

# NPL Update

Engagement with industry during  
implementation

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Industry Standing Group, 11 December 2025



# *How we plan to engage Industry during NPL implementation*



## **Multi-stakeholder workshop**

**What:** High-level workshop with all stakeholder groups (EMA, EC, NCAs, industry, patients, HCPs).

**When:** Organised as soon as practicable after the publication of the final legislative text in the Official Journal.

**Purpose:** Provide an overview of the foreseen changes and gather early reflections to guide implementation planning.



## **Industry Standing Group**

**What:** Main reference forum for Industry during NPL implementation.

**When:** Quarterly, according to the current planning.

**Purpose:** Share overarching progress, clarify questions, gather high-level input, and ensure alignment across stakeholders.



## **Industry platforms**

**What:** Operational channels for topic-specific discussions within their respective domains.

**When:** According to regular schedule, topics activated as needed

**Purpose:** Work through practical and technical implementation topics with full stakeholder representation.

# Operational engagement through the Industry Platforms



*The Platforms provide the operational space to work through implementation topics with full stakeholder representation.*

- The existing platforms (**Centralised Procedure, R&D, Pharmacovigilance**) remain the **primary channels** for topic-specific discussions.
- **Focus Groups (as needed):**
  - Established *within the relevant platform* for specific implementation questions.
  - Include **Industry representatives + EC + NCAs** to ensure full stakeholder representation.
  - Discussions are **operational**, focused on practical interpretation and implementation needs.
- **Feedback loop:**

Outcomes from Platform discussions will be reported back to the **Industry Standing Group** to ensure transparency and alignment.

# Keeping stakeholders informed and involved throughout implementation



## ISG

**Rely on the ISG** for regular updates on NPL implementation, including reporting from Platform Focus Groups.



## TOPIC-SPECIFIC WEBINARS

**Join targeted sessions** on specific implementation topics when additional clarification or guidance is required.



## NPL webpage

**Visit the new EMA NPL webpage** to stay informed on updates, key activities and implementation progress.



## PUBLIC CONSULTATION

**Provide input** on scientific guidelines as part of the standard EMA consultation process.



## NEWSLETTER

**Receive updates** on progress and activities through the Industry NPL section of the upcoming periodic Newsletter.



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