Tables, Figures, and Listings

Mock Shells for Clinical Study Report

Study Title: A Phase I Study of Compound Y in Patients with Cardiovascular Disease

Protocol Number: XYZ-280

Sponsor: BioTech Laboratories

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Table of Contents

1.0 TABLES

Table 14.1.1: Demographics and Baseline Characteristics

Characteristic	Statistic	Treatment A (N=XX)	Treatment B (N=XX)	Total (N=XX)
Age (years)	n			
	Mean (SD)			
	Median			
	Min, Max			
Age Categories, n (%)				
<65 years	n (%)			
≥65 years	n (%)			
Sex, n (%)				
Male	n (%)			
Female	n (%)			
Race, n (%)				
White	n (%)			
Black or African American	n (%)			
Asian	n (%)			
Other	n (%)			
Ethnicity, n (%)				
Hispanic or Latino	n (%)			
Not Hispanic or Latino	n (%)			
Region, n (%)				
North America	n (%)			
Europe	n (%)			
Asia	n (%)			
Other	n (%)			
Weight (kg)	n			
	Mean (SD)			
	Median			
	Min, Max			
Height (cm)	n			

	Mean (SD)			
	Median			
	Min, Max			
BMI (kg/m²)	n			
	Mean (SD)			
	Median			
	Min, Max			

SD = standard deviation; BMI = body mass index
Note: Percentages are based on the number of patients in the analysis population within each treatment group.

Table 14.1.2: Medical History

Medical History System Organ Class Preferred Term	Treatment A (N=XX) n (%)	Treatment B (N=XX) n (%)	Total (N=XX) n (%)
Blood and lymphatic system disorders			
Anemia			
Leukopenia			
Thrombocytopenia			
Cardiac disorders			
Atrial fibrillation			
Hypertension			
Palpitations			
Ear and labyrinth disorders			
Endocrine disorders			
Eye disorders			

Note: Medical history was coded using MedDRA version XX.X. A patient with multiple events within a category is counted only once in that category. Percentages are calculated based on the number of patients in the safety population.

Table 14.2.1: Primary Efficacy Analysis - Change from Baseline at Week 12

	Treatment A (N=XX)	Treatment B (N=XX)	Difference (95% CI)	p-value
Primary Endpoint				
n				
Baseline, Mean (SD)				
Week 12, Mean (SD)				
Change from Baseline, Mean (SD)				
LS Mean (SE)				
LS Mean Difference (SE)				
95% CI				
p-value				

CI = confidence interval; LS = least squares; SD = standard deviation; SE = standard error
Note: The primary analysis was based on a mixed model for repeated measures (MMRM) with treatment, visit, treatment-by-visit interaction, baseline value, and baseline-by-visit interaction as fixed effects.

Table 14.3.1: Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

System Organ Class Preferred Term	Treatment A (N=XX) n (%)	Treatment B (N=XX) n (%)	Total (N=XX) n (%)
Patients with at least one TEAE			
Blood and lymphatic system disorders			
Cardiac disorders			
Gastrointestinal disorders			
Abdominal pain			
Constipation			
Diarrhea			
Nausea			
Vomiting			
General disorders and administration site conditions			
Infections and infestations			
Nervous system disorders			
Dizziness			
Headache			
Somnolence			

TEAE = treatment-emergent adverse event
Note: Adverse events were coded using MedDRA version XX.X. A patient with multiple events within a category is counted only once in that category. Percentages are calculated based on the number of patients in the safety population.

Table 14.3.2: Summary of Laboratory Test Results - Change from Baseline

Parameter	Visit	Statistic	Treatment A (N=XX)	Treatment B (N=XX)
Hematology				
Hemoglobin (g/dL)	Baseline	n		
		Mean (SD)		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
White Blood Cell Count (10^9/L)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		

		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
Chemistry				
ALT (U/L)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
AST (U/L)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		

		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
Creatinine (mg/dL)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	

ALT = alanine aminotransferase; AST = aspartate aminotransferase; SD = standard deviation
Note: Laboratory values were analyzed based on the safety population.

Table 14.3.3: Summary of Vital Signs - Change from Baseline

Parameter	Visit	Statistic	Treatment A (N=XX)	Treatment B (N=XX)
Systolic Blood Pressure (mmHg)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
Diastolic Blood Pressure (mmHg)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		

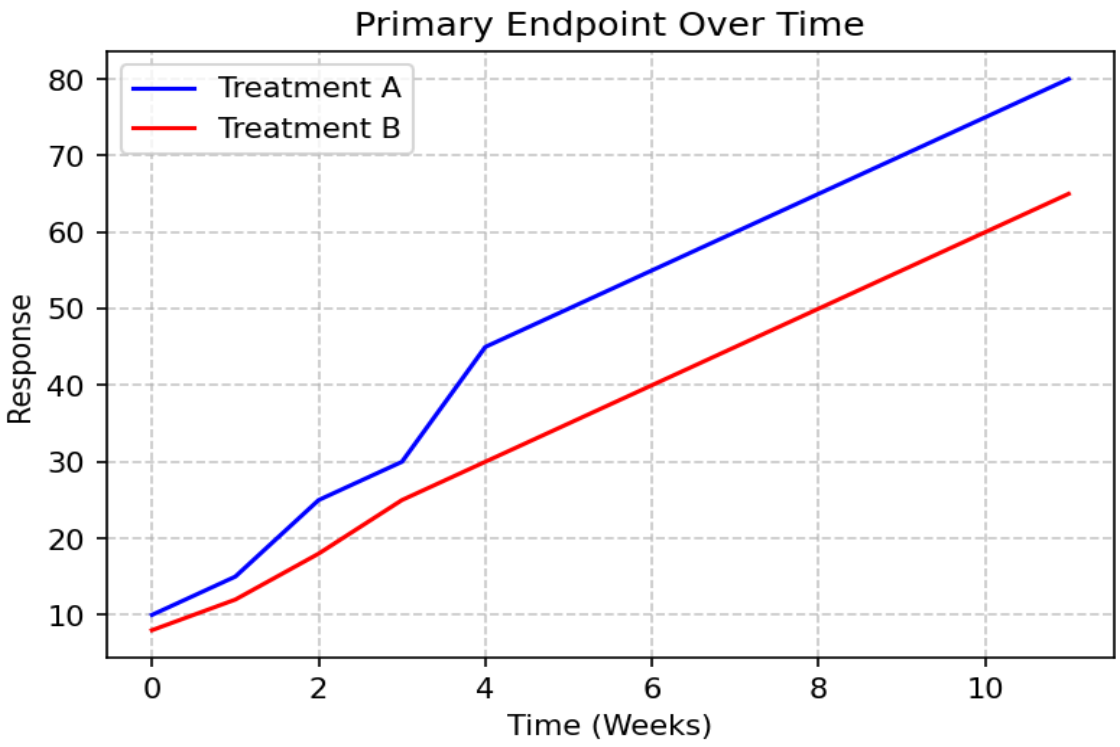
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
Heart Rate (bpm)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
Respiratory Rate (breaths/min)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		

		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
Temperature (°C)	Baseline	n		
		Mean (SD)		
		Median		
		Min, Max		
	Week 4	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 8	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	
	Week 12	n		
		Mean (SD)		
		Median		
		Min, Max		
		Change from Baseline,	Mean (SD)	

SD = standard deviation
Note: Vital signs were analyzed based on the safety population.

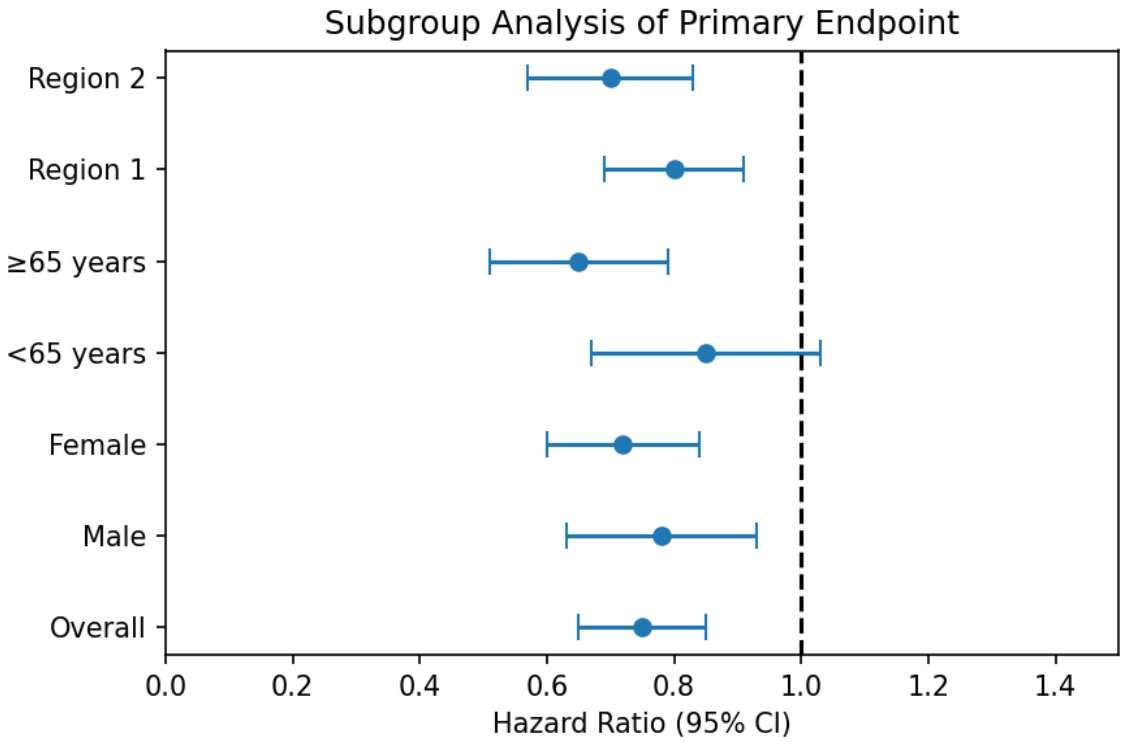
2.0 FIGURES

Figure 14.2.1: Primary Endpoint Over Time



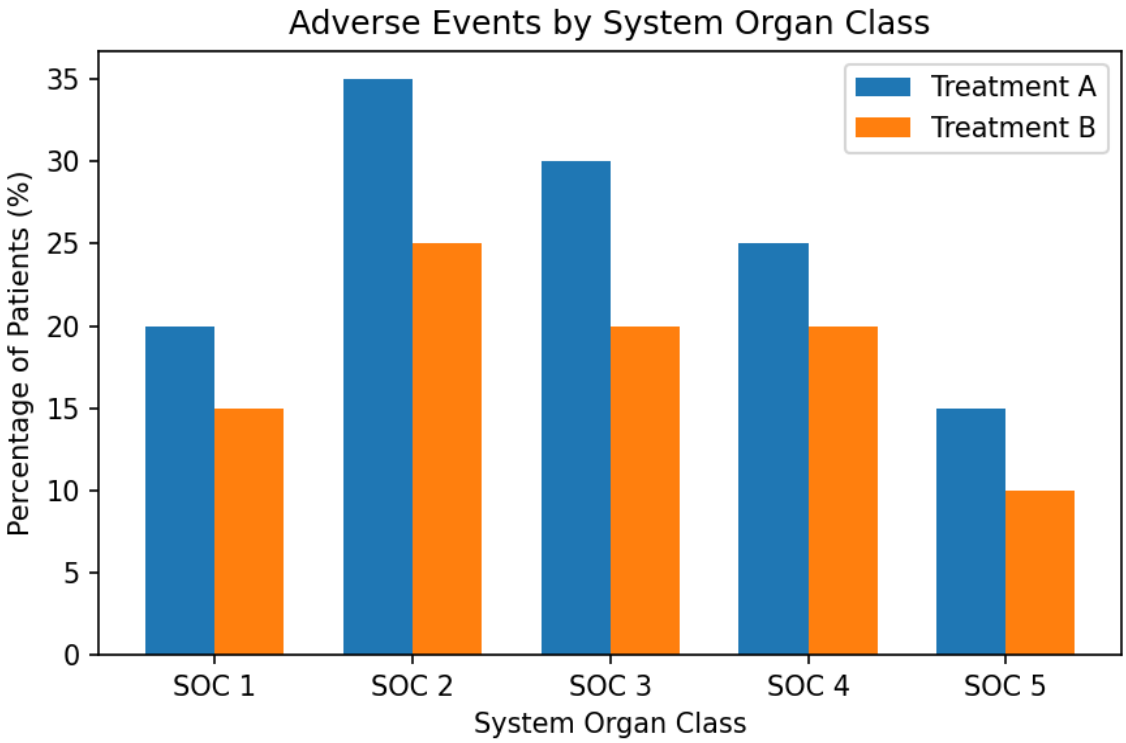
Note: Error bars represent standard error of the mean.

Figure 14.2.2: Subgroup Analysis of Primary Endpoint



Note: Hazard ratios and 95% confidence intervals shown. Values less than 1.0 favor treatment.

Figure 14.3.1: Adverse Events by System Organ Class



Note: Only adverse events occurring in ≥5% of patients in any treatment group are shown.

3.0 LISTINGS

Listing 16.2.1: Patient Disposition

Study Identifier	Treatment Group	Patient Identifier	Randomized	Completed Study	Reason for Discontinuation

Note: This listing provides patient disposition information for all randomized patients.

Listing 16.2.2: Protocol Deviations

Study Identifier	Center Number	Patient Identifier	Treatment Group	Visit	Date	Protocol Deviation Category	Protocol Deviation Description	Major/ Minor

Note: This listing provides protocol deviation information for all patients in the study.

Listing 16.2.3: Patients Excluded from Analysis Populations

Study Identifier	Center Number	Patient Identifier	Treatment Group	Excluded Population	Reason for Exclusion

Note: This listing provides information on patients excluded from analysis populations.

Listing 16.2.4: Demographic Data

Study Identifier	Center Number	Patient Identifier	Treatment Group	Age (years)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m²)

BMI = body mass index
Note: This listing provides demographic information for all randomized patients.

Listing 16.2.5: Concomitant Medications

Study Identifier	Center Number	Patient Identifier	Treatment Group	Medication Name	Indication	Start Date	Stop Date	Ongoing at Study End	Dose	Frequency	Route

Note: Concomitant medications include any medication taken during the treatment period.

Listing 16.2.6: Individual Efficacy Response Data

Study Identifier	Center Number	Patient Identifier	Treatment Group	Visit	Visit Date	Parameter 1	Parameter 2	Parameter 3	Parameter 4

Note: This listing provides individual efficacy data for patients in the full analysis set.

Listing 16.2.7: Adverse Event Listings

Study Identifier	Center Number	Patient Identifier	Treatment Group	System Organ Class	Preferred Term	Start Date	End Date	Ongoing	Severity	Serious	Related to Study Drug	Action Taken	Outcome

Note: Adverse events were coded using MedDRA version XX.X.

Listing 16.2.8: Individual Laboratory Measurements

Study Identifier	Center Number	Patient Identifier	Treatment Group	Visit	Visit Date	Laboratory Parameter	Result	Units	Reference Range	Clinically Significant Abnormality

Note: Out-of-range values are flagged in the clinically significant abnormality column.