

DEVIATION LOG

Complete deviation log and submit to ACCORD every 3 months unless timeframe for reporting specified in protocol

Trial Title	SHORT TITLE	Principal Investigator	XXX
EudraCT No.	2016-XXXXXX-XX	Site No.	01
REC No.	XX/XX/XXXX	Site Name	Royal Infirmary of Edinburgh
DEVIATION: Any change, divergence, or departure from GCP, the study design or procedures defined in the protocol			

Log Reviewed by PI: Sign: PI to review and sign/date before sending to ACCORD Date: _____

Log Received by ACCORD: Sign: ACCORD will sign/date on receipt and provide copy to PI/Trial manager Date: _____

NB: If the event could potentially have impacted upon (i) patient safety and/or (ii) Study outcome, please complete a Protocol Violation (CR010-F01)

Event No.	Event Date	Participant No.	Description of Deviation	*Code	Could Deviation Potentially Impact:		PI Informed (Sign/Date)	Site Actions (see guidance on page 6)	Sign/Date (action complete)
					Patient Safety?	Study Outcome?			
01	29MAR16	10010	Study follow up visit out with time frame detailed in protocol as participant was on holiday. Visit scheduled 14MAR16 (±2 weeks)		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Study visit performed 29MAR16. CRF annotated to explain deviation.	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): Research team to ask participants if they have any holidays scheduled and arrange visits around these where possible.	Sign/Date to confirm the preventative action is complete

***Deviation Codes (ACCORD USE ONLY):** A=Consent Procedure, B=Inclusion/Exclusion Criteria, C=AE Reporting, D=Randomization or Dosing, E=Study Procedures, F=Lab Procedures, G=Visit Schedule, H=Other

Event No.	Event Date	Participant No.	Description of Deviation	*Code	Could Deviation Potentially Impact:		PI Informed (Sign/Date)	Site Actions	Sign/Date (action complete)
					Patient Safety?	Study Outcome?			
02	03MAR16	100601	Participant forgot to take daily dose of study drug on 03Mar16. Commenced on 04Mar16		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Participant error. Participant missed one daily dose of study drug. Explanation given to participant, by the Research Nurse, on importance of taking study drug daily.	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): Continue to inform participants of requirements when taking informed consent and remind participants to read study drug label on bottle.	Sign/Date to confirm the preventative action is complete
03	02APR16	100502	Participant failure to return diary at Day 21 visit		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Diary to be returned at next visit (09APR16).	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): Not required as not clinically indicated.	Sign/Date to confirm the preventative action is complete

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					Patient Safety?	Study Outcome?			
04	04APR16	N.A.	Temperature of IMP storage in ward area not recorded on 04APR16-08APR16		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Review of existing data for trends suggest that temperature is unlikely to have gone out with range during this time (storage conditions in protocol 15-30 degrees Celsius). No further action required.	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): Discussions with support department to highlight the importance of recording temperature daily.	Sign/Date to confirm the preventative action is complete
05	10APR16	100578	Pelvic exam not carried out at screening		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Not applicable. Last exam carried out month before.	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): Not required as very recently performed and clinically not indicated.	Sign/Date to confirm the preventative action is complete

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Event No.	Event Date	Participant No.	Description of Deviation	*Code	Could Deviation Potentially Impact:		PI Informed (Sign/Date)	Site Actions	Sign/Date (action complete)
					Patient Safety?	Study Outcome?			
06	13APR16	100600	Drugs discarded by Research Nurse after use		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Pharmacy informed and discussed with staff involved.	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): Additional instructions and training to be given to staff.	Sign/Date to confirm the preventative action is complete
07	18APR16	100897	5 min observations not taken on time		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Person completing form to sign/date to confirm PI informed	Corrective (action taken to correct/document this deviation): Observations performed at 10 min	Sign/Date to confirm the corrective action is complete
					No <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>		Preventative (action taken to prevent this deviation occurring again): E-mail reminder sent to study team regarding importance of following the protocol. Checklist amended.	Sign/Date to confirm the preventative action is complete

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DEFINITIONS

Corrective Action: The immediate action taken when a deviation is discovered. The PI, or designee, will detail in the deviation log how the deviation was corrected (if applicable) at the time of discovery, and how this will be documented in the ISF.

Preventative Action: Includes investigation into the root cause of the deviation and the actions taken to ensure the deviation is not repeated. The PI, or designee, will detail in the deviation log how recurrence of this deviation will be prevented and how this will be documented in the ISF.