

INVESTIGATOR'S NOTES-TO-FILE

Investigator: _____ Project: _____

Study Site: _____ Sponsor: _____

Patient #: _____ Date: _____

Check the appropriate **non-compliance or protocol irregularity/non-compliance issue** as applies:

- _____ Informed Consent Document signed after patient started study procedures
- _____ Safety labs not collected as specified by the protocol
- _____ Inclusion/Exclusion criteria violated
- _____ Patient in simultaneous interventional trials
- _____ Required source data documentation could not be obtained
- _____ SAE not reported appropriately to the UK IRB
- _____ SAE not reported appropriately to the Sponsor
- _____ Drug accountability issue
- _____ Subject took excluded medication
- _____ Subject did not return study drug
- _____ Subject did not take medication as directed
- _____ Subject received the wrong study drug
- _____ Subject was seen outside the allowed visit interval
- _____ Required study procedure not completed
- _____ Other: (Specify) _____

Explain the reason for the irregularity/non-compliance issue(s):

Date Sponsor notified: ___/___/___

Date IRB notified: ___/___/___

Study Coordinator: _____ Date: _____
(Signature)

Investigator: _____ Date: _____
(Signature)

(NOTE: File a copy with subject's records if related to a specific patient)