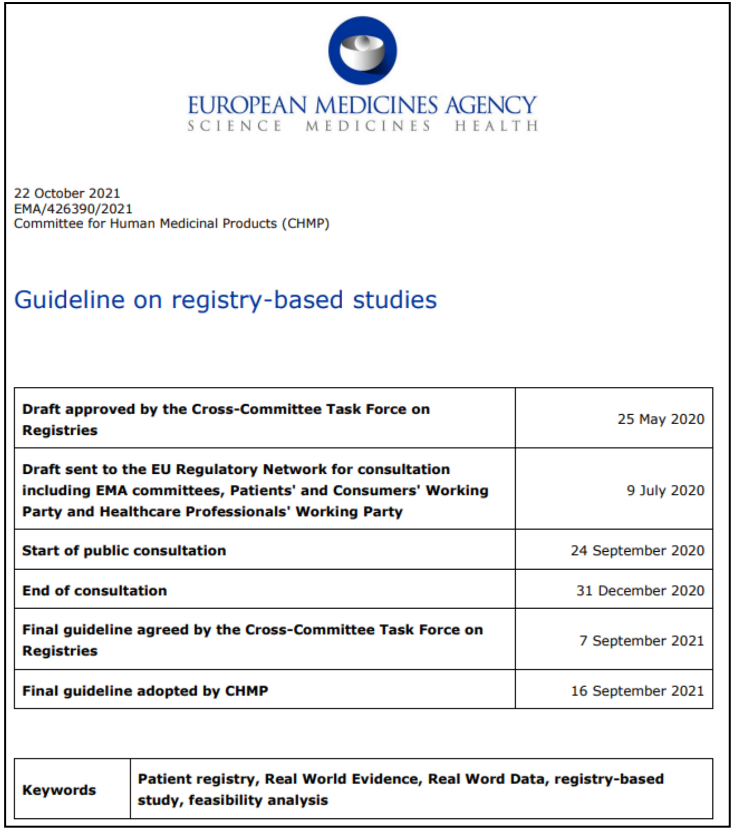
Survey results on the EMA guideline on registry-based studies

Multi-stakeholder workshop on Real World Data (RWD) quality and experience in use of Real-World Evidence (RWE) for regulatory decision-making
26-27 June 2023

Kelly Plueschke, Data Analytics and Methods Task Force

Guideline on registry-based studies



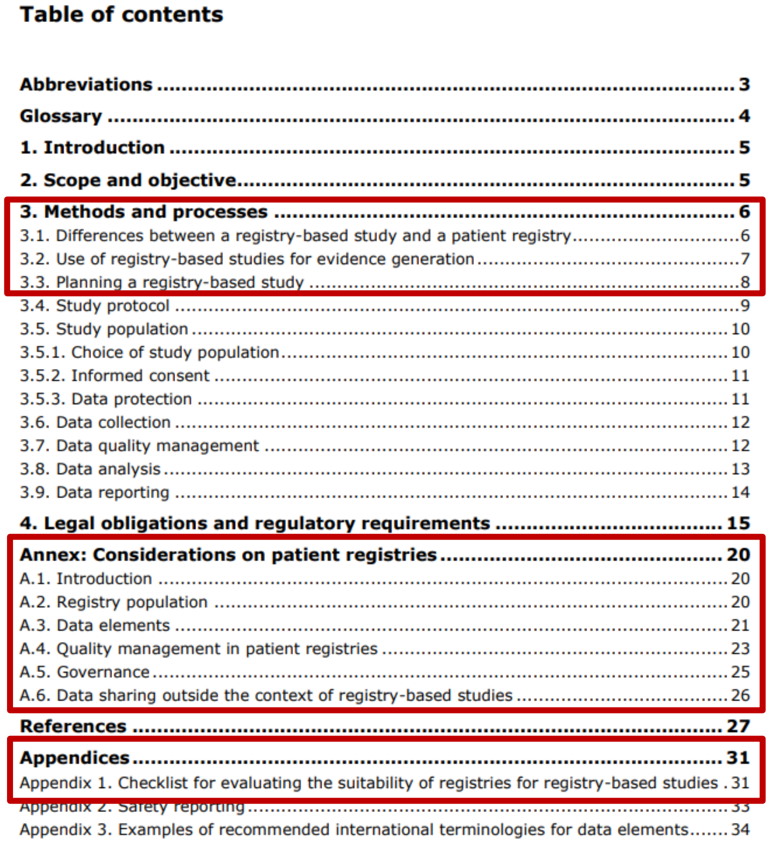
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 October 2021
EMA/426390/2021
Committee for Human Medicinal Products (CHMP)

Guideline on registry-based studies

Draft approved by the Cross-Committee Task Force on Registries	25 May 2020
Draft sent to the EU Regulatory Network for consultation including EMA committees, Patients' and Consumers' Working Party and Healthcare Professionals' Working Party	9 July 2020
Start of public consultation	24 September 2020
End of consultation	31 December 2020
Final guideline agreed by the Cross-Committee Task Force on Registries	7 September 2021
Final guideline adopted by CHMP	16 September 2021

Keywords	**Patient registry, Real World Evidence, Real Word Data, registry-based study, feasibility analysis**



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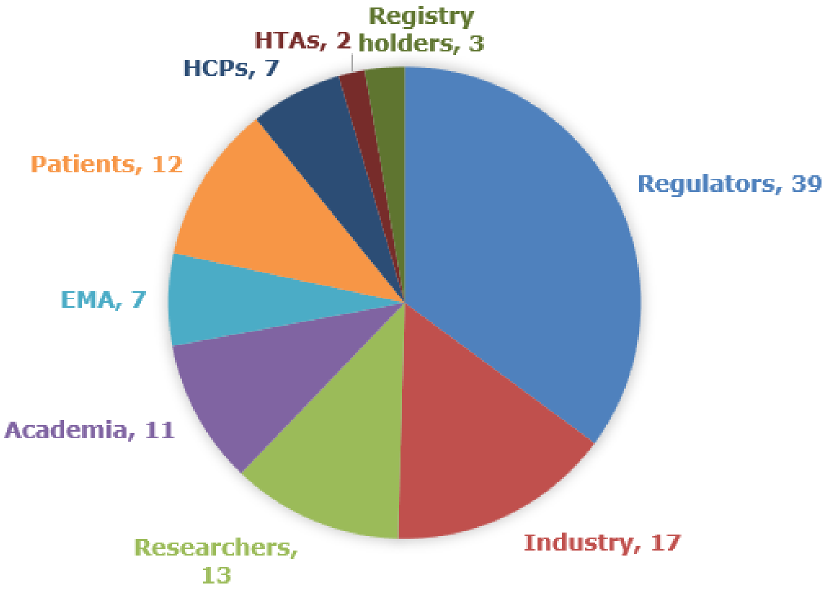
Background on the survey on Guideline on registry-based studies

Objectives

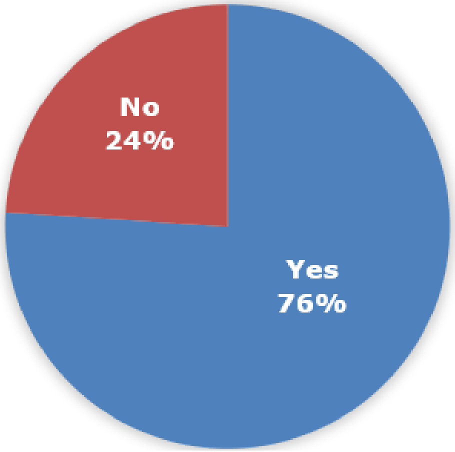
- To assess stakeholders' awareness
- To identify specific topics requiring clarification
- To understand training needs

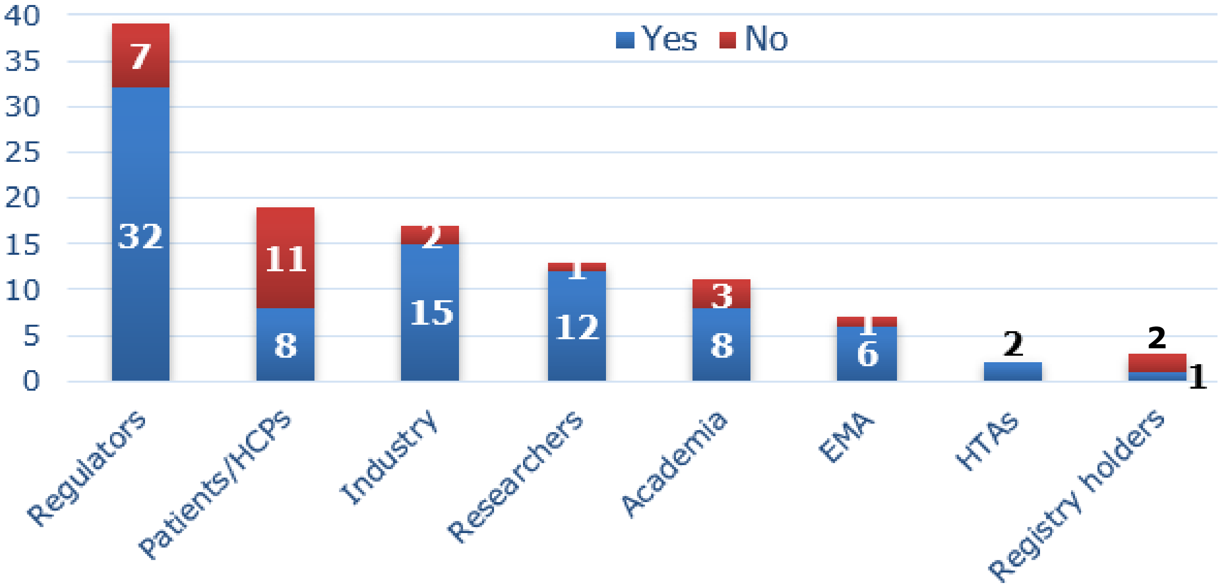
- Survey sent to stakeholders in May
- Number of responses: **111**



Main results

Awareness of the guideline (total: 111)

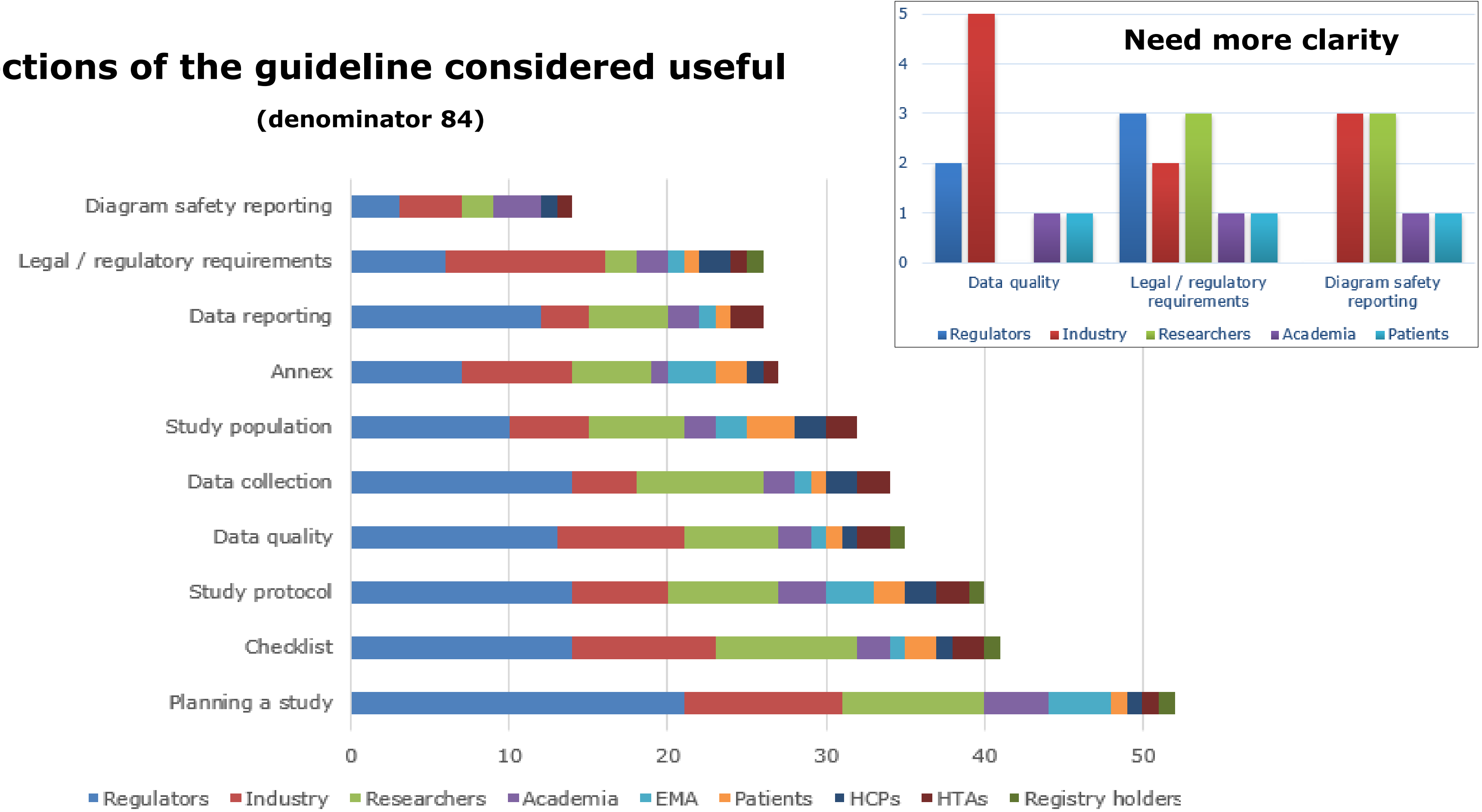




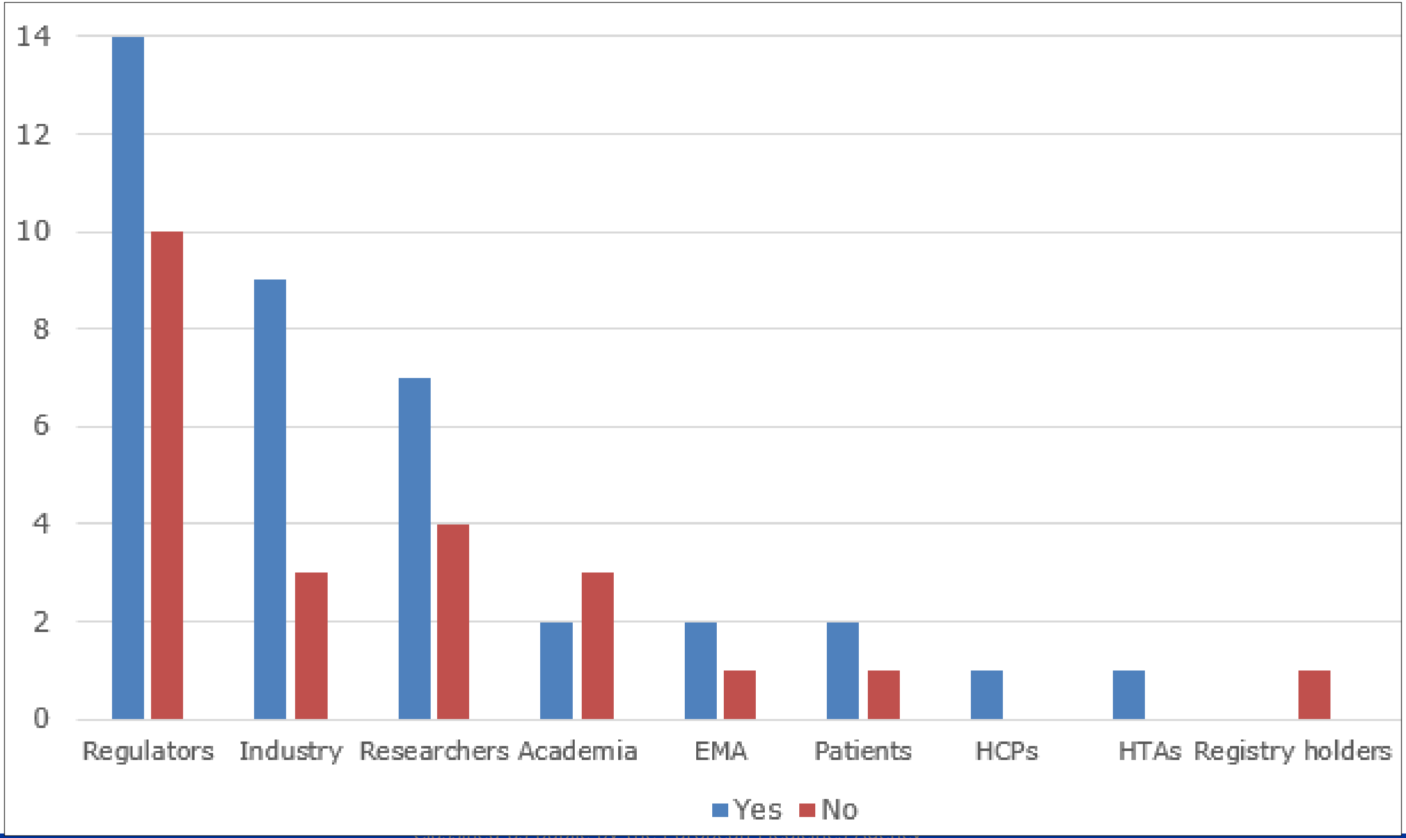
How?: EMA website and through interactions with EMA
Who?: Regulatory, epidemiology and research teams
Who else should know?: Clinical (medical/operational) + analysts

Sections of the guideline considered useful

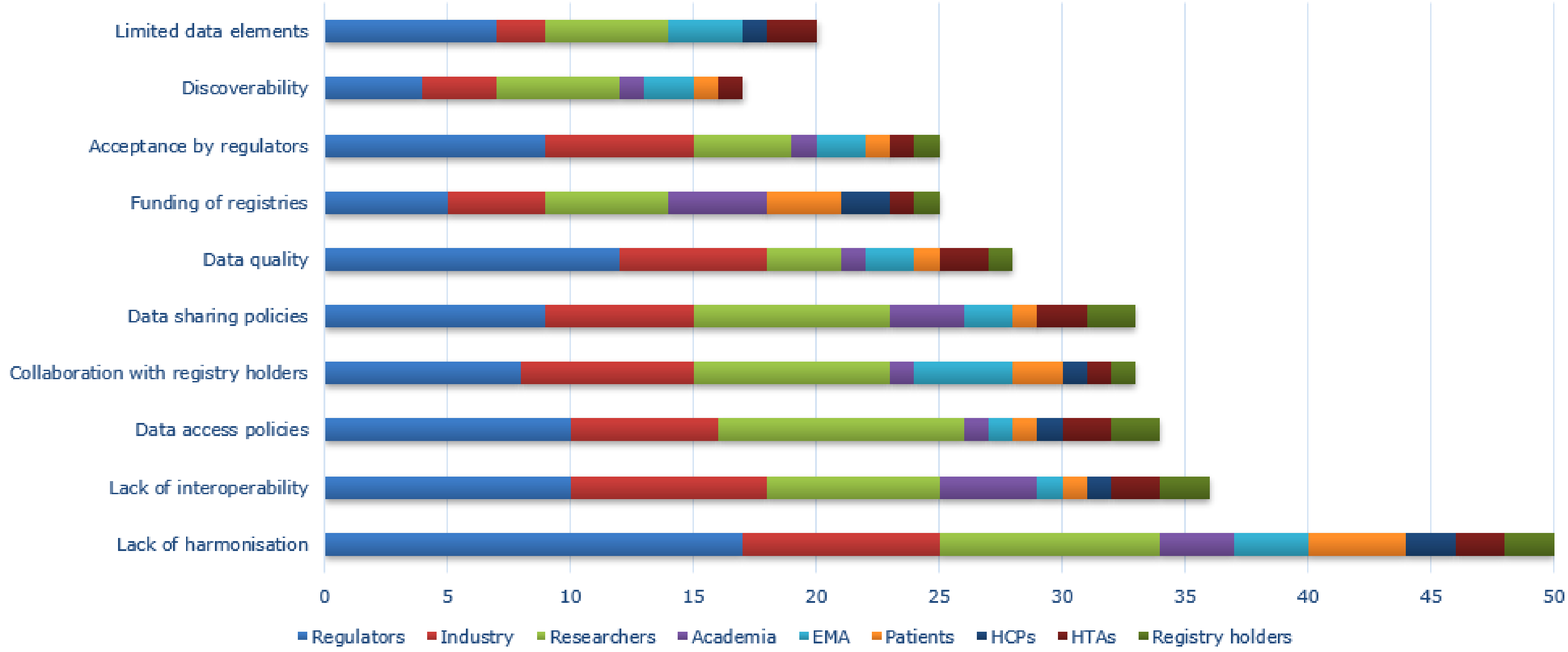
(denominator 84)



Guideline principles and recommendations applied (denominator 84)

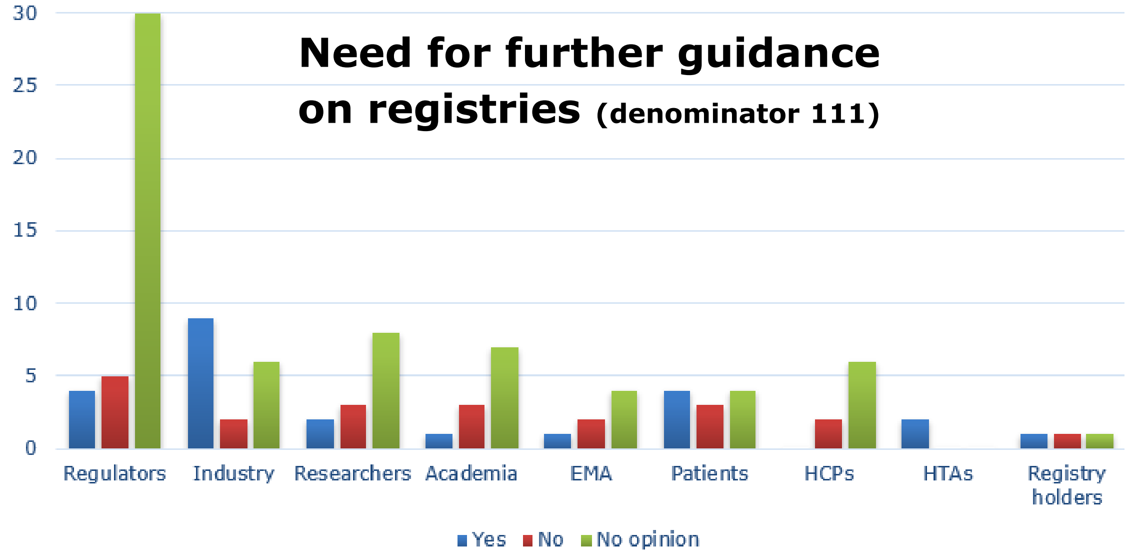


Possible barriers to implementation (denominator 111)



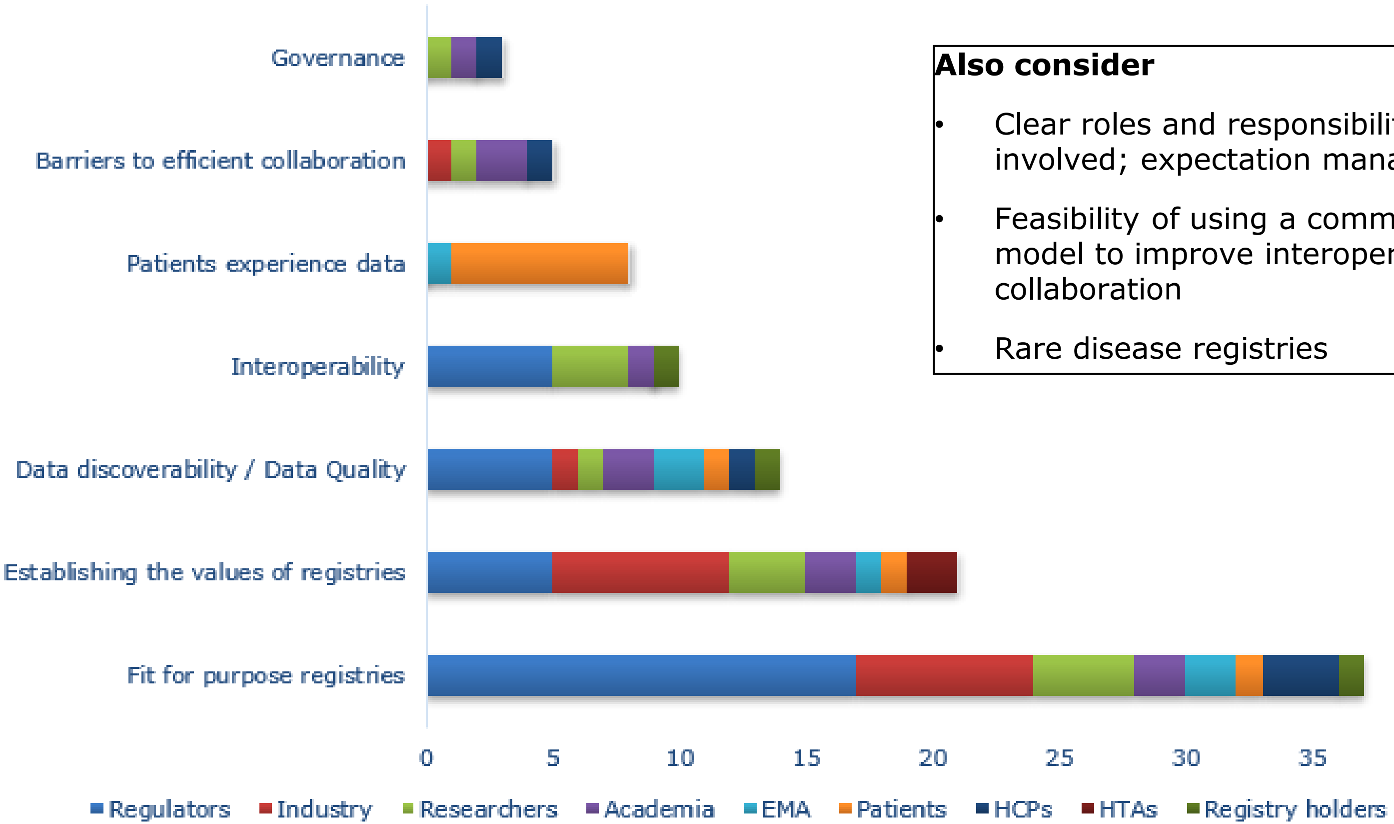
Stakeholder communication and engagement

- Workshops/webinars/educational videos with concrete use cases
- Q&A documents
- Checklists covering fit-for-purpose topics co-developed by EMA, industry, registries


Need for further guidance on registries (denominator 111)

- Clarity on acceptability criteria for secondary data
- Registry-based RCTs
- More concrete requirements for academia setting up registries/RBS
- Guidance on specific populations

Priority topics for multi-stakeholder workshop on registries (denominator 111)



Also consider

- Clear roles and responsibilities of all involved; expectation management
- Feasibility of using a common data model to improve interoperability and collaboration
- Rare disease registries

Take home messages

- EMA guideline on registry-based studies adopted and published in **October 2021**
- Main audience is **aware**, finds it **useful** and has **applied** its principles
- **Various factors** can limit its implementation → work needed at registries level on **data quality**, **collaboration policies** to enable use of the data
- Need for **further communication and engagement**
  - ✓ Workshops / webinars / educational videos
  - ✓ Consider development of a Q&A, interface with other (future) guidance on RWE
- **Priority topics** for a **multi-stakeholder workshop** on registries in **Q1 2024**

→ **Watch the space**

Any questions?

Further information

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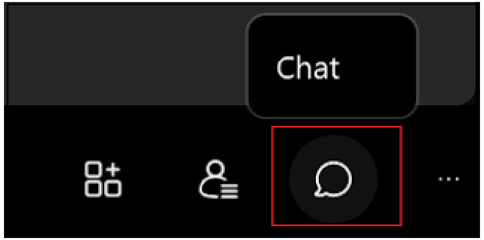
Session 3 panel discussion

- Patricia McGettigan (PRAC)
- Pamela Dobay, Meritxell Sabidó (Industry)
- Lars Wallentin (ESC)
- Kelly Plueschke (EMA)
- Mencía de Lemus (CAT)
- Peter Mol (Chair)

→ Feel free to include your questions in the Webex chat



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