

# Consumer Reported Outcome Measures (CROM) Task Force 2022 Annual Report

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2022 ONLINE CORESTA CONGRESS SSPT



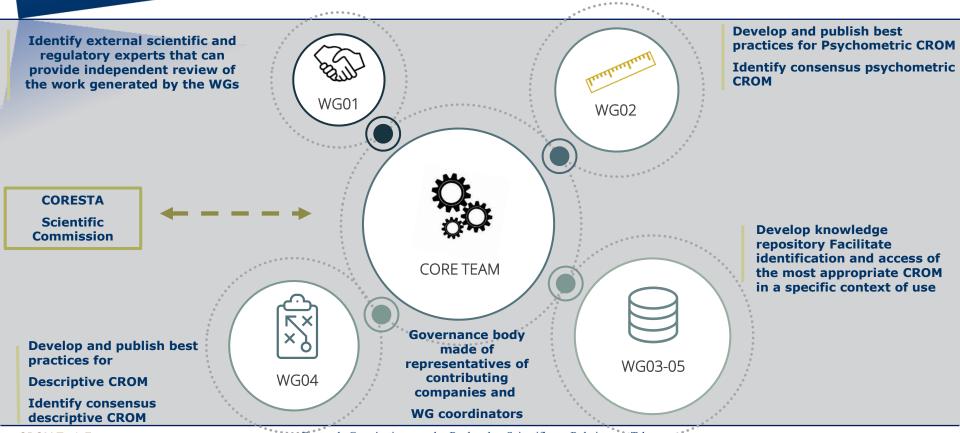
## **CROM Consortium Objective**

#### The main objective of the CROM consortium is:

- ➤ 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.



### **Governance Structure of CROM TF**





### **Outline: 2022 Activities**

- 1. WG01: engagement activities
- 2. CROM-269-NWIP: guidelines for psychometric CROM (WG02)
- 3. CROM-274-NWIP: guidelines for descriptive CROM (WG04)



Objective: Identify external scientific and regulatory experts that can provide independent review of the work generated by the WGs and support dissemination of WG work

#### **Key achievements in 2022**

- Workshop on TPPI studies from JUUL (May)
- ➤ Workshop on Risk Perception from PMI (Sep)
- ➤ Annual symposium on Abuse Liability (TBD)



#### **Workshop on May**

- 135 participants registered (23 non-members)
- 110 connected participants
- 59 views on the CORESTA website/Vimeo
- Article in CORESTA Newsletter Issue 63



CROM Virtual Workshop - May 2022 | CORESTA



#### Workshop on September 29, 2022

- 133 registrations (33 non-members)
- 98 connected participants
- 39 replays on Livestorm and 15 views via the CORESTA website/Vimeo
- Article for the next CORESTA Newsletter.



CROM Virtual Workshop - September 2022 | CORESTA



#### **Next CROM Symposium**

- The next virtual symposium will focus on abuse liability
- The symposium will act as a forum to share and discuss best practice principles to design and interpret abuse liability studies among researchers from various disciplines from industry and academia
- Date and agenda of the symposium will be made available on CORESTA website once finalized



### **WG02: Guidelines for Psychometric CROM**

- Objective: Review existing guidelines and develop CROM best practices for the tobacco industry with respect to Psychometric CROM
- Coordinators: McCaffrey, Stacey (JUUL) / Afolalu, Esther (PMI)

#### **❖** Members:

Chrea, Christelle (PMI)

Clark, Jeff (Liggett)

Kim, Mimi (RJRT)

Nishihara, Daisuke (JTI)

Prasad, Krishna (BAT)

Sarkar, Mohamadi (Altria)

Shetty, Mandara (BAT)



## **WG02: Guidelines for Psychometric CROM**

### **Key achievements 2022**

- All sections of the WG02 guidelines drafted
- Several rounds of review by WG02 members and external SMEs
- Currently incorporating feedbacks and seek alignment among WG members when necessary

#### **Next steps**

- Send to CORESTA scientific commission for review and then to respective review board of authoring companies (Q1 2023)
- Post guidelines on open platform (e.g., Qios) to get additional feedback from external SMEs (Q2 2023)
- Consolidate feedbacks and create final guidelines to be published on CORESTA website and submit to peer-reviewed journal (Q4 2023)



### WG04: Guidelines for Descriptive CROM

- Objective: Review existing guidelines/definitions regarding descriptive CROMs and develop best practices
- Coordinators: Mohamadi Sarkar (Altria)/Krishna Prasad (BAT)
- Members are identified with the following two roles
  - The advisory board:
    - Pierpaolo Magnani (PMI)
    - Esther Afolalu (PMI)
    - Xavier Cahours (ImpTob)
    - Lesley Giles (JTI)
    - Ryan Black (JUUL)
    - Stacey McCaffrey (JUUL)

#### Core working group:

- o Lai Wei (Altria)
- Mohamadi Sarkar (Altria)
- Emilie Clerc (PMI)
- Mandara Shetty(BAT)
- Krishna Prasad (BAT)
- Nicholas Goldenson (JUUL)
- Kim, Mimi M (RJR)



## **WG04: Guidelines for Descriptive CROM**

#### **Key achievements 2022**

- All sections of the WG04 guidelines drafted
- Several rounds of review by WG04 members and external SMEs
- Final draft incorporated feedbacks and alignment among WG members when necessary

#### **Next steps**

- Send to CORESTA scientific commission for review and then to respective review board of authoring companies (Q4 2022)
- Post guidelines on open platform (e.g., Qios) to get additional feedback from external SMEs (Q1 2023)
- Consolidate feedbacks and create final guidelines to be published on CORESTA website and submit to peer-reviewed journal (Q2 2023)



# **Thank You!**