**Monitoring Visit Report**

**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  
**Site Name:** Biotech City Medical Center – Clinical Research Unit  
**Investigator:** Dr. Jane Doe  
**Monitoring Visit Date:** August 15, 2024  
**Study Duration:** March 2, 2024 – September 22, 2024  
**Sponsor:** Novitor Pharmaceuticals Inc.

**1. Purpose and Objectives**

The purpose of this monitoring visit was to review study conduct, verify data integrity, ensure adherence to the protocol and Good Clinical Practice (GCP) guidelines, and to identify and resolve any issues prior to the study’s completion. The visit focused on subject enrollment, informed consent documentation, CRF accuracy, and compliance with safety reporting.

**2. Visit Overview**

**Visit Type:** Routine Monitoring Visit (Pre-Database Lock)  
**Duration of Visit:** 4 hours  
**Monitors Present:**

* John Miller, Clinical Research Associate (CRA)
* Susan Roberts, Senior CRA

**3. Site Activities Reviewed**

**3.1. Regulatory and Essential Documents**

* **Informed Consent Forms (ICFs):**  
  Reviewed copies for all enrolled subjects (Subjects NS-101 to NS-132). All forms were correctly dated and signed. No missing ICFs were noted.
* **IRB Approvals and Amendments:**  
  Confirmed that current IRB approval documents are on file, including the recent protocol amendment dated April 15, 2024.

**3.2. Subject Enrollment and Screening**

* **Screening Logs:**  
  Reviewed the Subject Enrollment/Screening Log. All entries are complete with proper documentation of inclusion/exclusion criteria and informed consent dates.
* **Randomization Records:**  
  Verified that randomization codes are maintained securely and that allocation is consistent with the protocol.

**3.3. Data Collection and CRF Accuracy**

* **CRFs/eCRFs:**  
  Conducted source data verification on 10 randomly selected subjects (e.g., NS-102, NS-105, NS-110, NS-115, NS-120, NS-125, NS-128, NS-130, NS-131, NS-132). Data entries for vital signs, laboratory results, and adverse event reporting were consistent with source documents.
* **Query Resolution:**  
  Reviewed the status of data queries in the Electronic Data Capture (EDC) system. Outstanding queries have been resolved within the required timeframe.

**3.4. Safety Reporting and Compliance**

* **Adverse Event Reporting:**  
  Confirmed that adverse events (AEs) and serious adverse events (SAEs) are documented appropriately. One instance of mild headache (subject NS-102) was reported and managed per protocol.
* **Protocol Deviations:**  
  One minor deviation noted: a subject visit (NS-113) occurred one day outside the protocol window. The deviation was documented, and corrective actions have been implemented.

**3.5. Data Management and Audit Trail**

* **Data Quality:**  
  Verified that all data entries have appropriate audit trails. The EDC system backups and data security measures are compliant with 21 CFR Part 11.

**4. Findings and Recommendations**

**4.1. Positive Findings**

* **Regulatory Compliance:**  
  The site has maintained up-to-date regulatory documents and adheres strictly to the protocol and GCP guidelines.
* **Data Integrity:**  
  CRF entries, source documentation, and query resolutions were accurate and timely.
* **Patient Safety:**  
  No serious safety concerns were identified. Monitoring of liver function and muscle enzymes is consistent with protocol requirements.

**4.2. Areas for Improvement**

* **Visit Scheduling:**  
  One subject visit was scheduled outside the allowed window (NS-113). While the deviation was minor and corrected, the site is advised to review scheduling procedures to avoid future occurrences.
* **Documentation Clarification:**  
  Minor clarifications are needed on a few CRF entries regarding concomitant medication use. These will be addressed in the next monitoring visit.

**5. Overall Assessment**

The monitoring visit at Biotech City Medical Center demonstrates that the study is being conducted in compliance with the protocol and regulatory requirements. Data quality is high, and patient safety is well maintained. The minor protocol deviation and documentation clarifications noted have been addressed by the site. Given the positive outcomes observed during the trial, these findings further support the decision to progress Novostatin into Phase 3 clinical trials.

**6. Action Items and Follow-Up**

| **Action Item** | **Responsible Party** | **Due Date** | **Status** |
| --- | --- | --- | --- |
| Review and adjust scheduling processes | Site Coordinator | August 30, 2024 | In Progress |
| Clarify concomitant medication entries | CRF Coordinator | August 25, 2024 | To Be Completed |
| Confirm resolution of minor deviation | Investigator | August 20, 2024 | Completed |

**7. Conclusion**

Based on the findings from this monitoring visit, the site is in good standing, and the data collected are robust and reliable. The positive safety and efficacy results observed in the trial, along with the overall compliance of the site, support the plan to advance Novostatin (Novitor) to Phase 3 clinical trials.

**Monitoring Report Prepared by:**  
John Miller, CRA  
Date: August 15, 2024

**Monitoring Report Reviewed by:**  
Susan Roberts, Senior CRA  
Date: August 16, 2024

**Investigator Signature:**

Dr. Jane Doe  
Date: August 16, 2024