## 1. CLINICAL DATA MANAGEMENT (CDM)

The Vendor shall oversee the data lifecycle from collection to database lock.

**CRF Design & Build:** Design of Case Report Forms (CRF) and setup of the Electronic Data Capture (EDC) system.

**UAT (User Acceptance Testing):** Coordination of UAT and resolution of findings.

**Data Cleaning:** Ongoing query generation, resolution, and data validation.

**Lab Data Management:** Integration of external lab data, unit normalization, and reconciliation with the EDC.

**Medical Coding:** Coding of Adverse Events (MedDRA) and Concomitant Medications (WHODrug Global).

**Database Lock:** Final quality control (QC), soft lock, and hard lock procedures.

## 2. CLINICAL RESEARCH ASSOCIATE (CRA) / MONITORING

**Site Selection:** Conducting Pre-Study Visits (PSV) to assess site suitability.

**Site Initiation:** Conducting Site Initiation Visits (SIV) and training site staff.

**Interim Monitoring:** Conducting Interim Monitoring Visits (IMV) to verify Source Data (SDV), drug accountability, and regulatory compliance.

**Close-Out:** Conducting Close-Out Visits (COV) and archiving site files.

## 3. BIOSTATISTICS & STATISTICAL PROGRAMMING

**SAP Development:** Writing and finalizing the Statistical Analysis Plan (SAP) and Mock Shells.

**CDISC Standards:**

**SDTM:** Mapping raw data to SDTM domains; creation of define.xml and Reviewer's Guide.

**ADaM:** Creation of Analysis Data Model datasets.

**TLFs:** Programming of Tables, Listings, and Figures (TLFs) using SAS.

**Statistical Analysis:** Conducting the analysis and contributing to the Clinical Study Report (CSR).

## 4. PHARMACOVIGILANCE (PV) & SAFETY

**Safety Database:** Setup and maintenance of the safety database.

**Case Processing:** Receipt, triage, entry, and QC of Serious Adverse Events (SAEs).

**Reporting:** Expedited reporting to Regulatory Authorities (e.g., FDA/EMA) and Ethics Committees.

**Safety Narrative:** Writing medical narratives for inclusion in the CSR.

## 5. PAYMENT SCHEDULE

**Upon Contract Signature:** 15% of Service Fees.

**Upon Final Protocol & SAP Approval:** 15% of Service Fees.

**Upon First Patient In (FPI):** 20% of Service Fees.

**Quarterly Payments:** Pro-rated based on work completed (units utilized).

**Upon Database Lock:** 15% of Service Fees.

**Upon Delivery of Final TLFs and Datasets:** Remaining Balance.

## KEY ASSUMPTIONS

**Protocol: Sponsor will provide the final protocol prior to database build.**

**Edits: Budget includes up to two (2) rounds of review/amendments for the SAP and eCRF. Additional rounds are out-of-scope.**

**SAE Volume: Budget assumes a maximum of 10 SAEs. Additional SAEs will be billed at the unit rate.**

**Data Quality: Lab data is assumed to be transferred in a standard ASCII or SAS format requiring minimal restructuring.**

**Coding Dictionaries: Sponsor holds valid subscriptions for MedDRA and WHODrug or will authorize Vendor to purchase on their behalf.**