



Consumer Reported Outcome Measures (CROM) Consortium Task Force Annual Report

CORESTA SSPT 2019

07 October 2019 – Hamburg



Definition of consumer-reported outcomes

- ❖ **Data collected by self-report from the subject of research (consumers*), whether it concerns perceived states, reports of behavior, or the combination of both, and understanding of messages.**

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



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)**



Rationale for a CROM Consortium

- ❖ **Recent examples of PMTAs and MRTPAs have shown that regulators require:**
 - **The use of robust, validated self-reported measures, either legacy or new**
 - **Adaptation of measure to fit product (if necessary)**
 - **Data on translations (evidence of cross-cultural equivalence) if data from studies conducted outside the US**



Proposed objective 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**



2017-2019 steps towards a CROM Consortium

Date, place	Actions
2017 - 2018	
October 7, 2017 CORESTA PUB SG Kitzbuehl, Austria	✓ Mapi/ICON representatives invited to present ERIQA* Project and PRO Harmonization meetings which led to the development of the FDA (CDER) PRO Guidance
April 4, 2018 CORESTA PUB SG Geneva, Switzerland	✓ Presentation of a possible approach for a CROM Consortium ✓ Decision to develop a NWIP to create a Task Force with requirement of a dedicated budget to set-up and manage activities within the Consortium
May to Oct 2018	✓ NWIP #190 presented to the CORESTA Scientific Commission on May 30 ✓ Goals of the CROM TF were defined as follows: <ul style="list-style-type: none">▪ Develop CROM approach for Tobacco and Nicotine Products under guidance of industry, academia and regulatory agency stakeholders▪ Adopt validation guidelines for CROM for use in the assessment of products with reduced risk potential▪ Create a repository of existing and new CROM instruments outlining measurement and validation approaches



2017-2019 steps towards a CROM Consortium

Date, place	Actions
2018 - 2019 October 22, 2018 CORESTA CROM TF Kunming, China	<ul style="list-style-type: none">✓ CROM Consortium Introductory meeting to present the objectives, potential structure of the consortium and pragmatic approach to initiate work without fundings✓ Launch of a Working Group 0 (WG0) whose goals were:<ol style="list-style-type: none">1. Clarify the goals of the Consortium, the research questions and the scope of work2. Oversee the development of the CROM Consortium: governance, structure, budget and funding mechanisms, engagement with 3rd parties3. Prepare execution of future phases: working groups (WGs), workplans
WG0 activities From Nov 2018 To Jul 2019	<ul style="list-style-type: none">✓ 7 TCs organized between all members of WG0 to work on goals✓ TC materials and minutes uploaded on CORESTA website



2017-2019 steps towards a CROM Consortium

Date, place	Actions
2018 - 2019 May 25, 2019 CROM TF Montreal, Canada	<ul style="list-style-type: none">✓ Review ongoing activities of WG0 and reach agreement on:<ol style="list-style-type: none">1. Definition of CROM2. Objectives of the consortium3. Structure of the consortium ✓ Agreement on a proposed budget and investment scheme for the consortium industry members
October 06, 2019 CROM TF Hamburg, Germany	<ul style="list-style-type: none">✓ Review ongoing activities of WG0 ✓ Identification of a coordinator (and depute) for each of the 4 working groups of the consortium ✓ Agreement on funding mechanism and need for governance model following discussion with CORESTA secretariat



WGO members in November 2018

Coordinator	CHREA Christelle	Philip Morris International, Switzerland
Rapporteur*	CAHOURS Xavier	Imperial Tobacco, France
Members	BLACK Ryan, McCAFFREY Stacey	Altria Client Services, USA
	PRASAD Krishna	British American Tobacco, UK
	ACQUADRO Catherine	ICON plc, France
	AYALA-FIERRO Felix	ITG Brands, USA
	GILES Lesley	JT International SA, Switzerland
	PARK Chul-Hoon	KT&G Research Institute, South Korea
	SHERWOOD Neil	Neil Sherwood Consulting, Switzerland
	SPIES Erica	Philip Morris Products SA, Switzerland
	SHIFFMAN Saul	Pinney Associates, USA
CURTIN Geoffrey, SMITH Jeffrey	RAI Services Company, USA	

*Rapporteur to CORESTA Scientific Commission



CROM TF core team members

Coordinator	CHREA Christelle	Philip Morris International, Switzerland
Rapporteur	CAHOURS Xavier	Imperial Tobacco, France
Members	BLACK Ryan, McCAFFREY Stacey SAKAR, Mohamadi	Altria Client Services, USA
	PRASAD Krishna	British American Tobacco, UK
	ACQUADRO Catherine	ICON plc, France
	AYALA-FIERRO Felix	Juul, USA
	GILES Lesley	Japan Tobacco International SA, Switzerland
	PARK Chul-Hoon	KT&G Research Institute, South Korea
	SHERWOOD Neil	Neil Sherwood Consulting, Switzerland
	SHIFFMAN Saul	Pinney Associates, USA
	CURTIN Geoffrey, SMITH Jeffrey	RAI Services Company, USA
	EVANS Sarah	Turning Point Brands, USA
	FRIEDRICH Deanna	Cambridge Cognition, USA



Update on CROM TF activities



Where are we on WGO objectives?

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

✓ **Done**

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

✓ **On-going**

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

✓ **Initiated**

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

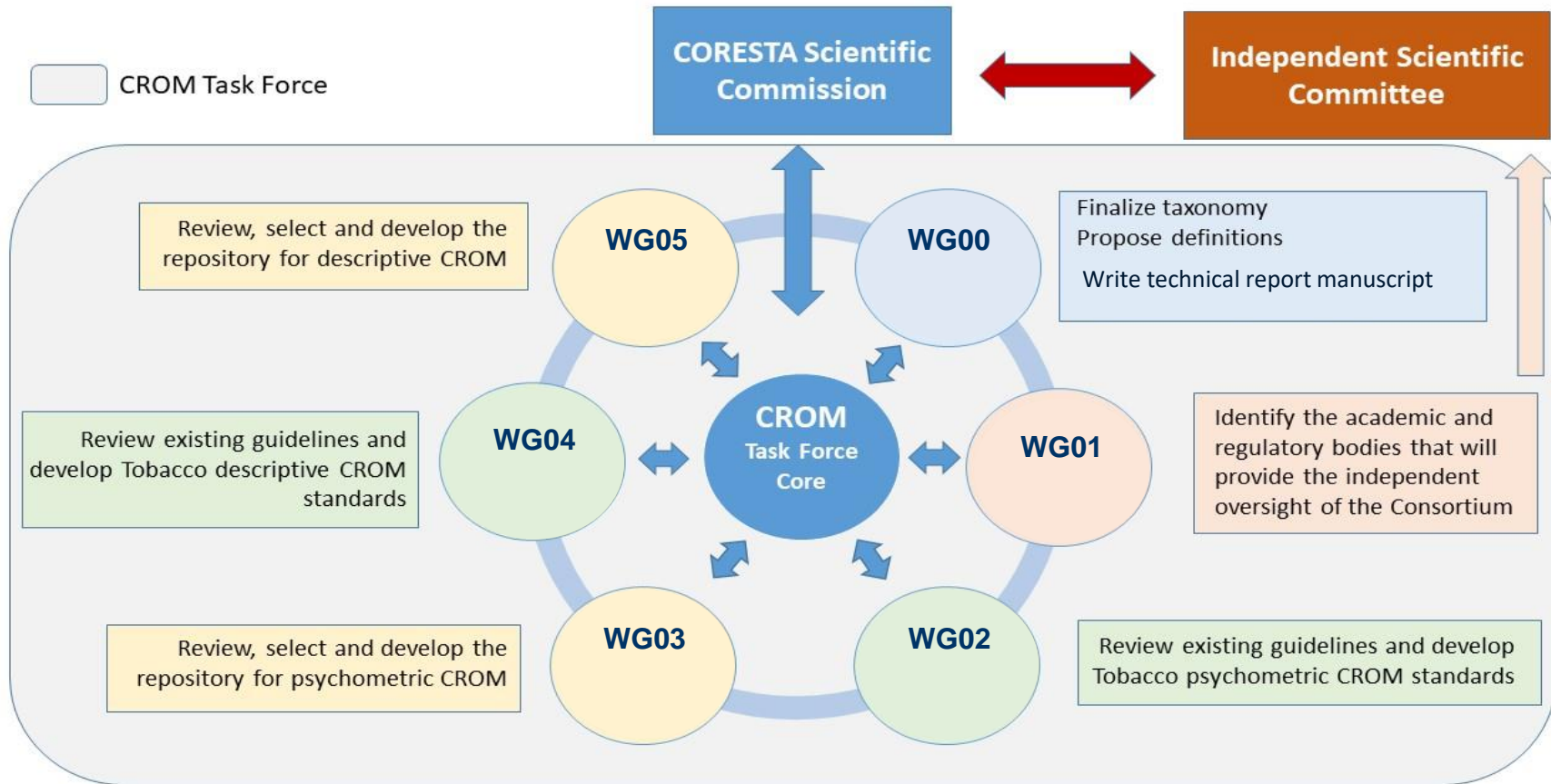
- ❖ **Based on a review of key literature around MRTP, alternative tobacco and nicotine products**
 - **Regulatory guidance**
 - **Public health reports**
 - **MRTPA/PMTA briefing packages**
 - **Review papers**

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

- Development of a potential structure and working plan with several working groups
- Ongoing engagement with CORESTA secretariat to establish consortium governance and funding mechanisms
- Funding approval from 6 tobacco industry (Altria, BAT/RJT, Imperial Tobacco, JTI, KT &G, PMI)



Consortium Structure: Overview



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

➤ During October 6th CROM TF meeting

- CROM consortium structure was refined and agreed upon
- Coordinator for each of the WGs was identified
- Engagement plan was discussed with some immediate actions



Next Steps for the CROM TF

	Who	What	By when
TF core team	Coordinator: C. Chrea	<ul style="list-style-type: none"> • Draft governance model • Establish funding/invoicing processes • Monthly TC with all WG coordinators 	Q1 2020
WG00	Coordinator: C. Acquadro	<ul style="list-style-type: none"> • Finalize taxonomy and review work and write technical report • Submit abstract to ISPOR US • Organize satellite workshop to established conference (e.g., SRNT) 	Q1 2020
WG01	Coordinator: S. Shiffman	<ul style="list-style-type: none"> • Draft NWIP describing objective and engagement plan with external experts 	Dec 2019
WG02-03	Coordinators: S. McCaffrey/C. Chrea	<ul style="list-style-type: none"> • Draft NWIPs including working plan, list of members, milestones and budget 	Dec 2019
WG04-05	Coordinators: M. Sakar/K. Prasad		



Thank You!