



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-REXA-08-US Clinical Study Report Appendix 16.3 CRFs of All Study Participants**

**Study Title:** A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting

**Study Number:** ZRHM-REXA-08-US

**Product Name:** Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)

**Study Initiated (first subject screened):** 17 December 2013

**Study Completed (last subject last visit):** 12 October 2014

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Andrea Donelli, Clinical Scientist  
Ruben Rosoky, MD PhD MFPM, Medical Safety Officer

**Version:** 1.0

**Date:** 47"O c{ "4238

This study was conducted in accordance with Good Clinical Practice.

#### **Confidentiality Statement**

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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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## 16.3 CRFS OF ALL STUDY PARTICIPANTS

### 16.3.1 SCREEN FAILURES

Subject 1003	Subject 1050
Subject 1004	Subject 1051
Subject 1005	Subject 1053
Subject 1006	Subject 1054
Subject 1007	Subject 1055
Subject 1008	Subject 1056
Subject 1011	Subject 1058
Subject 1012	Subject 1061
Subject 1013	Subject 1063
Subject 1014	Subject 1064
Subject 1015	Subject 1066
Subject 1016	Subject 1067
Subject 1017	Subject 1068
Subject 1018	Subject 1070
Subject 1019	Subject 1071
Subject 1020	Subject 1072
Subject 1021	Subject 1073
Subject 1022	Subject 1075
Subject 1025	Subject 1076
Subject 1026	Subject 1078
Subject 1027	Subject 1080
Subject 1029	Subject 1082
Subject 1030	Subject 1083
Subject 1032	Subject 1084
Subject 1033	Subject 1085
Subject 1034	Subject 1086
Subject 1035	Subject 1088
Subject 1036	Subject 1090
Subject 1037	Subject 1091
Subject 1039	Subject 1094
Subject 1040	Subject 1095
Subject 1043	Subject 1096
Subject 1044	Subject 1100
Subject 1045	Subject 1103
Subject 1046	Subject 1107
Subject 1047	Subject 1108
Subject 1048	Subject 1109
Subject 1049	Subject 1111



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Subject 1112	Subject 1173
Subject 1113	Subject 1174
Subject 1114	Subject 1175
Subject 1115	Subject 1176
Subject 1120	Subject 1178
Subject 1121	Subject 1179
Subject 1122	Subject 1180
Subject 1123	Subject 1182
Subject 1126	Subject 1183
Subject 1127	Subject 1184
Subject 1128	Subject 1185
Subject 1129	Subject 1186
Subject 1130	Subject 1187
Subject 1131	Subject 1188
Subject 1132	Subject 1189
Subject 1133	Subject 1190
Subject 1134	Subject 1191
Subject 1135	Subject 1192
Subject 1136	Subject 1193
Subject 1137	Subject 1196
Subject 1138	Subject 1199
Subject 1139	Subject 1200
Subject 1140	Subject 1201
Subject 1141	Subject 1204
Subject 1142	Subject 1205
Subject 1145	Subject 1206
Subject 1146	Subject 1207
Subject 1148	Subject 1208
Subject 1149	Subject 1211
Subject 1151	Subject 1213
Subject 1152	Subject 1214
Subject 1153	Subject 1215
Subject 1154	Subject 1216
Subject 1157	Subject 1217
Subject 1158	Subject 1220
Subject 1161	Subject 1222
Subject 1162	Subject 1223
Subject 1163	Subject 1224
Subject 1164	Subject 1225
Subject 1166	Subject 1226
Subject 1171	Subject 1227
Subject 1172	Subject 1228



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Subject 1229	Subject 1288
Subject 1231	Subject 1289
Subject 1232	Subject 1290
Subject 1236	Subject 1291
Subject 1237	Subject 1292
Subject 1239	Subject 1293
Subject 1240	Subject 1294
Subject 1241	Subject 1295
Subject 1242	Subject 1296
Subject 1243	Subject 1298
Subject 1244	Subject 1299
Subject 1245	Subject 1300
Subject 1248	Subject 1301
Subject 1249	Subject 1303
Subject 1250	Subject 1305
Subject 1254	Subject 1306
Subject 1255	Subject 1307
Subject 1256	Subject 1308
Subject 1257	Subject 1309
Subject 1258	Subject 1310
Subject 1259	Subject 1311
Subject 1260	Subject 2001
Subject 1262	Subject 2002
Subject 1263	Subject 2003
Subject 1264	Subject 2004
Subject 1266	Subject 2006
Subject 1268	Subject 2008
Subject 1269	Subject 2009
Subject 1270	Subject 2010
Subject 1271	Subject 2011
Subject 1272	Subject 2012
Subject 1273	Subject 2013
Subject 1274	Subject 2014
Subject 1275	Subject 2015
Subject 1276	Subject 2016
Subject 1277	Subject 2017
Subject 1278	Subject 2018
Subject 1279	Subject 2019
Subject 1282	Subject 2020
Subject 1284	Subject 2021
Subject 1285	Subject 2022
Subject 1287	Subject 2024



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Subject 2025	Subject 2083
Subject 2026	Subject 2084
Subject 2027	Subject 2088
Subject 2028	Subject 2090
Subject 2030	Subject 2091
Subject 2031	Subject 2092
Subject 2032	Subject 2093
Subject 2033	Subject 2094
Subject 2034	Subject 2096
Subject 2035	Subject 2097
Subject 2036	Subject 2098
Subject 2037	Subject 2099
Subject 2039	Subject 2101
Subject 2040	Subject 2102
Subject 2041	Subject 2103
Subject 2042	Subject 2104
Subject 2043	Subject 2105
Subject 2044	Subject 2107
Subject 2047	Subject 2108
Subject 2049	Subject 2111
Subject 2050	Subject 2112
Subject 2051	Subject 2114
Subject 2052	Subject 2117
Subject 2055	Subject 2118
Subject 2056	Subject 2119
Subject 2057	Subject 2121
Subject 2059	Subject 2122
Subject 2060	Subject 2123
Subject 2061	Subject 2124
Subject 2062	Subject 2125
Subject 2063	Subject 2126
Subject 2064	Subject 2128
Subject 2066	Subject 2129
Subject 2067	Subject 2130
Subject 2068	Subject 2131
Subject 2069	Subject 2132
Subject 2070	Subject 2133
Subject 2074	Subject 2134
Subject 2078	Subject 2135
Subject 2080	Subject 2139
Subject 2081	Subject 2141
Subject 2082	Subject 2142



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Subject 2144	Subject 2201
Subject 2145	Subject 2202
Subject 2147	Subject 2203
Subject 2149	Subject 2204
Subject 2150	Subject 2206
Subject 2151	Subject 2207
Subject 2152	Subject 2208
Subject 2153	Subject 2210
Subject 2154	Subject 2211
Subject 2156	Subject 2213
Subject 2157	Subject 2215
Subject 2158	Subject 2216
Subject 2159	Subject 2217
Subject 2160	Subject 2218
Subject 2161	Subject 2219
Subject 2163	Subject 2220
Subject 2166	Subject 2221
Subject 2167	Subject 2222
Subject 2168	Subject 2223
Subject 2170	Subject 2224
Subject 2171	Subject 2226
Subject 2172	Subject 2227
Subject 2173	Subject 2228
Subject 2175	Subject 2229
Subject 2177	Subject 2231
Subject 2178	Subject 2233
Subject 2179	Subject 2234
Subject 2180	Subject 2235
Subject 2181	Subject 2236
Subject 2182	Subject 2237
Subject 2183	Subject 2238
Subject 2184	Subject 2239
Subject 2185	Subject 2240
Subject 2186	Subject 2241
Subject 2189	Subject 2242
Subject 2190	Subject 2243
Subject 2191	Subject 2244
Subject 2192	Subject 2245
Subject 2193	Subject 2246
Subject 2195	Subject 2247
Subject 2198	Subject 2248
Subject 2199	Subject 2249



Subject 2250	Subject 2302
Subject 2252	Subject 2304
Subject 2253	Subject 2305
Subject 2254	Subject 2308
Subject 2255	Subject 2309
Subject 2256	Subject 2311
Subject 2258	Subject 2312
Subject 2259	Subject 2313
Subject 2261	Subject 2314
Subject 2263	Subject 2315
Subject 2264	Subject 2317
Subject 2265	Subject 2318
Subject 2266	Subject 2319
Subject 2267	Subject 2320
Subject 2268	Subject 2321
Subject 2269	Subject 2322
Subject 2270	Subject 2323
Subject 2271	Subject 2324
Subject 2272	Subject 2325
Subject 2273	Subject 2326
Subject 2275	Subject 2327
Subject 2276	Subject 2328
Subject 2277	Subject 2329
Subject 2278	Subject 2331
Subject 2279	Subject 2332
Subject 2280	Subject 2333
Subject 2281	Subject 2335
Subject 2282	Subject 2337
Subject 2283	Subject 2338
Subject 2284	Subject 2339
Subject 2286	Subject 2341
Subject 2288	Subject 2342
Subject 2289	Subject 2343
Subject 2290	Subject 2345
Subject 2291	Subject 2346
Subject 2293	Subject 2347
Subject 2294	Subject 2348
Subject 2295	Subject 2349
Subject 2296	Subject 2350
Subject 2297	Subject 2352
Subject 2300	
Subject 2301	





## 16.3.2 ENROLLED AND NOT RANDOMIZED

[Subject 1023](#)

[Subject 1098](#)

[Subject 1119](#)

[Subject 1233](#)

[Subject 2205](#)



### 16.3.3 RANDOMIZED

Subject 1001	Subject 1156
Subject 1002	Subject 1159
Subject 1009	Subject 1160
Subject 1010	Subject 1165
Subject 1028	Subject 1167
Subject 1031	Subject 1168
Subject 1038	Subject 1169
Subject 1041	Subject 1170
Subject 1042	Subject 1177
Subject 1052	Subject 1181
Subject 1057	Subject 1194
Subject 1060	Subject 1195
Subject 1062	Subject 1197
Subject 1065	Subject 1198
Subject 1069	Subject 1202
Subject 1074	Subject 1203
Subject 1077	Subject 1209
Subject 1079	Subject 1210
Subject 1081	Subject 1212
Subject 1087	Subject 1218
Subject 1089	Subject 1219
Subject 1092	Subject 1221
Subject 1093	Subject 1230
Subject 1097	Subject 1234
Subject 1099	Subject 1235
Subject 1101	Subject 1238
Subject 1102	Subject 1246
Subject 1104	Subject 1247
Subject 1105	Subject 1251
Subject 1106	Subject 1252
Subject 1110	Subject 1253
Subject 1117	Subject 1261
Subject 1118	Subject 1265
Subject 1124	Subject 1267
Subject 1125	Subject 1280
Subject 1143	Subject 1281
Subject 1144	Subject 1283
Subject 1147	Subject 1286
Subject 1150	Subject 1297
Subject 1155	Subject 1302



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Subject 1304	Subject 2162
Subject 2005	Subject 2164
Subject 2007	Subject 2165
Subject 2023	Subject 2169
Subject 2029	Subject 2174
Subject 2038	Subject 2176
Subject 2045	Subject 2187
Subject 2046	Subject 2188
Subject 2048	Subject 2194
Subject 2053	Subject 2196
Subject 2054	Subject 2197
Subject 2058	Subject 2200
Subject 2065	Subject 2209
Subject 2071	Subject 2212
Subject 2072	Subject 2214
Subject 2073	Subject 2225
Subject 2075	Subject 2230
Subject 2076	Subject 2232
Subject 2077	Subject 2251
Subject 2079	Subject 2257
Subject 2085	Subject 2260
Subject 2086	Subject 2262
Subject 2087	Subject 2274
Subject 2089	Subject 2285
Subject 2095	Subject 2287
Subject 2100	Subject 2292
Subject 2106	Subject 2298
Subject 2109	Subject 2299
Subject 2110	Subject 2303
Subject 2113	Subject 2307
Subject 2115	Subject 2310
Subject 2116	Subject 2316
Subject 2120	Subject 2330
Subject 2127	Subject 2334
Subject 2136	Subject 2336
Subject 2137	Subject 2340
Subject 2138	Subject 2344
Subject 2140	Subject 2351
Subject 2143	
Subject 2146	
Subject 2148	
Subject 2155	