



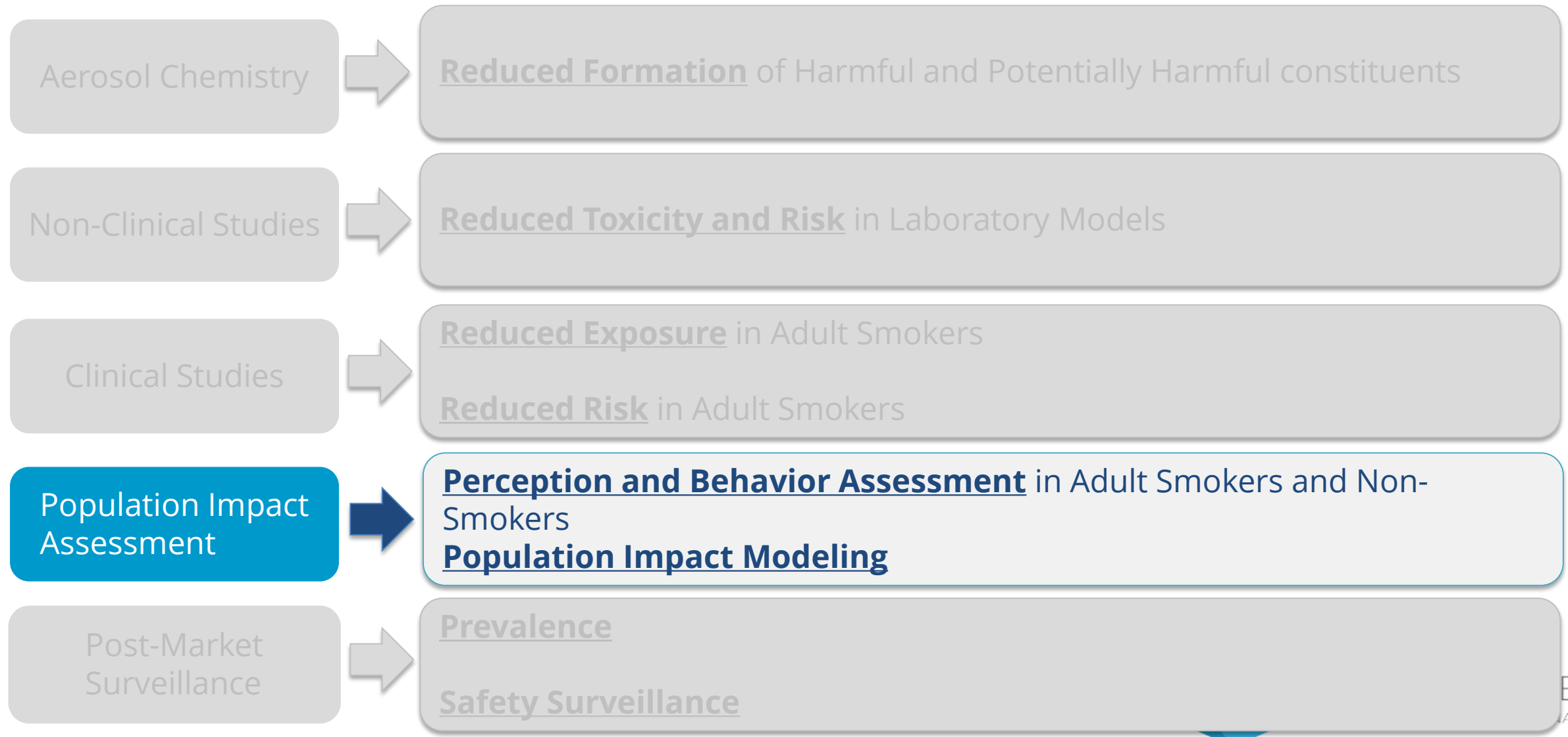
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Heat-not-Burn Products: Perception and Behavior Assessment Program Overview

Global Tobacco and Nicotine Forum 2015 Annual Meeting

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Philip Morris International
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Developing Scientific Evidence: An Overview of PMI's Approach



Preparing for Risk Communications

PMI's Objective

Commercialize products which:

- a) Reduce the health risks of smoking compared to combustible cigarettes;
- b) Are accepted by adult smokers and used instead of combustible cigarettes; and
- c) Reduce overall harm to the population



Balanced, scientifically substantiated communication

...can encourage adult smokers to switch to the products and not encourage use by non-smokers

Perception and Behavior Assessment

PMI has a comprehensive pre-market program in place to assess the impact of potential communication on:

- **Intent to use**
- **Comprehension**
- **Risk perception**
- **Usage**

Three Key Areas of Investigation

1

Effect on Tobacco Use Behavior Among Adult Smokers

Assessing the likelihood that adult smokers:

- will switch from cigarettes to *iQOS*
- use *iQOS* in conjunction with cigarettes
- switch back to cigarettes

2

Effect on Tobacco Use Initiation Among Adult Non-Smokers

Assessing the likelihood that adult never smokers and adult former smokers will initiate use of *iQOS*

3

Effect on Consumer Understanding and Perceptions

Assessing the effect potential communications will have on:

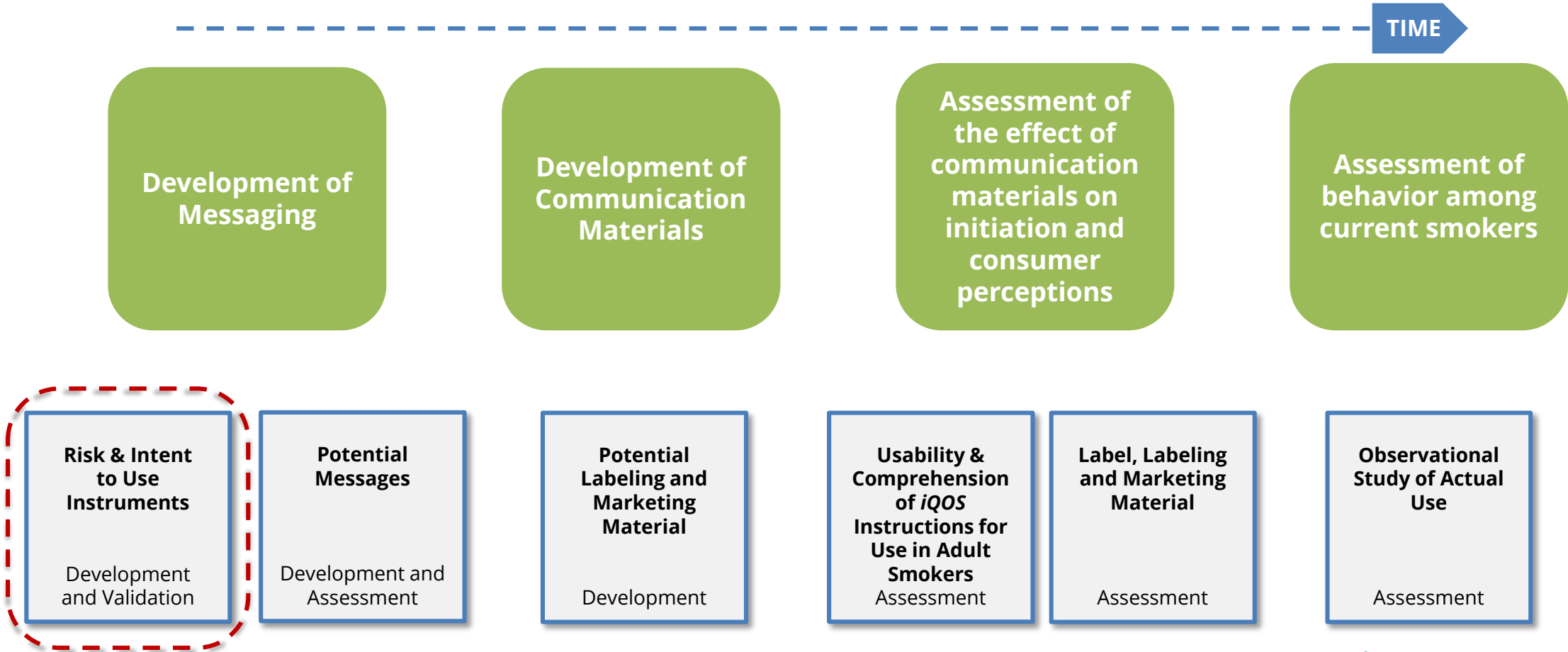
- enabling the public to comprehend information concerning modified exposure or risk claims
- public perception about the health risks of using *iQOS* in comparison to on-going smoking, NRTs and cessation



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Extended Program Overview

Supporting an FDA MRTPA application



Risk Perception and Intent to Use Instruments

PMI's Objective

Develop and validate measurement instruments to assess...

- **level of perceived risks**
- **intent to use**

...associated with different tobacco and nicotine-containing products



- Multi-country approach including North America, Asia and Europe
- Applicable to additional countries/languages by following best practice guidelines for language translation and cultural adaptation of PRO instruments (ISPOR)

Development and validation follows best practice guidelines



Development follows a rigorous process...

... and is based on FDA Guidance on Patient-Reported Outcomes

Phase 1: Initial Development

Development of a draft instrument tested for comprehension



Expert panels and literature review
Focus Groups (n=29)
Cognitive Debrief Interviews (n=98)

Phase 2: Item Reduction

Pilot instrument field-tested in large sample
Revise or eliminate items and finalize instrument



Cross-sectional online survey (n=2,020)

Phase 3: Validation

Assessment of reliability, validity and ability to detect change



Cross-sectional online survey (n=1,640)

Perceived Risk Instrument – Example

Perceived Risk Instrument domains:

a) Health Risk
(18 items)

b) Addiction Risk
(7 items)

c) Harm to Others
(2 items)



	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"/>

Intent to Use Questionnaire – Example

Intention to Try item (i.e. to sample)	Based on what you know about THS 2.2, how likely or unlikely are you ...						
		Definitely not	Very unlikely	Somewhat unlikely	Somewhat likely	Very likely	Definitely
	to try THS 2.2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Intention to Use items (i.e. continued usage)	A. If you try THS 2.2 and like it, how likely or unlikely are you...						
		Definitely not	Very unlikely	Somewhat unlikely	Somewhat likely	Very likely	Definitely
		to use THS 2.2 regularly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

29. B. If you try THS 2.2 and like it, how soon would you begin to ...							
		Within a week	Within a month	Within 3 months	Within 6 months	More than 6 months	Never
29-7	use THS 2.2 regularly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Note: THS2.2 refers to the unbranded version of *iQOS*

Preparing for Risk Communications



The ability to make balanced, scientifically substantiated **communications is critical to encourage adult smokers to switch** to Reduced Risk Products

PMI's comprehensive pre-market Perception and Behavioral Assessment program is designed to help **understand the perception of Reduced Risk Product claims** and the way in which the population is **likely to behave** if they are applied in a commercial context



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Reduced-Risk Products (“RRPs”) is the term the company uses to refer to products with the potential to reduce individual risk and population harm in comparison to smoking combustible cigarettes. PMI’s RRP’s are **in various stages of development and commercialization**, and we are conducting **extensive and rigorous scientific studies** to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke, and ultimately claims of reduced disease risk, when **compared to smoking combustible cigarettes**.

Before making any such claims, we will need to **rigorously evaluate the full set of data** from the relevant scientific studies to determine whether they substantiate reduced exposure or risk. Any such claims **may also be subject to government review and approval**, as is the case in the US today.



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Source: Philip Morris International
