



Consumer-Reported Outcome Measure (CROM) Best Practices and Guidelines with Respect to Descriptive CROM for Research on Tobacco and Nicotine-Containing Products

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Governance Structure of CROM Task Force

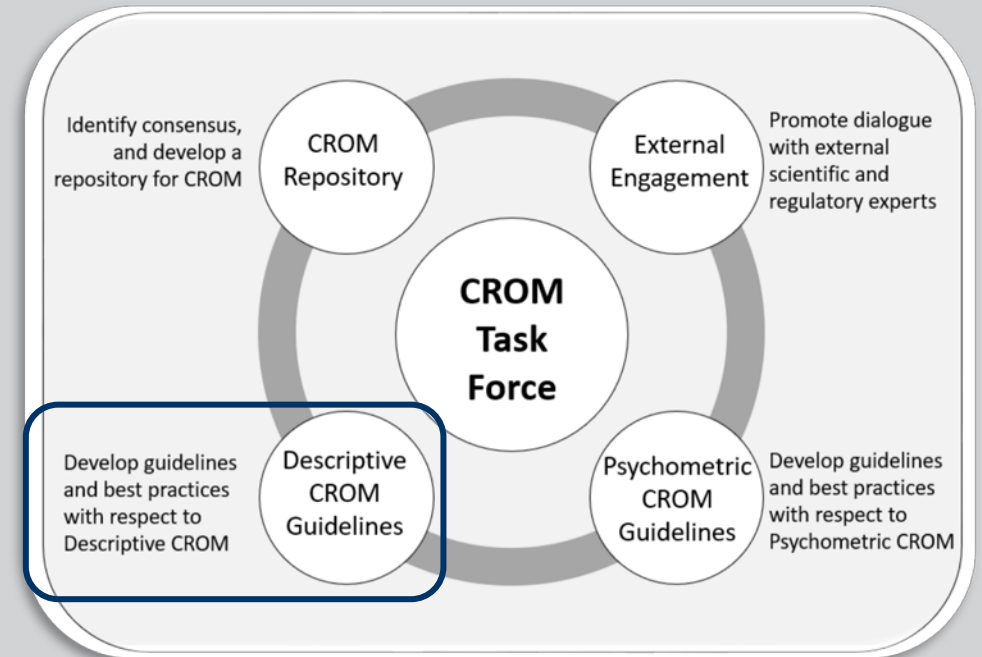
❖ The Need for CROM Best Practices and Guidelines in Tobacco Research

- Consumer-Reported Outcome Measures are critical components in tobacco research and regulatory decision-making process. The proposed best practices and guidelines will help achieve harmonization in the development and use of CROM across various tobacco researchers in academia and the tobacco industry.

❖ CROM Task Force

In November 2018, CORESTA formed the CROM Consortium Task Force (TF).

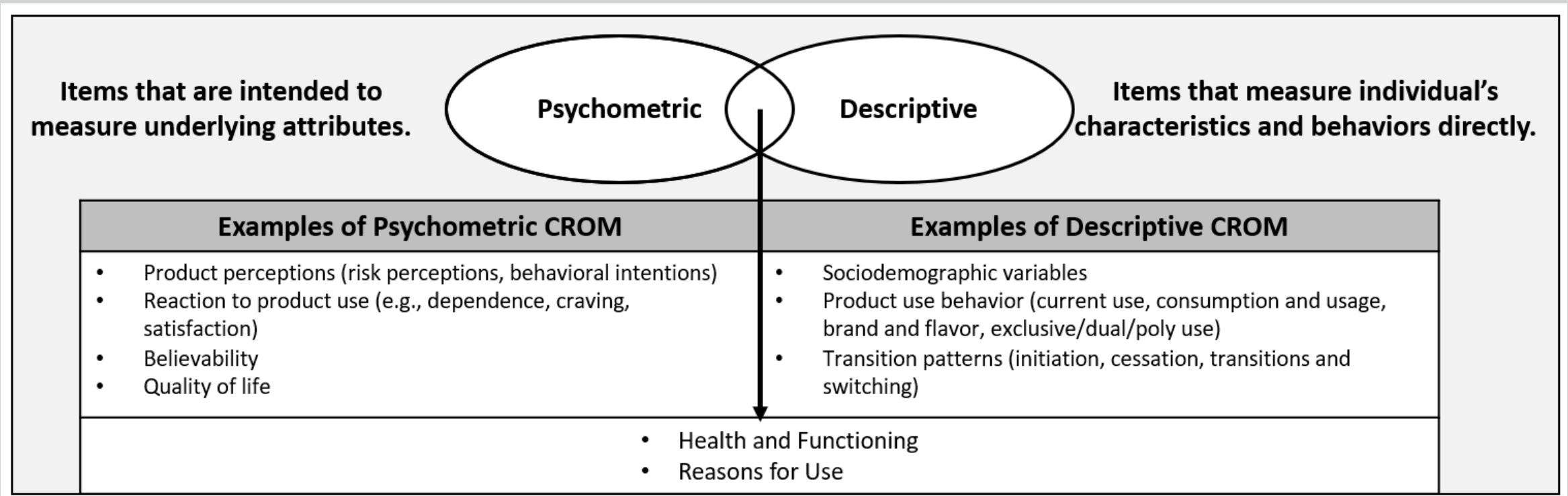
- **Primary Objective:** To provide guidance on the development, modification, and application of CROM, and facilitate identification and access to recommended CROM.
- **Contributing Companies:** Altria, PMI, BAT, RAIS, Imperial Brands and Juul Labs.





Descriptive CROM Definition

Descriptive CROM Definition: A self-reported survey outcome measure that is designed to directly measure individual characteristics and behaviors.





Descriptive CROM Guideline Development & Review Process

Development of Draft Guidelines on Descriptive CROM

Scientific Review and Dissemination

Review of Surveys

- Fifteen surveys
- 2 International
- 8 European
- 4 US
- 1 Japanese

Foundational Definitions

- Tobacco Product Classification
- Tobacco Product Use State

**Presented at
TSRC 2021**

Draft Guidelines

- Descriptive CROM recommendations based on existing survey items
- Development, modification and adaptation
- Survey design and development
- Data analysis and reporting

**Advisory
Board
Review**

**SME
Review**

Publish

Review and Revisions

**Current
Progress**

Dissemination: Poster/Oral Presentations, and Manuscript



Descriptive CROM Draft Guidelines Content Outline

❖ CROM Best Practices and Guidelines with Respect to Descriptive CROM Content Outline

Chapters

1. Proposed Best Practices and Guidelines for Descriptive CROM

2. Methodology

3. Foundational Definitions

4. Recommendations based on Existing Descriptive CROM

5. Development, Modification, and Adaptation of Descriptive CROM

6. Survey Design and Development

7. Data Analysis and Reporting



Chapter 4. Recommendations based on Existing Descriptive CROM

❖ Recommendations are provided for the following domains

➤ Population-Level Domain

- Demographics and Socioeconomic Status
- Tobacco Product Use Rate or Prevalence

➤ Product Category Level Domain

- Consumption
- Brand Usage
- Flavor Usage
- Initiation, Cessation, and Relapse

➤ Poly-/Cross-Category Level Domain

- Dual/Poly Usage
- Switching and Transitions

➤ Descriptive CROM Domains that overlap with Psychometric CROM

- Health and Health-Related Quality of Life
- Reasons for Tobacco Product Use



Chapter 4. Recommendations based on Existing Descriptive CROM

❖ Product Category Level Domain Example: Product Consumption

- Commonly used survey measures: number of days used in the past 30 days, and units used per day on days used
- Unit would differ per product category and may also be different for subcategories. The selection of measurement unit may depend on study objectives.

Combustible Cigarette

Number of cigarettes smoked per day

Note:

- 1) Should consider adding an upper limit for response options for a range of units (e.g., 100 cigarettes for cigarette per day)
- 2) May be helpful to remind the respondent that there are 20 cigarettes in one pack because sometimes smokers think of their cigarette consumption in packs.

Electronic Nicotine Delivery System (ENDS)

For Overall ENDS Category:

- times (or use occasions) per day and puffs per occasion*

For ENDS subcategories:

- number of disposable ENDS products used
- number of replaceable prefilled cartridges
- frequency of filling the ENDS product with e-liquid and number of milliliters of e-liquid the device holds

*Suggested by Liu et al. (2021). However, number of puffs per use occasion may be underestimated due to recall bias. It may indicate relative heaviness of use across individuals, but may not be a reliable measure to quantify the amount of nicotine taken over the course of several days. (Addicott et al., 2022)

1. Liu, Sherry T., et al. "Qualitative insights on how adult e-cigarette users describe quantity of e-cigarettes used—PATH Study 2018." Preventive Medicine Reports 23 (2021): 101421.

2. Addicott, Merideth, et al. "Biochemical validation of self-reported electronic nicotine delivery system and tobacco heaviness of use" The 2022 Annual College on Problems of Drug Dependence (CPDD) Scientific Meeting.



Chapter 5. Development, Modification, and Adaptation of Descriptive CROM

- ❖ **CROM modification and adaptation should be considered before developing a new CROM**

- ❖ **Modification and Adaptation**

- Types of modification (changes to content, applying to a new population, administration, etc.)
- Extent of modification (minor, moderate, substantial)
- Additional qualitative and quantitative evidence would be needed to support the modification

- ❖ **Development and Validation**

- Conceptual model development
- Item generation
- Cognitive testing
- Quantitative methods to evaluate CROMs

- ❖ **Measurement Equivalence**

- Multinational, Multiregional, and Multicultural Contexts (3MC) research to compare data and outcomes among the countries, “cultures”, and/or regions assessed.
- Challenges in the development of survey content: achieve measurement equivalence and minimize comparability errors
- Challenges in conducting the survey: achieve linguistic equivalence through linguistic validation process or the TRAPD (Translation, Review, Adjudication, Pretesting, and Documentation) method



Chapters 6 & 7. Survey Design and Data Analysis

❖ Chapter 6. Survey Design and Development

- Sampling Strategies and Recruitment
- Modes of Data Collection
- Principles of Questionnaire Design
- Survey Pre-Testing
- Post-Survey Processing

❖ Chapter 7. Data Analysis and Reporting

- Survey Weights
- Statistical Methods
- Missing Data
- Additional Considerations (e.g., reporting data with small numbers, subpopulation analysis)



Timelines for Review and Dissemination

❖ Next Steps

- Descriptive CROM Draft Guidelines under revisions with SME review (Q4 2022)
- Descriptive CROM Draft Guidelines to be made publicly available to gather more feedback (Q1 2023)
- Prepare Descriptive CROM Guidelines and manuscript for publication (Q1-Q2 2023)

❖ Dissemination

- Wei, L.; Clerc, E.; Shetty, M.; Chrea, C.; Prasad, K.; Sarkar, M., "Development of Recommendations of Descriptive Consumer-Reported Outcome Measures (Descriptive CROM) and Related Definitions in Tobacco and Nicotine Research", 74th Tobacco Science Research Conference (TSRC), August 2021.
- Wei, L.; Clerc, E.; Shetty, M.; Chrea, C.; Prasad, K.; Sarkar, M., "Recommendation of Descriptive Consumer-Reported Outcome Measures (Descriptive CROM) and Definitions in Tobacco and Nicotine Research: A Consensus Approach", CORESTA Smoke Science and Product Technology (SSPT2021) Virtual Conference, Oct 2021.



Acknowledgements and Contact Information

❖ Acknowledgements

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➤ Advisory Board Members

Pierpaolo Magnani, Esther Afolalu, Xavier Cahours, Lesley Giles, Ryan Black, Stacey McCaffrey

➤ CORESTA CROM Task Force and other CORESTA Sub-Groups and our SME Reviewers

❖ Interested in Joining the CROM Task-Force?

- Contact Christelle Chrea (Christelle.Chrea@pmi.com) if you would like to join the CROM Task Force to support other working groups to facilitate identification and access to recommended CROM.

UPCOMING Workshop: CROM Virtual Workshop on Risk Perception

September 29, 2022

Visit Site Below for Event Registration

<https://www.coresta.org>