Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Selection/Initiation

Site #: NY425
Protocol Number: FAL25
Investigator: Waring, Patrick

Sponsors:

Start Date : 11/1/2008
Completed Date: 11/1/2008

Location: Saint Johns Memorial Hospital: New York, NY

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

Initially Submitted on 11/22/2009 **Final Submission By Test6 CA on 11/22/2009 7:06 AM** **Approval By student13 student13 on 11/22/2009 7:08 AM**

Attendees

Last Name	First Name	Role
Emmerson	David	
Parrish	Robert	
Waring	Patrick	Principal Investigator

Checklist

Item	Question	Response	Issue	Comments
1	Were the roles and responsibilities of the Investigator and site staff discussed?	Yes		Roles & responsibilities of PI and SC were discussed at length. PI, SC, and Sub-Investigator will screen potential subjects and PI and SC will consent subjects. SC is designated as the Pharmacy contact. SC will receive, store, dispense and perform drug accountability. Only study coordinator has completed training by waching study instruction video. CRA reviewed certificate during visit.
2	Does the Investigator give assurance that he/she has the availability to conduct and supervise the study?	Yes		
3	Have study responsibilities been delegated to qualified staff and documented appropriately via the Site Staff Delegation and Signature Log (OP-F1-013) or equivalent document?	Yes		
4	Were training and documentation requirements related to the delegation of study responsibilities discussed?	Yes		CRA explained that all study staff must watch study video and attend Investigators meeting which will serve as Protocol training.
5	Was the Investigator informed that individual site staff (e.g., Investigator, Sub-Investigator, Study Coordinator) must complete study training prior to conducting study related procedures?	Yes		
6	Does the site have an adequate inventory of study supplies/materials (other than test article) to properly conduct the study?	Yes		The site has received its first shipment of study supplies. There are no outstanding issues regarding study supplies.
7	Does the site have the required equipment to perform the study?	Yes		
8	Can the Investigator provide adequate clinical space to accommodate this study?	Yes		CRA toured the facility and pharmacy at the site. Study materials will be maintained and locked in a separate locked room near Study Coordinator's office. The site has adequate space to accommodate the study.

Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Selection/Initiation

Site #: NY425
Protocol Number: FAL25
Investigator: Waring, Patrick

Sponsors:

Start Date : 11/1/2008
Completed Date: 11/1/2008

Checklist

Item	Question	Response	Issue	Comments
9	Does the Investigator anticipate using satellite sites or other off-site facilities?	No		
10	Were the Investigator's obligations, per applicable regulations and guidelines, as well as the repercussions for non-compliance discussed?	Yes		Principal Investigator is fully aware of his obligations pertaining to regulations, guidelines and non-compliance issues.
11	Were the current protocol and study procedures, including study objectives, design, inclusion/exclusion criteria and schedule of assessments discussed?	Yes		The protocol was discussed with the PI and the SC. The review of protocol procedures and study documents were reviewed with study staff as well. Monitor utilized Site Initiation slides provided by study sponsor. The following was discusses: Timelines, Study overview, inclusion/exclusion criteria, product description, drug accountability, randomization procedures, schedule of events, primary and secondary objectives, responsibilities of staff obtaining consent, and training of additional staff.
12	For blinded studies, were blinding procedures discussed?	NA		
13	Were procedures for handling and documenting deviations from the protocol/amendment(s), investigational plan, study requirements or applicable regulations and guidelines discussed?	Yes		Study Coordinator was instructed on docu[illegible]ting protocol deviations.
14	Were the definitions, reporting and documentation of Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Device Effects (ADEs) and/or any other immediately reportable safety events discussed?	Yes		CRA pointed [illegible] AE se[illegible]ion [illegible]f Study Ins[illegible]uction [illegible]aterials. Reporting and documentation of AE's versus SAE's w[illegible] rev[illegible]wed wi[illegible] PI [illegible]d SC sepr[illegible]ly.
15	Was the requirement for obtaining and maintaining IRB/IEC/REB approval to conduct the study discussed?	Ye[illegible]		
16	Were the Investigator's IRB/IEC/REB communication and reporting obligations discussed?	Yes		The site is using their local IRB - The Protocol and ICF are awaiting approval by the IRB. Site personnel stated that SAEs must be reported to IRB.
17	Were the possibility and notification procedures for audits and inspections by the sponsor, DCRI and/or regulatory authorities discussed?	Yes		
18	Was the site's access to the study subject population and method for subject identification discussed?	Yes		The patients will come from the PI and sub-investigator practices. The site will not advertise for the subjects.
19	Was subject recruitment, including target enrollment rate and timelines discussed?	Yes		They have had success in recruitment of previous similar studies. The sites feels they will be able to enroll 5-10 subjects per month, and anticipate recruitment as soon as they receive study drug.
20	Is the Investigator currently conducting another research study that would compete for the same patient population?	No		

Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Selection/Initiation

Site #: NY425
Protocol Number: FAL25
Investigator: Waring, Patrick

Sponsors:

Start Date : 11/1/2008
Completed Date: 11/1/2008

Checklist

Item	Question	Response	Issue	Comments
21	Did the Investigator express an ability to meet the enrollment requirements and timelines?	Yes		Principal Investigator feels that he can enroll 5-10 subjects per month.
22	Were registration, enrollment and/or randomization procedures, including the assignment of screening and subject numbers, discussed?	Yes		
23	Were procedures for obtaining and documenting written informed consent discussed?	Yes		CRA informed the site personnel that written consent must be obtained for all subjects before study related procedures are performed or given. The ICF that must be used must be the one approved by the IRB, and placed in the subjects medical record.
24	Will the site be utilizing electronic health records for this study?	No		
25	Were source document expectations and the availability of source documents which accurately and appropriately document the conduct of the study discussed?	Yes		The site has electronic and paper medical records. The monitor will be provided access to the electronic medical record as well as the original medical record. The worksheets provided by the study were reviewed with Study Coordinators. It will take approximately on week to obtain medical records.
26	If source data will be collected and stored electronically, were the basic aspects of the site's computer system, such as security and data recovery capabilities assessed?d?	NA		
27	Was the requirement for direct access to source documents by monitors, auditors and regulatory inspectors discussed?	Yes		
28	Were content, completion and submission guidelines for the CRF/eCRF and other applicable data forms discussed?	Yes		The SC was informed that all CRF pages for subjects that will be monitored must be completed prior to periodic monitoring visits. CRA informed PI that he must sign each AE and SAE page - which will be included in monitors follow-up letter.
29	Were data correction procedures discussed?	Yes		
30	Does the site have prior experience with Electronic Data Capture (EDC)?	NA		
31	Was training of the Investigator and relevant site staff on the applicable EDC system and security measures documented?	NA		
32	Were monitoring procedures and expectations (e.g., space, internet access, visit frequency, and staff availability) discussed?	Yes		The site personnel were informed the periodic monitoring visits will occurred every 4-6 weeks, depending on enrollment. The site was also informed that the PI should be available at each monitoring visit to review findings and to discuss what occurred during the visit. The monitor notified the SC they would been to be available thoughout the monitoring visits to resolve queries or any other issues. There is adequate space for the monitor to use during visits. Wireless connection is available.
33	Was the investigational status of the test article / intervention, including information from the	Yes		CRA reviewed investigator's brochure and instructions with site personnel

Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Selection/Initiation

Site #: NY425
Protocol Number: FAL25
Investigator: Waring, Patrick
Sponsors:
Start Date : 11/1/2008
Completed Date: 11/1/2008

Checklist

Item	Question	Response	Issue	Comments
	investigator's brochure, package insert or instructions for use discussed?			
34	Were the test article storage requirements discussed?	Yes		IP will be stored in locked filing cabinet in Study Coordinator's office. The office is also locked at close of business.
35	Are test article dispensing and storage areas appropriate (e.g., location, temperature, environmental factors, accessibility, security and space) for the study?	Yes		CRA infofrmed study coordinator that drug accountability logs must be kept in separate location. Study drug will be stored at room temperature and locked at al times.
36	Were procedures and documentation requirements (e.g., use of a drug accountability log) for test article receipt, use and return discussed?	Yes		
37	Were procedures and documentation requirements for disposition of unused test article at the study site discussed?	Yes		CRA reminded study coordinator that instr...ons for unused study drug were in regulatory instructions.
38	Was test article accountability (e.g., verification of receipt, storage conditions and documentation) performed?	Yes		No deficiencies w... ...enti...ed
39	Were laboratory procedures regarding collection, handling, shipment of samples and reporting of laboratory results discussed?	Yes		...he loca... l... wa... toured and i... ...equate to participate in the study. The Lab Director was informed of the p...cedu...es ...ega...ng the study and given study materials with instructions and contact information to study ...ers...nn... at ...he s...e.
40	Were content and maintenance requirements for the site's study file discussed?	Y...s		
41	Is the storage area for study records/materials adequate and secure?	Yes		Study records and mateials will be maintained and kept in the locked file cabinet in the SC office, which is locked at all times and office is locked at close of business.
42	Were record retention obligations discussed?	Yes		
43	Were visit findings, deficiencies, discrepancies and/or action items, including assigned responsibilities and timelines for completion discussed with the Investigator and applicable site staff?	Yes		There were no deficiencies found. All visit finding were reviewed with PI and SC.
44	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		

Protocol Deviation

Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Selection/Initiation

Site #:	NY425	**Sponsors:**	**Start Date :** 11/1/2008
Protocol Number:	FAL25		**Completed Date:** 11/1/2008
Investigator:	Waring, Patrick		

Protocol Deviation

None

Attachments

Attachment Name	Size (Bytes)	Type	Modified	Comments
Confirmation Letter 11-22-2009 7.04.04 AM	86,849	doc	11/22/2009	

Additional Observations / Comments