EDC Cover Letter to Investigators for Interim Signature Request

28-Nov-2012

Dr. Schmid,
Westgate Road,
Newcastle upon Tyne
Tyne and Wear (England)
Reference: MK 7009-009

Dear Dr. Dr. Schmid,

This letter is to inform you that the clinical data that you entered/ provided to Merck & Co., Inc., for referenced protocol as of October 9th 2012 will be made available for use in and Final filing. Attached to this letter is a Primary Investigator Signature Form. Please review this form, sign, photocopy, and return the original to Merck Sharp & Dohme Corp (local subsidiary) within two weeks of the date of this letter.

This interim signature does not replace the eSignature that is required at the end of the study.

Please keep your copy of the form with your other study documents and remember to keep all of these documents in compliance with regulatory retention requirements. Your Merck representative will notify you when such information can be discarded.

Sincerely,
Johana Quecano
Associate Global Data Management Specialist

cc: Megan Olberding (PDM)
Wagner, Kyle (TS)
Lisa Whiskin (CRA)
Castro, Nancy E. (DMS) Lead
MIDAS TMF or SORF

SOP500 Exhibit 1 Template Version 1.0





Final Frozen File Declaration by Investigator

Investigator Name (print): Dr. Schmid, Matthias

IND Compound Protocol Study Site IIN 76913 MK 7009 009 31 135773

By signing and dating this Primary Investigator Signature Form, I declare that information contained in the InForm Collector from the time of first patient consent date to all visits:

- 1. Includes the results of tests and evaluations performed on the dates specified
- 2. Has been reviewed by me or my delegate
- 3. Is accurate

Investigator Signature: X

* If at all possible, the Principal Investigator should sign; in cases where the investigator is not available, the Secondary Investigator may sign the form. In this case, please cross out the name at the top of the page and print in the Secondary Investigator name.

(DD-MMM-YYYY)

cc: MIDAS TMF/Clinical Site/Site Correspondence/Declaration by Investigator



