

Use of qualitative research to ensure we measure what matters to users of tobacco and nicotine products

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CORESTA CROM Symposium

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CROM Symposium 2020

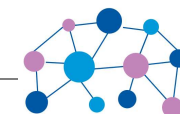
**Consumer Reported Outcome Measures
in Tobacco and Nicotine Research**

December 10, 2020 | 4:00 - 7:00 pm CET

A Virtual Event

The ABOUT**Toolbox** Initiative

Assessment of Behavioral OUTcomes
related to Tobacco and nicotine products



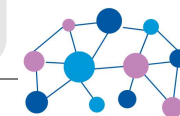
- A portfolio of **consumer-reported outcome measures** (CROM) to support **perception** and **behavior** assessment related to the use of tobacco and nicotine products (TNP)
- Developed in collaboration with scientific experts in the fields of measurement science, tobacco/nicotine research, and consumer perception
- By using best measurement and development practices, these measures are to be made **fit for purpose** to accurately assess both combustible and smoke-free TNPs



Current portfolio

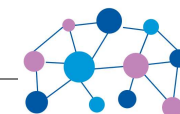


Available on PROQOLID, via the
Mapi Research Trust eProvide
platform
<https://eprovide.mapi-trust.org>



✓ ABOUT–Perceived Risk	➤ Measures respondents' perceptions of the individual and general risks associated with a range of TNPs.
✓ ABOUT–Product Experience	➤ Measures respondents' sensorial experience associated with a range of TNPs.
In development (2021) ABOUT–Tobacco Exposure	➤ Measures respondents' self-reported use of a range of TNPs.
✓ ABOUT–Dependence	➤ Measures respondents' perceived level of dependence associated with the use of a range of TNPs .
In development (2021) ABOUT–Health and Functioning	➤ Measures respondents' perception of health and functioning status associated with the use of a range of TNPs.

Measuring what matters



Guidance for Industry



Outcomes and outcome measures: Measuring what matters is in the eye of the beholder

Key words

■ Outcomes research ■ Measurement issues and assessments ■ Occupational therapy practice, research based

ISPOR TASK FORCE REPORTS

Content Validity—Establishing and Reporting the Evidence in Newly Developed Patient-Reported Outcomes (PRO) Instruments for Medical Product Evaluation: ISPOR PRO Good Research Practices Task Force Report: Part 1—Eliciting Concepts for a New PRO Instrument

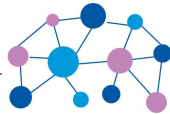
Donald L. Patrick, PhD, MSPH^{1,*}, Laurie B. Burke, RPh, MPH², Chad J. Gwaltney, PhD³, Nancy Kline Leidy, PhD⁴, Mona L. Martin, RN, MPA⁵, Elizabeth Molsen, RN⁶, Lena Ring, PhD⁷

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Food and Drug Administration. Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making 2020. Available from <https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>
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Food and Drug Administration. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims 2009. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims>
Backman CL. Outcomes and outcome measures: measuring what matters is in the eye of the beholder. *Can J Occup Ther*. 2005 Dec;72(5):259-64. doi: 10.1177/000841740507200501. PMID: 16435586.
Patrick D, Burke L, Gwaltney C, Leidy N, Martin M, Molsen E, et al. Content validity – establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO good research practices task force report: Part 1 – eliciting concepts for a new PRO instrument. *Value in Health*. 2011;14(8):967-77.

Measuring what matters



Guidance for Industry

From whom to get input, and why?

How to collect the information?

What to ask, and why?

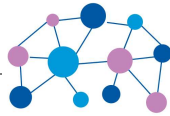
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¹Depart
Silver Spring, MD, USA; ²Department of Community Health, Brown University, Providence, RI, USA; and PRO Consulting, Pittsburgh, PA, USA; ³United Biosource
Corporation, Bethesda, MD, USA; ⁴Health Research Associates, Inc., Seattle, WA, USA; ⁵International Society for Pharmacoeconomics and Outcomes Research,
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Pharmacy, Uppsala University, Uppsala, Sweden

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Why develop ABOUT–Health and Functioning?

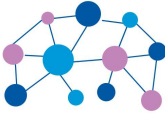


In light of **tobacco harm reduction** strategies and the increasing availability of **less harmful alternative smoke-free TNPs**:

- Important to measure self-reported experience and changes in the health and functioning status of individuals who switch from cigarettes smoking to using smoke-free TNPs
- No established fit-for-purpose and standardized TNP-specific measure

Develop a new **valid, reliable, responsive, interpretable, and adaptable** self-report measure to assess the **impact of different** tobacco and nicotine **products** on consumer's **health and functioning**

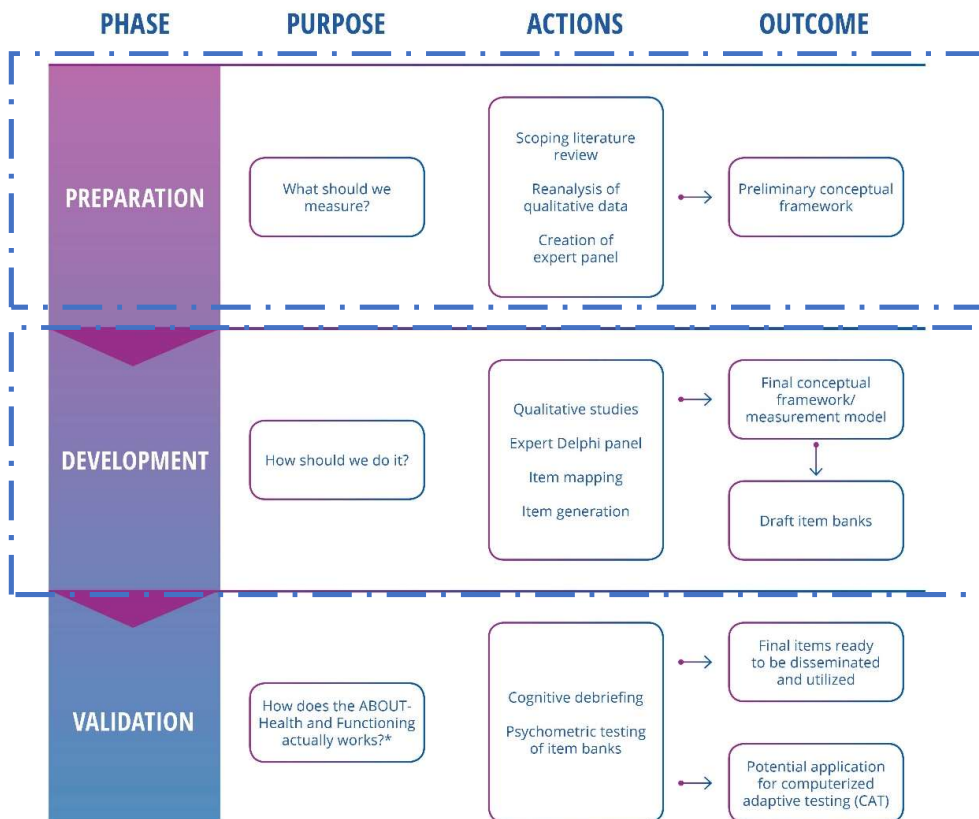
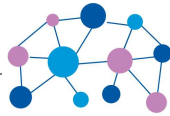
Why develop ABOUT–Health and Functioning?



“**Health** is a state of complete **physical**,
mental, and **social well-being** and not
merely the absence of disease or infirmity”

World Health Organization (WHO) Constitution

Project Roadmap



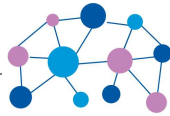
Triangulation of evidence led to:

Drafting of a **preliminary conceptual model**

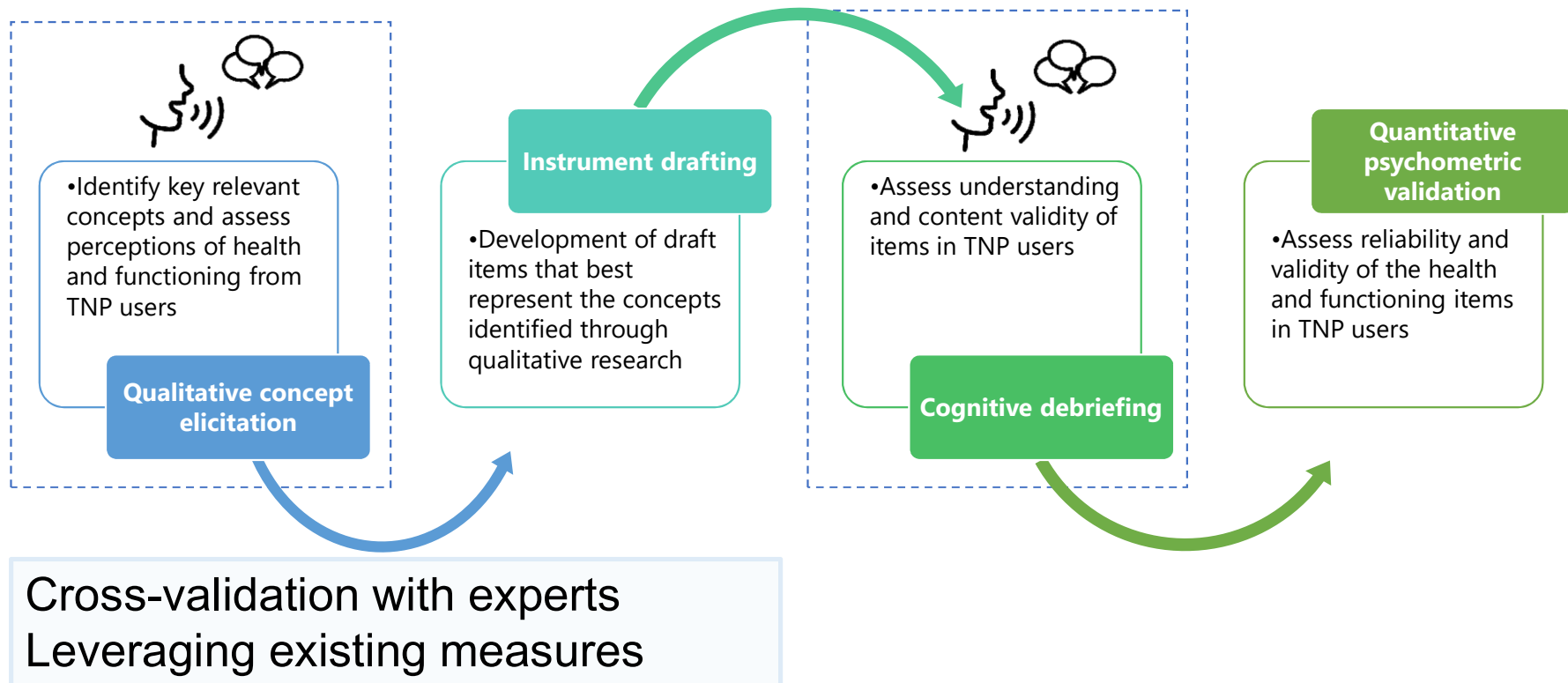
Identification of 69 **concepts across the core health and functioning domains** impacted by TNP use and conceptually related domains

* It is built on on the concepts of
 - *validity*: it measures what it is meant to measure;
 - *reliability*: it measures consistent and reproducible results between repeated assessments under several conditions.

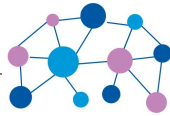
ABOUT–Health and Functioning Development



Where does the consumer voice come in?



ABOUT—Health and Functioning — Who and what to measure?



Target population

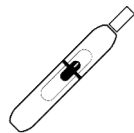
- Sufficient representation in the population (demographics [age, sex, ethnicity, education level etc.]; cultural background, and language; healthy population; health comorbidities)

Aspects of health and functioning that may change upon switching

- Experiences, perspectives, needs, and priorities important to consumers
- Signs and symptoms and how these affect day-to-day functioning and quality of life

• Applicability to a wide range of tobacco and nicotine product use characteristics

- Product types (switching from cigarettes to major types of smoke-free TNPs)
- User types (exclusive and multiple product use)



Heated Tobacco Products



Smokeless Tobacco

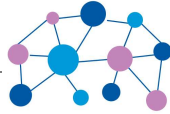


E-Cigarettes



Nicotine Replacement Therapy (NRT)

Qualitative Concept Elicitation



Objectives

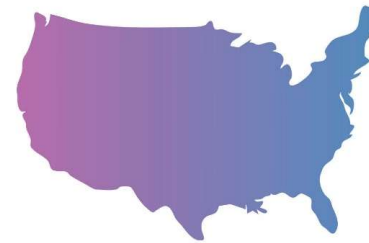
Identify key relevant concepts and assess perceptions of **health and functioning status** as expressed by consumers **who switched from cigarette smoking to smoke-free TNPs**



GERMANY
LONGITUDINAL
INTERVIEWS



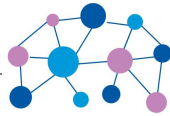
JAPAN
INDIVIDUAL
INTERVIEWS



USA
FOCUS
GROUP



Longitudinal Interviews Within a Clinical Study

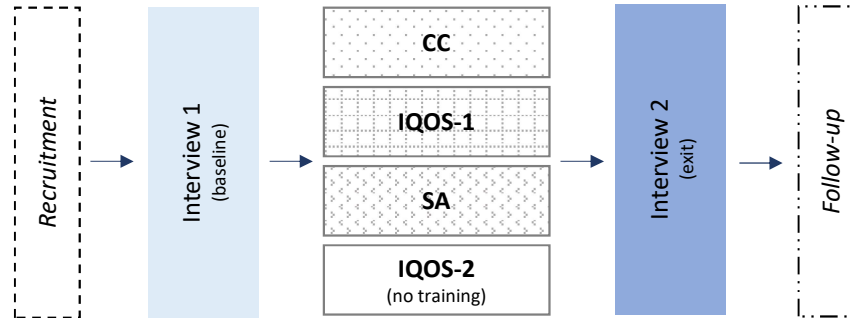


Settings

- **60-min interview**
- **Pre- and post-training** program of an exercise capacity clinical study

Participants

- Smoking + training program (n=12)
- Smoking abstinence + training program (n=13)
- Switching to IQOS + training program (n=14)
- Switching to IQOS (no training program) (n=6)

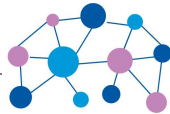


Methods

Interview guide with open-ended questions about:

- ☐ Smoking history/behaviors
- ☐ Physical activity history
- ☐ Experience in the training program
- ☐ Perceptions of health and functioning (and changes since participation in the study)

Individual Interviews



Settings

60-min F2F interviews in Tokyo and Osaka

Participants

- Smokers who switched to Glo or Ploom (n=5)
- Smokers who switched exclusively to IQOS (n=15)
- Smokers who switched to IQOS and still use cigarettes (n=15)

While smoking cigarettes



After switching to IQOS



Exclusive IQOS user, Osaka

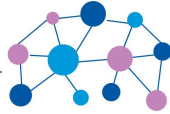
Methods

Semi-structured interview guide:

- ☐ Probes on the smallest to largest negative/positive changes upon switching to heated tobacco products
- ☐ Importance of any changes or stability
- ☐ Turning point retrospective techniques to discuss the transition when participants made the switch
- ☐ Visual collages to elicit concepts related to health and functioning before and after the switch



Focus Groups



Settings

Ten 90-min F2F focus groups
in the US (Boston, Dallas, Oklahoma,
Seattle, Atlanta)

Participants

- Exclusive e-cigarette (n=18)
- Dual e-cigarette and cigarette (n=18)
- Exclusive smokeless tobacco (n=18)
- Dual smokeless and cigarette (n=19)
- Exclusive NRT (n=9)
- Dual NRT and cigarette (n=10)

Methods

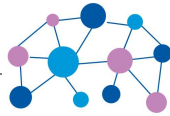
Open-ended semi-structured discussion guide

- ☐ Motivation to switch to smoke-free TNPs
- ☐ Potential positive/negative changes in health, functioning, and daily living since switching
- ☐ Reflection on the importance, timelines, and expectation of changes

Focus groups split by different TNPs and use types, age groups, and geographical rural/urban regions
Participants compared their experiences with those of others and used the group as cue to express their own views



Example of Health Concepts Elicited



Respiratory Symptoms

- Shortness of breath
- Cough
- Phlegm
- Frequent and lasting colds
- Lung discomfort
- "Black", "dirty" lungs vs "clean", "healthy" lungs
- Breathing
- Wheezing
- Chest heaviness

Oral Health Symptoms

- Teeth health (color, plaque stains)
- Bad breath
- Gum bleeding/pain
- Coating on tongue/teeth
- Black teeth
- Mouth ulcers
- Dry mouth

General physical condition (hygiene/appearance/senses)

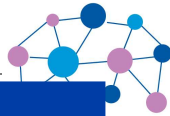
- Odor (self/clothes/hair)
- Coloring of fingers ,nails, skin
- Skin, hair, nail health
- Sense of smell
- Sense of taste
- Appetite
- Weight gain
- Eye stinging
- Eye Watering

Other physical health symptoms

- Energy
- Fatigue/tiredness
- Sleep problems
- Headaches
- Throat symptoms
- Hoarse/raspy voice
- Blood pressure
- Stomach symptoms
- Blood circulation
- Palpitations
- Racing/fast heartbeat
- Dizziness
- Heartburn

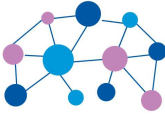
Concepts elicited in Japan, Germany and US
 Concepts elicited in Japan and US
 Concepts elicited in Germany and US
 Concepts elicited in Germany and Japan
 Concepts elicited only in Japan
 Concepts elicited only in US
 Concepts elicited only in Germany

Examples of Functioning Concepts Elicited



Physical functioning	Other functioning / daily activities	Cognitive functioning	Emotional functioning	Social functioning
<ul style="list-style-type: none"> •Physical fitness Climbing stairs •Running/jogging •Stamina/endurance •Walking •Cycling, swimming, hiking 	<ul style="list-style-type: none"> •Shopping •Sexual stamina Work productivity Time and productivity in the house/house chores Sexual desire Leisure activities/hobbies Basic activities (dressing) 	<ul style="list-style-type: none"> •Focus/concentration •Motivation to do a task •Memory •‘Wake up’ ‘Switch me on’ ‘refresh me’ 	<ul style="list-style-type: none"> •Relaxation •Stress management •Mood •Irritability •Guilt/shame •Confidence/self-esteem Life enjoyment 	<ul style="list-style-type: none"> •Social bonding with smokers and non-smokers •Stigma and perceptions from others •Interactions with children •Spouse/partner interactions •Family interactions •Interaction with colleagues •Peer pressure •Career opportunities •Going out to restaurants/bars •Going to events
<div> <p>Concepts elicited in Japan, Germany, and US</p> <p>Concepts elicited in Japan and US</p> <p>Concepts elicited in Germany and US</p> <p>Concepts elicited in Germany and Japan</p> <p>Concepts elicited only in Japan</p> <p>Concepts elicited only in US</p> <p>Concepts elicited only in Germany</p> </div>				

Further considerations from concept elicitation



Cause of changes

- Distinguishing the impact of other lifestyle changes (e.g., exercise) from the impact of switching (especially in relation to aspects of physical health)

Retrospective changes

- May be difficult to assess within the context of self-reported measurement of change

Significance of changes

- Healthy population vs. those with health comorbidities



WORLDWIDE
DELPHI
PANEL

Objectives

To **gain consensus and feedback** from **international experts** on the most important **health and functioning concepts impacted by** switching from smoking cigarette to using an alternative smoke-free TNP

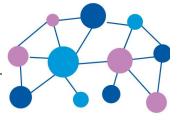
Settings

3 rounds of online survey combining qualitative and quantitative (MaxDiff ranking) assessments

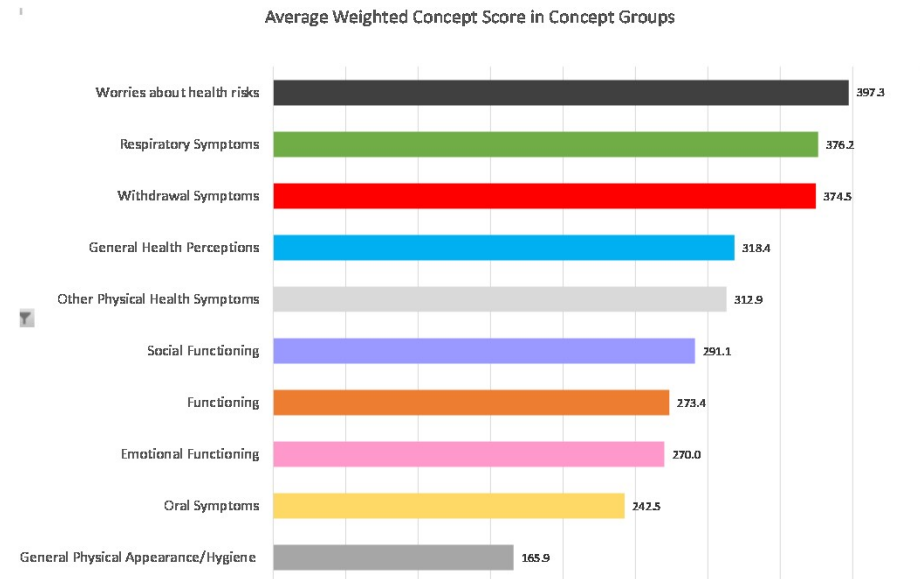
Participants

N=105 experts recruited globally, with min. 5 years of **clinical, academic, or professional experience** in smoking-related diseases, health-related quality of life, smoking cessation, dependence, and smoking-related health policy, including harm reduction

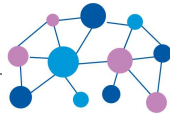
Cross-validation with Experts



Example Findings: Round 2 Experts Ranking



Leveraging existing measures



Objectives

Item mapping exercise to review conceptual coverage of existing self-report measures related to health and functioning and TNP use

Methods

Literature review and qualitative item mapping of 117 measures (~2600 items) to draft health and functioning conceptual model

Findings

- Broad range of measures and items partially assess concepts relevant to health and functioning in the context of TNP use
- Existing measures do not cover the full extent of relevant concepts
- Accurate and sensitive assessment of the impact of TNP use on health and functioning warrants further development of relevant items

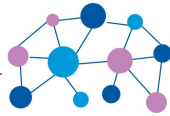
Example Item-to-concept mapping: Respiratory symptoms

	NisCl ^S	QLMI ^F	RHSQ ^I	RDS ^I	SAQ ^S	SGRQ ^F	SOBQ ^S	CRQ-SR ^S	PBA01-perceived risk ^R
Bringing up phlegm or mucus while coughing or not coughing	✓✓✓		✓✓			✓			
Shortness of breath or dyspnoea	✓✓✓ ✓✓✓ ≈≈≈	✓≈	≈			✓✓✓✓✓ ✓✓✓✓✓ ✓✓✓✓≈ ≈	✓✓✓✓✓ ✓✓✓✓✓ ✓✓✓✓✓ ✓✓✓✓✓	✓≈≈≈	≈≈≈
Cough	✓✓		✓	✓✓ ✓✓	✓	✓✓✓✓≈ ≈≈≈≈		✓	≈≈
Throat clearing									
Likelihood of getting a cold									≈
# items not mapped	1	12	8	0	9	15	0	0	21

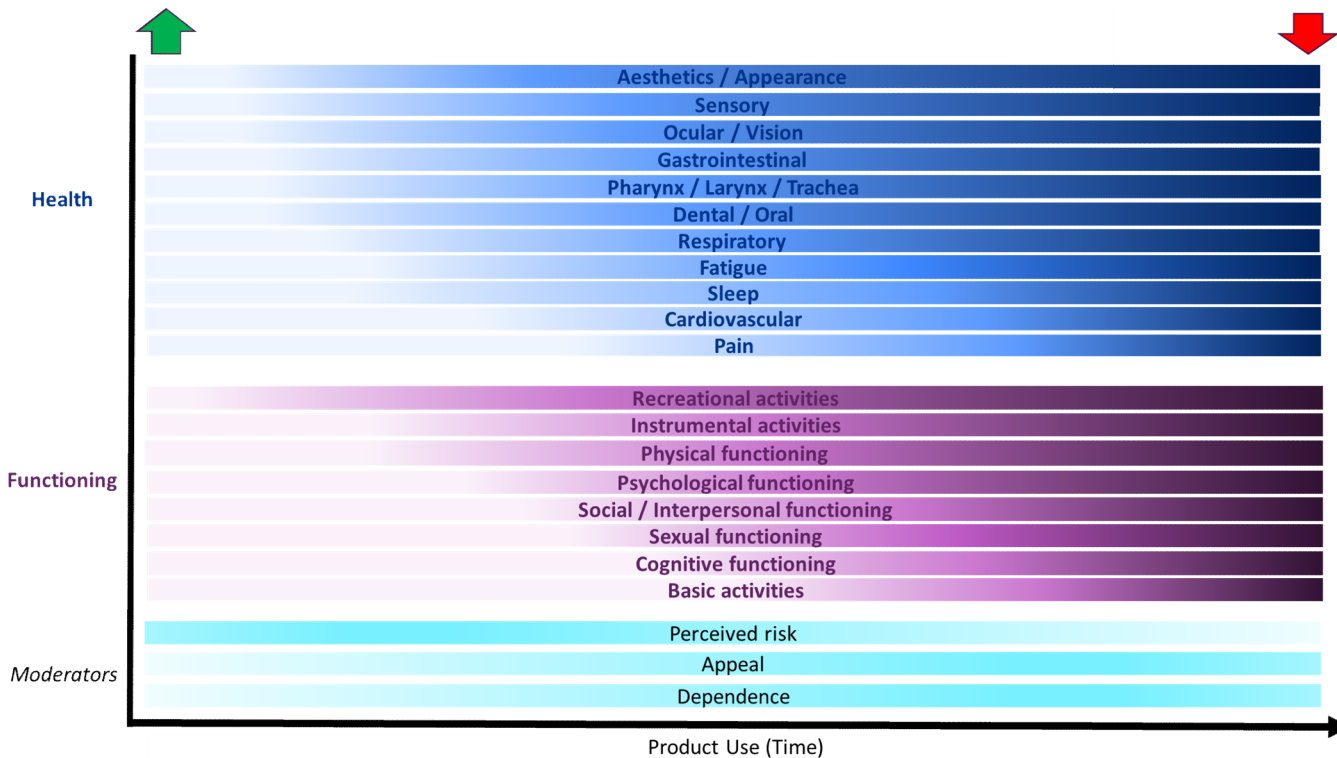
Note. ✓ indicates direct match, ≈ indicates partial match, ✓≈ indicates match in relation to TNP use.

Most common response option for instrument. S = severity, F = frequency, I = inventory, R = risk perception

What to measure? Output from development phase



HEALTH AND FUNCTIONING CONCEPTUAL MODEL



200+ ITEMS GENERATED

Health
Appearance
Gastrointestinal health
Cardiovascular health
Oral health
Throat and voice
Coughing, breathing, and lung health
Tiredness and sleep
General health

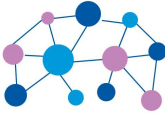
Daily functioning
Breathing during daily activities
Working life

Psychosocial functioning
Social functioning
Emotional wellbeing

Bother with smell

Health and Functioning Transition Global Items

Conclusion



Development of the ABOUT–Health and Functioning Measuring what matters to TNP consumers

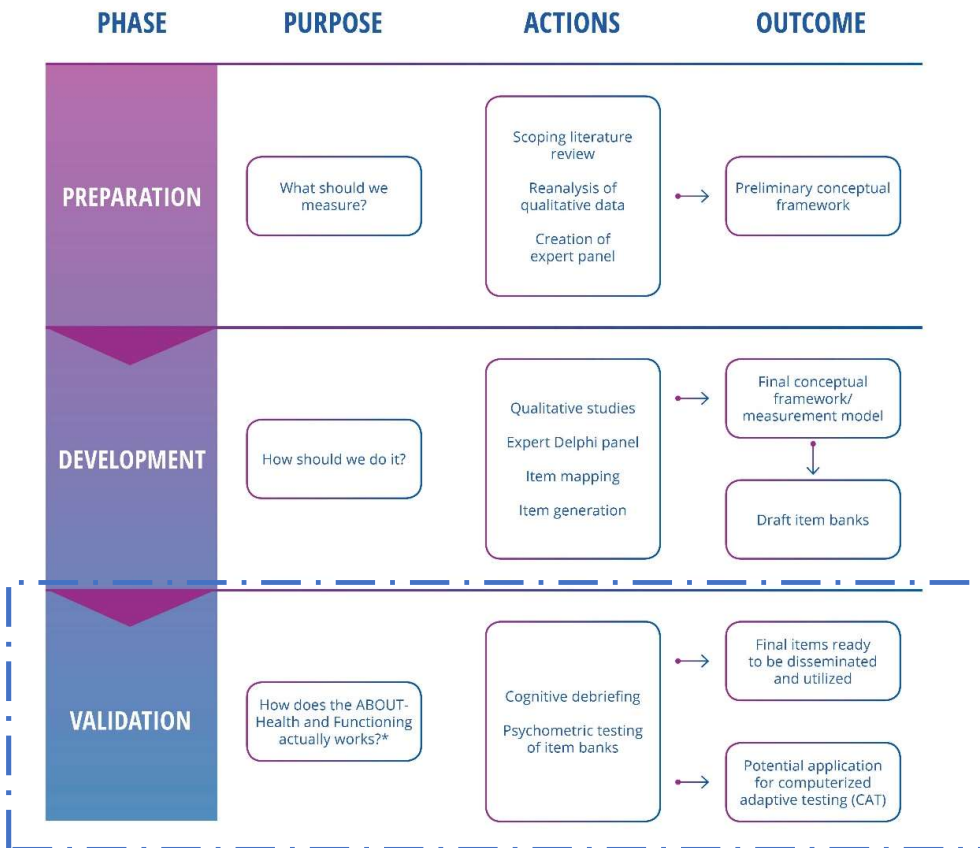
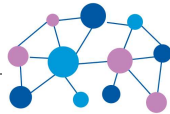
From **whom** to get input and **how** to collect the information?

- Multinational qualitative concept elicitation research among different types of TNPs consumers
- Cross-validation with an international expert Delphi Panel
- Item-mapping exercise to leverage existing self-report measures

What to measure and why?

- Document content validity and relevance to consumers
- Refine the conceptual and measurement model
- Generate draft items that best represent the most relevant concepts identified

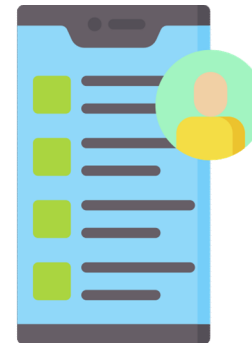
Next steps



Further input of consumer voice

Cognitive interviews in consumers

Evaluation of **appropriateness, and understanding** of draft items



Psychometric evaluation

Valid and reliable final items

CAT to facilitate efficient, accurate, engaging, and tailored administration

* It is built on on the concepts of
- *validity*: it measures what it is meant to measure;
- *reliability*: it measures consistent and reproducible results between repeated assessments under several conditions.



PMI SCIENCE
PHILIP MORRIS INTERNATIONAL

Thank you for your attention!

ACKNOWLEDGMENTS

PMI

Behavioral Science
Clinical Research
Project Management and Contracting
Consumer and Regulatory Insights
Real World Evidence
Legal Counsel
Scientific Engagement

Technical Consultants
Expert Panel
Modus Outcomes
ICON Plc
Zebra26/Dash Global
Research Participants



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