



Management of PMS
 GleneaglesCRC Pte Ltd
Study Specification Worksheet

Name of Sponsor: _____

Therapeutic Area: _____

Study Start and End Date: _____

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		
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		
Investigator Meeting Arrangement and Conduct (Group)		
Investigator Meeting Arrangement and Conduct (individual)		
Investigator Package (Protocol, CRFs etc) Preparation		
Investigator Package (Protocol, CRFs etc) Distribution		
GCP Training		
Study Contract Negotiation with Investigator		
Others:		

During Study	Sponsor (✓)	GCRC (✓)
CRF Collection by Site Visit		
CRF Collection by Courier		
Verification of CRF Completeness or Evaluability In Site		
Verification of CRF Completeness or Evaluability Off Site		
Verification of CRF Data with Source Documents		
CRF Query Generation/ Management		
CRF Tracking		
Investigator Payments		
CRF Return (If GCRI is not contracted to do Data Management)		
Visit Reports		
SAE reporting and Query Management		



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Pharmacovigilance		
Newsletters		
Others:		

Post Study	Sponsor (✓)	GCRC (✓)
Notification of Ethics Committee		
Notification of Regulatory Authority		
Archiving		
Others:		

Confirm:

Name: _____ Signature: _____ Date: _____