

# 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.

<sup>\*</sup>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

<sup>\*</sup>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	<ul> <li>✓ Presentation of a possible approach for a CROM Consortium</li> <li>✓ 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</li> </ul>
May to Oct 2018	<ul> <li>✓ NWIP #190 presented to the CORESTA Scientific Commission on May 30</li> <li>✓ Goals of the CROM TF were defined as follows:         <ul> <li>Develop CROM approach for Tobacco and Nicotine Products under guidance of industry, academia and regulatory agency stakeholders</li> <li>Adopt validation guidelines for CROM for use in the assessment of products with reduced risk potential</li> <li>Create a repository of existing and new CROM instruments outlining measurement and validation approaches</li> </ul> </li> </ul>

Cooperation Centre for Scientific Research Relative to Tobacco



## 2017-2019 steps towards a CROM Consortium

Date, place	Actions						
2018 - 2019							
October 22, 2018 CORESTA CROM TF Kunming, China	✓ CROM Consortium Introductory meeting to present the objectives, potential structure of the consortium and pragmatic approach to initiate work without fundings						
	<ul> <li>✓ Launch of a Working Group 0 (WG0) whose goals were:         <ol> <li>Clarify the goals of the Consortium, the research questions and the scope of work</li> </ol> </li> <li>Oversee the development of the CROM Consortium: governance, structure, budget and funding mechanisms, engagement with 3<sup>rd</sup> parties</li> <li>Prepare execution of future phases: working groups (WGs), workplans</li> </ul>						
WG0 activities From Nov 2018 To Jul 2019	<ul> <li>✓ 7 TCs organized between all members of WG0 to work on goals</li> <li>✓ TC materials and minutes uploaded on CORESTA website</li> </ul>						



## 2017-2019 steps towards a CROM Consortium

Date, place	Actions
2018 - 2019	
May 25, 2019 CROM TF Montreal, Canada	<ul> <li>✓ Review ongoing activities of WG0 and reach agreement on:         <ol> <li>Definition of CROM</li> <li>Objectives of the consortium</li> <li>Structure of the consortium</li> </ol> </li> <li>✓ Agreement on a proposed budget and investment scheme for the consortium industry members</li> </ul>
October 06, 2019 CROM TF Hamburg, Germany	<ul> <li>✓ Review ongoing activities of WG0</li> <li>✓ Identification of a coordinator (and deputee) for each of the 4 working groups of the consortium</li> <li>✓ Agreement on funding mechanism and need for gouvernance model following discussion with CORESTA secretariat</li> </ul>



### **WG0** 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
	<b>CURTIN Geoffrey, SMITH Jeffrey</b>	RAI Services Company, USA

<sup>\*</sup>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
	<b>CURTIN Geoffrey, SMITH Jeffrey</b>	RAI Services Company, USA
	EVANS Sarah	<b>Turning Point Brands, USA</b>
	FRIEDRICH Deanna	Cambridge Cognition, USA



### **Update on CROM TF activities**



### Where are we on WG0 objectives?

- 1. Clarify the goals of the Consortium, the research questions and the scope of work
- 2. Oversee the development of the CROM Consortium: governance, structure, budget and funding mechanisms, engagement with 3<sup>rd</sup> parties
- 3. Prepare execution of future phases: work plans, working groups (WGs)

✓ Done

✓ On-going

✓ Initiated



### **Key Deliverables Task 1**

- 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



### Poster STPOST58

### **Update on Task 1: How?**



### A consortium approach for consumer-reported outcome measures to assess @consortium tobacco- and/or nicotine-containing products

ACQUADRO C.1 on behalf of the CORESTA CROM Task Force: AYALA-FIERRO F.3; BLACK R.3; CAHOURS X.4; CHREA C.5; CURTIN G.5; GILES L.7; MCCAFFREY S.3; PARK C.H.5; PRASAD K.5; SHERWOOD N.12; SHIFFMAN S.11; SMITH J.5; SPIES E.5 1/Magi Research Trust, Lyon, France; 2/TG Brands, Greensboro, NC, USA; 3/Altria Client Services, Richmond VA, USA; 4/Imperial Brands, Paris, France; 9/Philip Morris Products S.A., Neuchâtel, Switzerland; 4/RAI Services Company, Winston-Salem, NC, USA; 7/JT International SA, Geneva, Switzerland: "KT&G Research Institute, Dacison, Republic of Korea: "British American Tobacco, Southampton, U.K.; "Neil Sherwood Consulting, Nyon, Switzerland: "Pinney Associates, Pittsburgh, PA, USA

- · In tobacco research, particularly regulatory research, it is essential to understand people's behaviors, intentions and motivations related to initiation, to continuation or quitting use of tobacco- and/or nicotine-containing products (TNPs), in order to measure the effects of these products (objective and subjective) as well as to comprehend behaviors associated to their use. Consumer-reported outcome measures (CROM) are part of the methods used to assess subjective effects, behaviors and motivations. Such measures have become particularly important with the advent of new TNPs and candidate modified risk tobacco products (cMRTPs). For instance, in its draft quidance on MRTP applications, the U.S. Food and Drug Administration (FDA) requires that applicants investigate the effect the TNPs and related marketing may have on tobacco use behavior among current tobacco users, and on tobacco use initiation among non-users (both never users and former users), as well as the effect of the TNPs' marketing on consumer understanding and perceptions?
- A CROM consortium has been considered within CORESTA to develop a scientific framework based on a shared vision. The goals are:
- ✓ To develop this approach under the guidance of industry, academia and regulatory agency stakeholders:
- To adopt validation guidelines for CROM for use in the assessment of TNPs with reduced risk potential;
- √ To create a repository of existing and new CROM instruments with documented measurement and validation.
- · Our objective is to present the preparatory steps for this proposed consortium:

- · A CROM Task Force (TF) was formed within the CORESTA PUB Sub-Group. To set specific goals, research questions, and scope of work of the future consortium, a qualitative review of key literature around MRTPs was initiated in November 2018. Documents included the U.S. FDA MRTP briefing documents (in the context of applications submitted by Altria Client Services, Philip Morris International, Reynolds American Services Company and Swedish Match), regulatory documents, selected review papers, and public health reports. See detailed list in
- · A data extraction form with definitions for each field was developed in order to ensure harmonized data extraction among the different TF members who reviewed one document each. Data relating to self-report measures were extracted in pre-market and post-market contexts, i.e., concepts to be measured (e.g., risk perceptions. dependence, etc.), populations to be assessed, methods recommended and/or used, psychometric information weight of self-report data in decision-making

ers

Type of document	Title/source						
Briefing documents	February 6, 2015 - FFSAC meeting NRTN4 - MRCC00108 Altha Client Services LLL on helbalf of US Smokeless Tobacco Company	February 6, 2019 - 175AC meeting MRTRs: - MR0000020-22, MR0000024-25, MR000027-29 Swedish Match Borth America (amendment)					
	for Cogenhagen® Snuff Flee Cut	for General Strue Products					
	September 13-14, 2018 - TPSAC meeting	January 24-25, 2018 - TPSAC meeting					
	MRTRic MRC000383 MR0000073  Payr olds American Incorporated Services Company on helpful of R.J.	MRTRA: MR0000059 MR0000061 Philip Morris Products S.A.					
	Reymolds American Incorporated Services Longistry on behalf of R.J. Reymolds Tobacco	Philip Morns Products S.A.					
	for Certie Street	for 1005					
	April \$-10, 2015 – TPSAC meesing						
	MRTPAs MRC000020 MR0000029 Secondals Match North America						
	for General Shus Products						
Regulatory	U.S. Department of Switch and Human Services, FDA, CTP Cuidements Industry, Premarket Tabasco Fronts of Applications for Evacuation Nicoline						
documents	Delivery Systems - Draft Guidance, May 2016. https://www.fda.gov/media/97602/cown.cod						
	U.S. Department of Health and Human Services, FDA, CTP, Guidance for Industry, Guidance for Industry, Modified Risk Tobacco Product Application						
	- Dor't Guider ov. March 2012. https://www.fds.gro/media/83303/download						
	U.S. Department of Health and Human Services, FCA, CTP, Guidance for Industry, Applications for Fremanies Review of New Tobacco Products						
	Graft guidance, September 2011. https://www.bla.gov/media/R1821/dovarboad						
	U.S. Department of Health and Human Services, HDA, CDLR, Guidance for Industry Label Comprehension Studies for Biorgrescription Drug Products.						
	August 2010. https://www.tca.gov/media/75628/download						
	DIRECTIVE 2014/43/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the approximation of the laws, regulations and ac winistrative						
	provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive						
	2001/97/EC, Official Journal of the European Union 25.4.2314. https://ec.europe.eu/health/sites/health/files/tobects/docs/dir. 201448. en.pd						
Review papers	Berman ML et al. Consortium on Methods Evaluating Tabacco: Research Tools to Inform US Tood and Drug Administration Regulation of Sirus.						
	NicatineTeb Res. 2018;20(11):1292-1300.						
	O'Connor Rt. Postmarketing surveillance for "modified-fisk" tobaccoproducts. Nicotine Tob Res., 2012;54(1):25-42.						
Regorts	Institute of Medicine, 2012. Scientiffic Standards for Studies on Modified Risk Tobasco Products. The National Academies Press: Washington DC,						
	USA: https://www.nep.adu/catalog/13284						
	CTP. Jobacco Regulatory Science Research Frogram at J.DA's Center for Jobacco Products: Summary and Highlights J.DACA, ELAKS 2020-2027, June						

Abbreviations: CDER: Center for Drug Evaluation and Research; CTP: Center for Tobacco Products; TP SAC: Tobacco Products Scientific Advisory Committee

2018, https://www.tdc.gov/media/114538/download

Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) - Hamburg Meeting

The analysis of the qualitative review led to three main outcomes: 1) the development of a consensus definition of consumer-reported outcomes (CRO); 2) a categorization scheme for the concepts of interest identified to assess TNPs; and 3) the development of a common taxonomy and definitions to qualify them.

### The CROM TF adopted the following definition: Consumer-reported outcomes are data collected by self-report from the subject of research, whether it concerns perceived states, reports of behavior, or the combination of both, and understanding of messages.

A consensus favonomy and related categorization (see Table 2) were developed Basically, concepts were distributed within eight categories, i.e., Product Perceptions Behavioral Intentions, Responses to Product: Consumer Comprehension: Health Literacy, Believability, Product Use Behavior, and Impact on Health and Functioning.

The development of definitions for each category and concept is currently on-going. Of note, the list of concepts is not exhaustive of all concepts measured in tobacco

### research, only those found in the documents reviewed are listed. How is risk perception measured?

To illustrate the heterogeneity identified across documents for the same concept, we present in Table 3 how risk perceptions for health in general and for specific diseases have been assessed in four distinct MRTPAs, in comparison to recommendations made by the U.S. FDA and the Institute of Medicine (IOM) on this specific type of

### Table 2. Consensual taxonomy for CRO concepts used in TNP evaluation

ategory	Subcategory	Concepts	Camel Snus
roduct Perceptions	Risk Perceptions	Risk Perceptions - Health (own personal risk); Risk	
		Perceptions – Diseases (own personal risk); Risk	
		Perceptions - Health (general risk); Risk Perceptions	
		- Diseases (general risk); Risk Perceptions -	
		Addiction (own personal risk); Hisk Perceptions -	
		Addiction (general risk); Risk Perceptions - Harm to	MRTPA
		Others (risk linked to personal behavior); Risk	Authorization
		Perceptions - Harm to Others (risk linked to others'	Altria -
		behavior]	Cogenhages
	Ease of use	Ease of use	Snuff
	Product appeal	Freduct appeal	
	Outcome expectancies	Expectations of quitting: Positive reinforcement -	
		Sensory satisfaction, Negative reinforcement -	
		Negative affect reduction: Appetite/Weight control:	
		Negative consequences	
			MRTPA
ehavioral Intentions		tikelihaad ta try; tikelihaad to use; tikelihaad to	original
		dual use; Likelihood to poly-use; Likelihood to	Swedish
		Initiate; Ekelihood to quit; Ekelihood to switch	Moteh - Sau
		Furchase Intent	annin's barn
esponses to Product	United to the use of the product	Dependence, Uking/Satisfaction, Taste/Sensory	
		offects; Reinforcing Effects	MRTPA
	Linked to the absence of the	Craving; Withdrawal symptoms	submission
	product		amendment
onsumer		Comprehension of messages	Swadlah
omprehension			Match - Snu
ealth Literacy		Health literacy	
ellevability		Believability of messages	
roduct Use Behavior		Cessation; Initiation; Product use pattern; Use not as	
		intended, like as intended, Telacoro use status;	Above
		Furchase experience; Purchase behavior	Sube
npact on Health and	Health-related Quality of Life	Health-related quality of life	
unctioning	Physical Functioning	Activities of daily living. Physical activities	Rela
	Mental Health	Anxiety: Depression; Irritability; Anhedonia; Mood	prodi

### Attention Decision-marine Memory draith Status Honita status/braith: Montal bookh status: Paysica health status Retigue; Pain; Sleep disorders

### Reference 1 U.S. Department of Health and Human Services, FDA, CTF, Guidance for Industry, Guidance for Industry, Medition Ref. Tabarce ProductApplications — Draft Californe, March 2012, https://www.fda.gov/mediar633900down.oad

ocial Functioning

### Table 3. Assessment of risk perception (health in general and specific diseases)

Specific Own Rink in Relative Absolute One-single Multi- None Example

Measures recommended or used

Types of risks

	general		risk				measure	and
FDA Guidance - PMTA	*			4	4	Y		4
FDA Guidance - MRTPA	¥ .			*	1			✓
IOM Report 2012	¥	V	¥	*	*			655 655 Ihr run
MRTPA submission: PMI -IQOS	*	~	~		4	¥	Parceived Health Flist collambed scale of the ADOUT Parceived Flisk	
MRTPA submission: RJRT - Camel Snus	¥	1		~	4	¥	One single from for bach product / disease contribution	
	*	~				~	ALCS's Specific (Absolute) Risk Scales	
MRTPA submission: Altria - Copenhagen Snuff	4			1	*		ALCS's (indirect) Reable Flink Strakes	
	¥			¥		V	Adapted from CIIC NATS, 2013- 2014)	
MRTPA original submission:	¥	V	¥			¥	Achoc Item	
Swedish Motch - Snus	~		~		~		Achoc Item	
MRTPA submission- amendment:	1	~		1		~	Adapted from the item used in the NOI HINTS	
Swadish Match - Saus	¥	*		×	V		Acapted from the stom used in the NOI HINTS	

### New NCI HINTS: National Cancer Institute (NCI) Health Information National Transa Survey

lative is defined as relative to risk perceptions associated with using other tobacco ducts, nicotine replacement therapy, quitting, and never using tobacco products.

- . The key outcomes presented here form the foundations of the CROM consortium . This work should facilitate a dialogue to develop common terminology, standards, and
- best practices for CROM in the tobacco space and emphasizes the need for more discussion between industry academia, and regulatory body stakeholders.

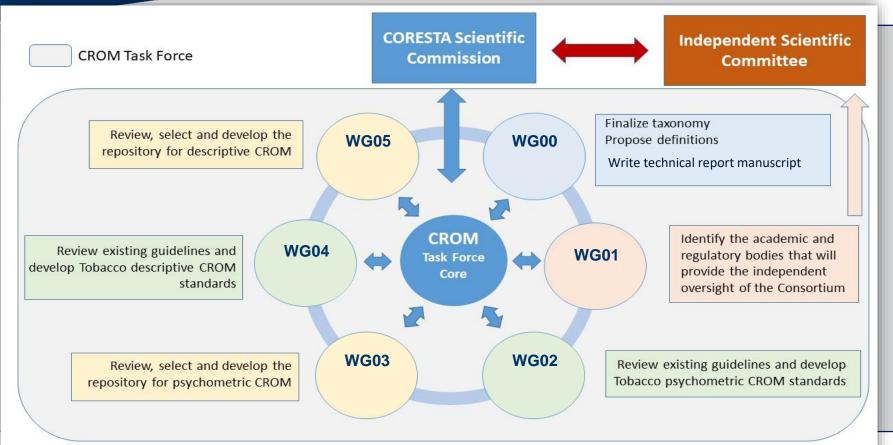


### **Key Achievements Task 2**

- 2. Oversee the development of the CROM Consortium: governance, structure, budget and funding mechanisms, engagement with 3<sup>rd</sup> 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**





### **Key Achievements Task 3**

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><li>Draft gourvenance model</li><li>Establish funding/invoicing processes</li><li>Monthly TC with all WG coordinators</li></ul>	Q1 2020
WG00	Coordinator: C. Acquadro	<ul> <li>Finalize taxonomy and review work and write technical report</li> <li>Submit abstract to ISPOR US</li> <li>Organize satellite workshop to established conference (e.g., SRNT)</li> </ul>	Q1 2020
WG01	Coordinator: S. Shiffman	<ul> <li>Draft NWIP describing objective and engagement plan with external experts</li> </ul>	Dec 2019
WG02-03	Coordinators: S. McCaffrey/C. Chrea	<ul> <li>Draft NWIPs including working plan, list of members, milestones and budget</li> </ul>	Dec 2019

Coordinators: M. Sakar/K. Prasad

WG04-05



### **Thank You!**