



Development of Best Practices and Guidelines for Descriptive Consumer-Reported Outcome Measures (Descriptive-CROM) and Related Definitions in Tobacco and Nicotine Research

CROM WG04 Presentation at TSRC 2021

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Background

❖ CORESTA

- Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) is an association founded in 1956 with the purpose of promoting international cooperation in scientific research relative to tobacco and its derived products.

❖ 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- In 2020, the United States Food & Drug Administration (FDA) published draft guidance on tobacco product perception and intention studies (“Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies” (FDA TPPIS draft guidance)), which is an important first step toward building the foundation for standards of measurements across the tobacco industry.
- While the FDA TPPIS draft guidance provides general recommendations pertaining to the development, adaptation, and use of Psychometric-CROM (e.g., perceptions/intentions), Descriptive-CROM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 needed to be established for new tobacco product categories.

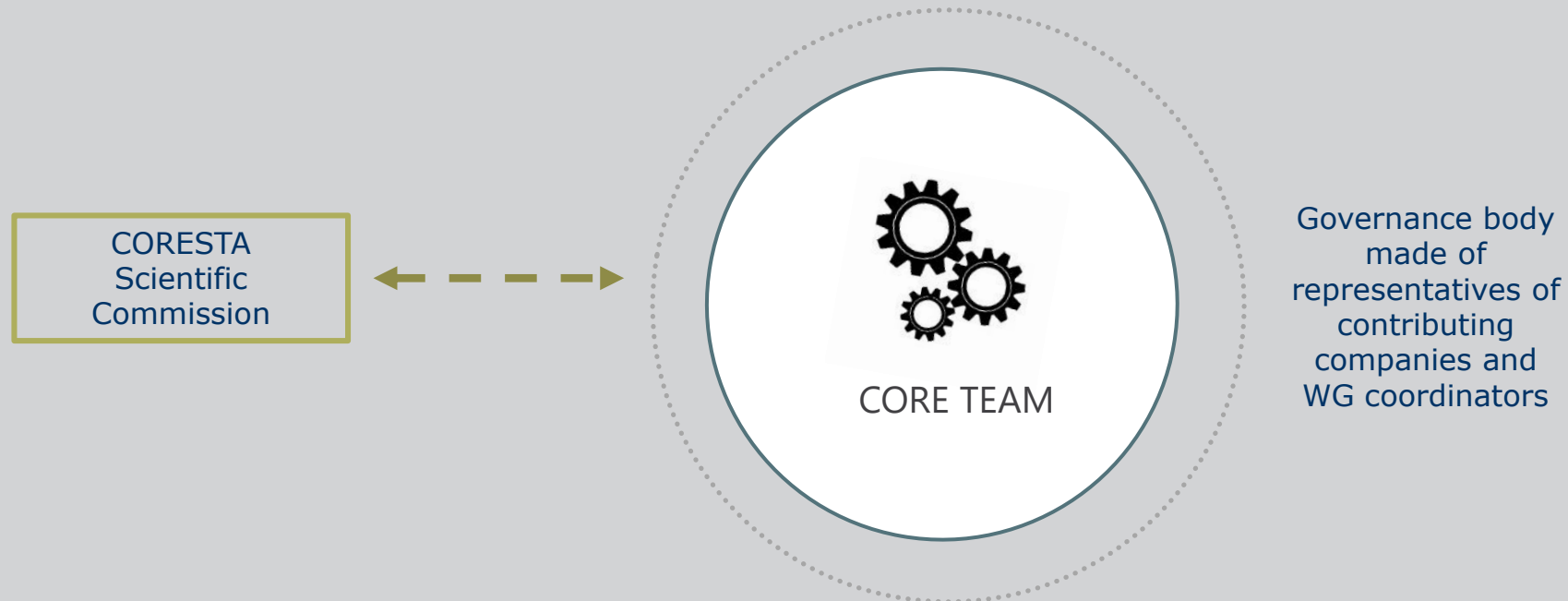


Governance Structure of CROM Task Force

❖ 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

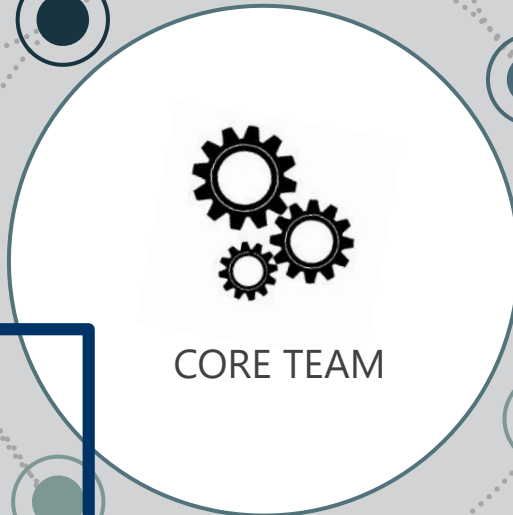
Identify external scientific and regulatory experts that can provide independent review



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

WG04 comprises seven core team members and an advisory board of six members with diverse experience in survey research, tobacco product use behavior and self-reported outcome measures.



Governance body made of representatives of contributing companies and WG coordinators

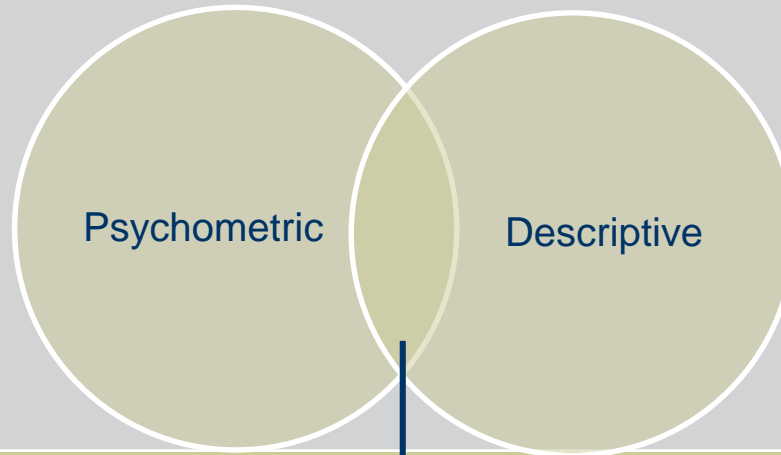




Descriptive-CROM Definition

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

Items which are intended to measure underlying attributes.



Items which measure characteristics and behavior directly (i.e., observable).

Examples of Psychometric-CROM	Examples of Descriptive-CROM
<ul style="list-style-type: none">• Product perceptions (risk perceptions, behavioral intentions)• Reaction to product use (craving, withdrawal, reinforcing effects, sensory effects, liking/satisfaction, dependence)• Believability• Comprehension• Health literacy• Quality of life	<ul style="list-style-type: none">• Sociodemographic variables• Product use behavior (current use, consumption and usage, brand and flavor, exclusive use/dual/poly use)• Transition patterns (initiation, cessation, transitions and switching)
<ul style="list-style-type: none">• Health and functioning<ul style="list-style-type: none">• Self-reported diagnostic status = descriptive• Respiratory symptom severity = psychometric	



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 and Oral Presentations, and Manuscript



Review of Tobacco Surveillance Surveys

Tobacco Surveillance Surveys Selected for Review

- Fifteen tobacco surveillance surveys that focus on adult populations were selected for review including 2 international, 8 European, 1 Japanese, and 4 US surveys.

Abbreviation	Full Name	Sample Size	Age	Funding Agency
International				
ITC	International Tobacco Control (with focus on ITC-UK and ITC-US)	Varies		Funding agencies from different country
GATS	Global Adult Tobacco Survey	Varies per country, 380,000 in total	15+	World Health Organization(WHO), Centers for Disease Control and Prevention (CDC)
Europe				
EB 87.1	Eurobarometer - Attitudes of Europeans towards tobacco and electronic cigarettes	~1000*28	15+	European Commission, European Parliament
ESS	European Social Survey	~1000*28	15+	European Research Infrastructure Consortium (ERIC)
STS	Smoking ToolKit Study	~1800	16+	Cancer Research UK, Pfizer and GSK
DEBRA	Deutsche Befragung zum Rauchverhalten	2000	14+	German Ministry of Health
SHP	Swiss Household Panel	~29,000	14+	Swiss National Science Foundation
SHS	Swiss Health Survey 2017: tobacco consumption	~22,000	15+	Swiss Confederation
EHIS	European Health Interview Survey	Varies per country	15+	European Commission
HET	Health on Equal Terms - Sweden	~20,000	16 - 84	Public Health Agency of Sweden
Asia				
Japan – NHNS	Japan - National Health and Nutrition Survey	~18,000	1+	Ministry of Health, Labour and Welfare
U.S.				
NHIS	National Health Interview Survey (Sample Adult Module)	~32,000	18+	CDC
NSDUH	National Survey on Drug Use and Health	~50,000	12+	Substance Abuse and Mental Health Services Administration (SAMHSA)
TUSCPS	Tobacco Use Supplement - Current Population Survey	~240,000	18+	FDA, National Cancer Institute (NCI)
PATH	Population Assessment of Tobacco and Health (PATH)	~45,000	12+	FDA, National Institutes of Health (NIH)

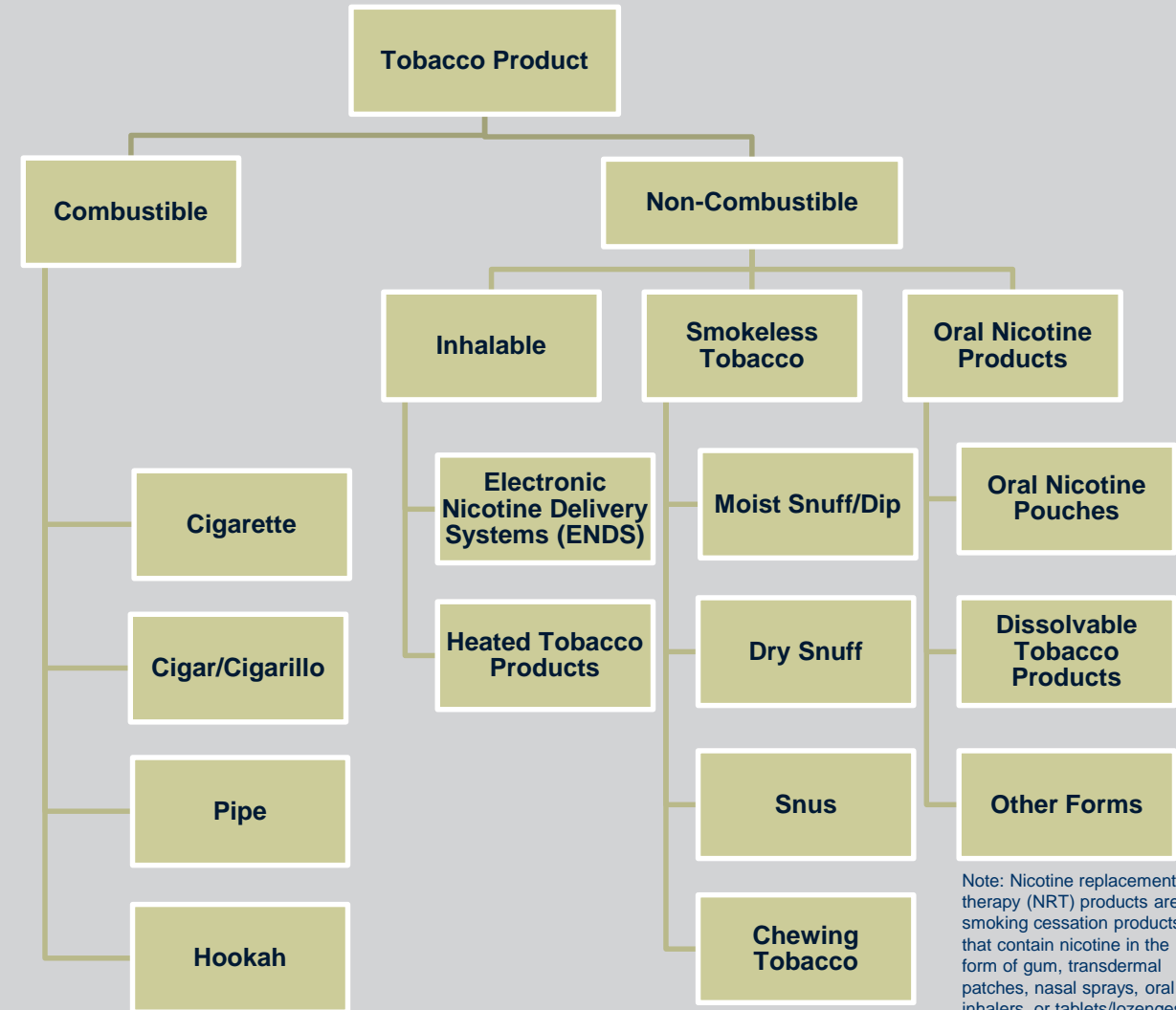


Foundational Definitions

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

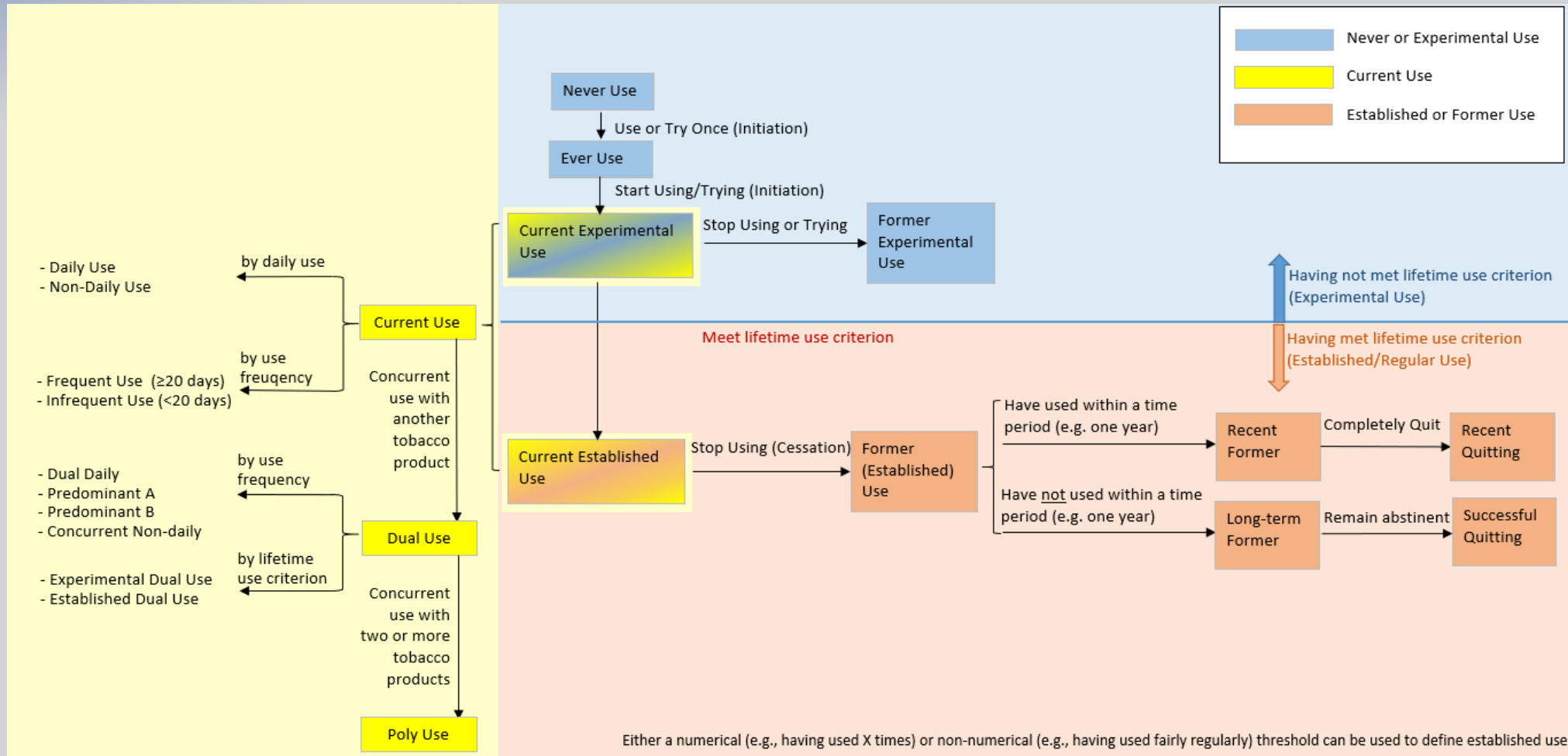




WG04 Foundational Definitions

Tobacco Product Use State

Descriptive-CROM: Conceptual Flow of Tobacco Product Use State

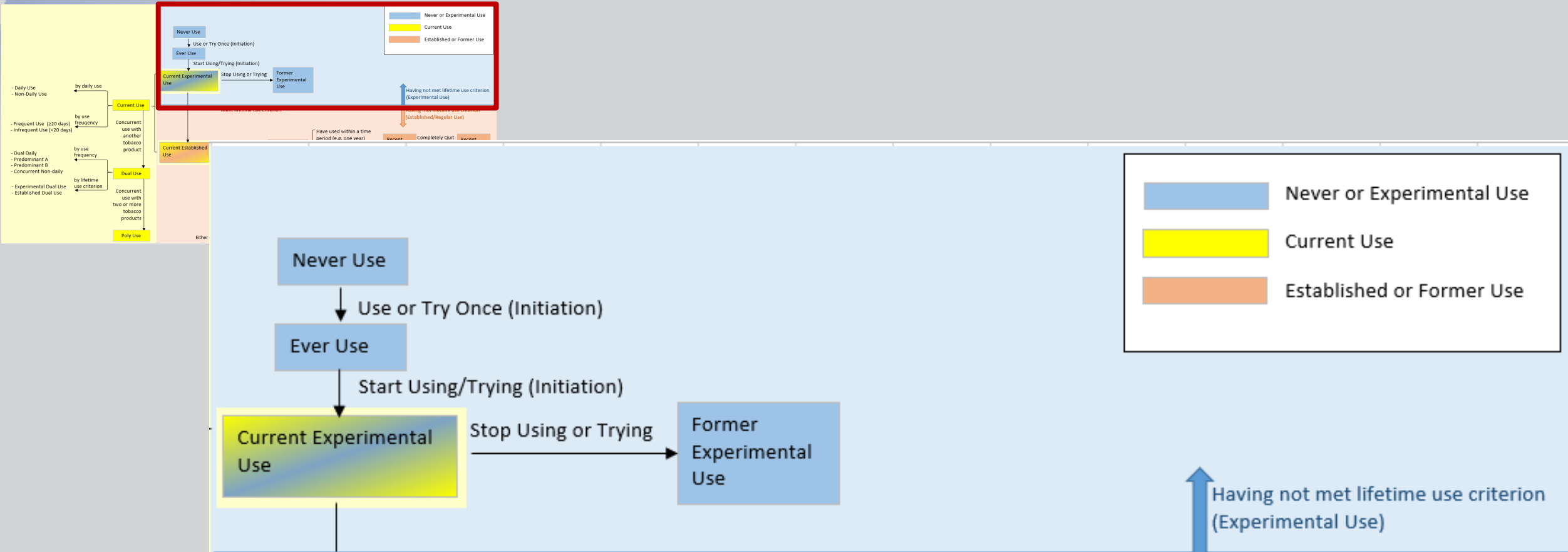




WG04 Foundational Definitions

Tobacco Product Use State

Descriptive-CROM. Conceptual Flow of Tobacco Product Use State

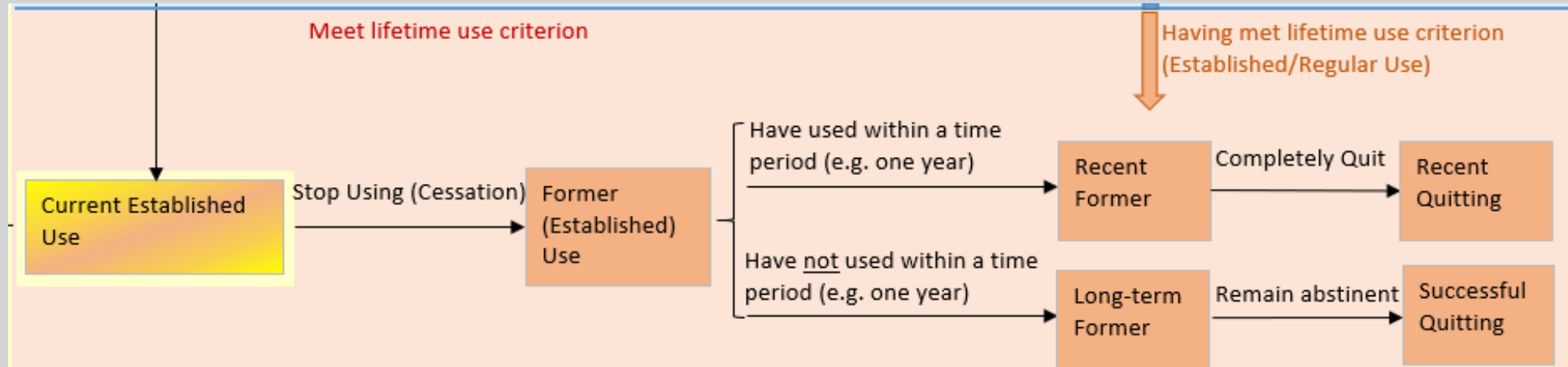




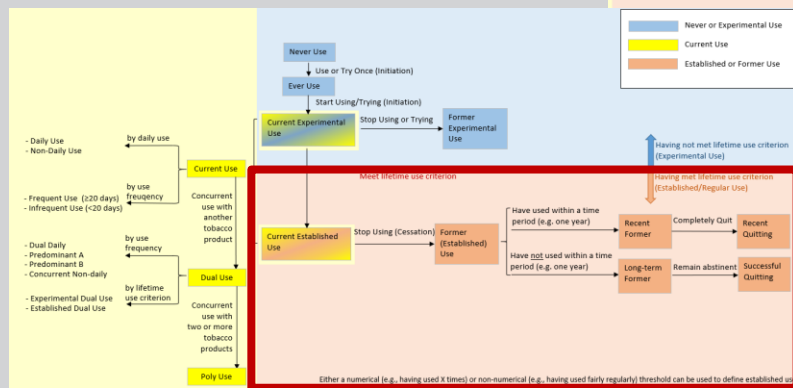
WG04 Foundational Definitions

Tobacco Product Use State

Descriptive-CROM. Conceptual Flow of Tobacco Product Use State



Either a numerical (e.g., having used X times) or non-numerical (e.g., having used fairly regularly) threshold can be used to define established use.

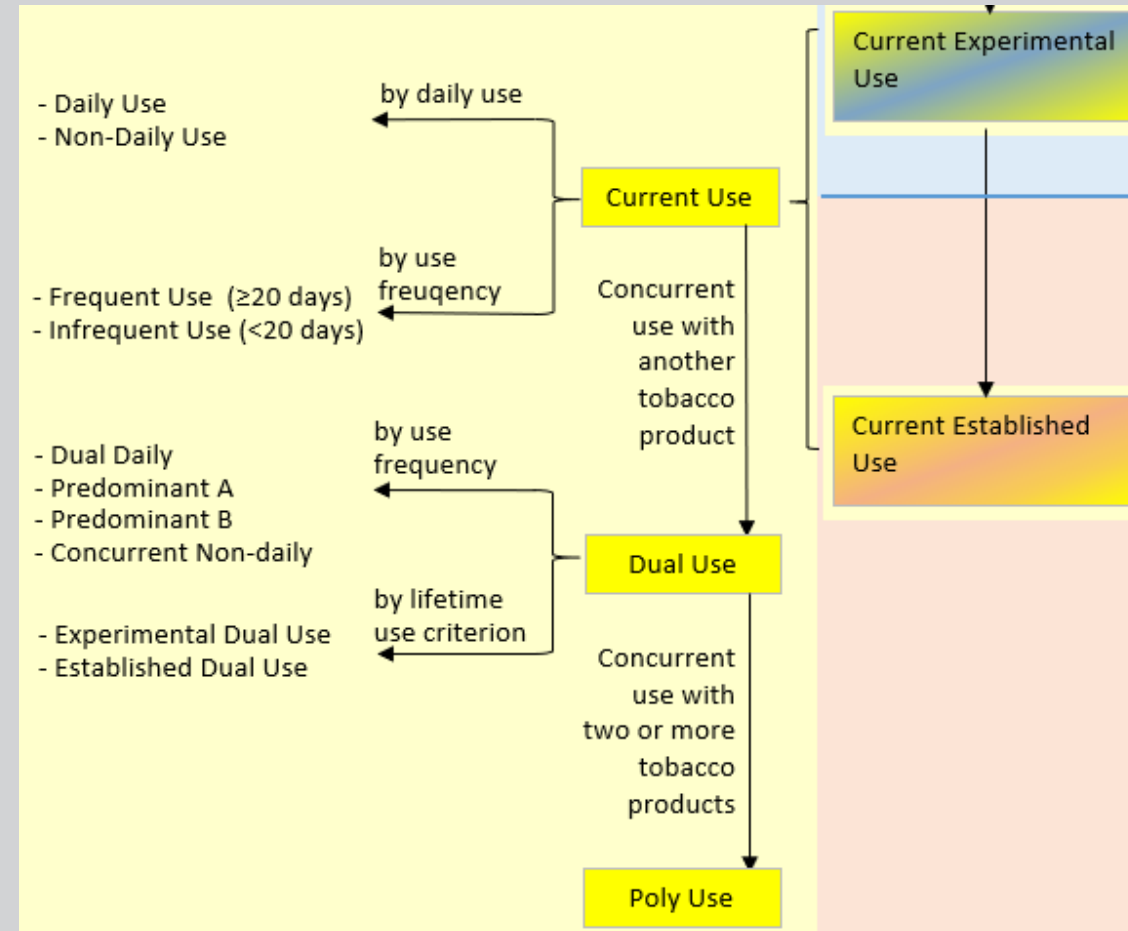
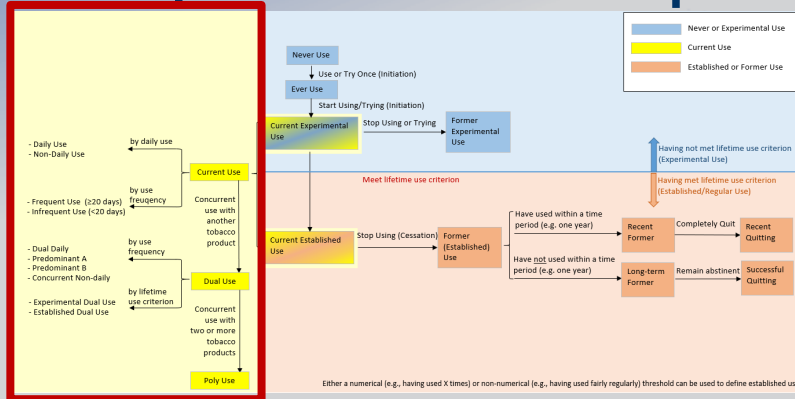




WG04 Foundational Definitions

Tobacco Product Use State

Descriptive-CROM. Conceptual Flow of Tobacco Product Use State





Descriptive-CROM Draft Guideline Content Outline

❖ Guideline Outline

Content Area	Overview of Content
Foundational Definitions	Tobacco product classifications and tobacco product use states.
Descriptive-CROM Recommendations	Recommendation of Descriptive-CROM based on existing survey measures.
Development, Modification and Adaptation of Descriptive-CROM	Best practices to develop, validate a new Descriptive-CROM, and to modify an existing Descriptive-CROM, etc.
Survey Design and Implementation	Recommendations of questionnaire design, survey administrations, survey testing, etc.
Data Analysis and Reporting	Recommendations of survey analysis, statistical methods, considerations of missing data and data reporting with small numbers, etc.



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.



Acknowledgement and Contact Info

❖ Acknowledgement

➤ 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 Sub-Groups

❖ Interested in Joining?

- Contact Lai Wei (lai.wei@altria.com) if you would like to join WG04 or be involved in the review process of the draft guidelines on Descriptive-CROM



Thank you!



Reference

- U.S. Food & Drug Administration (FDA). Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies Guidance for Industry. Draft Guidance. October 2020.
- McMillen, R., Maduka, J., & Winickoff, J. (2012). Use of emerging tobacco products in the United States. *Journal of environmental and public health*, 2012, 989474. <https://doi.org/10.1155/2012/989474>