



CROM* Task Force 2022 Annual Report

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

CORESTA SSPT 2023 Conference

Cancun, Mexico

October 11, 2023

** Consumer Reported Outcome Measures*

- **To provide guidance on how to develop, validate, identify, access and use CROM to evaluate tobacco and nicotine-containing products for pre-market and post-market purposes:**
 - **By reviewing existing standards on the development and validation of CROM and by reviewing information on CROM;**
 - **By providing recommendations on the development and validation of CROM;**
 - **By creating a knowledge repository to store CROM and facilitate identification and access of the most appropriate CROM in a specific context of use;**
 - **Through a cooperation platform involving tobacco industry and the guidance of academia and regulatory agency stakeholders.**

Governance & Structure of CROM TF

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



Develop and publish best practices and guidelines for Psychometric CROM



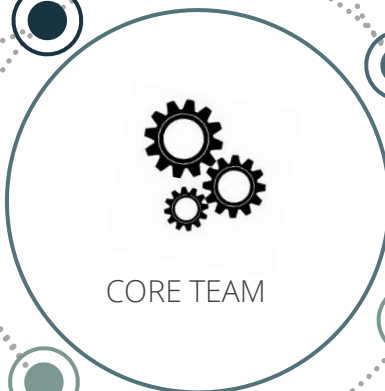
CORESTA
Scientific
Commission



Develop and publish best practices and guidelines for Descriptive CROM



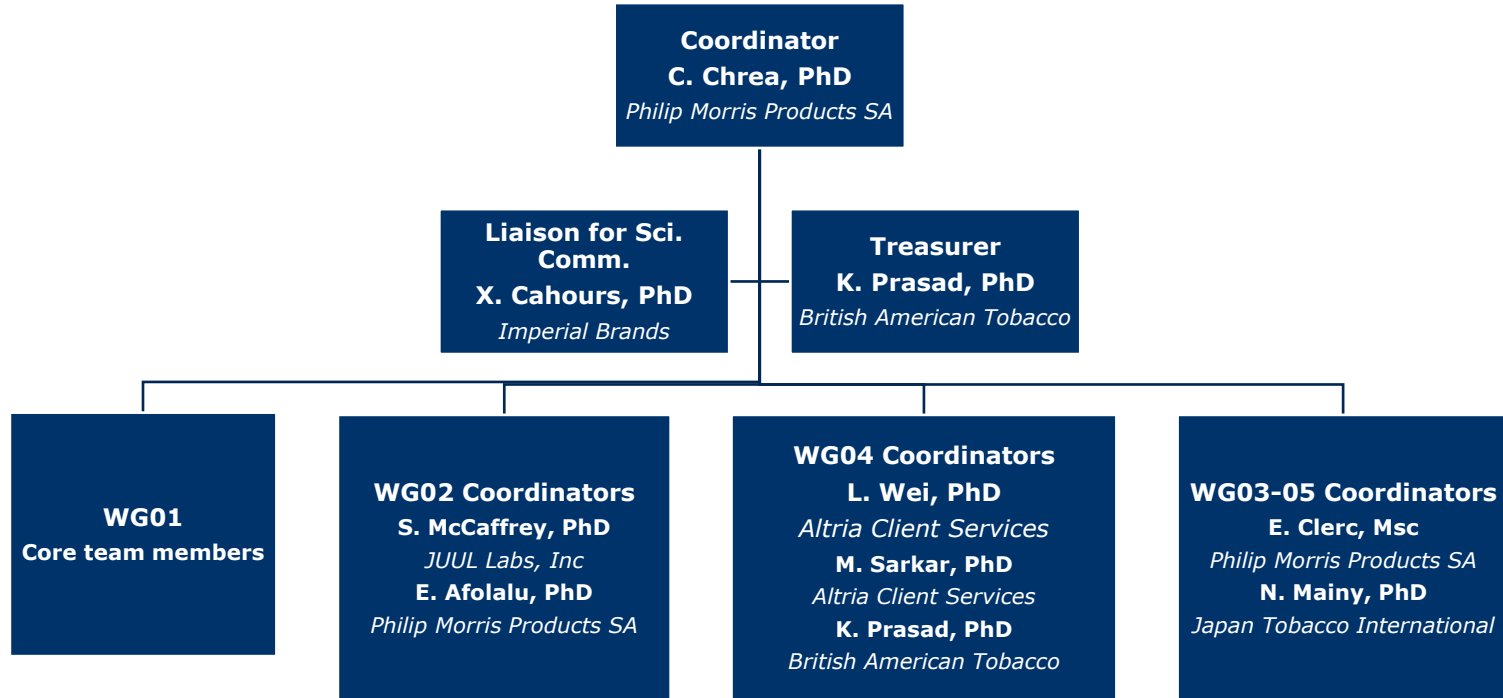
Develop knowledge repository
Facilitate identification and access of the most appropriate CROM in a specific context of use



Governance body made of representatives of contributing companies and WG coordinators



CROM TF Core Team





Outline: 2023 Activities

1. **WG01- Engagement activities (NWIP developed per activity)**
2. **WG02 - CROM-269-NWIP: guidelines for psychometric CROM**
3. **WG04 - CROM-274-NWIP: guidelines for descriptive CROM**
4. **WG03-05 - Development of a CROM repository (NWIP to be submitted by EOY)**



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**
- **Key achievements in 2023**
 - Annual virtual CROM Symposium (February)
 - CROM Symposium as part of CORESTA SSPT2023 Conference (October)
- **Next Steps**
 - Dissemination plan for the WG02 and WG04 best practices and guidelines
 - Organization of annual CROM Symposium 2024 and more...



WG01: External engagement activities

• Virtual CROM Symposium 2023 on Abuse liability February 13, 2023

- 226 registrations (45 nonmembers)
- Article on the CORESTA Newsletter Issue 65



CROM SYMPOSIUM 2023 | February 13, 2023 | Online Event



Dr Lynn Hull
CTP US FDA



Dr Megan Schroeder
CTP US FDA



Dr Andrea Vansickel
Altria Client Services



Dr Sarah Baxter-Wright
RAI Services



Dr Dai Yuki
Japan Tobacco Inc.



Dr Ryan Lanier
Pinney Associates



Dr Rob O'Brien
Supra Research



Dr Martha Bajec
HCD Research

AGENDA

4:00 p.m. - 4:05 p.m.	Introduction to the Symposium	Christelle Chrea, PhD CROM Consortium Coordinator
Part I: Abuse Liability Assessment of New Tobacco Products		
4:05 p.m. - 4:35 p.m.	Tobacco Product Abuse Liability	Lynn Hull, PhD Megan Schroeder, PhD Office of Science, CTP US FDA
4:35 p.m. - 5:05 p.m.	Challenges and Considerations Related to Human Abuse Liability Testing for Tobacco Products: Opportunities to Establish Tobacco-Specific Methods, Measures, and Evaluation Criteria	Andrea Vansickel, PhD Altria Client Services LLC Sarah Baxter-Wright, PhD RAI Services Company
5:05 p.m. - 5:25 p.m.	Assessment of the Exposure to Selected Smoke Constituents in Adult Smokers Using In-market Heated Tobacco Products: A Randomized, Controlled Study	Dai Yuki, PhD Japan Tobacco Inc.
5:25 p.m. - 5:35 p.m.	Break	
Part II: Abuse Liability Assessment of Other Substances		
5:35 p.m. - 5:55 p.m.	Abuse Liability Assessment of CNS-active Drugs in Development: History and Overview	Ryan Lanier, PhD Pinney Associates
5:55 p.m. - 6:15 p.m.	The Development of Testing-Based Approaches to Screen for Hazardous Ingredients and Formulations Used in Heated Inhalation Devices with Particular Emphasis on Cannabis Products	Rob O'Brien, PhD Supra Research and Development
6:15 p.m. - 6:30 p.m.	Building a Consumer Technical Model for Cannabis Products – Insights & Considerations	Martha Bajec, PhD HCD Research
Q&A and Panel Discussion		
6:30 p.m. - 7:00 p.m.	All presenters Chaired by Lesley Giles, PhD, JT International, and moderated by Nicholas Goldenson, PhD, JUUL Labs	



WG01: External engagement activities

• CROM Symposium on October 11, 2023 - CORESTA SSPT2023 Conference

- Organized by WG02
- Article on the CORESTA Newsletter Issue 66

CROM SYMPOSIUM			
Science Starts with Measurement: Essential Measurement Science for Self-Report in Tobacco and Nicotine Product Research			
<i>(please see page 145 for full programme and abstracts)</i>			
Starting at 8:50			Yucatán Room
No.	Time	Titles	Lead, Affiliation
CROM 01	20 min.	Overview of the psychometric CROM guidelines	Stacey McCAFFREY <i>Juul Labs, Inc.</i>
CROM 02	20 min.	Overview of psychometrics: the science of measurement	Stacey McCAFFREY <i>Juul Labs, Inc.</i>
BREAK – 5 minutes			
CROM Guest	20 min.	Risk perceptions in tobacco regulatory science	Alexander PERSOSKIE <i>FDA Center for Tobacco Products</i>
CROM 03	20 min.	Evaluating the psychometric properties of a CROM for use with a different product for which it was developed: the modified e-cigarette evaluation questionnaire (MCEQ) as a case study	Meghan MOREAN <i>Yale School of Medicine</i>
CROM 04	20 min.	Further validation of the ABOUT-Dependence measure: Extending assessment of perceived dependence on tobacco and nicotine products to users of a heated tobacco product (IQOS)	Esther AFOLALU <i>Philip Morris International</i>
CROM 05	20 min.	An illustration that one size may not fit all: assessing invariance of the WISDM scale in PATH across youth and young adult cohorts	Ryan BLACK <i>Juul Labs, Inc.</i>
CROM 06	20 min.	Can individuals with limited health numeracy use quantitative scales to make ratings of risk perceptions?	Saul SHIFFMAN <i>Pinney Associates</i>
BREAK – 10 minutes			
	20 min.	Discussion and Q&A	Mohamadi SARKAR <i>Altria Client Services</i> All speakers



WG02: Guidelines for Psychometric CROM

- **Develop CROM best practices with respect to Psychometric CROM for TNP research**
- **Coordinators: McCaffrey, Stacey (JUUL)/Afolalu, Esther (PMP)**
- **Members:**
 - *Black, Ryan (JUUL)*
 - *Chrea, Christelle (PMP)*
 - *Clark, Jeff (Liggett)*
 - *Curtin, Geoffrey (RJRT)**
 - *Giles, Lesley (JTI)*
 - *Kim, Mimi (RJRT)**
 - *Nishihara, Daisuke (JTI)*
 - *Prasad, Krishna (BAT)*
 - *Sarkar, Mohamadi (Altria)*
 - *Shetty, Mandara (BAT)*
- **SMEs:**
 - *Salzberger, Thomas (University of Vienna)*
 - *Shiffman, Saul (Pinney Associates)*
 - *Sulsky, Sandra (Ramboll US Consulting)*

* During their time as employee of RJRT



WG02: Guidelines for Psychometric CROM

- **Key achievements 2023**

- Finished the draft Psychometric CROM guidelines, submitted to CORESTA Scientific Commission (SC) and authors' companies for review August 2023

- **Next steps**

- Publish the guidelines on the CORESTA CROM website
- Publish the guidelines in a peer-review journal



WG04: Guidelines for Descriptive CROM

- Review existing guidelines/definitions regarding descriptive CROMs and develop best practices
- Coordinators: Lai Wei (Altria)/M. Sarkar (Altria)/K. Prasad (BAT)
- Core working group:
 - *Emilie Clerc (PMP)*
 - *Mandara Shetty (BAT)*
 - *Nicholas Goldenson (JUUL)*
 - *Mimi M Kim (RJRT)**
- Advisory board
 - *Pierpaolo Magnani (PMP)*
 - *Esther Afolalu (PMP)*
 - *Xavier Cahours (ImpTob)*
 - *Lesley Giles (JTI)*
 - *Ryan Black (JUUL)*
 - *Stacey McCaffrey (JUUL)*
- SMEs:
 - *Saul Shiffman (Pinney Associates)*
 - *Sandra Sulsky (Ramboll US Consulting)*

* During her time as employee of RJRT



WG04: Guidelines for Descriptive CROM

- **Key achievements 2023**

- Finalized draft guidelines
- Reviewed by over 10 SMEs with various background from different manufacturer companies
- Sent to CORESTA SC and author's company's review boards for review (Altria, BAT, PMP, and JUUL) (Aug 2023)

- **Next steps**

- Support the development of CROM repository
- Publish the guidelines on CORESTA CROM website
- Publish the guidelines in a peer-review journal



WG03-05: CROM Repository

- **Objective:** Create a knowledge repository for descriptive and psychometric CROMs and facilitate identification and access to the most appropriate CROM in a specific context of use.
- **Coordinators:** Emilie Clerc (PMP SA)
- **Core working group:**
 - *Nelly Mainy (JTI)*
 - *Krishna Prasad (BAT)*
 - *Lai Wei (Altria)*
 - *Emily Kim (KT&G)*
- **Advisory board and SMEs**
 - *Esther Afolalu (PMP)*
 - *Stacey McCaffrey (JUUL)*
 - *Christelle Chrea (PMP)*
 - *Karine Renard (JTI)*
 - *Laura Lines (BAT)*

Phase 0

- Review and select the appropriate platform for the repository for psychometric and descriptive CROMs

Phase 1

- Review and identify psychometric and descriptive CROMs, select the ones that meet CROM guidelines, populate the repository

Phase 2

- Disseminate to the scientific community, including the new repository structure, access information, and user guide to support CROM selection



WG03-05: CROM Repository

- **Key achievements 2023**
 - Definition of repository specifications
 - RFP to IQVIA, Transperfect, and Mapi Research Trust
 - Suppliers comparison and multidimension scoring matrix
 - Exploration of alternative solutions for repository (e.g., catalogue)
- **Next steps**
 - Supplier selection and contracting
 - Identification and selection of CROMs
 - Populate the repository



Impact of the CROM TF in the last 3 years

- **As part of its mission, the CROM TF has worked heartfully**
 - to be a recognized scientific authority on CROM science methodologies and to promote the communication between CROM researchers within industry, academia, and regulatory bodies to improve methodologies and quality of CROM-related research
- **Beside the development of the CROM guidelines and the repository**
 - Organization of 4 symposiums and 2 workshops with speakers from different industries, academia and regulatory bodies
 - 3 oral presentations at major Tobacco conferences
 - 3 poster presentations at PRO and Tobacco conferences



**A big thank you to
the CROM TF members
for the tremendous work and dedication**

**Thank you all
for your attention today!**