**Quality Assurance and Audit 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  
**Study Duration:** March 2, 2024 – September 22, 2024  
**Sponsor:** Novitor Pharmaceuticals Inc.  
**Investigational Product:** Novostatin (Novitor)  
**Report Version:** 1.0  
**Report Date:** September 30, 2024

**1. Introduction**

This Quality Assurance (QA) and Audit Report summarizes the findings from both internal and external audits conducted during the Phase 2 clinical trial of Novostatin (Novitor). The audits focused on data integrity, adherence to the study protocol, Good Clinical Practice (GCP) compliance, and overall trial conduct. The purpose of these audits was to identify any discrepancies or areas for improvement and to ensure the quality and reliability of the study data.

**2. Audit Scope and Objectives**

**2.1 Scope**

* **Internal Audits:**  
  Conducted by the Novitor Pharmaceuticals QA team across all participating sites and centralized data management processes.
* **External Audits:**  
  Performed by an independent auditing firm specializing in clinical research, with a focus on regulatory compliance and data integrity.

**2.2 Objectives**

* Verify adherence to the protocol and GCP guidelines.
* Assess the accuracy and completeness of data entry and management.
* Evaluate the handling and resolution of data queries and protocol deviations.
* Ensure that all safety, efficacy, and monitoring reports are appropriately documented.
* Provide recommendations for continuous improvement.

**3. Audit Methodology**

**3.1 Internal Audit Procedures**

* **Document Review:**  
  Examination of trial master files, eCRFs, informed consent forms, monitoring reports, and data management logs.
* **Site Visits:**  
  On-site inspections at 3 representative study sites to review source documents and CRF entries.
* **Interviews:**  
  Discussions with site coordinators, investigators, and data management personnel.

**3.2 External Audit Procedures**

* **Sampling:**  
  Random sampling of 20% of the subjects’ data from the central database.
* **Compliance Checks:**  
  Verification of regulatory submissions, IRB approvals, and adherence to the approved protocol.
* **Audit Trail Analysis:**  
  Review of EDC system audit trails and query resolution logs.

**4. Findings and Observations**

**4.1 Positive Findings**

* **Protocol Adherence:**  
  The majority of the study sites maintained strict adherence to the approved protocol. Informed consent forms and IRB approvals were complete and up-to-date.
* **Data Integrity:**  
  The EDC system’s audit trails confirmed that data entry, query resolution, and data cleaning processes were performed in accordance with the study procedures.
* **Monitoring and Reporting:**  
  Regular monitoring visits and timely resolution of queries were documented. All adverse events (AEs) and serious adverse events (SAEs) were appropriately reported.
* **Safety and Efficacy Documentation:**  
  Laboratory data, PK/PD reports, and imaging/biomarker analyses were thoroughly documented and met regulatory requirements.

**4.2 Areas for Improvement**

* **Documentation Consistency:**  
  Minor inconsistencies were observed in CRF entries regarding concomitant medication details at two sites. These issues were promptly addressed via corrective action plans.
* **Visit Scheduling:**  
  One instance of a subject visit occurring outside the allowed time window was identified (subject NS-113). The deviation was minor, and subsequent visits adhered to the protocol.
* **Query Resolution:**  
  While all queries were resolved, the average resolution time could be further reduced by enhancing training for site data entry staff.

**5. Audit Recommendations**

**5.1 Corrective Actions Implemented**

* **Enhanced Training:**  
  Additional training sessions on CRF completion and data query resolution have been scheduled for all site personnel.
* **Process Optimization:**  
  A review of the scheduling process is underway to prevent future deviations related to visit timing.
* **Documentation Review:**  
  A re-audit of CRF entries concerning concomitant medications has been completed to ensure uniformity across sites.

**5.2 Future Recommendations**

* **Periodic Audits:**  
  Continue to perform periodic internal audits throughout the study to monitor ongoing compliance and quality.
* **Real-Time Monitoring:**  
  Implement a real-time data monitoring system to quickly identify and address discrepancies.
* **Enhanced Communication:**  
  Strengthen communication channels between the sponsor, site personnel, and data management teams to improve query resolution times.

**6. Conclusion**

Both internal and external audits confirmed that the Phase 2 trial of Novostatin (Novitor) was conducted in compliance with the study protocol, GCP guidelines, and applicable regulatory requirements. Minor issues were identified and effectively corrected without compromising data integrity or patient safety. Overall, the audit findings support the positive outcomes of the trial and further substantiate the decision to advance Novostatin to Phase 3 clinical trials.

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