Assessing consumer responses to reduced risk products:
experience at Philip Morris International in developing fit-for-purpose self-report instruments

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ABOUToolbox
Assessment of Behavioral OUtcomes
related to Tobacco and nicotine products
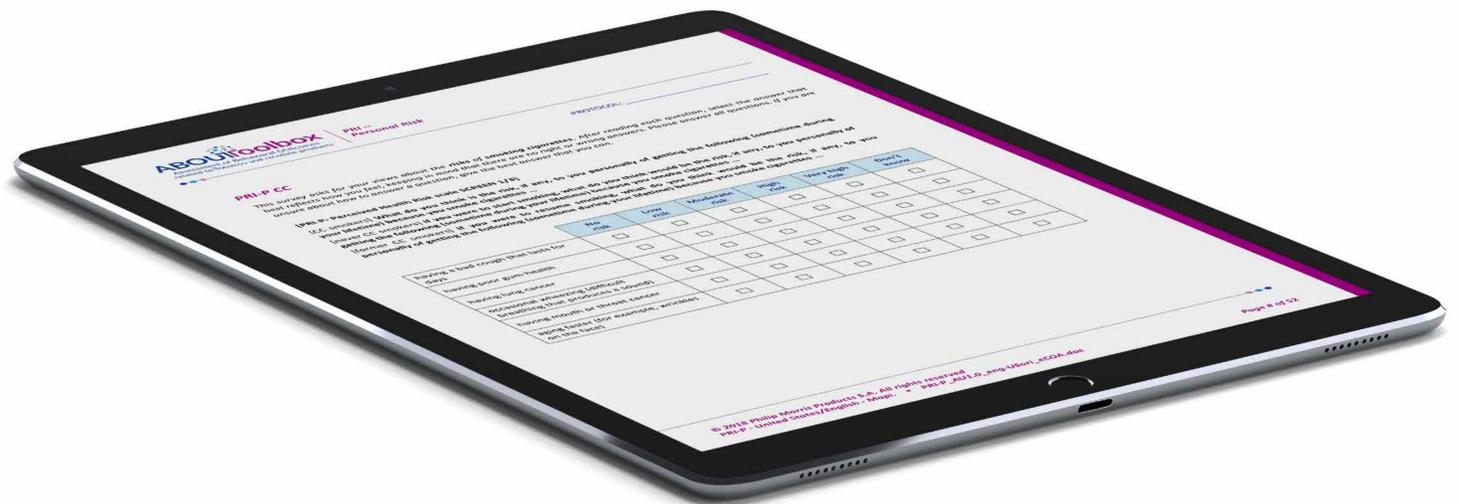
Introduction

To assess the full potential of Reduced-Risk Products (RRP*) for individual users and the population as a whole, PMI has implemented an assessment program in which consumer perception and behavior assessment are key components. In this context, valid and reliable self-report measures are needed to assess consumer perceptions and behaviors towards RRPs in comparison with other tobacco and nicotine products (TNPs). Although this need has been acknowledged for quite some time [1], the field of Tobacco Regulatory Research is still lacking scientifically designed, fit-for-purpose and consensus measures, mainly due to the lack of measurement best practices and specific guidelines that would facilitate standardization and comparison across studies. Here, we present a new initiative, the **ABOUT Toolbox** (**A**ssessment of **B**ehavioral **OU**tcomes related to **T**obacco and nicotine products), which aims at addressing this gap.

Methods
to develop and manage the ABOUT Toolbox

Development of the conceptual framework and item generation

① Define concepts of interest, context of use and intended population
② Generate conceptual model based on literature review, quali- tative study, and expert opinion
③ Generate draft instrument with items best representing concepts of interest, appropriate response options, format, and recall period
④ Evaluate content validity with cognitive debriefing interviews

Figure 1. Iterative process for the development of an ABOUT instrument
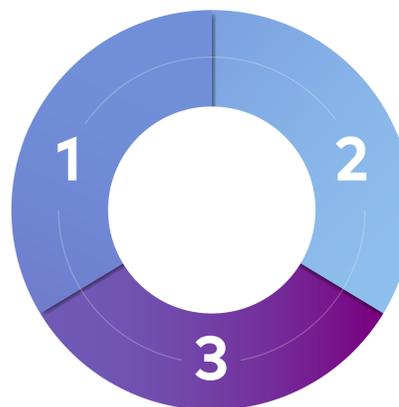
Confirmation of the conceptual framework and item reduction

① Identify items that best work together to form a scale and ensure that items are well targeted
② Ensure that response options work as intended
③ Ensure stability of the instrument across different population groups
④ Assess other measurement properties of the reduced-item instrument (construct validity, ability to detect change, score reliability)

Cross-validation of the psychometric properties, scoring rule and cultural adaptation

① Test cross-cultural equivalence (linguistic validation, psychometric properties, scoring)
② Finalize instrument (document content, formats, psychometric properties and scoring rule in a user manual)
③ Document instrument development and validation in publications
④ Make the instrument publically available

Inventory
of the ABOUT Toolbox

Table 1. Information on the ABOUT Toolbox and access to the instruments

Instrument	Concepts of interest (# items)	Context of use	Target population	Information on accessibility
Perceived risks	Health risk (18) Addiction risk (7) Harm to others (2) *Social and practical risk scales are currently under development*	All TNPs + Cessation	Adult current, former, and never TNP users	Available in PROQOLID under Perceived Risk Instrument (PRI) eprovide.mapi-trust.org/ instruments/perceived-risk-instrument
Dependence	Loss of control over use of TNPs (urgency to use upon waking up compulsion to use, difficulty to cease using, need to function normally, priority of using over social responsibilities, automaticity of using, self awareness of dependence)	All TNPs	Single or poly- TNP users	Available in PROQOLID towards the end of 2018
Product Experience	Satisfaction (3) Psychological reward (5) Craving reduction (1) Aversion (2) Enjoyment of respiratory tract sensation (1)	All TNPs Different recall periods	Adult current TNP users	Available in PROQOLID towards the end of 2018
Health and functioning	Body structure and function Activity Participation Personal factors Environmental factors	All TNPs + Cessation	Adult current and former TNP users	
Use history	Initiation Cessation Intensity of current and past use	All TNPs	Adult current, former, and never TNP users	Available in PROQOLID under the Smoking Questionnaire (SQ) eprovide.mapi-trust.org/ instruments/smoking-questionnaire2

Advantages
of using instruments from the ABOUT Toolbox

❶ Developed and validated with best-available science methods, straightforward to implement in clinical and population-based studies, and easy to interpret
❷ Created to be relevant and applicable across the whole spectrum of TNPs and across various population groups
❸ Designed to enhance standardization and comparison of data on perception and behaviors towards RRPs across academic, industry and public health research communities.
❹ Envisioning a rapidly expanding knowledge base with the goals of:
  ① informing further interpretation of consumer percep- tion data comparing a large spectrum of TNPs
  ② enabling public health and regulatory communities to make better-informed decisions for future regulation of RRPs and enhance surveillance activities associated with smoking-related disease.

For more detailed information and references please see the supplementary brochure.

TNP: Tobacco and nicotine product