

Benefit-Risk Working Group Call for Members

Background. The Benefit-Risk Assessment of Vaccines by TechnolOgy (BRAVATO) working group has developed standardized templates for the collection of key information for the development, efficacy, and safety of new vaccine candidates. The templates describe key characteristics of novel vaccine vectors and facilitate scientific discourse among key stakeholders by increasing transparency and comparability of information, and they provide a checklist-like tool for managing potentially complex risks and other vaccine properties. Over the past decade, academic, regulatory and industry groups have advanced the field of benefit-risk (B-R) assessment. Methodologic and regulatory policies advances in this field include the application of structured B-R frameworks, the increasing use of the patient perspective in regulatory submissions and review and growing roles for quantitative B-R models. A template is planned for the collection of key information for a structured B-R approach for vaccines. This will be an additional module that can be appended to the existing BRAVATO vaccine assessment templates or used independently to support these advancements in B-R.

We are recruiting interested and qualified benefit-risk experts to join the new working group. The opportunity is open to Collaboration Brighton members with expertise in B-R assessment of vaccines or drugs. Please also share recommendations of colleagues outside of Brighton, including from academia and industry, with this expertise. WG members should be able to meet via teleconference fortnightly, dedicate 8-12 hours/month towards template completion, contribute to the manuscript and manuscript submission process and consult with vaccine developers via CEPI.

Please email your CV to bc-coordinator@taskforce.org by 4 April 2021. Given the urgency of the pandemic, the working group will be expected to develop and share the template with vaccine developers within 5 months of the project start date. Working group meetings are intended to start in mid to late April 2021. Please provide your full name, current institution where you work and your CV highlighting your expertise in B-R assessment of vaccines or drugs in the email. We would also appreciate any recommendations of colleagues outside the Brighton Collaboration with B-R expertise.

Thank you.

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