Trial Title: TAILOR: Telims**A**rtan and **I**nsu**L**in **R**esistance in HIV
EudraCT Number: 2012-000935-18

Subject: Data omitted from the final analysis report and EUDRA-CT results

During site close down for the trial, data was identified for participants that had not been sent to CTRC by sites and subsequently was not present in the database at the time of database lock.

The impact the data received has on the trial results was assessed by the statistics team. The details of the data received and the assessment made by the statisticians in relation to the omitted data is listed below:

Form 12: 48 Week follow up

Participant is indicated as having DNA'd the visit, there is no impact on the results.

Form 14: Withdrawal from Trial

3 CRFs received:

1 CRF completed in error: the participant was a premature discontinuation from trial treatment.
1 CRF: withdrawn due to AE, no further data received post the withdrawal date. This participant was not included in the primary outcome analysis and is considered as lost to follow up for the secondary analyses.
1 CRF: lost to follow up, this participant is already classed as lost to follow up in the analysis

Form 15: End of Treatment

1 CRF received indicating the participant is lost to follow up. This participant was not included in the primary outcome analysis and this participant is classed as lost to follow up in the secondary analyses.

Form 4: Medical History

11 CRFs received; the data contained was not used in the analysis. The Chief Investigator reviewed the terms received and confirmed there was no impact on the eligibility of the participants.

Form 5: Concomitant Medication

1 CRF received, the data contained was not used in the analysis.

Form 6: Adverse Reactions

5 ARs received, no serious events the details for these Adverse Reactions are below. The data listed below was omitted from the analysis. These ARs have therefore not been uploaded to EUDRA-CT.

Adverse Event description	Arm
Drowsiness	B
Restlessness	B
Light headedness	B
Headache	D
Sleep pattern changes	D

Treatment diaries

33 diaries have been received; 4 of the diaries received related to participants used in the compliance analyses. The statistical team confirmed the data received would not have a material impact on the compliance analysis results.

Given the impact assessment against the trial results the Chief Investigator confirmed on 05/06/2018 and CTRC director on 08/06/2018 that the database did not need to be unlocked and the analysis rerun. The adverse reactions listed above were not uploaded to EudraCT as part of the results due to this decision.

Details of the serious breach are captured in the final analysis report. Full details of this event are also captured in the potential serious breach report (005) and this was submitted to Sponsor who reported the incident to the MHRA.