



Analysis of Whole Offer Test Data

Japan, Italy, Germany, Switzerland and South Korea

Summary Report

Study Title: Analysis of Whole Offer Test Data Japan, Italy, Germany, Switzerland and South Korea

Registration Number: Not Applicable

Product Name: THS (Tobacco Heating System) version 2.2

Sponsor: Philip Morris International

Version Number: 2.0

Revision Date : June 30, 2016

Authors: Steve Roulet¹, Pierpaolo Magnani¹, Gerd Kallischnigg², Stefano Badoglio¹, Kurt Ackermann³, Marcus Veit³, Antonio Ramazzotti¹, ¹Philip Morris International Management S.A., Lausanne, Switzerland, ²ARGUS - Statistics and Information Systems in Environment and Public Health, Berlin, Germany, ³FehrAdvice & Partners, Zurich, Switzerland

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris International Management S.A.



TABLE OF CONTENTS

1.	LIST OF ABBREVIATIONS, DEFINITIONS OF TERMS AND LIST OF VARIABLES	10
2.	BACKGROUND.....	16
3.	OBJECTIVES AND ENDPOINTS	17
4.	METHODS	19
5.	NUMBER OF STUDY PARTICIPANTS (ENROLLED AND ANALYZED)	21
6.	MAIN CRITERIA FOR INCLUSION.....	22
7.	TEST PRODUCT.....	23
8.	DURATION OF EXPOSURE	23
9.	SAMPLE SIZE.....	24
10.	STATISTICAL METHODS	25
11.	SUMMARY OF RESULTS.....	26
	JAPAN (JP)	26
	ITALY (IT).....	32
	GERMANY (DE)	38
	SWITZERLAND (CH).....	44
	SOUTH KOREA (KR)	50
	SUMMARY OF COUNTRY RESULTS	56
	SUPPLEMENTARY RESULTS AND ANALYSIS.....	58
12.	STRENGTHS AND LIMITATIONS OF THE STUDY	64
13.	REFERENCE LIST.....	65
14.	APPENDICES.....	66
	APPENDIX JAPAN 1: TRANSITION TABLES	67
	APPENDIX JAPAN 2: PATTERNS OF USAGE BEHAVIOR	77
	APPENDIX ITALY 1: TRANSITION TABLES	79
	APPENDIX ITALY 2: PATTERNS OF USAGE BEHAVIOR.....	89
	APPENDIX GERMANY 1: TRANSITION TABLES	91
	APPENDIX GERMANY 2: PATTERNS OF USAGE BEHAVIOR	101
	APPENDIX SWITZERLAND 1: TRANSITION TABLES	103
	APPENDIX SWITZERLAND 2: PATTERNS OF USAGE BEHAVIOR	113
	APPENDIX SOUTH KOREA 1: TRANSITION TABLES	115
	APPENDIX SOUTH KOREA 2: PATTERNS OF USAGE BEHAVIOR.....	125



LIST OF TABLES

Table 5-1: Participants enrolled at Phase 1	21
Table 5-2: Participants eligible for Phase 2	21
Table 5-3: Participants in the Full Analysis Set (FAS).....	21
Table 11-1: Start Using <i>HeatSticks</i> - Japan	26
Table 11-2: Switch to <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Japan	27
Table 11-3: Combined Use of CC and <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Japan	27
Table 11-4: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Japan	28
Table 11-5: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4 and "Switch to <i>HeatSticks</i> ") - Japan.....	28
Table 11-6: Usage Categories for Continued Use of <i>HeatSticks</i> - Japan	29
Table 11-7: Usage Categories for Early Stages of Using <i>HeatSticks</i> - Japan.....	30
Table 11-8: Effect of Using <i>HeatSticks</i> on Total Tobacco Product Use - Japan.....	31
Table 11-9: Start Using <i>HeatSticks</i> - Italy	32
Table 11-10: Switch to <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Italy	33
Table 11-11: Combined Use of CC and <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Italy	33
Table 11-12: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Italy	34
Table 11-13: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4 and "Switch to <i>HeatSticks</i> ") - Italy.....	34
Table 11-14: Usage Categories for Continued Use of <i>HeatSticks</i> - Italy	35
Table 11-15: Usage Categories for Early Stages of Using <i>HeatSticks</i> - Italy	36
Table 11-16: Effect of Using <i>HeatSticks</i> on Total Tobacco Product Use - Italy.....	37
Table 11-17: Start Using <i>HeatSticks</i> - Germany.....	38
Table 11-18: Switch to <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Germany	39
Table 11-19: Combined Use of CC and <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Germany.....	39
Table 11-20: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) - Germany.....	40
Table 11-21: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4 and "Switch to <i>HeatSticks</i> ") - Germany.....	40
Table 11-22: Usage Categories for Continued Use of <i>HeatSticks</i> - Germany.....	41
Table 11-23: Usage Categories for Early Stages of Using <i>HeatSticks</i> - Germany.....	42
Table 11-24: Effect of Using <i>HeatSticks</i> on Total Tobacco Product Use - Germany.....	43



Table 11-25: Start Using <i>HeatSticks</i> – Switzerland.....	44
Table 11-26: Switch to <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) – Switzerland	45
Table 11-27: Combined Use of CC and <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) – Switzerland.....	45
Table 11-28: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) – Switzerland.....	46
Table 11-29: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4 and “Switch to <i>HeatSticks</i> ”) - Switzerland.....	46
Table 11-30: Usage Categories for Continued Use of <i>HeatSticks</i> – Switzerland.....	47
Table 11-31: Usage Categories for Early Stages of Using <i>HeatSticks</i> – Switzerland.....	48
Table 11-32: Effect of Using <i>HeatSticks</i> on Total Tobacco Product Use – Switzerland ..	49
Table 11-33: Start Using <i>HeatSticks</i> – South Korea.....	50
Table 11-34: Switch to <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) – South Korea	51
Table 11-35: Combined Use of CC and <i>HeatSticks</i> (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) – South Korea.....	51
Table 11-36: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4) – South Korea.....	52
Table 11-37: Switch Back to CC (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4 and “Switch to <i>HeatSticks</i> ”) – South Korea	52
Table 11-38: Usage Categories for Continued Use of <i>HeatSticks</i> – South Korea.....	53
Table 11-39: Usage Categories for Early Stages of Using <i>HeatSticks</i> – South Korea.....	54
Table 11-40: Effect of Using <i>HeatSticks</i> on Total Tobacco Product Use – South Korea ..	55
Table 11-41: Country Results for Study Objectives 1 to 4 as assessed by the end of the observational period.....	58
Table 11-42: The three most frequently observed usage patterns of participants in the FAS per country.....	59
Table 11-43: The three most frequently observed usage patterns of participants who have started using <i>HeatSticks</i> by the end of study week 4 per country	60
Table 11-44: Comparisons of gender distributions between Switchers and Non-Switchers within the FAS	62
Table 11-45: Comparisons of age distributions between Switchers and Non-Switchers within the FAS	63
Table 14-1: Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan.....	67
Table 14-2: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	68



Table 14-3: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	69
Table 14-4: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	70
Table 14-5: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	71
Table 14-6: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	72
Table 14-7: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	73
Table 14-8: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	74
Table 14-9: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	75
Table 14-10: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 391$) - Japan	76
Table 14-11: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 638$) - Japan	77
Table 14-12: Patterns of Usage Behavior (Given 'Start Using <i>HeatSticks</i> ', $n = 391$) - Japan	78
Table 14-13: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	79
Table 14-14: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	80
Table 14-15: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	81
Table 14-16: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	82
Table 14-17: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	83



Table 14-18: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	84
Table 14-19: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	85
Table 14-20: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	86
Table 14-21: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	87
Table 14-22: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 193$) - Italy	88
Table 14-23: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 535$) - Italy	89
Table 14-24: Patterns of Usage Behavior (Given 'Start Using <i>HeatSticks</i> ', $n = 193$) - Italy	90
Table 14-25: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	91
Table 14-26: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	92
Table 14-27: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	93
Table 14-28: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	94
Table 14-29: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	95
Table 14-30: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	96
Table 14-31: CC Use, Combined Use, <i>HeatStick</i> - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	97
Table 14-32: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	98



Table 14-33: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	99
Table 14-34: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 189$) - Germany	100
Table 14-35: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 377$) - Germany	101
Table 14-36: Patterns of Usage Behavior (Given 'Start Using <i>HeatSticks</i> ', $n = 189$) - Germany	102
Table 14-37: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	103
Table 14-38: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	104
Table 14-39: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	105
Table 14-40: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	106
Table 14-41: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	107
Table 14-42: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	108
Table 14-43: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	109
Table 14-44: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	110
Table 14-45: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	111
Table 14-46: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 206$) - Switzerland	112
Table 14-47: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 416$) - Switzerland	113
Table 14-48: Patterns of Usage Behavior (Given 'Start Using <i>HeatSticks</i> ', $n = 206$) - Switzerland	114



Table 14-49: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	115
Table 14-50: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	116
Table 14-51: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	117
Table 14-52: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	118
Table 14-53: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	119
Table 14-54: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	120
Table 14-55: CC Use, Combined Use, <i>HeatStick</i> - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	121
Table 14-56: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	122
Table 14-57: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	123
Table 14-58: CC Use, Combined Use, <i>HeatStick</i> Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using <i>HeatSticks</i> ' by the End of Study Week 4, $n = 643$) – South Korea	124
Table 14-59: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 843$) – South Korea	125
Table 14-60: Patterns of Usage Behavior (Given 'Start Using <i>HeatSticks</i> ', $n = 643$) – South Korea	126



LIST OF FIGURES

Figure 4-1: Study Approach 19



1. LIST OF ABBREVIATIONS, DEFINITIONS OF TERMS AND LIST OF VARIABLES

List of Abbreviations

Abbreviation	Definition
CAPI	Computer Assisted Personal Interview
CC	Conventional Cigarette(s)
CH	Switzerland
CI	Confidence Interval(s)
DE	Germany
FAS	Full Analysis Set
FDA	Food and Drug Administration
ISDCF	Individual Safety Data Collection Form
IT	Italy
JP	Japan
KR	South Korea
MYO	Make Your Own
PBA	Perception and Behavior Assessment
PMI	Philip Morris International Management S.A.
RRP	Reduced Risk Product
RYO	Roll Your Own
SD	Standard Deviation
THS	Tobacco Heating System
THS 2.2	Tobacco Heating System 2.2
WHO	World Health Organization
WOT	Whole Offer Test



Definitions of Terms

Term	Definition
Conventional Cigarette (CC)	In this study, a ‘conventional cigarette’ is defined as a cigarette made of tobacco leaves wrapped into paper, with or without a filter, industrially manufactured or hand-rolled; excluding cigars, pipes, and cigarettes containing substances other than tobacco. While one end of the cigarette is lit, the other end is held to or in the mouth to inhale the smoke.
Full Analysis Set (FAS)	Participants who answered the interim phase, attended the final phase and completed at least 26 days in the diary are considered for the Full Analysis Set. ¹
<i>HeatSticks</i>	THS Tobacco Sticks designed to be used exclusively with the THS device.
Missing	Difference between the Study population (N) and the Full Analysis Set (FAS), i.e. N minus FAS.
Observational period	In this study, participants were able to purchase and consume <i>HeatSticks</i> during 28 days, i.e. four weeks. This time period is referred to as the observational period.
Participant	A legal age daily smoker aged between one year above the national legal smoking age and 64 years.
Patterns of Usage Behavior	Usage category (as defined further down) variations over the period of 4 study weeks.
Study material	In this study, the study material is all of the material provided to participants, including the study product itself, user and information manuals, marketing material (e.g. brochures) and return envelopes.
Study population (N)	Participants who were (a) eligible to do the Home Use Test and (b) agreed to participate in the observational period (i.e. agreed and took the product home) are included in the study population.
Study time	In this study, all Whole Offer Tests (WOTs) are staggered-entry studies and participants started on different days. Therefore, calendar time is translated into study time.
Study week	The data of 7 consecutive days at a time were consolidated into one study week. In total, there are 4 study weeks.

¹ A diary entry is considered as completed if the participant either reported the type of product used or declared “zero” consumption of CC and *HeatSticks*.

List of Variables

Variable	Description	Values	Data Source
Number of daily CC	Amount of CC consumed per day as self-reported by participants.	n = consumed n CC that day	Paper and Pencil
Number of daily <i>HeatSticks</i>	Amount of <i>HeatSticks</i> consumed per day as self-reported by participants.	n = consumed # <i>HeatSticks</i> that day	Paper and Pencil
Number of daily total tobacco products	The sum of CC and <i>HeatSticks</i> consumed per day as self-reported by participants.	n = consumed # CC and <i>HeatSticks</i> that day	Paper and Pencil
Number of weekly CC	Amount of CC consumed as self-reported by participants, measured each study week.	n = consumed # CC that study week	Paper and Pencil
Number of weekly <i>HeatSticks</i>	Amount of <i>HeatSticks</i> consumed as self-reported by participants, measured each study week.	n = consumed # <i>HeatSticks</i> that study week	Paper and Pencil
Number of weekly total tobacco products	The sum of CC and <i>HeatSticks</i> consumed per day as self-reported by participants, measured each study week.	n = consumed # CC and # <i>HeatSticks</i> that study week	Paper and Pencil
Average number of CC smoked per day before observational period	Amount of claimed CC consumed per day before the observational period as self-reported by participants during recruitment phase.	n = consumed # CC on average per day before the observational period	CAPI
Start using <i>HeatSticks</i>	A participant started using <i>HeatSticks</i> if he/she consumed 100 <i>HeatSticks</i> or more during the observational period, i.e. the cumulated value of <i>HeatSticks</i> consumed by a participant attains 100 or more (based on the analogous definition of smokers of CC in WHO, 2008). In study week: In any given study week, the number of participants who passed the threshold of 100 <i>HeatSticks</i> By study week: By any given study week, the cumulative number of participants who passed the threshold of 100 <i>HeatSticks</i>	1 = started using <i>HeatSticks</i> 0 = else	Paper and Pencil



Variable	Description	Values	Data Source
Early stages of using <i>HeatSticks</i>	In this study, the ‘early stages of using <i>HeatSticks</i> ’ is defined as: having consumed at least 1 but less than 100 <i>HeatSticks</i> (based on the analogous definition of smokers of CC in WHO, 2008).	1 = early stages of using <i>HeatSticks</i> 0 = else	Paper and Pencil
Continued use of <i>HeatSticks</i>	Same as start using <i>HeatSticks</i>	1 = started using <i>HeatSticks</i> 0 = else	Paper and Pencil
Switch to <i>HeatSticks</i>	<p>Precondition: Participants who started using <i>HeatSticks</i> by end of study week 4</p> <p>In study week: In any given study week, the number of participants whose <i>HeatStick</i> consumption constituted at least 70% of total tobacco consumption (calculated by dividing the number of <i>HeatSticks</i> by the number of total tobacco products) and who have not been considered as “having switched to <i>HeatSticks</i>” by the prior study week</p> <p>By study week: By any given study week, the number of participants whose <i>HeatStick</i> consumption constituted 70% or more of total tobacco consumption in the given study week</p>	1 = switch to <i>HeatSticks</i> 0 = else	Paper and Pencil
Combined use of CC and <i>HeatSticks</i>	<p>Precondition: Participants who started using <i>HeatSticks</i> by end of study week 4</p> <p>In study week: In any given study week, the number of participants whose <i>HeatStick</i> consumption constituted more than 30% and less than 70% of total tobacco and who, in the previous week, had a <i>HeatStick</i> consumption that was at most 30% or at least 70% of total tobacco consumption (calculated by dividing the number of <i>HeatSticks</i> by the number of total tobacco products)</p>	1 = combined use of CC and <i>HeatSticks</i> 0 = else	Paper and Pencil

Variable	Description	Values	Data Source
Switch back to CC	<p>By study week: By any given study week, the number of participants whose <i>HeatStick</i> consumption constitutes more than 30% and less than 70% of total tobacco consumption</p> <p>Precondition: Participants who started using <i>HeatSticks</i> by end of study week 4</p> <p>In study week: In any given study week, the number of participants who had switched to <i>HeatSticks</i> in any prior study week and whose <i>HeatStick</i> consumption dropped to 30% or less (calculated by dividing the number of <i>HeatSticks</i> by the number of total tobacco products) in the given study week, provided total tobacco consumption was greater than zero</p> <p>By study week: By any given study week, the number of participants who switched back to CC in the given study week or who switched back in any prior study week and who did not afterwards switch to <i>HeatStick</i> or Combined use</p>	<p>1 = switch back to CC</p> <p>0 = else</p>	Paper and Pencil
Usage categories	<p>This variable describes participants' usage category in each study week of the observational period and is calculated by dividing the number of <i>HeatSticks</i> by the number of total tobacco products (i.e. <i>HeatStick</i> use and CC use):</p> <p>-Zero <i>HeatStick</i> and CC use: no consumption of either CC or <i>HeatSticks</i></p> <p>- CC use: [0-30]% <i>HeatSticks</i> of number of total tobacco products</p> <p>- Exclusive CC use: [0-5]% <i>HeatSticks</i> of number of total tobacco products</p> <p>- Predominant CC use: [5-30]% <i>HeatSticks</i> of number of total tobacco products</p>	<p>0 = Zero <i>HeatStick</i> and CC use</p> <p>A = CC use</p> <p>1 = exclusive CC use</p> <p>2 = predominant CC use</p> <p>B = combined use</p> <p>3 = combined mostly CC use</p> <p>4 = combined balanced use</p> <p>5 = combined mostly <i>HeatStick</i> use</p> <p>C = <i>HeatStick</i> use</p>	Paper and Pencil



Variable	Description	Values	Data Source
	- Combined use:]30-70[% <i>HeatSticks</i> of number of total tobacco products	6 = predominant <i>HeatStick</i> use	
	- Combined mostly CC use:]30- 40[% <i>HeatSticks</i> of number of total tobacco products	7 = exclusive <i>HeatStick</i> use	
	- Combined balanced use: [40-60] % <i>HeatSticks</i> of number of total tobacco products		
	- Combined mostly <i>HeatStick</i> use:]60-70[% <i>HeatSticks</i> of number of total tobacco products		
	- <i>HeatStick</i> use: [70-100] % <i>HeatSticks</i> of number of total tobacco products		
	- Predominant <i>HeatStick</i> use: [70- 95] % <i>HeatSticks</i> of number of total tobacco products		
	- Exclusive <i>HeatStick</i> use:]95- 100] % <i>HeatSticks</i> of number of total tobacco products		



2. BACKGROUND

PMI has conducted a consumer market research study in a number of countries for one of its potential Reduced Risk Products (RRPs), the Tobacco Heating System (THS 2.2). This consumer market research study is called 'Whole Offer Test' (WOT) and was undertaken to evaluate the adult smoker response to different elements of THS 2.2 offer and the likelihood of switching from conventional cigarettes to THS 2.2.

THS 2.2 is comprised of a THS device and THS Tobacco Sticks named as "*HeatSticks*" designed to be exclusively used with the THS device.

The WOT has been conducted in five countries:

- In Japan (JP) from June to August 2013 (study participants were recruited in three locations: Nagoya, Osaka and Tokyo)
- In Italy (IT) from September to October 2013 (study participants were recruited in three locations: Bari, Milan and Rome)
- In Germany (DE) from September to October 2014 (study participants were recruited in three locations: Dresden, Hannover, and Munich)
- In Switzerland (CH) from October to December 2014 (study participants were recruited in five locations: Basel, Berne, Geneva, Lausanne and Zurich)
- In South Korea (KR) from April to June 2015 (study participants were recruited in two locations: Busan and Seoul)

This report comprises the key results from the five WOTs with respect to actual use of *HeatSticks*.

3. OBJECTIVES AND ENDPOINTS

The data from the WOTs has been analyzed according to five primary objectives and two secondary objectives, similar to the objectives of the [THS-PBA-07-US](#) (Actual Use Study of THS 2.2) study.

Primary Objectives and Endpoints

- 1) *Start Using HeatSticks* - The proportion of participants who 'start using' *HeatSticks*.
Endpoints (expressed based on weekly reporting as well as cumulated study week by study week):
 - Number of *HeatSticks* consumed; where 'start using' is defined as ≥ 100 *HeatSticks* consumed during the observational period, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 2) *Switch to HeatSticks* - The proportion of participants who 'start using' *HeatSticks* that 'switch' from CC to *HeatSticks*.
Endpoints (expressed based on weekly reporting as well as by the end of the observational period, i.e. study week 4):
 - Number of *HeatSticks* and CC consumed; where 'switch' is defined as $\geq 70\%$ of tobacco products used are *HeatSticks*, after participant 'starts using' *HeatSticks*, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 3) *Combined Use of CC and HeatSticks* - The proportion of participants who 'start using' *HeatSticks* that have 'combined use' of CC and *HeatSticks*.
Endpoints (expressed based on weekly reporting as well as by the end of the observational period, i.e. study week 4):
 - Number of *HeatSticks* and CC consumed; where 'combined use' is defined as $>30\%$ and $<70\%$ of tobacco products used are *HeatSticks*, after participant 'starts using' *HeatSticks*, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 4) *Switch Back to CC* - The proportion of participants who 'start using' *HeatSticks* that 'switch back' to CC after 'switching' to *HeatSticks*.
Endpoints (expressed based on weekly reporting as well as by the end of the observational period, i.e. study week 4):
 - Number of *HeatSticks* and CC consumed; where 'switch back' is defined as $\leq 30\%$ of tobacco products used are *HeatSticks*, after participant 'starts using' and 'switches' to *HeatSticks*, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary



- 5) *Usage Categories for Continued Use of HeatSticks* - How *HeatSticks* are consumed during continued use (≥ 100 *HeatSticks*, i.e. 'start using') according to 'usage categories' (e.g., 'CC use', 'Combined use', '*HeatStick* use').

Endpoints (expressed based on weekly reporting):

- Number of *HeatSticks* and CC consumed as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

Secondary Objectives and Endpoints

- 6) *Usage Categories for Early Stages of Using HeatSticks* - How *HeatSticks* are consumed during the early stages of use (1-99 *HeatSticks*) according to 'usage categories' (e.g., 'CC use', 'Combined use', '*HeatStick* use').

Endpoints (expressed based on weekly reporting):

- Number of *HeatSticks* and CC consumed as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 7) *Effect of Using HeatSticks on Total Tobacco Product Use* - The 'effect' of *HeatSticks* on the overall consumption of tobacco products (*HeatSticks* and CC).

Endpoints (expressed as difference between self-reported daily average CC consumption before the observational period and weekly reporting of CC+*HeatSticks* during the observational period):

- Number of *HeatSticks* and CC consumed, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary, compared to the number of CC consumed as declared by the study participants before the observational period.

4. METHODS

Study Design

The WOT consists of a single group, descriptive actual use study of THS involving an assessment of participants' self-reported, using a paper and pencil diary, stick-by-stick consumption of *HeatSticks* and of conventional cigarettes (CC) among a sample of adult daily smokers of CC.

Study Procedures

The target population was adult smokers living in the country in which the study was conducted. The sampling frame consisted of adult smokers living in the area of each of the selected research centers.

Each study included a quota sample of smokers aged between one year above the national legal smoking age (e.g., 19 years old) and 64 years. The sample was frequency matching the adult smoker population in terms of four characteristics: age, gender², social status, and main CC brand.

Study participants were recruited using databases maintained by market research agencies. Study participants were screened according to eligibility criteria (see section 6). Enrollment was conducted through interviews at a central facility in the study locations.

The study consisted of two phases. Phase 1 focused on assessing the responses to THS and hypothetical communication materials (e.g., pack design and other branded materials). Phase 2 focused on the actual use of THS and *HeatSticks*.

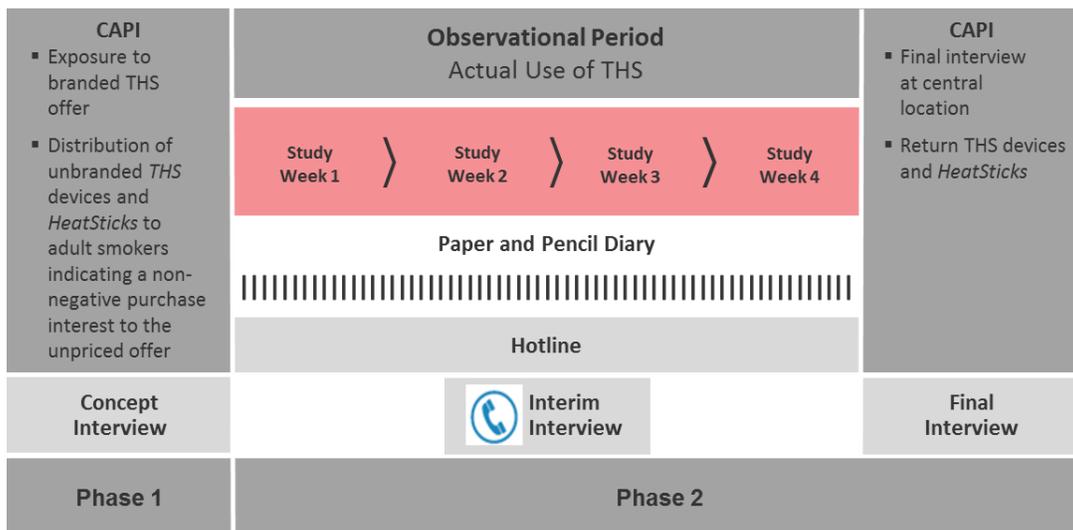


Figure 4-1: Study Approach

² In South Korea, the sample consisted of male participants only.



In Phase 2, study participants were able to take part in a four (4) week observational period. To be eligible for Phase 2, participants had to indicate a non-negative purchase interest, using a 5pt-scale, after trying a single *HeatStick*. During the observational period, participants had access to THS at no expense and were provided with an amount of *HeatSticks* corresponding with their self-reported daily consumption of CC multiplied by the number of days (i.e. 28 days) in the observational period. In contrast to Phase 1, during which participants were exposed to branded materials, the product taken home was unbranded. *HeatSticks* were Regular *HeatSticks* and/or Menthol *HeatSticks* (see [section 7](#) “Test Product” for details). Participants also had the possibility to order additional *HeatSticks* if needed through a dedicated telephone hotline. Participants were free to consume both CC and *HeatSticks ad libitum*. However, if they chose to consume CC, they had to purchase them at their own expense. Participants were asked to record their *HeatStick* and CC consumption on a stick-by-stick basis, using a paper and pencil daily diary. During the observational period, study participants were also asked to participate in interim interviews. This was to measure the overall liking of THS 2.2 after one week of usage, to ensure participants did not have any issues with the operation of the product and were comfortable with the diary completion instructions. At the end of the observational period, participants were asked to return to the central facility and hand back the THS and any unused *HeatSticks*.

Study participants were compensated for their participation according to local market research standards. Study participation was voluntary and respondents were asked to sign a confidentiality and consent form indicating they agreed with the conditions of the study. Study participants were free to withdraw from the study at any time without any obligation, penalty, or loss of the benefits to which they were entitled.

Starting with the Italian WOT, a “passive surveillance procedure” was included as part of the study procedures. This was done to collect safety data using Individual Safety Data Collection Forms (ISDCF) of spontaneously reported health problems collected by telephone hotline operators. This data is not included in this document but will be reported as part of the Tobacco Heating System (THS) safety reporting.

Whilst in Italy and Japan study participants were asked to report their e-cigarette consumption in their diaries, in Switzerland, Germany and South Korea participants were not given instructions to report e-cigarette consumption.

5. NUMBER OF STUDY PARTICIPANTS (ENROLLED AND ANALYZED)

Table 5-1: Number of participants comprising the sample of adult CC smokers who smoke more than 3 CC per day and who were enrolled to take part in the concept interviews (i.e. Phase 1):

Table 5-1: Participants enrolled at Phase 1

Country	Participants	% Males	% Females	Mean Age (Min, Max)
1) Japan	868	69.01%	30.99%	43.02 (21, 64)
2) Italy	800	50.25%	49.75%	40.01 (19, 64)
3) Germany	605	54.55%	45.45%	40.84 (19, 64)
4) Switzerland	581	51.12%	48.88%	38.87 (19, 64)
5) South Korea	1068	100.00%	0.00%	38.59 (20, 64)

Table 5-2: Number of participants who were eligible to take part in the actual use study (i.e. Phase 2), i.e., scoring at least 3 on a purchase intention scale from 1 to 5 [1 = definitely not, 5 = definitely], assessed after a single *HeatStick* trial and, agreeing to participate in the actual use study (observational period):

Table 5-2: Participants eligible for Phase 2

Country	Participants	% Males	% Females	Mean Age (Min, Max)
1) Japan	718	70.75%	29.25%	43.22 (21, 64)
2) Italy	571	50.09%	49.91%	39.06 (19, 64)
3) Germany	443	52.37%	47.63%	40.27 (19, 64)
4) Switzerland	516	51.94%	48.06%	38.98 (19, 64)
5) South Korea	936	100.00%	0.00%	38.43 (20, 64)

Table 5-3: Number of participants whose behavioral data was analyzed; i.e. participants who answered the interim phase, attended the final phase, and completed at least 26 days in the diary³ (i.e. in the Full Analysis Set (FAS)):

Table 5-3: Participants in the Full Analysis Set (FAS)

Country	Participants	% Males	% Females	Mean Age (Min, Max)
1) Japan	638	70.85%	29.15%	43.53 (21, 64)
2) Italy	535	51.03%	48.97%	38.97 (19, 64)
3) Germany	377	51.72%	48.28%	40.29 (19, 64)
4) Switzerland	416	51.92%	48.08%	38.42 (19, 64)
5) South Korea	843	100.00%	0.00%	38.24 (20, 64)

³ A diary entry is considered as completed if the participant either reported the type of product used or declared “zero” consumption of CC and *HeatSticks*.



6. MAIN CRITERIA FOR INCLUSION

For all five countries, the following inclusion criteria were applied:

- To be eligible for Phase 1, participants had to be:
 - Aged 1 year above the country legal smoking age. The upper age limit was 64 years old
 - Residing in the country for at least 1 year
 - Smokers of CC⁴ in the last 7 days
 - Smokers of at least 3 CC per day. All to have been smoking for at least 6 months, and at least 100 CC since reaching legal smoking age (as self-reported by each participant during the recruitment phase)
 - Available during the observational period
 - Not participated in any market research on tobacco products in the last 6 months
 - Not intending to leave the country for more than 3 days during the observational period. (For Switzerland, the criterion was not intending to leave the country for more than one week, rather than 3 days, during the observational period).
- The following participants were excluded from the study:
 - Participants who could not show proof of age at the central facility when coming for Phase 1
 - Participants unwilling to sign confidentiality and consent forms
 - Pregnant or breastfeeding females
 - Individuals working in the fields or market research, marketing, advertising, media or journalism, law, the tobacco industry, the health industry, political lobbying

Additional specific criteria were applied to reflect local specificities:

- Italy and Germany: Only smokers of non-menthol CC were recruited
- South Korea: All participants were male

⁴ In Italy, exclusive smokers of Roll Your Own (RYO) or Make Your Own (MYO) tobacco products in the last 7 days were also eligible.



7. TEST PRODUCT

The test products were Regular *HeatSticks* and Menthol *HeatSticks*. Depending on the country, respondents were given Regular *HeatSticks* or either Regular *HeatSticks* or Menthol *HeatSticks*. More specifically:

- Regular *HeatSticks* only: in Italy and Germany
- Either Regular *HeatSticks* or Menthol *HeatSticks*: in Japan, Switzerland and Korea

In all markets, with the exception of Japan, the products (i.e. Regular *HeatSticks* or Menthol *HeatSticks*) were allocated to participants regardless of the type of CC the participant was currently smoking. In Japan, adult smokers of regular CC received Regular *HeatSticks* and adult smokers of menthol CC received Menthol *HeatSticks*.

Alongside the tested products, participants were provided with the THS, composed of:

- A **HeatStick Holder (Holder)**, into which the *HeatStick* is inserted for consumption and which contains a heating element and a battery that provides the energy for a single usage comprising up to 14 inhalations. Kits provided to eligible participants contained two holders.
- A **Charger** into which the Holder is placed to recharge the battery after each usage. This unit contains a larger battery than the Holder and stores sufficient energy to charge the Holder for the consumption of a number of *HeatSticks* equivalent to approximately one pack of CC (i.e. 20 *HeatSticks*).
- A main **power supply** to charge the main unit.
- A **cleaning tool** to clean the Holder comprising two small brushes. In Germany and Korea, a third cleaning tool was provided alongside the two brushes (used to clean tobacco stuck in the holder).
- **Quick Start User Guide** and **User Guide**. In Korea, only the User Guide was given to participants.

8. DURATION OF EXPOSURE

In each country, the study was performed over a 28 day observational period.



9. SAMPLE SIZE

Enrolled at Phase 1 (number of participants comprising the sample of adult CC smokers who smoke more than 3 CC per day and who were enrolled to take part in the concept interviews):

- 1) Japan: 868 participants
- 2) Italy: 800 participants
- 3) Germany: 605 participants
- 4) Switzerland: 581 participants
- 5) South Korea: 1068 participants

Eligible for Phase 2 (number of participants who were eligible to take part in the behavioral stage; i.e., at least scoring 3 on a purchase intention scale from 1 to 5 [1 = definitely not, 5 = definitely]), assessed after a single *HeatStick* trial and, who agreed to participate in the observational period:

- 1) Japan: 718 participants
- 2) Italy: 571 participants
- 3) Germany: 443 participants
- 4) Switzerland: 516 participants
- 5) South Korea: 936 participants

Full Analysis Set (FAS) (number of study participants whose behavioral data was analyzed; i.e. participants who answered the interim phase, attended the final phase and completed at least 26 days in the diary⁵):

- 1) Japan: 638 participants
- 2) Italy: 535 participants
- 3) Germany: 377 participants
- 4) Switzerland: 416 participants
- 5) South Korea: 843 participant

⁵ A diary entry is considered as completed if the participant either reported the type of product used or declared “zero” consumption of CC and *HeatSticks*.



10. STATISTICAL METHODS

The WOT data was analyzed descriptively using STATA 12.1. The results are presented in frequency tables and measures of central tendency as well as dispersion are provided. 95% Confidence Intervals (95% CI) are reported to describe the precision of the results. Lower and upper CI limits are presented in square brackets. No specific hypotheses were tested.

Analysis of Primary Objectives

For the primary study objectives, ‘*Start Using HeatSticks*’ (objective 1), ‘*Switch to Predominantly Using HeatSticks*’ (objective 2), ‘*Combined Use of CC and HeatSticks*’ (objective 3), and ‘*Switch Back to Predominantly Using CC*’ (objective 4), proportions were analyzed for each study week of the observational period as well as by the end of the observational period. The assessment of the study objectives follows the definitions of variables as explained in detail in [section 1](#) (“List of Abbreviations Definitions of Terms and List of Variables”). For each country sample, the number of participants who were excluded from further analyses has been indicated in [section 9](#) (“Sample Size”). Also, for each study objective, the number of participants in the particular sample to be analyzed (i.e. *n*) has been indicated in each table.

For the primary study objective ‘*Usage Categories for Continued Use of HeatSticks*’ (objective 5), frequency tables present the percentage distribution of participants across the different ‘usage categories’ per study week. This data is also presented using transition tables. Transition tables present the percentage distribution of participants across the different ‘usage categories’ from one earlier study week to another later study week. Additional tables are used to show usage category variations over the observational period.

Analysis of Secondary Objectives

For the secondary study objective ‘*Usage Categories for Early Stages of Using HeatSticks*’ (objective 6), frequency tables present the percentage distribution of participants across the different ‘usage categories’ per study week.

For the secondary study objective ‘*Effect of Using HeatSticks on Total Tobacco Product Use*’ (objective 7), the daily average CC consumption before the observational period as self-reported by participants is compared with daily average total tobacco product use (CC+HeatSticks) for each study week of the observational period. In case of missing values (i.e., no indication of usage behavior on a particular day), the daily average total tobacco product use is computed as the ratio between total tobacco product use (CC+HeatSticks) in that study week and the number of diary days completely filled in that study week.

11. SUMMARY OF RESULTS

JAPAN (JP)

The number of participants who were eligible for Phase 2 in the Japanese WOT was $N = 718$. Out of these 718 participants, 80 were excluded from further analyses as they did not meet all of the criteria for inclusion in the FAS (see [section 9](#) “Sample Size”). The following analyses are thus based on the usage behavior of participants in the FAS ($n = 638$). For some of the analyses, only participants from the FAS who started using *HeatSticks* (i.e. passed the threshold of having smoked 100 *HeatSticks*) by the end of the observational period were considered ($n = 391$).

PRIMARY OBJECTIVES

1) *Start Using HeatSticks*

[Table 11-1](#) shows the percentage of participants in the FAS who started using *HeatSticks*. In study week 1, 9.56% (95% CI = [7.39%, 12.11%]) of participants consumed at least 100 *HeatSticks*. In study week 2, 25.24% [21.91%, 28.79%], in study week 3, 17.08% [14.24%, 20.23%] and in study week 4, 9.40% [7.25%, 11.94%]. By the end of study week 4, 61.29% [57.38%, 65.08%] of participants had started using *HeatSticks*.

Table 11-1: Start Using *HeatSticks* - Japan

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	638	638	638
Started Using in this Study Week	Frequency	61	161	109	60
	Percentage	9.56%	25.24%	17.08%	9.40%
	95% CI	[7.39%, 12.11%]	[21.91%, 28.79%]	[14.24%, 20.23%]	[7.25%, 11.94%]
Started Using by the End of this Study Week	Frequency	61	222	331	391
	Percentage	9.56%	34.80%	51.88%	61.29%
	95% CI	[7.39%, 12.11%]	[31.10%, 38.63%]	[47.92%, 55.82%]	[57.38%, 65.08%]

Note: Percentages in the table refer to the number of study participants in the FAS ($n = 638$). CI = Confidence Interval (Clopper-Pearson).

2) *Switch to HeatSticks*

Table 11-2 shows the percentage of participants who had started using and switched to *HeatSticks* by the end of the observational period. The proportion of participants who switched to *HeatSticks* declined over time from 31.97% [27.37%, 36.84%] in study week 1 to 6.65% [4.39%, 9.59%] in study week 4. By the end of study week 4, 46.29% [41.27%, 51.37%] of participants had switched to *HeatSticks*.

Table 11-2: Switch to *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Japan

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		391	391	391
Switched from CC to <i>HeatSticks</i> in this Study Week	Frequency	125	51	39	26
	Percentage	31.97%	13.04%	9.97%	6.65%
	95% CI	[27.37%, 36.84%]	[9.87%, 16.79%]	[7.19%, 13.38%]	[4.39%, 9.59%]
Switched from CC to <i>HeatSticks</i> by the End of this Study Week	Frequency	125	157	180	181
	Percentage	31.97%	40.15%	46.04%	46.29%
	95% CI	[27.37%, 36.84%]	[35.26%, 45.20%]	[41.01%, 51.12%]	[41.27%, 51.37%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 391). CI = Confidence Interval (Clopper-Pearson).

3) *Combined Use of CC and HeatSticks*

Table 11-3 shows the percentage of participants who had started using *HeatSticks* and used both CC and *HeatSticks* by the end of the observational period. The proportion of participants who started using both CC and *HeatSticks* reached 53.96% [48.88%, 58.99%] in study week 1 and then stabilized at a lower level for the subsequent weeks (maximum of 10.23% [7.41%, 13.67%] in study week 2; minimum of 7.93% [5.45%, 11.07%] in study week 3). By the end of study week 4, 39.90% [35.01%, 44.94%] of participants were using both CC and *HeatSticks*.

Table 11-3: Combined Use of CC and *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Japan

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		391	391	391
Combined Use in this Study Week	Frequency	211	40	31	35
	Percentage	53.96%	10.23%	7.93%	8.95%
	95% CI	[48.88%, 58.99%]	[7.41%, 13.67%]	[5.45%, 11.07%]	[6.31%, 12.23%]
Combined Use by the End of this Study Week	Frequency	211	178	155	156
	Percentage	53.96%	45.52%	39.64%	39.90%
	95% CI	[48.88%, 58.99%]	[40.51%, 50.61%]	[34.76%, 44.68%]	[35.01%, 44.94%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 391). CI = Confidence Interval (Clopper-Pearson).

4) *Switch Back to CC*

Table 11-4 shows the percentage of participants who had started using *HeatSticks* and switched back to CC by the end of the observational period. The proportion of participants who switched back to CC in a given study week was very low and ranged from 0.51% [0.06%, 1.84%] for study week 2 and 3 to 0.00% [0.00%, 0.94%] for study week 4. By the end of study week 4, no participant had switched back to CC.

Table 11-4: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Japan

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		391	391	391
Switched Back to CC in this Study Week	Frequency	NA	2	2	0
	Percentage	NA	0.51%	0.51%	0.00%
	95% CI	NA	[0.06%, 1.84%]	[0.06%, 1.84%]	[0.00%, 0.94%]
Switched Back to CC by the End of this Study Week	Frequency	NA	2	3	0
	Percentage	NA	0.51%	0.77%	0.00%
	95% CI	NA	[0.06%, 1.84%]	[0.16%, 2.23%]	[0.00%, 0.94%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 391). CI = Confidence Interval (Clopper-Pearson).

Table 11-5 shows the percentage of participants who had started using *HeatSticks* and switched back to CC **after switching to *HeatSticks***. By the end of study week 4, no participant had switched back to CC.

Table 11-5: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4 and "Switch to *HeatSticks*") - Japan

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		NA	125	157
Switched Back to CC in this Study Week	Frequency	NA	2	2	0
	Percentage	NA	1.60%	1.27%	0.00%
	95% CI	NA	[0.19%, 5.66%]	[0.15%, 4.53%]	[0.00%, 2.03%]
Switched Back to CC by the End of this Study Week	Frequency	NA	2	3	0
	Percentage	NA	1.60%	1.91%	0.00%
	95% CI	NA	[0.19%, 5.66%]	[0.40%, 5.48%]	[0.00%, 2.03%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period and who have switched to *HeatSticks* by the end of the preceding study week. CI = Confidence Interval (Clopper-Pearson).

5) Usage Categories for Continued Use of HeatSticks

Table 11-6 shows the percentage of participants in the FAS who passed the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 21.48% [17.51%, 25.89%] exclusively or 24.81% [20.60%, 29.40%] predominantly used *HeatSticks*, 39.90% [35.01%, 44.94%] used both CC and *HeatSticks* (*i.e. combined use*), and 13.81% [10.55%, 17.63%] predominantly or exclusively used CC.

Table 11-6: Usage Categories for Continued Use of *HeatSticks* - Japan

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	391	391	391	391
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	19	58	72	84
		Percentage	4.86%	14.83%	18.41%	21.48%
		95% CI	[2.95%, 7.48%]	[11.46%, 18.75%]	[14.7%, 22.62%]	[17.51%, 25.89%]
	Predominant <i>HeatStick</i> Use	Frequency	106	99	108	97
		Percentage	27.11%	25.32%	27.62%	24.81%
		95% CI	[22.76%, 31.81%]	[21.08%, 29.93%]	[23.25%, 32.34%]	[20.60%, 29.40%]
	Combined mostly <i>HeatStick</i> Use	Frequency	45	42	31	42
		Percentage	11.51%	10.74%	7.93%	10.74%
		95% CI	[8.52%, 15.10%]	[7.85%, 14.24%]	[5.45%, 11.07%]	[7.85%, 14.24%]
	Combined balanced Use	Frequency	114	104	85	79
Percentage		29.16%	26.60%	21.74%	20.20%	
95% CI		[24.70%, 33.93%]	[22.28%, 31.27%]	[17.75%, 26.16%]	[16.34%, 24.53%]	
Combined mostly CC Use	Frequency	52	32	39	35	
	Percentage	13.30%	8.18%	9.97%	8.95%	
	95% CI	[10.09%, 17.07%]	[5.67%, 11.36%]	[7.19%, 13.38%]	[6.31%, 12.23%]	
Predominant CC Use	Frequency	53	52	54	50	
	Percentage	13.55%	13.30%	13.81%	12.79%	
	95% CI	[10.32%, 17.35%]	[10.09%, 17.07%]	[10.55%, 17.63%]	[9.64%, 16.51%]	
Exclusive CC Use	Frequency	2	4	2	4	
	Percentage	0.51%	1.02%	0.51%	1.02%	
	95% CI	[0.06%, 1.84%]	[0.28%, 2.60%]	[0.06%, 1.84%]	[0.28%, 2.60%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	
	Percentage	0.00%	0.00%	0.00%	0.00%	
	95% CI	[0.00%, 0.94%]	[0.00%, 0.94%]	[0.00%, 0.94%]	[0.00%, 0.94%]	

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 391). CI = Confidence Interval (Clopper-Pearson).

SECONDARY OBJECTIVES

6) *Usage Categories for Early Stages of Using HeatSticks*

Table 11-7 shows the percentage of participants in the FAS who did not pass the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 24.29% [19.08%, 30.13%] exclusively or 51.42% [45.00%, 57.80%] predominantly used CC, 20.24% [15.41%, 25.80%] used both CC and *HeatSticks* (*i.e. combined use*), and 3.64% [1.68%, 6.80%] predominantly or exclusively used *HeatSticks*.

Table 11-7: Usage Categories for Early Stages of Using *HeatSticks* - Japan

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	247	247	247	247
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	1	0	2	3
		Percentage	0.40%	0.00%	0.81%	1.21%
		95% CI	[0.01%, 2.23%]	[0.00%, 1.48%]	[0.10%, 2.89%]	[0.25%, 3.51%]
	Predominant <i>HeatStick</i> Use	Frequency	4	4	3	6
		Percentage	1.62%	1.62%	1.21%	2.43%
		95% CI	[0.44%, 4.09%]	[0.44%, 4.09%]	[0.25%, 3.51%]	[0.90%, 5.21%]
	Combined mostly <i>HeatStick</i> Use	Frequency	7	4	5	7
		Percentage	2.83%	1.62%	2.02%	2.83%
95% CI		[1.15%, 5.75%]	[0.44%, 4.09%]	[0.66%, 4.66%]	[1.15%, 5.75%]	
Combined balanced Use	Frequency	35	29	20	25	
	Percentage	14.17%	11.74%	8.10%	10.12%	
	95% CI	[10.07%, 19.15%]	[8.01%, 16.43%]	[5.02%, 12.23%]	[6.66%, 14.58%]	
Combined mostly CC Use	Frequency	24	18	29	18	
	Percentage	9.72%	7.29%	11.74%	7.29%	
	95% CI	[6.33%, 14.11%]	[4.38%, 11.27%]	[8.01%, 16.43%]	[4.38%, 11.27%]	
Predominant CC Use	Frequency	160	145	126	127	
	Percentage	64.78%	58.70%	51.01%	51.42%	
	95% CI	[58.47%, 70.73%]	[52.29%, 64.91%]	[44.60%, 57.40%]	[45.00%, 57.80%]	
Exclusive CC Use	Frequency	16	47	62	60	
	Percentage	6.48%	19.03%	25.10%	24.29%	
	95% CI	[3.75%, 10.31%]	[14.33%, 24.49%]	[19.82%, 30.99%]	[19.08%, 30.13%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	1	
	Percentage	0.00%	0.00%	0.00%	0.40%	
	95% CI	[0.00%, 1.48%]	[0.00%, 1.48%]	[0.00%, 1.48%]	[0.01%, 2.23%]	

Note: Percentages in the table refer to the number of study participants who have not started using *HeatSticks* by the end of the observational period (*n* = 247). CI = Confidence Interval (Clopper-Pearson).

7) *Effect of Using HeatSticks on Total Tobacco Product Use*

Table 11-8 shows the effect of using *HeatSticks* on total tobacco product use (CC+*HeatSticks*). Compared to the claimed daily average consumption of CC before the observational period (FAS: Mean 16.52 [15.91, 17.13]; Started by End of Study Week 4: Mean 18.32 [17.54, 19.09]), participants in the FAS consumed 1.95 [1.61, 2.30] fewer tobacco products (*i.e.* CC+*HeatSticks*), and participants who had started using *HeatSticks* by the end of study week 4 consumed 1.32 [0.86, 1.77] fewer tobacco products on average per day in study week 4.

Table 11-8: Effect of Using *HeatSticks* on Total Tobacco Product Use - Japan

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
Full Analysis Set (FAS)	<i>n</i>	638	638	638	638
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	13.86	14.73	14.79	14.57
	SD	6.75	7.60	7.63	7.76
	95% CI	[13.34, 14.39]	[14.14, 15.33]	[14.19, 15.38]	[13.97, 15.17]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-2.66	-1.79	-1.74	-1.95
	SD	4.21	4.58	4.46	4.42
	95% CI	[-2.99, -2.33]	[-2.14, -1.43]	[-2.08, -1.39]	[-2.30, -1.61]
Started by End of Study Week 4	<i>n</i>	391	391	391	391
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	15.81	17.12	17.22	17.00
	SD	6.30	7.43	7.35	7.65
	95% CI	[15.18, 16.44]	[16.38, 17.85]	[16.49, 17.95]	[16.24, 17.76]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-2.51	-1.20	-1.10	-1.32
	SD	4.33	4.85	4.78	4.55
	95% CI	[-2.94, -2.08]	[-1.68, -0.72]	[-1.57, -0.62]	[-1.77, -0.86]

Note: In each cell, the mean is the average number of the sum of CC and *HeatSticks* consumed per day in the given study week. SD = Standard Deviation, CI = Confidence Interval.

ITALY (IT)

The number of participants who were eligible for Phase 2 in the Italian WOT was $N = 571$. Out of these 571 participants, 36 were excluded from further analyses as they did not meet all of the criteria for inclusion in the FAS (see [section 9](#) “Sample Size”). The following analyses are thus based on the usage behavior of participants in the FAS ($n = 535$). For some of the analyses, only participants from the FAS who had started using *HeatSticks* (i.e. passed the threshold of having smoked 100 *HeatSticks*) by the end of the observational period were considered ($n = 193$).

In Italy, 2.00% of participants recruited in Phase 1 were e-cigarette users. 42.80% of participants in the FAS reported at least one (1) e-cigarette consumption over the observational period. However, only 1.1% reported 28 e-cigarette consumption or more in total over the observational period, which corresponds to at least one e-cigarette consumption per day on average. For the purpose of this analysis, only CC and *HeatStick* consumption are reported; e-cigarette consumption was not considered.

PRIMARY OBJECTIVES

1) *Start Using HeatSticks*

[Table 11-9](#) shows the percentage of participants in the FAS who started using *HeatSticks*. In study week 1, 2.06% [1.03%, 3.65%] of participants consumed at least 100 *HeatSticks*. In study week 2, 11.03% [8.50%, 13.99%], in study week 3, 11.59% [9.00%, 14.61%] and in study week 4, 11.40% [8.83%, 14.40%]. By the end of study week 4, 36.07% [32.00%, 40.31%] of participants had started using *HeatSticks*.

Table 11-9: Start Using *HeatSticks* - Italy

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>	535	535	535	535
Started Using in this Study Week	Frequency	11	59	62	61
	Percentage	2.06%	11.03%	11.59%	11.40%
	95% CI	[1.03%, 3.65%]	[8.50%, 13.99%]	[9.00%, 14.61%]	[8.83%, 14.40%]
Started Using by the End of this Study Week	Frequency	11	70	132	193
	Percentage	2.06%	13.08%	24.67%	36.07%
	95% CI	[1.03%, 3.65%]	[10.34%, 16.24%]	[21.07%, 28.55%]	[32.00%, 40.31%]

Note: Percentages in the table refer to the number of study participants in the FAS ($n = 535$). CI = Confidence Interval (Clopper-Pearson).

2) *Switch to HeatSticks*

Table 11-10 shows the percentage of participants who started using and switched to *HeatSticks* by the end of the observational period. The proportion of participants who switched to *HeatSticks* declined over time from 30.05% [23.68%, 37.05%] in study week 1 to 3.63% [1.47%, 7.33%] in study week 4. By the end of study week 4, 29.02% [22.72%, 35.97%] of participants had switched to *HeatSticks*.

Table 11-10: Switch to *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Italy

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>	193	193	193	193
Switched from CC to <i>HeatSticks</i> in this Study Week	Frequency	58	17	13	7
	Percentage	30.05%	8.81%	6.74%	3.63%
	95% CI	[23.68%, 37.05%]	[5.22%, 13.73%]	[3.63%, 11.24%]	[1.47%, 7.33%]
Switched from CC to <i>HeatSticks</i> by the End of this Study Week	Frequency	58	60	58	56
	Percentage	30.05%	31.09%	30.05%	29.02%
	95% CI	[23.68%, 37.05%]	[24.64%, 38.13%]	[23.68%, 37.05%]	[22.72%, 35.97%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 193). CI = Confidence Interval (Clopper-Pearson).

3) *Combined Use of CC and HeatSticks*

Table 11-11 shows the percentage of participants who had started using *HeatSticks* and used both CC and *HeatSticks* by the end of the observational period. The proportion of participants who started using both CC and *HeatSticks* reached 59.07% [51.78%, 66.08%] in study week 1 and then stabilized at a lower level for the subsequent weeks (maximum of 10.88% [6.86%, 16.15%] in study week 2; minimum of 8.29% [4.81%, 13.11%] in study week 3). By the end of study week 4, 54.92% [47.61%, 62.08%] of participants used both CC and *HeatSticks*.

Table 11-11: Combined Use of CC and *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Italy

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>	193	193	193	193
Combined Use in this Study Week	Frequency	114	21	16	18
	Percentage	59.07%	10.88%	8.29%	9.33%
	95% CI	[51.78%, 66.08%]	[6.86%, 16.15%]	[4.81%, 13.11%]	[5.62%, 14.34%]
Combined Use by the End of this Study Week	Frequency	114	112	103	106
	Percentage	59.07%	58.03%	53.37%	54.92%
	95% CI	[51.78%, 66.08%]	[50.73%, 65.08%]	[46.07%, 60.56%]	[47.61%, 62.08%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 193). CI = Confidence Interval (Clopper-Pearson).

4) *Switch Back to CC*

Table 11-12 shows the percentage of participants who had started using *HeatSticks* and switched back to CC by the end of the observational period. The proportion of participants who switched back to CC in a given study week was very low and ranged from 0.52% [0.01%, 2.85%] in study week 2 to 2.59% [0.85%, 5.94%] in study week 4. By the end of study week 4, only 3.11% [1.15%, 6.64%] of participants had switched back to CC.

Table 11-12: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Italy

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		193	193	193
Switched Back to CC in this Study Week	Frequency	NA	1	3	5
	Percentage	NA	0.52%	1.55%	2.59%
	95% CI	NA	[0.01%, 2.85%]	[0.32%, 4.48%]	[0.85%, 5.94%]
Switched Back to CC by the End of this Study Week	Frequency	NA	1	4	6
	Percentage	NA	0.52%	2.07%	3.11%
	95% CI	NA	[0.01%, 2.85%]	[0.57%, 5.22%]	[1.15%, 6.64%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 193). CI = Confidence Interval (Clopper-Pearson).

Table 11-13 shows the percentage of participants who had started using *HeatSticks* and switched back to CC **after switching to *HeatSticks***. By the end of study week 4, 10.34% [3.89%, 21.17%] of participants had switched back to CC.

Table 11-13: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4 and "Switch to *HeatSticks*") - Italy

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		NA	58	60
Switched Back to CC in this Study Week	Frequency	NA	1	3	5
	Percentage	NA	1.72%	5.00%	8.62%
	95% CI	NA	[0.04%, 9.24%]	[1.04%, 13.92%]	[2.86%, 18.98%]
Switched Back to CC by the End of this Study Week	Frequency	NA	1	4	6
	Percentage	NA	1.72%	6.67%	10.34%
	95% CI	NA	[0.04%, 9.24%]	[1.85%, 16.20%]	[3.89%, 21.17%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period and who have switched to *HeatSticks* by the end of the preceding study week. CI = Confidence Interval (Clopper-Pearson).

5) Usage Categories for Continued Use of HeatSticks

Table 11-14 shows the percentage of participants in the FAS who passed the threshold of 100 HeatSticks by the end of the observational period. At the end of the observational period, 12.95% [8.56%, 18.53%] exclusively or 16.06% [11.18%, 22.02%] predominantly used HeatSticks, 54.92% [47.61%, 62.08%] used both CC and HeatSticks (i.e. combined use), and 16.06% [11.18%, 22.02%] predominantly or exclusively used CC.

Table 11-14: Usage Categories for Continued Use of HeatSticks - Italy

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	193	193	193	193
Usage Categories	Exclusive HeatStick Use	Frequency	11	19	22	25
		Percentage	5.70%	9.84%	11.40%	12.95%
		95% CI	[2.88%, 9.97%]	[6.03%, 14.95%]	[7.28%, 16.75%]	[8.56%, 18.53%]
	Predominant HeatStick Use	Frequency	47	41	36	31
		Percentage	24.35%	21.24%	18.65%	16.06%
		95% CI	[18.48%, 31.04%]	[15.7%, 27.7%]	[13.42%, 24.88%]	[11.18%, 22.02%]
	Combined mostly HeatStick Use	Frequency	28	23	18	18
		Percentage	14.51%	11.92%	9.33%	9.33%
		95% CI	[9.86%, 20.28%]	[7.71%, 17.34%]	[5.62%, 14.34%]	[5.62%, 14.34%]
	Combined balanced Use	Frequency	62	62	57	62
Percentage		32.12%	32.12%	29.53%	32.12%	
95% CI		[25.60%, 39.21%]	[25.60%, 39.21%]	[23.20%, 36.51%]	[25.60%, 39.21%]	
Combined mostly CC Use	Frequency	24	27	28	26	
	Percentage	12.44%	13.99%	14.51%	13.47%	
	95% CI	[8.13%, 17.94%]	[9.43%, 19.7%]	[9.86%, 20.28%]	[8.99%, 19.11%]	
Predominant CC Use	Frequency	20	21	29	29	
	Percentage	10.36%	10.88%	15.03%	15.03%	
	95% CI	[6.45%, 15.55%]	[6.86%, 16.15%]	[10.30%, 20.86%]	[10.30%, 20.86%]	
Exclusive CC Use	Frequency	1	0	3	2	
	Percentage	0.52%	0.00%	1.55%	1.04%	
	95% CI	[0.01%, 2.85%]	[0.00%, 1.89%]	[0.32%, 4.48%]	[0.13%, 3.69%]	
Zero HeatStick and CC Use	Frequency	0	0	0	0	
	Percentage	0.00%	0.00%	0.00%	0.00%	
	95% CI	[0.00%, 1.89%]	[0.00%, 1.89%]	[0.00%, 1.89%]	[0.00%, 1.89%]	

Note: Percentages in the table refer to the number of study participants who have started using HeatSticks by the end of the observational period (*n* = 193). CI = Confidence Interval (Clopper-Pearson).

SECONDARY OBJECTIVES

6) *Usage Categories for Early Stages of Using HeatSticks*

Table 11-15 shows the percentage of participants in the FAS who did not pass the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 16.08% [12.35%, 20.41%] exclusively or 52.92% [47.48%, 58.31%] predominantly used CC, 28.36% [23.64%, 33.46%] used both CC and *HeatSticks* (*i.e. combined use*), and 2.63% [1.21%, 4.94%] predominantly or exclusively used *HeatSticks*.

Table 11-15: Usage Categories for Early Stages of Using *HeatSticks* - Italy

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	342	342	342	342
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	0	0	1	3
		Percentage	0.00%	0.00%	0.29%	0.88%
		95% CI	[0.00%, 1.07%]	[0.00%, 1.07%]	[0.01%, 1.62%]	[0.18%, 2.54%]
	Predominant <i>HeatStick</i> Use	Frequency	8	16	6	6
		Percentage	2.34%	4.68%	1.75%	1.75%
		95% CI	[1.02%, 4.56%]	[2.70%, 7.49%]	[0.65%, 3.78%]	[0.65%, 3.78%]
	Combined mostly <i>HeatStick</i> Use	Frequency	12	13	5	5
		Percentage	3.51%	3.80%	1.46%	1.46%
95% CI		[1.83%, 6.05%]	[2.04%, 6.41%]	[0.48%, 3.38%]	[0.48%, 3.38%]	
Combined balanced Use	Frequency	77	49	51	41	
	Percentage	22.51%	14.33%	14.91%	11.99%	
	95% CI	[18.2%, 27.32%]	[10.79%, 18.5%]	[11.31%, 19.14%]	[8.74%, 15.91%]	
Combined mostly CC Use	Frequency	53	55	45	51	
	Percentage	15.50%	16.08%	13.16%	14.91%	
	95% CI	[11.83%, 19.78%]	[12.35%, 20.41%]	[9.76%, 17.21%]	[11.31%, 19.14%]	
Predominant CC Use	Frequency	179	175	200	181	
	Percentage	52.34%	51.17%	58.48%	52.92%	
	95% CI	[46.9%, 57.74%]	[45.74%, 56.58%]	[53.06%, 63.75%]	[47.48%, 58.31%]	
Exclusive CC Use	Frequency	13	34	34	55	
	Percentage	3.80%	9.94%	9.94%	16.08%	
	95% CI	[2.04%, 6.41%]	[6.98%, 13.61%]	[6.98%, 13.61%]	[12.35%, 20.41%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	
	Percentage	0.00%	0.00%	0.00%	0.00%	
	95% CI	[0.00%, 1.07%]	[0.00%, 1.07%]	[0.00%, 1.07%]	[0.00%, 1.07%]	

Note: Percentages in the table refer to the number of study participants who have not started using *HeatSticks* by the end of the observational period (*n* = 342). CI = Confidence Interval (Clopper-Pearson).

7) *Effect of Using HeatSticks on Total Tobacco Product Use*

Table 11-16 shows the effect of using *HeatSticks* on total tobacco product use (CC+*HeatSticks*). Compared to the claimed daily average consumption of CC before the observational period (FAS: Mean 12.70 [12.09, 13.30]; Started by End of Study Week 4: Mean 15.12 [14.16, 16.14]), participants in the FAS consumed 2.57 [2.11, 3.03] fewer tobacco products (i.e. CC+*HeatSticks*), and participants who had started using *HeatSticks* by the end of study week 4 consumed 1.67 [0.88, 2.47] fewer tobacco products on average per day in study week 4.

Table 11-16: Effect of Using *HeatSticks* on Total Tobacco Product Use - Italy

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
Full Analysis Set (FAS)	<i>n</i>	535	535	535	535
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	9.97	9.98	10.10	10.13
	SD	5.31	5.65	5.35	5.56
	95% CI	[9.52, 10.42]	[9.50, 10.46]	[9.65, 10.56]	[9.66, 10.60]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-2.73	-2.72	-2.60	-2.57
	SD	4.64	4.71	5.01	5.42
	95% CI	[-3.12, -2.33]	[-3.12, -2.32]	[-3.02, -2.17]	[-3.03, -2.11]
Started by End of Study Week 4	<i>n</i>	193	193	193	193
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	12.72	13.03	13.27	13.45
	SD	5.57	5.66	4.98	5.53
	95% CI	[11.93, 13.51]	[12.23, 13.83]	[12.57, 13.98]	[12.67, 14.24]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-2.40	-2.09	-1.85	-1.67
	SD	5.13	4.95	5.67	5.57
	95% CI	[-3.13, -1.67]	[-2.80, -1.39]	[-2.66, -1.05]	[-2.47, -0.88]

Note: In each cell, the mean is the average number of the sum of CC and *HeatSticks* consumed per day in the given study week. SD = Standard Deviation, CI = Confidence Interval.

GERMANY (DE)

The number of participants who were eligible for Phase 2 in the German WOT was $N = 443$. Out of these 443 participants, 66 were excluded from further analyses as they did not meet all of the criteria for inclusion in the FAS (see [section 9](#) “Sample Size”). The following analyses are thus based on the usage behavior of participants in the FAS ($n = 377$). For some of the analyses, only participants from the FAS who had started using *HeatSticks* (i.e. passed the threshold of having smoked 100 *HeatSticks*) by the end of the observational period were considered ($n = 189$).

PRIMARY OBJECTIVES1) *Start Using HeatSticks*

[Table 11-17](#) shows the percentage of participants in the FAS who started using *HeatSticks*. In study week 1, 9.28% [6.55%, 12.67%] of participants consumed at least 100 *HeatSticks*. In study week 2, 19.63% [15.74%, 24.00%], in study week 3, 13.26% [10.01%, 17.11%] and in study week 4, 7.96% [5.43%, 11.17%]. By the end of study week 4, 50.13% [44.97%, 55.29%] of participants had started using *HeatSticks*.

Table 11-17: Start Using *HeatSticks* - Germany

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		377	377	377
Started Using in this Study Week	Frequency	35	74	50	30
	<i>m</i>	9.28%	19.63%	13.26%	7.96%
	95% CI	[6.55%, 12.67%]	[15.74%, 24.00%]	[10.01%, 17.11%]	[5.43%, 11.17%]
Started Using by the End of this Study Week	Frequency	35	109	159	189
	<i>m</i>	9.28%	28.91%	42.18%	50.13%
	95% CI	[6.55%, 12.67%]	[24.38%, 33.77%]	[37.14%, 47.34%]	[44.97%, 55.29%]

Note: Percentages in the table refer to the number of study participants in the FAS ($n = 377$). CI = Confidence Interval (Clopper-Pearson).

2) *Switch to HeatSticks*

Table 11-18 shows the percentage of participants who started using and switched to *HeatSticks* by the end of the observational period. The proportion of participants who switched to *HeatSticks* reached 33.86% [27.15%, 41.09%] in study week 1 and then stabilized at a lower level for the subsequent weeks (maximum of 8.47% [4.92%, 13.38%] in study week 2; minimum of 5.82% [2.94%, 10.18%] in study week 3). By the end of study week 4, 37.04% [30.14%, 44.35%] of participants had switched to *HeatSticks*.

Table 11-18: Switch to *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Germany

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>	189	189	189	189
Switched from CC to <i>HeatSticks</i> in this Study Week	Frequency	64	16	11	12
	Percentage	33.86%	8.47%	5.82%	6.35%
	95% CI	[27.15%, 41.09%]	[4.92%, 13.38%]	[2.94%, 10.18%]	[3.32%, 10.83%]
Switched from CC to <i>HeatSticks</i> by the End of this Study Week	Frequency	64	64	67	70
	Percentage	33.86%	33.86%	35.45%	37.04%
	95% CI	[27.15%, 41.09%]	[27.15%, 41.09%]	[28.64%, 42.72%]	[30.14%, 44.35%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 189). CI = Confidence Interval (Clopper-Pearson).

3) *Combined Use of CC and HeatSticks*

Table 11-19 shows the percentage of participants who started using *HeatSticks* and used both CC and *HeatSticks* by the end of the observational period. The proportion of participants who started using both CC and *HeatSticks* declined over time from 57.67% [50.29%, 64.81%] in study week 1 to 6.35% [3.32%, 10.83%] in study week 4. By the end of study week 4, 43.39% [36.21%, 50.77%] of participants used both CC and *HeatSticks*.

Table 11-19: Combined Use of CC and *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Germany

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>	189	189	189	189
Combined Use in this Study Week	Frequency	109	18	15	12
	Percentage	57.67%	9.52%	7.94%	6.35%
	95% CI	[50.29%, 64.81%]	[5.74%, 14.63%]	[4.51%, 12.75%]	[3.32%, 10.83%]
Combined Use by the End of this Study Week	Frequency	109	103	98	82
	Percentage	57.67%	54.50%	51.85%	43.39%
	95% CI	[50.29%, 64.81%]	[47.11%, 61.74%]	[44.48%, 59.16%]	[36.21%, 50.77%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 189). CI = Confidence Interval (Clopper-Pearson).

4) *Switch Back to CC*

Table 11-20 shows the percentage of participants who started using *HeatSticks* and switched back to CC by the end of the observational period. The proportion of participants who switched back to CC in a given study week was very low and ranged from 2.65% [0.86%, 6.07%] for study week 2 to 1.06% [0.13%, 3.77%] for study week 3 and 4. By the end of study week 4, only 2.65% [0.86%, 6.07%] of participants had switched back to CC.

Table 11-20: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4) - Germany

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		189	189	189
Switched Back to CC in this Study Week	Frequency	NA	5	2	2
	Percentage	NA	2.65%	1.06%	1.06%
	95% CI	NA	[0.86%, 6.07%]	[0.13%, 3.77%]	[0.13%, 3.77%]
Switched Back to CC by the End of this Study Week	Frequency	NA	5	4	5
	Percentage	NA	2.65%	2.12%	2.65%
	95% CI	NA	[0.86%, 6.07%]	[0.58%, 5.33%]	[0.86%, 6.07%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 189). CI = Confidence Interval (Clopper-Pearson).

Table 11-21 shows the percentage of participants who had started using *HeatSticks* and switched back to CC **after switching to *HeatSticks***. By the end of study week 4, 7.46% [2.47%, 16.56%] of participants had switched back to CC.

Table 11-21: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4 and "Switch to *HeatSticks*") - Germany

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		NA	64	64
Switched Back to CC in this Study Week	Frequency	NA	5	2	2
	Percentage	NA	7.81%	3.13%	2.99%
	95% CI	NA	[2.58%, 17.30%]	[0.38%, 10.84%]	[0.36%, 10.37%]
Switched Back to CC by the End of this Study Week	Frequency	NA	5	4	5
	Percentage	NA	7.81%	6.25%	7.46%
	95% CI	NA	[2.58%, 17.30%]	[1.73%, 15.24%]	[2.47%, 16.56%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period and who have switched to *HeatSticks* by the end of the preceding study week. CI = Confidence Interval (Clopper-Pearson).

5) Usage Categories for Continued Use of HeatSticks

Table 11-22 shows the percentage of participants in the FAS who passed the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 15.34% [10.52%, 21.29%] exclusively or 21.69% [16.04%, 28.26%] predominantly used *HeatSticks*, 43.39% [36.21%, 50.77%] used both CC and *HeatSticks* (i.e. combined use), and 18.52% [13.25%, 24.80%] predominantly or exclusively used CC.

Table 11-22: Usage Categories for Continued Use of *HeatSticks* - Germany

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	189	189	189	189
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	13	19	27	29
		Percentage	6.88%	10.05%	14.29%	15.34%
		95% CI	[3.71%, 11.47%]	[6.16%, 15.25%]	[9.63%, 20.1%]	[10.52%, 21.29%]
	Predominant <i>HeatStick</i> Use	Frequency	51	45	40	41
		Percentage	26.98%	23.81%	21.16%	21.69%
		95% CI	[20.80%, 33.91%]	[17.93%, 30.53%]	[15.57%, 27.68%]	[16.04%, 28.26%]
	Combined mostly <i>HeatStick</i> Use	Frequency	29	23	16	17
		Percentage	15.34%	12.17%	8.47%	8.99%
		95% CI	[10.52%, 21.29%]	[7.87%, 17.7%]	[4.92%, 13.38%]	[5.33%, 14.01%]
Combined balanced Use	Frequency	62	59	57	48	
	Percentage	32.80%	31.22%	30.16%	25.40%	
	95% CI	[26.16%, 39.99%]	[24.69%, 38.35%]	[23.71%, 37.24%]	[19.36%, 32.22%]	
Combined mostly CC Use	Frequency	18	21	25	17	
	Percentage	9.52%	11.11%	13.23%	8.99%	
	95% CI	[5.74%, 14.63%]	[7.01%, 16.48%]	[8.75%, 18.90%]	[5.33%, 14.01%]	
Predominant CC Use	Frequency	16	20	18	26	
	Percentage	8.47%	10.58%	9.52%	13.76%	
	95% CI	[4.92%, 13.38%]	[6.58%, 15.87%]	[5.74%, 14.63%]	[9.19%, 19.50%]	
Exclusive CC Use	Frequency	0	2	5	9	
	Percentage	0.00%	1.06%	2.65%	4.76%	
	95% CI	[0.00%, 1.93%]	[0.13%, 3.77%]	[0.86%, 6.07%]	[2.20%, 8.85%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	1	2	
	Percentage	0.00%	0.00%	0.53%	1.06%	
	95% CI	[0.00%, 1.93%]	[0.00%, 1.93%]	[0.01%, 2.91%]	[0.13%, 3.77%]	

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 189). CI = Confidence Interval (Clopper-Pearson).

SECONDARY OBJECTIVES

6) *Usage Categories for Early Stages of Using HeatSticks*

Table 11-23 shows the percentage of participants in the FAS who did not pass the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 48.40% [41.07%, 55.79%] exclusively or 35.64% [28.80%, 42.93%] predominantly used CC, 11.17% [7.05%, 16.57%] used both CC and *HeatSticks* (*i.e. combined use*), and 2.66% [0.87%, 6.10%] predominantly or exclusively used *HeatSticks*.

Table 11-23: Usage Categories for Early Stages of Using *HeatSticks* - Germany

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	188	188	188	188
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	1	1	1	3
		Percentage	0.53%	0.53%	0.53%	1.60%
		95% CI	[0.01%, 2.93%]	[0.01%, 2.93%]	[0.01%, 2.93%]	[0.33%, 4.59%]
	Predominant <i>HeatStick</i> Use	Frequency	6	5	5	2
		Percentage	3.19%	2.66%	2.66%	1.06%
		95% CI	[1.18%, 6.82%]	[0.87%, 6.1%]	[0.87%, 6.1%]	[0.13%, 3.79%]
	Combined mostly <i>HeatStick</i> Use	Frequency	11	5	3	4
		Percentage	5.85%	2.66%	1.60%	2.13%
95% CI		[2.96%, 10.23%]	[0.87%, 6.10%]	[0.33%, 4.59%]	[0.58%, 5.36%]	
Combined balanced Use	Frequency	30	19	19	10	
	Percentage	15.96%	10.11%	10.11%	5.32%	
	95% CI	[11.03%, 21.99%]	[6.20%, 15.33%]	[6.20%, 15.33%]	[2.58%, 9.56%]	
Combined mostly CC Use	Frequency	26	14	11	7	
	Percentage	13.83%	7.45%	5.85%	3.72%	
	95% CI	[9.24%, 19.6%]	[4.13%, 12.18%]	[2.96%, 10.23%]	[1.51%, 7.52%]	
Predominant CC Use	Frequency	97	86	72	67	
	Percentage	51.60%	45.74%	38.30%	35.64%	
	95% CI	[44.21%, 58.93%]	[38.48%, 53.15%]	[31.32%, 45.65%]	[28.80%, 42.93%]	
Exclusive CC Use	Frequency	17	56	75	91	
	Percentage	9.04%	29.79%	39.89%	48.40%	
	95% CI	[5.36%, 14.08%]	[23.35%, 36.87%]	[32.84%, 47.27%]	[41.07%, 55.79%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	2	2	4	
	Percentage	0.00%	1.06%	1.06%	2.13%	
	95% CI	[0.00%, 1.97%]	[0.13%, 3.79%]	[0.13%, 3.79%]	[0.58%, 5.36%]	

Note: Percentages in the table refer to the number of study participants who have not started using *HeatSticks* by the end of the observational period (*n* = 188). CI = Confidence Interval (Clopper-Pearson).

7) *Effect of Using HeatSticks on Total Tobacco Product Use*

Table 11-24 shows the effect of using *HeatSticks* on total tobacco product use (CC+*HeatSticks*). Compared to the claimed daily average consumption of CC before the observational period (FAS: Mean 17.36 [16.43, 18.27]; Started by End of Study Week 4: Mean 19.60 [18.27, 20.92]), participants in the FAS consumed 4.72 [4.03, 5.41] fewer tobacco products (i.e. CC+*HeatSticks*), and participants who had started using *HeatSticks* by the end of study week 4 consumed 4.24 [3.18, 5.31] fewer tobacco products on average per day in study week 4.

Table 11-24: Effect of Using *HeatSticks* on Total Tobacco Product Use - Germany

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
Full Analysis Set (FAS)	<i>n</i>	377	377	377	377
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	13.07	13.29	13.02	12.64
	SD	7.03	7.44	7.74	7.35
	95% CI	[12.36, 13.78]	[12.53, 14.04]	[12.24, 13.80]	[11.89, 13.38]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-4.29	-4.07	-4.34	-4.72
	SD	6.18	6.46	6.77	6.84
	95% CI	[-4.91, -3.66]	[-4.72, -3.41]	[-5.02, -3.65]	[-5.41, -4.03]
Started by End of Study Week 4	<i>n</i>	189	189	189	189
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	15.74	16.04	15.92	15.36
	SD	6.70	7.26	7.50	7.34
	95% CI	[14.77, 16.70]	[15.00, 17.08]	[14.84, 17.00]	[14.30, 16.41]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-3.86	-3.56	-3.68	-4.24
	SD	6.63	7.08	7.71	7.42
	95% CI	[-4.81, -2.91]	[-4.57, -2.54]	[-4.78, -2.57]	[-5.31, -3.18]

Note: In each cell, the mean is the average number of the sum of CC and *HeatSticks* consumed per day in the given study week. SD = Standard Deviation, CI = Confidence Interval.

SWITZERLAND (CH)

The number of participants who were eligible for Phase 2 in the Swiss WOT was $N = 516$. Out of these 516 participants, 100 were excluded from further analyses as they did not meet all of the criteria for inclusion in the FAS (see [section 9](#) “Sample Size”). The following analyses are thus based on the usage behavior of participants in the FAS ($n = 416$). For some of the analyses, only participants from the FAS who had started using *HeatSticks* (i.e. passed the threshold of having smoked 100 *HeatSticks*) by the end of the observational period were considered ($n = 206$).

PRIMARY OBJECTIVES1) *Start Using HeatSticks*

[Table 11-25](#) shows the percentage of participants in the FAS who started using *HeatSticks*. In study week 1, 6.25% [4.12%, 9.02%] of participants consumed at least 100 *HeatSticks*. In study week 2, 19.71% [16.00%, 23.86%], in study week 3, 15.38% [12.05%, 19.22%] and in study week 4, 8.17% [5.73%, 11.23%]. By the end of study week 4, 49.52% [44.61%, 54.43%] of participants had started using *HeatSticks*.

Table 11-25: Start Using *HeatSticks* – Switzerland

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		416	416	416
Started Using in this Study Week	Frequency	26	82	64	34
	Percentage	6.25%	19.71%	15.38%	8.17%
	95% CI	[4.12%, 9.02%]	[16.00%, 23.86%]	[12.05%, 19.22%]	[5.73%, 11.23%]
Started Using by the End of this Study Week	Frequency	26	108	172	206
	Percentage	6.25%	25.96%	41.35%	49.52%
	95% CI	[4.12%, 9.02%]	[21.81%, 30.46%]	[36.57%, 46.25%]	[44.61%, 54.43%]

Note: Percentages in the table refer to the number of study participants in the FAS ($n = 416$). CI = Confidence Interval (Clopper-Pearson).

2) *Switch to HeatSticks*

Table 11-26 shows the percentage of participants who started using and switched to *HeatSticks* by the end of the observational period. The proportion of participants who switched to *HeatSticks* declined over time from 21.84% [16.40%, 28.12%] in study week 1 to 0.97% [0.12%, 3.46%] in study week 4. By the end of study week 4, 17.96% [12.97%, 23.90%] of participants had switched to *HeatSticks*.

Table 11-26: Switch to *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) – Switzerland

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		206	206	206
Switched from CC to <i>HeatSticks</i> in this Study Week	Frequency	45	11	11	2
	Percentage	21.84%	5.34%	5.34%	0.97%
	95% CI	[16.40%, 28.12%]	[2.70%, 9.35%]	[2.70%, 9.35%]	[0.12%, 3.46%]
Switched from CC to <i>HeatSticks</i> by the End of this Study Week	Frequency	45	45	47	37
	Percentage	21.84%	21.84%	22.82%	17.96%
	95% CI	[16.40%, 28.12%]	[16.40%, 28.12%]	[17.27%, 29.16%]	[12.97%, 23.90%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 206). CI = Confidence Interval (Clopper-Pearson).

3) *Combined Use of CC and HeatSticks*

Table 11-27 shows the percentage of participants who started using *HeatSticks* and used both CC and *HeatSticks* by the end of the observational period. The proportion of participants who started using both CC and *HeatSticks* reached 65.53% [58.61%, 72.00%] in study week 1 and then stabilized at a lower level for the subsequent weeks (maximum of 10.19% [6.42%, 15.16%] in study week 4; minimum of 8.74% [5.26%, 13.46%] in study week 2). By the end of study week 4, 60.68% [53.65%, 67.40%] of participants used both CC and *HeatSticks*.

Table 11-27: Combined Use of CC and *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) – Switzerland

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		206	206	206
Combined Use in this Study Week	Frequency	135	18	19	21
	Percentage	65.53%	8.74%	9.22%	10.19%
	95% CI	[58.61%, 72.00%]	[5.26%, 13.46%]	[5.64%, 14.03%]	[6.42%, 15.16%]
Combined Use by the End of this Study Week	Frequency	135	126	122	125
	Percentage	65.53%	61.17%	59.22%	60.68%
	95% CI	[58.61%, 72.00%]	[54.14%, 67.86%]	[52.18%, 66.00%]	[53.65%, 67.40%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 206). CI = Confidence Interval (Clopper-Pearson).

4) *Switch Back to CC*

Table 11-28 shows the percentage of participants who started using *HeatSticks* and switched back to CC by the end of the observational period. The proportion of participants who switched back to CC in a given study week was very low and ranged from 1.46% [0.30%, 4.20%] for study week 3 to 0.97% [0.12%, 3.46%] for study week 2 and 4. By the end of study week 4, only 1.94% [0.53%, 4.90%] of participants had switched back to CC.

Table 11-28: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4) – Switzerland

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		206	206	206
Switched Back to CC in this Study Week	Frequency	NA	2	3	2
	Percentage	NA	0.97%	1.46%	0.97%
	95% CI	NA	[0.12%, 3.46%]	[0.30%, 4.20%]	[0.12%, 3.46%]
Switched Back to CC by the End of this Study Week	Frequency	NA	2	4	4
	Percentage	NA	0.97%	1.94%	1.94%
	95% CI	NA	[0.12%, 3.46%]	[0.53%, 4.90%]	[0.53%, 4.90%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 206). CI = Confidence Interval (Clopper-Pearson).

Table 11-29 shows the percentage of participants who had started using *HeatSticks* and switched back to CC **after switching to *HeatSticks***. By the end of study week 4, 8.51% [2.37%, 20.38%] had switched back to CC.

Table 11-29: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4 and “Switch to *HeatSticks*”) - Switzerland

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		NA	45	45
Switched Back to CC in this Study Week	Frequency	NA	2	3	2
	Percentage	NA	4.44%	6.67%	4.26%
	95% CI	NA	[0.54%, 15.15%]	[1.4%, 18.27%]	[0.52%, 14.54%]
Switched Back to CC by the End of this Study Week	Frequency	NA	2	4	4
	Percentage	NA	4.44%	8.89%	8.51%
	95% CI	NA	[0.54%, 15.15%]	[2.48%, 21.22%]	[2.37%, 20.38%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period and who have switched to *HeatSticks* by the end of the preceding study week. CI = Confidence Interval (Clopper-Pearson).

5) Usage Categories for Continued Use of HeatSticks

Table 11-30 shows the percentage of participants in the FAS who passed the threshold of 100 HeatSticks by the end of the observational period. At the end of the observational period, 7.77% [4.50%, 12.31%] exclusively or 10.19% [6.42%, 15.16%] predominantly used HeatSticks, 60.68% [53.65%, 67.40%] used both CC and HeatSticks (i.e. combined use), and 21.36% [15.97%, 27.59%] predominantly or exclusively used CC.

Table 11-30: Usage Categories for Continued Use of HeatSticks – Switzerland

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	206	206	206	206
Usage Categories	Exclusive HeatStick Use	Frequency	9	13	20	16
		Percentage	4.37%	6.31%	9.71%	7.77%
		95% CI	[2.02%, 8.13%]	[3.40%, 10.55%]	[6.03%, 14.6%]	[4.50%, 12.31%]
	Predominant HeatStick Use	Frequency	36	32	27	21
		Percentage	17.48%	15.53%	13.11%	10.19%
		95% CI	[12.55%, 23.36%]	[10.87%, 21.22%]	[8.82%, 18.49%]	[6.42%, 15.16%]
	Combined mostly HeatStick Use	Frequency	21	17	16	20
		Percentage	10.19%	8.25%	7.77%	9.71%
		95% CI	[6.42%, 15.16%]	[4.88%, 12.88%]	[4.50%, 12.31%]	[6.03%, 14.60%]
Combined balanced Use	Frequency	81	76	69	72	
	Percentage	39.32%	36.89%	33.50%	34.95%	
	95% CI	[32.60%, 46.35%]	[30.29%, 43.88%]	[27.09%, 40.39%]	[28.46%, 41.89%]	
Combined mostly CC Use	Frequency	33	33	37	33	
	Percentage	16.02%	16.02%	17.96%	16.02%	
	95% CI	[11.29%, 21.76%]	[11.29%, 21.76%]	[12.97%, 23.90%]	[11.29%, 21.76%]	
Predominant CC Use	Frequency	26	34	33	42	
	Percentage	12.62%	16.50%	16.02%	20.39%	
	95% CI	[8.41%, 17.94%]	[11.71%, 22.29%]	[11.29%, 21.76%]	[15.11%, 26.54%]	
Exclusive CC Use	Frequency	0	0	3	2	
	Percentage	0.00%	0.00%	1.46%	0.97%	
	95% CI	[0.00%, 1.77%]	[0.00%, 1.77%]	[0.30%, 4.20%]	[0.12%, 3.46%]	
Zero HeatStick and CC Use	Frequency	0	1	1	0	
	Percentage	0.00%	0.49%	0.49%	0.00%	
	95% CI	[0.00%, 1.77%]	[0.01%, 2.67%]	[0.01%, 2.67%]	[0.00%, 0.18%]	

Note: Percentages in the table refer to the number of study participants who have started using HeatSticks by the end of the observational period (*n* = 206). CI = Confidence Interval (Clopper-Pearson).

SECONDARY OBJECTIVES

6) *Usage Categories for Early Stages of Using HeatSticks*

Table 11-31 shows the percentage of participants in the FAS who did not pass the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 38.57% [31.95%, 45.52%] exclusively or 40.48% [33.78%, 47.45%] predominantly used CC, 18.57% [13.55%, 24.50%] used both CC and *HeatSticks* (*i.e. combined use*), and 1.90% [0.52%, 4.80%] predominantly or exclusively used *HeatSticks*.

Table 11-31: Usage Categories for Early Stages of Using *HeatSticks* – Switzerland

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	210	210	210	210
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	1	1	2	2
		Percentage	0.48%	0.48%	0.95%	0.95%
		95% CI	[0.01%, 2.62%]	[0.01%, 2.62%]	[0.12%, 3.40%]	[0.12%, 3.40%]
	Predominant <i>HeatStick</i> Use	Frequency	3	3	1	2
		Percentage	1.43%	1.43%	0.48%	0.95%
		95% CI	[0.30%, 4.12%]	[0.30%, 4.12%]	[0.01%, 2.62%]	[0.12%, 3.40%]
	Combined mostly <i>HeatStick</i> Use	Frequency	4	2	3	2
		Percentage	1.90%	0.95%	1.43%	0.95%
		95% CI	[0.52%, 4.80%]	[0.12%, 3.40%]	[0.30%, 4.12%]	[0.12%, 3.40%]
Combined balanced Use	Frequency	35	27	25	27	
	Percentage	16.67%	12.86%	11.90%	12.86%	
	95% CI	[11.89%, 22.41%]	[8.65%, 18.15%]	[7.85%, 17.07%]	[8.65%, 18.15%]	
Combined mostly CC Use	Frequency	26	24	15	10	
	Percentage	12.38%	11.43%	7.14%	4.76%	
	95% CI	[8.25%, 17.61%]	[7.46%, 16.53%]	[4.05%, 11.51%]	[2.31%, 8.58%]	
Predominant CC Use	Frequency	125	110	100	85	
	Percentage	59.52%	52.38%	47.62%	40.48%	
	95% CI	[52.55%, 66.22%]	[45.40%, 59.30%]	[40.70%, 54.60%]	[33.78%, 47.45%]	
Exclusive CC Use	Frequency	16	42	63	81	
	Percentage	7.62%	20.00%	30.00%	38.57%	
	95% CI	[4.42%, 12.08%]	[14.81%, 26.06%]	[23.89%, 36.69%]	[31.95%, 45.52%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	1	1	1	
	Percentage	0.00%	0.48%	0.48%	0.48%	
	95% CI	[0.00%, 1.74%]	[0.01%, 2.62%]	[0.01%, 2.62%]	[0.01%, 2.62%]	

Note: Percentages in the table refer to the number of study participants who have not started using *HeatSticks* by the end of the observational period (*n* = 210). CI = Confidence Interval (Clopper-Pearson).

7) *Effect of Using HeatSticks on Total Tobacco Product Use*

Table 11-32 shows the effect of using *HeatSticks* on total tobacco product use (CC+*HeatSticks*). Compared to the claimed daily average consumption of CC before the observational period (FAS: Mean 17.25 [16.40, 18.10]; Started by End of Study Week 4: Mean 19.09 [17.79, 20.39]), participants in the FAS consumed 2.95 [2.32, 3.58] fewer tobacco products (i.e. CC+*HeatSticks*), and participants who had started using *HeatSticks* by the end of study week 4 consumed 2.05 [1.06, 3.04] fewer tobacco products on average per day in study week 4.

Table 11-32: Effect of Using *HeatSticks* on Total Tobacco Product Use – Switzerland

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
Full Analysis Set (FAS)	<i>n</i>	416	416	416	416
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	13.96	14.38	14.36	14.31
	SD	7.09	7.43	7.79	7.77
	95% CI	[13.27, 14.64]	[13.66, 15.09]	[13.61, 15.12]	[13.56, 15.05]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-3.30	-2.88	-2.89	-2.95
	SD	6.09	6.54	6.73	6.54
	95% CI	[-3.88, -2.71]	[-3.51, -2.25]	[-3.54, -2.24]	[-3.58, -2.32]
Started by End of Study Week 4	<i>n</i>	206	206	206	206
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	16.45	17.04	17.19	17.04
	SD	6.29	6.67	7.15	7.40
	95% CI	[15.59, 17.31]	[16.12, 17.95]	[16.21, 18.17]	[16.02, 18.05]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-2.64	-2.05	-1.90	-2.05
	SD	6.83	7.28	7.48	7.22
	95% CI	[-3.58, -1.70]	[-3.05, -1.05]	[-2.93, -0.87]	[-3.04, -1.06]

Note: In each cell, the mean is the average number of the sum of CC and *HeatSticks* consumed per day in the given study week. SD = Standard Deviation, CI = Confidence Interval.

SOUTH KOREA (KR)

The number of participants who were eligible for Phase 2 in the South Korean WOT was $N = 936$. Out of these 936 participants, 93 were excluded from further analyses as they did not meet all of the criteria for inclusion in the FAS (see [section 9](#) “Sample Size”). The following analyses are thus based on the usage behavior of participants in the FAS ($n = 843$). For some of the analyses, only participants from the FAS who had started using *HeatSticks* (i.e. passed the threshold of having smoked 100 *HeatSticks*) by the end of the observational period were considered ($n = 643$).

PRIMARY OBJECTIVES

1) *Start Using HeatSticks*

[Table 11-33](#) shows the percentage of participants in the FAS who started using *HeatSticks*. In study week 1, 13.88% [11.62%, 16.40%] of participants consumed at least 100 *HeatSticks*. In study week 2, 34.52% [31.31%, 37.84%], in study week 3, 18.51% [15.94%, 21.29%] and in study week 4, 9.37% [7.49%, 11.54%]. By the end of study week 4, 76.28% [73.26%, 79.11%] of participants had started using *HeatSticks*.

Table 11-33: Start Using *HeatSticks* – South Korea

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		843	843	843
Started Using in this Study Week	Frequency	117	291	156	79
	Percentage	13.88%	34.52%	18.51%	9.37%
	95% CI	[11.62%, 16.40%]	[31.31%, 37.84%]	[15.94%, 21.29%]	[7.49%, 11.54%]
Started Using by the End of this Study Week	Frequency	117	408	564	643
	Percentage	13.88%	48.40%	66.90%	76.28%
	95% CI	[11.62%, 16.40%]	[44.98%, 51.83%]	[63.61%, 70.08%]	[73.26%, 79.11%]

Note: Percentages in the table refer to the number of study participants in the FAS ($n = 843$). CI = Confidence Interval (Clopper-Pearson).

2) *Switch to HeatSticks*

Table 11-34 shows the percentage of participants who started using and switched to *HeatSticks* by the end of the observational period. The proportion of participants who switched to *HeatSticks* declined over time from 43.55% [39.67%, 47.48%] in study week 1 to 6.84% [5.02%, 9.08%] in study week 4. By the end of study week 4, 47.43% [43.52%, 51.38%] of participants had switched to *HeatSticks*.

Table 11-34: Switch to *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) – South Korea

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		643	643	643
Switched from CC to <i>HeatSticks</i> in this Study Week	Frequency	280	76	56	44
	Percentage	43.55%	11.82%	8.71%	6.84%
	95% CI	[39.67%, 47.48%]	[9.43%, 14.57%]	[6.65%, 11.16%]	[5.02%, 9.08%]
Switched from CC to <i>HeatSticks</i> by the End of this Study Week	Frequency	280	320	328	305
	Percentage	43.55%	49.77%	51.01%	47.43%
	95% CI	[39.67%, 47.48%]	[45.83%, 53.70%]	[47.07%, 54.94%]	[43.52%, 51.38%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 643). CI = Confidence Interval (Clopper-Pearson).

3) *Combined Use of CC and HeatSticks*

Table 11-35 shows the percentage of participants who started using *HeatSticks* and used both CC and *HeatSticks* by the end of the observational period. The proportion of participants who started using both CC and *HeatSticks* reached 50.23% [46.30%, 54.17%] in study week 1 and then stabilized at a lower level for the subsequent weeks (maximum of 10.26% [8.03%, 12.87%] in study week 4; minimum of 8.24% [6.24%, 10.64%] in study week 2). By the end of study week 4, 40.12% [36.31%, 44.03%] of participants used both CC and *HeatSticks*.

Table 11-35: Combined Use of CC and *HeatSticks* (Given 'Start Using *HeatSticks*' by the End of Study Week 4) – South Korea

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		643	643	643
Combined Use in this Study Week	Frequency	323	53	60	66
	Percentage	50.23%	8.24%	9.33%	10.26%
	95% CI	[46.30%, 54.17%]	[6.24%, 10.64%]	[7.20%, 11.85%]	[8.03%, 12.87%]
Combined Use by the End of this Study Week	Frequency	323	281	269	258
	Percentage	50.23%	43.70%	41.84%	40.12%
	95% CI	[46.30%, 54.17%]	[39.83%, 47.63%]	[37.99%, 45.76%]	[36.31%, 44.03%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 643). CI = Confidence Interval (Clopper-Pearson).

4) *Switch Back to CC*

Table 11-36 shows the percentage of participants who started using *HeatSticks* and switched back to CC by the end of the observational period. The proportion of participants who switched back to CC in a given study week was very low and ranged from 2.95% [1.79%, 4.58%] for study week 4 to 0.31% [0.04%, 1.12%] for study week 2. By the end of study week 4, 3.27% [2.03%, 4.95%] of participants had switched back to CC.

Table 11-36: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4) – South Korea

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		643	643	643
Switched Back to CC in this Study Week	Frequency	NA	2	4	19
	Percentage	NA	0.31%	0.62%	2.95%
	95% CI	NA	[0.04%, 1.12%]	[0.17%, 1.59%]	[1.79%, 4.58%]
Switched Back to CC by the End of this Study Week	Frequency	NA	2	4	21
	Percentage	NA	0.31%	0.62%	3.27%
	95% CI	NA	[0.04%, 1.12%]	[0.17%, 1.59%]	[2.03%, 4.95%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 643). CI = Confidence Interval (Clopper-Pearson).

Table 11-37 shows the percentage of participants who had started using *HeatSticks* and switched back to CC **after switching to *HeatSticks***. By the end of study week 4, 6.40% [4.01%, 9.62%] of participants had switched back to CC.

Table 11-37: Switch Back to CC (Given 'Start Using *HeatSticks*' by the End of Study Week 4 and "Switch to *HeatSticks*") – South Korea

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
	<i>n</i>		NA	280	320
Switched Back to CC in this Study Week	Frequency	NA	2	4	19
	Percentage	NA	0.71%	1.25%	5.79%
	95% CI	NA	[0.09%, 2.56%]	[0.34%, 3.17%]	[3.52%, 8.9%]
Switched Back to CC by the End of this Study Week	Frequency	NA	2	4	21
	Percentage	NA	0.71%	1.25%	6.40%
	95% CI	NA	[0.09%, 2.56%]	[0.34%, 3.17%]	[4.01%, 9.62%]

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period and who have switched to *HeatSticks* by the end of the preceding study week. CI = Confidence Interval (Clopper-Pearson).

5) *Usage Categories for Continued Use of HeatSticks*

Table 11-38 shows the percentage of participants in the FAS who passed the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 20.06% [17.03%, 23.37%] exclusively or 27.37% [23.96%, 30.99%] predominantly used *HeatSticks*, 40.12% [36.31%, 44.03%] used both CC and *HeatSticks* (i.e. combined use), and 11.98% [9.57%, 14.74%] predominantly or exclusively used CC.

Table 11-38: Usage Categories for Continued Use of *HeatSticks* – South Korea

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	643	643	643	643
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	71	121	145	129
		Percentage	11.04%	18.82%	22.55%	20.06%
		95% CI	[8.73%, 13.72%]	[15.87%, 22.06%]	[19.37%, 25.98%]	[17.03%, 23.37%]
	Predominant <i>HeatStick</i> Use	Frequency	209	199	183	176
		Percentage	32.50%	30.95%	28.46%	27.37%
		95% CI	[28.89%, 36.28%]	[27.39%, 34.68%]	[25%, 32.12%]	[23.96%, 30.99%]
	Combined mostly <i>HeatStick</i> Use	Frequency	103	70	63	70
		Percentage	16.02%	10.89%	9.80%	10.89%
		95% CI	[13.27%, 19.09%]	[8.59%, 13.55%]	[7.61%, 12.36%]	[8.59%, 13.55%]
Combined balanced Use	Frequency	165	152	148	136	
	Percentage	25.66%	23.64%	23.02%	21.15%	
	95% CI	[22.33%, 29.22%]	[20.40%, 27.12%]	[19.82%, 26.47%]	[18.06%, 24.51%]	
Combined mostly CC Use	Frequency	55	59	58	52	
	Percentage	8.55%	9.18%	9.02%	8.09%	
	95% CI	[6.51%, 10.99%]	[7.06%, 11.68%]	[6.92%, 11.50%]	[6.10%, 10.47%]	
Predominant CC Use	Frequency	39	41	42	65	
	Percentage	6.07%	6.38%	6.53%	10.11%	
	95% CI	[4.35%, 8.20%]	[4.61%, 8.55%]	[4.75%, 8.73%]	[7.89%, 12.70%]	
Exclusive CC Use	Frequency	0	0	2	12	
	Percentage	0.00%	0.00%	0.31%	1.87%	
	95% CI	[0.00%, 0.57%]	[0.00%, 0.57%]	[0.04%, 1.12%]	[0.97%, 3.24%]	
Zero <i>HeatStick</i> and CC Use	Frequency	1	1	2	3	
	Percentage	0.16%	0.16%	0.31%	0.47%	
	95% CI	[0.00%, 0.86%]	[0.00%, 0.86%]	[0.04%, 1.12%]	[0.10%, 1.36%]	

Note: Percentages in the table refer to the number of study participants who have started using *HeatSticks* by the end of the observational period (*n* = 643). CI = Confidence Interval (Clopper-Pearson).

SECONDARY OBJECTIVES

6) *Usage Categories for Early Stages of Using HeatSticks*

Table 11-39 shows the percentage of participants in the FAS who did not pass the threshold of 100 *HeatSticks* by the end of the observational period. At the end of the observational period, 30.00% [23.74%, 36.86%] exclusively or 40.50% [33.63%, 47.65%] predominantly used CC, 24.00% [18.26%, 30.53%] used both CC and *HeatSticks* (*i.e. combined use*), and 4.00% [1.74%, 7.73%] predominantly or exclusively used *HeatSticks*.

Table 11-39: Usage Categories for Early Stages of Using *HeatSticks* – South Korea

Assessment		Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
		<i>n</i>	200	200	200	200
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	4	1	2	3
		Percentage	2.00%	0.50%	1.00%	1.50%
		95% CI	[0.55%, 5.04%]	[0.01%, 2.75%]	[0.12%, 3.57%]	[0.31%, 4.32%]
	Predominant <i>HeatStick</i> Use	Frequency	10	12	4	5
		Percentage	5.00%	6.00%	2.00%	2.50%
		95% CI	[2.42%, 9.00%]	[3.14%, 10.25%]	[0.55%, 5.04%]	[0.82%, 5.74%]
	Combined mostly <i>HeatStick</i> Use	Frequency	10	4	5	2
		Percentage	5.00%	2.00%	2.50%	1.00%
		95% CI	[2.42%, 9.00%]	[0.55%, 5.04%]	[0.82%, 5.74%]	[0.12%, 3.57%]
Combined balanced Use	Frequency	41	30	19	18	
	Percentage	20.50%	15.00%	9.50%	9.00%	
	95% CI	[15.13%, 26.77%]	[10.35%, 20.72%]	[5.82%, 14.44%]	[5.42%, 13.85%]	
Combined mostly CC Use	Frequency	34	21	25	28	
	Percentage	17.00%	10.50%	12.50%	14.00%	
	95% CI	[12.07%, 22.94%]	[6.62%, 15.60%]	[8.26%, 17.90%]	[9.51%, 19.59%]	
Predominant CC Use	Frequency	93	98	95	81	
	Percentage	46.50%	49.00%	47.50%	40.50%	
	95% CI	[39.44%, 53.67%]	[41.88%, 56.15%]	[40.41%, 54.66%]	[33.63%, 47.65%]	
Exclusive CC Use	Frequency	8	34	47	60	
	Percentage	4.00%	17.00%	23.50%	30.00%	
	95% CI	[1.74%, 7.73%]	[12.07%, 22.94%]	[17.81%, 30.00%]	[23.74%, 36.86%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	3	3	
	Percentage	0.00%	0.00%	1.50%	1.50%	
	95% CI	[0.00%, 1.83%]	[0.00%, 1.83%]	[0.31%, 4.32%]	[0.31%, 4.32%]	

Note: Percentages in the table refer to the number of study participants who have not started using *HeatSticks* by the end of the observational period (*n* = 200). CI = Confidence Interval (Clopper-Pearson).

7) *Effect of Using HeatSticks on Total Tobacco Product Use*

Table 11-40 shows the effect of using *HeatSticks* on total tobacco product use (CC+*HeatSticks*). Compared to the claimed daily average consumption of CC before the observational period (FAS: Mean 15.17 [14.74, 15.60]; Started by End of Study Week 4: Mean 15.89 [15.39, 16.39]), participants in the FAS consumed 1.17 [0.76, 1.57] fewer tobacco products (i.e. CC+*HeatSticks*), and participants who had started using *HeatSticks* by the end of study week 4 consumed 0.46 [0.01, 0.93] fewer tobacco products on average per day in study week 4.

Table 11-40: Effect of Using *HeatSticks* on Total Tobacco Product Use – South Korea

Assessment	Statistics	Study Week 1	Study Week 2	Study Week 3	Study Week 4
Full Analysis Set (FAS)	<i>n</i>	843	843	843	843
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	13.78	14.12	14.01	14.00
	SD	6.01	6.74	7.01	6.98
	95% CI	[13.37, 14.18]	[13.67, 14.58]	[13.54, 14.48]	[13.53, 14.48]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-1.39	-1.05	-1.16	-1.17
	SD	4.97	5.66	6.08	6.02
	95% CI	[-1.73, -1.06]	[-1.43, -0.66]	[-1.57, -0.75]	[-1.57, -0.76]
Started by End of Study Week 4	<i>n</i>	643	643	643	643
Daily average Number of CC and <i>HeatStick</i> Consumption	Mean	14.96	15.52	15.49	15.43
	SD	5.82	6.56	6.77	6.81
	95% CI	[14.51, 15.41]	[15.01, 16.02]	[14.97, 16.02]	[14.90, 15.96]
Δ: Difference to daily average CC Consumption before the observational Period	Mean	-0.93	-0.38	-0.40	-0.46
	SD	5.06	5.66	6.10	6.06
	95% CI	[-1.32, -0.54]	[-0.81, 0.06]	[-0.87, 0.08]	[-0.93, 0.01]

Note: In each cell, the mean is the average number of the sum of CC and *HeatSticks* consumed per day in the given study week. SD = Standard Deviation, CI = Confidence Interval.



SUMMARY OF COUNTRY RESULTS

1) *Start Using HeatSticks:*

The proportion of study participants who consumed at least 100 *HeatSticks* by the end of the observational period ranged from between 36.07% (Italy) to 76.28% (South Korea). Across all countries, the proportion of participants passing the threshold of 100 *HeatSticks* peaked in study weeks 2 or 3, and declined in study week 4. This suggests that the study duration of four observational weeks was sufficient to assess relevant behavioral patterns.

2) *Switch to HeatSticks:*

By the end of the observational period, between 17.96% (Switzerland) and 47.43% (South Korea) of study participants who had started using *HeatSticks*, had switched to *HeatSticks*. This suggests that a rather substantial portion of adult smokers are able to substitute CC, completely or almost completely, with *HeatSticks*. Across all countries, the majority of participants switched to *HeatSticks* in the first study week, indicating that *HeatSticks* are adopted quickly by most participants who start using *HeatSticks*.

3) *Combined Use of CC and HeatSticks:*

Amongst study participants who started using *HeatSticks*, between 39.90% (Japan) and 60.68% (Switzerland) used both CC and *HeatSticks* by the end of the observational period.

4) *Switch Back to CC:*

The proportion of participants, amongst those who switched to *HeatSticks*, who had switched back to CC by the end of the observational period was low in all countries, ranging between 0.00% (Japan) and 10.34% (Italy). This seems to indicate that when adult smokers switch to *HeatSticks* and use them predominantly, the likelihood of relapsing to CC is limited over a period of 4 weeks.



5) *Usage Categories for Continued Use of HeatSticks:*

The proportion of participants who started using *HeatSticks* by study week 4 and adopted a usage behavior involving exclusive use of *HeatSticks* is between 7.77% (Switzerland) and 21.48% (Japan). This indicates that, for a portion of adult smokers, *HeatSticks* are able to represent an alternative to CC.

6) *Usage Categories for Early Stages of Using HeatSticks:*

Among participants who had not passed the threshold of 100 *HeatSticks* by the end of study week 4, the absolute majority predominantly used CC, ranging from 69.01% in Italy to 84.04% in Germany, which seems to indicate that the adoption of *HeatSticks* is either rapid or does not occur at all.

7) *Effect of HeatSticks on Total Tobacco Product Use:*

The daily average total tobacco consumption (i.e., *HeatSticks* + CC) measured during the observational period was approximately two sticks lower than the self-reported consumption (CC only) before the observational period. This was consistent across all countries and study weeks. This difference between consumption rates as assessed by the two different methods (self-reported and daily paper and pencil diary) is coherent with other findings (e.g. [Shiffman et al., 2002](#)), both in terms of its magnitude and direction. Based on the study data, there is no evidence that would suggest that the availability of *HeatSticks* would lead to an increase in daily average total tobacco product consumption (i.e. CC+*HeatSticks*).

SUPPLEMENTARY RESULTS AND ANALYSIS

Table 11-41 shows an overview of results concerning study objectives 1 to 4 across all countries.

Table 11-41: Country Results for Study Objectives 1 to 4 as assessed by the end of the observational period

Assessment	Statistics	JP	IT	DE	CH	KR
Full Analysis Set (FAS)	<i>n</i>	638	535	377	416	843
1) Start Using <i>HeatSticks</i>	Percentage	61.29%	36.07%	50.13%	49.52%	76.28%
Started by End of Study Week 4	<i>n</i>	391	193	189	206	643
2) Switch to <i>HeatSticks</i>	Percentage	46.29%	29.02%	37.04%	17.96%	47.43%
3) Combined Use of CC and <i>HeatSticks</i>	Percentage	39.90%	54.92%	43.39%	60.68%	40.12%
Switched to <i>HeatSticks</i>	<i>n</i>	180	58	67	47	328
4) Switch Back to CC	Percentage	0.00%	10.34%	7.46%	8.51%	6.40%

Note: For study objective 1, the percentages refer to the total number of participants in the corresponding country's FAS. For study objectives 2 to 3, the percentages refer to the total number of participants who have started using HeatSticks by the end of the observational period in the corresponding country. For study objective 4, the percentages refer to the total number of participants who have started using HeatSticks by the end of the observational period and switched to HeatSticks by the end of study week 3 in the corresponding country.

Table 11-42 and Table 11-43 give an overview of the three most frequently observed usage patterns amongst both all participants in the FAS and participants who started using *HeatSticks* by the end of the observational period. These tables were derived from assessing each participant's usage profile as indicated by the usage categories the participant belonged to over the course of the four study weeks. In all cases, the three most commonly observed usage patterns cover the usage behavior of the absolute majority of participants in the corresponding samples. The complete lists of usage patterns per country are provided in the [Appendices](#).

Across countries, the three most frequently observed patterns were generally stable from the beginning to the end of the observational period. For example, among participants who started using *HeatSticks* by the end of the observational period, between 9.22% (Switzerland) and 28.15% (South Korea) showed steady *Heatsticks* use throughout the observational period (see [Table 11-43](#)).

That is to say, across all countries, a substantial proportion of participants adopted a usage behavior involving predominant use of *HeatSticks* right from the first study week and then this behavior continued across the entire observational period.



Table 11-42: The three most frequently observed usage patterns of participants in the FAS per country

FAS: Usage Patterns				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
Japan (n = 638)						
CC	CC	CC	CC	156	24.45%	24.45%
Combined	Combined	Combined	Combined	105	16.46%	40.91%
HeatStick	HeatStick	HeatStick	HeatStick	83	13.01%	53.92%
Italy (n = 535)						
CC	CC	CC	CC	149	27.85%	27.85%
Combined	Combined	Combined	Combined	115	21.50%	49.35%
Combined	CC	CC	CC	34	6.36%	55.70%
Germany (n = 377)						
CC	CC	CC	CC	108	28.65%	28.65%
Combined	Combined	Combined	Combined	63	16.71%	45.36%
HeatStick	HeatStick	HeatStick	HeatStick	41	10.88%	56.23%
Switzerland (n = 416)						
CC	CC	CC	CC	120	28.85%	28.85%
Combined	Combined	Combined	Combined	94	22.60%	51.44%
Combined	CC	CC	CC	28	6.73%	58.17%
South Korea (n = 843)						
HeatStick	HeatStick	HeatStick	HeatStick	183	21.71%	21.71%
Combined	Combined	Combined	Combined	162	19.22%	40.93%
CC	CC	CC	CC	87	10.32%	51.25%

Note: 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'.

Table 11-43: The three most frequently observed usage patterns of participants who have started using HeatSticks by the end of study week 4 per country

'Start Using HeatSticks': Usage Patterns				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
Japan (n = 391)						
Combined	Combined	Combined	Combined	86	21.99%	21.99%
HeatStick	HeatStick	HeatStick	HeatStick	82	20.97%	42.97%
Combined	HeatStick	HeatStick	HeatStick	37	9.46%	52.43%
Italy (n = 193)						
Combined	Combined	Combined	Combined	64	33.16%	33.16%
HeatStick	HeatStick	HeatStick	HeatStick	29	15.03%	48.19%
Combined	Combined	CC	CC	10	5.18%	53.37%
Germany (n = 189)						
Combined	Combined	Combined	Combined	55	29.10%	29.10%
HeatStick	HeatStick	HeatStick	HeatStick	40	21.16%	50.26%
Combined	Combined	Combined	CC	10	5.29%	55.56%
Switzerland (n = 206)						
Combined	Combined	Combined	Combined	78	37.86%	37.86%
HeatStick	HeatStick	HeatStick	HeatStick	19	9.22%	47.09%
CC	CC	CC	CC	10	4.85%	51.94%
South Korea (n = 643)						
HeatStick	HeatStick	HeatStick	HeatStick	181	28.15%	28.15%
Combined	Combined	Combined	Combined	139	21.62%	49.77%
Combined	HeatStick	HeatStick	HeatStick	40	6.22%	55.99%

Note: 'Start Using HeatSticks' means participants who started using HeatSticks by the end of Study Week 4; 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'.



[Table 11-44](#) and [Table 11-45](#) show comparisons by country between the subsample of participants who switched to *HeatSticks* by the end of the observational period (Switchers) and the subsample of participants who did not (Non-Switchers) with respect to gender and age. Across all countries, the two subsamples (Switchers and Non-Switchers) are similar in terms of gender distribution. However, with respect to the distribution of participants of age 25 or above and participants below the age of 25, we observe differences for Italy (*Chi-square, p = .013*) and South Korea (*Chi-square, p = .039*). In these two countries, the subsample of Switchers consists of a lower proportion of participants below the age of 25 as compared to the subsample of Non-Switchers within the FAS. This means that it was predominantly adults above the age of 25 who finally switched to *HeatSticks* in these two countries, indicating that *HeatSticks* may be less attractive for young adult smokers.

Table 11-44: Comparisons of gender distributions between Switchers and Non-Switchers within the FAS

Assessment	Sample size	Percentage [95% CI binomial]	Percentage [95% CI binomial]
Japan			
	<i>n</i>	Male	Female
FAS	638	70.85% [67.15%, 74.35%]	29.15% [25.65%, 32.85%]
Non-Switchers	457	69.37% [64.91%, 73.56%]	30.63% [26.44%, 35.09%]
Switchers	181	74.59% [67.59%, 80.75%]	25.41% [19.25%, 32.41%]
Italy			
	<i>n</i>	Male	Female
FAS	535	51.03% [46.70%, 55.34%]	48.97% [44.66%, 53.30%]
Non-Switchers	479	50.94% [46.34%, 55.50%]	49.06% [44.50%, 53.64%]
Switchers	56	51.79% [38.03%, 65.34%]	48.21% [34.66%, 61.97%]
Germany			
	<i>n</i>	Male	Female
FAS	377	51.72% [46.55%, 56.87%]	48.28% [43.13%, 53.45%]
Non-Switchers	307	49.51% [43.78%, 55.25%]	50.49% [44.75%, 56.22%]
Switchers	70	61.43% [49.03%, 72.83%]	38.57% [27.17%, 50.97%]
Switzerland			
	<i>n</i>	Male	Female
FAS	416	51.92% [47.00%, 56.82%]	48.08% [43.18%, 53.00%]
Non-Switchers	379	52.24% [47.08%, 57.37%]	47.76% [42.63%, 52.92%]
Switchers	37	48.65% [31.92%, 65.60%]	51.35% [34.40%, 68.08%]
South Korea			
	<i>n</i>	Male	Female
FAS	843	100.00% [99.56%, 100.00%]	0.00% N/A
Non-Switchers	538	100.00% [99.31%, 100.00%]	0.00% N/A
Switchers	305	100.00% [98.80%, 100.00%]	0.00% N/A

Note: "(Non-)Switchers" means the subsample of participants who have (not) switched to HeatSticks by the end of the observational period.
CI binomial = Confidence Interval (Clopper-Pearson).

Table 11-45: Comparisons of age distributions between Switchers and Non-Switchers within the FAS

Assessment	Sample size	Mean (SD) [95% CI]	Percentage [95% CI binomial]	Percentage [95% CI binomial]
Japan	<i>n</i>	Age	Age ≤ 24	Age ≥ 25
FAS	638	43.53 (10.80) [42.69, 44.36]	5.33% [3.72%, 7.37%]	94.67% [92.63, 96.28]
Non-Switchers	457	43.28 (10.93) [42.27, 44.28]	5.69% [3.75%, 8.23%]	94.31% [91.77%, 96.25%]
Switchers	181	44.15 (10.46) [42.61, 45.68]	4.42% [1.93%, 8.52%]	95.58% [91.48%, 98.07%]
Italy	<i>n</i>	Age	Age ≤ 24	Age ≥ 25
FAS	535	38.97 (12.84) [37.88, 40.06]	17.19% [14.09%, 20.67%]	82.80% [79.33%, 85.91%]
Non-Switchers	479	38.60 (12.85) [37.45, 39.75]	18.58% [15.20%, 22.36%]	81.42% [77.64%, 84.80%]
Switchers	56	42.16 (12.43) [38.83, 45.49]	5.36% [1.12%, 14.87%]	94.64% [85.13%, 98.88%]
Germany	<i>n</i>	Age	Age ≤ 24	Age ≥ 25
FAS	377	40.29 (12.02) [39.07, 41.51]	10.88% [7.92%, 14.46%]	89.12% [85.54%, 92.08%]
Non-Switchers	307	40.50 (12.00) [39.15, 41.85]	10.42% [7.24%, 14.40%]	89.58% [85.60%, 92.76%]
Switchers	70	39.36 (12.15) [36.46, 42.26]	12.86% [6.05%, 23.01%]	87.14% [76.99%, 93.95%]
Switzerland	<i>n</i>	Age	Age ≤ 24	Age ≥ 25
FAS	416	38.42 (11.33) [37.33, 39.51]	13.70% [10.55%, 17.39%]	86.30% [82.61%, 89.45%]
Non-Switchers	379	38.53 (11.47) [37.37, 39.69]	14.51% [11.12%, 18.47%]	85.49% [81.53%, 88.88%]
Switchers	37	37.30 (9.82) [34.02, 40.57]	5.41% [0.07%, 18.19%]	94.59% [81.80%, 99.34%]
South Korea	<i>n</i>	Age	Age ≤ 24	Age ≥ 25
FAS	843	38.24 (9.64) [37.58, 38.89]	8.54% [6.74%, 10.64%]	91.46% [89.36%, 93.26%]
Non-Switchers	538	37.52 (9.52) [36.71, 38.32]	10.04% [7.63%, 12.89%]	89.96% [87.11%, 92.37%]
Switchers	305	39.50 (9.73) [38.41, 40.60]	5.90% [3.53%, 9.16%]	94.10% [90.83%, 96.47%]

Note: "(Non-)Switchers" means the subsample of participants who have (not) switched to HeatSticks by the end of the observational period.
SD = Standard Deviation, CI binomial = Confidence Interval (Clopper-Pearson), CI = Confidence Interval.



12. STRENGTHS AND LIMITATIONS OF THE STUDY

Below are highlighted some of the strengths of the WOT studies.

First, the sample of participants enrolled into the Phase 1 of the study was large and well controlled: quotas on age, gender (with the exception of South Korea, in which only males participants were considered) social status, and main CC brand were adhered to, ensuring that the study population was adequately frequency matching the adult smoker population. Therefore, results were based on a substantial number of participants, resulting in FAS sample sizes between 377 (Germany) and 843 (South Korea).

Second, the observational period of four weeks allowed for relevant behavioral patterns to manifest themselves.

Third, the data were assessed in two distinct regions, Europe and Asia, and five different countries. Additionally, the geographical coverage consisted of a minimum of two cities in South Korea and three cities in the other countries. This extensive coverage allowed for the observation of a wide range of potential usage patterns across a broad geographic spectrum.

Fourth, the compliance rate was very high in all of the countries, supporting the reliability of results. Between 80.62% (Switzerland) and 93.70% (Italy) of participants who were eligible for Phase 2 and agreed to participate in the observational period fulfilled the requirements for inclusion into the FAS.

There were also some limitations to the WOT studies, mostly intrinsically related to the fact that these studies were conducted in a premarket setting.

First, study participants received the product (i.e. *HeatSticks*) for free. It cannot be excluded that some participants might have used *HeatSticks* with the intention of saving money they would otherwise have spent on CC.

Second, only participants who indicated a non-negative purchase intention at the concept stage were eligible to take part in the behavioral stage. Therefore, it cannot be ruled out that adult smokers negatively disposed towards the product might have had a different rate of adoption of *HeatSticks*.

Third, despite the sampling strategy, which aimed at frequency matching the adult smoker population using quotas on age, gender, social status, and main CC brand, the WOT studies generated results that cannot be considered as nationally representative or cannot provide generalizable results for the entire adult smoker population.

Finally, it cannot be excluded that some study participants altered their smoking behavior during the study period because of increased awareness of their behavior due to the use of the diary.



13. REFERENCE LIST

WHO (World Health Organization). Measuring tobacco use behaviours. In: IARC Handbook of Cancer Prevention Volume 12. [Geneva]: World Health Organization; 2008. Available from: <http://www.iarc.fr/en/publications/pdfs-online/prev/handbook12/>

Shiffman, S., Gwaltney, C. J., Balabanis, M. H., Liu, K. S., Paty, J. A., Kassel, J. D., Hickcox, M. & Gnys, M. (2002). Immediate antecedents of cigarette smoking: An analysis from ecological momentary assessment. *Journal of Abnormal Psychology, 111(4)*, 531-545.



14. APPENDICES

The following pages contain appendices per country and show the transition tables as well as the patterns of usage behavior.



APPENDIX JAPAN 1: TRANSITION TABLES

Table 14-1: Use, Combined Use, *HeatStick* Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Study Week 1	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Study Week 0		Frequency					
		Usage Category	<i>HeatStick</i> Use	Percentage	-	-	-
(% Row; % Col)							
Combined Use	Frequency		-	-	-	-	-
	Percentage		-	-	-	-	-
	(% Row; % Col)						
CC Use	Frequency		125	211	55	0	391
	Percentage		31.97%	53.96%	14.07%	0.00%	100.00%
	(% Row; % Col)		(31.97%; 100.00%)	(53.96%; 100.00%)	(14.07%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)
Zero <i>HeatStick</i> and CC Use	Frequency	-	-	-	-	-	
	Percentage	-	-	-	-	-	
	(% Row; % Col)						
Total	Frequency	125	211	55	0	391	
	Percentage	31.97%	53.96%	14.07%	0.00%	100.00%	
	(% Row; % Col)	(31.97%; 100.00%)	(53.96%; 100.00%)	(14.07%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 1 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-2: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 0						
	Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-
Combined Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
CC Use		Frequency Percentage (% Row; % Col)	157 40.15% (40.15%; 100.00%)	178 45.52% (45.52%; 100.00%)	56 14.32% (14.32%; 100.00%)	0 0.00% (0.00%; NA)	391 100.00% (100.00%; 100.00%)
Zero <i>HeatStick</i> and CC Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	157 40.15% (40.15%; 100.00%)	178 45.52% (45.52%; 100.00%)	56 14.32% (14.32%; 100.00%)	0 0.00% (0.00%; NA)	391 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-3: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, *n* = 391) - Japan

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Study Week 0							
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	180 46.04% (46.04%; 100.00%)	155 39.64% (39.64%; 100.00%)	56 14.32% (14.32%; 100.00%)	0 0.00% (0.00%; NA)	391 100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	180 46.04% (46.04%; 100.00%)	155 39.64% (39.64%; 100.00%)	56 14.32% (14.32%; 100.00%)	0 0.00% (0.00%; NA)	391 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (*n* = 391).



TRANSITION TABLES (CONT'D)

Table 14-4: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Usage Category					
	Study Week 0	Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency	181	156	54	0	391
Percentage (% Row; % Col)		46.29% (46.29%; 100.00%)	39.90% (39.90%; 100.00%)	13.81% (13.81%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	
Zero <i>HeatStick</i> and CC Use	Frequency						
	Percentage (% Row; % Col)	-	-	-	-	-	
Total	Frequency	181	156	54	0	391	
	Percentage (% Row; % Col)	46.29% (46.29%; 100.00%)	39.90% (39.90%; 100.00%)	13.81% (13.81%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-5: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	106	17	2	0	125
Percentage (% Row; % Col)		27.11% (84.80%; 67.52%)	4.35% (13.60%; 9.55%)	0.51% (1.60%; 3.57%)	0.00% (0.00%; NA)	31.97% (100.00%; 31.97%)	
Combined Use	Frequency	47	138	26	0	211	
	Percentage (% Row; % Col)	12.02% (22.27%; 29.94%)	35.29% (65.40%; 77.53%)	6.65% (12.32%; 46.43%)	0.00% (0.00%; NA)	53.96% (100.00%; 53.96%)	
CC Use	Frequency	4	23	28	0	55	
	Percentage (% Row; % Col)	1.02% (7.27%; 2.55%)	5.88% (41.82%; 12.92%)	7.16% (50.91%; 50.00%)	0.00% (0.00%; NA)	14.07% (100.00%; 14.07%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)	
Total	Frequency	157	178	56	0	391	
	Percentage (% Row; % Col)	40.15% (40.15%; 100.00%)	45.52% (45.52%; 100.00%)	14.32% (14.32%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-6: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	104	18	3	0	125
Percentage (% Row; % Col)		26.60% (83.20%; 57.78%)	4.60% (14.40%; 11.61%)	0.77% (2.40%; 5.36%)	0.00% (0.00%; NA)	31.97% (100.00%; 31.97%)	
Combined Use	Frequency	68	117	26	0	211	
	Percentage (% Row; % Col)	17.39% (32.23%; 37.78%)	29.92% (55.45%; 75.48%)	6.65% (12.32%; 46.43%)	0.00% (0.00%; NA)	53.96% (100.00%; 53.96%)	
CC Use	Frequency	8	20	27	0	55	
	Percentage (% Row; % Col)	2.05% (14.55%; 4.44%)	5.12% (36.36%; 12.90%)	6.91% (49.09%; 48.21%)	0.00% (0.00%; NA)	14.07% (100.00%; 14.07%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)	
Total	Frequency	180	155	56	0	391	
	Percentage (% Row; % Col)	46.04% (46.04%; 100.00%)	39.64% (39.64%; 100.00%)	14.32% (14.32%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-7: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Usage Category					
Study Week 1		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	100	25	0	0	125
		Percentage (% Row; % Col)	25.58% (80.00%; 55.25%)	6.39% (20.00%; 16.03%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; NA)	31.97% (100.00%; 31.97%)
	Combined Use	Frequency	71	110	30	0	211
		Percentage (% Row; % Col)	18.16% (33.65%; 39.23%)	28.13% (52.13%; 70.51%)	7.67% (14.22%; 55.56%)	0.00% (0.00%; NA)	53.96% (100.00%; 53.96%)
	CC Use	Frequency	10	21	24	0	55
		Percentage (% Row; % Col)	2.56% (18.18%; 5.52%)	5.37% (38.18%; 13.46%)	6.14% (43.64%; 44.44%)	0.00% (0.00%; NA)	14.07% (100.00%; 14.07%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	181	156	54	0	391
		Percentage	46.29%	39.90%	13.81%	0.00%	100.00%
		(% Row; % Col)	(46.29%; 100.00%)	(39.90%; 100.00%)	(13.81%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-8: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Usage Category					
Study Week 2		Study Week 3	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	141	15	1	0	157
		Percentage (% Row; % Col)	36.06% (89.81%; 78.33%)	3.84% (9.55%; 9.68%)	0.26% (0.64%; 1.79%)	0.00% (0.00%; NA)	40.15% (100.00%; 40.15%)
	Combined Use	Frequency	37	124	17	0	178
		Percentage (% Row; % Col)	9.46% (20.79%; 20.56%)	31.71% (69.66%; 80.00%)	4.35% (9.55%; 30.36%)	0.00% (0.00%; NA)	45.52% (100.00%; 45.52%)
	CC Use	Frequency	2	16	38	0	56
		Percentage (% Row; % Col)	0.51% (3.57%; 1.11%)	4.09% (28.57%; 10.32%)	9.72% (67.86%; 67.86%)	0.00% (0.00%; NA)	14.32% (100.00%; 14.32%)
	Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	180	155	56	0	391
		Percentage (% Row; % Col)	46.04% (46.04%; 100.00%)	39.64% (39.64%; 100.00%)	14.32% (14.32%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



TRANSITION TABLES (CONT'D)

Table 14-9: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Usage Category					
Study Week 2		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	132	25	0	0	157
		Percentage (% Row; % Col)	33.76% (84.08%; 72.93%)	6.39% (15.92%; 16.03%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; NA)	40.15% (100.00%; 40.15%)
	Combined Use	Frequency	44	112	22	0	178
		Percentage (% Row; % Col)	11.25% (24.72%; 24.31%)	28.64% (62.92%; 71.79%)	5.63% (12.36%; 40.74%)	0.00% (0.00%; NA)	45.52% (100.00%; 45.52%)
	CC Use	Frequency	5	19	32	0	56
		Percentage (% Row; % Col)	1.28% (8.93%; 2.76%)	4.86% (33.93%; 12.18%)	8.18% (57.14%; 59.26%)	0.00% (0.00%; NA)	14.32% (100.00%; 14.32%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	181	156	54	0	391
		Percentage	46.29%	39.90%	13.81%	0.00%	100.00%
		(% Row; % Col)	(46.29%; 100.00%)	(39.90%; 100.00%)	(13.81%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391)



TRANSITION TABLES (CONT'D)

Table 14-10: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 391) - Japan

		Usage Category					
Study Week 3		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	155	25	0	0	180
		Percentage (% Row; % Col)	39.64% (86.11%; 85.64%)	6.39% (13.89%; 16.03%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; NA)	46.04% (100.00%; 46.04%)
	Combined Use	Frequency	23	121	11	0	155
		Percentage (% Row; % Col)	5.88% (14.84%; 12.71%)	30.95% (78.06%; 77.56%)	2.81% (7.10%; 20.37%)	0.00% (0.00%; NA)	39.64% (100.00%; 39.64%)
	CC Use	Frequency	3	10	43	0	56
		Percentage (% Row; % Col)	0.77% (5.36%; 1.66%)	2.56% (17.86%; 6.41%)	11.00% (76.79%; 79.63%)	0.00% (0.00%; NA)	14.32% (100.00%; 14.32%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	181	156	54	0	391
		Percentage (% Row; % Col)	46.29% (46.29%; 100.00%)	39.90% (39.90%; 100.00%)	13.81% (13.81%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 3 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 391).



APPENDIX JAPAN 2: PATTERNS OF USAGE BEHAVIOR

Table 14-11: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 638$) - Japan

FAS: Usage Patterns ($n = 638$)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
CC	CC	CC	CC	156	24.45	24.45
Combined	Combined	Combined	Combined	105	16.46	40.91
HeatStick	HeatStick	HeatStick	HeatStick	83	13.01	53.92
Combined	HeatStick	HeatStick	HeatStick	37	5.80	59.72
Combined	CC	CC	CC	34	5.33	65.05
Combined	Combined	HeatStick	HeatStick	22	3.45	68.50
CC	Combined	Combined	Combined	16	2.51	71.00
Combined	Combined	CC	CC	15	2.35	73.35
CC	CC	CC	Combined	12	1.88	75.24
Combined	CC	Combined	Combined	12	1.88	77.12
HeatStick	HeatStick	HeatStick	Combined	12	1.88	79.00
Combined	Combined	Combined	CC	11	1.72	80.72
Combined	Combined	Combined	HeatStick	11	1.72	82.45
CC	CC	Combined	Combined	10	1.57	84.01
CC	CC	Combined	CC	9	1.41	85.42
HeatStick	HeatStick	Combined	HeatStick	8	1.25	86.68
CC	Combined	CC	CC	7	1.10	87.77
Combined	HeatStick	HeatStick	Combined	6	0.94	88.71
HeatStick	Combined	Combined	Combined	6	0.94	89.66
HeatStick	Combined	HeatStick	HeatStick	6	0.94	90.60
CC	Combined	Combined	CC	5	0.78	91.38
CC	Combined	CC	Combined	4	0.63	92.01
CC	Combined	HeatStick	HeatStick	4	0.63	92.63
CC	HeatStick	HeatStick	HeatStick	4	0.63	93.26
Combined	CC	CC	Combined	4	0.63	93.89
Combined	Combined	CC	Combined	4	0.63	94.51
Combined	Combined	HeatStick	Combined	4	0.63	95.14
HeatStick	Combined	HeatStick	Combined	4	0.63	95.77
HeatStick	HeatStick	Combined	Combined	4	0.63	96.39
Combined	HeatStick	Combined	HeatStick	3	0.47	96.87
CC	CC	Combined	HeatStick	2	0.31	97.18
Combined	CC	Combined	CC	2	0.31	97.49
Combined	HeatStick	Combined	Combined	2	0.31	97.81
HeatStick	Combined	Combined	HeatStick	2	0.31	98.12
Other pattern	12	1.88	100.00			
Total				638	100.00	

Note: 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.



Table 14-12: Patterns of Usage Behavior (Given 'Start Using HeatSticks', n = 391) - Japan

'Start Using HeatSticks': Usage Patterns (n = 391)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
Combined	Combined	Combined	Combined	86	21.99	21.99
HeatStick	HeatStick	HeatStick	HeatStick	82	20.97	42.97
Combined	HeatStick	HeatStick	HeatStick	37	9.46	52.43
Combined	Combined	HeatStick	HeatStick	20	5.12	57.54
CC	CC	CC	CC	16	4.09	61.64
Combined	CC	CC	CC	15	3.84	65.47
HeatStick	HeatStick	HeatStick	Combined	12	3.07	68.54
Combined	Combined	Combined	HeatStick	11	2.81	71.36
CC	Combined	Combined	Combined	10	2.56	73.91
Combined	CC	Combined	Combined	9	2.30	76.21
Combined	Combined	CC	CC	8	2.05	78.26
HeatStick	HeatStick	Combined	HeatStick	7	1.79	80.05
Combined	Combined	Combined	CC	6	1.53	81.59
Combined	HeatStick	HeatStick	Combined	6	1.53	83.12
HeatStick	Combined	HeatStick	HeatStick	6	1.53	84.65
CC	CC	CC	Combined	5	1.28	85.93
CC	CC	Combined	Combined	5	1.28	87.21
HeatStick	Combined	Combined	Combined	5	1.28	88.49
CC	Combined	CC	CC	4	1.02	89.51
CC	Combined	Combined	CC	4	1.02	90.54
CC	Combined	HeatStick	HeatStick	4	1.02	91.56
CC	HeatStick	HeatStick	HeatStick	4	1.02	92.58
Combined	Combined	HeatStick	Combined	4	1.02	93.61
HeatStick	HeatStick	Combined	Combined	4	1.02	94.63
Combined	Combined	CC	Combined	3	0.77	95.40
HeatStick	Combined	HeatStick	Combined	3	0.77	96.16
Combined	HeatStick	Combined	Combined	2	0.51	96.68
Combined	HeatStick	Combined	HeatStick	2	0.51	97.19
HeatStick	Combined	Combined	HeatStick	2	0.51	97.70
CC	CC	CC	HeatStick	1	0.26	97.95
CC	CC	Combined	HeatStick	1	0.26	98.21
CC	Combined	CC	Combined	1	0.26	98.47
Combined	CC	Combined	CC	1	0.26	98.72
Combined	CC	HeatStick	HeatStick	1	0.26	98.98
Other pattern	4	1.02	100.00			
Total				391	100.00	

Note: 'Start Using HeatSticks' means participants who started using HeatSticks by the end of Study Week 4; 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.



APPENDIX ITALY 1: TRANSITION TABLES

Table 14-13: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Usage Category					
	Study Week 0	Study Week 1	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency	58	114	21	0	193
Percentage (% Row; % Col)		30.05% (30.05%; 100.00%)	59.07% (59.07%; 100.00%)	10.88% (10.88%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	
<i>Zero HeatStick</i> and CC Use	Frequency						
	Percentage (% Row; % Col)	-	-	-	-	-	
Total	Frequency	58	114	21	0	193	
	Percentage (% Row; % Col)	30.05% (30.05%; 100.00%)	59.07% (59.07%; 100.00%)	10.88% (10.88%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 1 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-14: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 0						
	Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-
Combined Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
CC Use		Frequency Percentage (% Row; % Col)	60 31.09% (31.09%; 100.00%)	112 58.03% (58.03%; 100.00%)	21 10.88% (10.88%; 100.00%)	0 0.00% (0.00%; NA)	193 100.00% (100.00%; 100.00%)
Zero <i>HeatStick</i> and CC Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
Total		Frequency Percentage (% Row; % Col)	60 31.09% (31.09%; 100.00%)	112 58.03% (58.03%; 100.00%)	21 10.88% (10.88%; 100.00%)	0 0.00% (0.00%; NA)	193 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-15: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Usage Category					
	Study Week 0	Study Week 3	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	58 30.05% (30.05%; 100.00%)	103 53.37% (53.37%; 100.00%)	32 16.58% (16.58%; 100.00%)	0 0.00% (0.00%; NA)	193 100.00% (100.00%; 100.00%)
	<i>Zero HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	58 30.05% (30.05%; 100.00%)	103 53.37% (53.37%; 100.00%)	32 16.58% (16.58%; 100.00%)	0 0.00% (0.00%; NA)	193 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-16: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Usage Category					
	Study Week 0	Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency	56	106	31	0	193
		Percentage (% Row; % Col)	29.02% (29.02%; 100.00%)	54.92% (54.92%; 100.00%)	16.06% (16.06%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)
	<i>Zero HeatStick</i> and CC Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
Total	Frequency	56	106	31	0	193	
	Percentage (% Row; % Col)	29.02% (29.02%; 100.00%)	54.92% (54.92%; 100.00%)	16.06% (16.06%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-17: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	43	14	1	0	58
Percentage (% Row; % Col)		22.28% (74.14%; 71.67%)	7.25% (24.14%; 12.50%)	0.52% (1.72%; 4.76%)	0.00% (0.00%; NA)	30.05% (100.00%; 30.05%)	
Combined Use	Frequency	14	91	9	0	114	
	Percentage (% Row; % Col)	7.25% (12.28%; 23.33%)	47.15% (79.82%; 81.25%)	4.66% (7.89%; 42.86%)	0.00% (0.00%; NA)	59.07% (100.00%; 59.07%)	
CC Use	Frequency	3	7	11	0	21	
	Percentage (% Row; % Col)	1.55% (14.29%; 5.00%)	3.63% (33.33%; 6.25%)	5.70% (52.38%; 52.38%)	0.00% (0.00%; NA)	10.88% (100.00%; 10.88%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)	
Total	Frequency	60	112	21	0	193	
	Percentage (% Row; % Col)	31.09% (31.09%; 100.00%)	58.03% (58.03%; 100.00%)	10.88% (10.88%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-18: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	37	19	2	0	58
Percentage (% Row; % Col)		19.17% (63.79%; 63.79%)	9.84% (32.76%; 18.45%)	1.04% (3.45%; 6.25%)	0.00% (0.00%; NA)	30.05% (100.00%; 30.05%)	
Combined Use	Frequency	17	77	20	0	114	
	Percentage (% Row; % Col)	8.81% (14.91%; 29.31%)	39.90% (67.54%; 74.76%)	10.36% (17.54%; 62.50%)	0.00% (0.00%; NA)	59.07% (100.00%; 59.07%)	
CC Use	Frequency	4	7	10	0	21	
	Percentage (% Row; % Col)	2.07% (19.05%; 6.90%)	3.63% (33.33%; 6.80%)	5.18% (47.62%; 31.25%)	0.00% (0.00%; NA)	10.88% (100.00%; 10.88%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)	
Total	Frequency	58	103	32	0	193	
	Percentage (% Row; % Col)	30.05% (30.05%; 100.00%)	53.37% (53.37%; 100.00%)	16.58% (16.58%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-19: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Usage Category					
Study Week 1		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	34	21	3	0	58
		Percentage (% Row; % Col)	17.62% (58.62%; 60.71%)	10.88% (36.21%; 19.81%)	1.55% (5.17%; 9.68%)	0.00% (0.00%; NA)	30.05% (100.00%; 30.05%)
	Combined Use	Frequency	17	74	23	0	114
		Percentage (% Row; % Col)	8.81% (14.91%; 30.36%)	38.34% (64.91%; 69.81%)	11.92% (20.18%; 74.19%)	0.00% (0.00%; NA)	59.07% (100.00%; 59.07%)
	CC Use	Frequency	5	11	5	0	21
		Percentage (% Row; % Col)	2.59% (23.81%; 8.93%)	5.70% (52.38%; 10.38%)	2.59% (23.81%; 16.13%)	0.00% (0.00%; NA)	10.88% (100.00%; 10.88%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	56	106	31	0	193
		Percentage	29.02%	54.92%	16.06%	0.00%	100.00%
		(% Row; % Col)	(29.02%; 100.00%)	(54.92%; 100.00%)	(16.06%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-20: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 2						
	<i>HeatStick</i> Use	Frequency	45	12	3	0	60
Percentage (% Row; % Col)		23.32% (75.00%; 77.59%)	6.22% (20.00%; 11.65%)	1.55% (5.00%; 9.38%)	0.00% (0.00%; NA)	31.09% (100.00%; 31.09%)	
Combined Use	Frequency	13	87	12	0	112	
	Percentage (% Row; % Col)	6.74% (11.61%; 22.41%)	45.08% (77.68%; 84.47%)	6.22% (10.71%; 37.50%)	0.00% (0.00%; NA)	58.03% (100.00%; 58.03%)	
CC Use	Frequency	0	4	17	0	21	
	Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	2.07% (19.05%; 3.88%)	8.81% (80.95%; 53.13%)	0.00% (0.00%; NA)	10.88% (100.00%; 10.88%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)	
Total	Frequency	58	103	32	0	193	
	Percentage (% Row; % Col)	30.05% (30.05%; 100.00%)	53.37% (53.37%; 100.00%)	16.58% (16.58%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-21: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Usage Category					
Study Week 2		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	41	14	5	0	60
		Percentage (% Row; % Col)	21.24% (68.33%; 73.21%)	7.25% (23.33%; 13.21%)	2.59% (8.33%; 16.13%)	0.00% (0.00%; NA)	31.09% (100.00%; 31.09%)
	Combined Use	Frequency	13	82	17	0	112
		Percentage (% Row; % Col)	6.74% (11.61%; 23.21%)	42.49% (73.21%; 77.36%)	8.81% (15.18%; 54.84%)	0.00% (0.00%; NA)	58.03% (100.00%; 58.03%)
	CC Use	Frequency	2	10	9	0	21
		Percentage (% Row; % Col)	1.04% (9.52%; 3.57%)	5.18% (47.62%; 9.43%)	4.66% (42.86%; 29.03%)	0.00% (0.00%; NA)	10.88% (100.00%; 10.88%)
	Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	56	106	31	0	193
		Percentage	29.02%	54.92%	16.06%	0.00%	100.00%
		(% Row; % Col)	(29.02%; 100.00%)	(54.92%; 100.00%)	(16.06%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).



TRANSITION TABLES (CONT'D)

Table 14-22: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 193) - Italy

		Usage Category					
Study Week 3		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	49	7	2	0	58
		Percentage (% Row; % Col)	25.39% (84.48%; 87.50%)	3.63% (12.07%; 6.60%)	1.04% (3.45%; 6.45%)	0.00% (0.00%; NA)	30.05% (100.00%; 30.05%)
	Combined Use	Frequency	5	88	10	0	103
		Percentage (% Row; % Col)	2.59% (4.85%; 8.93%)	45.60% (85.44%; 83.02%)	5.18% (9.71%; 32.26%)	0.00% (0.00%; NA)	53.37% (100.00%; 53.37%)
	CC Use	Frequency	2	11	19	0	32
		Percentage (% Row; % Col)	1.04% (6.25%; 3.57%)	5.70% (34.38%; 10.38%)	9.84% (59.38%; 61.29%)	0.00% (0.00%; NA)	16.58% (100.00%; 16.58%)
	Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)
	Total	Frequency	56	106	31	0	193
		Percentage (% Row; % Col)	29.02% (29.02%; 100.00%)	54.92% (54.92%; 100.00%)	16.06% (16.06%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 3 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 193).

APPENDIX ITALY 2: PATTERNS OF USAGE BEHAVIOR

Table 14-23: Patterns of Usage Behavior (Given the Full Analysis Set, n = 535) - Italy

FAS: Usage Patterns (n = 535)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
CC	CC	CC	CC	149	27.85	27.85
Combined	Combined	Combined	Combined	115	21.50	49.35
Combined	CC	CC	CC	34	6.36	55.70
HeatStick	HeatStick	HeatStick	HeatStick	30	5.61	61.31
Combined	Combined	CC	CC	24	4.49	65.79
Combined	Combined	Combined	CC	18	3.36	69.16
CC	Combined	CC	CC	14	2.62	71.78
CC	CC	CC	Combined	12	2.24	74.02
Combined	HeatStick	HeatStick	HeatStick	12	2.24	76.26
HeatStick	Combined	Combined	Combined	11	2.06	78.32
CC	CC	Combined	Combined	10	1.87	80.19
Combined	Combined	CC	Combined	9	1.68	81.87
CC	Combined	Combined	Combined	8	1.50	83.36
Combined	CC	CC	Combined	8	1.50	84.86
CC	Combined	Combined	CC	6	1.12	85.98
Combined	Combined	HeatStick	HeatStick	6	1.12	87.10
Combined	HeatStick	Combined	Combined	6	1.12	88.22
Combined	CC	Combined	Combined	5	0.93	89.16
Combined	Combined	Combined	HeatStick	4	0.75	89.91
Combined	HeatStick	Combined	CC	4	0.75	90.65
HeatStick	HeatStick	Combined	Combined	4	0.75	91.40
HeatStick	HeatStick	HeatStick	Combined	4	0.75	92.15
CC	CC	Combined	CC	3	0.56	92.71
CC	Combined	CC	Combined	3	0.56	93.27
Combined	CC	Combined	CC	3	0.56	93.83
HeatStick	Combined	HeatStick	HeatStick	3	0.56	94.39
HeatStick	HeatStick	Combined	CC	3	0.56	94.95
HeatStick	HeatStick	Combined	HeatStick	3	0.56	95.51
CC	Combined	HeatStick	HeatStick	2	0.37	95.89
CC	HeatStick	HeatStick	HeatStick	2	0.37	96.26
HeatStick	CC	CC	CC	2	0.37	96.64
HeatStick	Combined	CC	CC	2	0.37	97.01
CC	CC	CC	HeatStick	1	0.19	97.20
CC	HeatStick	CC	CC	1	0.19	97.38
Other pattern	14	2.62	100.00			
Total				535	100.00	

Note: 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.

Table 14-24: Patterns of Usage Behavior (Given 'Start Using HeatSticks', n = 193) - Italy

'Start Using HeatSticks': Usage Patterns (n = 193)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
Combined	Combined	Combined	Combined	64	33.16	33.16
HeatStick	HeatStick	HeatStick	HeatStick	29	15.03	48.19
Combined	Combined	CC	CC	10	5.18	53.37
HeatStick	Combined	Combined	Combined	10	5.18	58.55
Combined	HeatStick	HeatStick	HeatStick	8	4.15	62.69
Combined	Combined	Combined	CC	6	3.11	65.80
Combined	Combined	HeatStick	HeatStick	5	2.59	68.39
CC	CC	CC	CC	4	2.07	70.47
CC	Combined	Combined	Combined	4	2.07	72.54
Combined	CC	CC	CC	4	2.07	74.61
HeatStick	HeatStick	Combined	Combined	4	2.07	76.68
HeatStick	HeatStick	HeatStick	Combined	4	2.07	78.76
CC	CC	CC	Combined	3	1.55	80.31
CC	CC	Combined	Combined	3	1.55	81.87
Combined	CC	CC	Combined	3	1.55	83.42
Combined	Combined	Combined	HeatStick	3	1.55	84.97
Combined	HeatStick	Combined	Combined	3	1.55	86.53
HeatStick	Combined	HeatStick	HeatStick	3	1.55	88.08
HeatStick	HeatStick	Combined	CC	3	1.55	89.64
CC	Combined	HeatStick	HeatStick	2	1.04	90.67
CC	HeatStick	HeatStick	HeatStick	2	1.04	91.71
HeatStick	HeatStick	Combined	HeatStick	2	1.04	92.75
CC	CC	CC	HeatStick	1	0.52	93.26
CC	Combined	CC	Combined	1	0.52	93.78
CC	HeatStick	CC	CC	1	0.52	94.30
Combined	CC	CC	HeatStick	1	0.52	94.82
Combined	CC	Combined	CC	1	0.52	95.34
Combined	Combined	CC	Combined	1	0.52	95.85
Combined	Combined	HeatStick	CC	1	0.52	96.37
Combined	Combined	HeatStick	Combined	1	0.52	96.89
Combined	HeatStick	CC	Combined	1	0.52	97.41
Combined	HeatStick	HeatStick	CC	1	0.52	97.93
Combined	HeatStick	HeatStick	Combined	1	0.52	98.45
HeatStick	CC	CC	Combined	1	0.52	98.96
Other pattern	2	1.04	100.00			
Total				193	100.00	

Note: 'Start Using HeatSticks' means participants who started using HeatSticks by the end of Study Week 4; 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.



APPENDIX GERMANY 1: TRANSITION TABLES

Table 14-25: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Usage Category					
	Study Week 0	Study Week 1	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency	64	109	16	0	189
Percentage (% Row; % Col)		33.86% (33.86%; 100.00%)	57.67% (57.67%; 100.00%)	8.47% (8.47%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	
Zero <i>HeatStick</i> and CC Use	Frequency						
	Percentage (% Row; % Col)	-	-	-	-	-	
Total	Frequency	64	109	16	0	189	
	Percentage (% Row; % Col)	33.86% (33.86%; 100.00%)	57.67% (57.67%; 100.00%)	8.47% (8.47%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 1 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-26: CC Use, Combined Use, HeatStick Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using HeatSticks' by the End of Study Week 4, n = 189) - Germany

		Study Week 2	Usage Category				Total
			HeatStick Use	Combined Use	CC Use	Zero HeatStick and CC Use	
Usage Category	Study Week 0						
	Usage Category	HeatStick Use	Frequency Percentage (% Row; % Col)	-	-	-	-
Combined Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
CC Use		Frequency Percentage (% Row; % Col)	64 33.86% (33.86%; 100.00%)	103 54.50% (54.50%; 100.00%)	22 11.64% (11.64%; 100.00%)	0 0.00% (0.00%; NA)	189 100.00% (100.00%; 100.00%)
Zero HeatStick and CC Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	64 33.86% (33.86%; 100.00%)	103 54.50% (54.50%; 100.00%)	22 11.64% (11.64%; 100.00%)	0 0.00% (0.00%; NA)	189 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 2 of those participants who have started using HeatSticks by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-27: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Usage Category					
	Study Week 0	Study Week 3	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	67 35.45% (35.45%; 100.00%)	98 51.85% (51.85%; 100.00%)	23 12.17% (12.17%; 100.00%)	1 0.53% (0.53%; 100.00%)	189 100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	67 35.45% (35.45%; 100.00%)	98 51.85% (51.85%; 100.00%)	23 12.17% (12.17%; 100.00%)	1 0.53% (0.53%; 100.00%)	189 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-28: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Usage Category					
Study Week 0	Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total	
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	
	CC Use	Frequency	70	82	35	2	189
		Percentage (% Row; % Col)	37.04% (37.04%; 100.00%)	43.39% (43.39%; 100.00%)	18.52% (18.52%; 100.00%)	1.06% (1.06%; 100.00%)	100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
Total	Frequency	70	82	35	2	189	
	Percentage (% Row; % Col)	37.04% (37.04%; 100.00%)	43.39% (43.39%; 100.00%)	18.52% (18.52%; 100.00%)	1.06% (1.06%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-29: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	48	11	5	0	64
Percentage (% Row; % Col)		25.40% (75.00%; 75.00%)	5.82% (17.19%; 10.68%)	2.65% (7.81%; 22.73%)	0.00% (0.00%; NA)	33.86% (100.00%; 33.86%)	
Combined Use	Frequency	15	85	9	0	109	
	Percentage (% Row; % Col)	7.94% (13.76%; 23.44%)	44.97% (77.98%; 82.52%)	4.76% (8.26%; 40.91%)	0.00% (0.00%; NA)	57.67% (100.00%; 57.67%)	
CC Use	Frequency	1	7	8	0	16	
	Percentage (% Row; % Col)	0.53% (6.25%; 1.56%)	3.70% (43.75%; 6.80%)	4.23% (50.00%; 36.36%)	0.00% (0.00%; NA)	8.47% (100.00%; 8.47%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; NA)	0.00% (NA; 0.00%)	
Total	Frequency	64	103	22	0	189	
	Percentage (% Row; % Col)	33.86% (33.86%; 100.00%)	54.50% (54.50%; 100.00%)	11.64% (11.64%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-30: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	46	13	4	1	64
Percentage (% Row; % Col)		24.34% (71.88%; 68.66%)	6.88% (20.31%; 13.27%)	2.12% (6.25%; 17.39%)	0.53% (1.56%; 100.00%)	33.86% (100.00%; 33.86%)	
Combined Use	Frequency	20	77	12	0	109	
	Percentage (% Row; % Col)	10.58% (18.35%; 29.85%)	40.74% (70.64%; 78.57%)	6.35% (11.01%; 52.17%)	0.00% (0.00%; 0.00%)	57.67% (100.00%; 57.67%)	
CC Use	Frequency	1	8	7	0	16	
	Percentage (% Row; % Col)	0.53% (6.25%; 1.49%)	4.23% (50.00%; 8.16%)	3.70% (43.75%; 30.43%)	0.00% (0.00%; 0.00%)	8.47% (100.00%; 8.47%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	
Total	Frequency	67	98	23	1	189	
	Percentage (% Row; % Col)	35.45% (35.45%; 100.00%)	51.85% (51.85%; 100.00%)	12.17% (12.17%; 100.00%)	0.53% (0.53%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-31: CC Use, Combined Use, *HeatStick* - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, *n* = 189) - Germany

		Study Week 4	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	47	11	4	2	64
Percentage (% Row; % Col)		24.87% (73.44%; 67.14%)	5.82% (17.19%; 13.41%)	2.12% (6.25%; 11.43%)	1.06% (3.13%; 100.00%)	33.86% (100.00%; 33.86%)	
Combined Use	Frequency	22	66	21	0	109	
	Percentage (% Row; % Col)	11.64% (20.18%; 31.43%)	34.92% (60.55%; 80.49%)	11.11% (19.27%; 60.00%)	0.00% (0.00%; 0.00%)	57.67% (100.00%; 57.67%)	
CC Use	Frequency	1	5	10	0	16	
	Percentage (% Row; % Col)	0.53% (6.25%; 1.43%)	2.65% (31.25%; 6.10%)	5.29% (62.50%; 28.57%)	0.00% (0.00%; 0.00%)	8.47% (100.00%; 8.47%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	
Total	Frequency	70	82	35	2	189	
	Percentage (% Row; % Col)	37.04% (37.04%; 100.00%)	43.39% (43.39%; 100.00%)	18.52% (18.52%; 100.00%)	1.06% (1.06%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (*n* = 189).



TRANSITION TABLES (CONT'D)

Table 14-32: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 2						
	<i>HeatStick</i> Use	Frequency	56	6	1	1	64
Percentage (% Row; % Col)		29.63% (87.50%; 83.58%)	3.17% (9.38%; 6.12%)	0.53% (1.56%; 4.35%)	0.53% (1.56%; 100.00%)	33.86% (100.00%; 33.86%)	
Combined Use	Frequency	10	83	10	0	103	
	Percentage (% Row; % Col)	5.29% (9.71%; 14.93%)	43.92% (80.58%; 84.69%)	5.29% (9.71%; 43.48%)	0.00% (0.00%; 0.00%)	54.50% (100.00%; 54.50%)	
CC Use	Frequency	1	9	12	0	22	
	Percentage (% Row; % Col)	0.53% (4.55%; 1.49%)	4.76% (40.91%; 9.18%)	6.35% (54.55%; 52.17%)	0.00% (0.00%; 0.00%)	11.64% (100.00%; 11.64%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	
Total	Frequency	67	98	23	1	189	
	Percentage (% Row; % Col)	35.45% (35.45%; 100.00%)	51.85% (51.85%; 100.00%)	12.17% (12.17%; 100.00%)	0.53% (0.53%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-33: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Usage Category					
Study Week 2		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	51	11	1	1	64
		Percentage (% Row; % Col)	26.98% (79.69%; 72.86%)	5.82% (17.19%; 13.41%)	0.53% (1.56%; 2.86%)	0.53% (1.56%; 50.00%)	33.86% (100.00%; 33.86%)
	Combined Use	Frequency	15	67	20	1	103
		Percentage (% Row; % Col)	7.94% (14.56%; 21.43%)	35.45% (65.05%; 81.71%)	10.58% (19.42%; 57.14%)	0.53% (0.97%; 50.00%)	54.50% (100.00%; 54.50%)
	CC Use	Frequency	4	4	14	0	22
		Percentage (% Row; % Col)	2.12% (18.18%; 5.71%)	2.12% (18.18%; 4.88%)	7.41% (63.64%; 40.00%)	0.00% (0.00%; 0.00%)	11.64% (100.00%; 11.64%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)
	Total	Frequency	70	82	35	2	189
		Percentage	37.04%	43.39%	18.52%	1.06%	100.00%
		(% Row; % Col)	(37.04%; 100.00%)	(43.39%; 100.00%)	(18.52%; 100.00%)	(1.06%; 100.00%)	(100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).



TRANSITION TABLES (CONT'D)

Table 14-34: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 189) - Germany

		Usage Category					
Study Week 3		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	58	7	2	0	67
		Percentage (% Row; % Col)	30.69% (86.57%; 82.86%)	3.70% (10.45%; 8.54%)	1.06% (2.99%; 5.71%)	0.00% (0.00%; 0.00%)	35.45% (100.00%; 35.45%)
	Combined Use	Frequency	11	70	16	1	98
		Percentage (% Row; % Col)	5.82% (11.22%; 15.71%)	37.04% (71.43%; 85.37%)	8.47% (16.33%; 45.71%)	0.53% (1.02%; 50.00%)	51.85% (100.00%; 51.85%)
	CC Use	Frequency	1	5	17	0	23
		Percentage (% Row; % Col)	0.53% (4.35%; 1.43%)	2.65% (21.74%; 6.10%)	8.99% (73.91%; 48.57%)	0.00% (0.00%; 0.00%)	12.17% (100.00%; 12.17%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	1	1
		Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.53% (100.00%; 50.00%)	0.53% (100.00%; 0.53%)
	Total	Frequency	70	82	35	2	189
		Percentage (% Row; % Col)	37.04% (37.04%; 100.00%)	43.39% (43.39%; 100.00%)	18.52% (18.52%; 100.00%)	1.06% (1.06%; 100.00%)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 3 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 189).

APPENDIX GERMANY 2: PATTERNS OF USAGE BEHAVIOR

Table 14-35: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 377$) - Germany

FAS: Usage Patterns ($n = 377$)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
CC	CC	CC	CC	108	28.65	28.65
Combined	Combined	Combined	Combined	63	16.71	45.36
HeatStick	HeatStick	HeatStick	HeatStick	41	10.88	56.23
Combined	CC	CC	CC	27	7.16	63.40
Combined	Combined	Combined	CC	19	5.04	68.44
Combined	Combined	CC	CC	15	3.98	72.41
Combined	HeatStick	HeatStick	HeatStick	10	2.65	75.07
CC	Combined	Combined	CC	6	1.59	76.66
Combined	CC	Combined	CC	6	1.59	78.25
Combined	Combined	Combined	HeatStick	6	1.59	79.84
Combined	Combined	HeatStick	HeatStick	6	1.59	81.43
HeatStick	HeatStick	Combined	Combined	5	1.33	82.76
CC	Combined	Combined	Combined	4	1.06	83.82
Combined	CC	Combined	Combined	4	1.06	84.88
Combined	HeatStick	HeatStick	Combined	4	1.06	85.94
HeatStick	Combined	Combined	Combined	4	1.06	87.00
Combined	Combined	CC	Combined	3	0.80	87.80
CC	CC	CC	Zero	2	0.53	88.33
CC	CC	Combined	CC	2	0.53	88.86
Combined	CC	CC	Combined	2	0.53	89.39
Combined	Combined	HeatStick	Combined	2	0.53	89.92
Combined	HeatStick	Combined	Combined	2	0.53	90.45
HeatStick	CC	CC	CC	2	0.53	90.98
HeatStick	CC	Combined	HeatStick	2	0.53	91.51
HeatStick	Combined	CC	CC	2	0.53	92.04
HeatStick	Combined	Combined	HeatStick	2	0.53	92.57
HeatStick	Combined	HeatStick	HeatStick	2	0.53	93.10
HeatStick	HeatStick	Combined	HeatStick	2	0.53	93.63
HeatStick	HeatStick	HeatStick	Combined	2	0.53	94.16
CC	CC	CC	Combined	1	0.27	94.43
CC	CC	CC	HeatStick	1	0.27	94.69
CC	CC	Combined	Combined	1	0.27	94.96
CC	CC	HeatStick	CC	1	0.27	95.23
CC	CC	Zero	Zero	1	0.27	95.49
Other pattern	17	4.51	100.00			

Total**377****100.00**

Note: 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.

Table 14-36: Patterns of Usage Behavior (Given 'Start Using HeatSticks', n = 189) - Germany

'Start Using HeatSticks': Usage Patterns (n = 189)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
Combined	Combined	Combined	Combined	55	29.10	29.10
HeatStick	HeatStick	HeatStick	HeatStick	40	21.16	50.26
Combined	Combined	Combined	CC	10	5.29	55.56
Combined	HeatStick	HeatStick	HeatStick	9	4.76	60.32
CC	CC	CC	CC	6	3.17	63.49
Combined	Combined	Combined	HeatStick	6	3.17	66.67
Combined	Combined	CC	CC	5	2.65	69.31
Combined	Combined	HeatStick	HeatStick	5	2.65	71.96
CC	Combined	Combined	CC	3	1.59	73.54
CC	Combined	Combined	Combined	3	1.59	75.13
Combined	CC	CC	CC	3	1.59	76.72
Combined	Combined	CC	Combined	3	1.59	78.31
Combined	HeatStick	HeatStick	Combined	3	1.59	79.89
HeatStick	Combined	Combined	Combined	3	1.59	81.48
HeatStick	HeatStick	Combined	Combined	3	1.59	83.07
Combined	CC	Combined	CC	2	1.06	84.13
Combined	CC	Combined	Combined	2	1.06	85.19
Combined	HeatStick	Combined	Combined	2	1.06	86.24
HeatStick	CC	CC	CC	2	1.06	87.30
HeatStick	CC	Combined	HeatStick	2	1.06	88.36
HeatStick	Combined	Combined	HeatStick	2	1.06	89.42
HeatStick	Combined	HeatStick	HeatStick	2	1.06	90.48
HeatStick	HeatStick	HeatStick	Combined	2	1.06	91.53
CC	CC	Combined	CC	1	0.53	92.06
CC	CC	Combined	Combined	1	0.53	92.59
CC	Combined	CC	Combined	1	0.53	93.12
CC	HeatStick	HeatStick	HeatStick	1	0.53	93.65
Combined	CC	CC	HeatStick	1	0.53	94.18
Combined	CC	HeatStick	HeatStick	1	0.53	94.71
Combined	Combined	HeatStick	Combined	1	0.53	95.24
Combined	HeatStick	HeatStick	CC	1	0.53	95.77
HeatStick	CC	Combined	Combined	1	0.53	96.30
HeatStick	Combined	CC	CC	1	0.53	96.83
HeatStick	Combined	Combined	Zero	1	0.53	97.35
Other pattern	5	2.65	100.00			

Total**189****100.00**

Note: 'Start Using HeatSticks' means participants who started using HeatSticks by the end of Study Week 4; 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.



APPENDIX SWITZERLAND 1: TRANSITION TABLES

Table 14-37: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Usage Category					
Study Week 0		Study Week 1	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	45 21.84% (21.84%; 100.00%)	135 65.53% (65.53%; 100.00%)	26 12.62% (12.62%; 100.00%)	0 0.00% (0.00%; NA)	206 100.00% (100.00%; 100.00%)
	<i>Zero HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	45 21.84% (21.84%; 100.00%)	135 65.53% (65.53%; 100.00%)	26 12.62% (12.62%; 100.00%)	0 0.00% (0.00%; NA)	206 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 1 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-38: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 0						
	Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-
Combined Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
CC Use		Frequency Percentage (% Row; % Col)	45 21.84% (21.84%; 100.00%)	126 61.17% (61.17%; 100.00%)	34 16.50% (16.50%; 100.00%)	1 0.49% (0.49%; 100.00%)	206 100.00% (100.00%; 100.00%)
Zero <i>HeatStick</i> and CC Use		Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	45 21.84% (21.84%; 100.00%)	126 61.17% (61.17%; 100.00%)	34 16.50% (16.50%; 100.00%)	1 0.49% (0.49%; 100.00%)	206 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-39: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Usage Category					
	Study Week 0	Study Week 3	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	47 22.82% (22.82%; 100.00%)	122 59.22% (59.22%; 100.00%)	36 17.48% (17.48%; 100.00%)	1 0.49% (0.49%; 100.00%)	206 100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	47 22.82% (22.82%; 100.00%)	122 59.22% (59.22%; 100.00%)	36 17.48% (17.48%; 100.00%)	1 0.49% (0.49%; 100.00%)	206 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-40: CC Use, Combined Use, HeatStick Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using HeatSticks' by the End of Study Week 4, n = 206) - Switzerland

		Usage Category					
	Study Week 0	Study Week 4	HeatStick Use	Combined Use	CC Use	Zero HeatStick and CC Use	Total
Usage Category	HeatStick Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency	37	125	44	0	206
		Percentage (% Row; % Col)	17.96% (17.96%; 100.00%)	60.68% (60.68%; 100.00%)	21.36% (21.36%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)
	Zero HeatStick and CC Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
Total	Frequency	37	125	44	0	206	
	Percentage (% Row; % Col)	17.96% (17.96%; 100.00%)	60.68% (60.68%; 100.00%)	21.36% (21.36%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 4 of those participants who have started using HeatSticks by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-41: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Study Week 2	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	34	9	2	0	45
Percentage (% Row; % Col)		16.50% (75.56%; 75.56%)	4.37% (20.00%; 7.14%)	0.97% (4.44%; 5.88%)	0.00% (0.00%; 0.00%)	21.84% (100.00%; 21.84%)	
Combined Use	Frequency	11	108	15	1	135	
	Percentage (% Row; % Col)	5.34% (8.15%; 24.44%)	52.43% (80.00%; 85.71%)	7.28% (11.11%; 44.12%)	0.49% (0.74%; 100.00%)	65.53% (100.00%; 65.53%)	
CC Use	Frequency	0	9	17	0	26	
	Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	4.37% (34.62%; 7.14%)	8.25% (65.38%; 50.00%)	0.00% (0.00%; 0.00%)	12.62% (100.00%; 12.62%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	
Total	Frequency	45	126	34	1	206	
	Percentage (% Row; % Col)	21.84% (21.84%; 100.00%)	61.17% (61.17%; 100.00%)	16.50% (16.50%; 100.00%)	0.49% (0.49%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-42: CC Use, Combined Use, HeatStick Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using HeatSticks' by the End of Study Week 4, n = 206) - Switzerland

		Study Week 3	Usage Category				Total
			HeatStick Use	Combined Use	CC Use	Zero HeatStick and CC Use	
Usage Category	Study Week 1						
	HeatStick Use	Frequency	30	12	3	0	45
Percentage (% Row; % Col)		14.56% (66.67%; 63.83%)	5.83% (26.67%; 9.84%)	1.46% (6.67%; 8.33%)	0.00% (0.00%; 0.00%)	21.84% (100.00%; 21.84%)	
Combined Use	Frequency	15	97	22	1	135	
	Percentage (% Row; % Col)	7.28% (11.11%; 31.91%)	47.09% (71.85%; 79.51%)	10.68% (16.30%; 61.11%)	0.49% (0.74%; 100.00%)	65.53% (100.00%; 65.53%)	
CC Use	Frequency	2	13	11	0	26	
	Percentage (% Row; % Col)	0.97% (7.69%; 4.26%)	6.31% (50.00%; 10.66%)	5.34% (42.31%; 30.56%)	0.00% (0.00%; 0.00%)	12.62% (100.00%; 12.62%)	
Zero HeatStick and CC Use	Frequency	0	0	0	0	0	
	Percentage (% Row; % Col)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	0.00% (NA; 0.00%)	
Total	Frequency	47	122	36	1	206	
	Percentage (% Row; % Col)	22.82% (22.82%; 100.00%)	59.22% (59.22%; 100.00%)	17.48% (17.48%; 100.00%)	0.49% (0.49%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 3 of those participants who have started using HeatSticks by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-43: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Usage Category					
Study Week 1		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	22	19	4	0	45
		Percentage	10.68%	9.22%	1.94%	0.00%	21.84%
		(% Row; % Col)	(48.89%; 59.46%)	(42.22%; 15.20%)	(8.89%; 9.09%)	(0.00%; NA)	(100.00%; 21.84%)
	Combined Use	Frequency	14	96	25	0	135
		Percentage	6.80%	46.60%	12.14%	0.00%	65.53%
		(% Row; % Col)	(10.37%; 37.84%)	(71.11%; 76.80%)	(18.52%; 56.82%)	(0.00%; NA)	(100.00%; 65.53%)
	CC Use	Frequency	1	10	15	0	26
		Percentage	0.49%	4.85%	7.28%	0.00%	12.62%
		(% Row; % Col)	(3.85%; 2.70%)	(38.46%; 8.00%)	(57.69%; 34.09%)	(0.00%; NA)	(100.00%; 12.62%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	0	0
		Percentage	0.00%	0.00%	0.00%	0.00%	0.00%
		(% Row; % Col)	(NA; 0.00%)	(NA; 0.00%)	(NA; 0.00%)	(NA; NA)	(NA; 0.00%)
Total	Frequency	37	125	44	0	206	
	Percentage	17.96%	60.68%	21.36%	0.00%	100.00%	
	(% Row; % Col)	(17.96%; 100.00%)	(60.68%; 100.00%)	(21.36%; 100.00%)	(0.00%; NA)	(100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-44: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 2						
	<i>HeatStick</i> Use	Frequency	36	6	3	0	45
Percentage (% Row; % Col)		17.48% (80.00%; 76.60%)	2.91% (13.33%; 4.92%)	1.46% (6.67%; 8.33%)	0.00% (0.00%; 0.00%)	21.84% (100.00%; 21.84%)	
Combined Use	Frequency	9	103	13	1	126	
	Percentage (% Row; % Col)	4.37% (7.14%; 19.15%)	50.00% (81.75%; 84.43%)	6.31% (10.32%; 36.11%)	0.49% (0.79%; 100.00%)	61.17% (100.00%; 61.17%)	
CC Use	Frequency	2	13	19	0	34	
	Percentage (% Row; % Col)	0.97% (5.88%; 4.26%)	6.31% (38.24%; 10.66%)	9.22% (55.88%; 52.78%)	0.00% (0.00%; 0.00%)	16.50% (100.00%; 16.50%)	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	1	0	1	
	Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.49% (100.00%; 2.78%)	0.00% (0.00%; 0.00%)	0.49% (100.00%; 0.49%)	
Total	Frequency	47	122	36	1	206	
	Percentage (% Row; % Col)	22.82% (22.82%; 100.00%)	59.22% (59.22%; 100.00%)	17.48% (17.48%; 100.00%)	0.49% (0.49%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).



TRANSITION TABLES (CONT'D)

Table 14-45: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Usage Category					
Study Week 2		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	27	14	4	0	45
		Percentage (% Row; % Col)	13.11% (60.00%; 72.97%)	6.80% (31.11%; 11.20%)	1.94% (8.89%; 9.09%)	0.00% (0.00%; NA)	21.84% (100.00%; 21.84%)
	Combined Use	Frequency	8	99	19	0	126
		Percentage (% Row; % Col)	3.88% (6.35%; 21.62%)	48.06% (78.57%; 79.20%)	9.22% (15.08%; 43.18%)	0.00% (0.00%; NA)	61.17% (100.00%; 61.17%)
	CC Use	Frequency	2	12	20	0	34
		Percentage (% Row; % Col)	0.97% (5.88%; 5.41%)	5.83% (35.29%; 9.60%)	9.71% (58.82%; 45.45%)	0.00% (0.00%; NA)	16.50% (100.00%; 16.50%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	1	0	1
		Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.49% (100.00%; 2.27%)	0.00% (0.00%; NA)	0.49% (100.00%; 0.49%)
	Total	Frequency	37	125	44	0	206
		Percentage (% Row; % Col)	17.96% (17.96%; 100.00%)	60.68% (60.68%; 100.00%)	21.36% (21.36%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206)



TRANSITION TABLES (CONT'D)

Table 14-46: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 206) - Switzerland

		Usage Category					
Study Week 3		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	35	11	1	0	47
		Percentage (% Row; % Col)	16.99% (74.47%; 94.59%)	5.34% (23.40%; 8.80%)	0.49% (2.13%; 2.27%)	0.00% (0.00%; NA)	22.82% (100.00%; 22.82%)
	Combined Use	Frequency	2	104	16	0	122
		Percentage (% Row; % Col)	0.97% (1.64%; 5.41%)	50.49% (85.25%; 83.20%)	7.77% (13.11%; 36.36%)	0.00% (0.00%; NA)	59.22% (100.00%; 59.22%)
	CC Use	Frequency	0	9	27	0	36
		Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	4.37% (25.00%; 7.20%)	13.11% (75.00%; 61.36%)	0.00% (0.00%; NA)	17.48% (100.00%; 17.48%)
	Zero <i>HeatStick</i> and CC Use	Frequency	0	1	0	0	1
		Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	0.49% (100.00%; 0.80%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; NA)	0.49% (100.00%; 0.49%)
	Total	Frequency	37	125	44	0	206
		Percentage (% Row; % Col)	17.96% (17.96%; 100.00%)	60.68% (60.68%; 100.00%)	21.36% (21.36%; 100.00%)	0.00% (0.00%; NA)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 3 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 206).

APPENDIX SWITZERLAND 2: PATTERNS OF USAGE BEHAVIOR

Table 14-47: Patterns of Usage Behavior (Given the Full Analysis Set, *n* = 416) - Switzerland

FAS: Usage Patterns (<i>n</i> = 416)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
CC	CC	CC	CC	120	28.85	28.85
Combined	Combined	Combined	Combined	94	22.60	51.44
Combined	CC	CC	CC	28	6.73	58.17
Combined	Combined	CC	CC	20	4.81	62.98
HeatStick	HeatStick	HeatStick	HeatStick	19	4.57	67.55
Combined	Combined	Combined	CC	15	3.61	71.15
CC	CC	Combined	Combined	12	2.88	74.04
CC	Combined	CC	CC	8	1.92	75.96
CC	Combined	Combined	Combined	8	1.92	77.88
Combined	CC	Combined	Combined	8	1.92	79.81
Combined	HeatStick	HeatStick	HeatStick	8	1.92	81.73
HeatStick	Combined	Combined	Combined	8	1.92	83.65
HeatStick	HeatStick	HeatStick	Combined	8	1.92	85.58
Combined	Combined	CC	Combined	7	1.68	87.26
Combined	Combined	HeatStick	HeatStick	6	1.44	88.70
CC	CC	CC	Combined	4	0.96	89.66
CC	CC	Combined	CC	3	0.72	90.38
CC	Combined	Combined	CC	3	0.72	91.11
Combined	CC	Combined	CC	3	0.72	91.83
CC	Combined	CC	Combined	2	0.48	92.31
CC	Combined	HeatStick	Combined	2	0.48	92.79
Combined	CC	CC	Combined	2	0.48	93.27
Combined	HeatStick	Combined	Combined	2	0.48	93.75
HeatStick	CC	HeatStick	HeatStick	2	0.48	94.23
HeatStick	HeatStick	CC	CC	2	0.48	94.71
HeatStick	HeatStick	Combined	Combined	2	0.48	95.19
HeatStick	HeatStick	Combined	HeatStick	2	0.48	95.67
CC	CC	CC	Zero	1	0.24	95.91
CC	CC	HeatStick	HeatStick	1	0.24	96.15
CC	CC	Zero	CC	1	0.24	96.39
CC	HeatStick	Combined	CC	1	0.24	96.63
CC	Zero	CC	CC	1	0.24	96.87
Combined	Combined	Combined	HeatStick	1	0.24	97.12
Combined	Combined	HeatStick	Combined	1	0.24	97.36
Other pattern	11	2.64	100.00			
Total				416	100.00	

Note: 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.

Table 14-48: Patterns of Usage Behavior (Given 'Start Using HeatSticks', n = 206) - Switzerland

'Start Using HeatSticks': Usage Patterns (n = 206)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
Combined	Combined	Combined	Combined	78	37.86	37.86
HeatStick	HeatStick	HeatStick	HeatStick	19	9.22	47.09
CC	CC	CC	CC	10	4.85	51.94
Combined	Combined	CC	CC	8	3.88	55.83
Combined	Combined	Combined	CC	8	3.88	59.71
HeatStick	Combined	Combined	Combined	8	3.88	63.59
HeatStick	HeatStick	HeatStick	Combined	8	3.88	67.48
Combined	HeatStick	HeatStick	HeatStick	7	3.40	70.87
Combined	CC	CC	CC	6	2.91	73.79
Combined	CC	Combined	Combined	6	2.91	76.70
Combined	Combined	HeatStick	HeatStick	6	2.91	79.61
CC	Combined	Combined	Combined	5	2.43	82.04
Combined	Combined	CC	Combined	5	2.43	84.47
CC	CC	Combined	Combined	3	1.46	85.92
CC	Combined	Combined	CC	3	1.46	87.38
CC	CC	Combined	CC	2	0.97	88.35
Combined	CC	Combined	CC	2	0.97	89.32
Combined	HeatStick	Combined	Combined	2	0.97	90.29
HeatStick	HeatStick	CC	CC	2	0.97	91.26
HeatStick	HeatStick	Combined	Combined	2	0.97	92.23
CC	CC	CC	Combined	1	0.49	92.72
CC	CC	HeatStick	HeatStick	1	0.49	93.20
CC	Combined	HeatStick	Combined	1	0.49	93.69
Combined	CC	CC	Combined	1	0.49	94.17
Combined	Combined	Combined	HeatStick	1	0.49	94.66
Combined	Combined	HeatStick	Combined	1	0.49	95.15
Combined	Combined	Zero	Combined	1	0.49	95.63
Combined	HeatStick	CC	Combined	1	0.49	96.12
Combined	HeatStick	HeatStick	Combined	1	0.49	96.60
Combined	Zero	CC	CC	1	0.49	97.09
HeatStick	CC	CC	Combined	1	0.49	97.57
HeatStick	CC	HeatStick	HeatStick	1	0.49	98.06
HeatStick	Combined	HeatStick	HeatStick	1	0.49	98.54
HeatStick	HeatStick	Combined	CC	1	0.49	99.03
Other pattern	2	0.97	100.00			
Total				206	100.00	

Note: 'Start Using HeatSticks' means participants who started using HeatSticks by the end of Study Week 4; 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.



APPENDIX SOUTH KOREA 1: TRANSITION TABLES

Table 14-49: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 1 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
	Study Week 0	Study Week 1	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency	280	323	39	1	643
		Percentage (% Row; % Col)	43.55% (43.55%; 100.00%)	50.23% (50.23%; 100.00%)	6.07% (6.07%; 100.00%)	0.16% (0.16%; 100.00%)	100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
Total	Frequency	280	323	39	1	643	
	Percentage (% Row; % Col)	43.55% (43.55%; 100.00%)	50.23% (50.23%; 100.00%)	6.07% (6.07%; 100.00%)	0.16% (0.16%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 1 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-50: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
Study Week 0		Study Week 2	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	320 49.77% (49.77%; 100.00%)	281 43.70% (43.70%; 100.00%)	41 6.38% (6.38%; 100.00%)	1 0.16% (0.16%; 100.00%)	643 100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	320 49.77% (49.77%; 100.00%)	281 43.70% (43.70%; 100.00%)	41 6.38% (6.38%; 100.00%)	1 0.16% (0.16%; 100.00%)	643 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-51: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Study Week 0							
Usage Category	<i>HeatStick</i> Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Combined Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	CC Use	Frequency Percentage (% Row; % Col)	328 51.01% (51.01%; 100.00%)	269 41.84% (41.84%; 100.00%)	44 6.84% (6.84%; 100.00%)	2 0.31% (0.31%; 100.00%)	643 100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency Percentage (% Row; % Col)	-	-	-	-	-
	Total	Frequency Percentage (% Row; % Col)	328 51.01% (51.01%; 100.00%)	269 41.84% (41.84%; 100.00%)	44 6.84% (6.84%; 100.00%)	2 0.31% (0.31%; 100.00%)	643 100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-52: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 0 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
Study Week 0	Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total	
Usage Category	<i>HeatStick</i> Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	
	Combined Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	
	CC Use	Frequency	305	258	77	3	643
		Percentage (% Row; % Col)	47.43% (47.43%; 100.00%)	40.12% (40.12%; 100.00%)	11.98% (11.98%; 100.00%)	0.47% (0.47%; 100.00%)	100.00% (100.00%; 100.00%)
	Zero <i>HeatStick</i> and CC Use	Frequency					
		Percentage (% Row; % Col)	-	-	-	-	-
Total	Frequency	305	258	77	3	643	
	Percentage (% Row; % Col)	47.43% (47.43%; 100.00%)	40.12% (40.12%; 100.00%)	11.98% (11.98%; 100.00%)	0.47% (0.47%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 0 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-53: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 2 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
	Study Week 1	Study Week 2	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	244	34	2	0	280
		Percentage	37.95%	5.29%	0.31%	0.00%	43.55%
		(% Row; % Col)	(87.14%; 76.25%)	(12.14%; 12.10%)	(0.71%; 4.88%)	(0.00%; 0.00%)	(100.00%; 43.55%)
	Combined Use	Frequency	74	228	21	0	323
		Percentage	11.51%	35.46%	3.27%	0.00%	50.23%
		(% Row; % Col)	(22.91%; 23.13%)	(70.59%; 81.14%)	(6.50%; 51.22%)	(0.00%; 0.00%)	(100.00%; 50.23%)
	CC Use	Frequency	2	19	18	0	39
		Percentage	0.31%	2.95%	2.80%	0.00%	6.07%
		(% Row; % Col)	(5.13%; 0.63%)	(48.72%; 6.76%)	(46.15%; 43.90%)	(0.00%; 0.00%)	(100.00%; 6.07%)
	<i>Zero HeatStick</i> and CC Use	Frequency	0	0	0	1	1
		Percentage	0.00%	0.00%	0.00%	0.16%	0.16%
		(% Row; % Col)	(0.00%; 0.00%)	(0.00%; 0.00%)	(0.00%; 0.00%)	(100.00%; 100.00%)	(100.00%; 0.16%)
Total	Frequency	320	281	41	1	643	
	Percentage	49.77%	43.70%	6.38%	0.16%	100.00%	
	(% Row; % Col)	(49.77%; 100.00%)	(43.70%; 100.00%)	(6.38%; 100.00%)	(0.16%; 100.00%)	(100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 2 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-54: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Study Week 3	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	233	41	4	2	280
Percentage (% Row; % Col)		36.24% (83.21%; 71.04%)	6.38% (14.64%; 15.24%)	0.62% (1.43%; 9.09%)	0.31% (0.71%; 100.00%)	43.55% (100.00%; 43.55%)	
Combined Use	Frequency	87	207	29	0	323	
	Percentage (% Row; % Col)	13.53% (26.93%; 26.52%)	32.19% (64.09%; 76.95%)	4.51% (8.98%; 65.91%)	0.00% (0.00%; 0.00%)	50.23% (100.00%; 50.23%)	
CC Use	Frequency	7	21	11	0	39	
	Percentage (% Row; % Col)	1.09% (17.95%; 2.13%)	3.27% (53.85%; 7.81%)	1.71% (28.21%; 25.00%)	0.00% (0.00%; 0.00%)	6.07% (100.00%; 6.07%)	
Zero <i>HeatStick</i> and CC Use	Frequency	1	0	0	0	1	
	Percentage (% Row; % Col)	0.16% (100.00%; 0.30%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.16% (100.00%; 0.16%)	
Total	Frequency	328	269	44	2	643	
	Percentage (% Row; % Col)	51.01% (51.01%; 100.00%)	41.84% (41.84%; 100.00%)	6.84% (6.84%; 100.00%)	0.31% (0.31%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-55: CC Use, Combined Use, *HeatStick* - Transition Table Study Week 4 vs. Study Week 1 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Study Week 4	Usage Category				Total
			<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	
Usage Category	Study Week 1						
	<i>HeatStick</i> Use	Frequency	209	51	17	3	280
Percentage (% Row; % Col)		32.50% (74.64%; 68.52%)	7.93% (18.21%; 19.77%)	2.64% (6.07%; 22.08%)	0.47% (1.07%; 100.00%)	43.55% (100.00%; 43.55%)	
Combined Use	Frequency	90	187	46	0	323	
	Percentage (% Row; % Col)	14.00% (27.86%; 29.51%)	29.08% (57.89%; 72.48%)	7.15% (14.24%; 59.74%)	0.00% (0.00%; 0.00%)	50.23% (100.00%; 50.23%)	
CC Use	Frequency	5	20	14	0	39	
	Percentage (% Row; % Col)	0.78% (12.82%; 1.64%)	3.11% (51.28%; 7.75%)	2.18% (35.90%; 18.18%)	0.00% (0.00%; 0.00%)	6.07% (100.00%; 6.07%)	
Zero <i>HeatStick</i> and CC Use	Frequency	1	0	0	0	1	
	Percentage (% Row; % Col)	0.16% (100.00%; 0.33%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.16% (100.00%; 0.16%)	
Total	Frequency	305	258	77	3	643	
	Percentage (% Row; % Col)	47.43% (47.43%; 100.00%)	40.12% (40.12%; 100.00%)	11.98% (11.98%; 100.00%)	0.47% (0.47%; 100.00%)	100.00% (100.00%; 100.00%)	

Note: The above table shows the transitions in the usage behavior from Study Week 1 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-56: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 3 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
Study Week 2		Study Week 3	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	272	44	2	2	320
		Percentage (% Row; % Col)	42.30% (85.00%; 82.93%)	6.84% (13.75%; 16.36%)	0.31% (0.63%; 4.55%)	0.31% (0.63%; 100.00%)	49.77% (100.00%; 49.77%)
	Combined Use	Frequency	50	209	22	0	281
		Percentage (% Row; % Col)	7.78% (17.79%; 15.24%)	32.50% (74.38%; 77.70%)	3.42% (7.83%; 50.00%)	0.00% (0.00%; 0.00%)	43.70% (100.00%; 43.70%)
	CC Use	Frequency	5	16	20	0	41
		Percentage (% Row; % Col)	0.78% (12.20%; 1.52%)	2.49% (39.02%; 5.95%)	3.11% (48.78%; 45.45%)	0.00% (0.00%; 0.00%)	6.38% (100.00%; 6.38%)
	<i>Zero HeatStick</i> and CC Use	Frequency	1	0	0	0	1
		Percentage (% Row; % Col)	0.16% (100.00%; 0.30%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.16% (100.00%; 0.16%)
	Total	Frequency	328	269	44	2	643
		Percentage (% Row; % Col)	51.01% (51.01%; 100.00%)	41.84% (41.84%; 100.00%)	6.84% (6.84%; 100.00%)	0.31% (0.31%; 100.00%)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 3 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-57: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 2 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
Study Week 2		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	Zero <i>HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	237	64	16	3	320
		Percentage (% Row; % Col)	36.86% (74.06%; 77.70%)	9.95% (20.00%; 24.81%)	2.49% (5.00%; 20.78%)	0.47% (0.94%; 100.00%)	49.77% (100.00%; 49.77%)
	Combined Use	Frequency	63	178	40	0	281
		Percentage (% Row; % Col)	9.80% (22.42%; 20.66%)	27.68% (63.35%; 68.99%)	6.22% (14.23%; 51.95%)	0.00% (0.00%; 0.00%)	43.70% (100.00%; 43.70%)
	CC Use	Frequency	4	16	21	0	41
		Percentage (% Row; % Col)	0.62% (9.76%; 1.31%)	2.49% (39.02%; 6.20%)	3.27% (51.22%; 27.27%)	0.00% (0.00%; 0.00%)	6.38% (100.00%; 6.38%)
	Zero <i>HeatStick</i> and CC Use	Frequency	1	0	0	0	1
		Percentage (% Row; % Col)	0.16% (100.00%; 0.33%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.16% (100.00%; 0.16%)
	Total	Frequency	305	258	77	3	643
		Percentage	47.43%	40.12%	11.98%	0.47%	100.00%
		(% Row; % Col)	(47.43%; 100.00%)	(40.12%; 100.00%)	(11.98%; 100.00%)	(0.47%; 100.00%)	(100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 2 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).



TRANSITION TABLES (CONT'D)

Table 14-58: CC Use, Combined Use, *HeatStick* Use - Transition Table Study Week 4 vs. Study Week 3 (Given 'Start Using *HeatSticks*' by the End of Study Week 4, n = 643) – South Korea

		Usage Category					
Study Week 3		Study Week 4	<i>HeatStick</i> Use	Combined Use	CC Use	<i>Zero HeatStick</i> and CC Use	Total
Usage Category	<i>HeatStick</i> Use	Frequency	261	55	10	2	328
		Percentage (% Row; % Col)	40.59% (79.57%; 85.57%)	8.55% (16.77%; 21.32%)	1.56% (3.05%; 12.99%)	0.31% (0.61%; 66.67%)	51.01% (100.00%; 51.01%)
	Combined Use	Frequency	43	192	34	0	269
		Percentage (% Row; % Col)	6.69% (15.99%; 14.10%)	29.86% (71.38%; 74.42%)	5.29% (12.64%; 44.16%)	0.00% (0.00%; 0.00%)	41.84% (100.00%; 41.84%)
	CC Use	Frequency	0	11	33	0	44
		Percentage (% Row; % Col)	0.00% (0.00%; 0.00%)	1.71% (25.00%; 4.26%)	5.13% (75.00%; 42.86%)	0.00% (0.00%; 0.00%)	6.84% (100.00%; 6.84%)
	<i>Zero HeatStick</i> and CC Use	Frequency	1	0	0	1	2
		Percentage (% Row; % Col)	0.16% (50.00%; 0.33%)	0.00% (0.00%; 0.00%)	0.00% (0.00%; 0.00%)	0.16% (50.00%; 33.33%)	0.31% (100.00%; 0.31%)
	Total	Frequency	305	258	77	3	643
		Percentage (% Row; % Col)	47.43% (47.43%; 100.00%)	40.12% (40.12%; 100.00%)	11.98% (11.98%; 100.00%)	0.47% (0.47%; 100.00%)	100.00% (100.00%; 100.00%)

Note: The above table shows the transitions in the usage behavior from Study Week 3 to Study Week 4 of those participants who have started using *HeatSticks* by the end of Study Week 4 (n = 643).

APPENDIX SOUTH KOREA 2: PATTERNS OF USAGE BEHAVIOR

Table 14-59: Patterns of Usage Behavior (Given the Full Analysis Set, $n = 843$) – South Korea

FAS: Usage Patterns ($n = 843$)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
HeatStick	HeatStick	HeatStick	HeatStick	183	21.71	21.71
Combined	Combined	Combined	Combined	162	19.22	40.93
CC	CC	CC	CC	87	10.32	51.25
Combined	HeatStick	HeatStick	HeatStick	42	4.98	56.23
Combined	CC	CC	CC	32	3.80	60.02
HeatStick	HeatStick	HeatStick	Combined	29	3.44	63.46
Combined	Combined	Combined	CC	26	3.08	66.55
Combined	Combined	CC	CC	24	2.85	69.40
Combined	Combined	HeatStick	HeatStick	23	2.73	72.12
Combined	Combined	Combined	HeatStick	21	2.49	74.61
Combined	HeatStick	Combined	Combined	15	1.78	76.39
HeatStick	HeatStick	Combined	Combined	12	1.42	77.82
CC	Combined	Combined	Combined	11	1.30	79.12
Combined	Combined	HeatStick	Combined	10	1.19	80.31
Combined	HeatStick	HeatStick	Combined	10	1.19	81.49
HeatStick	Combined	HeatStick	HeatStick	10	1.19	82.68
CC	CC	CC	Combined	9	1.07	83.75
Combined	CC	CC	Combined	9	1.07	84.82
HeatStick	HeatStick	Combined	HeatStick	9	1.07	85.88
Combined	Combined	CC	Combined	8	0.95	86.83
HeatStick	Combined	Combined	Combined	8	0.95	87.78
HeatStick	Combined	Combined	HeatStick	8	0.95	88.73
HeatStick	HeatStick	HeatStick	CC	7	0.83	89.56
CC	CC	Combined	Combined	6	0.71	90.27
CC	Combined	CC	CC	6	0.71	90.98
Combined	CC	Combined	CC	6	0.71	91.70
CC	CC	Combined	CC	5	0.59	92.29
Combined	CC	Combined	Combined	5	0.59	92.88
Combined	HeatStick	Combined	HeatStick	5	0.59	93.48
HeatStick	HeatStick	Combined	CC	5	0.59	94.07
CC	Combined	Combined	CC	4	0.47	94.54
HeatStick	Combined	HeatStick	Combined	4	0.47	95.02
Combined	HeatStick	Combined	CC	3	0.36	95.37
CC	Combined	HeatStick	HeatStick	2	0.24	95.61
Other pattern	37	4.39	100.00			

Total**843****100.00**

Note: 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.

Table 14-60: Patterns of Usage Behavior (Given 'Start Using HeatSticks', n = 643) – South Korea

'Start Using HeatSticks': Usage Patterns (n = 643)				Frequency	Percentage	Cumulative Percentage
Study Week 1	Study Week 2	Study Week 3	Study Week 4			
HeatStick	HeatStick	HeatStick	HeatStick	181	28.15	28.15
Combined	Combined	Combined	Combined	139	21.62	49.77
Combined	HeatStick	HeatStick	HeatStick	40	6.22	55.99
HeatStick	HeatStick	HeatStick	Combined	28	4.35	60.34
Combined	Combined	HeatStick	HeatStick	23	3.58	63.92
Combined	Combined	Combined	HeatStick	20	3.11	67.03
Combined	Combined	Combined	CC	18	2.80	69.83
Combined	HeatStick	Combined	Combined	15	2.33	72.16
Combined	Combined	CC	CC	13	2.02	74.18
CC	Combined	Combined	Combined	11	1.71	75.89
Combined	Combined	HeatStick	Combined	10	1.56	77.45
Combined	HeatStick	HeatStick	Combined	10	1.56	79.00
HeatStick	Combined	HeatStick	HeatStick	10	1.56	80.56
HeatStick	HeatStick	Combined	Combined	10	1.56	82.12
Combined	CC	CC	CC	9	1.40	83.51
HeatStick	Combined	Combined	Combined	8	1.24	84.76
HeatStick	Combined	Combined	HeatStick	8	1.24	86.00
HeatStick	HeatStick	Combined	HeatStick	8	1.24	87.25
CC	CC	CC	CC	7	1.09	88.34
HeatStick	HeatStick	HeatStick	CC	7	1.09	89.42
CC	CC	Combined	Combined	5	0.78	90.20
Combined	Combined	CC	Combined	5	0.78	90.98
Combined	HeatStick	Combined	HeatStick	5	0.78	91.76
Combined	CC	Combined	Combined	4	0.62	92.38
HeatStick	HeatStick	Combined	CC	4	0.62	93.00
CC	Combined	Combined	CC	3	0.47	93.47
HeatStick	Combined	HeatStick	Combined	3	0.47	93.93
CC	CC	CC	Combined	2	0.31	94.25
CC	CC	Combined	CC	2	0.31	94.56
CC	Combined	CC	CC	2	0.31	94.87
CC	Combined	HeatStick	HeatStick	2	0.31	95.18
CC	HeatStick	HeatStick	HeatStick	2	0.31	95.49
Combined	CC	CC	Combined	2	0.31	95.80
Combined	CC	Combined	CC	2	0.31	96.11
Other pattern	25	3.89	100.00			

Total**643****100.00**

Note: 'Start Using HeatSticks' means participants who started using HeatSticks by the end of Study Week 4; 'CC' means 'CC Use'; 'Combined' means 'Combined Use'; 'HeatStick' means 'HeatStick Use'; 'Zero' means 'Zero HeatStick and CC Use'.