



PMI RESEARCH & DEVELOPMENT

Study ZRHR-REXC-03-EU **Clinical Study Report Appendix 16.1.6** **Randomization Scheme and Codes**

Study Title:	A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement
Study Number:	ZRHR-REXC-03-EU
Product Name:	Tobacco Heating System 2.2 (THS 2.2)
Study Initiated (first subject screened):	29 June 2013
Study Completed (last subject last visit):	26 September 2013
Principal Investigator and Affiliation:	Katarzyna Jarus-Dziedzic, MD, PhD BioVirtus Research Site Sp. z o.o., Mokra 7 05-830 Kajetany, Poland
Sponsor:	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
Sponsor Signatories:	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Andrea Donelli, Clinical Scientist Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician Kausar Aamir, MD, PhD, Medical Safety Officer
Version:	2.0
Date:	08 March 2016

This study was conducted in accordance with Good Clinical Practice.

Confidentiality Statement

This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.



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16.1.6.1 RANDOMIZATION SCHEME AND CODES

The file: PMI_Covance_ZRHR-REXC-03-EU_LIVE_9.00.000_SRL.txt, which is presented as the source in the footnote, is the LIVE randomization list provided by (b)(4).



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0001	Randomized	(b) (6)	33	Male	10-19 cig/day	1025	26JUL2013 04:34 PM	THS 2.2	107
POL	BIO	0002	Screen Failed		27	Male					
POL	BIO	0003	Screen Failed		31	Male					
POL	BIO	0004	Randomized		35	Female	10-19 cig/day	3011	26JUL2013 03:15 PM	THS 2.2	183
POL	BIO	0005	Screen Failed		57	Female					
POL	BIO	0006	Screen Failed		49	Male					
POL	BIO	0007	Screen Failed		36	Female					
POL	BIO	0008	Randomized		52	Female	>19 cig/day	4001	12JUL2013 06:27 PM	THS 2.2	221
POL	BIO	0009	Screen Failed		52	Male					
POL	BIO	0010	Randomized		29	Male	10-19 cig/day	1001	12JUL2013 06:36 PM	SA	101
POL	BIO	0011	Randomized		24	Male	10-19 cig/day	1009	12JUL2013 07:39 PM	THS 2.2	103



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0012	Screen Failed	(b) (6)	26	Male					
POL	BIO	0013	Randomized		27	Male	>19 cig/day	2009	26JUL2013 04:19 PM	SA	143
POL	BIO	0014	Randomized		40	Male	>19 cig/day	2004	12JUL2013 07:36 PM	THS 2.2	141
POL	BIO	0015	Randomized		24	Male	10-19 cig/day	1008	12JUL2013 07:31 PM	SA	102
POL	BIO	0016	Randomized		32	Female	10-19 cig/day	3001	12JUL2013 06:21 PM	THS 2.2	181
POL	BIO	0017	Randomized		21	Female	10-19 cig/day	3002	12JUL2013 06:25 PM	SA	181
POL	BIO	0018	Screen Failed		48	Male					
POL	BIO	0019	Screen Failed		29	Male					
POL	BIO	0020	Randomized		25	Female	10-19 cig/day	3003	12JUL2013 06:32 PM	THS 2.2	181
POL	BIO	0021	Randomized		27	Male	10-19 cig/day	1023	26JUL2013 04:21 PM	THS 2.2	106
POL	BIO	0022	Randomized		44	Female	>19 cig/day	4004	12JUL2013 07:33 PM	THS 2.2	221



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0023	Randomized	(b) (6)	50	Female	>19 cig/day	4005	12JUL2013 07:42 PM	THS 2.2	222
POL	BIO	0024	Screen Failed		38	Female					
POL	BIO	0025	Randomized		34	Female	10-19 cig/day	3004	12JUL2013 06:42 PM	CC	181
POL	BIO	0026	Screen Failed		32	Male					
POL	BIO	0027	Screen Failed		47	Male					
POL	BIO	0028	Randomized		52	Female	>19 cig/day	4002	12JUL2013 06:29 PM	SA	221
POL	BIO	0029	Randomized		29	Male	>19 cig/day	2001	12JUL2013 06:38 PM	CC	141
POL	BIO	0030	Randomized		28	Female	10-19 cig/day	3009	12JUL2013 07:53 PM	THS 2.2	183
POL	BIO	0031	Randomized		38	Male	>19 cig/day	2003	12JUL2013 06:52 PM	THS 2.2	141
POL	BIO	0032	Screen Failed		46	Female					
POL	BIO	0033	Screen Failed		42	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0034	Randomized	(b) (6)	32	Female	10-19 cig/day	3005	12JUL2013 06:44 PM	THS 2.2	182
POL	BIO	0035	Randomized		35	Male	10-19 cig/day	1004	12JUL2013 06:55 PM	CC	101
POL	BIO	0036	Screen Failed		45	Male					
POL	BIO	0037	Randomized		34	Male	10-19 cig/day	1014	26JUL2013 03:33 PM	CC	104
POL	BIO	0038	Randomized		32	Male	10-19 cig/day	1005	12JUL2013 07:07 PM	THS 2.2	102
POL	BIO	0039	Randomized		45	Male	10-19 cig/day	1002	12JUL2013 06:47 PM	THS 2.2	101
POL	BIO	0040	Screen Failed		22	Female					
POL	BIO	0041	Screen Failed		49	Male					
POL	BIO	0042	Randomized		38	Male	10-19 cig/day	1020	26JUL2013 04:02 PM	CC	105
POL	BIO	0043	Screen Failed		58	Male					
POL	BIO	0044	Randomized		50	Female	10-19 cig/day	3008	12JUL2013 07:20 PM	THS 2.2	182



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0045	Screen Failed	(b) (6)	24	Male					
POL	BIO	0046	Screen Failed		22	Male					
POL	BIO	0047	Screen Failed		34	Male					
POL	BIO	0048	Screen Failed		44	Female					
POL	BIO	0049	Randomized		25	Male	>19 cig/day	2002	12JUL2013 06:41 PM	SA	141
POL	BIO	0050	Screen Failed		36	Male					
POL	BIO	0051	Randomized		45	Female	10-19 cig/day	3013	26JUL2013 03:37 PM	SA	184
POL	BIO	0052	Randomized		50	Female	10-19 cig/day	3006	12JUL2013 07:15 PM	SA	182
POL	BIO	0053	Randomized		21	Female	10-19 cig/day	3007	12JUL2013 07:18 PM	CC	182
POL	BIO	0054	Screen Failed		35	Male					
POL	BIO	0055	Randomized		48	Female	>19 cig/day	4003	12JUL2013 07:11 PM	CC	221



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0056	Screen Failed	(b) (6)	26	Male					
POL	BIO	0057	Randomized		28	Male	10-19 cig/day	1003	12JUL2013 06:50 PM	THS 2.2	101
POL	BIO	0058	Screen Failed		25	Male					
POL	BIO	0059	Screen Failed		27	Male					
POL	BIO	0060	Randomized		39	Male	10-19 cig/day	1006	12JUL2013 07:23 PM	THS 2.2	102
POL	BIO	0061	Screen Failed		29	Female					
POL	BIO	0062	Randomized		23	Female	>19 cig/day	4006	12JUL2013 07:48 PM	SA	222
POL	BIO	0063	Randomized		37	Female	>19 cig/day	4009	26JUL2013 03:53 PM	SA	223
POL	BIO	0064	Randomized		27	Male	10-19 cig/day	1007	12JUL2013 07:26 PM	CC	102
POL	BIO	0065	Screen Failed		24	Male					
POL	BIO	0066	Randomized		23	Male	10-19 cig/day	1018	26JUL2013 03:49 PM	THS 2.2	105



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0067	Randomized	(b) (6)	24	Male	10-19 cig/day	1021	26JUL2013 04:16 PM	CC	106
POL	BIO	0068	Screen Failed		46	Male					
POL	BIO	0069	Randomized		35	Male	10-19 cig/day	1017	26JUL2013 03:46 PM	THS 2.2	105
POL	BIO	0070	Screen Failed		21	Female					
POL	BIO	0071	Randomized		29	Male	10-19 cig/day	1019	26JUL2013 04:00 PM	SA	105
POL	BIO	0072	Randomized		31	Male	>19 cig/day	2005	26JUL2013 03:20 PM	CC	142
POL	BIO	0073	Screen Failed		28	Male					
POL	BIO	0074	Randomized		30	Male	>19 cig/day	2006	26JUL2013 03:22 PM	THS 2.2	142
POL	BIO	0075	Screen Failed		25	Female					
POL	BIO	0076	Randomized		24	Male	10-19 cig/day	1012	26JUL2013 03:14 PM	SA	103
POL	BIO	0077	Screen Failed		50	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0078	Screen Failed	(b) (6)	49	Male					
POL	BIO	0079	Screen Failed		27	Male					
POL	BIO	0080	Randomized		22	Female	>19 cig/day	4011	26JUL2013 04:30 PM	CC	223
POL	BIO	0081	Screen Failed		40	Male					
POL	BIO	0082	Screen Failed		48	Female					
POL	BIO	0083	Randomized		46	Male	10-19 cig/day	1011	26JUL2013 03:13 PM	THS 2.2	103
POL	BIO	0084	Screen Failed		26	Male					
POL	BIO	0085	Randomized		22	Female	10-19 cig/day	3015	26JUL2013 03:55 PM	THS 2.2	184
POL	BIO	0086	Randomized		24	Male	>19 cig/day	2008	26JUL2013 03:35 PM	SA	142
POL	BIO	0087	Randomized		42	Female	>19 cig/day	4008	26JUL2013 03:16 PM	CC	222
POL	BIO	0088	Randomized		32	Female	10-19 cig/day	3016	26JUL2013 03:57 PM	THS 2.2	184



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0089	Screen Failed	(b) (6)	33	Female					
POL	BIO	0090	Randomized		22	Male	10-19 cig/day	1013	26JUL2013 03:32 PM	THS 2.2	104
POL	BIO	0091	Screen Failed		29	Female					
POL	BIO	0092	Screen Failed		27	Male					
POL	BIO	0093	Randomized		26	Male	>19 cig/day	2007	26JUL2013 03:30 PM	THS 2.2	142
POL	BIO	0094	Screen Failed		38	Female					
POL	BIO	0095	Screen Failed		60	Female					
POL	BIO	0096	Screen Failed		24	Male					
POL	BIO	0097	Screen Failed		32	Male					
POL	BIO	0098	Screen Failed		58	Male					
POL	BIO	0099	Screen Failed		51	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0100	Screen Failed	(b) (6)	32	Male					
POL	BIO	0101	Screen Failed		29	Male					
POL	BIO	0102	Screen Failed		34	Male					
POL	BIO	0103	Screen Failed		39	Male					
POL	BIO	0104	Randomized		31	Female	10-19 cig/day	3010	26JUL2013 03:08 PM	SA	183
POL	BIO	0105	Randomized		50	Female	10-19 cig/day	3012	26JUL2013 03:17 PM	CC	183
POL	BIO	0106	Randomized		22	Male	10-19 cig/day	1015	26JUL2013 03:41 PM	THS 2.2	104
POL	BIO	0107	Randomized		30	Female	>19 cig/day	4010	26JUL2013 04:25 PM	THS 2.2	223
POL	BIO	0108	Screen Failed		45	Female					
POL	BIO	0109	Screen Failed		50	Male					
POL	BIO	0110	Randomized		48	Female	>19 cig/day	4007	26JUL2013 03:10 PM	THS 2.2	222



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0111	Screen Failed	(b) (6)	21	Male					
POL	BIO	0112	Randomized		49	Male	>19 cig/day	2010	26JUL2013 04:32 PM	THS 2.2	143
POL	BIO	0113	Screen Failed		36	Male					
POL	BIO	0114	Randomized		23	Male	10-19 cig/day	1022	26JUL2013 04:17 PM	SA	106
POL	BIO	0115	Screen Failed		49	Male					
POL	BIO	0116	Screen Failed		29	Male					
POL	BIO	0117	Randomized		25	Male	10-19 cig/day	1010	26JUL2013 03:11 PM	CC	103
POL	BIO	0118	Randomized		37	Female	10-19 cig/day	3017	26JUL2013 04:22 PM	CC	185
POL	BIO	0119	Screen Failed		54	Female					
POL	BIO	0120	Screen Failed		49	Male					
POL	BIO	0121	Randomized		23	Female	10-19 cig/day	3014	26JUL2013 03:39 PM	CC	184



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0122	Randomized	(b) (6)	40	Male	10-19 cig/day	1024	26JUL2013 04:33 PM	THS 2.2	106
POL	BIO	0123	Randomized		23	Male	10-19 cig/day	1016	26JUL2013 03:45 PM	SA	104
POL	BIO	0124	Screen Failed		57	Male					
POL	BIO	0125	Screen Failed		56	Male					
POL	BIO	0126	Randomized		24	Male	>19 cig/day	2015	09AUG2013 05:41 PM	CC	144
POL	BIO	0127	Randomized		53	Male	10-19 cig/day	1028	09AUG2013 05:51 PM	SA	107
POL	BIO	0128	Randomized		38	Male	>19 cig/day	2016	09AUG2013 05:43 PM	SA	144
POL	BIO	0129	Randomized		37	Male	>19 cig/day	2014	09AUG2013 05:40 PM	THS 2.2	144
POL	BIO	0130	Randomized		22	Female	10-19 cig/day	3018	09AUG2013 05:33 PM	THS 2.2	185
POL	BIO	0131	Screen Failed		43	Male					
POL	BIO	0132	Screen Failed		47	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0133	Randomized	(b) (6)	36	Male	>19 cig/day	2018	09AUG2013 05:49 PM	SA	145
POL	BIO	0134	Randomized		36	Male	>19 cig/day	2013	09AUG2013 05:38 PM	THS 2.2	144
POL	BIO	0135	Screen Failed		21	Female					
POL	BIO	0136	Randomized		27	Female	10-19 cig/day	3019	09AUG2013 05:56 PM	THS 2.2	185
POL	BIO	0137	Randomized		27	Female	10-19 cig/day	3020	09AUG2013 05:58 PM	SA	185
POL	BIO	0138	Screen Failed		33	Male					
POL	BIO	0139	Randomized		27	Male	10-19 cig/day	1034	09AUG2013 06:39 PM	CC	109
POL	BIO	0140	Randomized		24	Female	10-19 cig/day	3023	09AUG2013 06:47 PM	CC	186
POL	BIO	0141	Screen Failed		64	Male					
POL	BIO	0142	Screen Failed		58	Female					
POL	BIO	0143	Screen Failed		55	Female					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0144	Screen Failed	(b) (6)	58	Male					
POL	BIO	0145	Randomized		26	Female	10-19 cig/day	3021	09AUG2013 06:02 PM	SA	186
POL	BIO	0146	Screen Failed		62	Female					
POL	BIO	0147	Randomized		57	Female	>19 cig/day	4014	09AUG2013 06:04 PM	THS 2.2	224
POL	BIO	0148	Randomized		45	Male	>19 cig/day	2011	09AUG2013 05:36 PM	CC	143
POL	BIO	0149	Randomized		47	Male	10-19 cig/day	1026	09AUG2013 05:45 PM	THS 2.2	107
POL	BIO	0150	Randomized		26	Male	>19 cig/day	2023	09AUG2013 06:36 PM	SA	146
POL	BIO	0151	Screen Failed		46	Female					
POL	BIO	0152	Randomized		28	Male	10-19 cig/day	1027	09AUG2013 05:48 PM	CC	107
POL	BIO	0153	Randomized		32	Female	>19 cig/day	4012	09AUG2013 05:32 PM	THS 2.2	223
POL	BIO	0154	Screen Failed		41	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0155	Randomized	(b) (6)	31	Female	>19 cig/day	4015	09AUG2013 06:05 PM	THS 2.2	224
POL	BIO	0156	Randomized		30	Male	>19 cig/day	2019	09AUG2013 05:54 PM	CC	145
POL	BIO	0157	Screen Failed		32	Male					
POL	BIO	0158	Screen Failed		49	Male					
POL	BIO	0159	Screen Failed		24	Female					
POL	BIO	0160	Randomized		29	Male	10-19 cig/day	1031	09AUG2013 06:31 PM	CC	108
POL	BIO	0161	Screen Failed		22	Male					
POL	BIO	0162	Randomized		45	Male	>19 cig/day	2017	09AUG2013 05:47 PM	THS 2.2	145
POL	BIO	0163	Screen Failed		54	Female					
POL	BIO	0164	Screen Failed		29	Male					
POL	BIO	0165	Screen Failed		22	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0166	Screen Failed	(b) (6)	47	Male					
POL	BIO	0167	Randomized		28	Male	>19 cig/day	2021	09AUG2013 06:08 PM	THS 2.2	146
POL	BIO	0168	Screen Failed		23	Male					
POL	BIO	0169	Randomized		24	Male	10-19 cig/day	1029	09AUG2013 06:27 PM	SA	108
POL	BIO	0170	Randomized		24	Male	10-19 cig/day	1030	09AUG2013 06:29 PM	THS 2.2	108
POL	BIO	0171	Screen Failed		33	Female					
POL	BIO	0172	Screen Failed		34	Male					
POL	BIO	0173	Screen Failed		21	Male					
POL	BIO	0174	Screen Failed		24	Male					
POL	BIO	0175	Screen Failed		24	Male					
POL	BIO	0176	Screen Failed		36	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0177	Randomized	(b) (6)	40	Male	>19 cig/day	2020	09AUG2013 06:06 PM	THS 2.2	145
POL	BIO	0178	Screen Failed		25	Male					
POL	BIO	0179	Screen Failed		51	Male					
POL	BIO	0180	Screen Failed		25	Male					
POL	BIO	0181	Randomized		30	Male	>19 cig/day	2012	09AUG2013 05:37 PM	THS 2.2	143
POL	BIO	0182	Screen Failed		29	Male					
POL	BIO	0183	Randomized		37	Male	10-19 cig/day	1033	09AUG2013 06:34 PM	THS 2.2	109
POL	BIO	0184	Screen Failed		41	Female					
POL	BIO	0185	Randomized		50	Female	>19 cig/day	4013	09AUG2013 06:00 PM	SA	224
POL	BIO	0186	Screen Failed		43	Female					
POL	BIO	0187	Randomized		40	Female	>19 cig/day	4016	09AUG2013 06:38 PM	CC	224



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0188	Screen Failed	(b) (6)	28	Male					
POL	BIO	0189	Randomized		30	Male	10-19 cig/day	1032	09AUG2013 06:32 PM	THS 2.2	108
POL	BIO	0190	Randomized		28	Female	10-19 cig/day	3022	09AUG2013 06:45 PM	THS 2.2	186
POL	BIO	0191	Randomized		26	Male	>19 cig/day	2022	09AUG2013 06:09 PM	CC	146
POL	BIO	0192	Randomized		48	Female	>19 cig/day	4017	09AUG2013 06:41 PM	THS 2.2	225
POL	BIO	0193	Randomized		32	Female	10-19 cig/day	3024	22AUG2013 07:08 PM	THS 2.2	186
POL	BIO	0194	Screen Failed		32	Male					
POL	BIO	0195	Randomized		30	Female	>19 cig/day	4029	22AUG2013 09:00 PM	THS 2.2	228
POL	BIO	0196	Randomized		28	Female	>19 cig/day	4030	22AUG2013 09:03 PM	THS 2.2	228
POL	BIO	0197	Randomized		35	Male	10-19 cig/day	1037	22AUG2013 09:43 PM	SA	110
POL	BIO	0198	Randomized		29	Male	>19 cig/day	2026	22AUG2013 08:15 PM	CC	147



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0199	Screen Failed	(b) (6)	52	Male					
POL	BIO	0200	Randomized		27	Female	>19 cig/day	4023	22AUG2013 08:22 PM	CC	226
POL	BIO	0201	Screen Failed		30	Male					
POL	BIO	0202	Randomized		26	Female	>19 cig/day	4022	22AUG2013 08:21 PM	THS 2.2	226
POL	BIO	0203	Randomized		36	Female	10-19 cig/day	3028	22AUG2013 07:50 PM	SA	187
POL	BIO	0204	Randomized		31	Female	>19 cig/day	4026	22AUG2013 08:39 PM	CC	227
POL	BIO	0205	Screen Failed		31	Female					
POL	BIO	0206	Randomized		24	Male	>19 cig/day	2027	22AUG2013 08:19 PM	THS 2.2	147
POL	BIO	0207	Screen Failed		25	Female					
POL	BIO	0208	Screen Failed		41	Female					
POL	BIO	0209	Screen Failed		43	Female					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0210	Randomized	(b) (6)	40	Female	>19 cig/day	4018	22AUG2013 06:53 PM	THS 2.2	225
POL	BIO	0211	Discontinued from Enrollment		39	Female	>19 cig/day				
POL	BIO	0212	Screen Failed		55	Female					
POL	BIO	0213	Screen Failed		44	Female					
POL	BIO	0214	Screen Failed		53	Male			22AUG2013 08:25 PM	THS 2.2	226
POL	BIO	0215	Screen Failed		56	Male					
POL	BIO	0216	Randomized		22	Female	>19 cig/day	4024			
POL	BIO	0217	Screen Failed		43	Male					
POL	BIO	0218	Randomized		21	Male	10-19 cig/day	1036	22AUG2013 08:55 PM	SA	109
POL	BIO	0219	Screen Failed		25	Male					
POL	BIO	0220	Randomized		40	Female	10-19 cig/day	3029	22AUG2013 08:07 PM	THS 2.2	188



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0221	Screen Failed	(b) (6)	21	Female					
POL	BIO	0222	Screen Failed		37	Female					
POL	BIO	0223	Screen Failed		37	Female					
POL	BIO	0224	Randomized		52	Female	10-19 cig/day	3027	22AUG2013 07:23 PM	CC	187
POL	BIO	0225	Screen Failed		28	Male					
POL	BIO	0226	Screen Failed		32	Male					
POL	BIO	0227	Screen Failed		56	Female					
POL	BIO	0228	Randomized		31	Female	10-19 cig/day	3025	22AUG2013 07:15 PM	THS 2.2	187
POL	BIO	0229	Randomized		38	Female	10-19 cig/day	3032	22AUG2013 08:31 PM	CC	188
POL	BIO	0230	Randomized		29	Male	>19 cig/day	2029	22AUG2013 08:58 PM	CC	148
POL	BIO	0231	Screen Failed		50	Female					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0232	Randomized	(b) (6)	43	Female	10-19 cig/day	3026	22AUG2013 07:17 PM	THS 2.2	187
POL	BIO	0233	Screen Failed	(b) (6)	52	Male					
POL	BIO	0234	Randomized	(b) (6)	31	Male	10-19 cig/day	1035	22AUG2013 07:53 PM	THS 2.2	109
POL	BIO	0235	Screen Failed	(b) (6)	26	Male					
POL	BIO	0236	Screen Failed	(b) (6)	34	Male					
POL	BIO	0237	Screen Failed	(b) (6)	28	Male					
POL	BIO	0238	Screen Failed	(b) (6)	27	Male					
POL	BIO	0239	Screen Failed	(b) (6)	64	Male					
POL	BIO	0240	Randomized	(b) (6)	36	Female	>19 cig/day	4021	22AUG2013 08:05 PM	SA	226
POL	BIO	0241	Randomized	(b) (6)	37	Male	>19 cig/day	2025	22AUG2013 08:10 PM	THS 2.2	147
POL	BIO	0242	Discontinued from Enrollment	(b) (6)	49	Male	>19 cig/day				



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0243	Screen Failed	(b) (6)	47	Female					
POL	BIO	0244	Randomized		39	Female	10-19 cig/day	3031	22AUG2013 08:28 PM	THS 2.2	188
POL	BIO	0245	Discontinued from Enrollment		51	Male	>19 cig/day				
POL	BIO	0246	Screen Failed		28	Male					
POL	BIO	0247	Discontinued from Enrollment		47	Female	10-19 cig/day				
POL	BIO	0248	Screen Failed		55	Female					
POL	BIO	0249	Randomized		60	Female	>19 cig/day	4019	22AUG2013 06:57 PM	SA	225
POL	BIO	0250	Screen Failed		29	Male					
POL	BIO	0251	Randomized		21	Female	10-19 cig/day	3030	22AUG2013 08:13 PM	SA	188
POL	BIO	0252	Randomized		44	Female	>19 cig/day	4027	22AUG2013 08:44 PM	SA	227
POL	BIO	0253	Screen Failed		59	Female					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0254	Screen Failed	(b) (6)	21	Female					
POL	BIO	0255	Randomized		41	Female	>19 cig/day	4028	22AUG2013 08:49 PM	THS 2.2	227
POL	BIO	0256	Randomized		27	Male	>19 cig/day	2024	22AUG2013 07:57 PM	THS 2.2	146
POL	BIO	0257	Screen Failed		24	Male					
POL	BIO	0258	Screen Failed		30	Female					
POL	BIO	0259	Screen Failed		26	Female					
POL	BIO	0260	Screen Failed		23	Male					
POL	BIO	0261	Screen Failed		53	Female					
POL	BIO	0262	Randomized		45	Female	>19 cig/day	4020	22AUG2013 08:00 PM	CC	225
POL	BIO	0263	Screen Failed		38	Male					
POL	BIO	0264	Randomized		36	Female	>19 cig/day	4025	22AUG2013 08:34 PM	THS 2.2	227



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0265	Randomized	(b) (6)	42	Male	>19 cig/day	2028	22AUG2013 08:52 PM	SA	147
POL	BIO	0266	Randomized		21	Female	>19 cig/day	4035	13SEP2013 07:25 PM	SA	229
POL	BIO	0267	Screen Failed		24	Female	10-19 cig/day	1039	13SEP2013 07:58 PM	THS 2.2	110
POL	BIO	0268	Screen Failed		31	Male					
POL	BIO	0269	Discontinued from Enrollment		21	Male					
POL	BIO	0270	Screen Failed		44	Male	10-19 cig/day	2034	13SEP2013 07:39 PM	SA	149
POL	BIO	0271	Screen Failed		38	Male					
POL	BIO	0272	Randomized		34	Male	>19 cig/day	2034	13SEP2013 07:39 PM	SA	149
POL	BIO	0273	Randomized		47	Male					
POL	BIO	0274	Screen Failed		54	Male	>19 cig/day	2034	13SEP2013 07:39 PM	SA	149
POL	BIO	0275	Screen Failed		48	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0276	Randomized	(b) (6)	31	Female	10-19 cig/day	3039	13SEP2013 08:25 PM	THS 2.2	190
POL	BIO	0277	Randomized		42	Male	>19 cig/day	2032	13SEP2013 07:13 PM	THS 2.2	148
POL	BIO	0278	Randomized		22	Male	10-19 cig/day	1040	13SEP2013 08:03 PM	CC	110
POL	BIO	0279	Randomized		52	Female	>19 cig/day	4041	13SEP2013 08:21 PM	THS 2.2	231
POL	BIO	0280	Screen Failed		48	Female					
POL	BIO	0281	Randomized		28	Male	>19 cig/day	2036	13SEP2013 07:52 PM	THS 2.2	149
POL	BIO	0282	Randomized		49	Female	10-19 cig/day	3038	13SEP2013 08:23 PM	THS 2.2	190
POL	BIO	0283	Randomized		26	Female	>19 cig/day	4034	13SEP2013 07:23 PM	CC	229
POL	BIO	0284	Screen Failed		25	Female					
POL	BIO	0285	Randomized		22	Male	10-19 cig/day	1041	13SEP2013 08:14 PM	CC	111
POL	BIO	0286	Screen Failed		25	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0287	Randomized	(b) (6)	43	Female	>19 cig/day	4036	13SEP2013 07:27 PM	THS 2.2	229
POL	BIO	0288	Discontinued from Enrollment		57	Female	>19 cig/day				
POL	BIO	0289	Randomized		51	Female	10-19 cig/day	3036	13SEP2013 07:55 PM	SA	189
POL	BIO	0290	Screen Failed		38	Male					
POL	BIO	0291	Randomized		35	Female	>19 cig/day	4033	13SEP2013 07:17 PM	THS 2.2	229
POL	BIO	0292	Randomized		21	Female	>19 cig/day	4037	13SEP2013 07:29 PM	SA	230
POL	BIO	0293	Screen Failed		41	Female					
POL	BIO	0294	Screen Failed		27	Male					
POL	BIO	0295	Screen Failed		25	Male					
POL	BIO	0296	Randomized		29	Male	10-19 cig/day	1038	13SEP2013 07:49 PM	THS 2.2	110
POL	BIO	0297	Screen Failed		40	Female					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0298	Randomized	(b) (6)	30	Female	10-19 cig/day	3037	13SEP2013 08:19 PM	CC	190
POL	BIO	0299	Discontinued from Enrollment		58	Female	10-19 cig/day				
POL	BIO	0300	Randomized		26	Female	10-19 cig/day	3035	13SEP2013 07:31 PM	THS 2.2	189
POL	BIO	0301	Randomized		23	Male	10-19 cig/day	1042	13SEP2013 08:29 PM	THS 2.2	111
POL	BIO	0302	Screen Failed		30	Male					
POL	BIO	0303	Screen Failed		29	Male					
POL	BIO	0304	Screen Failed		27	Male					
POL	BIO	0305	Screen Failed		22	Male					
POL	BIO	0306	Randomized		22	Male	>19 cig/day	2038	13SEP2013 08:32 PM	SA	150
POL	BIO	0307	Randomized		51	Male	>19 cig/day	2035	13SEP2013 07:41 PM	THS 2.2	149
POL	BIO	0308	Randomized		32	Male	>19 cig/day	2031	13SEP2013 07:11 PM	THS 2.2	148



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0309	Discontinued from Enrollment	(b) (6)	23	Male	>19 cig/day				
POL	BIO	0310	Screen Failed		33	Female					
POL	BIO	0311	Screen Failed		42	Female					
POL	BIO	0312	Discontinued from Enrollment		50	Male	>19 cig/day				
POL	BIO	0313	Randomized		26	Female	>19 cig/day	4039	13SEP2013 08:16 PM	CC	230
POL	BIO	0314	Screen Failed		24	Female					
POL	BIO	0315	Randomized		59	Female	>19 cig/day	4031	13SEP2013 07:05 PM	CC	228
POL	BIO	0316	Randomized		59	Female	10-19 cig/day	3033	13SEP2013 07:03 PM	THS 2.2	189
POL	BIO	0317	Randomized		50	Female	>19 cig/day	4032	13SEP2013 07:15 PM	SA	228
POL	BIO	0318	Randomized		21	Male	>19 cig/day	2037	13SEP2013 08:27 PM	CC	150
POL	BIO	0319	Screen Failed		21	Male					



Randomization Scheme and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
POL	BIO	0320	Randomized	(b) (6)	53	Female	>19 cig/day	4040	13SEP2013 08:17 PM	THS 2.2	230
POL	BIO	0321	Randomized		41	Female	>19 cig/day	4038	13SEP2013 07:53 PM	THS 2.2	230
POL	BIO	0322	Randomized		31	Male	>19 cig/day	2033	13SEP2013 07:33 PM	CC	149
POL	BIO	0323	Screen Failed		26	Male					
POL	BIO	0324	Screen Failed		35	Female					
POL	BIO	0325	Randomized		37	Male	>19 cig/day	2030	13SEP2013 07:09 PM	SA	148
POL	BIO	0326	Screen Failed		34	Female					
POL	BIO	0327	Screen Failed		38	Male					
POL	BIO	0328	Randomized		57	Female	10-19 cig/day	3034	13SEP2013 07:19 PM	CC	189
POL	BIO	0329	Screen Failed		59	Female					

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Source: PMI_Covance_ZRHR-REXC-03-EU_LIVE_9.00.000_SRL.txt SDTM.DM SDTM.SUPPDM SDTM.DS SDTM.FA
 Path: /cvm/projects/prj/development/000000106324/dev/listings/l_rand.sas
 Program Run: 23FEB15 cvn_jhardman Program Status: FINAL

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16.1.6.2 BIOSTATISTICAL ADDENDUM TO IXRS

B4: Withheld one page, vendor information





