



Biometrics Services
GleneaglesCRC Pte Ltd
Study Specification Worksheet

Name of Sponsor: _____

Type of Study: _____

Study Start Date: _____

Study End Date: _____

CRF Delivery: Accrual Batches At Once

No. of CRF Pages and Total CRFs: _____

CRF Type (electronic or paper): _____

Source of Database Program: Sponsor ClinTrial Epidata
 (with audit trail) (without audit trail)

Return of CRFs: batches at once

Services

Data Management	Sponsor (✓)	GCRC (✓)
Standard Operating Procedure to Use		
Randomization Plan		
Unblinding		
Data Handling Plan		
Database Generation & Screen Design		
CRF Annotation Plan		
Single Data Entry		
Double Data Entry		
Data Validation		
Database update		
Coding of Medications by WHO-DRUG		
Coding of Adverse Events by MedDRA		
SAE Reconciliation		
Query Generation and Resolution		
Archiving		
Provision of CRF Filing Folders*		
Return of CRFs*		
Others		

*this becomes a pass through cost if service is by GCRC

Statistics	Sponsor (✓)	GCRC (✓)
Standard Operating Procedure to Use		
Preparation of Statistical Analysis Plan		
Statistical Programming		
Generate Tables, Listings, and Graphs		
Statistical Analysis of All Variables		
Statistical Analysis of Efficacy Variables		
Statistical Analysis of Safety Variables		
Interim Analysis		



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Statistical Analysis Report		
Others		

Medical Writing	Sponsor (✓)	GCRC (✓)
Standard Operating Procedure to Use		
Provide Draft Study Report		
Provide Review Input		
Final Study Report		
Manuscript writing for journals		
Others		

Confirm:

Name: _____

Signature: _____

Date: _____