PROTOCOL VIOLATION REPORTING FORM

DO NOT SEND IDENTIFIABLE DATA WITH THIS FORM*

VIOLATION: A deviation that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being.

NB: If the event could NOT potentially have impacted upon (i) patient safety and/or (ii) study outcome, please complete an entry in the Protocol Deviation log (CR010-T01)

1. REPORT DETAILS

Trial Title	**SHORT TITLE**
EudraCT No.	**2016-XXXXXX-XX**
REC No.	**XX/XX/XXXX**
Principal Investigator	**XXX**
Site Name/No.	**Royal Infirmary of Edinburgh / 01**
Country Violation Recorded	**UK**
Participant number	**10001**

2. ASSESSMENT TO CONFIRM VIOLATION

Please confirm which of the following may have potentially been impacted by the violation:

Safety of Participant*	**Yes** ☐ **No** ☒	**Details:** No impact on participant safety.	**Sign/Date:** Person completing form to Sign/Date
Study Outcomes*	**Yes** ☒ **No** ☐	**Details:** If participant had received a dose of the IMP rather than the placebo (if randomised to the placebo arm of the study), this potentially could impact study outcomes.	**Sign/Date:** Person completing form to Sign/Date

3. DETAILS OF VIOLATION	
Date Occurred:	29MAR16
Description of Violation:	(*Indicate if the event constitutes an urgent safety measure – see SOP SCR005 for details regarding urgent safety measures*) Wrong treatment pack dispensed for participant 10001. Treatment pack 2543 dispensed instead of 2534.
***Code:**	*THIS WILL BE COMPLETED BY ACCORD (FOR INTENAL PURPOSES ONLY)*
PI Informed: (Sign/date)	Person completing form to sign/date to confirm PI informed
****Violation 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*	

4. ACTIONS TAKEN		
	Site Actions (see guidance in SOP CR011)	**Sign/Date (when action complete)**
Corrective Action:	*(action taken to correct/document this violation)* This error was raised by the Research nurse to pharmacy staff before the pack left pharmacy, and the Clinical Trial pharmacist informed. The correct pack was dispensed and paperwork completed to document the error.	Sign/Date to confirm the corrective action is complete
Preventative Action:	*(action taken to prevent this violation occurring again)* Pharmacy dispensing staff to be re-trained in study specific dispensing process and asked to re-read relevant SOPs. This training will be documented in the study pharmacy file.	Sign/Date to confirm the preventative action is complete
Conclusion – Justification of Actions: (PI or designee)	No actual impact on participant safety or study outcomes.	PI or designee to Sign/Date
Action Required:	**Participant(s) to remain on trial** ☒ **Participant(s) to be withdrawn from trial** ☐	Sign/Date to confirm the action is complete

5. INFORMATION SOURCE	
Name, Address and Telephone No.: (PI or designee)	**XXX**
Sign/Date: (PI or designee)	**XXX/XXX**
This form must be sent to ACCORD within 3 days of any trial site member becoming aware of violation (Fax +44 (0)131 242 9447 or e-mail (QA@accord.scot)	
Received by ACCORD (Sign/Date): ACCORD WILL SIGN/DATE ON RECEIPT AND PROVIDE COPY TO PI/TRIAL MANAGER	
***Violation Number (ACCORD internal use only):** THIS WILL BE COMPLETED BY ACCORD (FOR INTENAL PURPOSES ONLY)*	