GUIDELINE/FRAMEWORK					DESIGN FEATURES			DATA QUALITY				DATA LOGISTICS						
GEOGRAPHY	TITLE	REGULATOR/AUTHOR	DATE PUBLISHED	LINK TO GUIDANCE	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
					Please enter Y (Yes) if the term/concept is present in the guideline (the extent to which it is discussed, is not relevant to this assessment)													
Australia	Real World evidence and patient reported outcomes in the regulatory context	Australian Government Department of Health, Therapeutic Goods Association (TGA)	Nov 2021	RWE and PROs	Y	Y	Y	Y										
	Optimising the availability and use of Real World data and Real World evidence to support health technology assessment in Australia	Commissioned by Australian Government, Department of Health and Aged Care. Authored by NHMRC Medicines Intelligence Centre of Research Excellence (MI-CRE)	25 Mar 2024	Australia RWD & RWE	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y
	Real World evidence regulatory considerations for medical devices	Australian Government, Department of Health and Aged Care	Apr 2024	Australia RWE Regulatory	Y	Y	Y	Y	Y	Y	Y			Y		Y		
Brazil	Guia de boas práticas para estudos de dados do mundo real (best practice guide for Real-World studies)	Agência Nacional de Vigilância Sanitária (Anvisa)	26 Sep 2023	Brazil Anvisa Regulatory	Y	Y	Y	Y	Y	Y		Y		Y	Y	Y		
Canada	Elements of Real World Data/ Evidence quality throughout the prescription drug product life cycle	Government of Canada	04 Mar 2020	Canada RWD/E Quality	Y	Y	Y	Y	Y	Y			Y		Y	Y		
	Guidance for reporting Real-World evidence	Canada's Drug and Health Technology Agency (CADTH) and Health Canada	May 2023	CADTH Guidance for RWE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y				Y
China	Guidelines for Real-World evidence supporting drug development and review	National Medical Products Administration (NMPA)	Jan 2020	NMPA Guidelines	Y	Y	Y	Y	Y			Y	Y	Y	Y	Y	Y	
	Technical guidelines for Real-World studies to support drug development and review for children	NMPA	Sep 2020	NMPA Guidelines	Y													
	Guideline for clinical evaluation of medical devices using Real-World data	NMPA	Nov 2020	NMPA Guidelines for clinical evaluation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
	Technical guidelines for the use of Real-World data in clinical evaluation of medical devices (trial version)	Center For Medical Device Evaluation (CMDE), NMPA	Nov 2020	Technical guidelines	Y	Y	Y	Y	Y	Y	Y							
	Guiding principles of Real-World data used to generate Real-World evidence	NMPA	Apr 2021	NMPA RWD	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	Guidelines for drug Real-World research design and protocol framework (draft for comments) — DRAFT	CDE, NMPA	DRAFT – 07 Jul 2022	Guidelines for RW Study	Y	Y	Y	Y	Y			Y		Y	Y			
	Guidelines for communication of Real-World evidence supporting drug registration applications	CDE, NMPA	Feb 2023	CDE Guidelines	Y	Y	Y	Y	Y	Y	Y			Y	Y	Y		
	Guidelines for the application of Real-World data based on disease registries — DRAFT	CDE, NMPA	DRAFT – Nov 2023	CDE Guidelines for the Application of RWE based	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	Guidelines for regulatory review of Real-World study designs and statistical analyses for medical devices	CMDE, NMPA	Jan 2024	CMDE Guidelines for Regulatory Review	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	
Europe	Guideline on good pharmacovigilance practices (GVP) Module VIII — Post-authorization safety studies (Rev 3)	European Medicines Agency (EMA)	13 Oct 2017	GVP Module VIII	Y	Y	Y	Y		Y			Y			Y		
	Guideline on registry-based studies	EMA	16 Sep 2021	EMA Guideline	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	10th Revision of the ENCePP guide on methodological standards in pharmacoepidemiology	ENCePP	01 Jul 2022	*Not available	Y			Y	Y					Y	Y	Y		
	Good practice guide for the use of the metadata catalogue of Real-World data sources — DRAFT	EMA	DRAFT – 16 Nov 2022	EMA Good Practice Guide	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y		
	11th revision of the ENCePP guide on methodological standards in pharmacoepidemiology	ENCePP	13 Jul 2023	ENCePP v11 Guide	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Data quality framework for EU medicines regulation	EMA	30 Oct 2023	EMA Data Quality				Y	Y	Y	Y	Y				Y	Y	
	Reflection paper on use of real-world data in non interventional studies to generate real-world evidence — DRAFT	EMA	DRAFT – 15 Apr 2024	EMA RWD	Y	Y	Y	Y	Y	Y	Y		Y	Y				
International	Pursuing opportunities for harmonisation in using Real-World data to generate Real-world evidence, with a focus on effectiveness of medicines	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	May 2024	Harmonisation in Using RWD	Y			Y	Y	Y	Y	Y		Y				
	General principles on plan, design and analysis of pharmacoepidemiological studies that utilize Real-World data for safety assessment of medicines M14 — DRAFT	ICH	DRAFT – 21 May 2024	ICH M14 Draft Guidance	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
Japan	Basic principles on the use of medical information databases in post-marketing pharmacovigilance	PMDA	09 Jun 2017	PMDA Medical	Y	Y	Y	Y	Y	Y								
	Points to consider for ensuring data reliability on post marketing database study for drugs	Pharmaceuticals and Medical Device Agency (PMDA)	21 Feb 2018	PMDA Ensuring Data	Y	Y	Y	Y	Y	Y						Y		
	Instructions for protocols of the Post-Marketing Database Study	PMDA	30 Jan 2023	PMDA Instructions	Y	Y	Y	Y	Y	Y								
	Proceeding with consideration of the formulation of implementation plan for Post-Marketing surveillance of Pharmaceuticals	PMDA	18 Jul 2024	PMDA Proceeding	Y													
United Kingdom	MHRA guidance on the use of Real-World data in clinical studies to support regulatory decisions	MHRA	16 Dec 2021	MHRA guidance	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	
	NICE Real-World evidence framework	National Institute for Health and Care Excellence (NICE) — Recommended by Medicines and Healthcare products Regulatory Agency (MHRA)	23 Jun 2022	NICE real-world	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	DataSAT assessment template	NICE — Recommended by MHRA	23 Jun 2022	NICE Tools and Resources	Y	Y		Y	Y	Y	Y	Y	Y	Y		Y		
United States	Considerations for the use of Real-World data and Real-World evidence to support regulatory decision-making for drug and biological Products	U.S. Food and Drug Administration (FDA)	Aug 2023	FDA RWD & RWE	Y			Y	Y							Y		
	Real-World data: Assessing registries to support regulatory decision-making for drug and biological Products	FDA	Dec 2023	FDA RWD: Assessing	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
	Use of Real-World evidence to support regulatory decision-making for medical devices — DRAFT	FDA	DRAFT – 19 Dec 2023	Use of Real-World	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	
	Real-World evidence: Considerations regarding non-interventional studies for drug and biological products — DRAFT	FDA	DRAFT – Mar 2024	Real-World Evidence	Y	Y	Y	Y	Y						Y	Y		
	Real-World data: Assessing electronic health records and medical claims data to support regulatory decision-making for drug and biological Products; guidance for industry; availability	FDA	Jul 2024	Real-World Data	Y	Y	Y	Y	Y	Y	Y		Y			Y		
Other Frameworks	Determining Real-World Data's fitness for use and the role of reliability	Duke Margolis Center for Health policy	26 Sep 2019	RWD Fitness	Y		Y	Y	Y	Y		Y	Y			Y		
	ADVANCE database characterisation and fit for purpose assessment for multi-country studies on the coverage, benefits and risks of pertussis vaccinations	Sturkenboom et al.	12 Feb 2020	Global Studies	Y	Y			Y		Y	Y	Y	Y	Y	Y		Y
	Considerations when evaluating Real-World Data quality in the context of fitness for purpose	Reynolds et al.	6 May 2020	RWD Quality Fitness	Y		Y		Y	Y		Y	Y	Y	Y	Y	Y	Y
	Evaluating the feasibility of electronic health records and claims data sources for specific research purposes	Ritchey & Girman	07 May 2020	Feasibility of EHR	Y	Y	Y	Y	Y	Y	Y		Y					
	Suitability of databases in the Asia-Pacific for collaborative monitoring of vaccine safety	Duszynski et al.	23 Mar 2021	APAC Databases	Y	Y			Y	Y	Y		Y	Y	Y	Y	Y	Y
	The structured process to identify Fit-For-Purpose Data: A Data Feasibility Assessment Framework (SPIFD)	Gatto et al.	30 Oct 2021	SPIFD	Y	Y		Y	Y	Y						Y	Y	Y
	MINERVA: Metadata for data discoverability and study replicability in observational studies	Gini et al.	10 Jan 2022	MINERVA Framework	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	
	A structured process to identify Fit-for-Purpose study design and data to generate valid and transparent Real-World evidence for regulatory uses (SPIFD 2)	Gatto et al.	17 Mar 2023	SPIFD 2	Y	Y	Y		Y	Y		Y					Y	Y
	Assuring audit and inspection readiness — considerations for the use of RWD and RWE in regulatory decision-making	TransCelerate BioPharma	Dec 2023	Transcelerate Audit	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	Describing diversity of real world data sources in pharmacoepidemiologic studies: The DIVERSE scoping review	Gini et al.	09 May 2024	DIVERSE Framework	Y		Y			Y		Y		Y		Y	Y	

*ENCePP removed the 10th Revision from online forums. On 07 Nov 24 the ENCePP Secretariat stated that the "latest revision of the guide supersedes previous editions, which is why it is no longer available"