

<b>Monitor:</b>		<b>Investigator:</b>	
<b>Product Name:</b>		<b>Site Number:</b>	
<b>Protocol Number:</b>		<b>Visit Date(s):</b>	
<b>Sponsor:</b>			

Site Personnel Contacted	Title/Responsibility

Enrollment Status	
Number of subjects screened:	
Number of subjects randomized:	
Number of subjects active:	
Number of subjects discontinued:	
Number of subjects completed:	

Summary Report/Accomplishments	Y	N	N/A	Needed Actions/Comments
<b>Review New Data</b>				
Pre-Clinical or Clinical Data				
Adverse Events				
<b>Protocol Adherence</b>				
Inclusion/Exclusion Criteria				
Visit Scheduling				
Adverse Events				
Study Drug dosing				
Concomitant Medications				
Informed Consents				
<b>Case Report Forms</b>				
CRF completion				
CRF vs Source Documents				
CRF availability				
<b>Personnel Responsibilities</b>				
Principal Investigator				
Sub-Investigator				
Coordinator				
Pharmacist (if applicable)				
<b>Clinical Supplies</b>				
Quantity of Study Drug				
Storage				
Dispensing				
Packaging/Labeling/Coding				
Randomization				
Drug Disclosure Envelopes				
Expiration Dates				
Accountability				
Any new SAEs to report?				
Sign Monitor log				
Follow-up issues:				

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**Other Issues:**

**Action Items:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed):

Signature of Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed):