

PAAB 2018

MONTREAL | NOV 20
TORONTO | NOV 22

Have You Read the Proposed Code Change and Corresponding Guidance Document Relating to Real World Evidence?

Proposed Code Change

Guidance Document

Intended to help the pharmaceutical industry and PAAB reviewers interpret / apply the proposed code change

Feedback should be provided through your organization (such that PAAB receives a single collated set of comments from organization). This feedback should be provided by January 31, 2019 to BOTH of the following email addresses:

lorenzobiondi60@gmail.com
patrickm@paab.ca

HOW DID WE GET HERE?

Innovative Medicines Canada requested that the PAAB Board consider updating PAAB code standards relating to Real World Evidence (RWE) to reflect global trends in this evolving area. In response, the PAAB Board created an expert committee to:

- Review existing code standards
- Propose a code change, if warranted
- Create a guidance document corresponding to the proposed code change

THE REAL WORLD EVIDENCE COMMITTEE

The Real World Evidence Committee had the following members:

Lorenzo Biondi	RWE Committee Chair and Director of the PAAB Board
Dr. Walter Rosser	Chair of the PAAB Board
Denis Morrice	Director on the PAAB Board
Don Husereau	Senior Economic Advisor at the Canadian Pharmacists Association
Suvina Amin	Medical Evidence Lead at AstraZeneca Canada Inc.
Janey Shin	Director of Real World Evidence at Janssen Inc.
Andrew Leeson	Associate Creative Director Medical Copy at Ogilvy CommonHealth
Yin Man	PAAB Reviewer
Patrick Massad	PAAB Deputy Commissioner

THE PROPOSED CODE CHANGE

The proposed code change and the guidance document are the result of an environmental analysis which included consideration of trends regarding use of RWE to support pharma-related regulatory decisions in the United States, United Kingdom, European Union, and Japan. A detailed environmental scan of existing RWE quality assessment frameworks was also performed. The guidance document was particularly influenced by the following documents:

- A Questionnaire to Assess the Relevance and Credibility of Observational Studies to Inform Health Care Decision Making: An ISPOR-AMCP-NPC Good Practice Task Force Report
<https://www.sciencedirect.com/science/article/pii/S1098301514000096>

- Grace Checklist: A Validated Checklist for Evaluating the Quality of Observational Cohort Studies for Decision-Making Support
<https://www.graceprinciples.org/doc/GRACE-Checklist-031114-v5.pdf>

- Newcastle-Ottawa Quality Assessment Form for Case-Control Studies
<https://www.ncbi.nlm.nih.gov/books/NBK294460/bin/appb-fm4.pdf>

- Newcastle-Ottawa Quality Assessment Form for Cohort Studies
<https://www.ncbi.nlm.nih.gov/books/NBK115843/bin/appe-fm3.pdf>

- ROBINS-I Tool
<https://sites.google.com/site/riskofbiastool/welcome/home/current-version-of-robins-i/robins-i-tool-2016>

- CASP Case Control Study Checklist
<https://casp-uk.net/wp-content/uploads/2018/01/CASP-Case-Control-Study-Checklist.pdf>

CASP Cohort Study Checklist

<https://casp-uk.net/wp-content/uploads/2018/01/CASP-Cohort-Study-Checklist.pdf>

THE CRITERIA

The criteria in these documents were adapted in consideration to the nature of the PAAB review process, and the target use of the RWE (i.e. as evidentiary basis for presentations in healthcare product advertising).

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- 05 Outside speakers from Innovative Medicines Canada, Lundbeck...



From PAAB fundamentals, to understanding when and how to use RWE and AI for branded and non branded materials. PAAB's 2018 workshop is the must attend event anyone working on healthcare advertising, marketing or communication materials that circulate in the Canadian market.

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