG discussions and following additional analyses. The order of perceptions is not indicative.

- Limitations in the dissemination of successful research outputs need to be addressed to amplify the adoption and the use of novel methodologies across the scientific community
- Limitations in the adoption are also related to a hesitation of using novel methodologies or technologies that have not yet extensively proven its added value or regulatory endorsement
- Need to generate protocols and manuals that are practical for all stakeholders beyond the specific cases explored within the project and can ensure easy reproducibility
- Lack of infrastructure and platforms to ensure sustainability of research outputs (for further maturing and implementation)
- Research outputs are not fully in line with regulatory requirements, often due to poor anticipation of regulatory aspects and late interactions with regulators
- Limitation in academic knowledge and understanding of the regulatory environment and requirements
- Limitation in funding availability for supporting the finalization and optimization of research outcomes from previous projects
- Duration of regulator-agreed approaches to validate research outputs
- Lack of regulatory acceptance and validation leaves adoption of research outputs challenging
- Different expectations and priorities between academia and industry
- Difficulties at several levels (e.g., logistics, contracts, supply chain) to ensure future access to resources and knowledge needed for reproducibility and full adoption of research outcomes (e.g. assays, reagents, replication protocols)
- Lack of collaboration and synergies among different projects and consortia working on related topics and outcomes or working with related methods and tools
- Lack of alignment on relevant standards and evaluation criteria across actors involved in the research and translation process

- Lack of centralized strategies to track implementation and adoption of research outputs
- Legal and operational challenges related to global collaboration, slowing down research and translation processes
- Lack of sufficient visibility, with primarily larger projects more readily visible, e.g. EU-funded projects, while contributing studies may or may not be published

Core members

Industry	***EMA***
Nick Sykes (EFPIA) – *FG Industry Coordinator*	Ralf Herold - *FG Chair*
Paul Bolot (EFPIA)	Pierpaolo Moscariello – *FG EMA Coordinator*
Bettina Doepner (EUCOPE)	Spiros Vamvakas
Gloria Garcia-Palacios (Vaccine Europe)	Emmanuel Cormier
Nina Heiss (EuropaBio)	Maria Filancia
Antoine Manson (EFPIA)	Marie-Helene Pinheiro
Amine Messaoudi (EUCOPE)	
Magda Papadaki (EFPIA)	
Solange Rohou (EFPIA)	
Nicola Wilson (Vaccine Europe)	

Publications on regulatory strategy and intelligence

This is an incomplete collection, based on the IHI "Regulatory considerations for IMI/IHI projects - Guide for applicants and project consortia."[34] The publications represent examples of how IMI funded consortia have undertaken regulatory intelligence and regulatory strategy to optimise their outputs.

- ARDAT: Current global regulatory landscape for biodistribution & shedding assessment of rAAV gene therapies & recommendations of the IMI ARDAT consortium on future directions https://doi.org/10.18609/cgti.2022.056
- BEAT-DKD: Biomarker qualification at the European Medicines Agency: A review of Biomarker Qualification Procedures from 2008 to 2020 https://doi.org/10.1002/cpt.2554
- ConcePTION: Predicting Drug Transfer Into Human Milk With the Simcyp Simulator: A Contribution From the ConcePTION Project https://doi.org/10.1002/psp4.70066
- HARMONY deliverable "Qualification for novel methodologies' stakeholders guide" https://cordis.europa.eu/project/id/116026/results https://doi.org/10.3389/fphar.2023.1192770

[34] https://www.ihi.europa.eu/sites/default/files/uploads/Documents/ProjectResources/Guide_RegulatoryConsiderationsIMI_IHI_Projects_final.pdf

- IDEA-FAST: Regulatory Qualification of a Cross-Disease Digital Measure: Benefits and Challenges from the Perspective of IMI Consortium IDEA-FAST https://doi.org/10.1159/000533189
- LITMUS: NAFLD and NASH biomarker qualification in the LITMUS consortium – Lessons learned https://doi.org/10.1016/j.jhep.2022.11.028
- MOBILISE-D: Toward a Regulatory Qualification of Real-World Mobility Performance Biomarkers in Parkinson's Patients Using Digital Mobility Outcomes https://doi.org/10.3390/s20205920
- PREFER: How can patient preferences be used and communicated in the regulatory evaluation of medicinal products? Findings and recommendations from IMI PREFER and call to action
- RADAR-AD: The Use of Remote Monitoring Technologies: A Review of Recent Regulatory Scientific Advices, Qualification Opinions, and Qualification Advices Issued by the European Medicines Agency https://doi.org/10.3389/fmed.2021.619513
- Trials@Home: Regulatory Interactions and Learnings—RADIAL the Trials@Home Proof-of-Concept Trial on Decentralization https://doi.org/10.1002/cpt.70078

- Brumsfeld et al Delivering regulatory impact from consortium-based projects https://doi.org/10.1038/d41573-025-00098-8
- Saesen et al. Involvement of the European Medicines Agency in multi-stakeholder regulatory science research projects: experiences of staff members and project coordinators. Frontiers in Medicine. https://doi.org/10.3389/fmed.2023.1181702