



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-REXA-08-US Clinical Study Report Appendix 16.1.7 Audit Certificates**

**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

**Principal Investigator and Affiliation:** Dr William Lewis, Covance Dallas Site  
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Daytona Beach, FL 32117

**Sponsor:** Philip Morris Products S.A.  
PMI Research & Development  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland

**Sponsor Signatories:** Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist  
Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician  
Andrea Donelli, Clinical Scientist  
Ruben Rosoky, MD PhD MFPM, Medical Safety Officer

**Version:** 30

**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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## **16.1.7 AUDIT CERTIFICATES**

**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.

<b>AUDIT No.:</b>	<i>NA-14-125</i>
<b>AUDIT TYPE:</b>	<i>Study Audit</i>
<b>SCOPE:</b>	<i>Philip Morris (PMI) Covance Study number 8278-008 Protocol ZRHM-REXA-08-US Daytona Beach CRU</i>
<b>DATE(s) CONDUCTED:</b>	<i>12-14 March 2014</i>
<b>LEAD AUDITOR:</b>	<i>Shana Dressel, Senior Quality Assurance Liaison</i>
<b>AUDIT TEAM:</b>	<i>N/A</i>

Please file this Audit Certificate in the Trial Master File.

  
Signature  
Shana Dressel  
Senior Quality Assurance Liaison

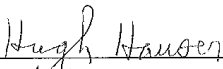
*14 April 2014*  
Date

**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.

<b>AUDIT No.:</b>	NA-14-110
<b>AUDIT TYPE:</b>	General Study Compliance
<b>SCOPE:</b>	<p>Phillip Morris Inc. ZRHM-REXA-08-US, Covance # 8278-008 Dr. Lewis, Principal Investigator Covance Dallas Clinical Research Unit</p> <p>This was a general study compliance audit that consisted of a review of select study data from 4 subjects, DOR and training documentation, Accountability logs G2 and G4, and direct observation of urine collection and processing on Feb 19-20, 2014.</p>
<b>DATE(s) CONDUCTED:</b>	19-27 Feb. 2014
<b>LEAD AUDITOR:</b>	Shana Dressel, Quality Assurance Specialist
<b>AUDIT TEAM:</b>	NA

**Please file this Audit Certificate in the Trial Master File.**

  
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**Signature**

Hugh Hauser  
Senior Manager, Regulatory Compliance and Quality Assurance\*

16 May 2016  
\_\_\_\_\_  
**Date**

\*Original audit certificate could not be located. This certificate was generated based on the content of the audit report.