



Recommendation of Descriptive Consumer-Reported Outcome Measures (Descriptive-CROM) and Definitions in Tobacco and Nicotine Research: A Consensus Approach

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Background

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

- Consumer-Reported Outcome Measures (CROM) are critical components in tobacco research. Alignment in the development and use of CROM is needed for pre-market and post-market evaluations.
- In 2020, the United States Food & Drug Administration (FDA) published draft guidance on tobacco product perception and intention studies (“Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies” [FDA TPPIS draft guidance]), which is an important first step toward building the foundation for standards of measurements across the tobacco industry.
- While the FDA TPPIS draft guidance provides general recommendations pertaining to the development, adaptation, and use of Psychometric-CROM (e.g., perceptions/intentions), Descriptive-CROM (e.g., consumption/usage) is another essential component to describe tobacco product users and their product use behaviors in tobacco research.
- With novel tobacco products being introduced into the market, foundational definitions (i.e., tobacco product classifications and use states) are need to be established for new tobacco product categories.



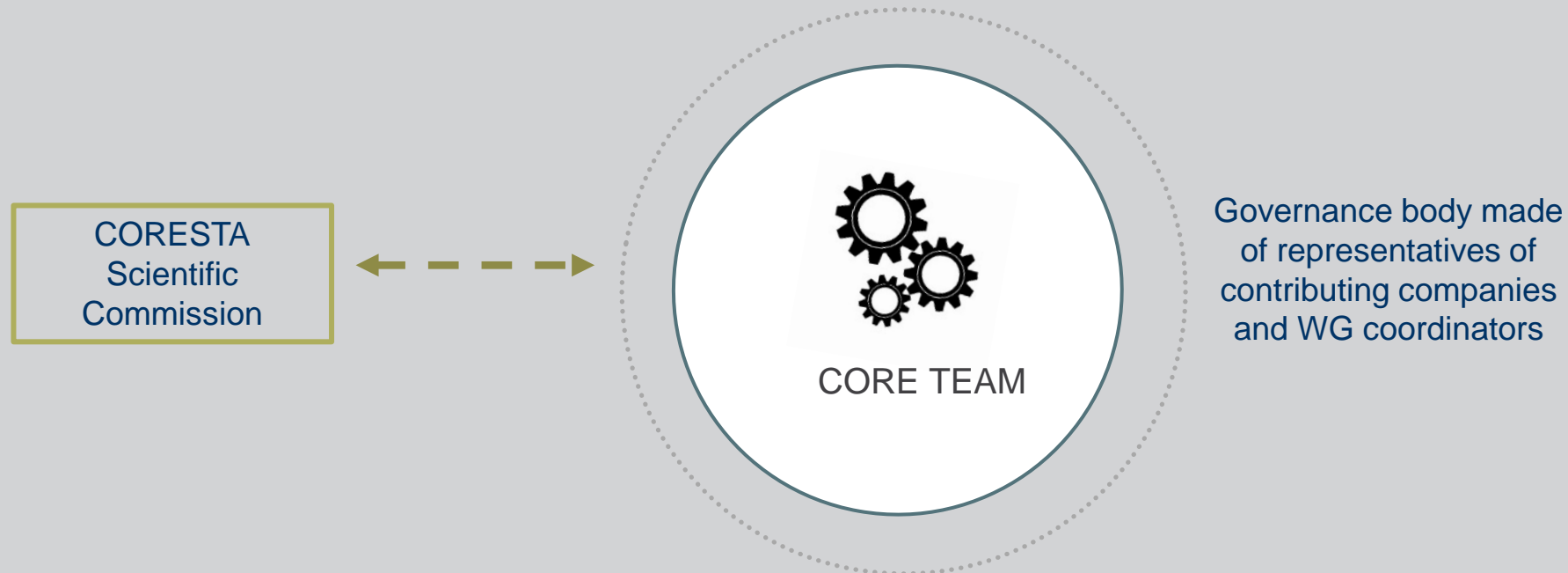


Governance Structure of CROM Task Force

❖ 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.
- Five working groups (WG) were established to achieve the primary objective.





Governance Structure of CROM Task Force

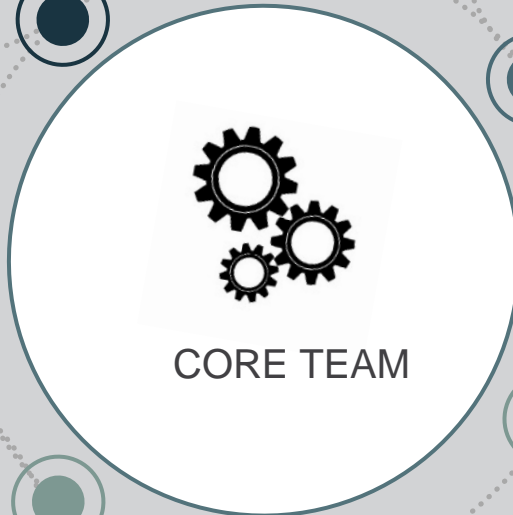
Identify external scientific and regulatory experts that can provide independent review



Develop and publish best practices for Psychometric-CROM



CORESTA
Scientific
Commission



Develop knowledge repository to facilitate identification and access to the recommended CROM in a specific context of use



Develop and publish best practices for Descriptive-CROM and related definitions



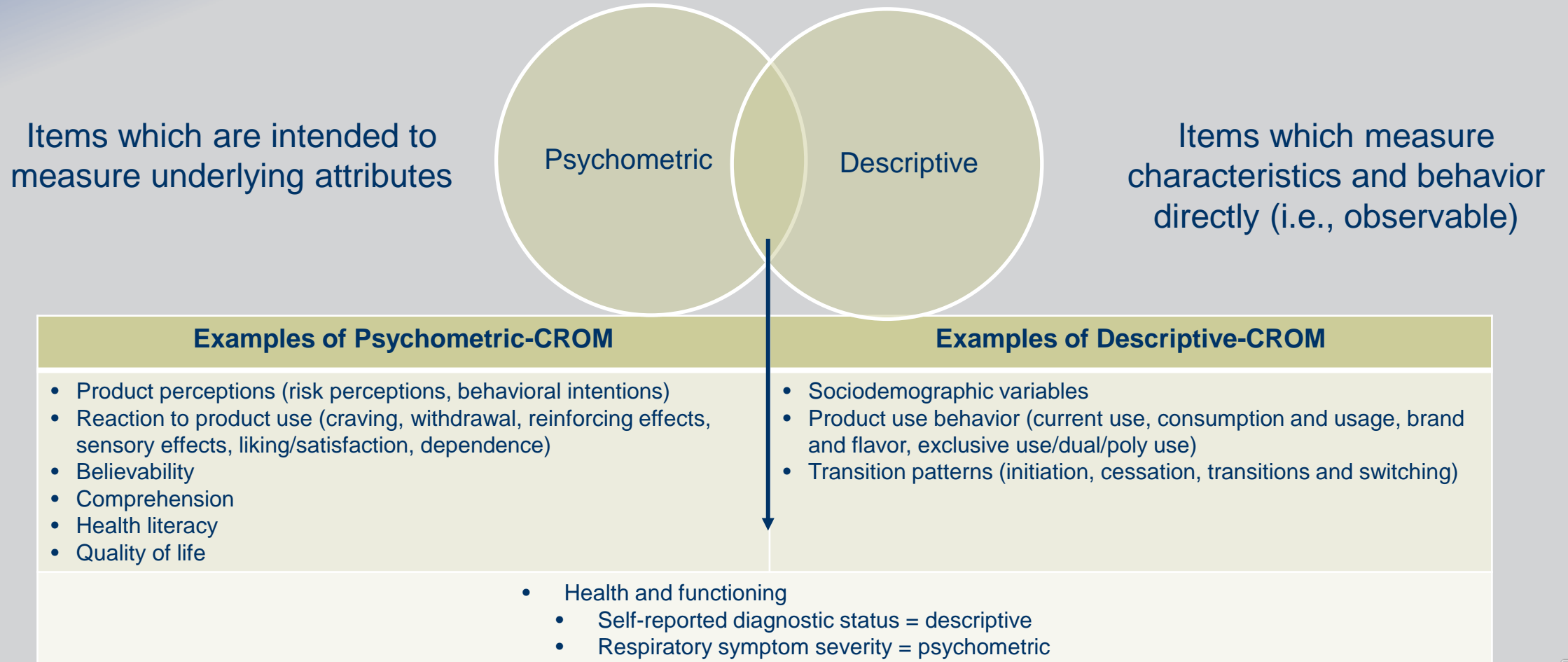
Governance body made of representatives of contributing companies and WG coordinators





Descriptive-CROM Definition

Descriptive-CROM: Factual survey items that are direct measures of individual characteristics and behaviors





Descriptive-CROM Guideline Development & Review Process

Development of Draft Guideline on Descriptive-CROM

Scientific Review and Dissemination

Review of Tobacco Surveillance Surveys

Fifteen existing tobacco surveillance surveys

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

Foundational Definitions

- Tobacco Product Classification
- Tobacco Product Use State

Draft Guideline

- 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

Dissemination: Poster, Oral Presentations, and Manuscript



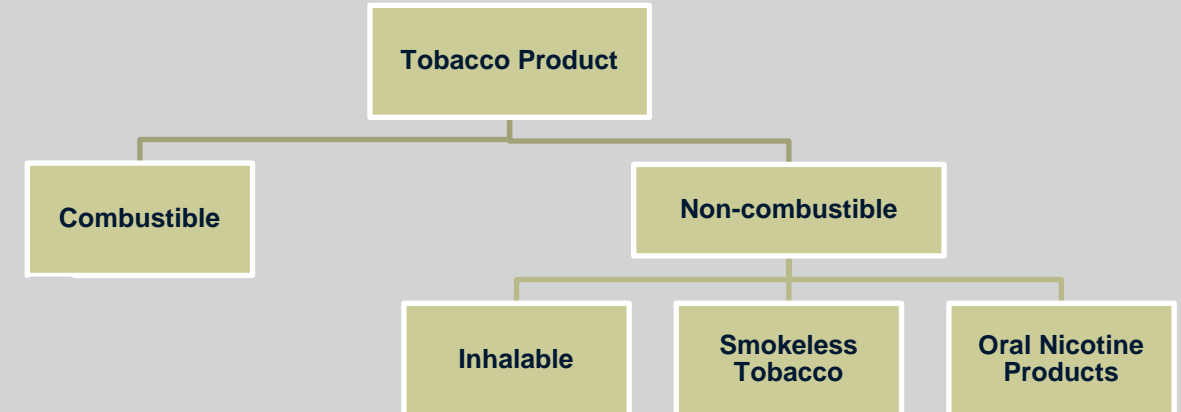


1. Foundational Definitions

Tobacco Product Classification

Tobacco Product Classification

- Tobacco product classification is needed as survey items are evaluated at each tobacco category/subcategory level.
- Gaps identified
 - Different classifications were found for the non-combustible tobacco products.
 - Clear classifications are needed for emerging tobacco product categories.
- Proposed Tobacco Product Classification

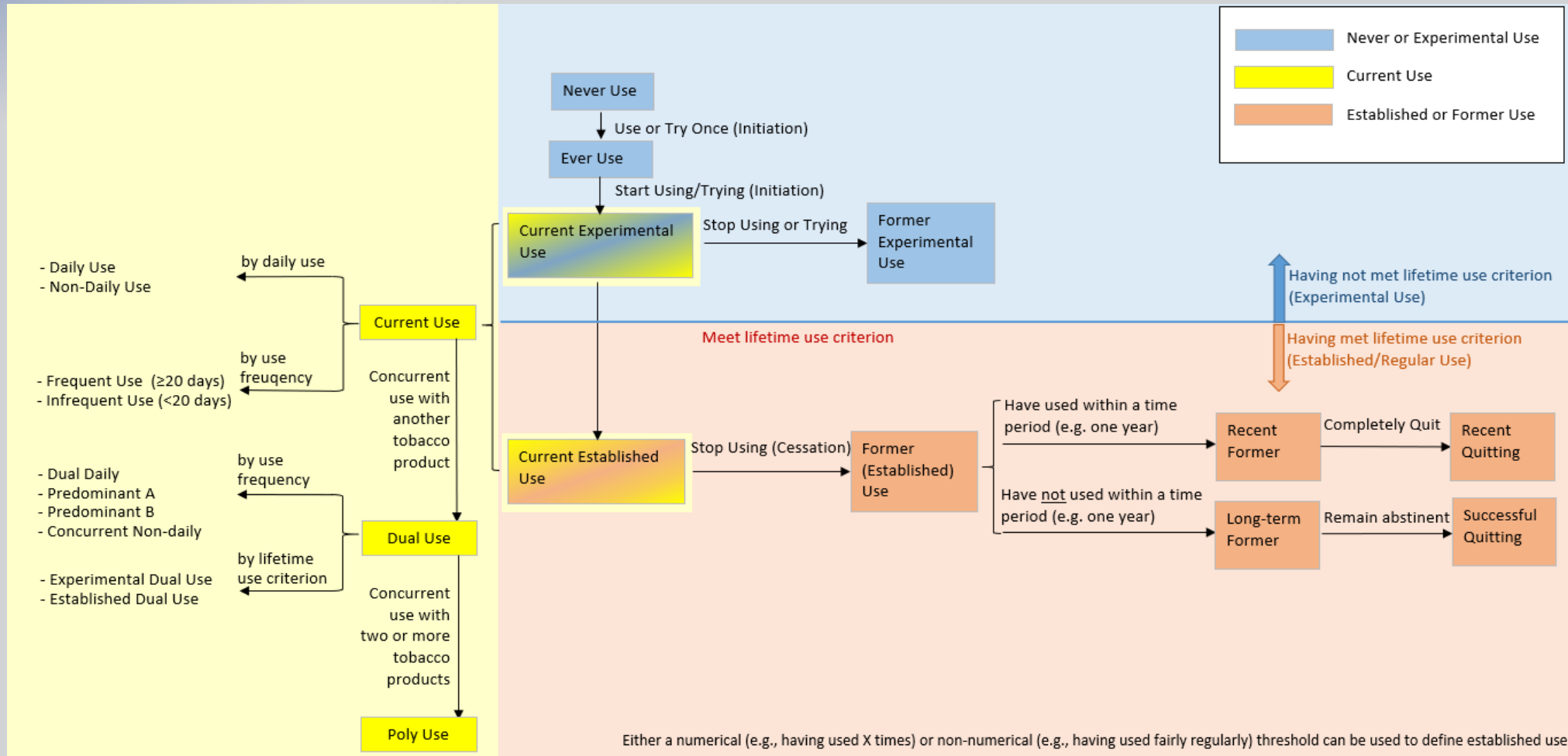




1. Foundational Definitions

Tobacco Product Use State

Descriptive-CROM: Conceptual Flow of Tobacco Product Use State





2. Descriptive-CROM Recommendations

Based on Existing CROM

❖ Population Level Domain Group

- Demographics: Age, Gender, Race, Ethnicity, ...
- Prevalence: Ever, Current, Lifetime Established Use, ...

❖ Product Category Level Domain Group

- Usage & Consumption: number of days used, number of units used per day on days used, types used, ...
- Brand & Flavor: brand used most often, flavors used in the past 30 days,...
- Initiation & Cessation: year of first use, age of first use, quit attempts, time since quit, ...

❖ Cross-Category Level Domain Group

- Single, Dual & Poly Use: Concurrent use, time to first use, ...
- Transitions and Switching: switched from A to B, ...





3. Development, Modification and Adaptation of Descriptive-CROM

❖ Development and Validation

- Attributes of a quality Descriptive-CROM: reliability, validity, responsiveness, interpretability
- Typical development or evaluation process for Descriptive-CROM

❖ Modification and Adaptation

- Context and requirement of modification and adaptation
- Examples of modifications: changing the target population, adapted existing CROM to a new category, etc.
- Cognitive testing

❖ Linguistic and Cultural Adaptation

- Linguistic and cultural equivalence
- Adaptation methods and recommendations

❖ Additional Considerations

- Measurement equivalence for cross-national surveys





4. Survey Design and Implementation

5. Data Analysis and Reporting

❖ 4. Survey Design and Implementation

- Questionnaire design
- Survey administration mode
- Survey structure
- Survey pre-testing

❖ 5. Data Analysis and Reporting

- Survey analysis
- Statistical methods
- Missing data and missing data imputations
- Additional considerations





Timeline for Review and Dissemination

❖ Next Steps

- Descriptive-CROM Draft Guideline ready for SME review (Q4 2021)
- Descriptive-CROM Draft Guideline SME review and revisions (2022)
- Prepare Descriptive-CROM Guideline and manuscript for publication (Q4 2022)

❖ 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 Info

❖ Acknowledgements

➤ Core Team Members

Lai Wei, Emilie Clerc, Mandara Shetty, Nicholas Goldenson, Mimi Kim, Krishna Prasad, Mohamadi Sarkar

➤ Advisory Board Members

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

➤ CORESTA CROM Task Force and other CORESTA working groups

❖ Interested in Joining?

- Contact Lai Wei (lai.wei@altria.com) if you would like to be involved in the review process of the draft guidelines on Descriptive-CROM





Thank you!

