



PMI RESEARCH & DEVELOPMENT

Study ZRHR-REXC-03-EU Clinical Study Report Appendix 16.1.7 Audit Certificates

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
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Sponsor: Philip Morris Products S.A.
PMI Research & Development
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Sponsor Signatories: Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist
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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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16.1.7 AUDIT CERTIFICATE

**COVANCE****Quality Assurance and Compliance
Audit Certificate**

The Quality Assurance and Compliance Group of Covance Clinical Development Services have conducted the following independent audit in accordance with the applicable requirements of Good Clinical Practice and current auditing procedures.

AUDIT No.:	L-13-233
AUDIT TYPE:	Investigator Site Audit
SCOPE:	PMI Study ZRHR-REXC-03-EU BioVirtus, Kajetany, Warsaw, Poland
DATE(s) CONDUCTED:	29 & 30 Oct 2013 (at site), 06 Nov 2013 (in-house file review)
LEAD AUDITOR:	Dorothy Hancock, Principal QA Specialist
AUDIT TEAM:	Arash Farpour, QA Associate

Please file this Audit Certificate in the Trial Master File.

D Hancock
Signature
Dorothy Hancock
Principal QA Specialist

17 July 2014
Date