18 November 2022

Submission of comments on "Data Quality Framework for EU medicines regulation" (EMA/Data Analytics and Methods Task Force /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).

ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648

P +1-609-586-4981
F +1-609-586-4982

info@ispor.org
www.ispor.org

November 18, 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 "**Data Quality Framework for EU medicines regulation."** 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)*
	This is a very informative and well-organized document. Since it can be somewhat technical, it would be helpful to provide, wherever possible, definitions and/or examples of terms whose meanings may not be immediately obvious to a reader not already well-versed in this terminology.	
	The places where "fit-for-purpose" is briefly interpreted for each quality dimension are helpful starting points here. Given the importance of judging what is fit-for-purpose in specific situations, however, we hope that future guidance in this area will provide more scenarios and examples of how "fit-for-purpose" will be judged for regulatory purposes.	

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)*
195-197		Comment: An example of an "intrinsic determinant" – actually of all 3 types - would be helpful here. Proposed change (if any):	
247-250		Comment: Is the difference between data and metadata really not well defined, if you can tell when a bit of data is one or the other? Proposed change (if any): "any given bit of information may be metadata in one context (eg, instrument provider for a test) and metadata in a different one (e.g, if assessing measurement bias).	
272		Comment: Please define, or give an example, of what an "entity" is. Proposed change (if any):	
325-327		Comment: It may be useful also to show an example of a plausibility test within a given record. Proposed change (if any): Within a given record, a height and weight combination that results in a BMI less than 5 seems implausible and suggests that at least one	

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)*
		of those two measures is inaccurate.	
325-327		Comment: It may be useful also to show an example of a plausibility test within a given record. Proposed change (if any): Within a given record, a height and weight combination that results in a BMI less than 5 seems implausible and suggests that at least one of those two measures is inaccurate.	325-327
310-311		Comment: Having the interpretation of what "fit-for-purpose" means for each of these dimensions is quite helpful. Proposed change (if any):	
352-353		Comment: We suggest replacing "easily" with "necessarily." There are situations where coverage can easily be measured, eg, if there is another data set on the same topic that covers a broader population. Proposed change: Coverage cannot necessarily be measured, as the total information may not be definable or accessible.	

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