Appendix F

Initiation Visit Report Form

DCP PROJECT
CLINICAL INITIATION VISIT REPORT

I. SITE INFORMATION

Instructions: Please provide the requested information for each of the items listed below. Provide comments whenever necessary or helpful.

Name of Clinical Site:

Protocol Name:

NCI Protocol Number:

Date(s) of Visit:

Conducted by:

DCP Representative(s) Present:

Clinical Site Personnel Present at the Visit:

NAME	TITLE	ORGANIZATION	PRESENT AT MEETING
	Principal Investigator		
	Site Coordinator		
	Pharmacist		
	Other		

Additional Comments:

CLINICAL INITIATION VISIT CHECKLIST

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Background and Purpose of Study				
Study Objectives and Design				
Study Procedures				
Clinical Evaluations				

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Laboratory Evaluations				
Schedule of Evaluations				
Implications of Missed Evaluations				
Protocol Deviations/Violations				
Toxicity Management				
Protocol Initiation and Enrollment				
Informed Consent Process				
Screening/Pre-Entry Period				
Exemptions				
Registration/Randomization				
Recruitment/Retention				
Anticipated Start of Enrollment				
Staff Roles and Responsibilities				
Source Documentation				
Study Drug Prescriptions				
Agent Dispensing Procedures				
Informed Consent				
CRF Completion				
Specimen Storage				
Registration/Randomization				
Regulatory Update				
Blinding Procedures				
Quarterly Report Preparation				
DCP OC-RDC Data Entry and Management (Consortia trials only)				
Agent Information and SAE Reporting				
Procedures and Forms				
Receipt, Review, and Filing of Investigator's Brochure				
Receipt, Review, and Filing of Package Insert				
Receipt, Review, and Filing of any Safety Reports				
Off-Treatment and Study Endpoints				
Evaluations for Treatment/Study Discontinuation				
Study Endpoints				
Data Collection				
Procedures				
CRF Completion Guidelines				
Common Errors Noted in Data Collection				
Corrections				
Form Update Procedures				

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Plans for Missed Visits				
Disposition of Forms				
NCI CTC Version				
Source Documentation				
What Is Acceptable				
Shadow Files				
Electronic Sources				
Case Report Forms as Source Documents				
Document Retention				
Database Management				
DCP OC-RDC (Consortia trials only)				
Other Data Management System(s) to be Used				
Quality Assurance Procedures				
Data Queries and/or Discrepancy Management				
List of Staff who will perform data entry and QA (MAH trials only)				
List of Staff who have been approved for data entry, QA, and monitoring in DCP OC-RDC (Consortia trials only)				
Policy and Procedure Manuals				
DCP Study Site Monitoring Manual (MAH trials only)				
Clinical Trials Resource (CTR) Website				
DCP SOPs (Consortia trials only)				
MIMP (Consortia trials only)				
Master DMP (Consortia trials only)				
Other (list under comments)				
Regulatory Documentation Review				
Site Signature/Delegation of Responsibilities form				
IRB/IEC Documentation				
IRB/IEC - Approval Letter				
IRB/IEC-Approved Informed Consent Form				
IRB/IEC-Approved Advertisements				
IRB/IEC-Approved Participant Information Sheets				
IRB/IEC-Annual Renewal				
Amendments				

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Assurance Number				
Form 1572				
Investigator CVs, signed and dated				
Current medical licenses				
Documentation of Human Participants Protection Training				
Financial Disclosure Form				
Laboratory Certification				
Laboratory Normal Ranges				
DHHS and FDA Regulations/GCP Guidelines				
Documentation of IRB/IEC Submission of Investigator's Brochures				
Documentation of IRB/IEC Submission of Package Inserts				
Documentation of IRB/IEC Submission of Safety Reports				
Submission of Data Safety and Monitoring Plans				
DCP Reporting Requirements				
Amendments				
Adverse Events Reporting Using NCI CTCAE v.3.0				
SAE Reporting				
Case Report Forms				
Progress Reports				
Final Reports				
Protocol Deviations Form and Reporting				
Record Keeping Requirements				
Participant Screening Log				
Participant Identification Logbook				
Site Signature/Delegation of Responsibilities form				
Site Visit Log				
Original Signed Informed Consent Forms				
Source Documents/Confidentiality				
Study-Related Correspondence (including study related e-mails and records of phone conversations)				
Laboratory Procedures				
Specimen Storage and Disposition				

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Shipping Procedures				
Specimen Shipping Log				
Specimen Collection, Processing and Storage				
Pharmacy				
Dissemination of Information to the Pharmacist				
Drug Storage & Accountability				
Pharmacy Guidelines				
Current Protocol Version				
Documentation of Informed Consents				
Investigator's Brochures– Pharmacy Receipt				
Safety Reports– Pharmacy Receipt				
Package Inserts– Pharmacy Receipt				
Communication				
Quality Assurance Plan				
Communication				
With DCP Staff				
With Participating Sites				
With Monitoring Contractor				
With Regulatory Contractor				
Site Monitoring and Auditing				
Purpose				
Frequency				
Reports and Distribution				
Site Monitoring at Participating Sites (by Lead Site)				
Conduct of Pharmacy Audit				
Conduct of Quality Assurance Audit (Consortia trials only)				

ACTION ITEMS IDENTIFIED:

ADDITIONAL COMMENTS/GENERAL IMPRESSIONS OF SITE PERFORMANCE:

Prepared by: Date:

(Signature)