16 November 2022

Submission of comments on "Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources" (EMA/787647/2022)

Comments from:

Name of organisation or individual	ISPOR—The Professional Society for Health Economics and Outcomes Research
(Optional) Email address to be contacted by EMA for further clarification	rwillke@ispor.org

Disclaimer:

☒ *Please fill in the optional email address field and mark this checkbox if you consent to be contacted by the European Medicines Agency for the purpose of obtaining further clarifications on your comments.*

For further information regarding the protection of your personal data in relation to the processing of this questionnaire, please find annexed a data protection statement.

Please note that these comments, the identity, and the affiliation of the sender may be published unless a specific objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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Improving healthcare decisions

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November 16, 2022

Dear Europeans Medicines Agency:

ISPOR – the professional society for health economics and outcomes research - is pleased to respond on behalf of its membership on your consultation "**Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources."** We thank you for the opportunity to comment on this draft guideline.

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. We have a large membership living and working in 110 countries globally; nearly 20% (1 in 5) of our membership resides within the European Union and 40% within Europe. Members across our organization come from a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences and journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by members of our Health Science Policy Council, with comments solicited from several of our membership groups, including our, Real-Work Evidence Steering Committee, Statistical Methods in HEOR Special Interest Group, Real-World Evidence Special Interest Group, and our Policy Outlook Committee. The attached document provides a synthesis of their comments. We hope they prove useful.

ISPOR would be happy to answer any questions about our response, as well as participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Nancy S. Berg
CEO & Executive Director
ISPOR

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Thank you for this opportunity to evaluate high-quality work, which clearly was a major effort. We have a number of comments and recommendations, mainly minor, and hope you will find them beneficial.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Line 114		Comment: Missing verb in sentence Proposed change (if any):	
Line 164		Comment: Although it does have a standard meaning, if the term "suitability" has any more specialized meaning in this guidance, it would be useful to present it at the beginning of this section. Proposed change (if any):	
Line 235		Comment: Information about diagnostic images is not included. Output of diagnostic images are sometime critical to identify patient and their level of disease. Proposed change (if any): C6.22 diagnostic images/examinations	
Line 354-356		Comment: Some other aspects of the study could be useful for evaluating suitability of the data source, e.g, the sampling technique used to obtain the sampled population, and the methods and key variables used to avoid or correct to potential biases, limitations stated in the study report regarding the reliability of the data, and whether the analysis and report followed the protocol or were unable to follow it due to data limitations. Proposed change (if any): Some verification may be applied to the description of the study population; the sample size originating from the	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		data source included in the report; the sampling technique used to obtain the sampled population; the nature and categories of variables included in the analysis; the methods and key variables used to avoid or correct to potential biases; the coding system provided; limitations stated in the study report regarding the reliability of the data; and whether the analysis and report followed the protocol or were unable to follow it due to data limitations.	
Lines 413-449		Comment: For primary data collection, more information is needed on the people who performed the data collection. Are they one person or different data collectors? Did they receive sufficient training to do so or do they have the competencies? Also, despite the discussion of data entry and curation, more details would be useful on how the researchers reduced errors; e.g. if the process was performed by two researchers independently, etc... Proposed change (if any): Add a section 5.1.1.x called Primary Data Collection Considerations, including the above information.	
Lines 450-501		Comment: Somewhere in this range, perhaps in 5.1.1.12, it would be useful to know if and where "synthetic" versions of the data set are available or can be created	
Line 514 (table)		Comment: C6.10 Information on use of other hospital units, eg, stepdown, rehab, is available in some data and can be useful, especially for cost-effectiveness analysis C6.20 Medical device section should be expanded in order to be able to understand at which level of detail class III implantable devices are identifiable (class or single device).	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Add a session for diagnostic images/examination Proposed changes (if any): Add 6.10.2 Information on other units, eg, stepdown, rehab, is available C6.20 Where data source capture information of medical device by Class (I, IIa, IIb, III) C6.22 Diagnostic images/examination	
Line 536		Comment: Sociodemographic information on labor force participation or employment status, is available in some data and can be useful, especially for cost-effectiveness analysis Proposed change: add a bullet for "labor force participation/employment status"	
Lines 595-597		Comment: We suggest a reference to health data governance principles here, e.g.,: https://healthdataprinciples.org/principles Proposed change (if any): Description of the documents or links to webpages that describe the observance of health data governance principles; overall governance, processes and procedures for data capture and management, data access, data quality check and validation results, utilisation for research purposes. (including the link above).	
Line 657		Comment: If consent is not required, a reason should be listed. Also, please include the type of consent: written or oral and what ethical guidelines were followed; e.g. Helsinki guidelines. Proposed change (if any): - Not required, and if not, the reason not required	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		- Whether oral or written - Ethical guidelines followed	
Line 699 (table)		Comment: 5.1.5.3. Cause of death vocabulary OPCS is specific for UK; we suggest to includes others Proposed change (if any): OPCS/other- or procedure codes/classification	
Line 707-708		Comment: Proposed change (if any): We suggest adding to the paragraph "for patient generated data other than the tools listed above, reference to the tool and its validation should be included, if available"	
Line 744		Comment: The reference to 5.1.5.4 is QoL and not diagnosis. Proposed change (if any): It appears that this should be 5.1.5.3.	

Annex: Data protection statement

All personal data provided within this questionnaire will be processed by EMA in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.
This data protection statement provides details on how the Agency, in its capacity as data controller, will process the information that you have given in your questionnaire.
Internally, the Head of Data Analytics and Methods is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation. The contact details of the Internal Controller are the following: datacontroller.analytics@ema.europa.eu

Collection of data
EMA will collect all the personal data in this questionnaire, such as your name, organisation/company, email address, your view on the topics concerned where such information is provided. Please do not reveal any other personal data in the free text fields. EMA does not directly intend to collect personal data but to use the aggregated data for the purpose of this consultation.

Your consent to the processing of your data
When you submit this questionnaire including your name/organisation's name and email address, you consent that EMA will process your personal data you provided as explained in this data protection statement. You may also withdraw your consent later at any time. However, this will not affect the lawfulness of any data processing carried out before your consent is withdrawn.

Start of data processing
EMA will start processing your personal data as soon as this questionnaire is received.

Purpose of data processing
The purpose of the present data processing activity is to collect the views of stakeholders and/or concerned individuals in relation to the particular subject-matter of the consultation. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

Location of data storage
All data is stored within a secure data centre of EMA which is password protected and only available to EMA staff members.

Publication of data
The comments and the identity of the sender may be published unless a specific objection is received.

Retention period

If you complete and send this questionnaire, your personal data will be kept until the results have been completely analysed and utilised. Your personal data will be deleted at the latest 1 year after the questionnaire was submitted.

Your rights
You have the right to access and receive a copy of your personal data processed, as well as to request rectification or completion of these data. You may also request erasure of the data or restriction of the processing in accordance with the provisions of Regulation (EU) 2018/1725. You can exercise your rights by sending an e-mail to datacontroller.analytics@ema.europa.eu

Complaints
If you have any complaints or concerns about the processing of your personal data, you can contact EMA's Data Protection Officer at dataprotection@ema.europa.eu

You may also lodge a complaint with the European Data Protection Supervisor: edps@edps.europa.eu

For more details on how EMA processes personal data, please see the general EMA Data Protection and Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement