**Investigator Site Files (ISFs) / Monitoring Visit Summaries**

**Study Title:**  
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Novostatin (Novitor) in Patients with Hypercholesterolemia

**Protocol Number:** NSP-002-2024  
**Study Duration:** March 2, 2024 – September 22, 2024  
**Sponsor:** Novitor Pharmaceuticals Inc.  
**Investigational Product:** Novostatin (Novitor)

**1. Overview**

This document summarizes the key components of the Investigator Site Files (ISFs) and provides monitoring visit summaries for the Phase 2 trial of Novostatin (Novitor) conducted at Biotech City Medical Center – Clinical Research Unit. These documents serve as evidence of trial conduct, data integrity, and adherence to protocol and Good Clinical Practice (GCP) guidelines, thereby supporting the trial’s operational integrity.

**2. Contents of the Investigator Site Files (ISFs)**

The ISFs for Biotech City Medical Center contain the following essential documents:

* **Regulatory Documents:**
  + Study Protocol (NSP-002-2024) and subsequent amendments (e.g., Amendment 1 dated April 15, 2024)
  + Ethics Committee/IRB Approvals and Correspondence
  + Informed Consent Forms (ICFs) and patient consent logs
* **Operational Documents:**
  + Site Initiation Visit (SIV) reports and training materials
  + Subject Enrollment/Screening Logs and Randomization Records
  + Case Report Forms (CRFs)/Electronic CRFs (eCRFs)
  + Monitoring Visit Reports and Protocol Deviation Logs
* **Safety and Data Management Documents:**
  + Adverse Event (AE) and Serious Adverse Event (SAE) Reports
  + Laboratory Data Summaries and Central Lab Reports
  + Pharmacokinetic/Pharmacodynamic (PK/PD) Reports
* **Miscellaneous:**
  + Investigator’s Brochure (IB)
  + Audit and Quality Assurance (QA) Reports

**3. Monitoring Visit Summary**

**3.1 Site Information**

* **Site Name:** Biotech City Medical Center – Clinical Research Unit
* **Principal Investigator:** Dr. Jane Doe
* **Site Coordinator:** Sarah Thompson, RN
* **Location:** 456 Health Blvd, Biotech City, State, Country

**3.2 Monitoring Visit Details**

**Visit 1: Site Initiation Visit (SIV)**

* **Date:** March 1, 2024
* **Objectives:**
  + Confirm site readiness, review study protocol, CRF instructions, and GCP requirements.
  + Train site personnel on study procedures, data entry, and query resolution.
* **Key Observations:**
  + All essential regulatory documents were available.
  + Training session completed with 100% attendance.
* **Action Items:**
  + Follow-up training scheduled for CRF data entry best practices.
* **Monitoring Report Prepared by:** John Miller, CRA
* **Site Signature:** Dr. Jane Doe (SIV acknowledged)

**Visit 2: Routine Monitoring Visit**

* **Date:** June 15, 2024
* **Objectives:**
  + Verify adherence to protocol and confirm data accuracy through source document verification (SDV) for a random sample of subjects.
  + Review informed consent documentation and query resolution status.
  + Evaluate subject safety and AE reporting.
* **Key Findings:**
  + 20 randomly selected CRFs were compared with source documents; 95% data accuracy was observed.
  + Minor discrepancies identified in concomitant medication entries; these were corrected via data queries.
  + AE reporting was timely and complete.
* **Action Items:**
  + Site to conduct a refresher training on CRF documentation and update SOPs regarding data entry.
* **Monitoring Report Prepared by:** John Miller, CRA
* **Site Signature:** Dr. Jane Doe (Reviewed and acknowledged)

**Visit 3: Pre-Database Lock Monitoring Visit**

* **Date:** September 10, 2024
* **Objectives:**
  + Final review of all ISF documents prior to database lock.
  + Confirm resolution of all outstanding data queries and protocol deviations.
  + Verify that all AE/SAE reports are complete and that ISFs are current.
* **Key Findings:**
  + All ISF sections are complete, and the latest amendment (Amendment 1) is filed.
  + Outstanding queries have been resolved; the ISF includes a complete log of query resolutions.
  + Protocol deviations were documented and corrective actions implemented.
* **Action Items:**
  + None. Site ready for database lock.
* **Monitoring Report Prepared by:** Susan Roberts, Senior CRA
* **Site Signature:** Dr. Jane Doe (Final review completed)

**4. Summary and Conclusion**

The ISFs at Biotech City Medical Center have been maintained in accordance with regulatory and GCP guidelines. Regular monitoring visits have confirmed that all study documents, including regulatory approvals, consent forms, CRFs, and safety reports, are complete and accurate. Minor issues identified during monitoring have been promptly addressed with corrective actions. The operational integrity of the trial has been upheld throughout the study period, supporting the positive outcomes observed. Based on these findings, the trial is ready to advance to Phase 3 clinical development.

**Prepared by:**  
John Miller, Clinical Research Associate  
Date: September 30, 2024

**Reviewed by:**  
Susan Roberts, Senior CRA  
Date: September 30, 2024

**Approved by Principal Investigator:**

Dr. Jane Doe  
Date: September 30, 2024