



# **Consumer Reported Outcome Measures (CROM) Task Force 2021 Annual Report**

Coordinator: Dr Christelle Chrea (PMI)  
SC Liaison: Dr Xavier Cahours (IMB)

**SSPT2021 Virtual Conference SSPT**



# Objectives for the CROM Task Force

- ❖ **To provide guidance on how to develop, validate, select, access and use consumer-reported outcome measures (CROM) to evaluate tobacco and nicotine-containing products for pre-market and post-market purposes**
  - **By reviewing existing information on measures**
  - **By developing guidance on the development and validation of measures**
  - **By creating a knowledge repository to store measures and facilitate identification and access**
  
- ❖ **Through a cooperation platform involving tobacco industry and the guidance of academia and regulatory agency stakeholders**



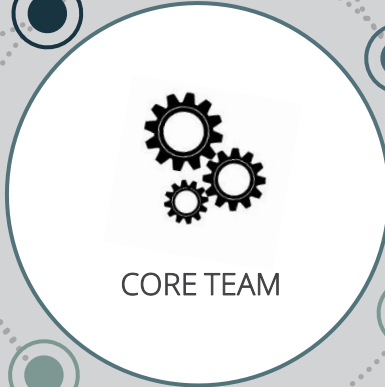
# Consortium Structure: Overview

Identify external scientific and regulatory experts that can provide independent review of the work generated by the WGs



Develop and publish best practices for Psychometric CROM  
Identify consensus psychometric CROM

CORESTA  
Scientific  
Commission



Develop knowledge repository  
Facilitate identification and access of the most appropriate CROM in a specific context of use



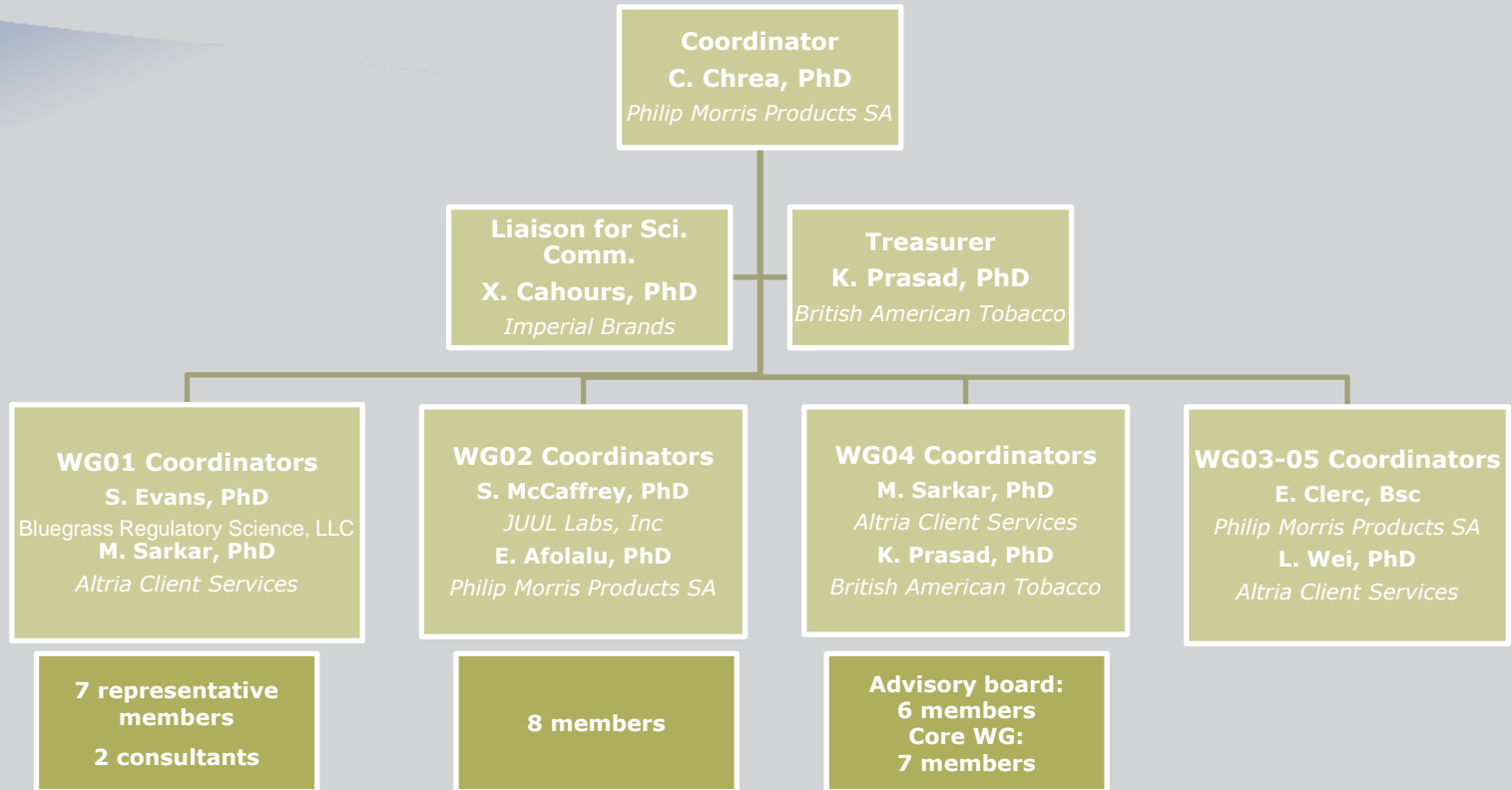
Develop and publish best practices for  
Descriptive CROM  
Identify consensus descriptive CROM

Governance body consisting of representatives of contributing companies and WG coordinators





# Consortium Task Force Core Team





# 2021 activities in a nutshell

- ❖ 1 biannual meeting held on 27th May 2021
- ❖ 10 monthly meetings for the core team
- ❖ 37 biweekly meetings across the WGs
- ❖ 4 oral presentations and 2 posters at international conferences
- ❖ 1 Symposium to be held on December 9th



# WG01: External engagement activities

- ❖ **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
- ❖ **Coordinators:** Mohamadi Sarkar (Altria)/Sarah Evans (Bluegrass Regulatory Science, LLC)

## ➤ **CROM core team members**

- *Christelle Chrea (PMI)*
- *Xavier Cahours (ImpTob)*
- *Lesley Giles (JTI)*
- *Krishna Prasad (BAT)*
- *Stacey McCaffrey (JUUL)*
- *Mimi Kim (RJRT)*

## ➤ **External consultants:**

- *Karen Gerlach (Womble Bond Dickinson)*
- *Janine Pillitteri (Womble Bond Dickinson)*



# WG01: External engagement activities

## Key Accomplishment in 2021

- Completed 12 biweekly meetings since May 2021
- Supported WG02 for the submission of the comments to US FDA docket
- On boarded 2 consultants to identify opportunities and channels for external engagements
- Reached out to 25 experts in survey methodology for the CROM Symposium 2021



# WG01: External engagement activities

## CROM Symposium 2021

- ❖ This year, the virtual symposium focuses on *survey methodology* and will address multiple topics including cross-sectional and longitudinal survey design, implementation, analysis, and interpretation.
- ❖ The symposium will act as a forum to share and discuss best practice principles to design surveys among researchers from various disciplines from industry and academia
- ❖ Agenda of the symposium will be made available on CORESTA website once finalized
- ❖ Date and time: 9 December, 2021 - 4:00 pm – 7:00 pm CET
- ❖ Virtual meeting on Teams





# WG02: Standards for Psychometric CROM

- ❖ **Objective:** Review existing guidelines and develop CROM standards for the tobacco industry with respect to Psychometric CROM
- ❖ **Coordinators:** McCaffrey, Stacey (JUUL) / Afolalu, Esther (PMI)
- ❖ **Members:**
  - Black, Ryan (JUUL)
  - Chrea, Christelle (PMI)
  - Clark, Jeff (Liggett)
  - Kim, Mimi (RJRT)
  - Nishihara, Daisuke (JTI)
  - Prasad, Krishna (BAT)
  - Sarkar, Mohamadi (Altria)
  - Shetty, Mandara (BAT)



# WG02: Standards for Psychometric CROM

## Phase 0

Timeline: June-December, 2020

Key Activities: Devise a detailed approach for developing CROM guidelines and take initial steps toward execution.

### Deliverables:

- ❖ list of members with associated roles and responsibilities
- ❖ an operational definition of Psychometric CROM (scope of Psychometric vs. Descriptive CROM)
- ❖ approach for the literature review, list of literature to be reviewed
- ❖ detailed work plans and timelines for Phase 1
- ❖ detailed budget for Phase 1
- ❖ plan for external engagement in 2021

## Phase 1

Timeline: January 2021- September 2022

Key Activities: Engage in information-gathering activities; synthesize and analyze findings; draft and finalize CROM standards.

- ❖ Disseminate (formally or informally) the draft guidelines during development in order to obtain feedback and support from peers/subject matter experts (SMEs).

### Deliverables:

- ❖ complete literature review
- ❖ draft Psychometric CROM guidelines
- ❖ conference presentations of draft guidelines
- ❖ final Psychometric CROM guidelines
- ❖ manuscript(s) for peer-review publication



# WG02: Standards for Psychometric CROM

## Key achievements 2021

- Completed 7 WG02 meetings
- Completed literature review and majority of the identified papers summarized
- Drafted outline of the WG02 guidelines which was reviewed by WG02 team members
- Presented the outline of the guidelines in 4 international conferences as per dissemination plan
  - SRNT virtual poster (Feb)
  - ISPOR virtual poster (Apr)
  - ISOQOL virtual oral presentation (Oct)
  - CORESTA SSPT oral presentation (Oct)
- Sections of the guidelines currently drafted and 2 external consultants secured to provide input/review
- Comments submitted to the US FDA docket on new draft guidance on Principles for Designing and Conducting TPPI Studies



# WG04: Standards for Descriptive CROM

- ❖ **Objective:** Review existing guidelines/definitions regarding descriptive CROMs
- ❖ **Coordinators:** Mohamadi Sarkar (Altria)/Krishna Prasad (BAT)

## ➤ **The advisory board:**

- *Pierpaolo Magnani (PMI)*
- *Esther Afolalu (PMI)*
- *Xavier Cahours (ImpTob)*
- *Lesley Giles (JTI)*
- *Ryan Black (JUUL)*
- *Stacey McCaffrey (JUUL)*

## ➤ **Core working group:**

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



# WG04: Standards for Descriptive CROM

## Phase plan

- ❖ Phase 0: Select members who could provide expertise and guidance in developing the recommendations; define roles and accountabilities. Establish specific deliverables and milestones
- ❖ Phase 1: Review existing guidelines/definitions for descriptive CROM based on large national surveys (e.g. PATH, Smoking ToolKit), identify gaps and make recommendations (Q1 2021)
- ❖ **Phase 2: Develop consensus measure(s) of each relevant construct (e.g., demographics, tobacco product use behavior) and identify gaps where new descriptive CROM may be necessary and create a summary guideline document (Q3-Q4 2021)**



# WG04: Standards for Descriptive CROM

## Key Accomplishment in 2021

- Completed 18 core team meetings and 3 meetings with advisory board
- Reviewed and summarized survey items from 15 tobacco surveillance surveys
- Proposed foundation definitions for tobacco product classification and tobacco product use states
- Developed and reviewed the outline of the draft guideline
- Completed the main sections in the draft guideline for internal review
- Discussed potential overlap and alignment with WG02
- Presented at 2 international conferences as per dissemination plan
  - TSRC oral presentation (Aug)
  - CORESTA oral presentation (Oct)



**Thank You!**