



Consumer Reported Outcome Measures (CROM) Task Force

2020 Annual Report2020_Report_TF-CROM_Chrea

Coordinator: Dr Christelle Chrea (PMI)

SC Liaison: Dr Xavier Cahours (IMB)

2020 ONLINE CORESTA CONGRESS SSPT



Rationale for a CROM Consortium

- ❖ To inform their evaluation process, regulatory agencies, such as the U.S. Food and Drug Administration (FDA), have set solid standards on the type of science-based evidence required to demonstrate that a tobacco product can benefit public health
- ❖ Consumer-Reported Outcome Measures (CROM) are an essential component of the evaluation of new tobacco products and MRTP candidates in terms of consumers* risk perceptions, behaviors, behavioral intentions and understanding of product information

*Consumers include current users and never users (who are potential users)



Objectives for the Consortium

- ❖ **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**



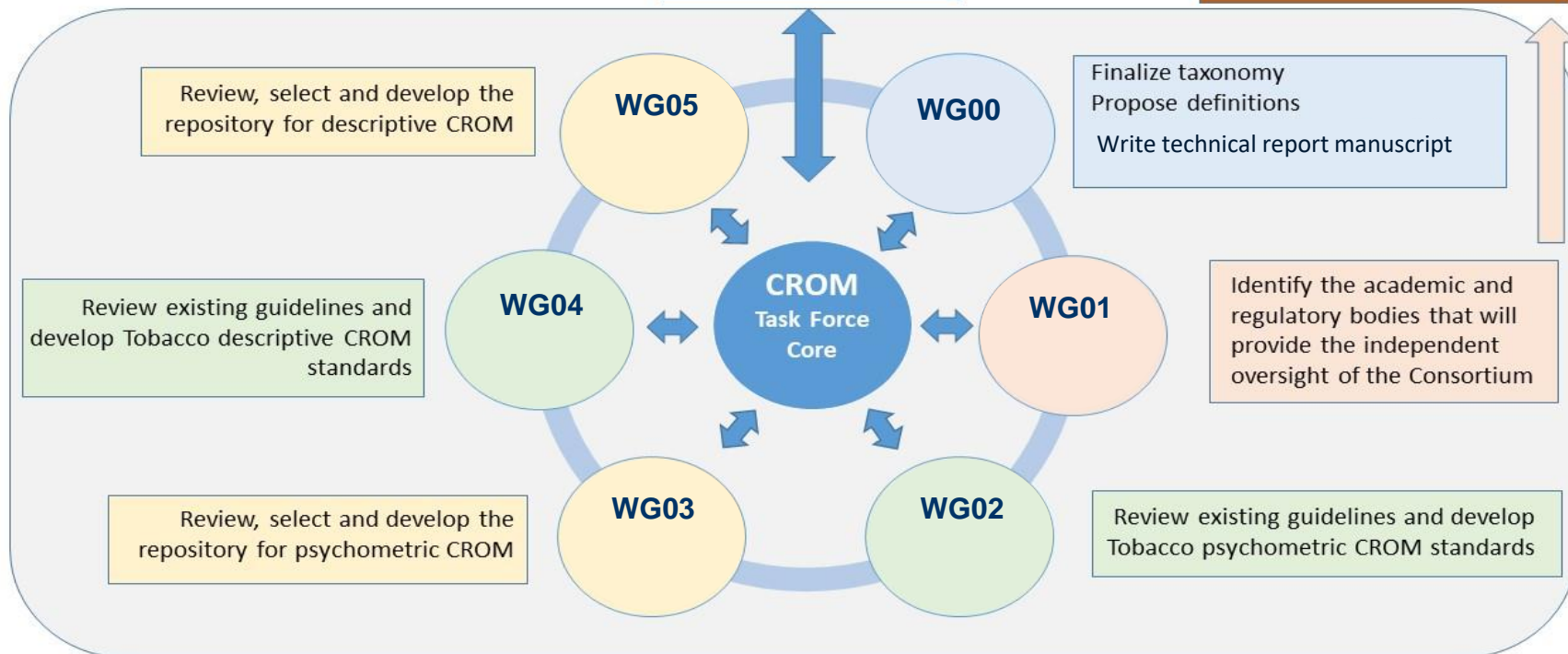
Consortium Structure: Overview

 CROM Task Force

CORESTA Scientific Commission



Independent Scientific Committee





CROM TF Core Members

Coordinator	CHREA Christelle	Philip Morris International, Switzerland
SC Liaison	CAHOURS Xavier	Imperial Tobacco Brands, France
Members	BLACK Ryan, McCAFFREY Stacey	JUUL, USA
	PRASAD Krishna, SHETI Mandara	British American Tobacco, UK
	SAKAR Mohamadi, WAI Lei	Altria Client Services, USA
	EVANS Sarah	Turning Point Brands, USA
	GILES Lesley, NISHIHARA Daisuke	JT International SA, Switzerland
	PARK Heather	KT&G Research Institute, South Korea
	AFOLALU Esther, CLERC Emilie	Philip Morris Products SA, Switzerland
	SHIFFMAN Saul	Pinney Associates, USA
	CURTIN Geoffrey	RAI Services Company, USA
	ACQUADRO Catherine	ICON plc, France



Outline: 2020 Activities

1. **PUB-190-NWIP: Formation of CROM Task Force (WG00)**
2. **CROM-269-NWIP: standards for psychometric CROM (WG02)**
3. **CROM-274-NWIP: standards for descriptive CROM (WG04)**
4. **CROM webinar (part of WG01: engagement activities)**



WG00: Formation of CROM Task Force

1. Clarify the goals of the Consortium, the research questions and the scope of work

- ❖ Technical report in preparation based on poster presented at CORESTA Congress 2019 and submission planned for Q4 2020

2. Oversee the development of the CROM Consortium: governance, structure, budget and funding mechanisms, engagement with 3rd parties

- ❖ Funding secured from 7 tobacco stakeholders

 - In 2019: Altria, BAT/RJT, IMB, JTI, KT&G, PMI

 - In 2020: JUUL

- ❖ Governance model and invoicing process agreed with CORESTA general secretary

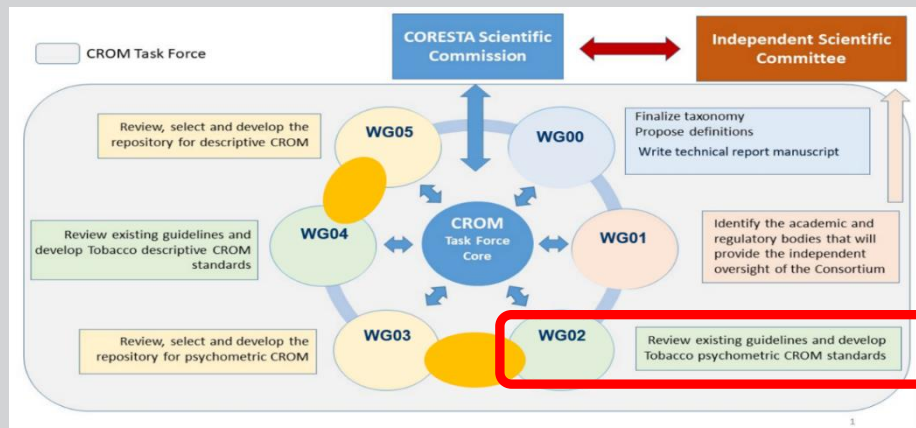
- ❖ Cost sharing agreement drafted by CORESTA Legal Firm reviewed by 6 out of 7 founders- to be executed by EOY

3. Prepare execution of future phases: work plans, working groups (WGs)

- ❖ Kick off of WG02 and WG04 with NWIPs approved in June and August respectively

WG02: Standards for Psychometric CROM

Objective: Review existing guidelines and develop CROM standards for the tobacco industry with respect to Psychometric CROM*



* Although the definitions of Psychometric CROM will be more fully defined and refined as part of WG02 activities, Psychometric CROM can be loosely defined as *items which are intended to measure underlying attributes (e.g. craving)*. Conversely, Descriptive CROM represent items that measure behavior directly (i.e. could be observed by a third party) (e.g. number of days a product was used in the past 7 days).



WG02: Standards for Psychometric CROM

❖ **Coordinators: McCAFFREY Stacey (JUUL) / AFOLALU Esther (PMI)**

❖ **Members:**

BLACK Ryan (JUUL)

CHREA Christelle (PMI)

CLARK Jeff (Liggett)

CURTIN Geoffrey (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 standards 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 - December, 2021

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

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

Deliverables:

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



WG02: Standards for Psychometric CROM

❖ Key achievements of Phase 0

- Completed 7 WG02 bi-weekly meetings following the initial kick-off meeting (June 2nd, 2020)
- Drafted the timelines, key activities, and deliverables for both phases of work (i.e., Phase 0: Preparation, Phase 1: Development of CROM Standards)
- Generated working operational definitions of Psychometric and Descriptive CROM in collaboration with WG04 members
- Classified concepts from the CROM WG0 taxonomy as Psychometric or Descriptive CROM in collaboration with WG04 members
- Identified 5 primary components of the Psychometric CROM standards, and collaboratively defined these components (i.e., (1) appropriate content, (2) adaptation/modification of an existing CROM, (3) application/implementation and interpretation of CROM in research, (4) development process and validation, (5) linguistic/cultural translation)
- Defined the role of literature in the context of the approach to developing the Psychometric CROM standards
- Compiled working list of applicable literature for WG02 review (N ~50 documents)
- Assigned the majority of literature to reviewers (*still in progress*)
- Initiated review, utilizing shared excel summary document
- Established a shared workspace to collaborate (SharePoint)
- Identified conferences for external presentation as part of 2021 dissemination plan



WG04: Standards for Descriptive CROM

Objective: Review existing guidelines/definitions regarding descriptive CROMs

❖ **What are “Descriptive” CROMs?**

➤ **Descriptive CROM represent items that are**

• **Direct measures of behavior which may include:**

- Binary outcomes, e.g. sex
- Continuous measures, e.g. average number of cigarettes smoked per day
- Categorization of the population, e.g. dual users

➤ **While a consensus-based approach may work for some measures, others may require at minimum cognitive validation.**



WG04: Standards for Descriptive CROM

❖ **Coordinators: Mohamadi Sarkar (Altria) / Krishna Prasad (BAT)**

❖ **Members are identified with the following two roles**

➤ ***The advisory board:***

- *MAGNANI Pierpaolo (PMI)*
- *AFOLALU Esther (PMI)*
- *CAHOURS Xavier (ImpTob)*
- *GILES Lesley (JTI)*
- *BLACK Ryan (JUUL)*
- *McCAFFREY Stacey (JUUL)*

➤ ***Core working group:***

- *PRASAD Krishna (BAT)*
- *SHETTY Mandara (BAT)*
- *CLERC Emilie (PMI)*
- *SARKAR Mohamadi (Altria)*
- *WEI Lai (Altria)*



WG04: Standards for Descriptive CROM

❖ 2020 Plan

- Identify members in core team and advisory board and established deliverables and milestones (Aug)
- Identify available guidelines/surveys/publications to develop CROM Standard (Oct-Nov)
 - Focus on legal age and above adult population
- Identify the domains and develop the list of descriptive CROM Measures (Nov-Dec)
 - Tobacco usage monitoring versus post-market surveillance of a specific product

❖ 2021 Plan

- Review available resources and develop Descriptive CROM Measure Summary (Q1 2021)
- Develop consensus measures, identify gaps and make recommendations (e.g. modification of existing descriptive CROM, optimal measures of use behavior)
- Disseminate to deliverables to the scientific community (Q2/Q3 2021)
 - Summary of Descriptive CROM Measures
 - Recommended measurements that meet the new standards and appropriate applications



❖ **Twofold purpose:**

- To introduce the CROM Consortium to CORESTA members that are not experts in CROM
- To engage more globally with the external scientific community about the purpose of the CROM Consortium

❖ **Webinar will contain three parts**

- Part I: Purpose of the CROM Consortium and perspective from the pharmaceutical industry with Patient reported outcomes (PRO)
- Part II: Cases studies on CROM development, analysis and interpretation
- Part III: Audience Q&A with panel presenters

❖ **Agenda of the webinar will be made available on CORESTA website once NWIP approved by CORESTA Scientific Commission**

❖ **Date and time: 3rd or 10th of December, 2020 / 4:00 pm - 7:00 pm CET**

❖ **Virtual meeting on Teams**



Thank You!