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Sonia Zebachi

Navigating the Real World: A Scoping Review of Structured Frameworks to Effectively Identify, Evaluate, and Select Real-World Data Sources for Fit-for-Purpose Studies

Sonia Zebachi¹, Julien Tanniou¹, Elisabeth Bakker², Sieta T. de Vries², Rossella Di Bidino⁴, Entela Xoxi⁵, Anna Glaser³, Gianluigi Savarese⁶, Jan Hillert³, Peter G.M. Mol², Kelly Plueschke⁷, Billy Amzal¹, Ghinwa Y. Hayek¹, Jeverson Moreira¹

¹Quinten Health, Paris, France, ²University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, Groningen, The Netherlands, ³Karolinska Institute - Department of Clinical Neuroscience, Stockholm, Sweden, ⁴Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, ⁵Alta Scuola di Economia e Management dei Sistemi Sanitari (ALTEMS) - Università Cattolica del Sacro Cuore, Rome, Italy, ⁶Karolinska Institute - Department of Medicine, Stockholm, Sweden, ⁷European Medicines Agency (EMA), Amsterdam, Netherlands

*QR code to abstract
will be added by
conference team*



Aim

- Identify “**structured**” frameworks (tools/methods) **to identify**, and/or **assess**, and/or **select “fit-for-purpose”** RWD for regulatory purposes with a special focus on registries.
- Perform a **comparative analysis using the criteria** of the identified structured frameworks.

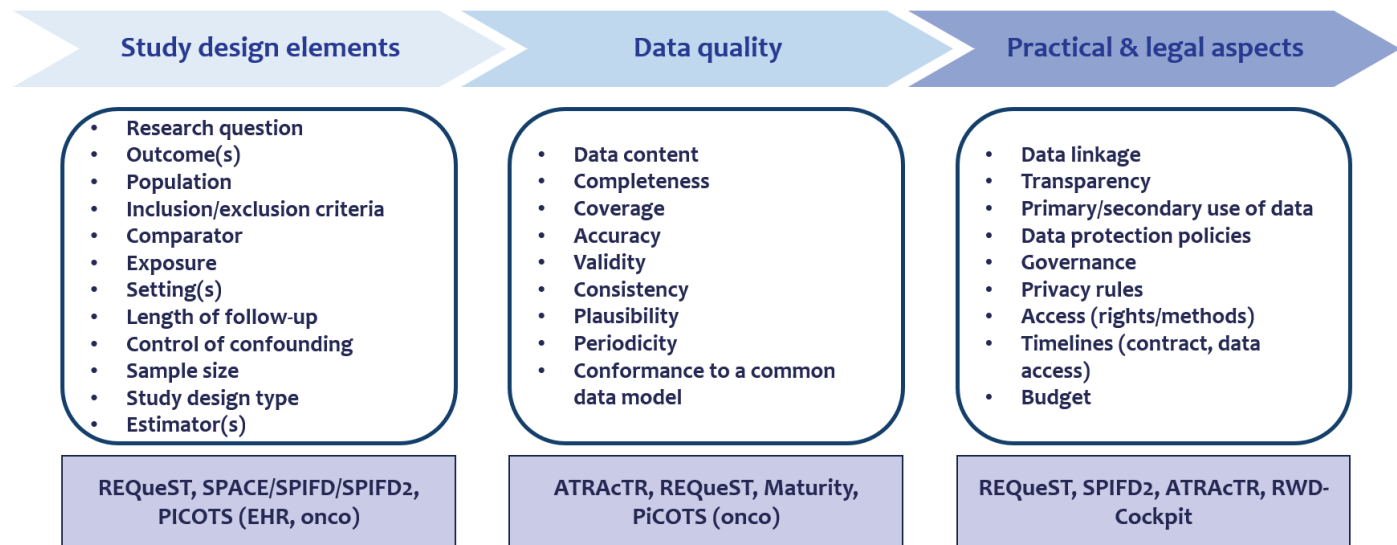
Methods

- Scoping review [2013-2023] through **PubMed, Web of Science and Scopus**.
- Combination of search terms: RW, registries, fit-for-purpose or fit-for-use, and regulatory.
- Definition of ‘**fit-for-purpose**’: whether data seems of sufficient quality to generate relevant and reliable evidence to inform regulatory decision-making.

Results

- **9 frameworks** identified from 54 articles, **none** allowing RWD **discoverability** (potential detection).
- Structured Preapproval and Postapproval Comparative study design (**SPACE**), Structured Process to Identify Fit-For-Purpose Data (**SPIFD 1 & 2**), **PICOTS** (Populations, Interventions, Comparators, Outcome(s), Timing and Setting), **MATURITY, PICOTS – 3-step** conceptual mode for oncology, **RWD-Cockpit**, Registry Evaluation and Quality Standards Tool (**REQuest**), and Authentic Transparent Relevant Accurate Track-Record (**ATRaCTR**).

Figure 1. List of criteria captured across the nine identified frameworks



Conclusion

- Several frameworks for RWD assessment, choice of use should be based on the prioritised criteria.
- Strong need for a tool **combining discoverability and assessment** for ‘fit-for-purpose’ RWD (cf. **More-Europa Tool**)