

Study Details						
Study Code:						
Compound:						
Therapeutic Area:						
Phase:						
Study Title:						
Project Management	Unit			Responsibility		
Activity	Frequency	Quantity	CRO	Sponsor	Shared	
Project Management Start-up		Site Month(s)				
Project Management Maintenance		Site Month(s)				
Project Management Close-out		Site Month(s)				
Project Mangement Plan (including project timelines and regulatory plan)		per Study				
Perform Co-monitoring visits with CRAs		per Study				
Sponsor/CRO Project Planning Meeting		Hour(s)				
Sponsor/CRO Project Launch Meeting		Hour(s)				
Sponsor/CRO Project Team Training		Hour(s)				
Sponsor/CRO Global Project Team Teleconference		per Month				
Sponsor/CRO Project Team Teleconference		Hour(s)				
Face-to-Face Meetings between CRO and Sponsor		Hour(s)				
Face-to-Face Meeting(s) at Sponsor Facility		Meeting(s)				
Face-to-Face Meeting(s) CRO Facility		Meeting(s)				
Set-up Central Files (i.e. Financial Files, CVs, 1572s, IRB, SAEs, Correspondance, Investigational Products, Trip Reports)		per Study				
Generate Essential Document Packages		Site(s)				
Study Start-up Report (i.e. Number of Potential Sites Contacted, Number of Sites Recruited, Calendar of Pre-study Visits and Site Initiation Visits, Number of Sites with Investigator Contacts, Regulatory Document Collection Status, Number of Sites with Fi		Report(s)				

Study Conduct Report (i.e. Number of Subjects Screened, Number of Subjects Randomized, Number of Subjects in Follow-up, Number of Subjects Completed, Number of Subject Screen Failures, Number of Completed CRFs or Completed Visits in the Field, Number of C		Report(s)				
Monthly Reports (i.e. Summary of Weekly Reports, Number of SAEs by Site, Report of Known or Anticipated Issues and Resolutions, Status of Submitted Visit Reports, Approved Patient Protocol Exceptions, Maintain Protocol Deviation Log, Project Team Training		Report(s)				
Prepare/Distribute Newsletters		Newsletter(s)				
Clinical Trial Document Preparation	Unit			Responsibility		
Activity	Frequency	Quantity	CRO	Sponsor	Shared	
Draft/Write Protocol		per Study				
Develop Protocol Amendments non-Administrative		per Study				
Develop Protocol Amendments Administrative		per Study				
Develop Informed Consent Form (ICF)/ Subject Information Sheet (SIS)		per Study				
Develop Subject Screening Log (per Log)		per Study				
Develop Case Report Form (CRF), per unique CRF		CRF(s)				
Develop Subject Diary Cards; Subject Trial Cards		Card(s)				
Develop Subject Questionnaire, per Questionnaire		Questionnaire(s)				
Develop Case Report Form (CRF) Completion Guidelines; Case Report Form (CRF) Instruction Guide		per Study				
Develop Monitoring Guidelines; Monitoring Manual		per Study				
Development and Distribution of Quality Plan		per Study				
Develop Serious Adverse Events (SAEs) Plan		per Study				
Assemble and Distribute Investigator Site Binder		Site(s)				

Develop Investigator Drug Brochure (IDB), Investigator Brochure (IB)		per Study				
Develop Pharmacy Binder		per Study				
Document Translation		per Study				
Study Initiation	Unit			Responsibility		
Activity	Frequency	Quantity	CRO	Sponsor	Shared	
Prepare Enrollment System		per Study				
Hire Contractors/Vendors		per Study				
Monitor and Audit Contractors/Vendors		per Study				
Clinical Site Identification; Investigator Identification and Qualification		Site(s)				
Pre-qualification visit Qualification of Clinical Sites		Site(s)				
Pre-qualification Call (1 hour call, 2 hour follow up)		Call(s)				
Central IRB Preparation and Submission for Regulatory Approval		per Study				
Prepare Regulatory Documentation: Clinical Site Local Documentation; Local Institutional Review Board (IRB)/Local Ethics Committee (EC) Submissions		Site(s)				
Central IRB Annual Review		per Site				
Local IRB Annual Review		per Site				
Prepare Clinical Trial Agreement Template; Investigator Contract Research Agreement		per Study				
Budgeting/Negotiation/Contracting: Investigator Agreements; Investigator Grants private sites		Site(s)				
Budgeting/Negotiation/Contracting: Investigator Agreements; Investigator Grants, Academic sites (please use in addition to code SS050)		Academic Site(s)				
Negotiate Contract only		Site(s)				
Negotiate Budget only		Site(s)				
Manage Investigator Grant Payments; Handle Investigator Grant Payments		Payment(s) per site				
Prepare and Attend One day Investigator Meeting		Meeting(s)				
Initiation Visit; Initiation of Clinical Sites		per Site				
Initiation Call (2 hour call, 1 hour preparation, 1 hour follow up)		Call(s)				

Ship Study Material to Clinical Sites; Provide Sites with Study Supplies		Site(s)				
Patient Recruitment (per screened patient)		Patient(s) screened				
Study Conduct	Unit			Responsibility		
Activity	Frequency	Quantity	CRO	Sponsor	Shared	
Maintain Study Files		Site Month(s)				
In-House Site Management; Clinical Site Management		Site Month(s)				
Conduct Site Training of Personnel; Update Site Training of Personnel		Site(s)				
Assure Good Clinical Practices (GCP)/Regulatory Compliance		Site(s)				
Clinical Monitoring; Interim Visit Study/Site Monitoring; Monitoring of Clinical Sites; Site Contacts and Monitoring Responsibilities; On-Site Monitoring		Visit(s)				
Conduct additional day of Interim Monitoring Visits (8 hour visit)		Visit(s)				
Site Close-outs; Close-out of Sites; Study Close-out Visits		Site(s)				
Close out call (2 hour call, 2 hours follow up)		Call(s)				
Medical Monitoring by Physician; Medical Management		Hour(s)				
Medical Monitoring		Hour(s)				
Provide General Medical Support		Hour(s)				
Provide Medical Support to Clinical Sites		Hour(s)				
Provide Medical Support to Contract Research Associates (CRAs)		Hour(s)				
Provide Medical Support to Data Management		Hour(s)				
Provide Medical Support to Project Team		Hour(s)				
Answer Patient Eligibility Questions, Protocol-related Questions, and Specific Patient Safety Issues		Hour(s)				
Complete the Medical Review of Coding; Complete the Medical Review of Listings		Hour(s)				
Provide Study-specific Training to the Clinical Team		Hour(s)				
Perform Medical Safety Review of Laboratory Reports for Alert Values		Hour(s)				

Provide FDA Liason Support		Hour(s)				
Randomization & Clinical Supply Management; Central Randomization Services; Clinical Drug Supplies		per Study				
Monthly IT Support -Database Maintenance/Ongoing Technical Support		Month(s)				
Store/Ship/Supply Clinical Materials; Ship/Store Clinical Supplies; Ship/Store Clinical Drug Supplies; Ship/Store Drug Supplies		Site(s)				
Integrated Voice Response System (IVRS) per project fees		per Study				
Integrated Voice Response System (IVRS) monthly fees		Month(s)				
Serious Adverse Events (SAEs) Processing; Serious Adverse Events (SAEs) Reporting/Pharmacovigilance; Reconcile Serious Adverse Events (SAEs); Adverse Events (AEs)/Serious Adverse Events (SAEs) Reporting; Serious Adverse Events (SAEs) Reconciliation		SAE(s)				
Serious Adverse Event (SAEs) Reports/Form,SAE Naratives		SAE(s)				
Process IND Safety Letters						
Submission of Reports to FDA of SAE						
Investigational New Drug Application (IND) Safety Report		per Study				
Site Audit, Regulatory Compliance		per Study				
Filing Country Submission, Regulatory Package and Obtain License National Regulatory Submissions		per Study				
Data Management	Unit		Responsibility			
Activity	Frequency	Quantity	CRO	Sponsor	Shared	
Project Management for Data Management; Data Management-Project Management (including staff supervision, interaction with third party suppliers, and provision of all SOP and staff documentation)		Site Month(s)				
Data Management Reports		Report(s)				
Study IT Support		per Study				

Monthly IT Support -Database Maintenance/Ongoing Technical Support		Month(s)				
Train Data Management Team Training		per Study				
Data Management Plan (including Source Documentation Verification Plan and Data Cleaning Plan)		per Study				
Verify and Track Case Report Form (CRFs)		CRF(s)				
Verify and Track Replicate Case Report Form (CRFs)		CRF(s)				
Scanning Unique CRF page		CRF(s)				
Scanning Replicate Case Report Form (CRFs)		CRF(s)				
Design of Database and Screens; Database Set-up and Study Programming (including Program Checks)		per Study				
Server charges for Electronic Data Capture		month(s)				
IT charges for Electronic Data Capture		month(s)				
Electronic Case Report Form (e-CRF) Development		per Study				
Query sites to update Electronic Case Report Form (e-CRF) (with translations)		per Study				
Apply Data Validation Checks Outside of Electronic Data Capture (EDC) System		per Study				
Electronic File Management		per Study				
Electronic Data Tracking		per Study				
Testing of Database and Screens; Data Testing		per Study				
Data Cleaning (unique CRF)		CRF(s)				
Data Cleaning (Replicate Case Report Form (CRFs))		CRF(s)				
Data Entry (unique CRF)		CRF(s)				
Data Entry (Replicate Case Report Form (CRFs))		CRF(s)				
Adverse events coding		per patient				
Serious Adverse Events Coding		SAE(s)				
Concomitant events coding		per patient				
Manage External Data; Set up time; Central Lab/Tertiary Suppliers of Data/ Third-Party Suppliers of Data/ 3rd-Party Suppliers of Data		per Study				
Medical Coding		CRF(s)				
Medical Coding (Replicate Case Report Form (CRFs))		CRF(s)				

Quality Control (QC) of Data Entry		CRF(s)				
Quality Control (QC) of Data Entry (Replicate Case Report Form (CRFs))		CRF(s)				
Queries Management; Document Process Management and Queries		Query (s) per subject				
Protocol Violators		Violation(s)				
Data Changes		Query (s) per subject				
Quality Assurance (QA) (Data Management); Quality Assurance (QA) Audit		Audit(s)				
Local Lab Data, Laboratory Normals per Site		per Site				
Pre-Lock Data Management Report (DMR)		Report(s)				
Interim Database Lock by suppressing all write access (for defined period or data set)		per Study				
Database Lock by suppressing all Write access		per Study				
Unblinding Data		per Study				
Electronic Transfer of Subject Tracking to Sponsor; Data Test Transfer		per Study				
Data Transfer		per Study				
Data Processing and Validation; Data Validation:Data Management; Processing;		per Study				
Upload coding dictionary		per Study				
Biostatistics	Unit		Responsibility			
Activity	Frequency	Quantity	CRO	Sponsor	Shared	
Specification of Protocol Deviations (SPD)		per Study				
Statistical Analysis Plan (SAP); Statistical Analysis; Reporting and Analysis Plan (RAP)		per Study				
Write Statistical Section of Protocol Programming (Data Analysis)		per Study				
Protocol Deviations; Deviations/Populations Meeting (Pre-analysis Review)		Hour(s)				
Finalize Blinded Deviations/Supply Randomization Schedule		Hour(s)				
Check for Treatment Administration Errors once Study is Unblinded ; Finalize Study Populations		Hour(s)				

Produce Analyze and Quality Control (QC) Draft Tables, Figures and Listings (TFLs) (pre-Database Lock (DBL))		per Study				
Blinded Tables, Figures and Listings (TFL) Meeting		per Study				
Clinical Study Report Preparation and Delivery; Full report, draft and QC,		per Study				