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# Assessing User Behavior and Risk Perceptions: A Case Study from Philip Morris International

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ENDS Conference  
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# Overview

- Existing Tobacco and Nicotine Product (TNP) Behavioral Frameworks
- PhenX Toolkit: Tobacco Regulatory Research Collections
- Application of Regulatory Guidance in the Development of Measurement Instruments
- Case Study: ABOUT-Perceived Risk

# Existing Tobacco and Nicotine Product (TNP) Behavioral Frameworks

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# Why Are Tobacco and Nicotine Product (TNP) Behavioral Frameworks of Interest?

- Identify tobacco use patterns and characterize transitions over time
- Identify factors predicting (**driving/hindering**) tobacco use patterns and transitions

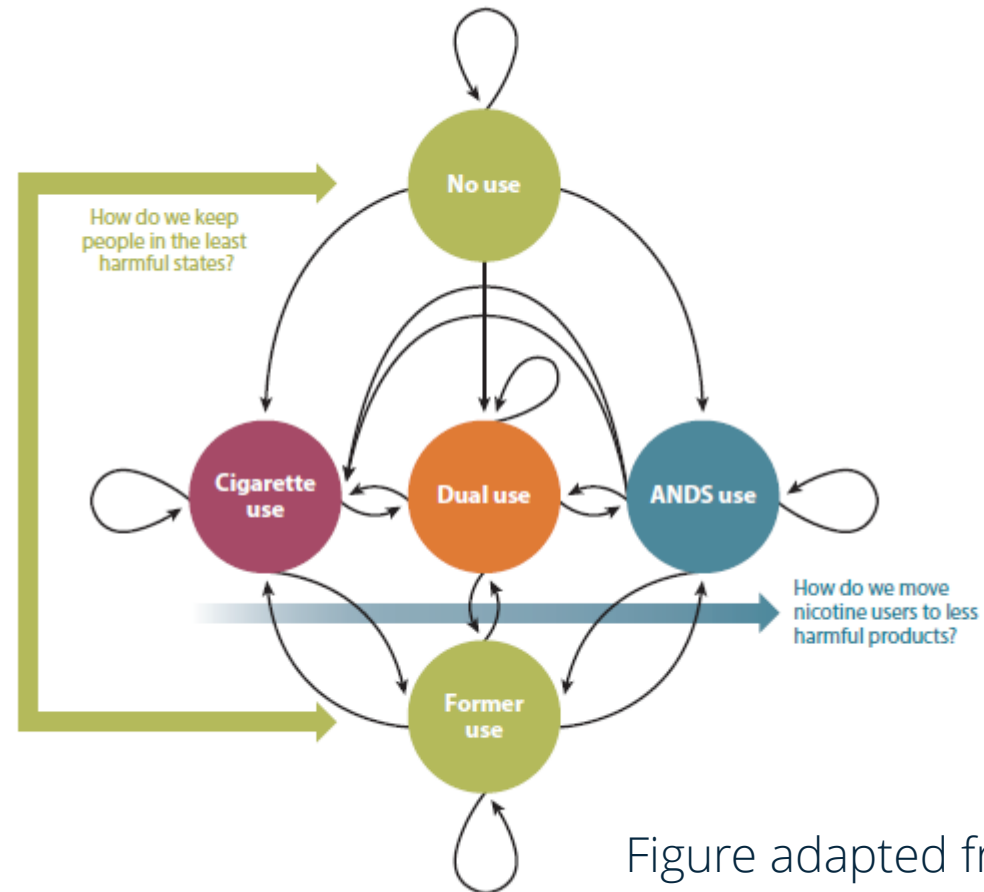


Figure adapted from Abrams et al. (2018)

# Three-Dimensional Conceptual Space for Alternative Nicotine Delivery Systems (ANDS)

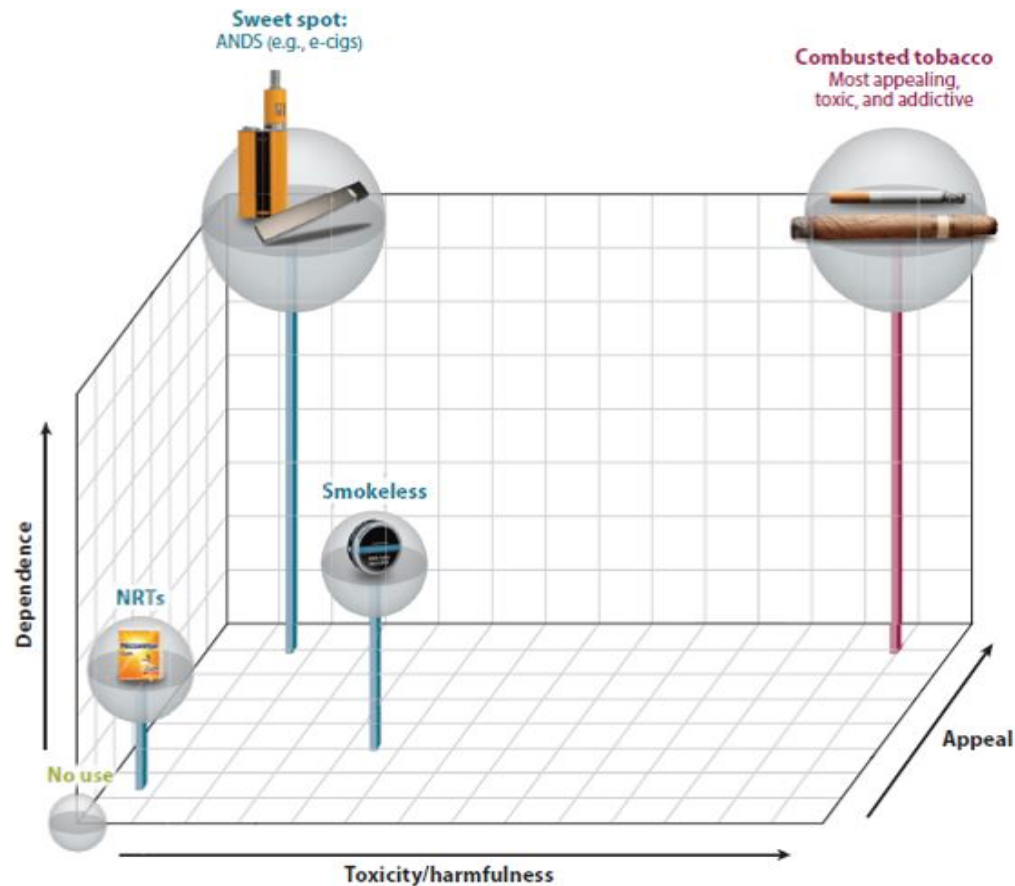
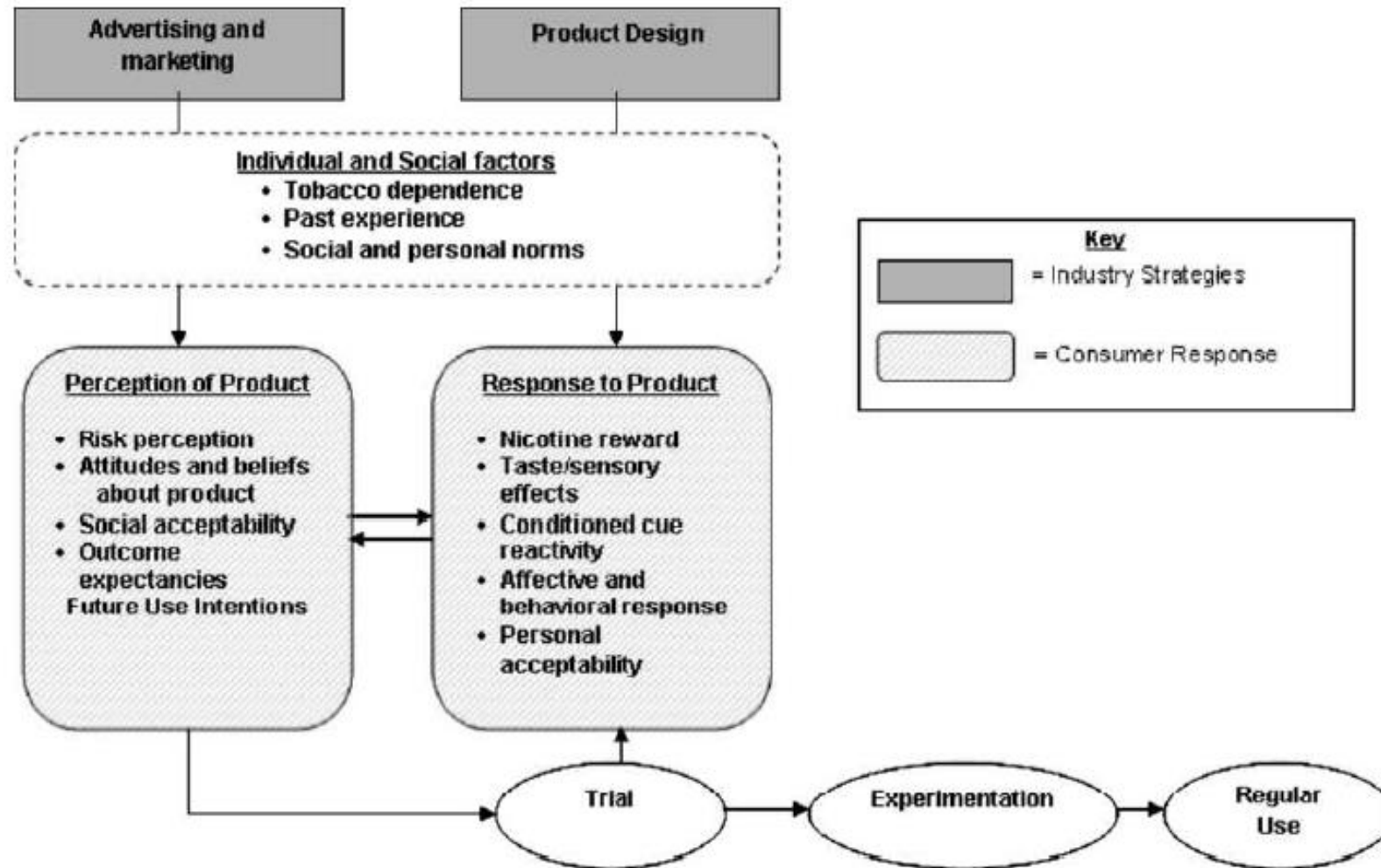


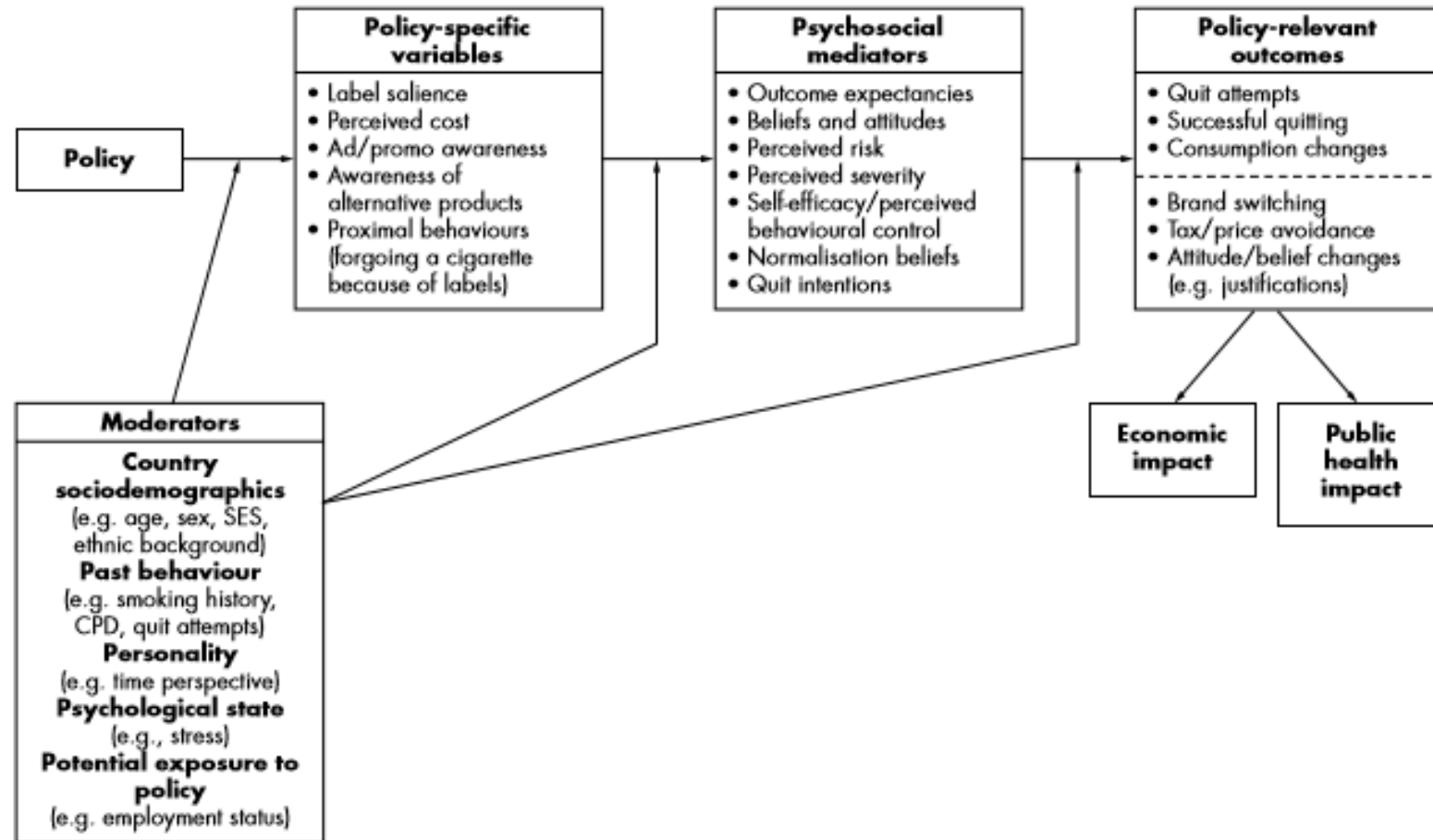
Figure 2

Multidimensional framework for nicotine-containing products. Nicotine and tobacco products can be depicted within a three-dimensional conceptual space: harmfulness (x-axis), appeal or popularity (z-axis), and satisfaction, which includes degree of dependence (y-axis). Appeal is a complex function of attractiveness, as well as cost, accessibility, and marketing practices, and appeal is related to satisfaction, including factors such as nicotine levels, taste, flavors, sensory characteristics, and dependence liability. This figure provides a roadmap with which to envision where a specific class of products can be placed. The top, back, right corner depicts the most popular (appealing), highly satisfying (dependence), and toxic space, whereas no use at all is zero on all three axes. Combusted products are, by far, the most appealing, satisfying, and toxic. The bottom, front, left space depicts products that have low toxicity but little appeal or satisfaction. NRTs are not used by many and are thus not appealing or satisfying and unlikely to displace cigarettes at a population level. Minimizing risk while making a net population health impact requires products to successfully compete with and replace smoking. Thus, the sweet spot, where ANDS products fall, is depicted by high appeal and satisfaction but low toxicity along with intermediate products such as Swedish-type snus, which has successfully displaced cigarettes in Sweden. Abbreviations: ANDS, alternative nicotine delivery systems; e-cigs/e-vapor, electronic cigarettes; NRTs, nicotine replacement therapies.

# Consumers' Responses to a Potential Reduced Exposure Products (PREP)



# The International Tobacco Control (ITC) Project Conceptual Framework



**Figure 1** Conceptual model illustrating the hypothesised causal chain of how tobacco control policies exert their influence on tobacco use behaviours. CPD, cigarettes per day; SES, socioeconomic status.

# The HAVE Framework Underlying PATH Study

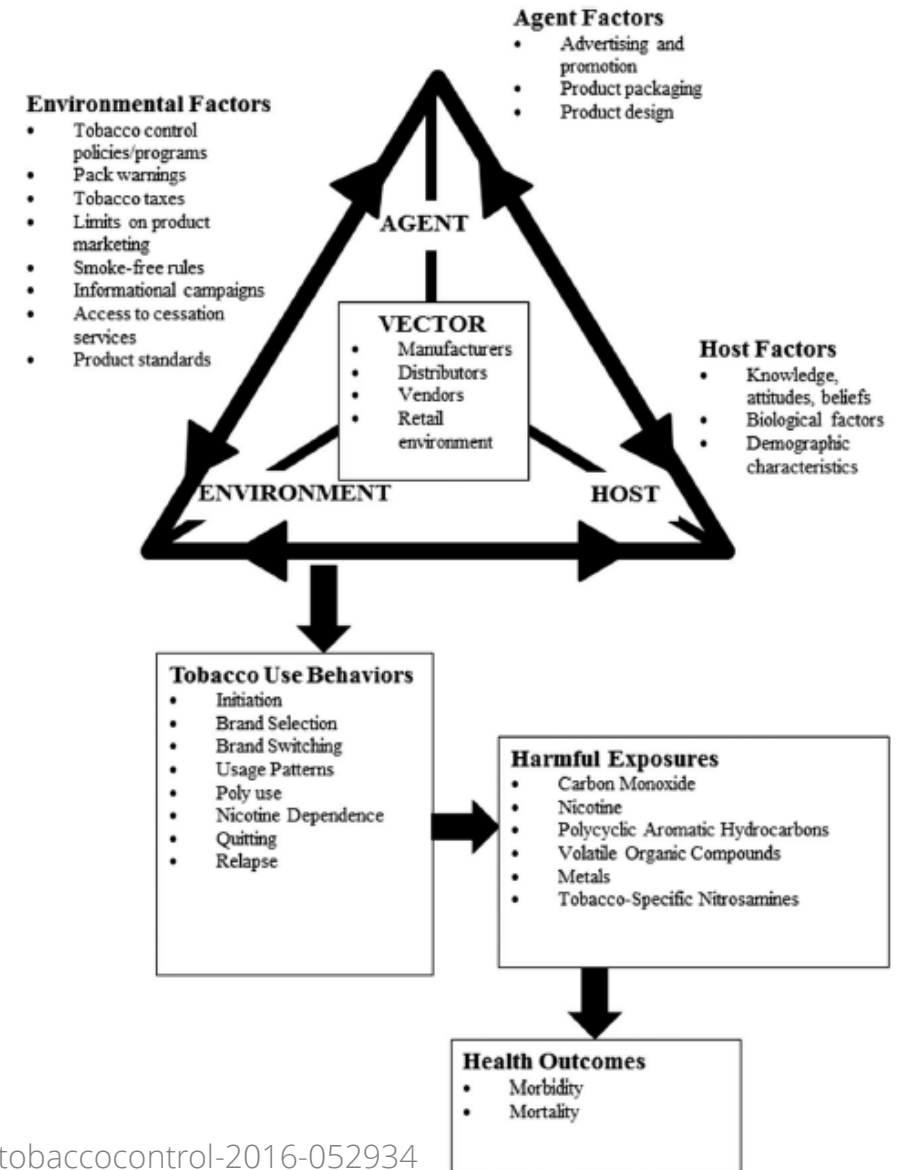
**Figure 1** Host, agent, vector and environment model applied to tobacco with examples of constructs within each domain.<sup>11</sup>

HOST = tobacco product user

AGENT = tobacco product

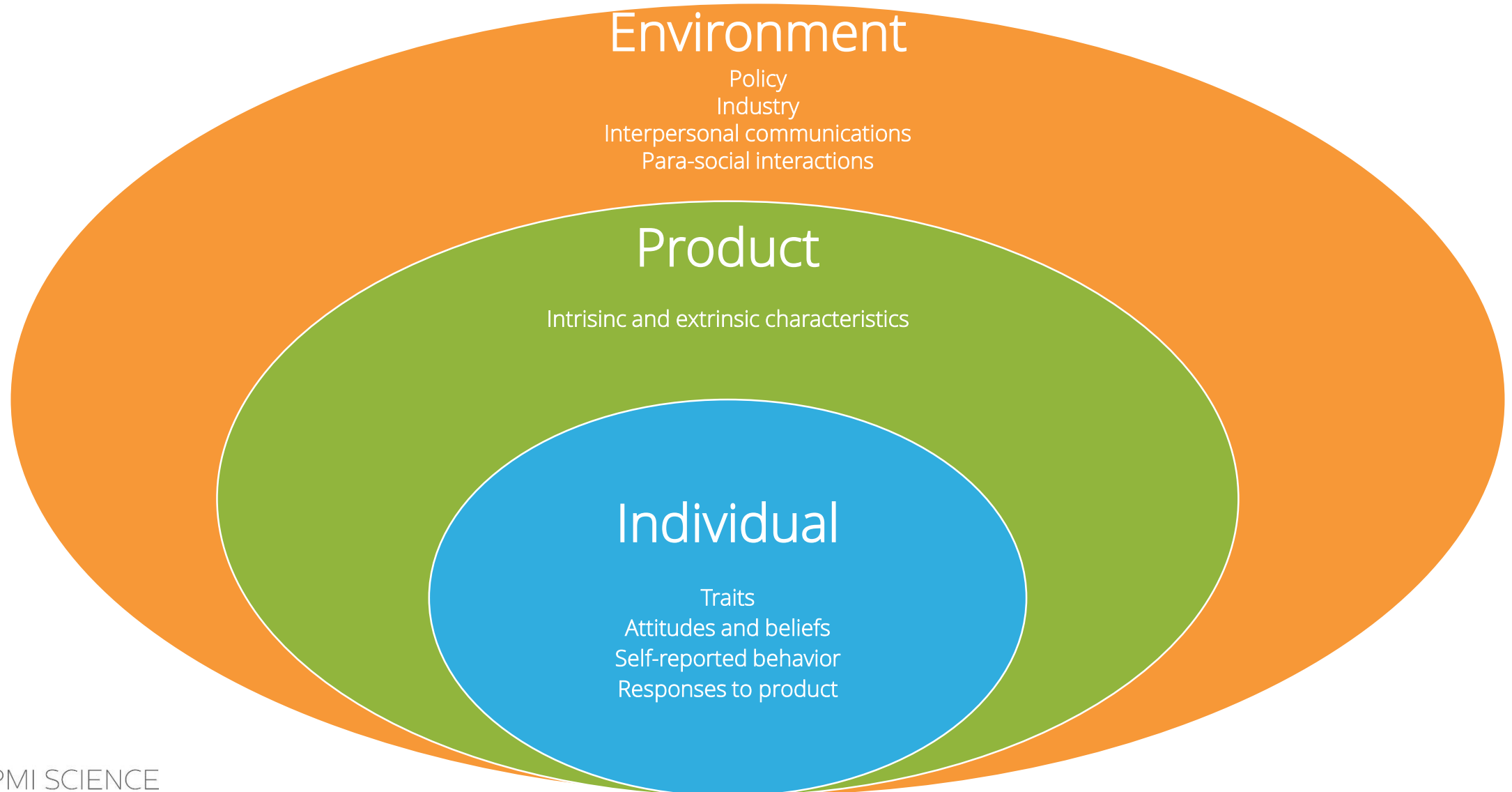
VECTOR = industry and retailer

ENVIRONMENT = tobacco control and contextual factors





# Summary of Concepts from Conceptual Models



# PhenX Toolkit: Tobacco Regulatory Research Collections

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# PhenX Measures for Tobacco Regulatory Research

- U.S. FDA's Center for Tobacco Products and the National Institutes of Health Tobacco Regulatory Science Program
- Expand the depth and breadth of tobacco-related measures
- Goal: establish consensus measures in tobacco regulatory research

# PhenX Toolkit: Available Measures

<p><b>Core Tier 1</b> Deemed relevant and essential to all areas of tobacco regulatory research and require very little time to collect</p>	<ul style="list-style-type: none"> <li>▶ Current Age</li> <li>▶ Ethnicity</li> <li>▶ Race</li> <li>▶ Gender</li> <li>▶ Current Marital Status</li> </ul>	<ul style="list-style-type: none"> <li>▶ Current Educational Attainment</li> <li>▶ Current Employment Status</li> <li>▶ Use of Tobacco Products</li> <li>▶ Tobacco – Nicotine Dependence</li> <li>▶ Electronic Nicotine Product Device Type</li> </ul>	<p><b>Agent</b> Assessment of the tobacco product</p>	<ul style="list-style-type: none"> <li>▶ Tobacco Brand and Variety</li> <li>▶ Passive Exposures to Tobacco Products</li> <li>▶ Nicotine Content</li> <li>▶ Tobacco Warning Label Exposure and Recall</li> </ul>	<ul style="list-style-type: none"> <li>▶ History of Switching to Lower Tar and Nicotine Cigarettes</li> <li>▶ Physical Properties of Tobacco Products</li> <li>▶ Tobacco Product Adulteration–Vent or Filter Blocking</li> </ul>
<p><b>Core Tier 2</b> Also relevant to many areas of TRR but are more specialized and require a greater time commitment</p>	<ul style="list-style-type: none"> <li>▶ Annual Family Income</li> <li>▶ Child-reported Parental Education Attainment</li> <li>▶ Self-reported General Health Status</li> <li>▶ Veteran Status</li> <li>▶ Peer and Family Influence on Smoking</li> <li>▶ Flavor Preference – e-cigarettes</li> <li>▶ Tobacco Brand and Variety</li> <li>▶ Self-reported Tobacco Product Price Paid</li> <li>▶ Exposure to Tobacco Advertising on the Internet and Social Media</li> </ul>	<ul style="list-style-type: none"> <li>▶ Internalizing, Externalizing, and Substance Use Disorders Screener</li> <li>▶ Self-Reported Craving</li> <li>▶ Smoking Quit Attempts</li> <li>▶ Passive Smoke Exposure</li> <li>▶ Cotinine</li> <li>▶ Blunt Use</li> </ul>	<p><b>Vector</b> Assessment of the industry and retailer activities</p>	<ul style="list-style-type: none"> <li>▶ Use of Tobacco Products</li> <li>▶ Self-reported Tobacco Product Purchase Location</li> <li>▶ Self-reported Exposure to Tobacco Product Sponsorships</li> <li>▶ Illicit Tobacco Products</li> <li>▶ Self-reported Tobacco Product Price Paid</li> <li>▶ Tobacco Industry and Retailer Public Relations</li> <li>▶ Self-reported Exposure to Tobacco Product Advertisements</li> </ul>	<ul style="list-style-type: none"> <li>▶ Self-reported Exposure to Tobacco Advertising at Point of Sale</li> <li>▶ Exposure to Tobacco Marketing Through Internet and Social Media Use</li> <li>▶ Self-reported Exposure to and Use of Price Promotions for Tobacco Products</li> <li>▶ Use of a Regular Brand of Tobacco</li> <li>▶ Standardized Tobacco Assessment for Retail Settings</li> </ul>
<p><b>Host: Social/Cognitive</b> Assessment of the Intrapersonal factors that influence product use, including cognitive, affective, motivational, and perceptual factors</p>	<ul style="list-style-type: none"> <li>▶ Behavior Economics/Purchase Behavior</li> <li>▶ Quality of Communication about Smoking</li> <li>▶ Attention</li> <li>▶ Peer and Family Influence on Smoking</li> <li>▶ Hedonic Tone or Response to Pleasurable Situations</li> <li>▶ Susceptibility to Smoking Cigarettes</li> </ul>	<ul style="list-style-type: none"> <li>▶ Multigroup Ethnic Identity</li> <li>▶ Frequency of Communication About Smoking</li> <li>▶ Motivation to Quit</li> <li>▶ Distress Tolerance</li> <li>▶ House Rules About Tobacco Use</li> </ul>	<p><b>Environment</b> Assessment of other environmental factors influencing tobacco use</p>	<ul style="list-style-type: none"> <li>▶ Self-reported Exposure to Smoking on Television and in the Movies</li> <li>▶ Media Use</li> <li>▶ State Tobacco Control Public Policies</li> <li>▶ Youth Cigarette Purchase Behaviors and Experiences</li> <li>▶ Local Tobacco Control Public Policies</li> <li>▶ Interpersonal Communication about Anti-tobacco Advertising</li> <li>▶ Social Norms About Tobacco</li> </ul>	<ul style="list-style-type: none"> <li>▶ Aided and Confirmed Awareness of Televised Anti-tobacco Advertisements</li> <li>▶ Neighborhood-level Racial/Ethnic Composition</li> <li>▶ Perceived Effectiveness of Anti-tobacco Advertising</li> <li>▶ Worksite Policies</li> <li>▶ Compliance with Cigarette Packaging and Labeling Policies</li> </ul>
<p><b>Host: Biobehavioral</b> Assessment of the descriptive, behavioral, or biological measures that characterize product use, exposure, and potential or actual adverse health outcomes</p>	<ul style="list-style-type: none"> <li>▶ Withdrawal from Tobacco Use</li> <li>▶ Flavor Preference–e-cigarettes</li> <li>▶ Pregnancy Status–Mother and Baby Health</li> <li>▶ Cotinine in Serum</li> <li>▶ Pregnancy Status and Tobacco Use</li> </ul>	<ul style="list-style-type: none"> <li>▶ Cue Reactions to Tobacco Stimuli</li> <li>▶ Expired Carbon Monoxide</li> <li>▶ Amount, Type, and Frequency of Recent Cigarette Use</li> <li>▶ NNAL in Urine</li> </ul>			

# PhenX Toolkit: Available Measures

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Remaining challenge: most measures have been developed in the context of cigarette use/smoking behavior

Fit-for-purpose instruments must be developed

# Application of Regulatory Guidance in the Development of Measurement Instruments

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# Regulatory Requirements

## M RTP draft guidance (2012)

- FDA recommends applicants to submit scientific studies assessing consumers' beliefs about the health risks of using the product relative to:
  - Other tobacco products
  - Cessation aids
  - Quitting all tobacco use



## Guidance on Patient-Reported Outcome Measures (2009)

- FDA recommendations for patient-reported rating scales highlight the importance of conceptually sound, reliable, and valid measures

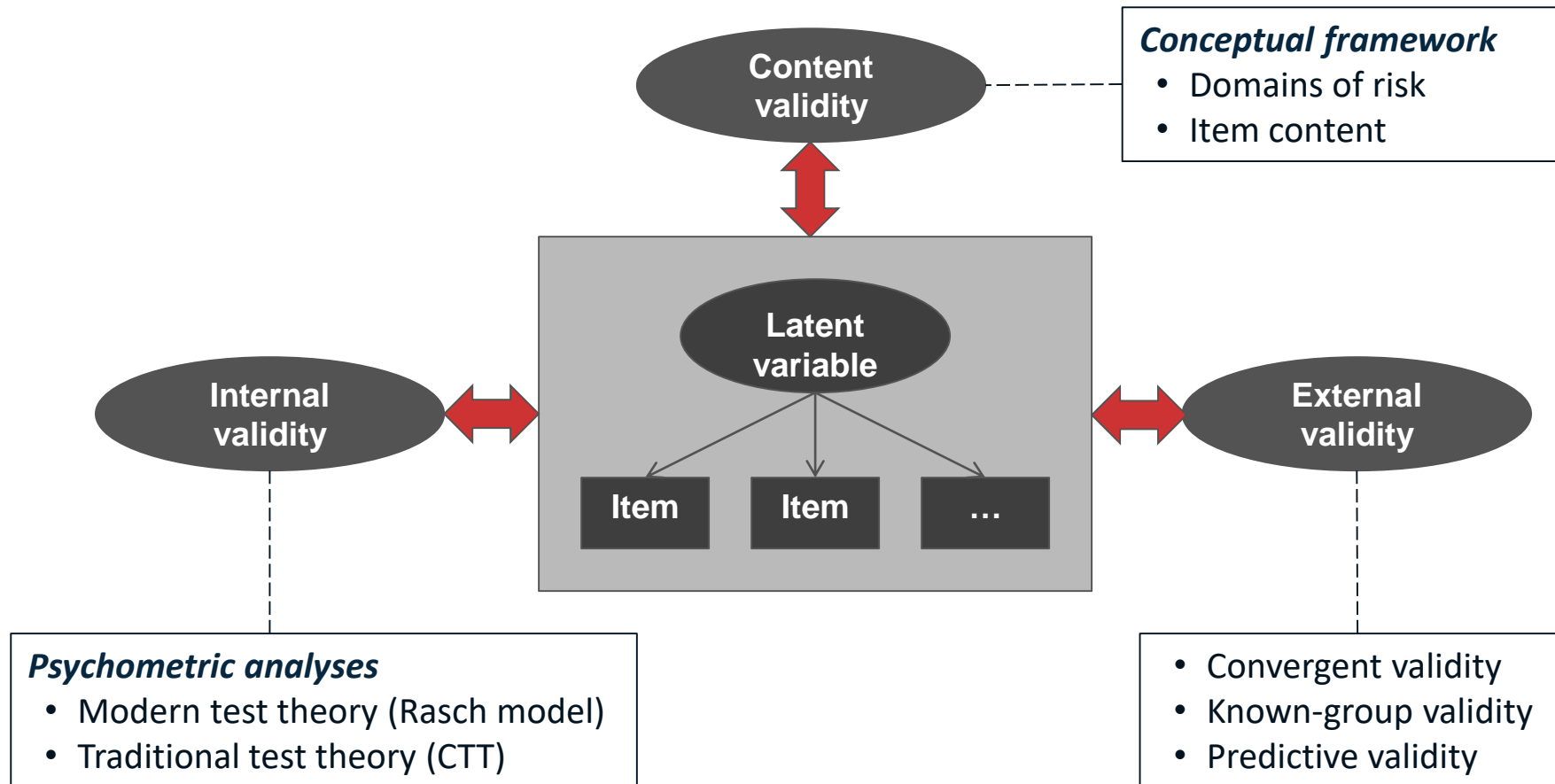


# Problems with Single Item Scales/Visual Analog Scales (VAS)

- Single ambiguous question to represent a complex problem
- May not be measuring what you think/hope
- Poor reliability
- Poor ability to detect change
- May provide misleading information
- Very difficult to evaluate measurement properties



# Challenge of Measuring Latent Constructs



# US Food and Drug Administration's Center for Tobacco Products' Expectations on Risk Perception Measure

FDA briefing document for the Tobacco Products Scientific Advisory Committee (TPSAC) meeting on Swedish Match Modified Risk Tobacco Products Application (MRTPA)

- Measures of relative and absolute risk perception:

*"Results concerning the relative risks of snus compared to cigarettes are only part of the picture [...]. Equally important are public perceptions of the absolute (i.e., non-comparative) health risks of snus use... Understanding the appropriateness of the absolute level of risk perception, although highly challenging, is crucial to evaluation whether consumers have an appropriate understanding of the modified risk information."*

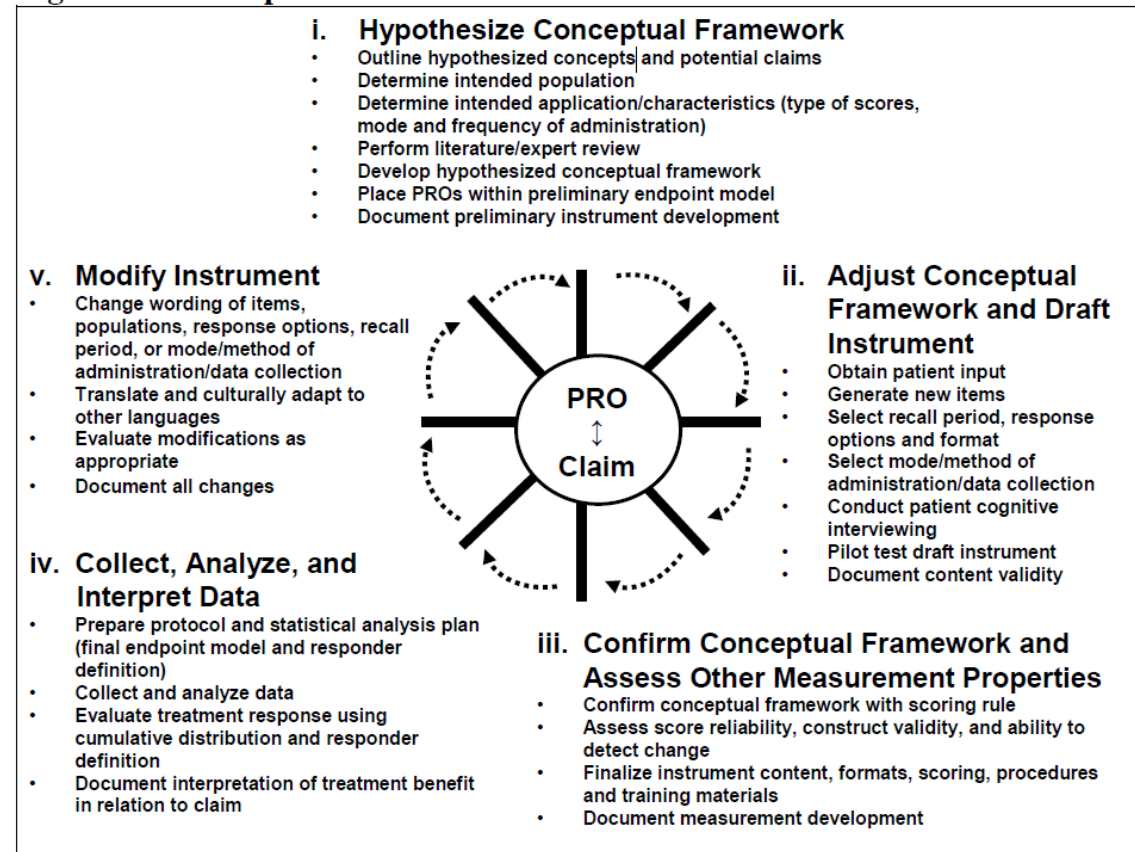
# FDA CTP Expectations on Risk Perception Measure

## Feedback from the Meeting Information Package on PMI's Perception and Behavior Assessment Program

- *“FDA recommends that [...] provide clear scientific rationale and justification for the selected measures and response options.”*
- *“We recommend that cognitively test the questions, the response options and the instrument itself to ensure that participants are likely to respond appropriately to the questions.”*
- *“We have concerns about the validity of measures developed using questions that force respondents to respond to questions to which they may have no response.”*
- *“We recommend that you develop a plan for ensuring that a translation of the questionnaire [...] conveys a common understanding of the concepts being measured across cultures and languages.”*

# Development of a Self-report Instrument: An Iterative Process

Figure 3. Development of a PRO Instrument: An Iterative Process



## Phase 1: Development of Conceptual Framework & Item Generation

- Develop conceptual framework and preliminary items from consumers' input, expert panels, and literature review
- Develop draft instrument and test for comprehension



## Phase 2: Scale Formation & Item Reduction

- Pilot instrument field-tested in large representative sample of target population to confirm the conceptual framework
- Revise or eliminate items and finalize instrument



## Phase 3: Final Psychometric Validation of the Instrument

- Confirm conceptual framework with scoring rule
- Assess score reliability, construct validity, and ability to detect change
- Finalize instruments and document measurement development

# Case Study: ABOUT–Perceived Risk (Previously Perceived Risk Instrument)

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# PMI Instruments



Instrument	Concepts of interest (# items)	Context of use	Target population	Information on accessibility
Perceived Risk	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) <a href="https://eprovide.mapi-trust.org/instruments/perceived-risk-instrument">https://eprovide.mapi-trust.org/instruments/perceived-risk-instrument</a>
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 in 2019
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 in 2019
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) <a href="https://eprovide.mapi-trust.org/instruments/smoking-questionnaire2">https://eprovide.mapi-trust.org/instruments/smoking-questionnaire2</a>

# PMI Fit-for-Purpose 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) <a href="https://eprovide.mapi-trust.org/instruments/perceived-risk-instrument">https://eprovide.mapi-trust.org/instruments/perceived-risk-instrument</a>
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# Our Three-Phase Methodological Approach

## Phase 1: Development of Conceptual Framework & Item Generation

- **Literature review** on risk perception and available instruments
- **29 focus groups**, run in 4 countries (U.K., U.S., Italy and Japan)
- **1 KOL meeting** and 15 workshops with experts for instrument development
- **Cognitive Debriefing Interviews** in U.K. and U.S. to test comprehension (**N=98**), and in Italy and Japan for linguistic validation of translated versions (**N=20**)

## Phase 2: Scale Formation & Item Reduction

- **Cross-sectional web survey** conducted among respondents from U.S. population (**N= 2020**)
- **Classical Test Theory and Rasch Model Measurement psychometric analyses** to identify items that best perform as a scale for different subpopulations and different tobacco products (**targeting, item fit, reliability, item invariance, construct validity**)

## Phase 3: Final Psychometric Validation of the Instrument

- **Cross-sectional web survey** conducted among respondents from U.S. (**N = 1640**), Italy (**N=1623**), and Japan (**N= 1618**)
- **Classical Test Theory and Rasch Model analyses** to cross-validate results from the first survey, **calibrate final scales, establish the scoring rule, and confirm cross-cultural comparability** of the instrument



# ABOUT—Perceived Risk

<b>Total number of items</b>	<b>Scales</b> <ul style="list-style-type: none"><li>• Perceived Health Risk: 18 items</li><li>• Perceived Addiction Risk: 7 items</li></ul> <b>Single items</b> <ul style="list-style-type: none"><li>• Perceived Harm to Others: 2 items</li></ul>
<b>Response scale</b>	5-point Likert-like scale 0=no risk, 1=low risk, 2=moderate risk, 3=high risk, 4=very high risk A “I do not Know” response option is also proposed for each item.
<b>Mode of administration</b>	Self-administered Psychometric validation on electronic method
<b>Scoring</b>	<ul style="list-style-type: none"><li>• <b>18-item Perceived Health Risk scale</b> Sum raw score converted into a Rasch-derived measure on a 0-to-100 scale</li><li>• <b>7-item Perceived Addiction Risk scale</b> Sum raw score converted into a Rasch-derived measure on a 0-to-100 scale</li><li>• <b>Perceived Harm to Others</b> No total score, each item is described using standard descriptive statistics</li></ul>

# Context of Use of the ABOUT–Perceived Risk

## Intended Population

- Adult smokers with no intention to quit
- Adult smokers motivated to quit
- Adult former smokers
- Adult never smokers

## Frame of reference

- Ensure stability of the measurement across:
  - Different tobacco and nicotine-containing products
  - Different sub-populations
  - Different cultures

## Cognitive orientation

- Perceived risk for the individual respondent -> Personal version
- Perceived risk for the population in general -> General version

# Application of the ABOUT–Perceived Risk: Example for an MRTP

## Perceived Health Risk of an MRTP

If you were to start using <MRTP name>, what do you think would be the risk, if any, to you personally of getting the following (sometime during your lifetime) because you use <MRTP name>...						
	No risk	Low risk	Moderate risk	High risk	Very high risk	Don't know
having a bad cough that lasts for days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having poor gum health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having lung cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
occasional wheezing (difficult breathing that produces a sound)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having mouth or throat cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
aging faster (for example, wrinkles on the face)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
being sick with frequent minor illnesses (for example, coughs and colds)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having regular respiratory infections (for example, bronchitis, pneumonia)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having a serious illness (for example, chest pain, vascular disorder, diabetes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having reduced stamina	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having emphysema (serious lung disease)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having a cough early in the morning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
losing some sense of taste	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having heart disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
an earlier death	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having sores of the mouth or throat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
being physically unfit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having other types of cancer (besides mouth, throat, or lung)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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# Application of the ABOUT–Perceived Risk for Different Smoking Status

## Perceived Addiction Risk of NRTs for a current smoker

If you were to stop smoking cigarettes and start using NRTs instead, what do you think would be the risk, if any, to you personally of experiencing the following because you use NRTs... ..						
	No risk	Low risk	Moderate risk	High risk	Very high risk	Don't know
being unable to quit NRTs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feeling addicted to NRTs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
having to use NRTs to feel better	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feeling like you have to use NRTs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feeling like you can't stop using NRTs even though you know it is not good for you	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feeling unable to quit NRTs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

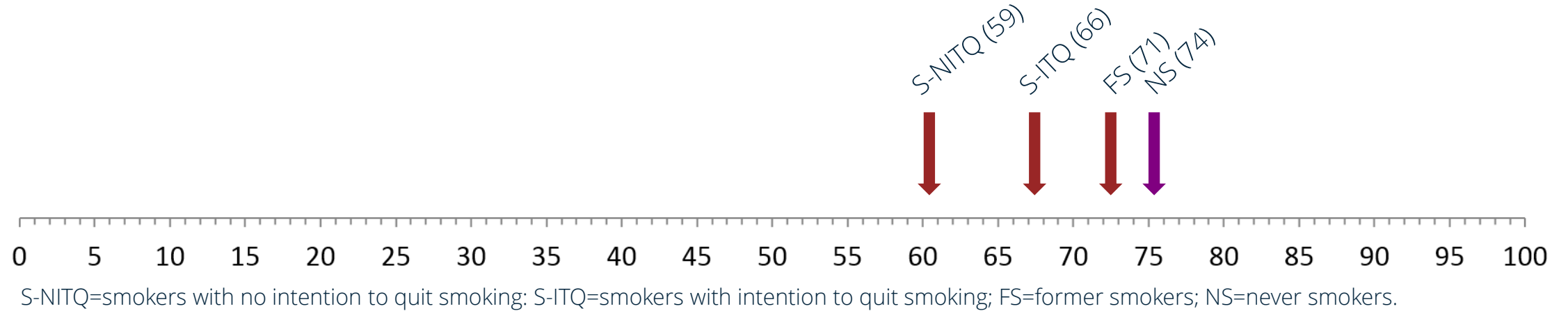
## Perceived Harm to others of cigarettes for a never smoker

If you were to start smoking, what do you think would be the risk, if any, to others because you smoke cigarettes ...						
	No risk	Low risk	Moderate risk	High risk	Very high risk	Don't know
harming others through your second hand smoke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
harming the unborn baby because you (the mother or the father) use <product name> during pregnancy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

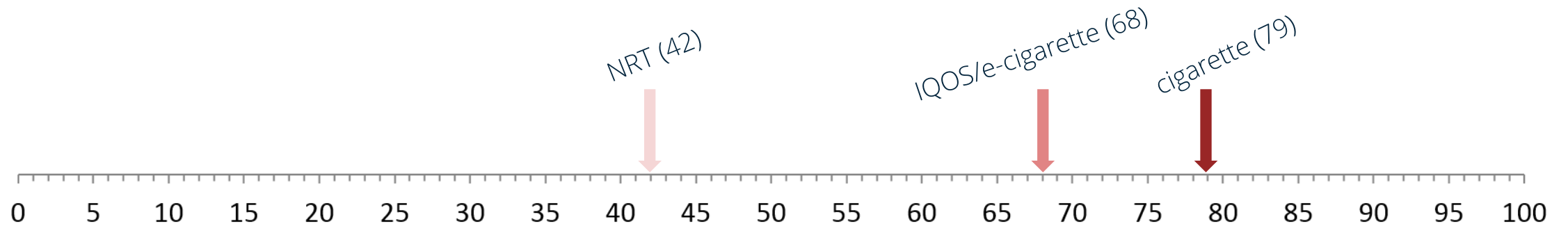
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# Application of the ABOUT–Perceived Risk

Comparison of Health Risk for cigarettes among different smoking status



Comparison of tobacco and nicotine products on Addiction Risk



# In Brief

- The ABOUT–Perceived Risk fills an important gap by providing a validated psychometric instrument for measuring and comparing the perceived risk of tobacco-related products from the consumer’s perspective
- Considering the defined context of use, the instrument provides a comparable measurement for Personal/General risk, different smoking status groups, various products, and different cultures
- Potential to support clinical and population-based studies and evidence-based product assessment to meet regulatory requirements
- The ABOUT–Perceived Risk and its user manual is publically available through MAPI Research Trust

<https://eprovide.mapi-trust.org/index.php/instruments/about-perceived-risk-formally-perceived-risk-instrument-pri>

# Conclusion

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# Conclusion

- Several behavioral conceptual models that try to explain predict TNP behaviors exist
- Measures exist; however, development of fit-for-purpose measures is required
- FDA's PRO guidance provides the framework for the development of new measurement instruments
- To address measurement challenges, multiple-item measurement instruments should be considered over single items
- PMI's ABOUT–Perceived Risk provides a case study of measurement instrument development in a regulatory context



# Interested in measuring TNP behaviors and antecedents to behaviors?



**Cooperation Centre for Scientific Research Relative to Tobacco**

*Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac*

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**TASK FORCES**

**CROM - Consumer Reported Outcome Measures Consortium - 2018**

Thank you.  
Questions?

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