Development of Consumer-Reported Outcome Measure (CROM) Guidelines for the Tobacco Industry with Respect to Psychometric CROM Using a Consortium-Based Approach

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2Philip Morris Products, S.A.
3RAI Services Company
4JT International
5British American Tobacco
6Altria Client Services
The Need for CROM Best Practices and Guidelines in Tobacco Research

- CROM are a critical component of tobacco regulatory research.
- CDER PRO guidance (2009, 2020) is not directly translatable to CROM in tobacco regulatory research and may differ from CTP’s expectations.
- In October 2020, CTP published draft guidance for industry “Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies” (draft TPPIS guidance).
- This draft guidance is limited to the development, adaptation, and use of measures of perceptions, intentions, and understanding within the context of tobacco product perception studies.
- Need for additional guidelines which more broadly encompass:
  1. other types of CROM (e.g., dependence, craving)
  2. the use of CROM in other research areas (e.g., clinical studies)

Consumer Reported Outcome Measures (CROM):
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.

CDER = Center for Drug Evaluation and Research; CTP = Center for Tobacco Products
CORESTA formed the CROM Consortium Task Force (TF) in November 2018

CROM TF includes 6 working groups
### Psychometric CROM

**Items that are intended to measure underlying attributes.**

**Examples of Psychometric CROM**
- Product perceptions (risk perceptions, behavioral intentions)
- Reaction to product use (dependence, craving, withdrawal, reinforcing effects, sensory effects, liking/satisfaction)
- Believability
- Comprehension
- Health literacy
- Quality of life

**Examples of Descriptive CROM**
- Sociodemographic variables
- Transition patterns (initiation, cessation, switching)
- Product use behavior (frequency and intensity of use, exclusive use, dual/poly use, unintended use)

**Items that measure behavior directly (i.e., observable).**

- Health and functioning
  - Self-reported diagnostic status = descriptive
  - Respiratory symptom severity = psychometric
Working Group 02 (WG02)

- WG02, formed in June 2020, includes 11 researchers with diverse backgrounds and expertise.
  - e.g., psychometrics, patient-reported outcomes, survey methodology, tobacco product use behavior, clinical

Approach for Developing the Guidelines

- Consensus-based approach, consistent with approaches taken by prominent research organizations (e.g., ISPOR).
- WG02 members, in conjunction with external SMEs, are collaboratively drafting the initial guidelines based on review of relevant literature and expertise.
- Collaborative, iterative process, with peer-review as an integral factor driving each iteration of guideline development.
  - Various avenues for SME participation (e.g., authorship opportunities, confidential/anonymous participation).

ISPOR = The Professional Society for Health Economics and Outcomes Research; SME = subject matter expert
Current best practices and guidelines for the use of psychometric CROM in tobacco regulatory research

- Recommendations are grounded in science
- Not intended to reflect unattainable standards or to be prescriptive
- Researchers should be knowledgeable about these best practices, and then make an informed decision as to what extent they are applicable or necessary for a particular study
- What is considered best practices may evolve over time
- Complements FDA TPPIS draft guidance for industry; is not intended to replace or supersede regulatory guidance
Define the CROM endpoint strategy in the context of the research

- Facilitates determination of whether (a) an existing CROM is appropriate, (b) an existing CROM might be modified to meet the researcher’s needs, or (c) it is necessary to develop a new CROM

Modifying an existing CROM

Developing and validating a new CROM

Application, scoring, and interpretation of CROM
# Defining the CROM endpoint strategy in the context of the research

<table>
<thead>
<tr>
<th>Considerations</th>
<th>Description/Examples</th>
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<tbody>
<tr>
<td>Operational definition of the construct to be measured</td>
<td>What are the components of the construct which should be represented in the CROM? (construct representation)</td>
</tr>
<tr>
<td>Define context of use within the study</td>
<td>Type of study (clinical trial, cross-sectional TPPIS, etc.) Study sample and target population</td>
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<tr>
<td>Endpoint model</td>
<td>Does the CROM address a primary, secondary, exploratory study objective?</td>
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<tr>
<td>Score interpretation</td>
<td>How is the CROM score(s) interpreted? Is a single total score, or multiple scale scores generated?</td>
</tr>
<tr>
<td>Psychometric functioning</td>
<td>What are the psychometric properties of greatest importance within the context of the study? (e.g., ability to detect change, known-groups validity, equivalence of scores across product categories, predictive validity, etc.)</td>
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</table>
| Administration considerations              | Mode/method of administration  
• Does the study necessitate electronic administration on devices with different screen sizes?  
• Does the CROM need to be administered/scored electronically (e.g., CAT)?  
Frequency of administration (assessment schedule) and recall period  
Length of administration (respondent burden)  
Context of administration                                                                         |
| Accessibility                               | Licensing fees, permission to use, copyright clearance                                                                                                                                                    |

This assessment reflects a critical first step to guide the decision:  
• leverage existing “off-the-shelf” CROM  
• modify existing CROM  
• develop a new CROM
Examples of modifications/adaptations:

➢ To assess different target population (e.g., former tobacco user) or tobacco product/category
➢ Modifying the instructions and/or the items/response options
➢ Adding images of products to aid respondents
➢ Utilizing a subset of the items, or adding new items
➢ Changing mode or method of administration
➢ Modifying the format of administration (e.g., administering items from a grid individually)
➢ Linguistic and cultural translation of an existing CROM

The type of evidence (qualitative, quantitative) and extent of the evidence which may be useful to support the adaptation/modification depends on various factors, such as:

➢ The extent of the modifications (minor, moderate, major)
➢ Way in which the modified instrument will be used and interpreted

Modification may not always warrant additional testing
Developing and validating a new CROM

- This table illustrates activities which may be included in CROM development but is not intended to be prescriptive.
- The CROM development process is often iterative, and each activity is not always applicable or needed.
- CROM development and validation is not necessarily a linear process that ends with quantitative psychometric evaluation.

<table>
<thead>
<tr>
<th>Defining the Construct</th>
<th>Initial drafting of the CROM</th>
<th>Qualitative/ mixed-methods to refine CROM</th>
<th>Quantitative psychometric evaluation</th>
</tr>
</thead>
</table>
| • Operational definition of construct to be measured, including theoretical structure | • Consider:  
  • general best practices in instrument drafting  
  • mode/method of administration, programming instructions  
  • Use of ITM is recommended  
  • May leverage literature, existing CROM, SMEs | • Individual cognitive debriefing interviews with end-users to refine the draft CROM and obtain evidence of content validity  
  • SMEs and psychometricians may be consulted on revisions | • Administer CROM to end-users for purposes of psychometric evaluation  
  • Iterative process driven by empirical and theoretical rationale; often incorporates analyses from different theoretical approaches  
  • CROM may be modified during psychometric evaluation  
  • Develop User’s Guide (empirically supported scoring and interpretation) |
| • Can take the form of a conceptual model (visual representation of key components and content, theoretical structure)  
  • Can facilitate evaluation of construct representation  
  • May include various sources of input (e.g., SMEs, literature) | | | |
| SMEs = subject matter experts; ITM = item tracking matrix; “end-users” = individuals who are representative of intended respondents (users) of the CROM | | | |

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Need to be cautious and purposeful when applying, scoring, and interpreting CROM within the context of a study

Examples of application considerations:
- Application of CROM (e.g., mode/method of administration) should be consistent with the instrument's intended use
- Timing of data collection (e.g., at the end of each day or at the end of the week in an actual use study)
- Context of administration (e.g., order of CROM administration within a survey, participant reactivity if CROM are administered by study staff, etc.)
- Device screen size and layout for electronic administration
- Consistency of administration (e.g., across study sites, across screen sizes)

Scoring/interpretation considerations:
- Scoring (calculation of scores, handling missing data, etc.) and interpretation (interpretation of total score, determination of clinical meaningfulness, etc.) consistent with User's Guide and/or SAP
- Empirical support (validation) for score interpretation, and the researcher should not extrapolate beyond the validated interpretation
WG02 is currently in the process of finishing the initial draft of the Psychometric CROM guidelines.

WG02 is actively seeking collaboration from individuals with diverse perspectives and expertise representing public health, academia, and the tobacco industry throughout the guideline development process.

WG02 welcomes anyone interested in participating in this initiative to contact the WG02 coordinators:

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You can also visit our website for the latest SME opportunities:

https://www.coresta.org/groups/consumer-reported-outcome-measures-consortium