MSR91

What are unmet needs for the use of registries in regulatory/HTA decision-making in Europe? A survey-based approach from the More-EUROPA project

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Introduction

- Patient registries emerge as a useful source of information required at multiple stages of the drug lifecycle[1].
- The identification and selection of fit-for-purpose registries play a critical role in drug evaluation[2].
- The process remains laborious, time-consuming, and ad-hoc.
- **Objective:** To capture the best practices among identified stakeholders in utilizing registry data to guide the creation of an efficient screening tool for identifying appropriate registries for fit-for-purpose studies.
- **Project:** The More-EUROPA project, involving 15 public and private organizations from 7 EU countries, evaluates the effective and ethical use of registry data to support patient-centered decisions by drug regulators and Health Technology Assessment (HTA) agencies in Europe.

Methods

- **Identify and invite 24 stakeholders** working in the field of real-world evidence generation (regulatory/HTA drug evaluation, registry holders, researchers, and pharmaceutical industrial).
- Respond to an **online KAP survey**[3] comprised of 74 questions.
- **Conduct a 1-hour stakeholder interview** with 2 members of our team for respondents to share their experiences concerning the use of registries or RWD in regulatory/HTA and RWE studies.
- This survey completes the insights from literature reviews conducted in parallel (see posters MSR30 and MSR61).

Table 1. Stakeholders invited and interviewed

FIELD OF ACTIVITY	# CONTACTED	# INTERVIEWED
REGULATORY/HTA DRUGS EVALUATION PERSPECTIVE	15	9
ACADEMIC/REGISTRY HOLDERS AND/OR USERS PERSPECTIVE	4	2
INDUSTRY PERSPECTIVE	5	1
TOTAL	**24**	**12**

Results

- **12 respondents participated (Table 1).**
- **Knowledge:** Different strategies are deployed to identify pertinent registries, with literature review methods being the most cited (**Figure 1**).
- **Attitudes and opinions:** Most respondents think that the nature of registry holders impacts access **(Figure 2)**.
- **Practice**: Respondents prioritize registry repositories (e.g., ENCEPP) as preferred ways to look for relevant registries followed by studies repositories, and AI-powered search engines (e.g., Pubmed, Semantic Scholar). Few cited connecting with KOLs or specialized websites.
- **Challenges:** Data access and provision was the most relevant aspect cited as challenges associated with registry data (**Figure 3**).

Figure 1. Knowledge about registries identification*

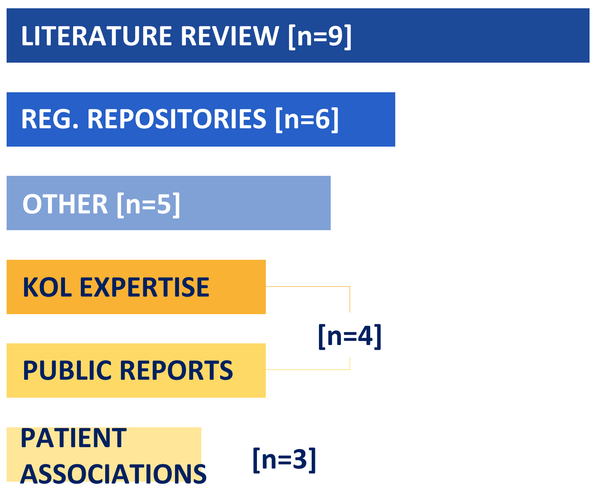


Figure 2. Attitudes and opinions

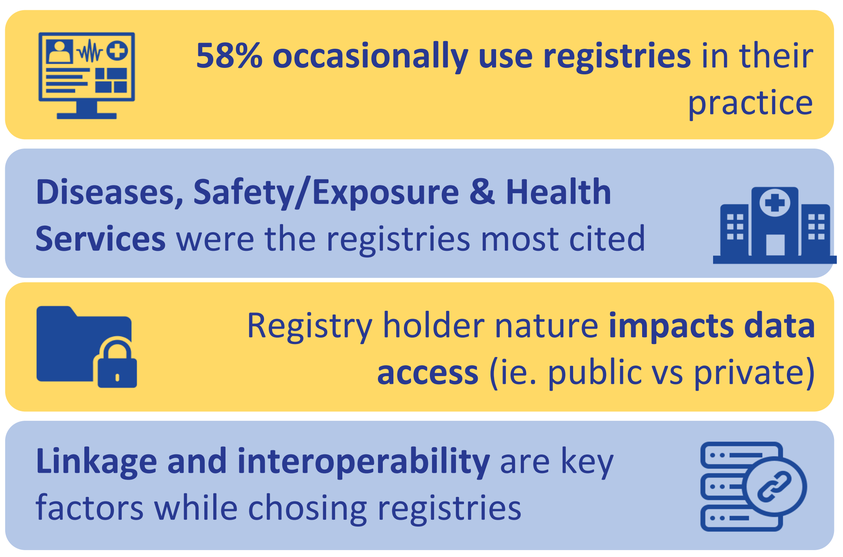
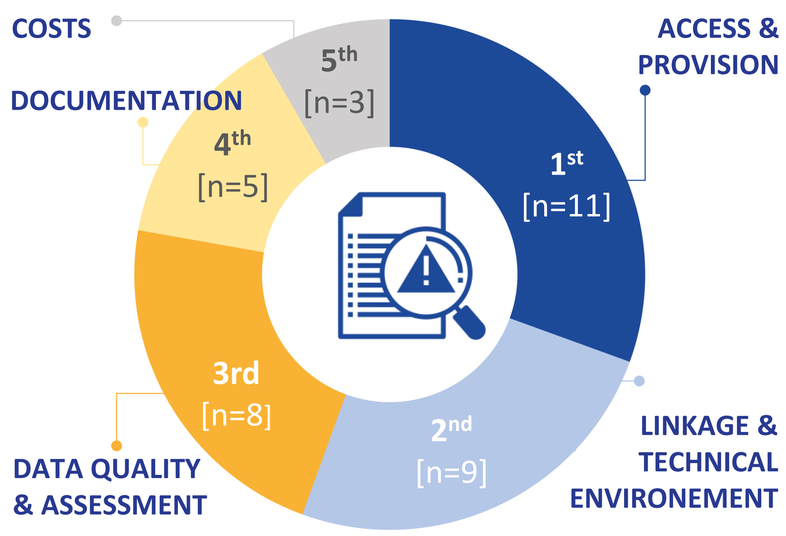


Figure 3. Top 5 challenges in practices*



** Numbers depicted inside [ ] indicates the counts for which each item was cited*

Conclusions

- Although limited feedbacks from pharmaceutical perspective, our survey and interviews offers valuable insights into stakeholder perceptions, preferences and unmet needs for registries identification and assessment.
- These findings will support the next steps of this project to develop an automated tool for identifying, selecting, and assessing registries.
- Future iterations with stakeholders and users on desired features, such as accessibility and coverage, will further guide the design and implementation of the tool.

Acknowledgments

We would like to thank all the stakeholders and project members who agreed to voluntarily contribute with their expertise and feedback in the survey and interviews to corroborate our working package tasks on More-EUROPA project

References: 1. Ramagopalan SV, Simpson A, Sammon C. Can real-world data really replace randomised clinical trials? BMC Med. 2020 Jan 15;18:13. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6961357/
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This project has received funding from the European Union's Horizon Europe Research and Innovation Actions under grant no. 101095479 (More-EUROPA). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union nor the granting authority. Neither the European Union nor the granting authority can be held responsible for them.

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