Clinical Trip Report

Duke Clinical Research Institute

FALCON : Periodic Monitoring

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

Sponsors:

Start Date : 12/1/2005
Completed Date: 12/1/2005

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 student13 student13 on 11/24/2009 12:45 PM Approval By student14 student14 on 11/24/2009 12:49 PM

Attendees

Last Name	First Name	Role
Atkinson	William	Study Coordinator
Cunningham	Marcus	Principal Investigator

Checklist

Item	Question	Response	Issue	Comments
1	Total number of screened subjects	2		
2	Total number of screen failures	0		
3	Total number of enrolled/randomized subjects	2		
4	Total number of active subjects (including those in follow-up)	2		
5	Total number of discontinued subjects	0		
6	Total number of completed subjects	0		
7	Are accurate, complete and current subject logs being maintained?	Yes		
8	Are the screening and enrollment rates in alignment with study expectations?	Yes		There are no deficiencies identified
9	Were all monitored subjects eligible for the study?	Yes		
10	Is written informed consent documented, in accordance with applicable regulations and guidelines, for all subjects consented since the last monitoring visit?	Yes		ICF Sectiton has more detailed information.
11	Are source documents available that accurately and appropriately document study conduct?	Yes		The monitor completed 100% SDV of visit.
12	Was CRF/eCRF data reviewed for completeness, accuracy, legibility and consistency with the source documents?	Yes	Y	CRFs were reviewed for completeness. Monitor reminded site personnel to enter all data wthin 5 days of the study visit and requested that the missing data be entered as soon as possbile. Monitor will need to verify these CRFs at next PMV.
13	Are all dose and/or treatment modifications documented in the CRF/eCRF?	Yes		
14	Are adverse events, concomitant medications and intercurrent illnesses documented in the	Yes		There are no adverse events, concomitant meds or intercurrent illnesses to report.

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	CRF/eCRF?			
15	Are missed visits, examinations or other study related procedures clearly documented, including the reason?	NA		There have been no missed visits.
16	For subjects who will not complete the study, has the reason for non-completion been documented?	NA		
17	Have only the Investigator or authorized staff made corrections, additions, or deletions to the CRF/eCRF?	Yes		
18	Are data queries being resolved in a timely manner?	No		The monitor reviewed the one queyi with the SC on day 1 & 2 of the visit. SC stated that she would answer them during the visit, which she did. Monitor reminded SC that all queries should be completed as soon as possible.
19	Is there any apparent evidence that the EDC security measures have been compromised?	No		
20	Have protocol/amendments been approved by the IRB/IEC/REB?	NA		
21	Has the site been compliant with the continuing review requirements of their IRB/IEC/REB?	Yes		
22	Is the Investigator providing 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		
23	Is the protocol/amendment or investigational plan being followed (e.g., subject visits performed per schedule of assessments, etc.)?	Yes		
24	Were protocol deviations reviewed and discussed with the Investigator?	NA		There are no Protocol Deviations to report
25	Are appropriate procedures being followed to maintain the study blind?	Yes		
26	For monitored subjects, are all Serious Adverse Events (SAEs), Adverse Device Effects (ADEs), malfunctions or other immediately reportable safety events documented and reported appropriately?	Yes		No SAEs for either subject prior to monitoring visit are reported. Monitor did not identify any potential for SEAs. One investigator alert was reported to the IRB.
27	Are test article storage conditions acceptable?	Yes		
28	Was test article accountability performed?	Yes		The Monitor reviewed drug accountabiliy: Proper completion of the accountability log was reviewed with the

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				Study Coordinator. Study drug is maintained in a locked cabinet in the research office. The monitor retrieved a copy of the room temperature log.
29	Is the receipt, use and return of test article controlled and documented?	Yes		
30	Is there a sufficient supply of test article within expiry date timelines?	Yes		
31	Has administration of test article been per protocol?	Yes		
32	Is there evidence that necessary instruction regarding the proper use, handling, storage and return of test article is being provided to subjects?	Yes		Site provides subject with documentation regarding test article storage and return upon initial enrollment, and reviews information at each visit.
33	Has disposition of unused test article at the study site been documented and in compliance with both the sponsor's authorized procedures and applicable regulatory requirement(s)?	NA		There has been no unused test articles to date.
34	Were the emergency codebreaks assessed to confirm they are being appropriately stored and utilized?	NA		
35	Are laboratory/biological samples being 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?			
36	Are accurate, complete and current essential documents being maintained?	Yes		Site personnel is completing essential documentation in a timely manner. The monitor reminded SC to keep up with the documentation when additional subjects are enrollled.
37	Was the Site Staff Delegation and Signature Log (OP-F1-013) or equivalent document reviewed?	Yes		No deficiencies identified on the Site Staff Delegation and Signature Log. Monitor collected a copy.
38	Have study responsibilities been appropriately delegated to authorized and qualified site staff?	Yes		
39	If study responsibilities have been delegated, has appropriate training been provided and documented?	Yes		Monitor collected all training documentation for site personnel
40	Are the Investigator and site staff performing their specified study responsibilities in accordance with the protocol/amendment(s) and any other written agreement between the sponsor and	Yes		

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	Investigator/institution?			
41	Are the Investigator and site staff still adequately informed about the study and still capable of safely and properly conducting the study?	Yes		
42	If there were any changes to the Investigator, site staff and/or facilities since the last monitoring visit, were they properly documented?	No		There are no changes in Site staff since last visit.
43	Is there evidence that supports Investigator involvement and adequate study oversight?	Yes		Investigator has signed all study documentation and participated in the monitoring visit. PI is aware of all aspects of study, personnel, and subject issues.
44	Are the facilities and study supply inventories (other than test article) still adequate to properly conduct the study?	Yes		
45	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		There were no violations to inclusion/exclusion criteria or any protocol deviations. The site provided access to entire medical record for both subjects. Monitor discussed sorce documentation with SC, suggesting to sort forms by subject and storing them in one location. SC expressed understanding. The monitor will review process at PMV2.
46	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?	NA		There is no evidence of Non-compliance
47	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?	NA		
48	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		Monitor collected a copy site visit logs

Follow Up

Activity Type	Visit Date	Description	Status	Assigned To	Resolution	Completed Date
CRF Questions/Issues	12/1/2005	Some missing data from 2 CRFs. Study Coordinator to complete.	Open	Test6 CA	Monitor will need to verify these CRFs at next PMV	
Regulatory Documentation	10/20/2005	Regulatory Binder was not completely reviewed during SIV. CRA will complete review at first PMV.	Done	Test6 CA	Reg Binder was reviewed and is in proper order.	12/1/2005

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Source Doc Verification	12/1/2005	SC to sort forms by subject and store them in one location.	Open	Test6 CA	Monitor to review at PMV 2	
Study Med Prep/Admin	10/20/2005	The site would like to have an additional shipment of IP because they expect to be a high enroller.	Done	Test6 CA	Site will receive 1 extra shipment of study drug and a re-supply rate will be determined based on enrollment. Monitor confirmed that study drug was received and properly documented.	11/1/2005

Protocol Deviation

None

ICF

Subject ID	ICF Type	ICF Signature	Version Date	Source Doc Verified D...	Comments
ca204bth	ICF	1/15/2006	5/1/2005	12/1/...05	
ca204jwk	ICF	12/1/2005	5/1/2005	12/1/...5	

CRF

Subject ID	Visit Type	Visit	Source Doc Verified	Retrieval Date	Page Number	Comments
ca204bth	Screening		12/1/2005	12/1/2005	1-10	
ca204jwk	Screening		12/1/200...	12/1/2005	1-10	

Attachments

Attachment Name	Size (Bytes)	Type	Modified	Comments
Confirmation Letter 11-22-2009 8.17.27 AM	33,792	doc	11/22/2009	
Investigator Study File Inventory	21,194	doc	11/24/2009	

Additional Observations / Comments