



PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-08-US Clinical Study Report Appendix 16.2 CRFs for Deaths, Other Serious Adverse Events, and Withdrawals for Adverse Events

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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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 CRFS FOR DEATHS, OTHER SERIOUS ADVERSE EVENTS, AND WITHDRAWALS FOR ADVERSE EVENTS

16.2.1 CASE REPORT FORMS FOR SERIOUS ADVERSE EVENTS: SUBJECT NUMBER 1119

Exposed and Not Randomized

[Subject 1119](#)



16.2.2 CASE REPORT FORMS FOR DEATHS

Not applicable.



16.2.3 WITHDRAWALS FOR ADVERSE EVENTS

Exposed and Not Randomized

[Subject 1233](#)

[Subject 1098](#)

[Subject 2205](#)