

7.3.1 Tabulated Index of Clinical studies

Study Type : Studies in Adult Human Subjects

| Full reference | Citation & File name | Filepath |
|---|----------------------|---|
| Philip Morris International. Unpublished on file data. Internal Report. A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 (THS 2.2) following single use in smoking, healthy subjects compared to conventional cigarettes and nicotine nasal spray. ZRHR-PK-01-EU. 2015. ClinicalTrial.gov Identifier: NCT01967732 | ZRHR-PK-01-EU | 7 STUDYANA\73 HUMAN\731 CLIN\01 PK01EU\Report\ ZRHR-PK-01- EU_CSR_FINAL_v1.0 |
| Philip Morris International. Unpublished on file data. Internal Report. A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 (THS 2.2) following single use in smoking, healthy subjects compared to conventional cigarettes and nicotine gum. ZRHR-PK-02-JP. 2015. ClinicalTrial.gov Identifier: NCT01959607 | ZRHR-PK-02-JP | 7 STUDYANA\73 HUMAN\731 CLIN\02 PK02JP\Report\ CSR_FINAL_v1.0 |
| Philip Morris International. Unpublished on file data. Internal Report. A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, but 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. ZRHR-REXC-03-EU. 2016. ClinicalTrial.gov Identifier: NCT01959932 | ZRHR-REXC-03-EU | 7 STUDYANA\73 HUMAN\731 CLIN\03 REXC03EU\Report\ZRHR- REXC-03- EU_CSR_FINAL_v2.0_08March 2016 |

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| Philip Morris International. Unpublished on file data. Internal Report. 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 from conventional cigarettes to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to smokers continuing to use conventional cigarettes for 5 days in confinement. ZRHR-REXC-04-JP. 2015. ClinicalTrial.gov Identifier: NCT01970982 | ZRHR-REXC-04-JP | 7 STUDYANA\73 HUMAN\731 CLIN\04 REXC04JP\Report\ZRHR-REXC-04-JP_CSR_Final_v1.0 |
| Philip Morris International. Unpublished on file data. Internal Report. A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine gum. ZRHM-PK-05-JP. 2015. ClinicalTrial.gov Identifier: NCT01967706 | ZRHM-PK-05-JP | 7 STUDYANA\73 HUMAN\731 CLIN\05 PK05JP\Report\ZRHM-PK-05-JP_CSR_FINAL_v1.0 |
| Philip Morris International. Unpublished on file data. Internal Report. A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine nasal spray. ZRHM-PK-06-US. 2016. ClinicalTrial.gov Identifier: NCT01967719 | ZRHM-PK-06-US | 7 STUDYANA\73 HUMAN\731 CLIN\06 PK06US\Report\ZRHM-PK-06-US_CSR_FINAL_v2.0 |

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| <p>Philip Morris International. Unpublished on file data. Internal Report. A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in healthy smokers switching to 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 85 days in an ambulatory setting. ZRHM-REXA-07-JP. 2016 ClinicalTrial.gov Identifier: NCT01989156</p> | <p>ZRHM-REXA-07-JP</p> | <p>7 STUDYANA\73 HUMAN\731 CLIN\07 REXA07JP\Report\ZRHM-REXA-07 CSR v1.0</p> |
| <p>Philip Morris International. Unpublished on file data. Internal Report. 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. ZRHM-REXA-08-US. 2016. ClinicalTrial.gov Identifier: NCT01989156</p> | <p>ZRHM-REXA-08-US</p> | <p>7 STUDYANA\73 HUMAN\731 CLIN\08 REXA08US\Report\ZRHM-REXA-08-US CSR v1.0_25May2016</p> |

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