**Data Management Plan (DMP)**

**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.  
**Document Version:** 1.0  
**Date:** April 30, 2024

**1. Introduction**

This Data Management Plan (DMP) describes the data collection, cleaning, validation, storage, and reporting procedures for the Phase 2 clinical trial of Novostatin (Novitor). The primary goal is to ensure that high-quality, accurate, and complete data are generated, managed, and available for analysis to support the positive outcomes observed in this trial, which are intended to support the transition to Phase 3.

**2. Data Management Team and Responsibilities**

* **Data Manager:**
  + Name: Dr. Emily Carter
  + Responsibilities: Overall oversight of data management activities, ensuring compliance with Good Clinical Practice (GCP), and managing the Electronic Data Capture (EDC) system.
* **Data Entry/CRF Coordinator:**
  + Name: Michael Lee
  + Responsibilities: Overseeing data entry from paper CRFs into the EDC, conducting source data verification (SDV), and addressing data queries.
* **Statistical Analyst:**
  + Name: Sarah Patel
  + Responsibilities: Data extraction, preparation for statistical analysis, and maintaining audit trails of data modifications.
* **IT Support and Database Administrator:**
  + Name: Kevin Wong
  + Responsibilities: Managing the EDC system (using Medidata Rave®), ensuring system security, backup, and troubleshooting.

**3. Data Collection Procedures**

**3.1 Data Sources**

* **Electronic Case Report Forms (eCRFs):**  
  All clinical data will be collected via an EDC system with pre-programmed eCRFs. These eCRFs are designed to capture patient demographics, laboratory results, adverse events, and visit-specific assessments.
* **Source Documents:**  
  Source documents such as patient medical records, laboratory reports, and imaging data will be maintained at the study sites and used for verification during monitoring visits.

**3.2 Data Entry**

* **Direct Entry:**  
  Investigators or designated site personnel will directly enter data into the EDC system during or immediately after each study visit.
* **Double Data Entry:**  
  Critical variables (e.g., primary endpoint measures such as LDL cholesterol) will undergo double data entry for verification.
* **Data Entry Guidelines:**  
  All personnel will be trained on the eCRF instructions and standard operating procedures (SOPs) for data entry to ensure consistency and accuracy.

**4. Data Cleaning Procedures**

**4.1 Query Management**

* **Automated Edit Checks:**  
  The EDC system is configured with built-in edit checks to identify missing or inconsistent data. For example, an edit check will flag LDL cholesterol values that fall outside expected ranges.
* **Manual Query Resolution:**  
  The Data Manager will generate and review data queries on a weekly basis. Site personnel are required to resolve queries within 48 hours.
* **Query Documentation:**  
  All queries and resolutions will be documented in the system audit trail to maintain transparency and traceability.

**4.2 Data Review and Reconciliation**

* **Periodic Data Review Meetings:**  
  Weekly teleconferences will be held with site coordinators to discuss data discrepancies and ensure timely resolution.
* **Source Data Verification (SDV):**  
  Monitors will perform SDV during routine site visits to reconcile eCRF entries with source documents.

**5. Data Validation Procedures**

**5.1 Data Validation Rules**

* **Range Checks:**  
  Numeric fields, such as laboratory values, will be validated against pre-specified ranges (e.g., LDL cholesterol expected to be between 50–300 mg/dL).
* **Consistency Checks:**  
  Data consistency will be verified between related fields (e.g., ensuring dosing information corresponds with visit dates).
* **Date Checks:**  
  Visit dates will be cross-checked with protocol-specified windows to ensure data is collected within the appropriate time frame.

**5.2 Validation Reports**

* **Weekly Validation Reports:**  
  Automated reports will be generated weekly by the EDC system to list data inconsistencies and missing data points.
* **Final Data Validation:**  
  A comprehensive data validation report will be generated at the end of data collection, prior to database lock, to certify that all data are complete and accurate.

**6. Data Storage and Security**

**6.1 Electronic Data Storage**

* **EDC System:**  
  All study data will be stored in Medidata Rave® which complies with 21 CFR Part 11. Data backups will occur daily and be stored securely.
* **Access Control:**  
  Role-based access will be enforced. Only authorized personnel will have access to the EDC system, and each access will be logged.

**6.2 Data Confidentiality**

* **Patient Anonymity:**  
  Subject identifiers will be coded to protect patient confidentiality. The linkage between subject IDs and patient names will be maintained separately at each site.
* **Data Encryption:**  
  Data will be encrypted during transmission and at rest in compliance with institutional and regulatory guidelines.

**7. Data Lock and Database Closure**

**7.1 Pre-Lock Activities**

* **Final Data Cleaning:**  
  All outstanding queries must be resolved, and a final data review meeting will be held.
* **Sign-Off:**  
  The Data Manager, Principal Investigator, and Sponsor Representative will sign off on the final dataset.

**7.2 Database Lock**

* **Lock Date:**  
  The database is scheduled to be locked within 4 weeks after the final patient visit (anticipated lock date: October 20, 2024).
* **Post-Lock Access:**  
  Post-lock, the database will be archived, and any further modifications will require formal amendment and approval.

**8. Data Reporting**

* **Interim Reports:**  
  Interim data quality and progress reports will be generated monthly for internal review and regulatory compliance.
* **Final Study Report:**  
  The final clinical study report will include comprehensive tables, figures, and listings generated from the locked database. All analyses will be performed according to the Statistical Analysis Plan (SAP).

**9. Quality Assurance and Audit**

* **Internal Audits:**  
  Periodic audits will be conducted by the Quality Assurance (QA) team to verify compliance with this DMP.
* **External Audits:**  
  Regulatory authorities may perform audits. The study team will maintain full audit trails and data documentation for review.

**10. Appendices**

* **Appendix A:** Data Management Standard Operating Procedures (SOPs)
* **Appendix B:** EDC System User Manuals
* **Appendix C:** Sample Data Validation Report
* **Appendix D:** Audit Trail Documentation