Building on 'Contemporary Practice and Considerations for Real-World Data (RWD) Source Identification and Feasibility Assessment': Mapping Feasibility Criteria Across 46 Real-World Evidence (RWE) Guidance Documents

RWD133

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OBJECTIVES

- Regulators and payers are placing increased importance on the transparent reporting of feasibility criteria and selection of data sources for RWE studies; however, a globally accepted feasibility assessment pathway is not available.[1–7]
- *Contemporary Practice and Considerations for RWD Source Identification and Feasibility Assessment* identified and mapped 14 key feasibility criteria against 14 published RWE guidance documents during an ISPE funded inititiave.[8]
- Building on those results, this project aimed to identify and evaluate additional RWE guidance documents across additional geographies and those newly released (after 2022).

METHODOLOGY

- IQVIA reviewed 14 documents from the ISPE funded initiative and 32 additional RWE guidelines (published between June 2017- July 2024).
- 14 feasibility criteria developed by the ISPE initiative were slightly adapted for this effort to ensure reproducibility.
- Next, feasibility criteria were mapped across each of the 46 guidelines to confirm the presence or absence of the term in each document.
- All mapping was conducted by two independent reviewers with adjudication by a third if discrepancies were identified.
- Results underwent a formal peer-review process.

RESULTS

- The percentage of guidelines that were missing each of the 14 feasibility criteria are provided in Figure 1.
- Among the mapped guidance documents, the majority (97.8%) lacked mention of ≥1 feasibility criterion (Fig. 2).
- The 11th Revision of the ENCePP Guide was the only document mentioning all 14 criteria, a notable change from the 10th Revision (Fig. 2).[9,10]
- More than half of the guidance documents are missing mention of ≥4 criteria (27/46 [58.7%]) and almost one third (14/46 [30.4%]) are missing mention of ≥7 of the criteria (Fig 2.)

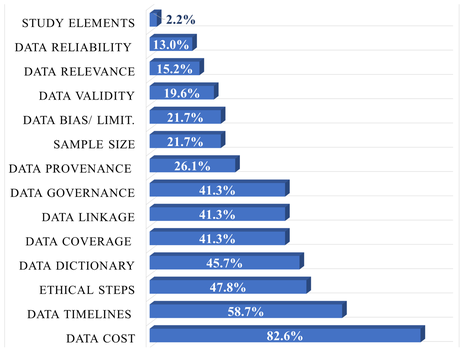

Fig. 1 Missingness Across Guidance Documents

INSIGHTS FROM GUIDANCE REVIEW

- Guidance review led to the identification of six critical gap.
- Recommendations to regulators and stakeholders were generated for each gap.
- IQVIA's **O**perational **A**ssessment **S**trategy to **I**dentify Fit-For-Purpose Data **S**ources for RWE Studies (OASIS) was developed.
- OASIS Framework mitigates gaps identified across guidance documents.

1	2	3	4	5	6
Recommendation	**Recommendation**	**Recommendation**	**Recommendation**	**Recommendation**	**Recommendation**
Regulators aim to align on feasibility criteria terms & definitions	Guidance mentions some feasibility criteria (the 'what') but few techniques for evaluation (the 'how')	Feasibility assessments should be structured in at least two stages according to ICH[10]	CDM feasibility implications are needed for studies with multiple data sources/countries	Regulators aim to provide exemplary feasibility assessment result templates in guidelines	Specific requirements for data holders related to transparent reporting of quality measures
Mitigation	**Mitigation**	**Mitigation**	**Mitigation**	**Mitigation**	**Mitigation**
Knowledge gained from this mapping effort generated a global glossary in the OASIS Framework	OASIS provides both qualitative & quantitative methods of evaluation for each feasibility criteria	OASIS provides a menu of feasibility stages tailored to the study, regulator preferences, & timelines	IQVIA includes CDM experts & data access specialists across 100+ countries	OASIS provides evaluation methods, results tables, & regulator specific feasibility checklists	OASIS has integrated QMS & data quality related questions for data holders into feasibility tools

CONCLUSIONS

- This review demonstrates that, despite the availability of many RWE guidance documents, there remains a need for globally harmonized feasibility criteria with aligned definitions that consider regulator-driven recommendations and timelines.
- Updates to, or expansion of guidance is warranted to address gaps in methodological considerations, multi-country and/or multi-data source evaluations, standardized templates for disseminating results to regulators, and data holder quality management.

Guideline/Framework				Design Features			Data Quality				Data Logistics						
Geography	Abbreviated Title	Regulator/Author	Date	Study Elements (outcomes, exposures, covariates, etc.)	Sample Size	Data Bias / Limitations	Data Relevancy	Data Reliability	Data Validity	Data Coverage	Data Dictionary/ Definitions	Data Linkage	Data Governance /Collaboration	Data Source Ethical Considerations	Data Provenance /Collection Methods	Data Access/ Lag Timelines	Data Cost
				Y (Yes) is present if the term/concept is in the guideline (the extent to which it is discussed was not evaluated)													
Australia																	
	RWE & PRO's in Regulatory Context	**TGA**	Nov 2021	Y	Y	Y	Y										
	RWD & RWE to Support HTA in AU	**NHMRC MI-CRE**	Mar 2024	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y
	RWE for Med. Devices	**TGA**	Apr 2024	Y	Y	Y	Y	Y	Y	Y			Y		Y		
Brazil																	
	Best Practice Guide for RW Studies	**Anvisa**	Sep 2023	Y	Y	Y	Y	Y	Y		Y		Y	Y	Y		
Canada																	
	RWD/E Quality through Drug Cycle	**HC**	Mar 2020	Y	Y	Y	Y	Y	Y			Y		Y	Y		
	Guidance for Reporting RWE	**CADTH & HC**	May 2023	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y				Y
China																	
	RWE Drug Development	**NMPA**	Jan 2020	Y	Y	Y	Y	Y			Y	Y	Y	Y	Y	Y	
	RW Drug Develop for Children		Sep 2020	Y													
	Eval of Med. Devices Using RWD		Nov 2020	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
	RWD Eval. of Med. Devices		Nov 2020	Y	Y	Y	Y	Y	Y	Y							
	Principles of RWD to Generate RWE		Apr 2021	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	RWE Supporting Drug Applications		Feb 2023	Y	Y	Y	Y	Y			Y		Y	Y			
	Drug RW Research & Protocol		Jul 2022	Y	Y	Y	Y	Y	Y	Y			Y	Y	Y		
	RWD Based on Registries		Nov 2023	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	RW Study for Med. Devices		Jan 2024	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	
Europe																	
	GVP Module VIII PASS Rev 3	**EMA**	Oct 2017	Y	Y	Y	Y		Y			Y			Y		
	Registry-Based Studies		Sep 2021	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	Metadata Catalogue of RWD Sources		Nov 2022	Y			Y	Y					Y	Y	Y		
	ENCePP Guide v10	**ENCePP**	Jul 2022	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y		
	ENCePP Guide v11		Jul 2023	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Data Quality for EU Medicines Reg.	**EMA**	Oct 2023				Y	Y	Y	Y	Y				Y	Y	
	RWD in NIS to Generate RWE		Apr 2024	Y	Y	Y	Y	Y	Y	Y		Y	Y				
Global																	
	Harmonisation in RWD to RWE	**ICH**	May 2024	Y			Y	Y	Y	Y	Y		Y				
	RWD for Safety ICH M14		May 2024	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
Japan																	
	Data Reliability on Post Market Study	**PMDA**	Feb 2018	Y	Y	Y	Y	Y	Y								
	Databases in Post-market Pharmacovig.		Jun 2017	Y	Y	Y	Y	Y	Y						Y		
	Protocols of the Post-Marketing Study		Jan 2023	Y	Y	Y	Y	Y	Y								
	Post-Marketing Surveillance		Jul 2024	Y													
UK																	
	NICE RWE framework	**NICE**	Jun 2022	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	
	DataSAT Assessment Template		Jun 2022	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	RWD to Support Regulatory Decisions	**MHRA**	Dec 2021	Y	Y		Y	Y	Y	Y	Y	Y	Y		Y		
USA																	
	RWD & RWE for Drugs & Biologics	**FDA**	Aug 2023	Y			Y	Y							Y		
	RWD: Registries for Drugs & Biologics		Dec 2023	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
	RWE: NIS for Drugs & Biologics		Mar 2024	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	
	RWE for Medical Devices		Dec 2023	Y	Y	Y	Y	Y						Y	Y		
	RWD: Assessing EHR & Claims Data		Jul 2024	Y	Y	Y	Y	Y	Y			Y			Y		
Other																	
	Suitability of Databases Vaccine Safety	**Duszynski et al.**	Mar 2021	Y		Y	Y	Y	Y		Y	Y			Y		
	ADVANCE for Studies on Vaccinations	**Sturkenboom et al.**	Feb 2020	Y	Y			Y		Y	Y	Y	Y	Y	Y		Y
	Evaluating RWD Quality FFP	**Reynolds et al.**	May 2020	Y		Y		Y	Y		Y	Y	Y	Y	Y	Y	Y
	SPIFD Framework	**Gatto et al.**	Oct 2021	Y	Y	Y	Y	Y	Y	Y		Y					
	SPIFD 2 Framework	**Gatto et al.**	Mar 2023	Y	Y			Y	Y	Y			Y	Y	Y	Y	Y
	Feasibility of EHR & Claims Sources	**Ritchey & Girman**	May 2020	Y	Y		Y	Y	Y						Y	Y	Y
	RWD Fitness for Use and Reliability	**Duke**	Sep 2019	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	
	MINERVA Framework	**Gini et al.**	Jan 2022	Y	Y		Y	Y		Y						Y	Y
	DIVERSE Framework	**Gini et al.**	May 2024	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	Audit Readiness for RWD & RWE	**TransCelerate**	Dec 2023	Y		Y			Y		Y		Y		Y	Y	

Abbreviations: ANVISA, Brazilian Health Regulatory Agency; APAC, Asia-Pacific; AU, Australia; CADTH, Canada Agency for Drugs and Technologies in Health; EHR, electronic health records; EMA, European Medicines Agency; ENCePP, European Network of Centres for Pharmacoepidemiology; eval., evaluation; FDA, U.S. Food and Drug Administration; FFP, fit(ness)-for-purpose; HC, Health Canada; ICH, International Council for Harmonsiation; MHRA, Medicines and Healthcare products Regulatory Agency; Med., medical; NHMRC MI-CRE., National Health and Medical Research Council Medicines Intelligence Centre and Research Excellence; NICE, National Institute for Health and Care Excellence; NMPA, National Medical products Administration; NIS, non interventional studies; pharmacovig., pharmacovigilance; PMDA, Pharmaceuticals and Medical Devices Agency; PROs, patient reported outcomes; RWD, Real world data; RWE, real world evidence; TGA, Therapeutic Goods Administration; UK, United Kingdom; USA, United States of America

Fig. 2 Mapping Feasibility Criteria Across RWE Guidance Documents

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