



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2026
EMA/MB/389167/2025 - Adopted
Management Board

Minutes of the 130th meeting of the Management Board

Held in Amsterdam on 17-18 December 2025

The Chair of the Management Board opened the meeting, which was held as a face-to-face meeting, The Board was informed that posters would be on display during the lunch break of the second day, for Board members to further familiarise themselves on how the Agency anticipates and responds to emerging trends in the medicines landscape, ranging from scientific innovation and real-world data to strengthening our approaches to tackling misinformation.

1. Draft agenda for 17-18 December 2025 meeting

[EMA/MB/331769/2025] The agenda was adopted with no amendments.

2. Declaration of competing interests related to the agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics 'B.6 Programming 2026-2029', 'B.8 d. EMA 2026 risk-based audit plan and 2026-2028 strategic audit plan' and 'B.9 - Breach of trust procedures for scientific committee members and experts and for Management Board members.' The Secretariat informed the board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes from the 129th meeting, held on 02 October 2025, adopted via written procedure

[EMA/MB/313357/2025] The Management Board noted the final minutes, adopted by written procedure on 14 November 2025.



A. Points for automatic adoption/endorsement

A.1 Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2026

[EMA/MB/293332/2025] The Management Board endorsed the 2026 financial compensation scheme and workload estimation for the National Competent Authorities' (NCA) involvement in the linguistic checking of product-related information in their respective national languages. The financial compensation scheme is reviewed every year based on the inflation rate and will be increased by 3% in 2026.

A.2 Revised composition of the ETF for preparedness

[EMA/206184/2025], [EMA/MB/377945/2025] The Management Board endorsed the revised composition of the Emergency Task Force (ETF) for preparedness in accordance with Article 15 of the Regulation (EU) 2022/123, as proposed by the ETF Co-Chairs. As five ETF members had recently stepped down, the ETF Co-Chairs have proposed appointing five new experts with comparable profiles to ensure continuity of expertise particularly for ongoing work on antimicrobial resistance (AMR), following the same replacement approach applied to a previous change in ETF composition in 2024.

B.1 Highlights of the Executive Director

The Management Board noted an oral update from the Executive Director, who reflected on her commitment at the start of her mandate and the Agency's main achievements over the past five years, including the response to COVID-19 and the delivery of vaccines and therapeutics, strengthened cooperation under the One Health approach, progress in digitalisation and data use, actions to support the sustainability of the European medicines regulatory network, as well as a continued commitment to prioritising staff wellbeing and engagement in the "new normal".

Looking ahead to the next 16 months, the Executive Director outlined her commitment to the three main focus areas that will guide the Agency's work and are reflected in the Single Programming Document. These include re-imagining EMA in preparation for the new pharmaceutical legislation and associated changes to the regulatory and operating model; supporting innovation for public and animal health through strengthened clinical trials, early development support, and the effective use of data, digital tools and real-world evidence; and continued investment in EMA staff and the European medicines regulatory network to ensure the capacity, skills and resilience needed to meet future challenges.

In addition she highlighted two areas of potential strategic importance were highlighted, relating to women's health and the Agency's international role where she was confident that significant progress could be made.

Following the presentation, the Board welcomed the Executive Director's reflections and the clarity of the priorities outlined for the coming period. Members expressed appreciation for the clear presentation of the Executive Director's commitment for the next 16 months, particularly in light of the upcoming pharmaceutical legislation and the need to manage demanding timelines for centralised procedures. Several members congratulated the Executive Director on her reappointment and expressed support for the continued direction and vision presented.

As a concluding remark, the Chair informed the Board that the Executive Director had received an invitation from the Centre of Regulatory Excellence (CoRe) at Duke–National University of Singapore Medical School to join its Advisory Board for a two-year term starting in 2026. The Chair explained that the CoRe Advisory Board provides strategic guidance on regulatory science, health policy and system strengthening at global level. The Chair confirmed that he had been consulted on the current request and had agreed to the Executive Director’s participation.

B.2 Report from the European Commission

The Management Board noted an update from the DG SANTE representative on the following files: revision of the EU pharmaceutical legislation; the Critical Medicines Act; the Biotech Act; the targeted revision of the Medical Devices Regulations (MDR/IVDR); and the EU Action Plan on cardiovascular health (EU Safe Hearts Plan).

The political agreement reached on 11 December on the revision of the pharmaceutical legislation represents a once-in-a-generation revision that, amongst other things, introduces a modulated incentive system to drive innovation in areas of high societal value, establishes the concept of regulatory sandboxes, creates a transferable exclusivity voucher to support development of new antimicrobials, strengthens medicine shortages prevention and notification requirements, and streamlines EMA’s structure while granting patients and healthcare professionals membership in CHMP. Finalisation and publication of the new Directive and Regulation are expected in the first half of 2026, followed by a two-year implementation phase, although some provisions will take effect earlier. The Critical Medicines Act has completed its passage through the Council and is nearing finalisation in the European Parliament. The co-legislators are expected to commence trilogue negotiations in January 2026.

The Biotech Act legal proposal focuses on accelerating the time-to-market of biotechnology innovations by, for example, streamlining clinical trial authorisations in health biotech, clarifying regulatory pathways for borderline and combination products, and strengthening EFSA’s capacity to provide scientific advice to companies. The Act also aims to bolster Europe’s strategic biotechnology base by supporting high-impact projects that expand biomanufacturing capacity, develop specialised skills and connect biotech clusters across the EU. In addition, it incentivises the development of innovative biotech medicines through enhanced IP protection, provides targeted support to increase competitiveness in biosimilars, and mobilises private investment through a new EIB-backed financing initiative.

The MDR/IVDR revised legal proposal sets-out a streamlined and more predictable regulatory framework by reducing administrative burden, improving the efficiency of notified body assessments, introducing more proportionate conformity requirements for lower-risk and special-needs medical devices, advancing digitalisation, and ensuring better alignment with other EU legislation, such as the AI Act. As regards the EMA, the revision strengthens the scientific and regulatory role of the medical device expert panels, assigns the Agency new responsibilities for identifying and facilitating the sharing of information on shortages of critical medical devices, and supporting coordination of national competent authorities for medical devices on classification issues, conformity assessment derogations, clinical evaluations and investigations, as well as some vigilance and market surveillance activities.

The Safe Hearts Plan underscores the heavy burden of cardiovascular diseases, with 1.7 million deaths each year - mostly preventable - affecting 62 million people and costing EUR 282 billion annually. With one in three children overweight or obese and cases projected to rise by 90% by 2050, the plan proposes ten flagship initiatives in the areas of prevention, early detection, better treatment and care.

The Management Board also noted an update from the DG RTD representative on the implementation of the EU Life Sciences Strategy. The Life Science Strategy for Europe was unveiled in July 2025 as a broad, cross-sectoral framework with 24 actions - including 11 flagship initiatives - designed to make Europe the most attractive global hub for life sciences by 2030. The strategy spans the entire innovation journey: building a strong research and innovation ecosystem, ensuring rapid market uptake of new technologies, and preparing end-users for adoption in an evolving societal environment. Key areas of work include a Clinical Research Investment Plan, efforts to establish ATMP Centres of Excellence that integrate physical facilities with skills, regulatory expertise, supplier networks, hospitals, investors, and companies, and significant investments in new approach methodologies to advance non-animal testing. The Clinical Research Investment Plan aims to facilitate funding for multi-country trials and improve access to fragmented infrastructures - skills, data, regulatory interfaces, and physical platforms - in alignment with funding needs and other key goals identified via the ACT-EU programme.

The DG RTD representative also highlighted upcoming opportunities in the Horizon Europe 2026–2027 work programme, which mobilises EUR 1.3 billion for health-related research, alongside calls under Global Health EDCTP3 and the Innovative Health Initiative, whose funding areas reflect priorities identified in the Life Science Strategy. Following the publication of an article in Nature Reviews with joint EMA–HMA–EC recommendations for advancing pharmacogenomics in medicine regulation and in clinical practice, implementation of the joint recommendations is now underway and remains a priority for DG RTD.

Several Management Board members expressed appreciation and congratulated the Commission’s representative for these significant legislative achievements, the progress on the MDR/IVDR revision and EMA’s expanded coordination role with national authorities for medical devices. Some questions for clarification were raised regarding the proposed extra year of IP protection in the Biotech Act, specifically whether it functions like a supplementary protection certificate (SPC), on the scope of the EMA inspectorate, and on definitions used in the Biotech Act related to investigational medicinal product and interventional clinical trial and challenges experienced for investigator-initiated and non-commercial clinical trials in the EU.

The DG SANTE representative emphasised that the Biotech Act includes a dedicated section on academic trials, demonstrating the Commission’s awareness of these challenges. He explained that the Act is primarily an industrial-policy initiative, as regulatory action is only one of its five pillars, and confirmed that academic stakeholders had been engaged throughout the year. He also outlined the conditions for the Act’s proposed one-year SPC extension for certain biotechnology medicines: new active substance, new mechanism of action, trials in more than 2 EU MSs and EU-based manufacturing. In response to a question, he further clarified that the Clinical Trials Regulation revision included in the Biotech Act foresees cooperation between national competent authorities and the Agency for inspections in third countries for investigational medicinal products, upon request, similar to what is foreseen in the new pharmaceutical legislation. The RTD representative added that the Commission will develop an interactive regulatory navigation tool to assist researchers and innovators, particularly early in development, by mapping EU regulatory requirements.

The patients’ representative warmly welcomed the pharmaceutical legislation reform, expressing satisfaction that patients’ priorities such as incentive modulation, i.e. higher incentives to developers addressing an (high) unmet medical need, and patient voting rights have been included. They cautioned, however, that patients’ participation depends on a very small pool of individuals already serving on committees such as the PRAC, and therefore stressed the need for adequate support during implementation to ensure patient representatives can manage the additional workload effectively.

The European Parliament representative congratulated the Commission on securing a compromise on the pharmaceutical legislation despite difficult negotiations. He commented that Europe may still struggle to attract investments in innovation but emphasised that the new legislation will significantly strengthen efforts against antimicrobial resistance and medicine shortages. He also highlighted the reform as an important step forward for EMA giving it a more efficient structure aligned with current realities, welcomed the MDR/IVDR revision in light of changed circumstances since those regulations were first adopted, and praised the Commission's strong stance on major public health initiatives, from the EU Cancer Plan to the new cardiovascular health strategy. He also commented that Member States should be encouraged to develop national plans for cardiovascular health, following the successful model used for cancer.

Another Board member expressed appreciation for the inclusion of the veterinary sector in the Biotech Act, sought clarification on whether regulatory sandboxes could operate at both EU and national levels and suggested that a voucher mechanism could also have been valuable for biotechnology products on zoonotic diseases. Replying again, the DG SANTE representative confirmed that the veterinary sector is fully reflected in the Biotech Act, including through regulatory sandbox provisions and in areas linked to GMO legislation, which could be highly relevant for veterinary innovation. He noted that veterinary-specific measures include an SPC mechanism for zoonoses and that sandboxes could function at both EU and national levels.

B.3 Report from PDCO chair

The Management Board noted an oral report from the Chair of the Paediatric Committee (PDCO).

The PDCO Chair informed that paediatric investigation plans (PIPs) remain the Committee's core activity, with workload continuing to rise: nearly 900 applications in 2024 and around 100 procedures discussed per plenary meeting. While silent adoptions help manage volume, new tasks under the revised pharmaceutical legislation, such as mechanism-of-action PIPs, will add further complexity. Despite this, paediatric regulatory requirements continue to deliver public health benefits, with growing numbers of approved paediatric indications.

The Chair highlighted several initiatives to support paediatric development. The Stepwise PIP Pilot, created to address situations where early data are limited, has been positively received; it allows iterative definition of key elements and will be now embedded in the new legislation. PDCO is also implementing the ICH E11A guideline on paediatric extrapolation, supported by a multidisciplinary expert group to strengthen methodology, address knowledge gaps, and ensure consistent application across the network.

Coordination with the Clinical Trials Coordination Group (CTCG) has intensified to improve feasibility of multinational paediatric trials. A recent joint workshop revealed substantial variation among Member States in interpreting the Clinical Trials Regulation's Article 32 (inclusion of minors), directly affecting trial timelines. Planned actions include mapping national legal frameworks, reviewing guidance, and strengthening communication channels between CTCG and PDCO. Engagement with patients and medical societies remains central, with structured input taken into account for PIP opinions and a dedicated patients training programme during the EMA annual patient training day for high quality patient input into PIPs planned for 2026.

Looking ahead, the PDCO Chair emphasised that while the paediatric regulation has delivered nearly 600 new indications in children, paediatric drug development remains scientifically and operationally challenging with persistent unmet needs, especially in younger age groups. Maintaining strong, coherent paediatric expertise within EMA and the wider network will be essential under the new legislation. An agile structure capable of handling both complex and routine cases, involving EMA,

Member States, healthcare providers, and patient representatives, will be key to sustaining Europe's progress in paediatric medicines.

A Board member underlined that paediatric development requires distinct approaches rather than treating children as "small adults," and welcomed recent efficiency gains in PDCO processes that help smaller Member States contribute effectively, noting also the impact of the new pharmaceutical legislation. They supported stronger early dialogue, expanded use of modelling and extrapolation, and continued capacity building across scientific committees and, also, stressed the value of international cooperation and reliance. The patients' representative thanked PDCO for ensuring patients' voices are heard and highlighted the importance of maintaining collaboration, continuity and institutional memory as the PDCO moves into its next phase.

B.4 Selection procedure for the next EMA Executive Director

The Management Board noted the presentation by DG SANTE representative on preliminary timelines setting out the main steps for the appointment of the successor of the Agency's Executive Director, whose renewed mandate expires on 30 April 2027. Ahead of the Board meeting, a written procedure was launched to gather comments from Board members on the draft vacancy notice and none were received by the deadline, thus the notice was considered acceptable by the Board.

The members of the Board underlined the importance of launching the procedure as early as possible and of foreseeing potential delays within the timeline, in order to ensure that a new Executive Director can be appointed in due time, given that 16 months remain in the mandate of the current Executive Director. The DG SANTE representative confirmed it will keep the Management Board informed of the progress. The Board also appointed Karl Broich (member for Germany) as observer for the Management Board to the preselection panel, as proposed by the Chair, who will inform DG SANTE accordingly.

B.5 Preparation for implementation of the new EU pharmaceutical legislation, once adopted

[EMA/378998/2025], [EMA/MB/378997/2025] The Management Board endorsed the EMA's proposal for the New Pharmaceutical Legislation (NPL) Implementation Governance Structure.

Further to indication at previous Board meetings, the EMA presented a proposed governance model to steer preparation for implementation of the new pharmaceutical legislation (NPL), noting that the final text is expected early next year but that preparation must begin immediately. Successful implementation will require careful coordination given the complexity of the stakeholder landscape, the impact on virtually all regulatory processes, and the large number of forthcoming implementing and delegated acts, all within a two-year timeline. To manage this, EMA proposed a clear, adaptive governance structure, balancing needs for inclusiveness with rapid decision-making. Six delivery streams were identified: centralised procedures and committee reform; development support; environmental risk assessment and 3Rs; quality and manufacturing; shortages; and a miscellaneous legal and regulatory workstream (e.g. looking at definitions, AMR vouchers). Existing Network working groups, such as scientific working parties, IT governance, and EMA's stakeholder engagement groups, would be used to support the implementation rather than creating new ones.

Each delivery stream would be jointly sponsored by an EMA and a Management Board representative, with civil-society representation added for the centralised procedure. Above these streams, a new NPL Oversight Group would provide strategic direction, prioritise work, and manage risks, reporting to the

Management Board. The Oversight Group would consist of EMA's Executive Director and senior management representatives, Management Board members (including the MB Chair and the HMA Chair), and a European Commission representative, with Committee Chairs invited when relevant. Next steps include nominations for delivery stream sponsors and Oversight Group membership, and preparation of a cross-cutting implementation masterplan mapping responsibilities, timelines and interdependencies across the legislation.

The DG SANTE representative stressed the importance of discussing governance for the new pharmaceutical legislation early, noting that implementation will be fast-moving and resource-intensive. Around 100 delegated/implementing acts will need to be drafted, requiring coordinated effort across the Commission, EMA and the NCAs' network. Mindset and cultural change will be as important as procedural adjustments.

Board members broadly welcomed EMA's early planning but underlined challenges relating to readiness and workload. Several members highlighted that national authorities must absorb multiple major reforms simultaneously - including the Critical Medicines Act and the Biotech Act - while maintaining ongoing regulatory responsibilities. They stressed the importance of aligning centralised and decentralised authorisation procedures (MRP/DCP), ensuring change-readiness, and dedicating adequate resources.

Concerns were raised that the workload may increase substantially in the network without extra staffing. Participants called for a critical review of existing activities, warning that simply adding new layers without removing old ones is unsustainable. EMA underlined that the reform is a unique opportunity to simplify processes rather than adding new layers, and that early strategic steering is crucial.

Multiple interventions reinforced the need for a small, agile NPL Oversight Group. Maintaining balanced representation in the overall governance between larger and smaller Member States and ensuring geographical diversity were also seen as important. It was emphasised that governance will need to function across three layers simultaneously - EU, decentralised (MRP/DCP) and national (NCA) level - making lean structures at EMA essential. A request was made for civil society representation also in the development-support workstream, given the strong patient involvement in areas such as paediatric and orphan medicines. The Management Board Chair reminded that the Oversight Group should be seen as a MB level structure, even if some individuals hold dual roles at EMA/HMA level, underlining that effective coordination, strategic guidance, and balanced participation is indispensable for the proper functioning of this governance model. It was also noted that expert input via the delivery streams will be essential.

The Board agreed to proceed with the NPL Oversight Group composition of four EMA senior managers (including the EMA ED and head of human medicines division), four Management Board members representing medicines agencies (including the MB chair and HMA chair), and one Commission representative and with ad-hoc engagement of the chairs of CHMP, PRAC and CMDh when relevant. The Board also agreed to apply the presented guiding principles (including geographical diversity) in the overall governance, and to have joint sponsorship of delivery streams by an EMA and a Management Board representative, with civil-society representation added for the centralised procedure and committees and for the development-support workstreams. The MB chair invited any interested Board members to contact him to express interest as a delivery stream sponsor or Oversight Group member.

B.6 Programming 2026-2029

- a) Final programming document 2026-2028 and 2026 budget

b) Preliminary programming document 2027-2029

[EMA/MB/372981/2025], [EMA/MB/354198/2025;], [EMA/366818/2025], [EMA/354245/2025] [EMA/343092/2025], [EMA/MB/358368/2025] The Management Board adopted the Single Programming Document (SPD) for 2026-2029 which was presented as a single document, made up of the final updated 2026-2028 programming document, including the final 2026 work programme, budget and establishment plan, and the draft programming document for 2027-2029. Spanning over a four-year period, it sets out the priorities and main focus areas that guide the Executive Director in implementing the budget and deploying the resources made available to the Agency.

MB Topic Coordinators Eija Pelkonen, Franck Fourès, Grzegorz Cessak, and Aimad Torqui, along with the MB Chair, reviewed and presented these documents to the Board.

The 2026–2029 SPD reflects a revised structure aimed at full integration of the European Medicines Agencies Network Strategy to 2028 and improved readability. The multiannual programming covers 42 areas of work, represented in the annual work programme through workload and performance indicators. EMA noted that, should recent and future legislation with a significant impact on its activities be published during 2026, it may return to the Board with a proposal for an amended or updated document.

Following EMA's PESTLE analysis carried out in May 2025, the general context of the SPD was updated to reflect eight main influencing factors shaping the Agency's operating environment in the coming years. For the 2026–2028 planning period, the Agency continues to focus on key investments to address challenges arising from sustained resource constraints across the EU Medicines Regulatory Network, the reform of the EU pharmaceutical legislation, financial and geopolitical pressures, increasing expectations around transparency and communication, the growing importance of data and real-world evidence, accelerating digitalisation and the use of artificial intelligence, developments in the international environment, and the impact of multiple legislative initiatives beyond pharmaceutical legislation.

The Multi-annual Work Programme for 2026–2029 has also been developed to support the Agency's vision of providing a fast path from innovation to safe and effective medicines. The Topic Coordinators presented an overview of the programme to the Board. They explained that the 2026 annual work programme will mainly focus on three priority areas: preparation for the changes introduced by the new EU pharmaceutical legislation, support to innovation for public and animal health, and continued investment in staff and the European medicines regulatory network to build the capacity and capability needed to meet future challenges. The Agency will modernise the regulatory system in response to scientific and technological advances, enhance efficiency through digitalisation and artificial intelligence, and strengthen early development support to facilitate timely access to new medicines in the European Union and in order to deliver these priorities.

The 2026 budget was presented in the context of the SPD and the Agency's priorities for the coming year. The Topic Coordinators summarised that, based on current knowledge and assumptions, the budget is balanced and adequately funds the planned activities. It foresees increased payments to Member States' National Competent Authorities in line with activity levels, funding for network development initiatives, including Network Training Centre activities, as well as scientific studies, real-world data and enhanced communication campaigns to combat misinformation. It also includes measures to improve operational efficiency through outsourcing, digitalisation and process automation.

Significant investment is foreseen under the IT budget, including continued support for pan-European systems such as clinical trials, product and substance data, SPOR and the IRIS collaboration platform, as well as cybersecurity. The Topic Coordinators concluded that, while the overall IT budget remains stable, greater focus will be placed on cost transparency, cloud optimisation, reuse of existing

platforms and the progressive integration of artificial intelligence to support digital transformation and control operating costs.

Regarding staffing, the proposed establishment plan for 2026, includes additional fee-funded posts linked to increased product workload and legislative implementation preparations. The Agency indicated that additional posts are required to address the continuously increasing fee-funded product workload.

The Topic Coordinators underlined that the SPD sets out a number of 'negative priorities', explaining that workload has increased in several areas and that, despite mitigation measures and the use of alternative resourcing arrangements, capacity constraints continue to affect the Agency's ability to deliver fully on certain activities. The investment of additional Temporary Agent posts would enhance the Agency's capacity and pace to adequately deliver in some important areas. These areas include technology lifecycle management, the assessment and integration of artificial intelligence opportunities, transparency-related work and international regulatory cooperation.

In view of these pressures and the continued growth in fee-related workload and additional tasks, the Topic Coordinators presented the Agency's intention to request additional Temporary Agent posts for 2027 to support the effective and sustainable delivery of its responsibilities.

The Board welcomed the revised structure of the SPD and thanked EMA, the Topic Coordinators and all colleagues involved. Some members raised questions regarding the allocation of additional Temporary Agent posts, and if resources would be sufficient to support new requirements for EMA under the one-substance-one assessment legislation and the Critical Medicines Act, in particular the vulnerability assessment, also in view of limited capacity in the network.

The DG SANTE representative referred to the challenging EU budgetary context, including pressures linked to the next Multiannual Financial Framework, and highlighted that requests for additional resources for EMA would need to be considered against competing priorities. He the importance of timely preparation for implementation of the new pharmaceutical legislation and welcomed the inclusion of a disclaimer noting that the budget and work programme may need to be presented again to the Board in 2026 to reflect recent and future legislative developments, notably the impact on CTIS. EMA explained that workload growth is driven by the expanding product portfolio and new legislative obligations, that investment is required to achieve efficiencies, and confirmed that while some limited resources had previously been made available for extended mandate activities, further capacity would be required to support substantial activities under the Critical Medicines Act and shortages management

Members welcomed efforts to improve cost control in relation to the IT budget, while encouraging further optimisation and improved interoperability with National Competent Authorities (NCAs). EMA also acknowledged some concerns raised on IRIS and confirmed that further enhancements will be pursued during the planned IRIS transition in close collaboration with NCAs and industry. A few members expressed concerns regarding the management of ageing IT systems highlighted under the negative priorities, noting the associated operational and cybersecurity risks. EMA explained that the inclusion of 'negative priorities' does not indicate that activities are discontinued but reflects constraints on the pace at which improvements can be delivered, and confirmed that cybersecurity remains a key focus, with ongoing efforts to monitor vulnerabilities and mitigate risks while progressing remediation within available resources.

The Agency will reflect any final comments received, circulate the final document to the Board and submit it to the European Commission and other institutions in line with the applicable deadlines.

- c) Preparation of a written procedure for non-automatic carry-over of appropriations from 2025 to 2026

The Management Board noted the need for a written procedure to be launched in early 2026 for non-automatic carry-over of appropriations from 2025 to 2026 for which most of the preparatory stages of the commitment procedure have been concluded in line with the Agency's financial regulation.

B.7 New Fee Regulation implementation: update on the time collection data by procedure types in accordance with Annex VI to Regulation (EU) 2024/568

[EMA/MB/359144/2025], [EMA/MB/359047/2025] The Management Board noted an update on the time collection data by procedure types in accordance with Annex VI to Regulation (EU) 2024/568.

The Board was reminded of the agreed approach adopted at its December 2024 meeting for collecting time spent by rapporteurs, co-rapporteurs (and equivalent roles), in accordance with the new Fee Regulation and the related Working Arrangements, for four types of procedures. EMA informed the Board that the first round of time collection, covering 28 procedures started and completed in the first half of 2025, has been finalised. The information provided by NCAs was reviewed and discussed by the Management Board sub-group at its October meeting. EMA noted that this exercise is taking place at an early stage of implementation of the New Fee Regulation and that experience will continue to develop over time. Variations in time spent across procedures were observed, potentially reflecting differences in complexity of individual procedures, and EMA indicated that this will be further addressed through refinements to the reporting template provided to NCAs. The MB sub-group also noted that reporting tools are still maturing and supported the development of a guidance to support the distinction between scientific and technical tasks. The next round of data collection is planned for January 2026 to cover the second half of 2025, for the same types of procedures. In line with the legal requirements of the New Fee Regulation, aggregated working hours will be published on EMA's website without identifying individual Member States.

B.8 Audit topics

- a) Revised composition of Management Board Audit and Risks Group (MBARG)

[EMA/MB/374864/2025] The Management Board adopted the revised composition of Management Board Audit and Risks Group (MBARG). The MB Chair noted that the Group was established with three to six members, each serving a renewable two-year term. Its final composition was agreed in October 2023, with current members continuing until mid-December for continuity. A November call for interest produced two new nominees: Sergejs Akulics and Marko Korenjak. The four current members agreed to serve a second term, while one member will step down, as they are retiring at the end of 2025. The MBARG will therefore have four continuing and two new members, with the new terms starting on 18 December 2025.

- b) MBARG activities

[EMA/MB/356789/2025] The Management Board noted an update on MBARG activities.

The MBARG Chair reported notable progress since the June Management Board meeting, following two key sessions: an ad hoc meeting on 24 June 2025 on the future organisation of the Internal Audit Capability (IAC) and the regular meeting on 7 November 2025. The June meeting addressed significant staffing changes, based on a broader rethink of EMA's internal audit function's structure. By November, multiple agreed actions had been implemented. EMA advanced its plan to expand its audit co-sourcing,

preparing a two-year tender to build stable partnerships and support knowledge transfer. The IAC staffing model is also taking shape: Franck Diafouka has been formally appointed Head of the IAC, one auditor joined in November, and another will start in January 2026. A more integrated risk-based approach is now evident in the draft 2026 Audit Plan, directly linked to EMA's risk register and the themes of the European Medicines Authorities Network Strategy to 2028. Governance improvements include reviewing MBARG composition, simplifying meeting presentations, and developing an EMA Assurance Map by mid-2026.

c) Updated Internal audit charter of the EMA's internal audit capability

[EMA/209787/2017], [EMA/MB/360449/2025] The Management Board adopted the updated Internal audit charter of the EMA's internal audit capability. The Head of the IAC explained that the Charter has been updated to reflect organisational changes introduced in the Executive Director's decision renaming the function from Audit Advisory (AF-AUD) to Internal Audit Capability (AF-IAC). Aside from this administrative update, the charter remains unchanged and fully aligned with Global Internal Audit Standards.

d) EMA 2026 risk-based audit plan and 2026–2028 strategic audit plan

[EMA/258521/2025], [EMA/MB/258509/2025] The Management Board adopted the EMA 2026 risk-based audit plan and the 2026–2028 strategic audit plan, including the decision to transfer the audit on 'Enterprise Architecture' to next year.

The Head of IAC presented the 2026 Audit Plan and outlook for the coming years. The plan is prepared in accordance with the Financial Regulation, the newly revised Global Internal Audit Standards, and the updated Internal Audit Charter.

In 2026, the IAC will operate with a team of four auditors, including two new staff member completing probation. A major development is the launch of a two-year co-sourcing tender to bolster capacity and build long-term partnerships with external audit firms.

The risk-based audit plan for 2026 is closely aligned with EMA's risk register. It includes audits planned on cybersecurity, contractor management, DARWIN EU, talent management, management of pharmacovigilance IMPACT studies; EC's Internal Audit Service (IAS) reviews on quality and risk management; audits by external auditors on medical literature monitoring and certification of the financial accounts by the European Court of Auditors. Forward-looking audit plans for 2027–2028 cover: system development lifecycle, legacy systems, environmental management, access to documents, EudraVigilance Data Protection, AI, optimised work environment, HR topics, procurement, implementation of the veterinary regulation and governance. Finally, the IAC will continue reinforcing collaboration with internal and external stakeholders and modernising audit tools, methods, and digital practices.

B.9 Breach of trust procedures for scientific committee members and experts and for Management Board members

[EMA/MB/309079/2012], [EMA/154320/2012], [EMA/MB/359463/2025] The Management Board adopted a revised breach of trust procedures for scientific committee members and experts and for Management Board members.

EMA presented the revised breach of trust procedures, following a review of their implementation and in response to recommendations from a 2024 internal audit on the effective management of competing interests. EMA explained that the proposed changes aim to bring greater clarity and consistency to the procedures, in particular by clearly distinguishing between the preliminary investigation of information

suggesting a potential breach and the formal initiation and conduct of a breach of trust procedure. The revised procedures also clarify the factors triggering initiation, focusing on cases involving apparent intention or gross negligence, in order to ensure a proportionate approach.

EMA outlined the main procedural changes for scientific committee members and experts, including the replacement of the current hearing board with a dedicated Breach of Trust Board, chaired by the Deputy Executive Director, which will conduct hearings and adopt decisions. Appeals will be decided by the Executive Director, ensuring a clear separation between first-instance and appeal decisions. EMA also explained that consultation of the Management Board on individual cases involving scientific committee members is proposed to be removed, while ensuring that the relevant nominating authority is informed and that the Board continues to be informed via the annual report on independence. For Management Board members, EMA presented clarifications to the procedural steps, including the role of the Agency and the Executive Director in initiating procedures, the possibility of temporary suspension in consultation with the Management Board Chair, and arrangements for hearings and appeals to safeguard the rights of the member concerned.

During the discussion, members welcomed the clarity of the revised procedures and sought confirmation on their practical application. EMA confirmed that breach of trust procedures have so far not to be applied to Management Board members and have been used only on very rare occasions in relation to scientific committee members and experts.

The Management Board also noted the updated guidance on the handling of notifications by scientific committee members, Management Board members and other group members of their intention to engage in occupational activities, which was tabled under item C.4. and which will be published on the EMA website.

B.10 Report on the data protection activities by EMA in accordance with the EU Data Protection Regulation

[EMA/137320/2022], [EMA/MB/37871/2025] The Management Board endorsed the updated EudraVigilance Joint Controllership Agreement between EMA, national competent authorities and the European Commission, and noted a report on the data protection activities of EMA in accordance with the EUDPR.

The Joint Controllership Agreement was updated to reflect the addition of the Signal and Safety Analytics platform to the EudraVigilance system and to include a dedicated Data Protection Notice for such platform informing data subjects about the processing of their personal data and their rights under the EU Data Protection Regulation (EUDPR).

The EMA Data Protection Officer (DPO) highlighted that 2025 was a particularly intensive year driven by increased digitalisation across the Agency. The growing number of new IT systems and software required extensive assessment for security and data protection compliance (data protection impact assessments). Numerous new and renewed contracts and tenders underwent routine checks, reflecting the expanding workload. Transparency remained a priority and the DPO noted substantial activity in drafting and updating Data Protection Notices (DPNs), which inform stakeholders on how their personal data is processed. There was a clear rise in data subject requests, including access, rectification, and erasure of personal data, requiring careful review. EMA also contributed to the European Data Protection Supervisor's (EDPS) thematic self-assessment on the 'right to erasure'. Data breach management capacity was assessed as strong: four breaches were notified to the EDPS, all classified as low risk. Three notified cases were fully closed after discussion with the EDPS.

A major exercise in 2025 was the dedicated security and data protection audit of the IRIS platform. Security controls performed well, while improvements were recommended in the areas of documentation and staff training. All recommendations from the EDPS's 2023 audit on EudraVigilance have been implemented to the EDPS's satisfaction. EMA continued conducting Data Protection Impact Assessments (DPIAs) for higher-risk processing, including the new Signal and Safety Analytics platform, which required prior EDPS consultation. Collaboration with other EU DPOs intensified, especially on topics like the EDPS recommendations on Microsoft 365. EMA also worked jointly on DPIAs for Copilot and for administrative and disciplinary procedures and contributed to improved DPIA templates and guidance.

Training remained a key focus. EMA developed new online modules, including general data protection learning and specialised AI-related courses, available via EU-NTC. Internal guidance was modernised into short "quick bites" for easier use. Tools supporting compliance with cloud service provider requirements were also produced. Finally, EMA monitored new EDPS and EU guidance relevant to its work, including documents on pseudonymisation, IT risk management, AI governance, and changes introduced to the EUDPR via the Digital Omnibus legal proposal. The DPO concluded by reaffirming strong progress and EMA's commitment to maintaining strong data protection standards.

B.11 DARWIN EU update

The Board noted an update on DARWIN EU. Since its establishment in 2022, DARWIN EU has evolved into a key capability for generating real-world evidence in support of regulatory decision-making across the medicinal product lifecycle. More than 100 studies have been initiated, with over 30 data partners contributing health data from more than 188 million patients across 16 European countries. EMA highlighted the growing impact of DARWIN EU on regulatory evaluations, post-authorisation activities and public-health decision-making, as well as its contribution to strengthening methodological standards and regulatory expertise. Looking ahead, the next phase of DARWIN EU will focus on further expanding the network, aligning with the European Health Data Space and strengthening the use of advanced analytics, including artificial intelligence. EMA also informed the Board that a competitive tender will be launched in the first half of 2026 for a follow-on "DARWIN EU2" for the period 2027–2032.

During the discussion, Members supported the continued development of DARWIN EU while underlining the importance of clearly positioning real-world evidence alongside clinical trial data. EMA also clarified that study timelines depend on data readiness and the complexity of research questions, emphasised the need for sustained investment in data quality and standards, and confirmed that safeguards are in place to ensure continuity during the upcoming tender and to further engage NCAs in future use cases.

B.12 Update from Network Data Steering Group (NDSG)

The Board noted the recent activities of the Network Data Steering Group. The first data strategy for medicines regulation has been published, outlining a clear approach to ensure that the European medicines regulatory network's data assets are well governed, meet high standards of quality and deliver value to stakeholders. Further updates were provided on strengthening product master data, including agreed recommendations to support a harmonised, EU-wide approach to medicinal product information, with next steps focusing on improved data quality, governance and consistent implementation across the network.

The Board also noted progress on artificial intelligence (AI), including the endorsement of an AI tools framework to support responsible sharing and reuse of AI solutions across the network, the development of AI literacy tools, and ongoing work on a joint HMA/EMA AI use-cases roadmap to

prioritise areas where AI can deliver the greatest regulatory value and guide coordinated implementation. In addition, agreement was reached on a proposal for training, including modules on AI, to be rolled out to the network starting in the first quarter of 2026 through the EU Network Training Centre Learning Management System. The Board welcomed these developments, and highlighted the importance of data readiness, including SPOR, noting that the ongoing product master data feasibility work will help inform discussions on resource needs, data governance and alignment across the network.

B.13 Clinical trials in the EU

- Legislative update

The Management Board noted the legislative update on clinical trials presented by the DG SANTE representative. The update highlighted the strengthened role of the Reporting Member State in leading scientific, ethical and regulatory reviews, earlier integration of ethical review in Part I, increased flexibility through parallel substantial modifications and more predictable sponsor–regulator interactions. The DG SANTE representative presented the clinical trials regulation related elements of the Biotech Act, outlining measures to simplify and streamline the EU clinical trial framework. These include reducing authorisation timelines for multinational clinical trials through streamlined processes and stronger coordination and mutual reliance between Member States, a single core dossier, mandatory EU-harmonised templates, a single assessment for combined medicine and device or IVD studies, a harmonised legal basis for personal data processing, a new minimal-intervention trial category requiring only ethical review, and accelerated pathways for public health emergencies. The update also highlighted provisions supporting innovation, including the use of AI and digital tools, regulatory sandboxes, and targeted derogations for selected investigational ATMPs.

During the discussion, Members welcomed the ambition of the Commission’s legal initiatives to improve the EU clinical trials environment as part of the Biotech Act. Clarification was provided on the new minimal-intervention trial category, confirming that it applies to authorised medicines within the existing low-intervention framework. The DG SANTE representative confirmed that the legislative proposal remains open to further refinement during the legislative co-decision process and encouraged continued feedback from the Board and Member States.

- CTIS report and update

[EMA/MB/375961/2025], [EMA/375941/2025] The Management Board noted the report and was informed of continued progress with the Clinical Trials Information System (CTIS). By 30 November 2025, nearly 12,870 initial clinical trials, including initial, transitional and resubmitted trials, had been submitted, with 10,670 decisions issued by Member States. Following completion of the knowledge transfer to the new supplier, the CTIS modernisation roadmap has started and has now entered the implementation phase, setting out actions and deliverables through to 2028. EMA highlighted that the Biotech Act introduces significant changes to the Clinical Trials Regulation, which will have a substantial impact on the CTIS architecture, including new requirements related to product dossiers, which may require further analysis and adjustments to the development roadmap. The modernisation activities would need to be re-sequenced to accommodate these changes. Progress was also reported on recommendations from the CTIS Simplification Taskforce to improve user-friendliness, as well as on preparations for the new safety module and related change management activities planned for the first half of 2026. The Board was also informed of the upcoming Internal Audit Service audit of CTIS, which commenced in December 2025, and which outcome will be provided at a future Board meeting.

- ACT EU highlights

The Management Board noted the update on the Accelerating Clinical Trials in the EU (ACT EU) initiative. EMA provided an overview of the priority actions undertaken in 2025, focusing on supporting implementation of the Clinical Trials Regulation, improving trial design and methodologies, strengthening safety oversight and enhancing stakeholder engagement.

The Danish MB member presented highlights from the annual ACT EU Network matrix meeting, noting that the outcomes of the meeting feed into the revision of the ACT EU workplan for 2026–2027 and into HMA initiatives. The stakeholder co-chair of the Multi-stakeholder Platform and its Advisory Group, highlighted their active role in ACT EU governance through regular consultations and the annual meeting held in October 2025, which focused on innovation in EU clinical trials, including patient involvement, AI and digitalisation, ethical review and methodologies. The Austrian MB member presented the HMA-led FAST-EU initiative with a pilot expected to start in January 2026 and aims to increase the attractiveness of Europe for clinical trials. The pilot will launch in January 2026 and will provide useful insights for the implementation of the Biotech Act.

The Board acknowledged the continued progress of ACT EU and the introduction of a new metrics framework, including agreed targets and key performance indicators to monitor the EU clinical trials environment. EMA highlighted the interactive dashboard that will be used by the European medicines regulatory network (EMRN) to monitor performance from 2026, with a public dashboard ready for April 2026. Looking ahead, EMA outlined next steps, including finalising the 2026–2027 ACT EU workplan, further aligning activities with Network and stakeholder priorities, continuing discussions on the future of consolidated scientific and regulatory advice pilots, and supporting the roll-out of the dashboard with dedicated training for network users in early 2026.

B.14 Technology Capability Investment Plan (TCIP) to 2028

[EMA/MB/377957/2025], [EMA/379954/2025] The Management Board noted the Technology Capability Investment Plan (TCIP) to 2028.

The updated TCIP replaces the current version of the Plan which was issued in 2022 and has been revised due to the significant evolution of the digital landscape, particularly the emergence of generative AI systems, and to ensure alignment with the objectives of the European Medicines Agencies Network Strategy to 2028. The TCIP remains the central framework guiding EMA's technology-related decisions and investment priorities. As many EMA systems interface directly with those of National Competent Authorities (NCAs), the Plan also provides strategic direction for the network as regards long-term technology planning.

To prepare the revision, EMA conducted a survey of NCA IT directors, with 43 responses received. The survey showed considerable fragmentation across the network: different and often incompatible software versions hinder collaborative work, and multiple parallel systems replicate similar functions at national level. Although NCAs share broadly similar digital ambitions, disparities in investment limit the development of a coherent, common technological foundation. These findings reinforce the need for coordinated planning and strengthened interoperability.

The updated TCIP reflects several major developments. EMA is transitioning from exploratory AI use to deploying AI at operational scale, moving towards advanced autonomous systems while ensuring responsible implementation. The plan also supports a shift from project-based IT delivery to a digital product lifecycle model, enabling continuous evolution of core IT systems. Further priorities include modernising the enterprise architecture, introducing a shared data platform to enhance network-wide

data exchange, and adopting a structured management approach on Application Programming Interfaces to improve how EMA connects with NCA systems. The plan also promotes greater cost transparency and includes a capability map that links business needs to defined technology platforms, helping to avoid unnecessary system development and ensuring new requirements fit into EMA's architecture. The TCIP identifies multiple areas for strengthened collaboration across the network, including submission and procedure management, central repositories, common data viewers, API management, and enhanced digital collaboration tools.

Reacting to the EMA presentation, a Board member emphasised that fragmented IT systems undermine future efficiency across the European network and that enhanced IT alignment between EMA and national authorities will be essential for future success.

B.15 2025 EMA Annual Report on the implementation of the EMA's Anti-Fraud Strategy

[EMA/MB/381088/2025], [EMA/380151/2025] The Management Board noted the EMA Annual Report on the implementation of the EMA's Anti-Fraud Strategy in 2025.

The EMA's annual report outlined progress made throughout 2025 and the planned priorities for 2026, confirming that activities remain aligned with the updated Anti-Fraud Strategy endorsed by the Management Board in June 2025. The Board was informed that no new fraud-related incidents were reported in 2025 and the European Anti-Fraud Office (OLAF) did not open any investigations concerning EMA. This outcome reflects a stable internal control environment and a generally sound level of staff awareness. During the year the EMA conducted an internal survey on fraud awareness and reporting procedures, which showed strong understanding among staff, although several areas for further improvement were identified. An information session in November reinforced knowledge on fraud reporting and whistleblowing for both new and existing personnel. EMA is also in the process of updating its external reporting policy to ensure continued compliance.

The Agency completed an important strategic milestone by leading the EU Agencies Network's work with OLAF on a template for administrative arrangements governing information exchange between EU agencies and OLAF for the purposes of fraud investigations. In 2026, EMA aims to finalise administrative arrangement with OLAF tailored to EMA's mandate, following an internal impact assessment. Another priority is the launch of an EMA-wide fraud risk assessment using the newly adopted OLAF methodology. This cross-functional exercise will lead, among other things, to the creation of a 'red-flags' registers in different internal areas. Further planned initiatives focus on continuing to promote an anti-fraud culture in EMA and include finalising a new anti-fraud charter, launching an internal information hub and Suggestion Box on fraud-related activities, and updating the anti-fraud training programme including mandatory training for all staff.

List of written procedures during the period from 23 September to 03 December 2025:

- Consultation procedure for the adoption of the 129th EMA Management Board meeting minutes. The minutes were adopted.
- Consultation procedure on the draft vacancy notice for the selection of EMA's next Executive Director. The draft vacancy notice was accepted.

Documents for information

- [EMA/MB/316806/2025] Outcome of written procedures finalised during the period from 23 September to 03 December 2025
- [EMA/MB/379882/2025], [EMA/MB/379888/2025] summary of transfers in budget 2025 and summary of implementation of assigned revenue
- Network portfolio report
- [EMA/MB/381019/2025], [EMA/366830/2024] Guidance on handling of EMA scientific committees, Management Board or other EMA group members' intention to engage in occupational activities
- [EMA/MB/376660/2025], [EMA/379205/2025] 2024 Environmental Statement (under the standard of the EU Eco-Management and Audit Scheme)
- [EMA/MB/357668/2025] European Court of Auditors Annual report on EU agencies for the 2024 financial year (section 3.19 - EMA)

List of participants at the 130th meeting of the Management Board, 17-18 December 2025

Chair: Rui Santos Ivo

	Participants
Belgium	Hugues Malone (<i>member</i>) Charles Denonne (<i>alternate</i>)
Bulgaria	<i>Apologies received from Bulgaria</i>
Czech Republic	Boráň Tomáš (<i>member</i>) Jiří Bureš (<i>alternate</i>)
Croatia	Siniša Tomić (<i>member</i>)
Denmark	Nils Falk Bjerregaard (<i>member</i>) Mette Aaboe Hansen (<i>alternate</i>) Birgitte Faber (<i>support observer</i>)
Germany	Karl Broich (<i>member</i>) Wiebke Löbker (<i>support observer</i>)
Estonia	<i>Apologies received from Estonia</i>
Ireland	Lorraine Nolan (<i>member</i>) Gráinne Power (<i>observer</i>)
Greece	Spyridon Th. Sapounas (<i>member</i>)
Spain	María-Jesús Lamas Díaz (<i>member</i>) Consuelo Rubio Montejano ¹ (<i>alternate</i>)

	Participants
	Antonio Blázquez (<i>support observer</i>) Celia Caballero (<i>support observer</i>)
France	Catherine Paugam-Burtz (<i>member</i>) Franck Foures (<i>alternate</i>) Miguel Bley (<i>support observer</i>)
Italy	Robert Nisticò (<i>member</i>) Armando Magrelli (<i>alternate</i>) Marta Giovanna Toma (<i>support observer</i>)
Cyprus	Helena Panayiotopoulou (<i>member</i>) Irimi Chrysafi Fanidou (<i>alternate</i>)
Latvia	Sergejs Akuličs (<i>alternate</i>)
Lithuania	Dovilė Marcinkė ¹ (<i>member</i>)
Luxembourg	Anna Chioti (<i>member</i>)
Hungary	Beatrix Horváth (<i>alternate</i>)
Malta	Anthony Serracino Inglott (<i>member</i>)
Netherlands	Paula Loekemeijer (<i>member</i>) Aimad Torqui (<i>alternate</i>) Roelie Marinus (<i>support observer</i>)
Austria	Günter Waxenecker (<i>member</i>)
Poland	Grzegorz Cessak (<i>member</i>) Marcin Kolakowski (<i>alternate</i>) Magdalena Pajewska-Lewandowska (<i>support observer</i>)
Portugal	Susana Guedes Pombo (<i>alternate</i>) Maria João Morais (<i>support observer</i>)
Romania	Razvan Prisada (<i>member</i>)
Slovakia	Katarína Massányiová (<i>alternate</i>)
Slovenia	Momir Radulovic (<i>member</i>)
Finland	Eija Pelkonen (<i>member</i>) Anna Siira ¹ (<i>alternate</i>)
Sweden	Ann Lindberg (<i>member</i>) Åsa Kumlin Howell ¹ (<i>alternate</i>)
European Parliament	Kristina Garuolienė (<i>member</i>) Cristian Silviu Buşoi (<i>member</i>)
European Commission	Rainer Becker (DG SANTE) (<i>alternate</i>) Pilar Aguar Fernández (DG RTD) (<i>alternate</i>) Agnès Mathieu-Mendes (DG RTD) (<i>support observer</i>)
Representatives of patients' organisations	Marco Korenjak (<i>member</i>) Virginie Hivert (<i>member</i>)
Representative of doctors' organisations	Denis Lacombe (<i>member</i>)
Representative of veterinarians' organisations	Christophe Buhot (<i>member</i>)
EEA-EFTA states	Rúna Hauksdóttir Hvanberg (Iceland) (<i>member</i>) Vlasta Zavadova (Liechtenstein) (<i>member</i>) Trygve Ottersen ¹ (Norway) (<i>member</i>) Katrine Heier (Norway) (<i>support observer</i>)

¹ Restrictions applied for agenda item B.6, B.8 and B.9

Guest Speaker	Sabine Scherer, Chair of the PDCO
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European Medicines Agency	<p>Emer Cooke Ivo Claassen Peter Arlett Zaïde Frias Hilmar Hamann Emmanuel Cormier Alexis Nolte Nerimantas Steikunas Melanie Carr Steffen Thirstrup Hilde Boone Georgia Gavriilidou Franck Diafouka Martin Harvey-Allchurch Rebecca Harding Manuela Mura Michael Lenihan Zahra Hanaizi Sabine Brosch Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin Andrea Tzoneva</p>
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