



Management of Clinical Trial
GleneaglesCRC Pte Ltd
Study Specification Worksheet

Name of Sponsor: _____

Therapeutic Area: _____

Study Start and End Date: _____ **Recruitment period (mths):** _____

Number of Investigators: _____ **Total Patients:** _____ **No. of sites:** _____

Planned Sites: _____

Services

Pre-Study	Sponsor (✓)	GCRC (✓)
Protocol Development		
CRF Development		
Informed Consent Form Development		
Translation of Informed Consent		
Development of Patient Diaries		
Translation of Patient Diaries		
Development of Patient Questionnaires		
Translation of Patient Questionnaires		
Vendor Qualification and Negotiation (i.e. Laboratories, Diagnostic Services, etc.)		
Investigator Selection		
Site Selection		
Ethics Committee Submission Dossier Preparation		
Ethics Committee Submission and Follow-up		
Regulatory Submission Dossier Preparation		
Regulatory Submission and Follow-up		
Importation of Study Medication		
Investigator Meeting Arrangement and Conduct		
Site Initiation Visit		
Randomization Plan		
Drug Management (Logistics and Storage)		
GCP Training		
Study Contract Negotiation with Investigator		
Others:		

During Study	Sponsor (✓)	GCRC (✓)
Patient Recruitment		
Monitoring Visits (Preparation/Actual Visit/PostVisit Activities/ Report)		
Study Management		
CRF Query Management		
SAE Reporting/ Query Management		
Pharmacovigilance		



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Investigator Payments		
Newsletters		
Advertising		
Others:		

Post Study	Sponsor (✓)	GCRC (✓)
Notification of Ethics Committee		
Notification of Regulatory Authorities		
Close Out Visit		
Arrangement of External Archiving of Study Documents		
Others:		

Confirm:

Name: _____ Signature: _____ Date: _____