

The EMA Product Development Coordinator

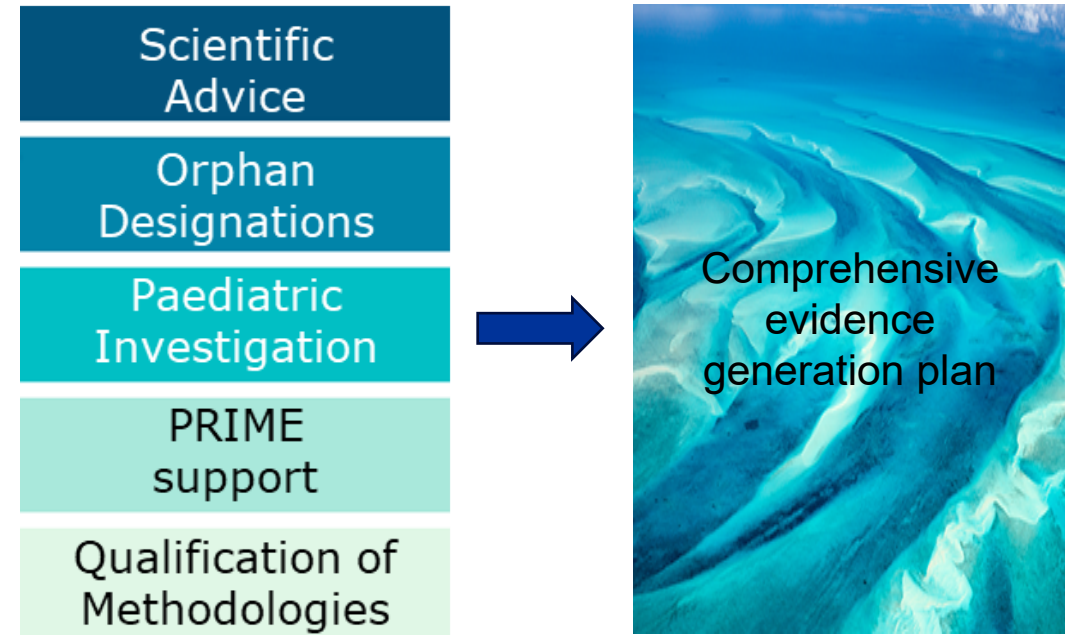
Piloting a new role to strengthen product development support

14th Industry stakeholder platform on research and development support, 3 July 2025



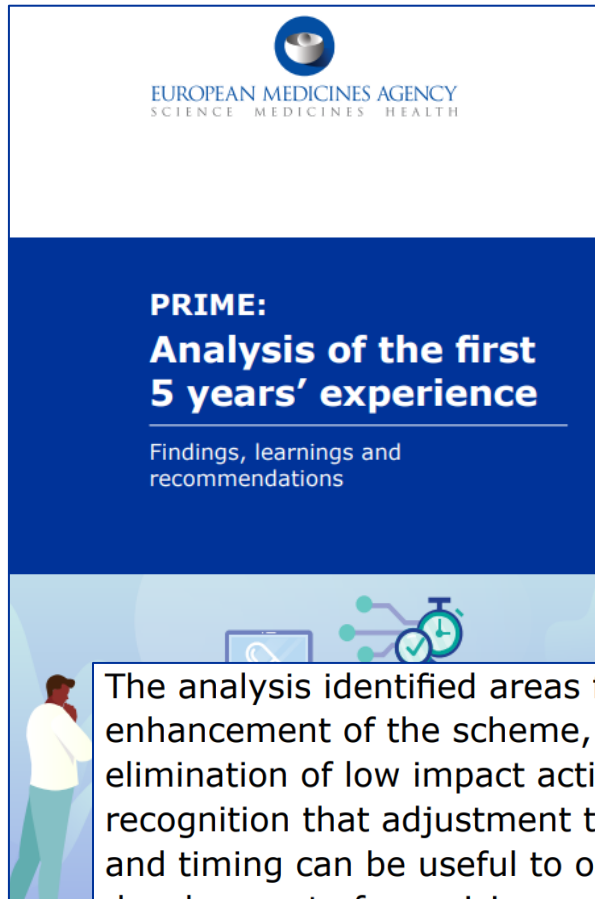
Moving development support from **process** to **product** focus

- Need for **holistic development support** by connecting the evidence planning across processes.
- Developers' call for **stewardship** (aka 'lighthouse') through different **scientific dialogue** possibilities
 - Identify anticipated complexities
 - Specialised expertise in an early stage.
- Product Development Coordinator (PDC)* to enable **interconnectivity** across regulatory development support interactions.



*Role also referred to as Development Product Lead (DPL) and Development Support Coordinator (DSC) before

Piloting the PDC concept for PRIME products



- PRIME already entails a **dedicated EMA contact** point to coordinate the support offered throughout the scheme
- New features (expedited scientific advice, development tracking, submission readiness discussions) require **strengthened scientific contributions** by the coordinator
- PRIME products cover **a range of** therapeutic areas and product types
- Inclusion of **PRIME in legislation** is expected to increase volume and scrutiny

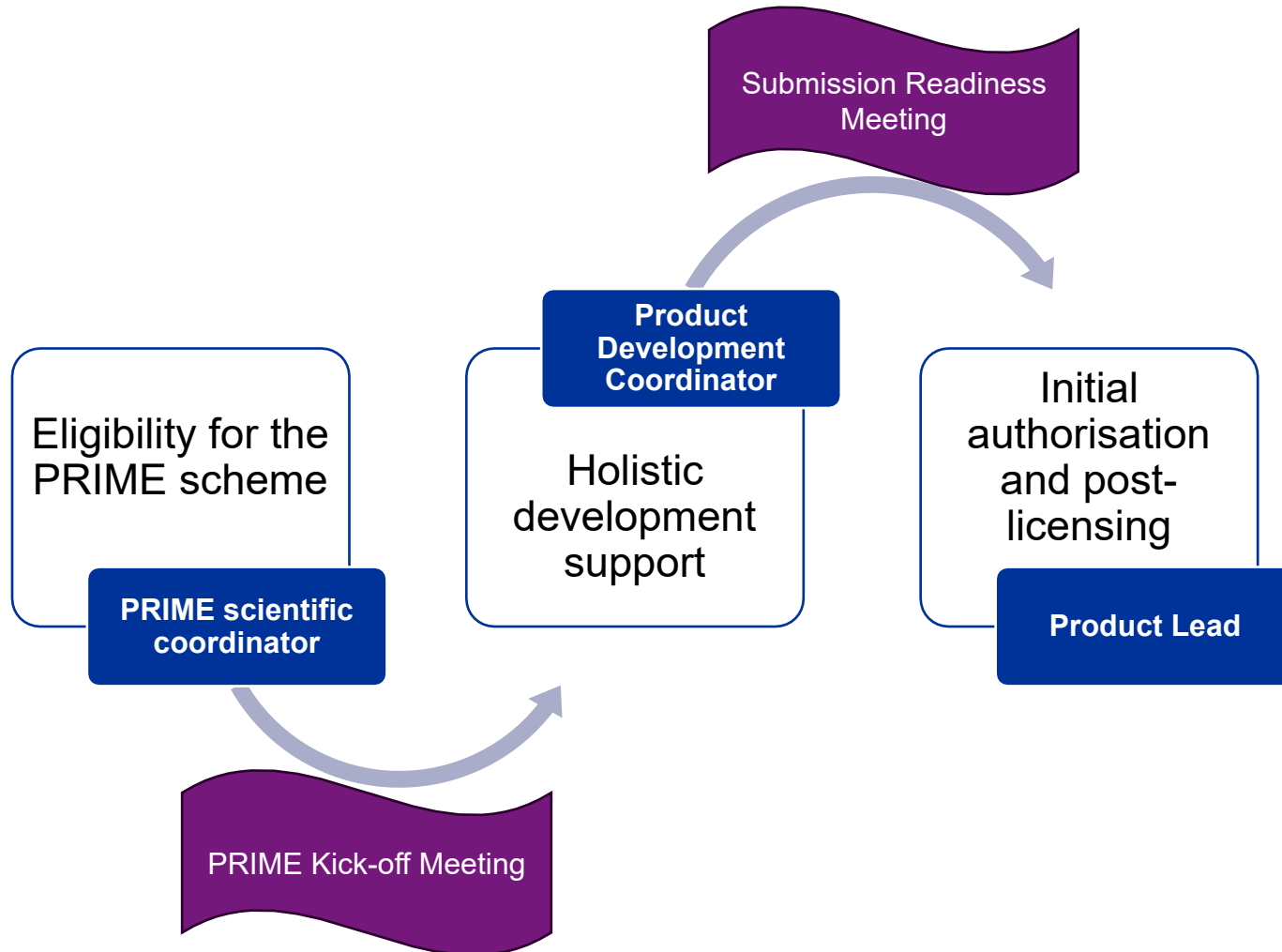
The role of the PDC for PRIME products

- Act as **primary contact point** for the developer of PRIME products;
- Provides technical and procedural support for **all product queries**;
- **Facilitate interactions** with colleagues in development support and functions across the EMA Human Medicines Division (such as Therapeutic areas, Quality, Inspections, Reg. Affairs) and Task Forces, as required.

PDC key features

- Assigned based on specific clinical expertise related to their relevant therapeutic area and/or product types of expertise
- Has expertise in the development support procedures, particularly scientific advice
- Promotes efficient communication between EMA and PRIME developers
- Ensures accurate and high-quality output to all regulatory and scientific queries

Milestones and EMA contacts along the life-cycle of a PRIME product



- Handover of lead contact role at pre-defined milestones
- Engagement of leads across the life-cycle to enable knowledge transfer and experience gain

Step-wise introduction of the new role during the pilot

The PDC role requires **cross-skilling** of scientific officers in the development support interactions, i.e. orphan designation and maintenance, paediatric investigation plan and waivers as well as scientific advice

- Step 1: PDC to support all scientific advice requests for a PRIME product including advising applicants on plans and managing requests for expedited scientific advice; keep oversight of all development activities (tracker), engage in other development support activities
- Step 2: officers from other development support areas start training and managing scientific advice procedures; and scientific advice officers to train in and start managing ad-hoc orphan and paediatric procedures
- Step 3: scientific officers from across development support to assume the PDC role; Power BI workload management tools ensure fair workload distribution

Pilot starting in July 2025

- Duration **2 years**, with mid-term review
- Total number **18-24 PRIME developments** to be covered
- Open to **scientific advice officers** meeting the required competencies; scientific officers from other functions may take up the role as PDC provided they assume responsibilities of step 1
- Commitment to **contribute to measuring impact** and providing feedback during pilot review meetings

Criteria for measuring the pilot to include (details to be developed):

- Number and nature of ad hoc queries and development support interactions
- Consistency of development support
- Structured feedback from developers and from coordinators, at milestone events and at the closure of the pilot
- Resource commitment for the PDC and operational feasibility

Discussion points

- The role and its gradual implementation
- The proposed measures to capture the impact of the pilot