Advantage Clinical

Protocol Deviation Report

Protocol:	EARLY- AC-NA-001
Investigator:	Dr. Fiona Duncan
Subject Number / Identifier:	FG-011
Sponsor:	Advantage Clinial
Date of Report	01September2016

Describe the protocol Deviation:

Subject did not have Day 30 labs drawn per protocol

Describe the reason for the protocol deviation:

The subject did not report to the lab to have Day 30 labs drawn as they were not reminded by the study coordinator

Was this protocol deviation pre-approved from the sponsor?

□ Yes X No

If No; when was this protocol deviation reported to the sponsor: N/A

When was this protocol deviation reported to the IRB: 30October2016

Was this protocol deviation incurred in the immediate interest of protecting patient / subject safety?

□ Yes X No

If No; describe the preventative action that will be put in place to prevent this deviation from occurring in the future:

The study coordinator reviewed the protocol requirements for Day 30 lab draws. Prompts were added to the study coordinator's visit worksheet to remind subjects to attend the lab for blood draws within the protocol visit windows of +/- 5 days.

Form Completed by (print): Study Coordinator 1

Signature: Signature

Date: 30October2016

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