



CROM Symposium 2020

**Consumer Reported Outcome Measures
in Tobacco and Nicotine Research**

December 10, 2020 | A Virtual Event



A definition of CROM

Consumer-Reported Outcome Measures are self-reported observations that represent information intrinsic to the consumer, which cannot be obtained otherwise

Psychometric CROM

Intended to measure underlying psychological attributes (i.e., not directly observable), such as reinforcing effects of a product

Descriptive CROM

Items which measure behavior directly (i.e., observable), such as the number of days a product was used in the past 7 days



WHO IS CORESTA

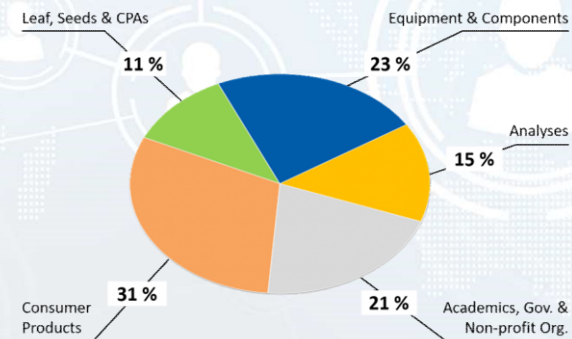
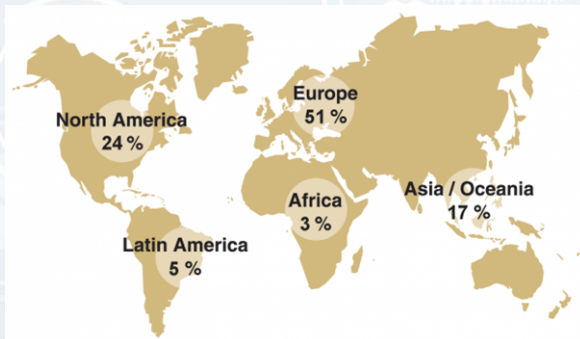
Centre de **Co**opération pour les **Re**cherches **Sci**entifiques Relatives au **Tab**ac

Cooperation Centre for Scientific Research Relative to Tobacco

Association founded in 1956, ruled by French law

Vision

To be recognized by our members and relevant external bodies as an authoritative source of publicly available, credible science and best practices related to tobacco and its derived products.





Agenda

SETTING THE SCENE FOR CROM

4:00 p.m.- 4:15 p.m.	A consortium approach for consumer-reported outcome measures for assessing tobacco and nicotine-containing products	Christelle Chrea, PhD <i>Philip Morris Products SA</i>
4:15 p.m.- 4:45 p.m.	The FDA Guidance on PROs and the Regulation of Modified Risk Tobacco Products (MRTP)	Donald Patrick, PhD <i>University of Washington</i>
4:45 p.m.- 5:05 p.m.	Audience Q&A following panel presentations	Mohamadi Sarkar, PhD <i>Altria Services</i> Panel presenters

CASE STUDIES ON CROM

5:05 p.m.- 5:25 p.m.	Use of qualitative research to ensure we measure what matters to users of tobacco and/or nicotine products	Esther Afolalu, PhD <i>Philip Morris Products SA</i>
5:25 p.m.- 5:45 p.m.	Measurement Matters: Psychometric Analysis of the PATH Youth Dependence Scale	Ryan Black, PhD <i>JUUL Labs Inc.</i>
5:45 p.m.- 6:00 p.m.	Break	
6:00 p.m.- 6:20 p.m.	Establishing traceability of self-reported dependence measurement through the use of crosswalks	Thomas Salzberger, PhD <i>WU Wien</i> Saul Shiffman, PhD <i>Dinvey Associates</i>
6:20 p.m.- 7:00 p.m.	Audience Q&A following panel presentations	



Virtual Event – Ground Rules



Microphones and camera should **remain off** during the whole duration of the symposium for **attendees**



During the presentations, you will have the opportunity to **ask questions** using the **meeting chat**. The moderator will relay the questions during the **Q&A sessions**



A Consortium Approach for Consumer Reported Outcome Measures for Assessing Tobacco and Nicotine-Containing Products

C. Chrea, Coordinator of the CROM Consortium Task Force

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Objective of the Consortium

- To provide guidance on how to **develop, validate, select, access and use 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 facilitate identification and access
- Through a **cooperation platform** involving tobacco industry and the guidance of academia and regulatory agency stakeholders



Consortium Members' Representation

43%

US & Canada

49%

Switzerland, UK,
Germany,
France,
Sweden

8%

Korea, China

Since October 2018
37 members meeting twice a year

13 Manufacturers of Tobacco and Nicotine Products
5 Technology companies
5 consulting agencies and academic researchers



Governance Structure of CROM TF

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

CORESTA
Scientific
Commission



WG01



WG02

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



CORE TEAM

Governance body
made of
representative of
contributing
companies and
WG coordinators



WG04



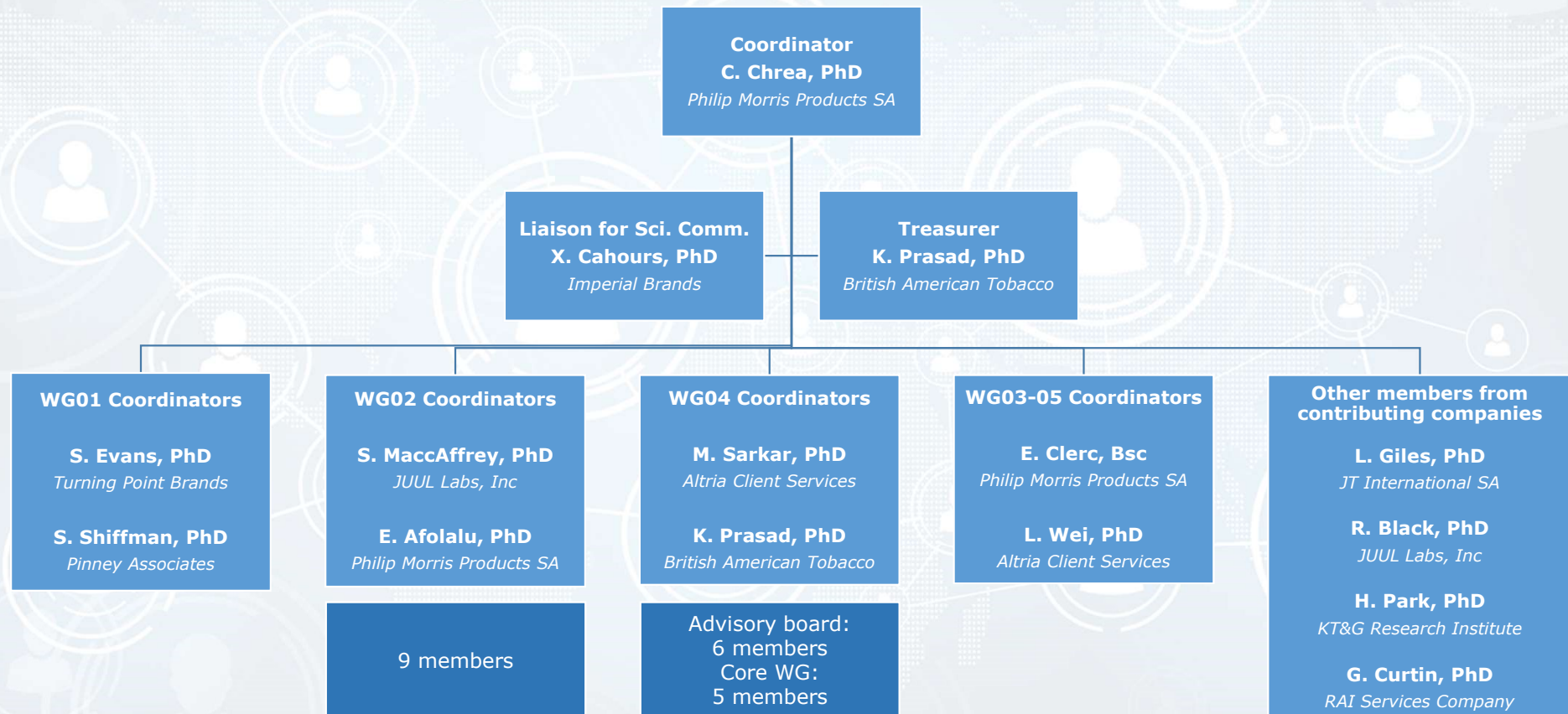
WG03-05

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



Consortium Task Force Core Team





Research Plan 2020-2022

Working groups	2020				2021				2022			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WG01					Identify academic and regulatory experts	Coordinate external inputs Organize symposia for status update		Support Dissemination				
WG02			Preparatory Phase		Phase 1: Development best practices for psychometric CROM using a consensus-based approach				Phase 2: Dissemination			
WG04			Preparatory Phase		Phase 1: Development consensus descriptive CROM Identify gaps & make recommendations			Phase 2: Dissemination				
WG03-05						Phase 1: Select repository platform		Phase 2: Review and select consensus CROM Develop metadata for the repository				



Take Home Message

- CROM might help inform on the **public health impact of novel products** potentially less harmful than cigarettes
- There is currently **no consensus assessment** of the scientific merits of different CROM used in **tobacco regulatory science**
- There is a need for **developing best practices** to ensure that **CROM are valid and reliable**, and used as per the **intended context of use**
- The CORESTA CROM Consortium could serve as a **multi-stakeholder collaborative platform** to enhance the **harmonization of CROM in tobacco regulatory science**

T H A N K Y O U



<https://www.coresta.org/groups/consumer-reported-outcome-measures-consortium>



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