Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Close-Out

Site #: CA204
Protocol Number: FAL25
Investigator: Cunningham, Marcus

Sponsors:

Start Date : 4/10/2006
Completed Date: 4/10/2006

Location: Los Angeles Research Institute: Los Angeles, CA

Investigation Product/Test Article: Laftr
Visit Mechanism: On-site

Initially Submitted on 11/24/2009 **Final Submission By Test6 CA on 11/24/2009 1:51 PM** **Approval By student13 student13 on 11/24/2009 1:52 PM**

Attendees

Last Name	First Name	Role

Checklist

Item	Question	Response	Issue	Comments
1	Total number of screened subjects	10		
2	Total number of screen failures	5		
3	Total number of enrolled/randomized subjects	5		
4	Total number of active subjects (including those in follow-up)	0		
5	Total number of discontinued subjects	0		
6	Total number of completed subjects	5		
7	Have accurate, complete and current subject logs been maintained?	Yes		All subje logs re com lete nd accurat
8	Were all monitored subjects eligible for the study?	Yes		
9	Is written informed consent documented, in accordance with applicable regulations and guidelines, for all subjects consented since the last monitoring visit?	es		
10	Were source documents available that accurately and appropriately document study conduct?	Yes		Study Coordinator made all sorce documentation available to monitor for final review.
11	Was CRF/eCRF data reviewed for completeness, accuracy, legibility and consistency with the source documents?	Yes		
12	Were all dose and/or treatment modifications documented in the CRF/eCRF?	Yes		
13	Were adverse events, concomitant medications and intercurrent illnesses documented in the CRF/eCRF?	NA		There were no AEs for SAE identified.
14	Were missed visits, examinations or other study related procedures clearly documented, including the reason?	Yes		

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15	For subjects who have not completed the study, has the reason for non-completion been documented?	NA		All subjects completed the study
16	Have only the Investigator or authorized site staff made corrections, additions, or deletions to the CRF/eCRF?	Yes		
17	Have all CRFs/eCRFs been completed, signed (if applicable) by the Investigator, and transmitted/retrieved?	Yes		There is one CRF that that the investigator did not sign. PI reviewed and signed the CRF during the close-out visit.
18	Have all data queries been resolved?	Yes		
19	Is there any apparent evidence that the EDC security measures have been compromised?	No		
20	Has the site been compliant with the continuing review requirements of their IRB/IEC/REB?	Yes		All the appropriate documentation from the IR[illegible] is recorded in the Regulatory Binder
21	Has the Investigator provided reports, notifications, applications, and/or submissions to the IRB/IEC/REB or Health Authorities that are accurate, complete, timely, legible, dated and identify the study?	Yes		
22	Has the protocol/amendment or investigational plan been followed (e.g., subject visits performed per schedule of assessments, etc.)?	Yes		
23	Were protocol deviations reviewed and discussed with the Investigator?	NA		There were no protocol deviations during the study.
24	Have appropriate procedures for maintaining the study blind been followed?	Yes		
25	For monitored subjects, were all Serious Adverse Events (SAEs), Adverse Device Effects (ADEs), malfunctions or other immediately reportable safety events documented and reported appropriately?	NA		There were no SAEs/AEs or other reportable safety issues at this site.
26	Was final test article accountability performed?	Yes		
27	Has the receipt, use and return of test article been controlled and documented?	Yes		Monitor collected a copy of the documentation.
28	Has administration of test article been per protocol?	Yes		
29	Has disposition of unused test article at the study	Yes		

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	site been documented and in compliance with both the sponsor's authorized procedures and applicable regulatory requirement(s)?			
30	Was all unused test article returned and/or destroyed?	Yes		All unused test article was destroyed. Monitor collected documentation.
31	Were copies of the completed test article accountability logs retrieved?	Yes		
32	Were the emergency codebreaks assessed to confirm they were appropriately stored and utilized?	Yes		There were no deficiencies identified
33	Were all emergency codebreaks returned and/or destroyed?	NA		
34	Were laboratory/biological samples stored and shipped in compliance with the protocol/amendment, investigational plan, study requirements, applicable regulations and guidelines and in accordance with the biological risk associated with the handling and/or delayed shipment of those samples?	Yes		
35	Were arrangements made for continued storage, shipment and/or destruction of remaining laboratory samples and supplies?	No		No arrangements are necessary for continued storage, shipment or destruction of samples and supplies. Site has documentation of all use, dissemination and destruction of all study supplies.
36	Was a final inventory of the site's study file performed?	Yes		Everything is in order
37	Are there any outstanding essential documents?	No		
38	Was the Site Staff Delegation and Signature Log (OP-F1-013) or equivalent document reviewed?	Yes		Monitor retrieved a copy of the Signature Log
39	Have study responsibilities been appropriately delegated to authorized and qualified site staff?	Yes		
40	If study responsibilities have been delegated, has appropriate training been provided and documented?	Yes		
41	Have the Investigator and site staff performed their specified study responsibilities in accordance with the protocol/amendment(s) and any other written agreement between the sponsor and Investigator/institution?	Yes		

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42	If there were any changes to the Investigator, site staff and/or facilities since the last monitoring visit, were they properly documented?	NA		There were no changes since the last monitoring visit
43	Were all remaining study supplies (other than test article) and special equipment returned and/or destroyed?	Yes		Monitor retrieved documentation regarding remaining study supplies.
44	Were the Investigator's on-going reporting obligations regarding SAEs, ADEs, malfunctions or other immediately reportable safety events explained?	Yes		
45	Was the Investigator reminded of their obligation to notify the IRB/IEC/REB of study completion or closure, and to provide DCRI with a copy of the notification?	Yes		Investigator was reminded, and will provide documentation upon receipt from the IRB.
46	Was the Investigator reminded of their obligation to update Financial Disclosure information for one year following study completion and/or where applicable, that Conflict of Interest (COI) information must be updated per the relevant Government Office/Institute regulation?	Yes		
47	Were the study record retention requirements discussed?	Yes		Site was reminded the per GCP guideline, they are required to retain study records for a period of 2 years. The site was informed that these records include the reg binder, manual of procedures, study medication shipment invoices, drug accountability logs, etc. If the PI relocates, custody of the records may be transferred to another person or group, but must be noted in writing to the sponsor.
48	Were arrangements for final study payment discussed?	Yes		
49	Was the study publication policy discussed?	Yes		
50	Was the possibility of audits/inspections and related notification procedures discussed?	Yes		SC was instructed that the PI should notify the sponsor of an audit, and that study related documents must be made available in the even of an audit.
51	Were visit findings, deficiencies, discrepancies, deviations, action items and/or corrective actions, including assigned responsibilities and timelines for completion discussed with the Investigator and applicable site staff?	Yes		
52	If there was evidence of non-compliance with the protocol/amendment(s), investigational plan, study requirements, and/or applicable regulations and guidelines, was it documented and reported to the Lead CRA or designee in an expeditious manner?	No		

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53	If the non-compliance was serious and/or persistent, was it documented and reported immediately to the Lead CRA and Project Leader for appropriate escalation to Clinical Operations' Leadership, DCRI QA/RC and sponsor?	Yes		
54	Was the Site Visit Log (OP-F2-013) or equivalent document signed by the monitor and co-signed by a member of the site staff?	Yes		
55	Was a copy of the final Site Visit Log (OP-F2-013) or equivalent document retrieved?	Yes		
56	Was a copy of the final Site Staff Delegation and Signature Log (OP-F1-013) or equivalent document retrieved?	Yes		

Follow Up

Activity Type	Visit Date	Description	Status	Assigned To	Resolution	Completed Date
Close-Out	4/10/2006	PI to contact the CRA via phone to disucss the Investigator's obligations no later than Maya 1.	Done	Test6 CA	PI contacted the monitor on May 1 and confirmed receipt of IRB notification of study close out. PI faxed a copy of IRB letter to CRA.	5/1/2006
CRF Questions/Issues	12/1/2005	Some missing data from CRF. Study Coordinator to complete	Done	Test6 CA	Monitor will need to verify these CRFs at next PMV	1/25/2006
Source Doc Verification	12/1/2005	SC to sort forms by subject and store them in one location.	Done	Test6 CA	Monitor to review at PMV 2	3/15/2006

Protocol Deviation

None

ICF

Subject ID	ICF Type	ICF Signature	Version Date	Source Doc Verified Date	Comments

CRF

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CRF

Subject ID	Visit Type	Visit	Source Doc Verified Date	Retrieval Date	Page Number	Comments
ca204bth	Enrollment	SS-1-2	2/10/2006	4/10/2006	1-10	
ca204dmt	Enrollment	SI-1-01	11/3/2005	4/10/2006	1-6	
ca204jwk	Enrollment	AB-3-4	3/2/2005	4/10/2006	2-7	

Attachments

Attachment Name	Size (Bytes)	Type	Modified	Comments
Confirmation Letter 11-24-2009 1.46.35 PM	32,311	doc	11/24/2009	
Investigator Study File Inventory	21,194	doc	11/24/2009	
Study Drug Destruction Documentation	5,520	doc	11/24/2009	

Additional Observations / Comments

Monitor's overall general assessment of the Site is that they are a model site for clinical studies.