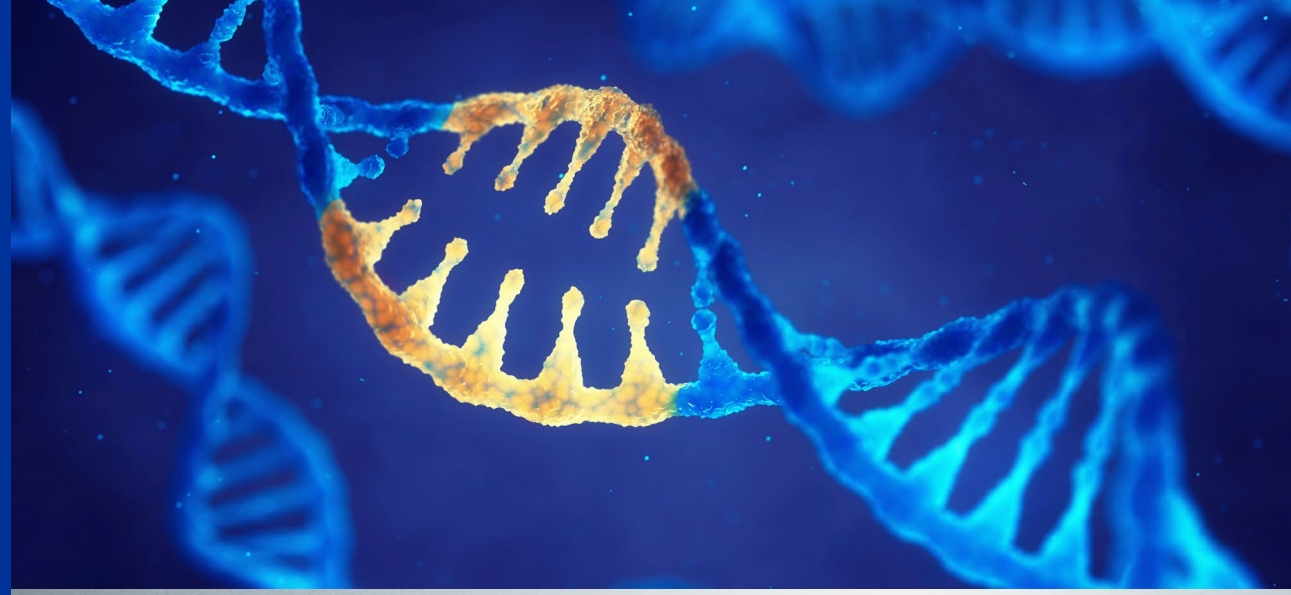
EMA
EUROPEAN MEDICINES AGENCY

Implementation of pilot initiatives based on first 5 years' experience of PRIME: - Analysis

15th Industry stakeholder platform on research and development support

Kevin Cunningham – EMA PRIME Scientific Coordinator

04 December 2025



New PRIME Pilot Features: incorporating recommendations from the PRIME 5-year analysis

- ❑ **March '25:** Pilot conclusion
- ❑ **April/May '25:** Network/Industry Surveys
- ❑ **October '25**: EMA Committee discussions of **main findings** and **recommendations**.
- ❑ **Nov 4th:** PRIME Oversight Group discussion and agreement on key recommendations of the pilot
- ❑ **Oct/Nov**: PRIME Industry Sounding Board consultation
- ❑ **Dec 1st**: CHMP adoption of recommendations
- ❑ **Dec 4th:** Industry stakeholder platform on R&D support

Development tracker – key learnings & recommendations

What worked well?

- The tracker facilitates Rapporteurs' effective **planning for regulatory submissions** and **resource planning** *(Network survey)*
- Format and structure enables **effective tracking of critical development issues** *(Network survey)*

Areas for improvement

- More **user-friendly format/structure** to reduce **administrative burden** *(Industry survey)*
- Tool not supporting developer **planning/tracking of emerging issues** and **regulatory action** *(Industry survey)*
- **EMA/Rapporteur feedback** on submission, **action plan** for emerging high-impact issues *(Industry survey)*

Adopted Recommendations (in consultation with Sounding Board)

- Refine the development tracker structure and format to improve user-friendliness and interpretation.
- Amend guidance with more detailed instructions on required level of detail and formatting.
- Further integrate the development tracker as a support tool for iterative scientific advice, evidence generation and preparation of a mature dossier to facilitate submission readiness and accelerated assessment.
- Refine process for regular EMA/Rapporteur feedback on tracker submission to promote communication on identified issues, plans for mitigation, and impact on regulatory roadmap
- Consider in future an improved implementation (subject to availability of IT and knowledge management tools) for tracking of planned regulatory interactions, and identified risks/impact on milestones/mitigation

Expedited Scientific Advice – key learnings & recommendations

What worked well?

- ExpSA **decreased the overall timeline from submission to receipt of final advice** compared to the standard procedure.
- ExpSA **promoted Rapporteur team engagement** in the provision of SA via SAWP coordinators
- ExpSA met expectations for dynamic/flexible scientific support; and delivered advice in time to implement in the development programme *(Industry survey)*

Areas for improvement

- To further decrease procedure duration; consider further accelerated, agile SA delivery outside established timelines and SAWP plenary meetings
- Broadening scenarios where expSA can be requested

Adopted Recommendations (in consultation with Sounding Board)

- Increase clarity on when expSA can be utilized via guidance on the specific questions/topics where expSA applies
- Increase predictability with timelines for submission and receipt of expedited advice.
- Broaden specific scenarios in which expSA can be sought, including key issues identified in PRIME KOM/SRM, with agreed follow-up
- EMA will consider, together with the Network, mechanisms for

  i) further decreasing the ExpSA procedure duration,

  ii) further increasing the agility of advice and developer interactions outside of the established SA timelines and SAWP plenary meetings.

Submission Readiness Meeting– key learnings and recommendations

What has worked?

- SRM identified well the outstanding scientific/regulatory risks to the planned MAA *(Network survey)*
- SRM facilitated discussion on data maturity/timing of MAA, obtaining/maintaining AA (*Industry survey*)
- SRM replaces need for Rapporteur PSM in most cases, streamlining pre-submission phase

Areas for improvement?

- Rapporteur teams did not consider SRM facilitated agreement on data maturity/timing of MAA, CMA (reluctance to pre-assess)
- Surveys suggest focus on SA issues/deviations, intended MAA basis, data maturity, GMP/GCP, MAA timelines
- More flexible timing w.r.t. MAA, HTA involvement, structured follow up for outstanding risks *(Industry survey)*

Adopted Recommendations (in consultation with Industry Sounding Board)

- Further focus on aspects critical for the submission and assessment of the MAA: implementation of Scientific advice, MAA data maturity, MAA basis, accelerated assessment
- Strengthened EMA product team involvement to support efficient pre-submission activities (facilitated through Product Development Coordinator)
- Establish clear routes for timely follow-up of outstanding risks (e.g. expSA and monitoring through development tracker)
- EMA, with the Network, will give consideration to more flexible timing of the meeting to support discussion on the MAA data package, and to facilitate broader participation

PRIME Product Coordinator Pilot Launched July 2025

- SA scientific officers nominated as PDC
- **21 PRIME development products** included; scope for inclusion of new PRIME products
- Contact points notified July 2025
- Products cover Oncology, Haematology, Endocrinology/metabolism, Ophthalmology, Congenital/genetic disorders, Dermatology, Cardiovascular
- PRIME developers represent Academia (1) SME (7) and non-SME Pharma (13)

Criteria for measuring the pilot to include:

- Number of formal interactions and ad hoc queries and time spent on them
- Number of issues/topics raised to PRIME Rapporteur by PDC (from development tracker or other ad hoc/informal interactions)
- Experience of PRIME developers (elicited via survey):
  - Efficiency in dealing with PRIME-related matters (formal interactions or ad hoc queries)
  - Perceived added value through provision of input on regulatory and scientific evidence matters

Translating pilot feature experience into optimised PRIME support

- New features are maintained as standard elements of PRIME support
- Refinements to the features, with updated PRIME guidance, will be implemented following publication of pilot report (Q1 2026)
- The **PRIME product development coordinator** is a key facilitator of the optimised PRIME features through
    - expert development support throughout scientific evidence generation phase
    - procedural stewardship of expSA
    - experience and knowledge transfer at SRM
- Optimised PRIME scheme serves to strengthen support for innovative products addressing unmet medical needs in preparation for a future operation under NPL

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Thank you

kevin.cunningham@ema.europa.eu

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