



PMI RESEARCH & DEVELOPMENT

Study ZRHM-PK-05-JP **Clinical Study Report Appendix 16.2** **CRFs for Deaths, Other Serious Adverse Events, and** **Withdrawals for Adverse Events**

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| Study Title: | 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 |
| Short Title: | Nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) |
| Study Number: | ZRHM-PK-05-JP |
| Product Name: | Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) |
| Study Initiated (first subject screened): | 01 August 2013 |
| Study Completed (last subject last visit): | 16 November 2013 |
| Principal Investigator and Affiliation: | F. Nobuoka, MD Ageo Medical Clinic 3133 Haraichi, Ageo City Saitama 362-0021, Japan |
| Sponsor: | Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland |
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| Version: | 1.0 |
| Date: | 12 May 2015 |

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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16.2.1 CASE REPORT FORMS FOR SERIOUS ADVERSE EVENTS

Not applicable.



16.2.2 CASE REPORT FORMS FOR DEATHS

Not applicable.



16.2.3 CASE REPORT FORMS FOR WITHDRAWALS FOR ADVERSE EVENTS

Not applicable.