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THS2.2 – A Heat-not-Burn Product Scientific Results to Date

Presentation at JMSAAS2016,
Luncheon Seminar

Gizelle Baker, PhD, Director Epidemiology and Biostatistics
Patrick Picavet, MD, Director Clinical Assessment

Philip Morris International Research & Development, Philip Morris Products SA
October 8th 2016

** Note: for the purposes of publishing on our science website we have altered the presentation to remove all commercial terminology which has been replaced with generic terms*

Agenda

- What is THS2.2?
- Results from pharmacokinetic studies in Japan
- Results from the exposure reduction studies in Japan
- The LYFE study – a post-market behavioral cohort study in Japan
- Conclusion

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THS2.2 – A Heat-not-Burn Product

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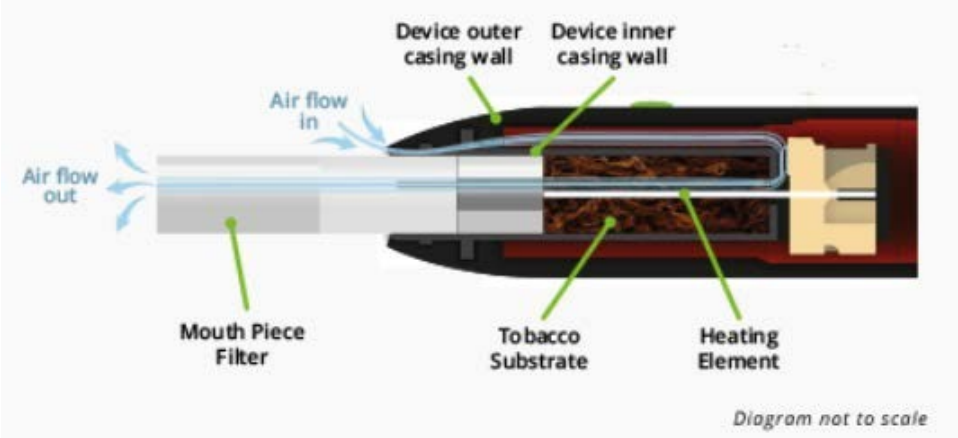
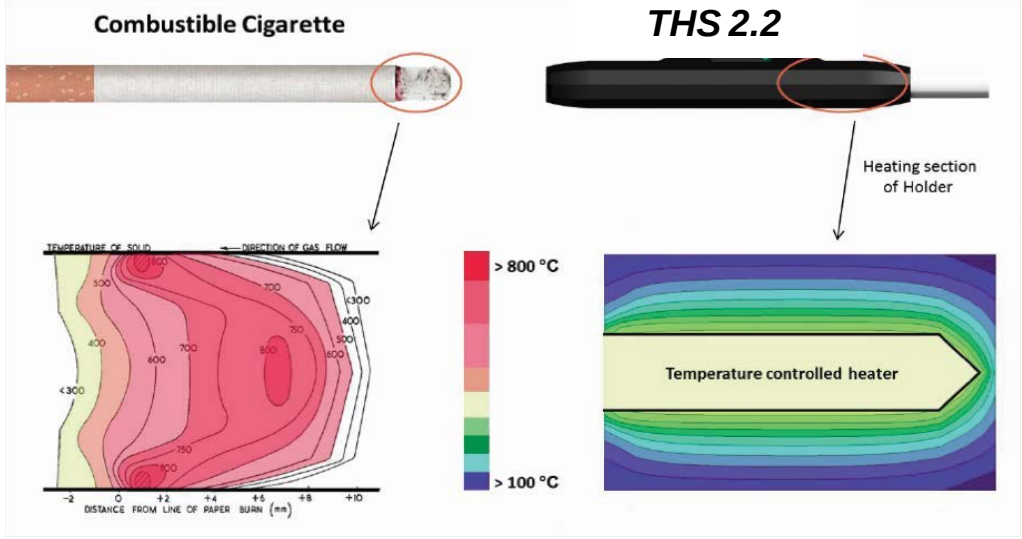
Heating Tobacco Rather than Burning It

Heat-not-Burn products such as THS2.2 are designed to:

- Heat tobacco without combustion
- Significantly reduce or eliminate the formation of harmful and potentially harmful compounds
- Preserve elements of the taste, sensory experience, nicotine delivery profile and ritual characteristics of cigarettes





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PMI's Assessment Strategy

Assessment Layers	Evidence Levels	Risk Framework	Evidence for Reduced Exposure	Evidence for Reduced Toxicity	Evidence for Reduced Risk
Clinical	**V.** Reduced Exposure and Reduced Risk in Humans		Reduced exposure studies		Clinical Risk Markers
Systems Toxicology	**IV.** Reduced Risk in Laboratory Systems		Animal model of disease study; *In vitro* studies	Animal model of disease study; *In vitro* studies	Animal model of disease study
Pre-Clinical Toxicology	**III.** Reduced Toxicity		*In vivo* studies	*In vitro* studies; *in vivo* studies	Pulmonary endpoints *in vivo*
Aerosol Chemistry	**II.** Reduced Formation		Aerosol Characterization; Indoor Air Quality		
Product Design and Controls	**I.** Absence of Combustion		Product Design Principles; Combustion Control		

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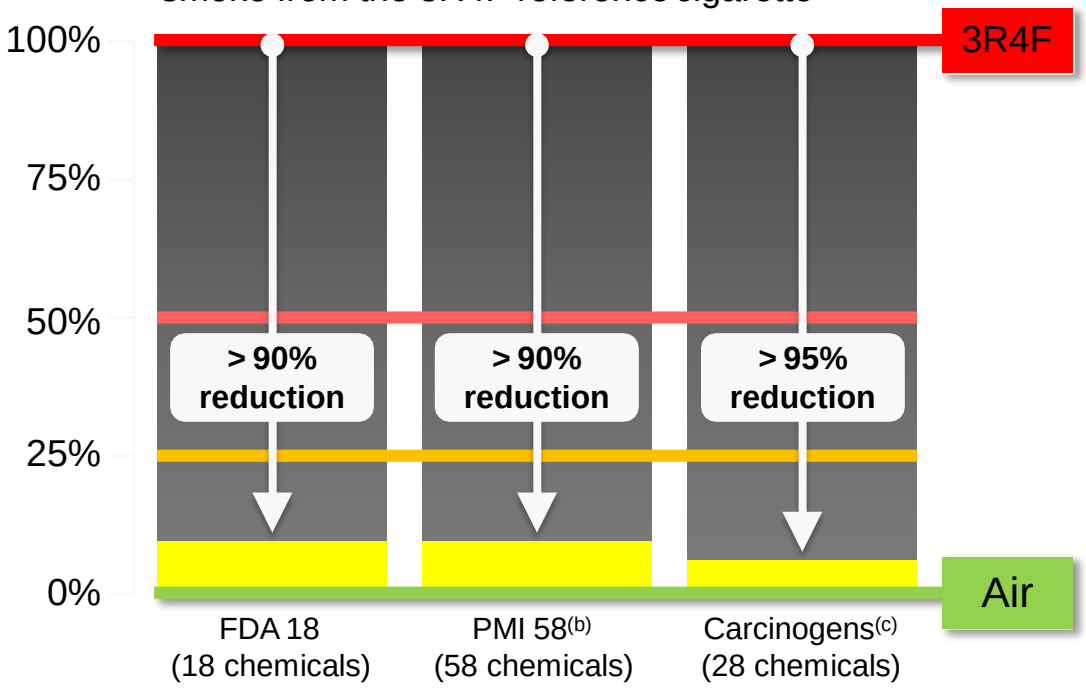
THS2.2:
Reduced Formation Leads to Reduced Toxicity In Vitro

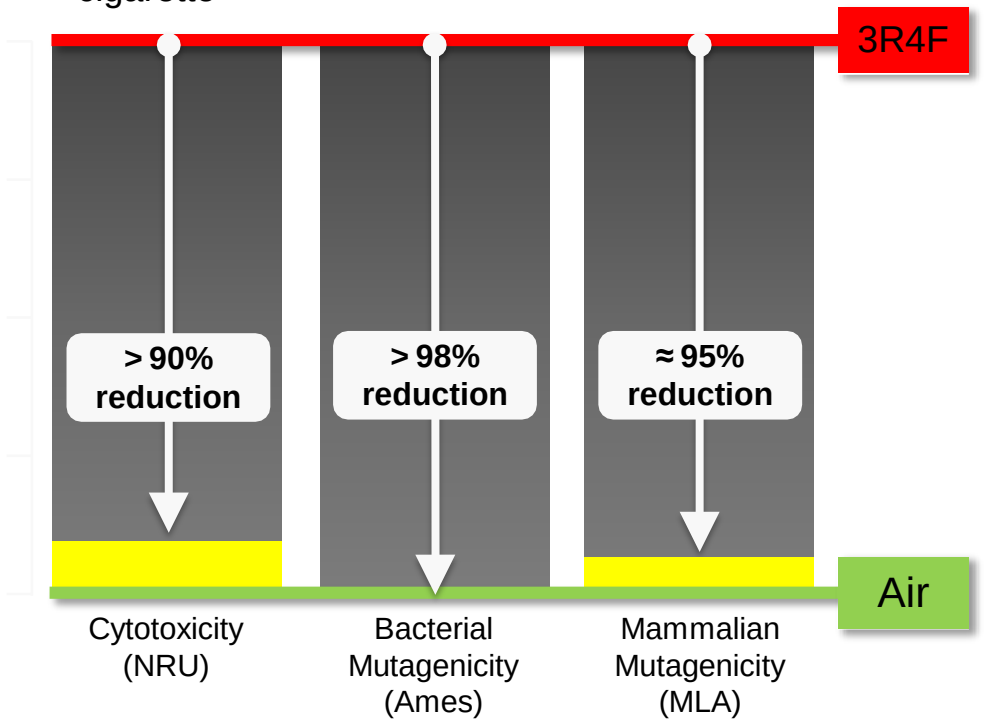
Reduced Formation

Average reductions in formation of HPHCs for THS2.2 compared to levels measured in smoke from the 3R4F reference cigarette[a]



Reduced Toxicity

Average reductions in toxicity compared to levels measured for the 3R4F reference cigarette



(a)Aerosol collection with Intense Health Canada's Smoking Regime: 55 mL puff volume, 2-second puff duration, 30-second interval puff. Comparison on a per-stick basis. Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter

(b) The PMI 58 list includes the FDA 18 and (c) the 28 carcinogens of the IARC Groups 1, 2A and 2B

Note: 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 cigarettes. These data alone do not represent a claim of reduced exposure or risk

Source: PMI Research & Development

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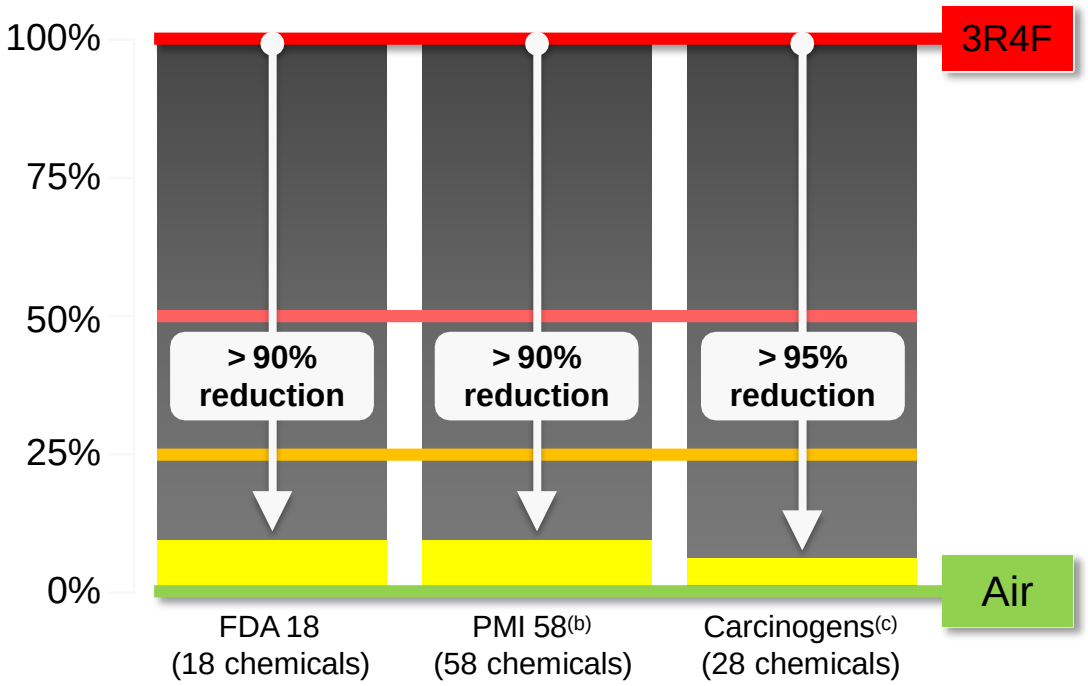
THS2.2:
Reduced Formation Leads to Improved Indoor Air Quality

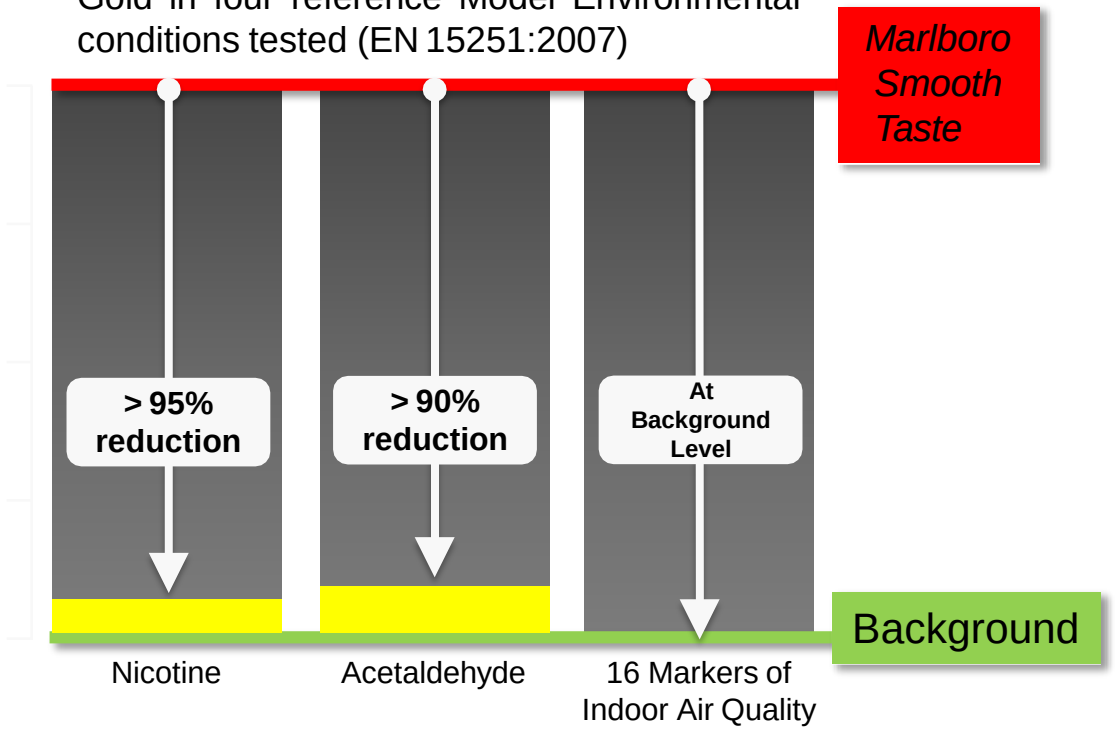
Reduced Formation

Average reductions in formation of HPHCs for THS2.2 compared to levels measured in smoke from the 3R4F reference cigarette[a]



Improved Indoor Air Quality

Use of THS2.2 does not negatively impact indoor air quality as compared to *Marlboro* Gold in four reference Model Environmental conditions tested (EN 15251:2007)



(a)Aerosol collection with Intense Health Canada's Smoking Regime: 55 mL puff volume, 2-second puff duration, 30-second interval puff. Comparison on a per-stick basis. Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter

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Note: 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 cigarettes. These data alone do not represent a claim of reduced exposure or risk.

BKG is background concentrations when non-smoking panelists were present in the controlled room Source: PMI Research & Development

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PMI's Approach to Clinical Assessment

1	2	3
Pharmacokinetics / Pharmacodynamics	**Reduced exposure**	**Exposure response**
Measures • Nicotine uptake • Subjective effects	**Measures** • Exposure to harmful and potentially harmful constituents • Clinical Risk Endpoints • Subjective effects • Safety monitoring	**Measures** • Changes in clinical risk endpoints • Safety monitoring
1 week at clinic • CC and NRT comparators • Multiple countries, races & ethnicities	**1 week at Clinic (3 months at home)** • Including assessment of dual use • Smoking abstinence arm • Multiple countries, races & ethnicities	**6 + 6 months at home** • Assessment of smoking behaviors, e.g. dual use of • US, multiple races & ethnicities

CC = combustible cigarette
NRT = Nicotine Replacement Therapy

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PK/PD Studies – Design & Results

Japan

PK-02
Regular

ClinTrial.gov ID: NCT01959607

PK-05
Menthol

ClinTrial.gov ID: NCT01967706

A Pharmacokinetic/Pharmacodynamic Study:

- *62 healthy adult smokers*
- *Confined setting*
- *Open-label, cross-over*
- *Single Product use*

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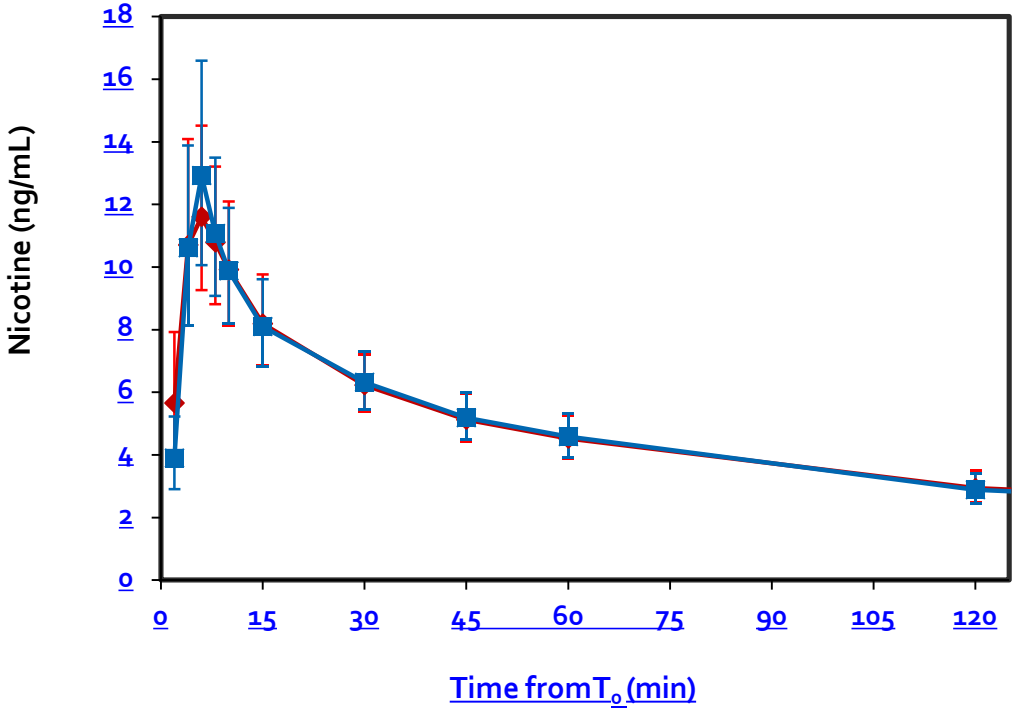
PK Studies – Japan

PK Profiles – THS2.2 and CC

THS2.2 CC

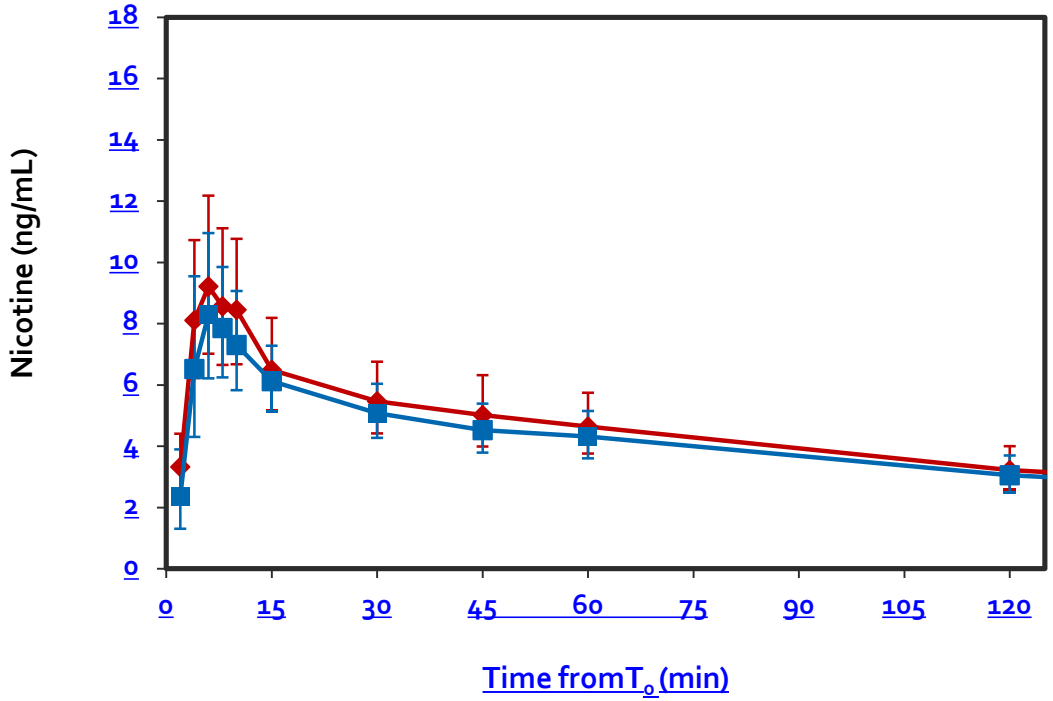
PK-02 Study JP

Regular



PK-05 Study JP

Menthol



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PK Studies – Japan

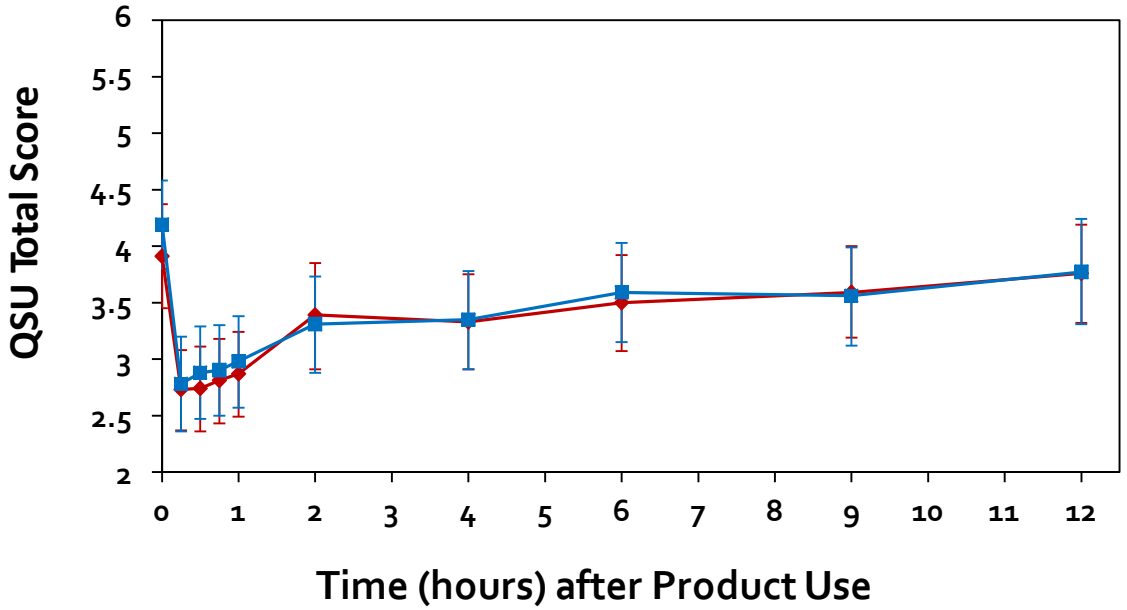
Analysis of QSU-brief questionnaire

THS2.2 CC

PK 02 Study JP

Regular

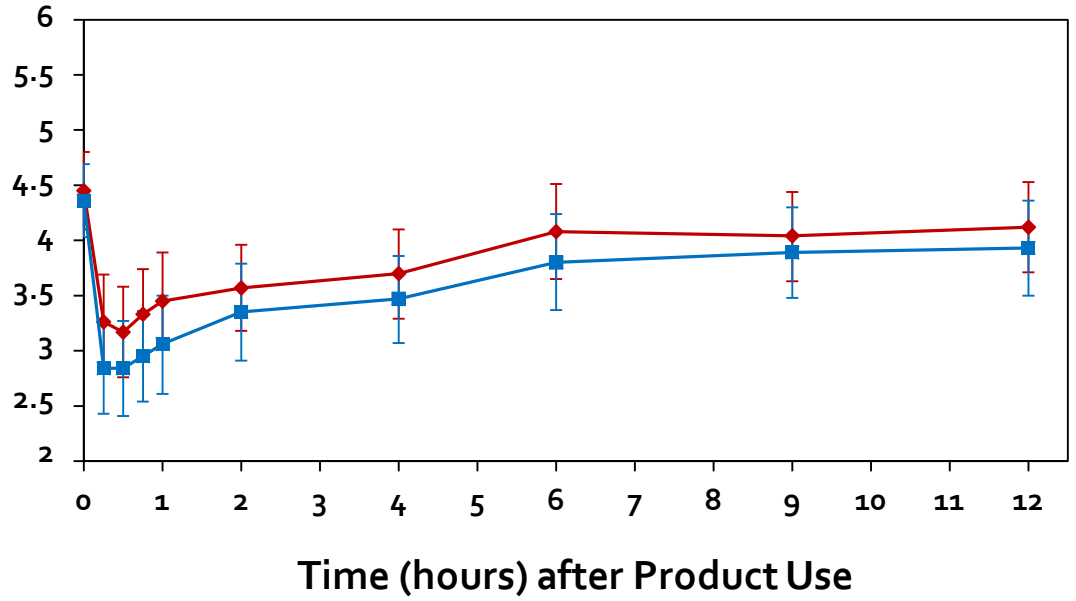
Analysis of QSU-brief Questionnaire - Total Score



PK 05 Study JP

Menthol

Analysis of QSU-brief Questionnaire - Total Score



PK Studies – Japan

Conclusions

- The maximum concentration of nicotine was similar for PK studies in Japan, both for the menthol and regular version of THS2.2.
- Results from the smoking urges questionnaires (QSU-brief) were consistent within studies and in line with the PK profiles

The Role of Nicotine in Harm Reduction

The Tobacco Advisory Group of the Royal College of Physicians opined in 2007:

"*that **nicotine itself is not especially hazardous**, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved*."

The U.S. Food and Drug Administration (FDA) noted "*the existence of a continuum of nicotine-delivering products **that pose differing levels of risk to the individual***."

In addressing the regulation of other newer forms of tobacco and nicotine products, the FDA stated, "*to the extent that certain products are shown to be less harmful, **they could help reduce the overall death and disease toll from tobacco product use**…"*

Royal College of Physicians, HARM REDUCTION IN NICOTINE ADDICTION: HELPING PEOPLE WHO CAN'T QUIT, Preface (2007) (http://www.rcplondon.ac.uk/publications/harm-reduction-nicotine-addiction) (hereafter "Royal College of Physicians").

FDA Proposed Deeming Regulations at 23147.Id.

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Reduced Exposure Studies – Design & Results

Japan

REXC-04
Regular

ClinTrial.gov ID: NCT01970982

REXA-07
Menthol

ClinTrial.gov ID: NCT01970995

Reduced Exposure Study in healthy, adult smokers:

- *160 healthy adult smokers*
- *Confined and ambulatory setting*
- *Open-label study*
- *Ad-libitum product use*

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Reduced Exposure Study in Confinement in Japan

Study Design and Objectives

Primary Objective:

To demonstrate the reduction of biomarkers of exposure (BoExp) in smokers switching from conventional cigarettes (CC) to THS2.2 as compared to smokers continuing to smoke CC.

Primary Endpoints:

Monohydroxybutenyl-mercapturic acid (MHBMA), 3-Hydroxypropyl-mercapturic acid (3-HPMA), S-Phenyl-mercapturic acid (S-PMA), Carboxyhemoglobin (COHb) after 5 days of exposure in confinement and Total 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (Total NNAL) after 90 days of exposure in an ambulatory setting (REXA-07 study only).

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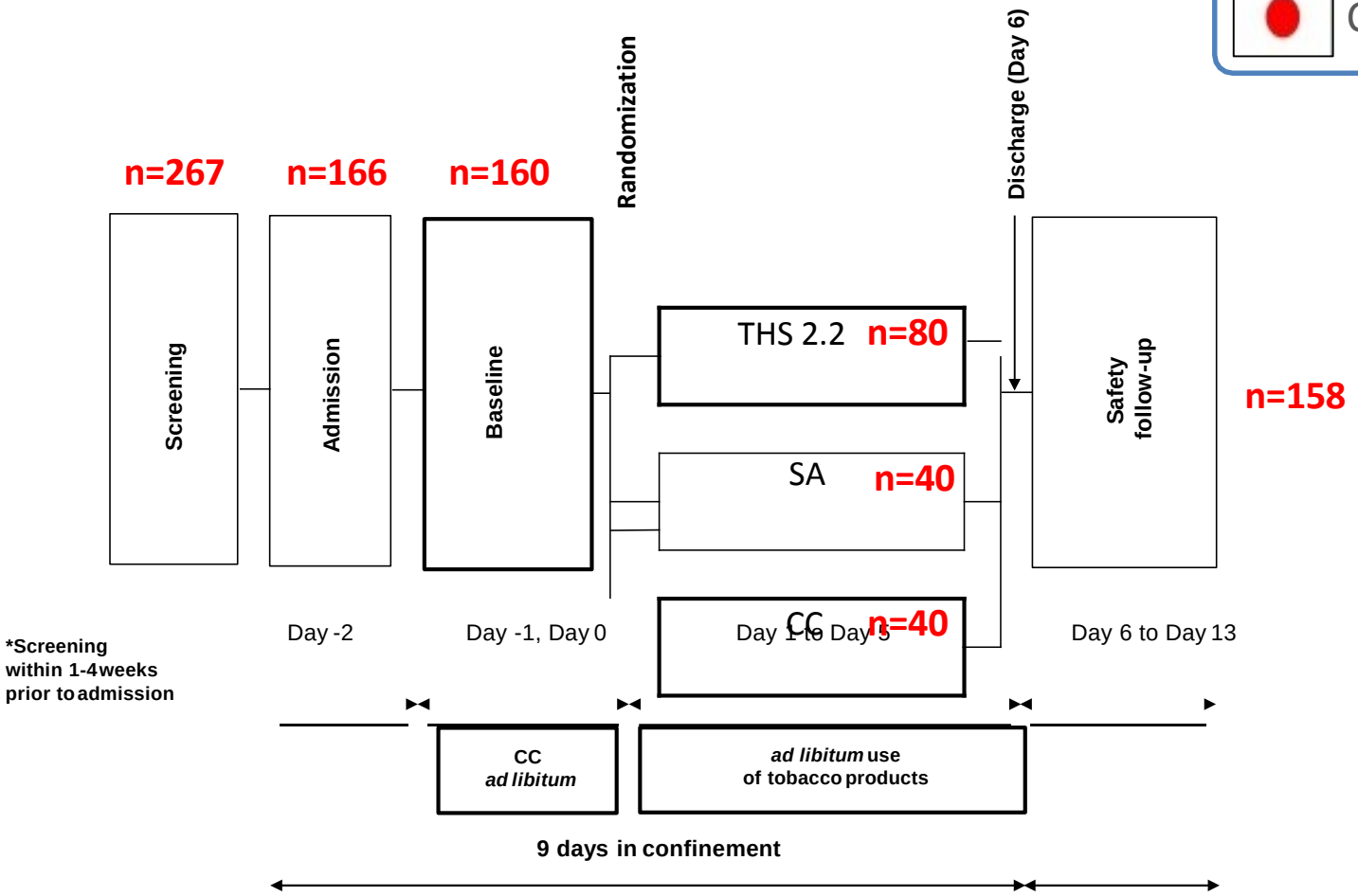
HPHC Characteristics and Related Biomarkers of Exposure

PMI Biomarker	Smoke Constituents	FDA 2012 (FDA-18)	Toxicity **(FDA, IARC)**	Formation Temperature °C	Estimated Biomarker Elimination Half-life
3-HPMA	Acrolein	x	Respiratory, cardiovascular	200-400	10h
S-PMA	Benzene	x	Carcinogenic (1), cardiovascular, reproductive and developmental	290-350 (max @ 450-600)	9 to 15h
MHBMA	1,3-Butadiene	x	Carcinogenic (1), respiratory, reproductive and developmental	Not reported	4 to 16h
COHb	Carbon monoxide	x	Cardiovascular, reproductive and developmental	200-400 (550-900)	1 to 6h
CEMA	Acrylonitrile	x	Possibly carcinogenic (2B), respiratory	400-550	1-2 days
4-ABP	4-Aminobiphenyl	x	Carcinogenic (1)	500-950	26h
1-NA	1-Naphtylamine	x	Not classifiable as carcinogenic to humans	500-950	
2-NA	2-Naphtylamine	x	Carcinogenic (1)	500-950	9h
Total NNAL	NNK	x	Carcinogenic (1)	direct transfer	10-18 days
Total NNN	NNN	x	Carcinogenic (1)	direct transfer	15h
o-Toluidine	ortho-Toluidine	-	Carcinogenic (1)	pyrolysis	10 to 16h
1-OHP	Pyrene	-	Surrogate for Polycyclic Aromatic Hydrocarbons	400-600	20h
B[a}P	Benzo[a]pyrene	x	Carcinogenic (1)	450-600	3 to 4h
S-BMA	Toluene	x	Respiratory, reproductive and developmental	200-350 (400-550)	9h
HEMA	Ethylene Oxide	-	Carcinogenic (1) , respiratory, reproductive and developmental	Not reported	5h
3-HMPMA	Crotonaldehyde	x	Not classifiable as carcinogenic to humans	<400	2 days

1 Week Reduced Exposure Study in Confinement in Japan

Study Design and Disposition

ClinicalTrials.gov ID: NCT01970982



First subject screened:
23 July 2013

Last subject last visit :
09 December 2013

THS 2.2: Tobacco Heating System 2.2; SA: smoking abstinence; CC: conventional cigarettes.

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1 Week Reduced Exposure Study in Japan

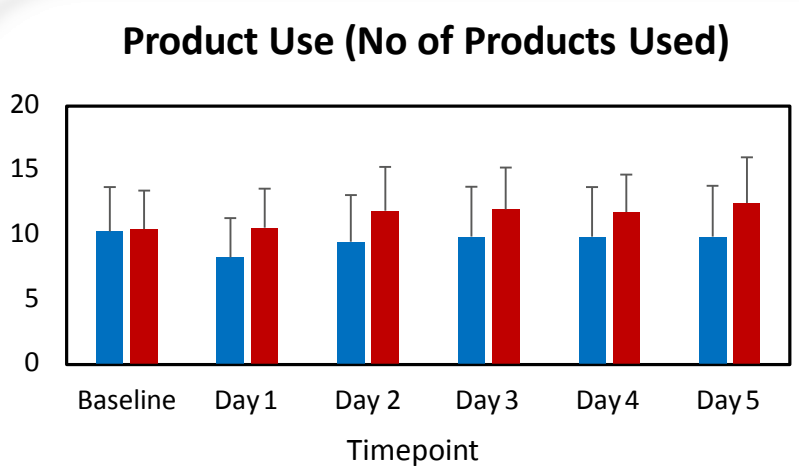
Population Characteristics Japan

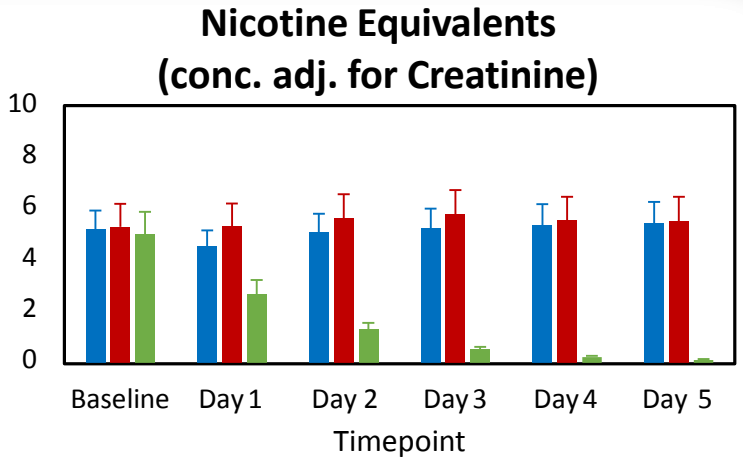
Characteristics	iQOS 2.2 (N=80)	CC (N=40)	SA (N=40)	Overall (N=160)
Females – n (%)	40 (50)	20 (50)	20 (50.0)	80 (50)
Age (years) - Mean±SD	37.6 ± 11.7	37.2 ± 11.7	35.9 ± 10.6	37.1 ± 11.4
BMI (kg/m^2) - Mean±SD	22.8 ± 2.7	22.9 ± 2.7	22.8 ± 2.8	22.8 ± 2.7
Daily mCC Consumption– n (%) 10-19 cig/day > 19 cig/day	 44 (55.0) 36 (45.0)	 22 (55.0) 18 (45.0)	 21 (52.5) 19 (47.5)	 87 (54.4) 73 (45.6)
ISO Tar yields – n (%) 1-5 mg 6-8 mg 9-10 mg > 10 mg	 30 (37.5) 22 (27.5) 13 (16.3) 15 (18.8)	 16 (40.0) 10 (25.0) 8 (20.0) 6 (15.0)	 18 (45.0) 10 (25.0) 7 (17.5) 5 (12.5)	 64 (40.0) 42 (26.3) 28 (17.5) 26 (16.3)
$ISO_{Nicotine}$ ≤0.6mg – n (%) $ISO_{Nicotine}$ > 0.6mg – n (%)	41 (51.3) 39 (48.8)	22 (55) 18 (45)	25 (62.5) 15 (37.5)	88 (55.0) 72 (45.0)

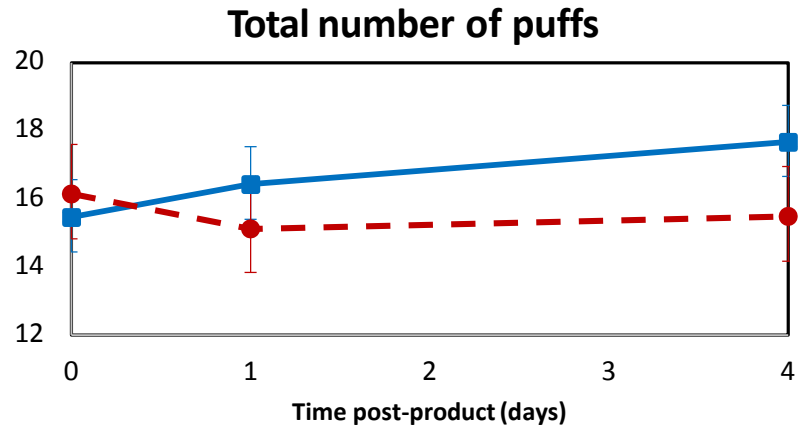
1 Week Reduced Exposure in Japan

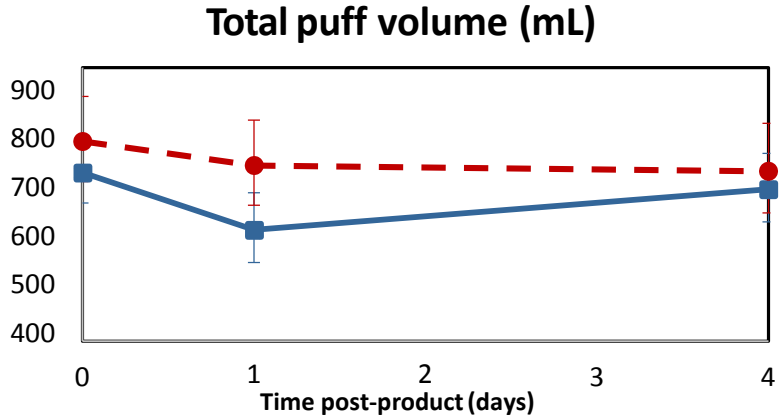
Product Use, Puffing Topography and Nicotine Exposure

THS2.2 CC SA









- Product use increased slightly from Baseline to Day 5.
- Overall Nicotine Exposure showed no significant difference between CC and THS 2.2
- Topography indicates smooth transition to THS 2.2

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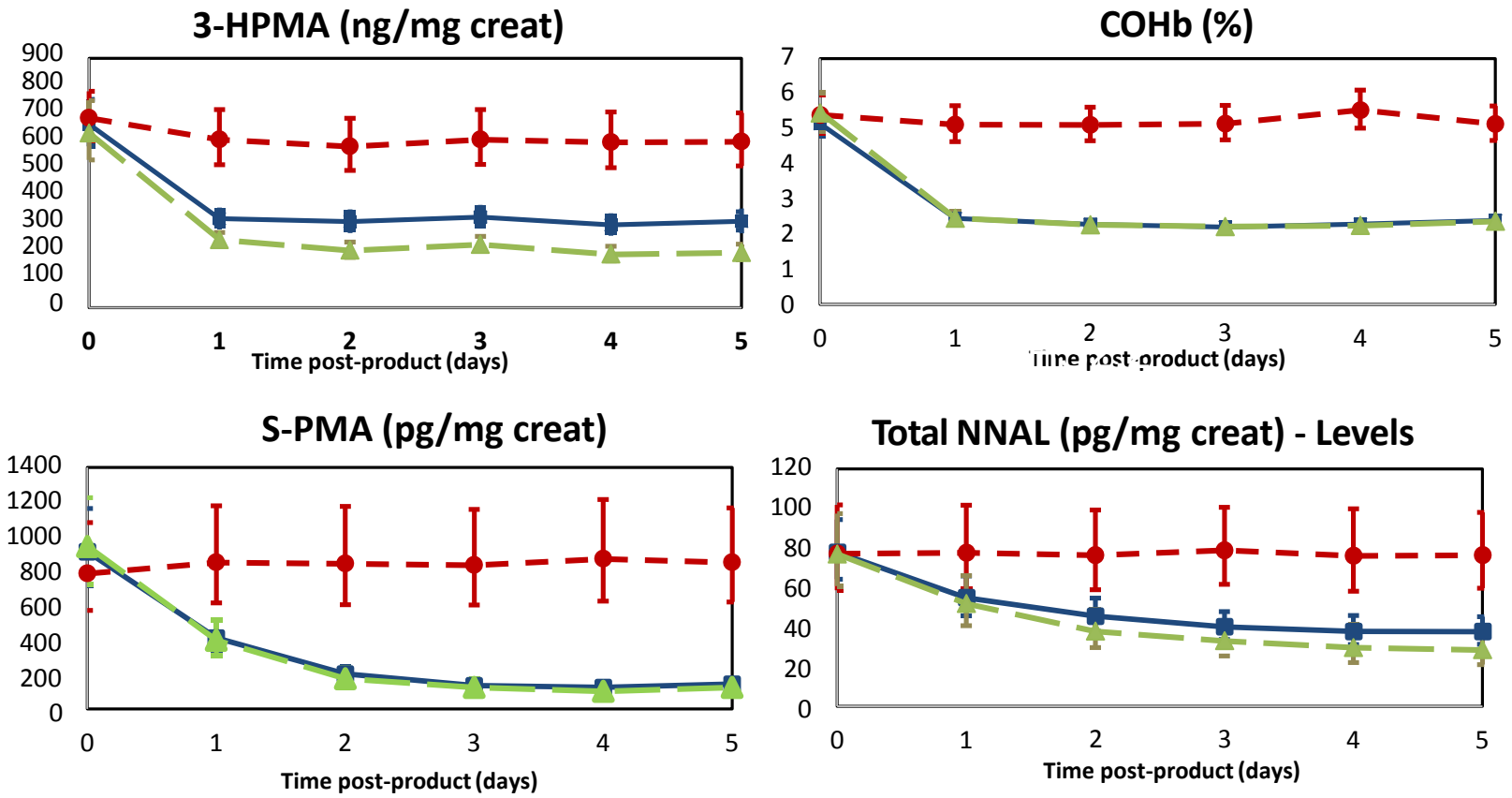
1 Week Reduced Exposure in Japan

Exposure Reduction to Selected HPHCs

THS2.2 CC SA



The reduction in levels of Biomarker of Exposure approaches levels observed on smoking cessation in Japan.

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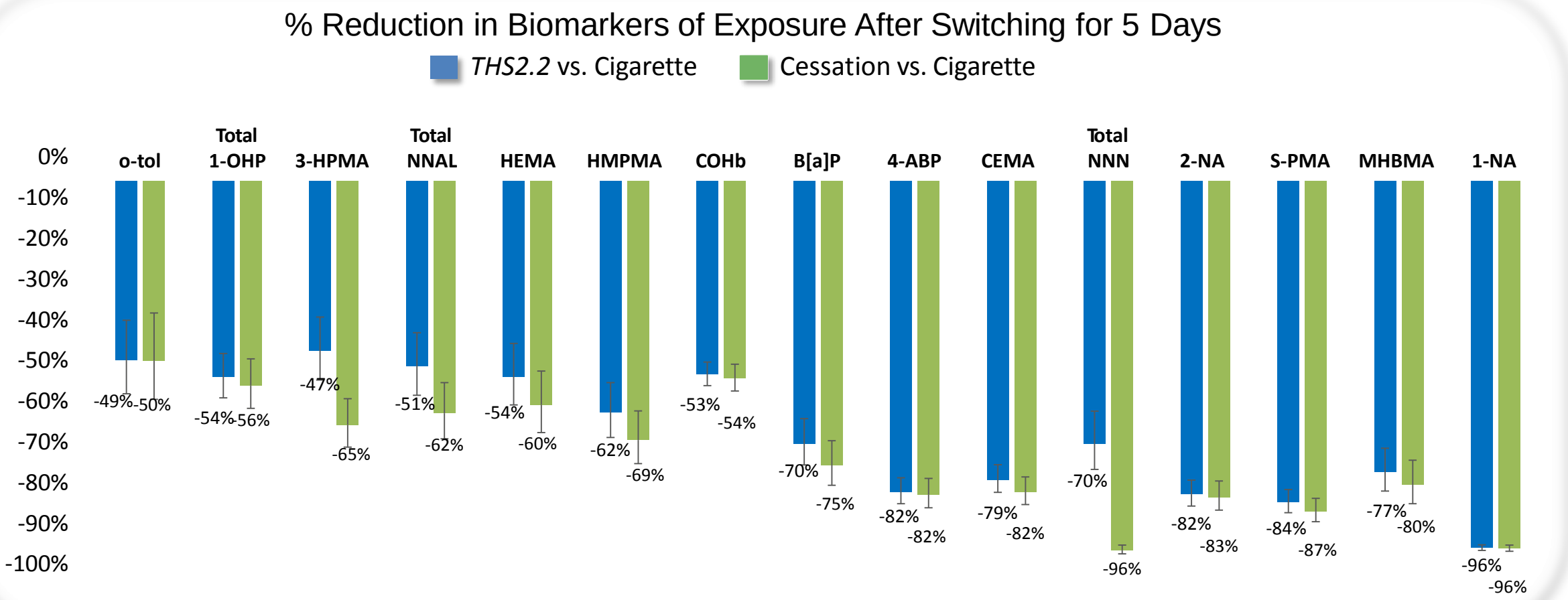
1 Week Reduced Exposure in Japan

Exposure Reduction to Selected HPHCs

THS2.2 CC SA



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Conclusions

1. The reduction in levels of Biomarker of Exposure approaches levels observed on smoking cessation in adult Japanese smokers in these studies.
2. Product use increased slightly from Baseline to Day 5 with overall Nicotine Exposure showing no significant difference between CC and THS2.2.
3. Product use for CC and THS2.2 is lower in Japan, compared to other studies we have conducted. This supports also the lower levels of BoExp observed at Baseline in JP.
4. Puffing Topography indicates fast and natural adaptation to THS2.2 in Japan, with the adaption process driven by an increased puffing frequency (count and interval) in Japan.

3 Month Reduced Exposure in Japan
Study Title and Primary Objective

Study Title:

- A randomized, controlled, open-label, 3-arm parallel group, multi center study to demonstrate reductions in exposure to selected smoke constituents in healthy smokers switching to THS2.2 Menthol or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 85 days in an ambulatory setting.

Primary Objective:

- To demonstrate the reduction of biomarkers of exposure (BoExp) to harmful and potentially harmful constituents (HPHCs) in smokers switching from menthol conventional cigarette (mCC) to THS2.2 menthol compared to smokers continuing to smoke mCC

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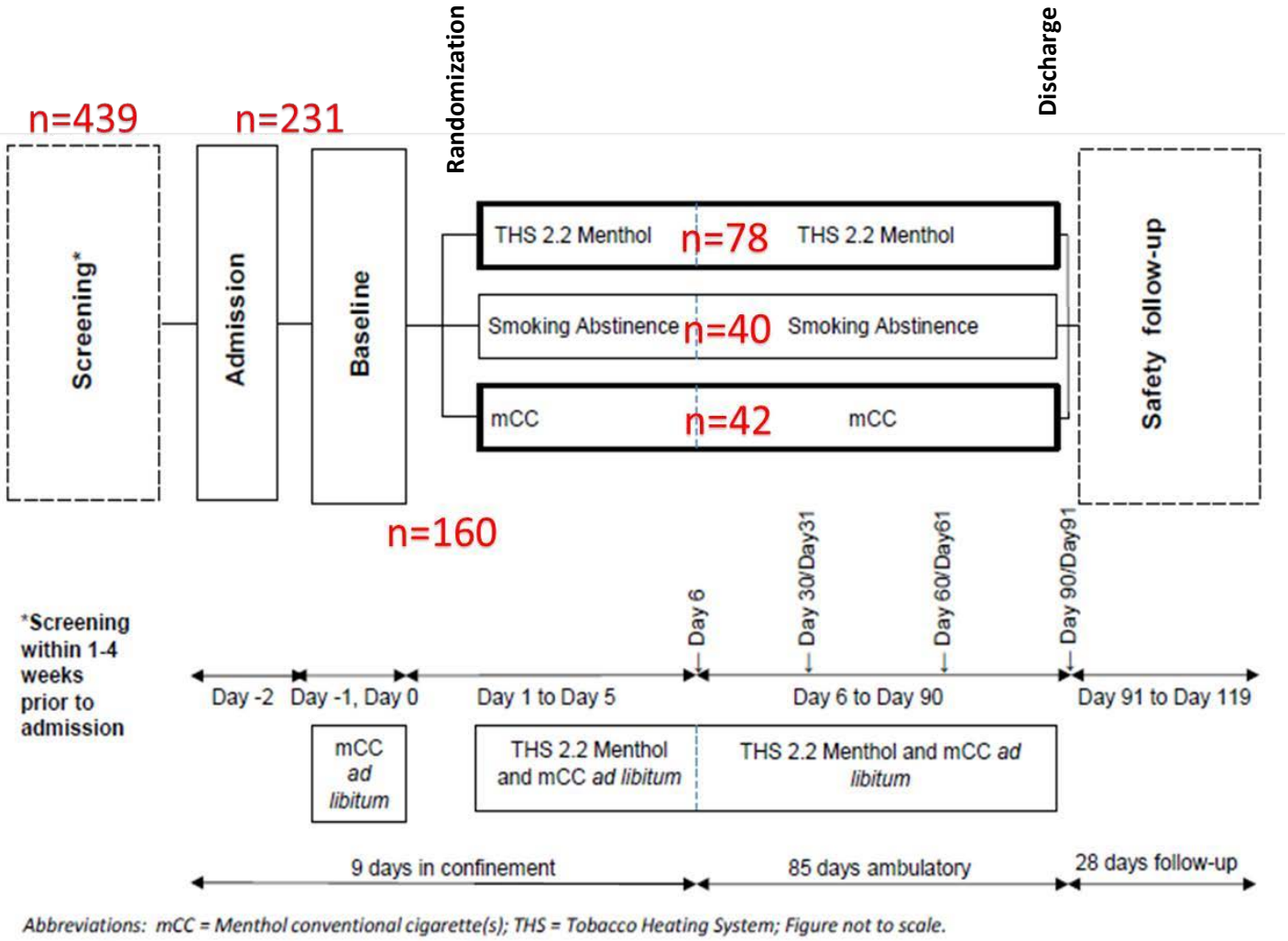
3 Month Reduced Exposure in Japan

Study Design and Disposition

ClinicalTrials.gov ID: NCT01970995



Abbreviations: mCC = Menthol conventional cigarette(s); THS = Tobacco Heating System; Figure not to scale.

First subject screened:

01 August 2013

Last subject last visit :

03 July 2014

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3 Month Reduced Exposure in Japan

Population Characteristics

Characteristics	THS2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall (N=160)
Females – n(%)	33 (42.3)	17 (40.5)	18 (45.0)	68 (42.5)
Age (years) - Mean±SD	37 ± 11	37 ± 11	37 ± 10	37 ± 11
BMI Normal Weight– n(%)	60 (76.9)	32 (76.2)	32 (80.0)	124 (77.5)
Daily mCC Consumption– n(%) 10-19 cig/day > 19 cig/day	40 (51.3) 38 (48.7)	23 (54.8) 19 (45.2)	21 (52.5) 19 (47.5)	84 (52.5) 76 (47.5)
ISO Tar yields – n(%) 1-5 mg 6-8 mg 9-10 mg > 10 mg	46 (59.0) 21 (26.9) 7 (9.0) 4 (5.1)	22 (52.4) 14 (33.3) 4 (9.5) 2 (4.8)	23 (57.5) 12 (30.0) 2 (5.0) 3 (7.5)	91 (56.9) 47 (29.4) 13 (8.1) 9 (5.6)
ISO Nicotine ≤0.6mg – n(%)	63 (80.8)	32 (76.2)	30 (75.0)	125 (78.1

THSm2.2= THS 2.2 Menthol, mCC menthol Conventional Cigarettes, SA:smoking abstinence, SD:standard deviation

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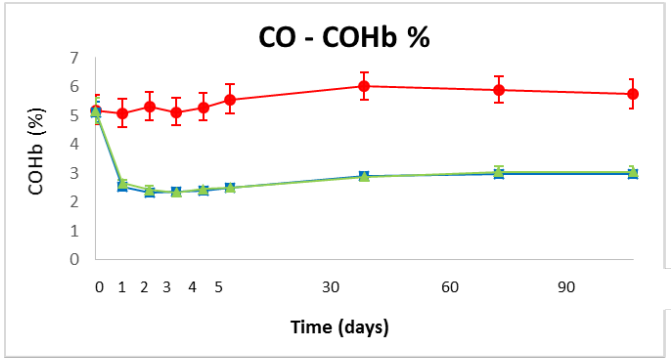
3 Month Reduced Exposure in Japan

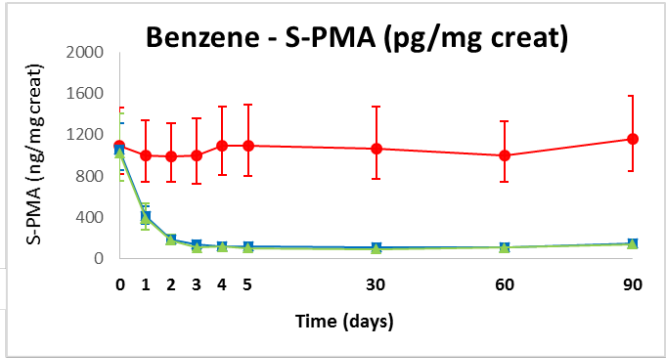
Demonstrates Reduced Exposure

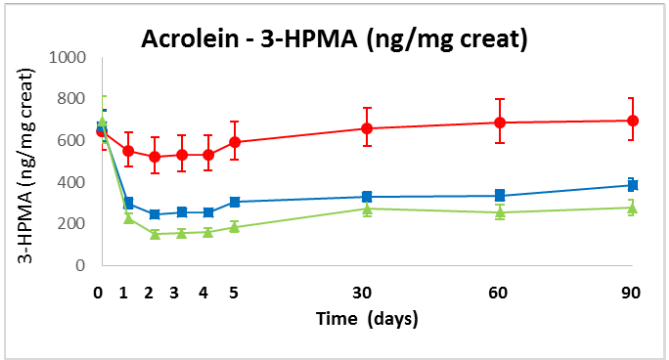
THS2.2 CC SA

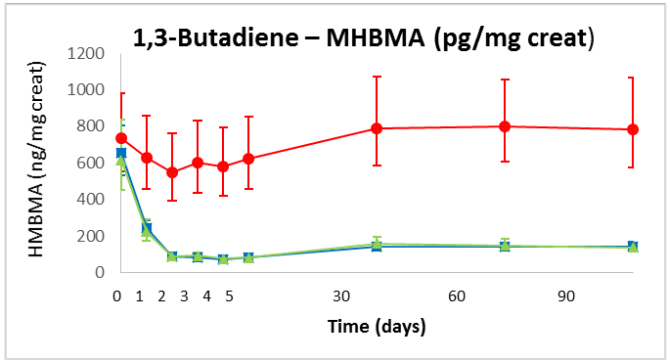
Adult smokers used the products ad libitum

Adult smokers randomized to cigarettes or *THS2.2* were free to use the product as often as they wished, in confinement (5 days) and then ambulatory (85 days)









Levels of exposure to harmful and potentially harmful chemicals when smokers switch to THS2.2 approach the levels observed in those who quit smoking during the study

Note: These data alone do not represent a claim of reduced risk.
Source: PMI Research and Development; Registered on clinicaltrials.gov: NCT 01970995

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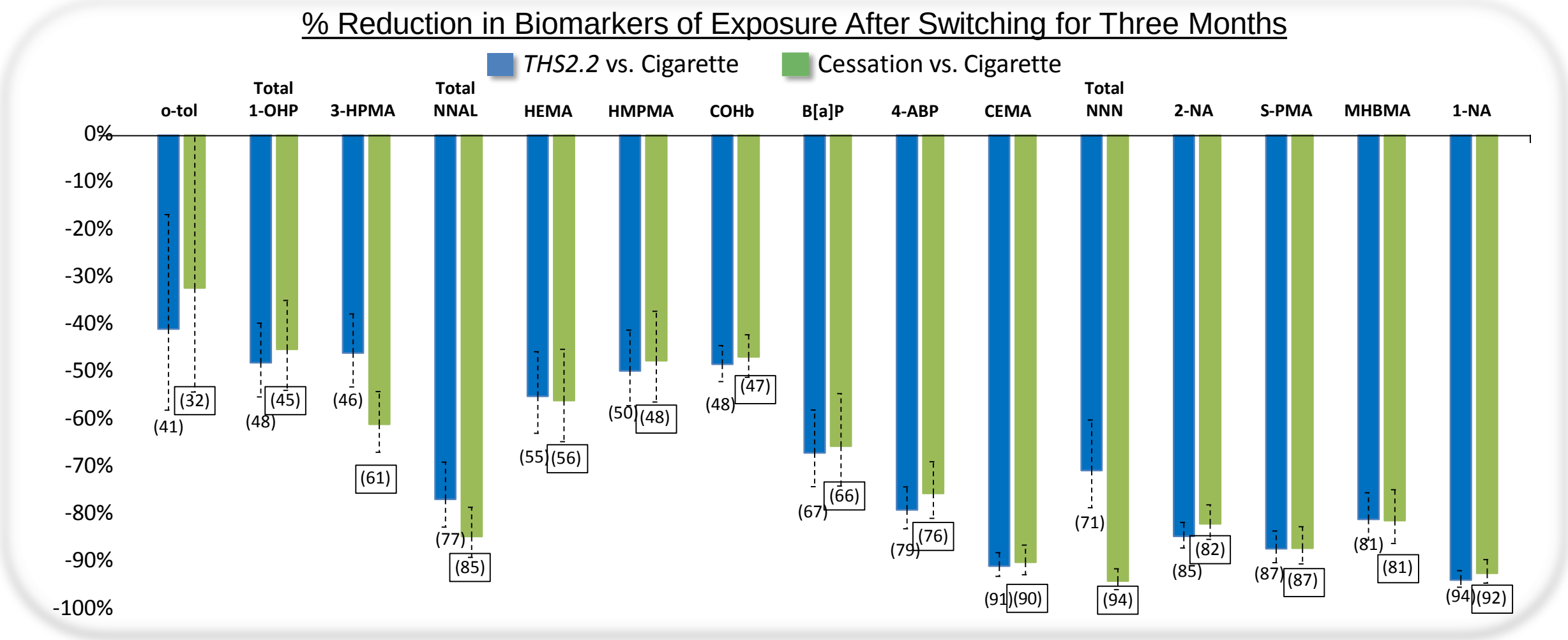
3 Month Reduced Exposure in Japan

Exposure Reduction to Selected HPHCs



Note: 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 cigarettes. These data alone do not represent a claim of reduced exposure or reduced risk Source: PMI Research & Development

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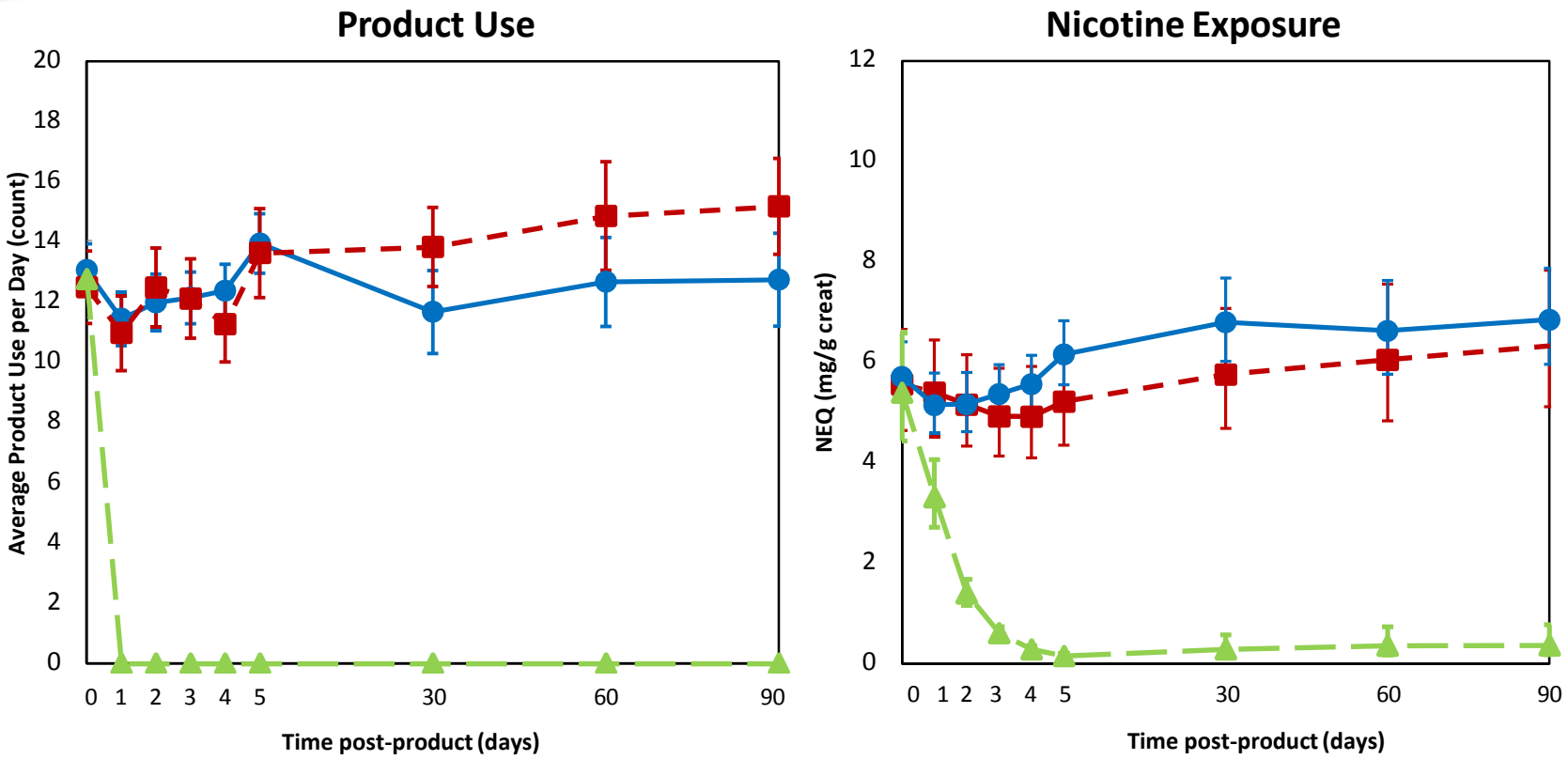
3 Month Reduced Exposure in Japan

Product Use, Puffing Topography and Nicotine Exposure

THS2.2 CC SA



Product Use fluctuated over the period of the study indicating an adaptation process to THS2.2 but resulting in comparable product use at Baseline and Day 90. Nicotine exposure was similar at Day 90.

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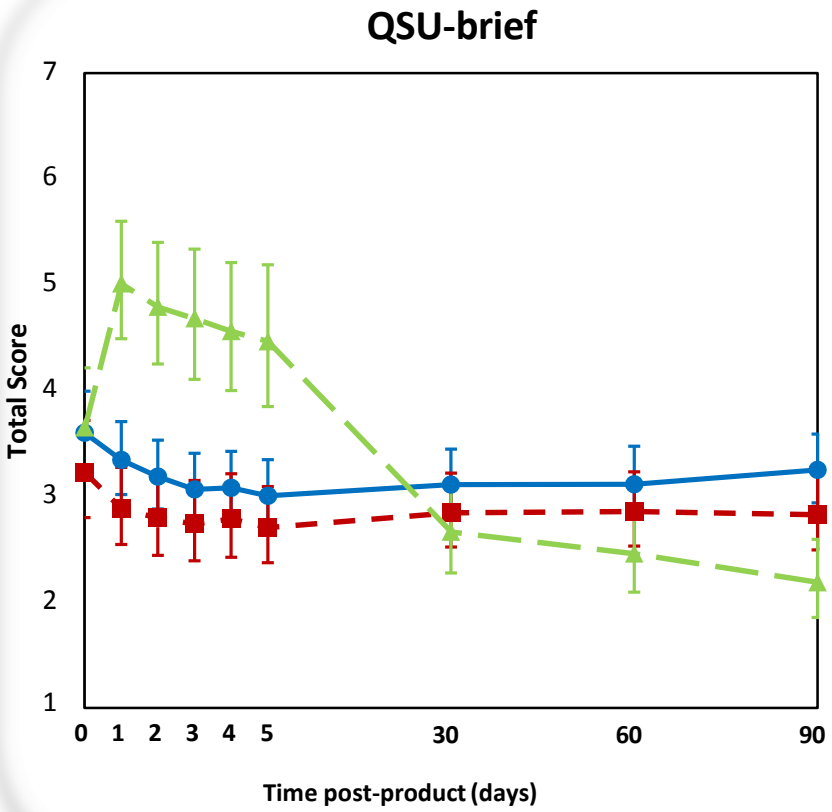
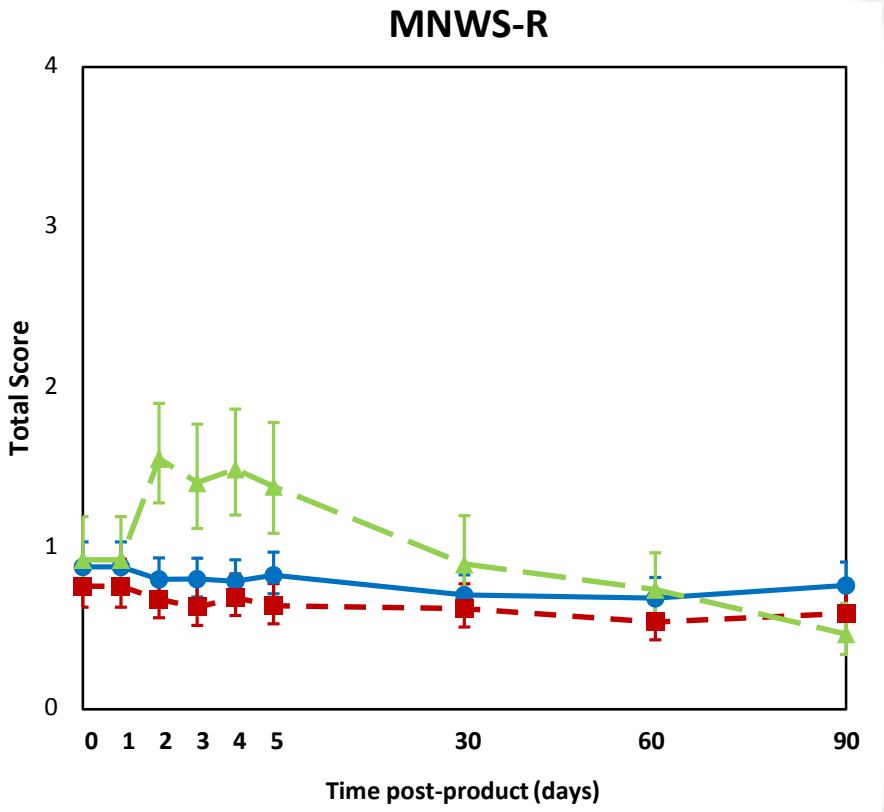
3 Month Reduced Exposure in Japan

Subjective Effects – QSU brief & Minnesota Withdrawal Scale

THS2.2 CC SA





Levels in Urge-to-Smoke and withdrawal symptoms in smokers who switch to THS2.2 were comparable to those reported by CC smokers.

QSU-brief scores reported on a 7-point scale. Higher values indicate greater intensity of urge.
MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

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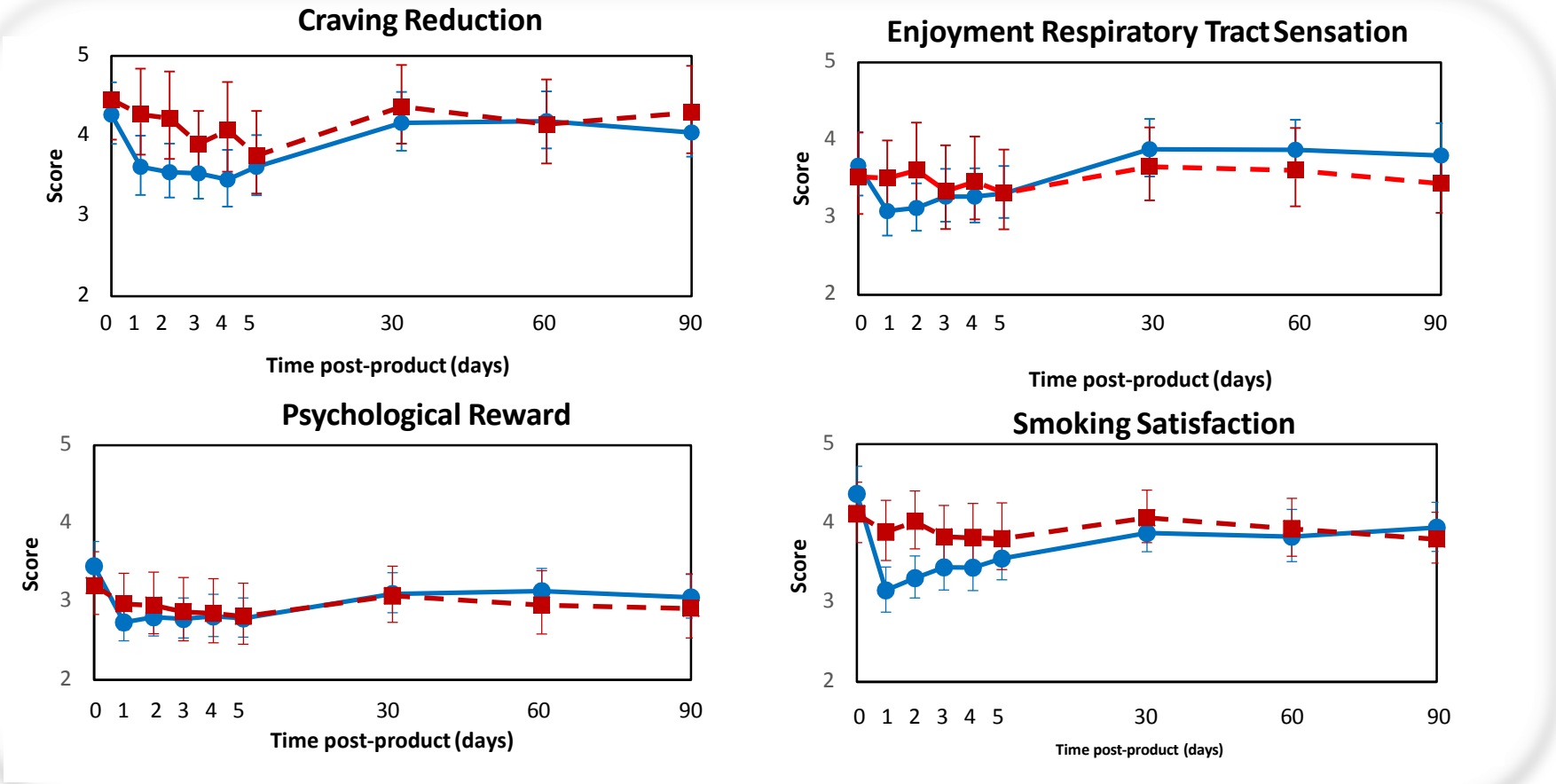
3 Month Reduced Exposure in Japan

Subjective Effects – MCEQ sub-domains

THS2.2 CC



Levels of craving reduction, enjoyment, psychological reward and smoking satisfaction in smokers who switch to THS2.2 are the comparable to those reported by CC smokers

mCEQ scores on a seven-point scale where 7 = "Extremely" and 1 = "Not at All".
mCEQ Aversion subscale not shown; no notable differences were observed.

Graphs display means and 95% confidence intervals

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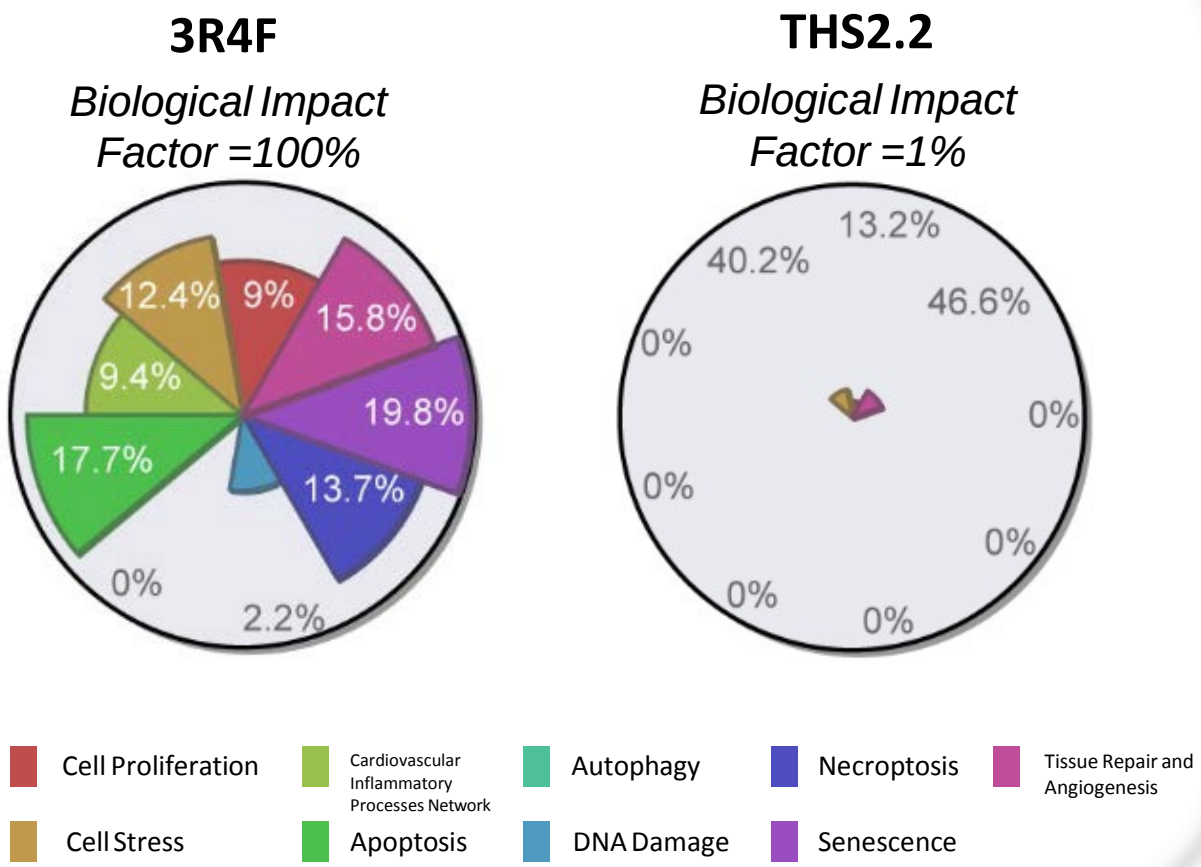
Laboratory Models Show Reduced Activity in Cellular Mechanisms of Disease



THS2.2 aerosol is over 10 times less active than reference cigarette smoke in key mechanisms leading to atherosclerotic plaque formation and endothelial cell dysfunction, which are important in cardiovascular disease development

Note: These data alone do not represent a claim of reduced exposure or reduced risk.

Ref: Poussin, C., A. et al (2016). System s toxicology-based assessment of the candidate modified risk tobacco product THS2.2 for the adhesion of monocytic cells to human coronary arterial endothelial cells. Toxicology 339: 73-86.

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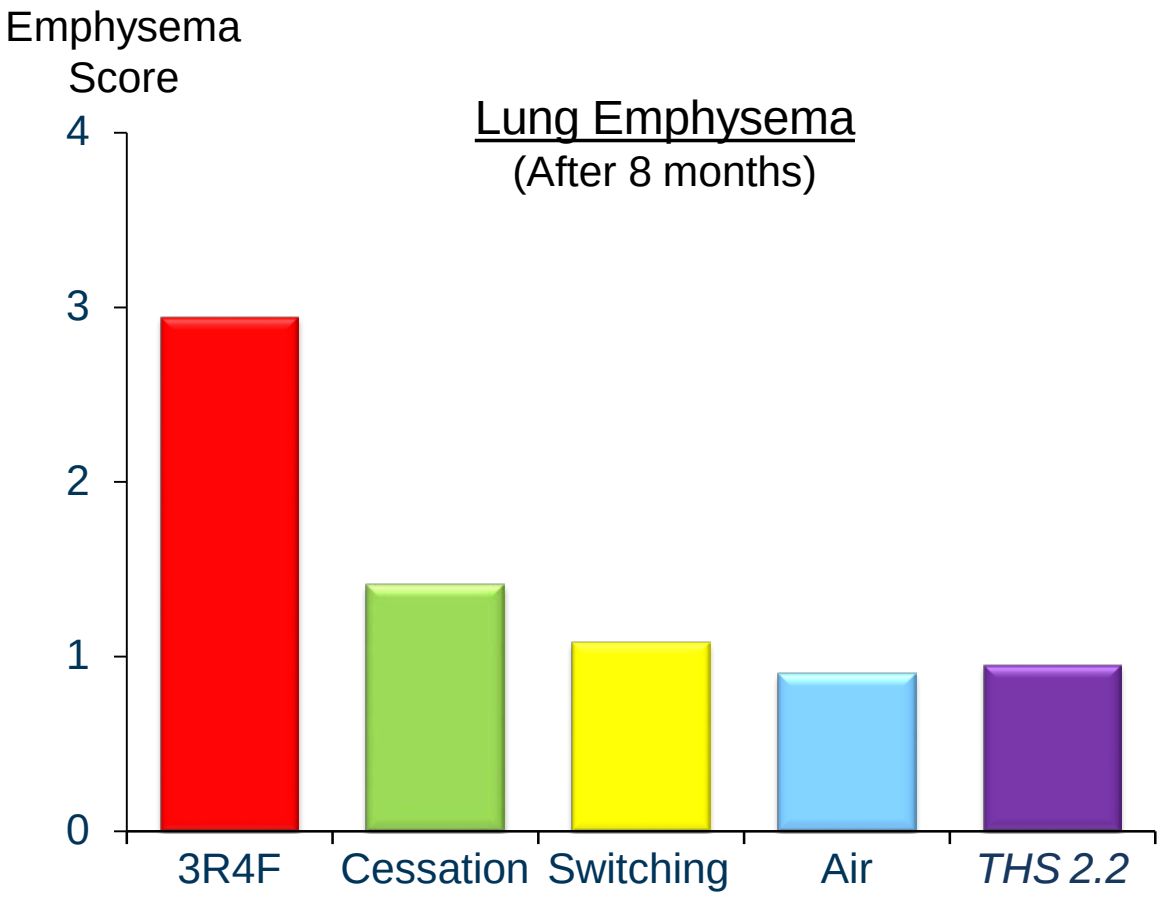
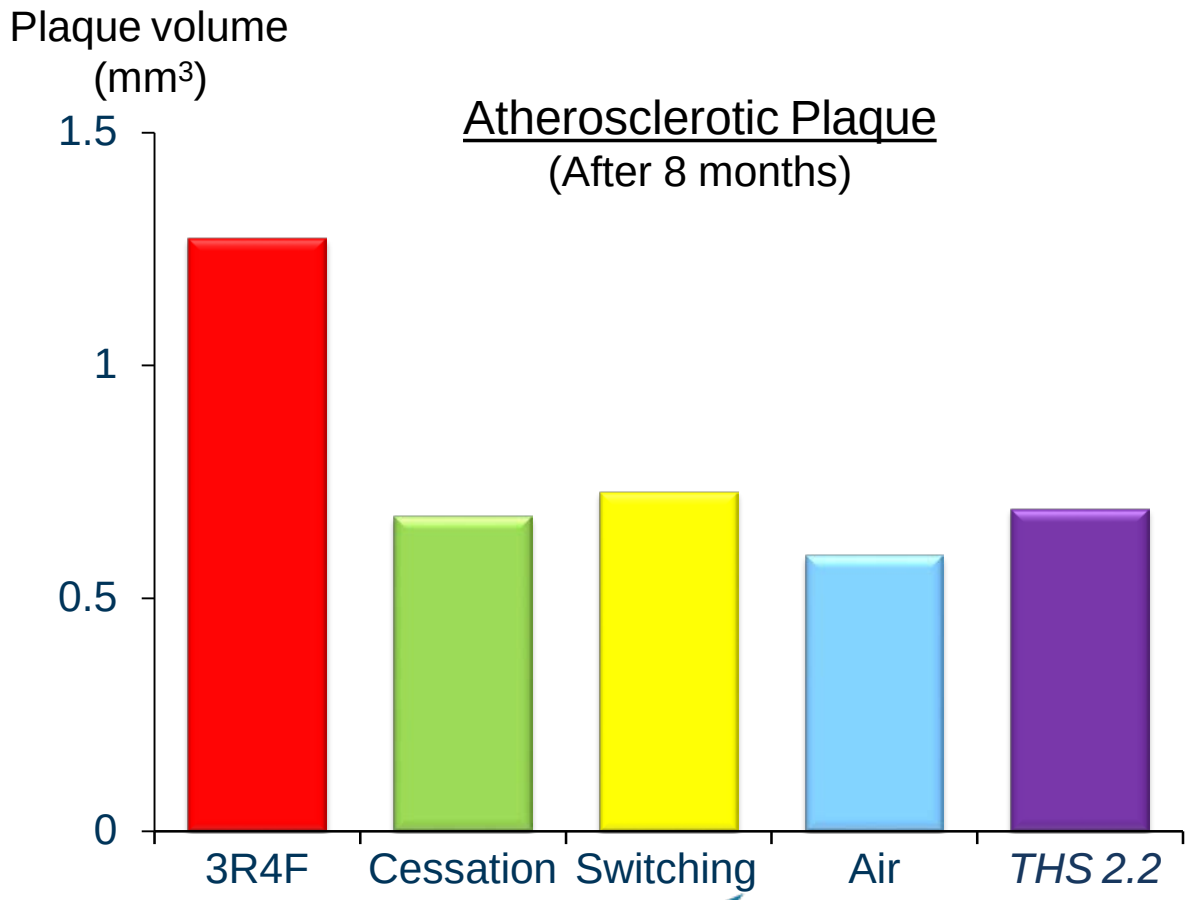
THS2.2: Impact on Disease Endpoints

Disease Endpoint for COPD



Disease Endpoint for CVD



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Clinical Studies Indicate Favorable Changes in Clinical Risk Endpoints

Disease Mechanisms	Expected Direction of Change	Effect of Cessation	Effect of Switching to THS2.2	Direction of Change
Lipid Metabolism (HDL-C)	Increase	6.4 mg/dL ↑	4.5 mg/dL ↑	Same direction as cessation
Inflammation (WBC)	Decrease	-0.40 10^9/L ↓	-0.57 10^9/L ↓	Same direction as cessation
Endothelial Dysfunction (sICAM-1)	Decrease	10.9 % ↓	8.7 % ↓	Same direction as cessation
Oxidative Stress (8-epi-$PGF_{2\alpha}$)	Decrease	5.9 % ↓	12.7 % ↓	Same direction as cessation
Clotting (11-DTX-B_2)	Decrease	19.4 % ↓	9.0 % ↓	Same direction as cessation

These studies measured the levels of 5 clinical risk markers closely associated with cardiovascular disease.

Measurements of these markers in smokers who switched to THS2.2 showed that the majority of beneficial effects that were seen in the smoking cessation arm were preserved.

Note: These data alone do not represent a claim of reduced risk.
Source: PMI Research and Development; Registered on clinicaltrials.gov: NCT01970995

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The Potential of Heat-not-Burn Products on the example of THS2.2 to Contribute to Tobacco Harm Reduction

In summary, we can conclude the following about THS2.2:

- **Combustion does not** occur during normal operation of THS2.2 with HeatSticks
- the aerosol generated by THS2.2 has 90 to 95% less harmful and potentially harmful compounds compared to a reference cigarette
- the aerosol is 90 to 95% less toxic than smoke from a reference cigarette
- Use of THS2.2 does not negatively impact indoor air quality as compared to Marlboro Gold in four reference Model Environmental conditions tested (EN 15251:2007)
- in three-month clinical study in Japan, the average exposure reduction to 15 harmful and potentially harmful compounds in smokers who switched to THS2.2 approached the levels observed in smokers who quit smoking for the duration of the study

***The totality-of-the-evidence collected to date is very encouraging**, in terms of individual risk reduction potential and harm reduction on a population level.*

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Note Reduced-Risk Products ("RRPs") is the term PMI uses to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes

The LYFE Study

P1-PMC-01-JP

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Lifestyle research for Your Future Environment

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Post-Market Cohort Study – Study Design

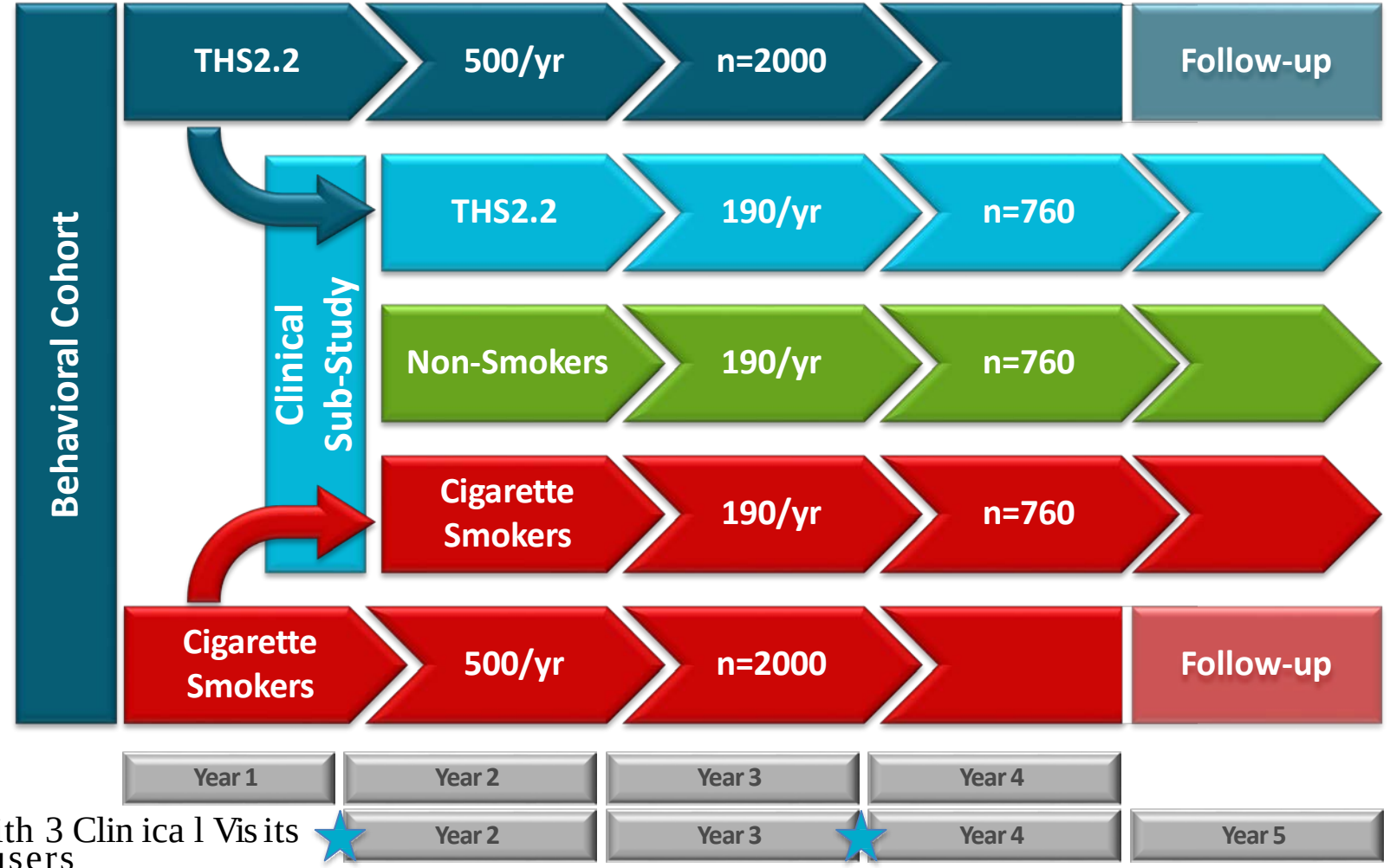
LYFE
Lifestyle research for Your Future Environment

15 Sites in Japan:

- 200 THS 2.2 users
- 2000 Cigarette smokers
- 760 Non-smokers

First Participant:

April 1st, 2016



Follow-up: Up to 5 years of follow-up with 3 Clinical Visits
Recruitment: 4 waves of new THS 2.2 users
★ Indicates Clinical Sampling Visit

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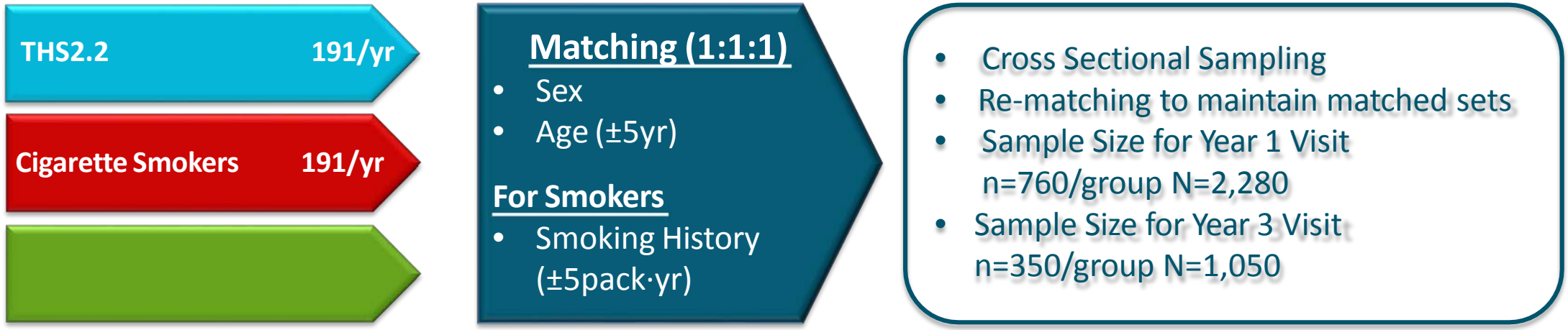
Clinical Sub-Study: Cross Sectional Sampling



OBJECTIVES:

1. Exposure (Total NNN, Total NNAL and nicotine equivalents) – Assessed at 1 year
2. Clinical Risk Markers

Cardiovascular Disease

- Cholesterol (total cholesterol, HDL-cholesterol and LDL-cholesterol), triglycerides, high sensitivity C-reactive protein, soluble intracellular adhesion molecule
- White blood cell count and carboxyhemoglobin (COHb)
- 11-dehydrothromboxane B2 (11-DTX-B2), and 8-epi-prostaglandin-alpha (8-epi-PGF2α)
- Systolic and diastolic blood pressure and metabolic syndrome

Lung Function

- Forced expiratory volume in 1 second (FEV_1)

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Reduced-Risk Products ("RRPs") is the term PMI uses to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes.

PMI's RRPs are in various stages of development and commercialization outside the United States in a number of countries, 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 cigarettes.

Before making any such claims, we will 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 authorization, as is the case in the United States today.

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Questions?

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Thank you for your attention.