CDASH V 1.1 - Protocol Deviations

Record ID _____

Protocol Deviations

Were there any protocol deviations?

◯ No
◯ Yes
(Enter "Yes" if a protocol deviation occurred and "No" if none occurred. Ensure that any adverse event, concomitant medication use, newly discovered medical history, etc. which triggers a protocol deviation is noted in the respective CRF.)

Record all protocol deviations from time of consent THROUGH study completion.

What was the protocol deviation term?

_____
(Record the verbatim text of the protocol deviation.)

What was the protocol deviation start date?

_____
(Record the start date of the deviation using the DD-MM-YYYY format.)

What was the protocol deviation start time?

_____
(If appropriate, record the time the deviation started using the HH:MM (24-hour clock) format.)

What was the protocol deviation end date?

_____
(Record the stop date of the deviation using the DD-MM-YYYY format.)

What was the protocol deviation end time?

_____
(If appropriate, record the time the deviation ended using the HH:MM (24-hour clock) format.)

What is the protocol deviation ID?

_____
(Record unique identifier for each protocol deviation for this subject.Number sequence for all following forms should not duplicate existing numbers for the subject.)

Acknowledgement:CDISC wishes to acknowledge all the companies that have generously donated their resources in staff, time and other forms support to develop the CDASH standard. For more information on CDASH implementation please