

## Conduits The Institutes for Translational Sciences

## **SITE INITIATION Checklist**

The purpose of this document is to provide the Lead Site with a system for performing study initiation visits.

## **Instructions:**

The following items should be addressed when initiating a participating site into a multi-center trial.

- Fill in the participating site information, and the names of the attendees. Attach a roster if necessary.
- Some items may need to be discussed in detail, while others only need verification.
- Mark the appropriated box, "YES", "NO" or "N/A", after each item.
- Add any necessary comments or action items.
- Many items can be verified before the actual site initiation. These items are marked with asterisks (\*\*).

<ul> <li>Sign and date the checklist. File with oth</li> </ul>	er participat	ting site do	ocument	S.		
Site Information						
Name of Participating Site:				Initiation Visit Method:		
DF/HCC Protocol Number:				☐ On-Site		
Date:	☐ Teleconference					
Conducted by:	Other (specify)					
Lead Site Personnel in attendance						
NAME	TITLE					
Participating Site Personnel in attendance -	See attache	ed attend	ance sh	eet		
	_					
Items Discussed/Verified	Yes	No	N/A	Actions / Comments		
Staffing Allocations						
**Clinical staff						
**Study staff						
**Pharmacy staff						
**Research Laboratory staff						
List equipment needed for the study. Check the availability of each item.  **						

Background and Purpose of Study Study Objectives and design Study Procedures Drug administration procedures Clinical evaluations for each visit Specimens to be obtained and frequency Special specimens-timing (PK, or other) Specimen logs (PK, or other) Procedure for recording and reporting Protocol Deviations Informed Consent and Enrollment Informed Consent Procedures Eligibility criteria Central registration and randomization Adverse Event Reporting AE/SAE Reporting Procedures Notification process Toxicity parameters Treatment Discontinuation Required Evaluations Early stopping rules, DLT levels Data Collection and Submission Format and timelines Case report form completion guidelines Queries and corrections eDC training Source Documentation Case Report Forms as Source Document Retention Communications Communications Communications Communications Communications Communications	Items Discussed / Verified	Yes	No	N/A	Actions / Comments
Study Procedures Drug administration procedures Clinical evaluations for each visit Specimens to be obtained and frequency Special specimens-timing (PK, or other) Specimen logs (PK, or other) Procedure for recording and reporting Protocol Deviations Informed Consent and Enrollment Informed Consent Procedures Eligibility criteria Central registration and randomization Adverse Event Reporting AE/SAE Reporting Procedures Notification process Toxicity parameters Treatment Discontinuation Required Evaluations Early stopping rules, DLT levels Data Collection and Submission Format and timelines Case report form completion guidelines Queries and corrections eDC training Source Documentation Case Report Forms as Source Document Retention Communications	Background and Purpose of Study				
Drug administration procedures Clinical evaluations for each visit Specimens to be obtained and frequency Special specimens-timing (PK, or other) Specimen logs (PK, or other) Procedure for recording and reporting Protocol Deviations Informed Consent and Enrollment Informed Consent Procedures Eligibility criteria Central registration and randomization  Adverse Event Reporting AE/SAE Reporting Procedures Notification process Toxicity parameters Treatment Discontinuation Required Evaluations Early stopping rules, DLT levels Data Collection and Submission Format and timelines Case report form completion guidelines Queries and corrections eDC training Source Documentation Case Report Forms as Source Document Retention Communications	Study objectives and design				
Clinical evaluations for each visit  Specimens to be obtained and frequency  Special specimens-timing (PK, or other)  Specimen logs (PK, or other)  Procedure for recording and reporting Protocol Deviations  Informed Consent and Enrollment  Informed Consent Procedures  Eligibility criteria  Central registration and randomization  Adverse Event Reporting  AE/SAE Reporting Procedures  Notification process  Toxicity parameters  Treatment Discontinuation  Required Evaluations Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines  Case report form completion guidelines  Queries and corrections eDC training  Source Documentation  Case Report Forms as Source Document Retention  Communications	Study Procedures				
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Special specimens-timing (PK, or other)  Specimen logs (PK, or other)  Procedure for recording and reporting Protocol Deviations  Informed Consent and Enrollment  Informed Consent Procedures  Eligibility criteria  Central registration and randomization  Adverse Event Reporting  AE/SAE Reporting Procedures  Notification process  Toxicity parameters  Treatment Discontinuation  Required Evaluations Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines  Case report form completion guidelines  Queries and corrections eDC training  Source Documentation  Case Report Forms as Source Document Retention  Communications	Clinical evaluations for each visit				
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Informed Consent Procedures  Eligibility criteria  (Eligibility waivers not permitted.)  Central registration and randomization  Adverse Event Reporting  AE/SAE Reporting Procedures  (All IRB reporting requirements must be met.)  Notification process  Toxicity parameters  Treatment Discontinuation  Required Evaluations  Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines  Case report form completion guidelines  Queries and corrections  eDC training  Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications					
Eligibility criteria (Eligibility waivers not permitted.)  Central registration and randomization  Adverse Event Reporting  AE/SAE Reporting Procedures (All IRB reporting requirements must be met.)  Notification process Toxicity parameters  Treatment Discontinuation Required Evaluations Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines Case report form completion guidelines  Queries and corrections eDC training  Source Documentation Acceptable documentation Case Report Forms as Source Document Retention  Communications	Informed Consent and Enrollment				
Central registration and randomization  Adverse Event Reporting  AE/SAE Reporting Procedures  Notification process  Toxicity parameters  Treatment Discontinuation  Required Evaluations  Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines  Case report form completion guidelines  Queries and corrections  eDC training  Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	Informed Consent Procedures	1			
Central registration and randomization  Adverse Event Reporting AE/SAE Reporting Procedures  Notification process  Toxicity parameters  Treatment Discontinuation Required Evaluations Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines Case report form completion guidelines  Queries and corrections eDC training  Source Documentation Acceptable documentation Case Report Forms as Source Document Retention  Communications	Eligibility criteria				(Fligibility waivers not permitted.)
AE/SAE Reporting Procedures  Notification process  Toxicity parameters  Treatment Discontinuation  Required Evaluations  Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines  Case report form completion guidelines  Queries and corrections  eDC training  Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	Central registration and randomization				(-3)
Notification process  Toxicity parameters  Treatment Discontinuation  Required Evaluations Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines Case report form completion guidelines  Queries and corrections eDC training  Source Documentation Acceptable documentation Case Report Forms as Source Document Retention  Communications	Adverse Event Reporting				
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Required Evaluations Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines Case report form completion guidelines  Queries and corrections eDC training  Source Documentation Acceptable documentation Case Report Forms as Source Document Retention  Communications	Toxicity parameters				
Early stopping rules, DLT levels  Data Collection and Submission  Format and timelines Case report form completion guidelines Queries and corrections eDC training  Source Documentation Acceptable documentation Case Report Forms as Source Document Retention  Communications	Treatment Discontinuation				
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Case report form completion guidelines  Queries and corrections  eDC training  Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	Data Collection and Submission				
Queries and corrections  eDC training  Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	Format and timelines				
EDC training  Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	Case report form completion guidelines				
Source Documentation  Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	Queries and corrections				
Acceptable documentation  Case Report Forms as Source  Document Retention  Communications	eDC training				
Case Report Forms as Source  Document Retention  Communications	Source Documentation				
Document Retention Communications	Acceptable documentation				
Communications	Case Report Forms as Source				
	Document Retention				
Farmet and for your av	Communications				
Format and frequency	Format and frequency				
Site contact(s)	Site contact(s)				
Monitoring	Monitoring				
Site monitoring visits	Site monitoring visits				
DSMC/DSMB requirements	DSMC/DSMB requirements				

Items Discussed / Verified	Yes	No	N/A	Actions / Comments
Regulatory and Record Keeping				
**Inter-institutional Agreement/Contract				
**IRB Assurance Number				
**Site Specific FDA Form 1572				
**CVs				
**IRB-Approvals (initial and all amendments)				
**IRB-Approved Informed Consent				
**IRB-Approved Advertisements				
**AE/SAE Reports				
**IND Safety Reports				
**Case Report Forms				
Continuing Review Reports				
Final/Closure Reports				
**Site Delegation of Authority Log				
Signed Informed Consents				
Study-related Correspondence				
Additional Comments				
			•	
Signature of Person Completing Form / Date				