

Consumer Reported Outcome Measures Consortium (CROM)

To support regulatory decision-making on new tobacco products, there is a need for developing scientifically credible standards to ensure that consumer-reported outcomes measures (CROM) are valid and reliable, i.e., they accurately measure what they set out to measure. To that end, the CROM Consortium Task Force, created within the CORESTA Product Use Behaviour (PUB) Sub-Group in October 2018, has been working on the foundation of a consortium to establish best practices and guidelines for the integration of CROM in the tobacco regulatory process.

The introductory meeting of the CROM Task Force was held in Kunming, China, on 22 October 2018 where 25 participants attended. The overall purpose of the CROM Consortium was presented by Christelle Chrea (Philip Morris Products) and Catherine Acquadro (ICON) and the discussion led to the decision to create a Working Group 0 (WG0) with the following specific targets:

- To clarify the goals of the Consortium, the research questions and the scope of work.
- To oversee the development of the CROM Consortium: governance, structure, budget and funding mechanisms and engagement with third parties.
- To prepare a workplan for the execution of future phases for the working groups (WGs).

The WG0 created after Kunming had monthly teleconferences between November 2018 and May 2019 with 14 participating members, representing eight tobacco stakeholders. During this six-month period, the WG0: 1) developed a definition of Consumer-Reported Outcomes, 2) reviewed key documents (guidance, reports, articles and MRTPA briefing packages), extracted the information according criteria agreed upon by the group, and compiled the information; 3) developed a taxonomy on concepts to be measured for pre- and post-marketing purposes in tobacco regulatory science.

All these activities were reviewed during the second CROM Task Force meeting held in Montreal, Canada on 24 May 2019 where 17 participants attended. Decision was made during the meeting to present the work of WG0 as a poster at the annual CORESTA SSPT Conference in Hamburg in October 2019. During the meeting, the Task Force members also agreed on the following targets for the CROM consortium:

To provide guidance on how to develop, validate, identify, access and use CROM to evaluate tobacco and nicotine-containing products for pre-market and post-market purposes:

- By reviewing existing standards on the development and validation of CROM and by reviewing information on CROM;
- By providing recommendations on the development and validation of CROM;
- By creating a knowledge repository to store CROM and facilitate identification and access of the most appropriate CROM in a specific context of use;
- Through a cooperation platform involving tobacco industry and the guidance of academia and regulatory agency stakeholders.

During the third Task Force meeting held in Hamburg, Germany on 6 October 2019, the consortium structure, working plan and funding mechanisms were agreed upon between the Task Force members. Specific working groups will lead the execution of specific objectives, while an independent scientific committee, composed of academic and public health researchers, will be constituted to guide and review the outcomes of the other working groups. The CORESTA Scientific Commission will provide overall oversight of the consortium to ensure conformity of the work with CORESTA standards. The Task Force members will remain the central oversight component of the consortium from a scientific, operational and financial view point.

To ensure the credibility and excellence of the deliverables produced by the CROM consortium, it is paramount to get technical support from external subject matter experts for the execution of the working plan. An initial financial investment from six tobacco stakeholder members of the CROM has already been confirmed and the development of the governance model and funding mechanisms of the CROM consortium is currently ongoing with the view to have them in place by early 2020. The coordinators of each WG have been nominated and they now have the task to develop a New Working Item Proposal (NWIP) to define the specific objectives, working plan, milestones, deliverables and budget for the WG they are coordinating.

We are encouraging all CORESTA members who are interested to reach out to Christelle Chrea (christelle.chrea@pmi.com) or Catherine Acquadro (cacquadro@mapigroup.com), Coordinators of the CROM Task Force, to discuss willingness to get involved in the CROM consortium, as a funding or contributing member. More information is also available on the CROM webpage on the CORESTA website at <https://www.coresta.org/groups/consumer-reported-outcome-measures-consortium>.



*Christelle CHREA
CROM TF Coordinator*



*Catherine ACQUADRO
CROM TF Co-coordinator*