

Study Start-Up Visit Agenda

- I. Protocol Over**
 - A. Back
 - B. Study Design and Study Objectives
 - C. Inclusion/Exclusion Criteria
 - D. Time and Events Scheduling including visit windows
 - E. Study Procedures Overview
 - F. Study Product(s) Overview
 - G. Specimen Collection and Processing
 - H. Risks and Benefits
 - I. Safety Reporting
 - J. Study Flow/Study Plan and Logistics
 - K. Data Analysis Plan

- II. Recruitment Strategy**
 - A. Project Timelines/Recruitment Goals
 - B. Study Population
 - C. Screening/Identification of potential participants
 - D. Recruitment Methods (Advertisements, social media, radio, print, scripts etc.)
 - E. Competing Protocols Workload
 - F. Enrollment/Informed Consent Process, including a mock study visit
 - G. Participant Compensation/Velos, as applicable
 - H. Participant Retention Procedures

- III. Site Staff Responsibilities**
 - A. Communication Plan and Contact List
 - 1. Potentials
 - 2. Study Status
 - 3. Adverse events, unanticipated problems, protocol deviations

- IV. Investigational Products, Devices, and Specimens**
 - A. Receipt, shipment, and storage
 - B. Inventory, accountability, and reconciliation
 - C. Handling Instructions/Transport

- V. Supplies and Equipment**
 - A. Storage and Calibration
 - B. Emergency Response Supplies and System

- VI. Data Management (Collection, Data Entry, Good Documentation Practices)**
 - A. Source Documents and Case Report Forms
 - 1. Study Data Storage and Archiving
 - B. Electronic Data Capture (EDC)/Remote Data Entry/Capture (RDE/RDC)/REDCap
 - 2. Location for Data Entry Area and/or EDC (RDC) entry
 - C. Electronic Medical Record Use and Access-Inpatient and Ambulatory
 - D. Regulatory maintenance of essential documents
 - E. Monitoring Plan, Internal QA & QA Plan

- VII. Facilities Discussion Tour (as applicable)**
 - A. Regional Sites/Study Locations
 - B. Patient Exam Rooms/Intake Areas
 - C. Monitoring Plan and Monitoring Area