



Cancer Medicines as Pathfinder

Proposal for a Focus Group of the Industry Stakeholder Platform on the Centralised Procedure

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Cancer Medicines as Pathfinder

- **Extraordinary pace of innovation and development** to address **high unmet medical need** and **complex evidence generation**
- Regulatory **resilience** and **flexibility**: Can we **maximise efficiency and maintain excellence** in addressing the needs?
- Build further on **international collaboration, interaction with stakeholders, regulatory tools, and science**



Engagement and Interaction; Regulatory Science

Topic	Action
Stakeholder and interested parties input	• Roundtable with industry (oncology R&D and regulatory); • Collaboration with leading learned societies (ESMO and EHA); academia • Patients: Conversations on cancer

- Proposal for an Industry Focus Group
 - Objectives
 - Call for nomination

Objectives of Focus Group and Next Steps

- Discuss opportunities to gain efficiency during assessment
 - Involve experienced EMA/network and industry experts
 - “Low hanging fruit” but also “stretch goals”
 - Run “pilot” projects (oncology to start)
- Case studies to learn/set examples
- Expand scope
 - Strategic initiatives in development and evaluation (e.g., build on international collaboration)

Next steps: Call for nomination (formalize informal group); FG to meet 1Q2025

