

### Report of Investigator Monitoring Visit Observations

Item Observed	Deficiencies Noted	Required Investigator Actions
Case report forms	None	None
Subject #1		
Subject #2		
Source documentation	Subject #1 missing copy of the radiography report demonstrating subject eligibility	Obtain a copy of the radiography report and attach it to the case report form. Also, please fax a copy to the sponsor to confirm subject eligibility.
Regulatory document file	None	None
Drug supplies and documentation	The date the drug was actually dispensed to each subject is not recorded on the drug disposition record.	Enter the date the drug was dispensed for both Subject #1 and Subject #2 at the first visit. Be sure to record the date each subject returned the empty or partially-used container, and when the next container was dispensed.
Continued acceptability of facilities	None	None
Protocol adherence	None	None
Adverse event reporting	None	None
Other:		
Signature of sponsor representative:		Date: