**Appendices and Supplemental Materials**

This section provides additional supporting documentation for the Phase 2 clinical trial of Novostatin (Novitor). It includes detailed subject listings, supplementary tables and figures that support the primary study report, and sample statistical outputs with programming code used for the analysis. These materials are provided to ensure full transparency and reproducibility of the study findings.

**Appendix A: Detailed Subject Data Listings**

**Sample Individual Subject Data Listing (n = 5 of 200)**

The following table presents sample individual subject data for key variables. The full listing (available as an Excel file in the study archive) contains data for all 200 randomized subjects.

| **Subject ID** | **Treatment Group** | **Age** | **Sex** | **Baseline LDL (mg/dL)** | **Week 24 LDL (mg/dL)** | **% Change in LDL** | **AEs Reported** | **Disposition** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| NS-001 | Novostatin | 55 | Male | 162 | 129 | -20.4% | Mild headache | Completed |
| NS-002 | Placebo | 60 | Female | 157 | 150 | -4.5% | None | Completed |
| NS-003 | Novostatin | 47 | Female | 158 | 125 | -20.9% | Mild GI discomfort | Completed |
| NS-004 | Novostatin | 63 | Male | 165 | 132 | -20.0% | Muscle cramps | Completed |
| NS-005 | Placebo | 52 | Male | 160 | 155 | -3.1% | None | Completed |

*Note: Full dataset includes additional demographics, safety labs, and pharmacokinetic parameters.*

**Appendix B: Additional Tables and Figures**

**Table B1: Subgroup Analysis of LDL Reduction by Age Group**

| **Age Group (Years)** | **Novostatin (n)** | **Mean % LDL Reduction** | **Placebo (n)** | **Mean % LDL Reduction** | **p-value** |
| --- | --- | --- | --- | --- | --- |
| 18–45 | 30 | -19.8% | 28 | -4.2% | < 0.001 |
| 46–60 | 40 | -20.7% | 42 | -5.0% | < 0.001 |
| >60 | 30 | -21.2% | 30 | -4.8% | < 0.001 |

**Figure B1: LDL Cholesterol Reduction Over Time**

*Description:*  
A line graph displaying the mean percentage change in LDL cholesterol from baseline to Week 24 for both Novostatin and placebo groups.  
*(The figure illustrates a clear divergence in LDL reduction between the two groups, with the Novostatin arm achieving a sustained reduction by Week 24.)*

**Figure B2: Kaplan–Meier Curve for Time to First AE**

*Description:*  
A Kaplan–Meier plot demonstrating the time to first reported adverse event for subjects in both treatment groups.  
*(The plot shows a similar safety profile between groups with only minor differences in the onset of AEs.)*

**Appendix C: Statistical Outputs and Programming Code**

**C1. Example Statistical Output (Summary Table for Primary Efficacy Endpoint)**

The following output was generated using SAS and R software for the ANCOVA model evaluating the primary endpoint (percentage change in LDL cholesterol).

**SAS Output Excerpt:**

java

Copy

PROC GLM DATA=analysis;

CLASS Treatment;

MODEL LDL\_Change = Baseline\_LDL Treatment;

MEANS Treatment / TUKEY;

RUN;

*Output Summary:*

* **Treatment Effect (Novostatin vs. Placebo):** Estimate = -15.7%, p < 0.001
* **Baseline LDL Coefficient:** Significant adjustment factor with p < 0.05.

**C2. R Code Snippet for Primary Endpoint Analysis**

r

Copy

# Load necessary libraries

library(tidyverse)

library(car)

# Read in dataset

data <- read.csv("Novostatin\_Phase2\_Data.csv")

# Fit ANCOVA model

ancova\_model <- aov(LDL\_PercentChange ~ Treatment + Baseline\_LDL, data = data)

summary(ancova\_model)

# Extract estimated mean differences

library(emmeans)

emmeans\_model <- emmeans(ancova\_model, ~ Treatment)

summary(emmeans\_model)

# Plot mean percentage change in LDL over time

ggplot(data, aes(x = Visit\_Week, y = LDL\_PercentChange, color = Treatment)) +

stat\_summary(fun = mean, geom = "line") +

stat\_summary(fun.data = mean\_se, geom = "errorbar", width = 0.2) +

labs(title = "Mean Percentage Change in LDL Cholesterol Over Time",

x = "Week", y = "LDL % Change")

*Output Summary:*

* **Estimated Mean LDL % Change (Novostatin):** -20.5%
* **Estimated Mean LDL % Change (Placebo):** -4.8%
* **p-value for Treatment Effect:** < 0.001

**Appendix D: Copies of Additional Supplementary Materials**

* **D1. Detailed CRF Listings:** Printed copies and electronic files of complete subject data listings.
* **D2. Central Laboratory Report:** Complete QC reports and raw data summaries from Central Lab Solutions Inc.
* **D3. Imaging Core Laboratory Report:** Detailed CIMT measurement reports and imaging quality assurance documentation.
* **D4. Audit Trail Documentation:** Summaries of data query resolutions and system audit trails.
* **D5. Regulatory Correspondence:** Copies of key communications with regulatory agencies regarding data analysis and trial conduct.

*These appendices and supplemental materials provide comprehensive documentation that underpins the findings reported in the Final Clinical Study Report for Novostatin (Novitor). The materials ensure transparency, reproducibility, and compliance with regulatory requirements as the study transitions to Phase 3 development.*

**Prepared by:**  
John Miller, Clinical Research Associate  
Date: 1/22/25

**Reviewed by:**  
Susan Roberts, Senior CRA  
Date: 1/22/25

**Approved by Investigator:**

Dr. Jane Doe  
Date: 1/22/25