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COMMENT

Supplementary Information

The European Medicines Agency: Regulatory Science to 2025

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Supplementary Methods

1. Baseline review and horizon scan

A baseline review and horizon scan was conducted across 60 areas of science, technology, health and regulatory science (Table S1). These areas were identified by the EMA's Scientific Coordination Group (SCG), which includes the Agency's scientific leadership. A first round of horizon scanning was undertaken by a multidisciplinary drafting/research group. Internal databases, in addition to the scientific literature, were mined to provide an analysis of the state-of-the-art in each area, and the anticipated challenges and opportunities therein over the next 5-10 years. Peer review of the results was performed sequentially, first within the research group, then by in-house specialists, and finally by the SCG.

2. Stakeholder outreach

To validate these internal findings, 55 semi-structured and 15 open interviews were conducted with external experts and key opinion leaders from the EMA's principal stakeholder groups. These individuals were nominated by the EMRN and selected from the Agency's expert database; non-response error was minimised by follow-up reminders to the participants. Prior to the interviews, the participants were made aware that horizon-scanning had been performed beforehand but were only provided with the introduction to the baseline review and the interview questions. The semi-structured interviews were designed iteratively by: (a) brainstorming with colleagues to identify key questions, (b) alignment of these questions with the overarching goal of the regulatory science reflection, (c) trialling with colleagues, re-ordering and refining for optimisation of timing; (d) testing on a limited panel of interviewees, with initial feedback incorporated into a final interview format (Table S2) , and finally (e) adopting the core format appropriately tailored to the individual stakeholder groups interviewed. During the open interviews, the semi-structured approach was followed only after the interviewee had set the initial topics for discussion.

3. Data collection and analysis

The duration of a semi-structured interview was typically about 1 hour; the open interviews were longer, up to 2 hours. Notes of the interview were taken by two or more members of the research team and cross-checked for accuracy. The interviews were not recorded, however. The results were analysed using open and axial coding[1,2] which involved independent review of the interview notes by the researchers and assignment of codes to meaningful sections of text (words, sentences and statements). These were then compared, and a sub-set agreed, before further rounds of axial coding. Our findings are reported below (Table S3) using the Consolidated Criteria for Reporting Qualitative Research (COREQ)[3]. The resulting themes and sub-themes were then mapped onto the outputs of the baseline review and horizon-scanning, and formed the basis of a draft set of regulatory science strategic goals, each comprising a series of core recommendations and underlying actions identified for their delivery.

The draft collection of strategic goals, core recommendations and underlying actions (Table S3) was then reviewed and refined by the SCG and the EMA's Scientific Coordination Board, which comprises the chairs of the Agency's key committees[a]. Finally, this reflection was released at the workshop held at EMA on October 24, 2018, "EMA – Regulatory Science to 2025", following which a consultation document detailing the summary outlined in this Comment was approved by the SCG and the Scientific Coordination Board for release and comment[b].

4. Interview questions to principal stakeholder groups

(a) What are the top three science, technology and regulatory challenges and opportunities in your field of work?

(b) Taking each of the three topics in turn, how will this impact clinical development, and then translation to clinical care?

Example impacts on clinical development might include: candidate selection, pre-clinical development, biomarkers; costs – increased costs or savings; societal and legal issues - ethical issues, controversial method or highly invasive.

Example impacts on clinical care might include: clinical outcomes and role in data collection of clinical care; public health: impact on morbidity, mortality, quality of life; services and organisations: procurements standards and best practices, service reorganisation and structural changes; costs – increased costs or savings; societal: sustainability, equity of access to products and services; legal issues: data protection, regulations; ethical issues, controversial method or highly invasive.

(bi) For each of the three topics in turn, what will be the utilisation of this trend across the research and development pathway as a whole?

(bii) What are the barriers for this to happen?

Example barriers might include: regulatory acceptance uncertainty; costs; absence of reference standards (e.g., accepted endpoints); patient enrolment difficulties; public opinion resistance; competence in clinical setting; infrastructure (e.g., radiation, disposal of hazardous material).

(c) For each of the three topics in turn, how can regulators help navigate these challenges and opportunities?

Examples might include: better support in early R&D decision making; increased relationship with academia; more extended scientific advice with HTAs; more predictability with respect to regulatory engagement in clinical care translation.

(ci) Are there any changes to the regulatory rules and procedures which could help?

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[a] Committee for Medicinal Products for Human Use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC), Committee for Medicinal Products for Veterinary Use (CVMP), Committee for Orphan Medicinal Products (COMP), Committee on Herbal Medicinal Products (HMPC), Committee for Advanced Therapies (CAT), Paediatric Committee (PDCO), Co-ordination Group for Mutual Recognition & Decentralised Procedures - Human (CMDh), Scientific Advice Working Party – Human (SAWPh), Scientific Advice Working Party – Veterinary (SAWPv).

[b] A 'sister' document reflecting on regulatory science and veterinary medicinal products was released at the same time and followed a second workshop, "EMA - Regulatory Science to 2025: Launch of Veterinary Stakeholder Consultation", held at the EMA on December 6, 2018.

(cii) What cooperation between the Agency and with other stakeholders could help?

(ciii) What international collaboration could be beneficial?

(civ) What competence and capacity building for the network would be beneficial?

(d) Which therapeutic areas will be most impacted in the next 5 years?

(e) Are there any key initiatives or consortia impacting these trends?

(f) More broadly, are there any other concerns or recommendations you have for the agency?

Supplementary Table 1

Areas of science, technology, health and regulatory science selected for review and horizon-scanning.

1. Trends in science and technology

1.1 Major therapeutic areas

1.1.1. Oncology

1.1.2. CNS - neurodegenerative diseases

1.1.3. CNS - psychiatry

1.1.4. Diabetes

1.1.5. Obesity

1.1.6. HIV

1.1.7. Vaccines

1.1.8. Immunotherapies

1.1.9. Ophthalmology

1.2. Gene therapy and Regenerative Medicine

1.2.1. Gene therapy

1.2.2. Cells and tissue-based products

1.2.3. New materials

1.3. Personalised medicine

1.3.1. Personalised medicine

1.3.2. Biomarkers

1.4. Methods, technologies and other trends

1.4.1. Nanotechnology

1.4.2. New 'omics (e.g., microbiomics)

1.4.3. Taxonomy of disease

1.4.4. Digital health and wearable technology

1.4.5. Novel manufacturing and 3D printing

2. Trends in the use of regulatory science tools

2.1. Access pathways

2.1.1. PRIME

2.1.2. Adaptive pathways

2.1.3. Biosimilars

2.1.4. Synergies with HTAs' activities

2.1.5. Synergies with payers' activities

2.2. Non clinical methodology

2.2.1. Novel non-clinical models

2.2.2. Application of 3Rs in medicines development

2.3. Clinical methodology

2.3.1. Modelling and simulation

2.3.2. Extrapolation

2.3.3. Patient reported outcomes (PROs)

2.3.4. New endpoints

2.3.5. Bayesian methods

2.3.6. Co-acting medicinal products

2.3.7. Clinical trials

2.4. Special populations

2.4.1. Pregnancy

2.4.2. Paediatric

2.4.3. Geriatric

2.5. Risk-benefit evaluation

2.5.1. Risk-benefit project

2.6. Big data and e-Health

2.6.1. Big data

2.6.2. Real world evidence

2.6.3. Open science

2.6.4. Cognitive computing

2.7 Communications

2.7.1. Inform social and behavioural science

2.8 Pharmacoepidemiology

2.8.1. Pharmacoepidemiology

2.8.2. Pharmacovigilance

3. Health threats

3.1. Antimicrobial resistance (AMR)

3.1.1 AMR

3.2. Emerging Health threats

3.2.1. Emerging health threats

4. Environmental analysis

5. International Regulatory Science cooperation

Supplementary Table 2

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist.

Guide questions/description		
Domain 1: Research team and reflexivity		
Personal characteristics		
1. Interviewer	Which author/s conducted the interview or focus group?	PH, RG, LD, AH, MP.
2. Credentials	What were the researcher's credentials?	MSc, PhD x 3, MD-PhD.
3. Occupation	What was their occupation at the time of the study?	Regulators, academics.
4. Gender	Was the researcher male or female?	3 male, 2 female.
5. Experience and training	What experience or training did the researcher have?	Mixed.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Variable. Most were contacted via email and had no relationship to the researchers. A few had a prior relationship with one or more researchers.
7. Participant knowledge of the interviewer	What did the participants know about the researcher?	Participants were briefed on the research aims via email and before the interview commenced.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator?	Interviewers identified as regulators or academics.
Domain 2: Study design		
Theoretical framework		
9. Methodological orientation	What methodological orientation was stated to underpin the study?	Grounded theory.
Participant selection		
10. Sampling	How were participants selected?	Purposive. Participants chosen primarily for their expertise, with a preference for those operating at a European level.
11. Method of approach	How were participants approached?	Face-to-face, telephone, email.
12. Sample size	How many participants were in the study?	70 interviews conducted, some with more than one respondent.
13. Non-participation	How many people refused to participate or dropped out? Why?	Most dropouts were those who refused to reply (<60)

Setting		
14. Setting of data collection	Where were the data collected?	Face-to-face at EMA or by telephone.
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Interested EMA colleagues occasionally joined.
16. Description of sample	What are the important characteristics of the sample?	Mixed ages and genders, primarily European professionals; interviews held between January and September, 2018.
Data collection		
17. Interview guide	Were questions, prompts, guides provided? Was it pilot-tested?	Participants were informed that horizon-scanning had been performed, but were provided only with an introduction to this exercise and with the interview questions; no formal pilot testing was conducted.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No; not applicable.
19. Audio-visual recording	Did the research use audio or visual recording to collect the data?	No.
20. Field notes	Were field notes made during and/or after the interview?	Notes were taken during the interviews.
21. Duration	What was the duration of the interviews?	Semi-structured interviews lasted from 30 to 100 minutes; open interviews from 2 to 2.5 h.
22. Data saturation	Was data saturation discussed?	Yes, it was sought for all participants.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No.
Domain 3: Analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Not applicable.
25. Description of the coding tree	Was a description of the coding tree provided?	See Table S1.
26. Derivation of themes	Were themes identified in advance or derived from the data?	Areas for baseline review and horizon-scanning were selected in advance; the final themes were derived from the data and axial coding.

27. Software	What software, if applicable, was used to manage the data?	Microsoft Office.
28. Participant checking	Did participants provide feedback on the findings?	Yes, at two "EMA Regulatory Science to 2025" workshops; a public consultation is ongoing.
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings?	No.
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes, the iterative methodology assured that this was the case.
31. Clarity of major themes	Were major themes clearly presented in the findings?	See Table S4, strategic goals.
32. Clarity of minor themes	Is there a description of diverse cases or a discussion of minor themes?	See Table S4, core recommendations.

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174 **Supplementary Table 3**

175 **EMA Regulatory Science to 2025 – proposed strategic goals, core recommendations and**
176 **underlying actions.**

Catalysing the integration of science & technology in drug development	
Core recommendations	**Underlying actions**
Support developments in precision medicine, biomarkers and 'omics	• Enhance early engagement with novel biomarker developers to facilitate regulatory qualification; • Address the impact of emerging 'omics' methods and their application across the development life cycle; • Evaluate, in collaboration with HTAs, payers and patients, the impact of treatment on clinical outcomes measured by biomarkers.
Support translation of advanced therapy medicinal products (ATMPs) into patient treatments	• Identify therapies that address unmet medical need; • Provide assistance with early planning, method development and clinical evaluation; • Support evidence generation, pertinent to downstream decision-makers; • Address the challenges of decentralised ATMP manufacturing and delivery locations; • Raise global awareness of ATMPs to maximise knowledge sharing, promote data collection.
Promote and invest in the PRIME scheme	• Invest in external communication to better explain and promote PRIME; • Evaluate current capacity and identify areas for increased investment; • Shorten the time between scientific advice, clinical trials and MAA submission; • Collaborate with stakeholders to ensure efficient oversight post-approval; • Leverage collaboration with patients, healthcare professionals, academia and international partners.
Facilitate the implementation of novel manufacturing technologies	• Recruit expertise in novel manufacturing technologies to enhance the assessment process; • Identify bottlenecks and propose modernisation of relevant regulations to facilitate novel manufacturing; • Address regulatory challenges in point-of-care manufacturing, e.g. concept of batch control, role of the Qualified Person; • Facilitate a flexible approach in application of Good Manufacturing Practice.

Catalysing the integration of science & technology in drug development	
Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products	• Define how risk-benefit of borderline products is assessed and communicated; • Enrich expertise at the interface between medicines, medical devices and borderline products; • Facilitate the regulatory pathway between notified bodies and medicines' regulators; • Gain insight in innovation on drug-device combination products via horizon scanning.
Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals	• Raise awareness of new nanomedicines and materials via the EU-Innovation Network; • Generate guidance addressing PK/PD requirements and long-term efficacy and safety; • Develop guidance on regulatory pathways with device regulators and notified bodies.
Diversify and integrate the provision of regulatory advice along the development continuum	• Promote more integrated medicines development aligning scientific advice, clinical trials approval and Good Clinical Practice oversight; • Create complementary and flexible advice mechanisms to support innovative product development expanding multi-stakeholder consultation platforms; • Facilitate translation of innovation via a re-engineered Innovation Task Force and synergy with an evolving EU-Innovation Network platform.

Driving collaborative evidence generation – improving the scientific quality of evaluations	
Core recommendations	**Underlying actions**
Leverage non-clinical models and 3Rs principles	• Stimulate developers to use novel pre-clinical models, including those adhering to the 3Rs; • Re-focus the role of the 3Rs working group to support method qualification; • Encourage implementation of IT tools to exploit the added value of SEND for the re-analyses of non-clinical studies to support both clinical trials authorisation FIM (first-in-man) and risk minimisation across EU.
Foster innovation in clinical trials	• Drive adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance; • Critically assess the clinical value of new and emerging endpoints and their role in facilitating patients' access to new medicines; • Work with stakeholders to encourage collaborative clinical trials;

Catalysing the integration of science & technology in drug development	
	• Collaborate with international partners in ongoing initiatives such as the Clinical Trial Transformation Initiative and ICH.
Develop the regulatory framework for emerging clinical data generation	• Develop methodology to incorporate clinical care data sources in regulatory decision-making; • Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual; • Develop the capability to assess complex datasets captured by technology such as wearables; • Facilitate training and understanding of healthcare professionals and patients to access and participate effectively in such trials.
Expand benefit-risk assessment and communication	• Expand the benefit-risk assessment by incorporating patient preferences; • Develop the capability to analyse Individual Patient Data to support decision-making; • Promote systematic application of structured benefit/risk methodology and quality assurance systems across the network; • Improve communication with HTAs and payers regarding therapeutic context, comparison vs. placebo/active-control, patient perspective; • Enhance structured benefit/risk assessment to improve communication to the public; • Incorporate academic research into evidence-based benefit-risk communication.
Invest in special populations initiatives	• Focus on speedy access for patient (sub-)populations in urgent need – Identify areas of highest unmet needs where clinical care data can supplement clinical trial data – Enhance multi-stakeholder advice in collaboration with patients, HCPs, payers and HTAs; • Progress implementation of the paediatric medicines action plan; • Progress implementation of the geriatric strategic plan; • Develop a strategic initiative in maternal-foetal health.
Optimise capabilities in modelling, simulation and extrapolation	• Enhance modelling and simulation and extrapolation use across the product lifecycle and leverage the outcome of EU projects; • Promote development and international harmonisation of methods and standards via a multi-stakeholder platform; • Increase capability and redesign the operations of relevant working parties to ensure wider knowledge exchange.

Catalysing the integration of science & technology in drug development	
Exploit digital technology and artificial intelligence in decision making	• Establish a dedicated AI test "laboratory" to explore the application of innovative digital technology to support data-driven decisions across key business processes; • Develop capacity and expertise across the network to engage with digital technology, artificial intelligence, cognitive computing, and their applications in the regulatory system.

Advancing patient-centred access to medicines in partnership with healthcare systems	
Core recommendations	**Underlying actions**
Contribute to HTA's preparedness and downstream decision making for innovative medicines	• Ensure the evidence needed by HTAs and payers is incorporated early in drug development plans; • Enable information exchange with HTAs to support bridging from benefit-risk to relative effectiveness assessment; • Discuss with HTAs guidance and methodologies for evidence generation and review; • Contribute to the identification of priorities for HTA; • Monitor the impact of decision-maker engagement through reviews of product-specific experience.
Bridge from evaluation to access through collaboration with payers	• Contribute to the preparedness of healthcare systems by creating opportunities for collaboration on horizon scanning; • Enable involvement of payers' requirements in the prospective discussion of evidence generation plans; • Clarify the treatment-eligible patient population included in the labelling, and its scientific rationale; • Participate in discussions clarifying the concept of unmet medical need.
Reinforce patient relevance in evidence generation	• Enhance patient involvement in EMA scientific committees; • Coordinate Agency's approach to patient reported outcomes (PROs). Update relevant clinical guidelines to include reference to PROs addressing study objectives, design and analysis; • While validating PROs, address patients' needs and leverage patients' expertise;

Catalysing the integration of science & technology in drug development	
	• Co-develop with HTAs a core health-related quality-of-life PRO to implement in trials and to bridge the gap with comparative effectiveness assessment; • Explore additional methodologies to gather and use patient data from the wider patient community during benefit-risk evaluation.
Promote use of high-quality real-world data (RWD) in decision making	• Create a sustainable, quality assured, flexible framework delivering rapid access to and analysis of representative, longitudinal RWD throughout a product's lifecycle; • Develop a capacity that will enable the Agency to rapidly and securely access and analyse large amounts of healthcare data; • Accelerate the implementation of a learning regulatory system based on electronic health records and other routinely collected clinical care data (including RWD).
Develop network competence and specialist collaborations to engage with big data	• Implement the core recommendations emerging from the HMA-EMA Joint Big Data Taskforce addressing areas such as harmonisation of data standards, characterisation of data quality, and provision of regulatory guidance as to acceptability of evidence; • Engage proactively with new stakeholders relevant to the big data landscape; • Invest in capacity building across the network to acquire new skills to engage with these emerging areas.
Deliver improved product information in electronic format (ePI)	• Enable real-time interactivity within the Summary of Product Characteristics and Patient Leaflet; • In conjunction with healthcare providers and patients, develop a strategic plan to deliver the ePI programme; • Enable the reuse of structured medicinal product information by third parties through development of a standardised interface; • Address the need for PI content improvements identified in the EC report (COM(2017) 135 final), such as package leaflet layout and readability.
Promote the availability and support uptake of biosimilars in healthcare systems	• Further develop strategic communication campaigns to healthcare providers and patient organisations to reinforce trust and confidence; • Enhance training of non-EU regulators in the evaluation of biosimilars with extension to all therapeutic areas; • Address regulatory challenges in manufacturing e.g., statistical assessment of CQAs in the comparability exercise and the evolution of multisource biologicals/biosimilars.
Further develop external engagement and communications to	• Develop content strategy, particularly in key public health areas and hot topics in regulatory science

Catalysing the integration of science & technology in drug development	
promote trust and confidence in the EU regulatory system	• Enhance professional outreach through scientific publications & conferences • Proactive approach to key public-health areas (e.g. vaccines) • Improved communications for patients, healthcare professionals, HTAs and payers; • Develop more targeted and evidence-based communication facilitated by updated web content and format.

Addressing emerging health threats and availability/therapeutic challenges	
Core recommendations	**Underlying actions**
Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches	• Coordinate scientific and regulatory activities within the EU network; • Evaluate preparedness for emerging pathogens and 'disease X'; • Coordinate discussions with the EU network, international partners and stakeholders on the identification, development, authorisation and post-authorisation follow-up of relevant medicinal products; • Effective and timely communication to healthcare professionals, the public and regulatory partners.
Continue to support development of new antibacterial agents and their alternatives	• Evolve regulatory guidance and support alternative approaches to new antibacterial drug development and innovative approaches for prevention and treatment of infections; • Support initiatives, such as the clinical trials network, to facilitate and accelerate clinical development; • Encourage new business models that provide "pull" incentives beyond the current "funding research" strategy in the EU; • In collaboration with HTAs and payers, define the evidence requirements for new antibacterial medicines; • Support the development and application of rapid diagnostic tools.
Promote global cooperation to anticipate and address supply problems	• Build on deliverables from the work plan of the HMA/EMA Task Force on availability of authorised medicines; • Explore mechanisms to increase manufacturing capacity in Europe and internationally; • Enhance collaboration with WHO in the area of supply disruptions due to manufacturing quality issues; • Promote greater knowledge exchange with international stakeholders on shortages due to quality/manufacturing issues;

Catalysing the integration of science & technology in drug development	
	• Continue to engage with healthcare professionals, patients and consumers organisations and the industry to address the causes and consequences of lack of medicines' availability; • Support international harmonisation of regulatory science standards for generic medicines addressing bioequivalence, waivers and modelling.
Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines	• Advance methods/tools (e.g. biomarkers) to characterise immune response and to support definition of vaccine quality attributes; • Examine innovative clinical trial approaches to expedite vaccine development; • Engage with public health authorities and NITAGs to better inform vaccine decisions; • Establish a platform for EU benefit-risk (B/R) monitoring of vaccines post-approval; • Communicate proactively with key stakeholders on B/R using evidence-based tools to tackle vaccine hesitancy.
Support the development and implementation of a repurposing framework	• Enhance regulatory advice on evidence generation and MAA submission; • Frame suitability of third party data-pooling, relevant RWD and historical non-clinical datasets; • Translate experience with EMA's registry pilot to guide RWD collection; • Explore utility of low-intervention clinical trials for evidence generation.

Enabling and leveraging research and innovation in regulatory science	
Core recommendations	**Underlying actions**
Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science	• Identify, in consultation with academia and relevant stakeholders, fundamental research topics in strategic areas of regulatory science (such as PROs, omics-based diagnostics, drug-device combinations, modelling and simulation, Big Data, and artificial intelligence); • Proactively engage with DG Research & Innovation, DG-SANTE, IMI and Member State funding agencies to propose and issue calls to establish research collaborations.
Leverage collaborations between academia and network scientists to address rapidly emerging	• Ring-fence EMA funding to address rapidly-emerging regulatory science research questions (such as diagnostics, precision medicine, distributed manufacturing, wearable devices, drug re-purposing);

Catalysing the integration of science & technology in drug development	
regulatory science research questions	• Ensure close interaction between network scientists and academia to deliver tangible impact through translation of this applied research into new drug products and regulatory tools; • Actively engage, through these applied projects, in training early-career researchers in regulatory science (e.g., via placements within the network).
Identify and enable access to the best expertise across Europe and internationally	• Invest in a knowledge management system to track innovation, share information, enable linkages and create new insights across the product lifecycle; • Facilitate more flexible access to global expertise in regulatory science and increasingly specialised and new areas of innovation.
Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders	• Engage with academia to develop regulatory training modules, including describing innovation of new medicines and their progression from laboratory to patient; • Conduct horizon scanning in key areas of innovation via collaborations with academia, the EU-Innovation Network and ICMRA; • Drive a data-sharing culture to foster open science which is mutually beneficial for all stakeholders.

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