Table 1.1 Incidence of AEs by Preferred Term and System Organ Class

System Organ Class	Preferred Term	Treatment Group 1 (N=X)	Treatment Group 2 (N=Y)
Any System Organ Class			
	Any Preferred Term	n (%)	n (%)
Blood and Lymphatic System Disorders			
	Anemia	n (%)	n (%)
	Neutropenia	n (%)	n (%)
Gastrointestinal Disorders			
	Diarrhea	n (%)	n (%)
	Nausea	n (%)	n (%)
	Vomiting	n (%)	n (%)
General Disorders and Administration Site Conditions			
	Fatigue	n (%)	n (%)
	Pyrexia	n (%)	n (%)
Nervous System Disorders			
	Headache	n (%)	n (%)
	Dizziness	n (%)	n (%)
Skin and Subcutaneous Tissue Disorders			
	Rash	n (%)	n (%)

	Pruritus	n (%)	n (%)

AE: Adverse event
Adverse events before treatment start date are not considered.
AE's also include treatment emergent events.

Table 1.2 Incidence of Serious AEs by Preferred Term and System Organ Class

System Organ Class	Preferred Term	Treatment Group 1 (N=X)	Treatment Group 2 (N=Y)
Any System Organ Class			
	Any Preferred Term	n (%)	n (%)
Blood and Lymphatic System Disorders			
	Anemia	n (%)	n (%)
	Neutropenia	n (%)	n (%)
Gastrointestinal Disorders			
	Diarrhea	n (%)	n (%)
	Nausea	n (%)	n (%)
	Vomiting	n (%)	n (%)
General Disorders and Administration Site Conditions			
	Fatigue	n (%)	n (%)
	Pyrexia	n (%)	n (%)
Nervous System Disorders			
	Headache	n (%)	n (%)
	Dizziness	n (%)	n (%)

Skin and Subcutaneous Tissue Disorders			
	Rash	n (%)	n (%)
	Pruritus	n (%)	n (%)

AE: Adverse event
Serious AE: Serious Adverse event
Adverse events before treatment start date are not considered.
AE's also include treatment emergent events.

Table 1.3 Incidence of AEs Leading to Discontinuation by Preferred Term and System Organ Class

System Organ Class	Preferred Term	Treatment Group 1 (N=X)	Treatment Group 2 (N=Y)
Any System Organ Class			
	Any Preferred Term	n (%)	n (%)
Blood and Lymphatic System Disorders			
	Anemia	n (%)	n (%)
	Neutropenia	n (%)	n (%)
Gastrointestinal Disorders			
	Diarrhea	n (%)	n (%)
	Nausea	n (%)	n (%)
	Vomiting	n (%)	n (%)
General Disorders and Administration Site Conditions			
	Fatigue	n (%)	n (%)
	Pyrexia	n (%)	n (%)

Nervous System Disorders			
	Headache	n (%)	n (%)
	Dizziness	n (%)	n (%)
Skin and Subcutaneous Tissue Disorders			
	Rash	n (%)	n (%)
	Pruritus	n (%)	n (%)

AE: Adverse event
Adverse events leading to discontinuation
Adverse events before treatment start date are not considered.
AE's also include treatment emergent events.

Table 2.1 Summary of Laboratory Values - Hematology

Parameter	Statistic	Treatment Group 1 (N=X)	Treatment Group 2 (N=Y)
Hemoglobin (g/dL)	N		
	Mean (SD)		
	Median		
	Min, Max		
White Blood Cell Count (x10^9/L)	N		
	Mean (SD)		
	Median		
	Min, Max		
Platelet Count (x10^9/L)	N		
	Mean (SD)		

	Median		
	Min, Max		

Summary statistics for laboratory parameters.
Values presented at baseline and each post-baseline visit.

Table 2.2 Summary of Laboratory Values - Chemistry

Parameter	Statistic	Treatment Group 1 (N=X)	Treatment Group 2 (N=Y)
Alanine Aminotransferase (U/L)	N		
	Mean (SD)		
	Median		
	Min, Max		
Aspartate Aminotransferase (U/L)	N		
	Mean (SD)		
	Median		
	Min, Max		
Total Bilirubin (µmol/L)	N		
	Mean (SD)		
	Median		
	Min, Max		
Creatinine (µmol/L)	N		
	Mean (SD)		
	Median		

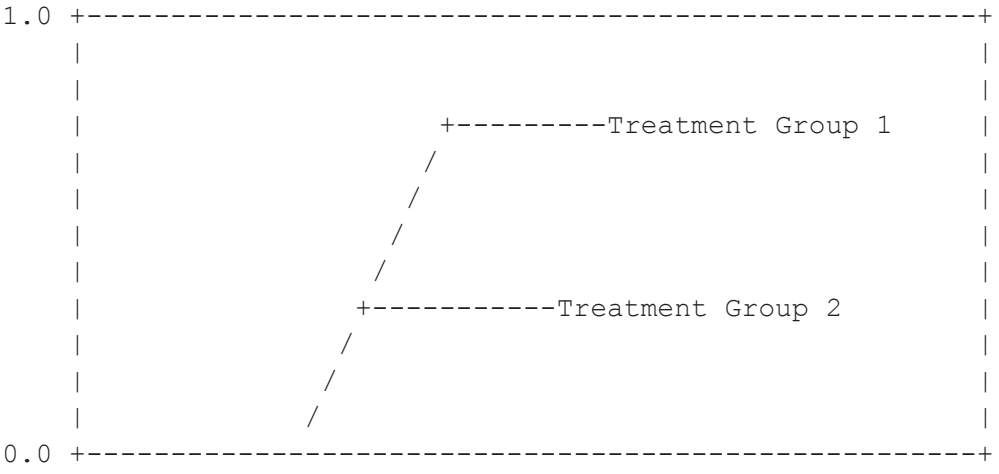
	Min, Max		

Summary statistics for laboratory parameters.
Values presented at baseline and each post-baseline visit.

Table 2.3 Summary of Laboratory Values - Urinalysis

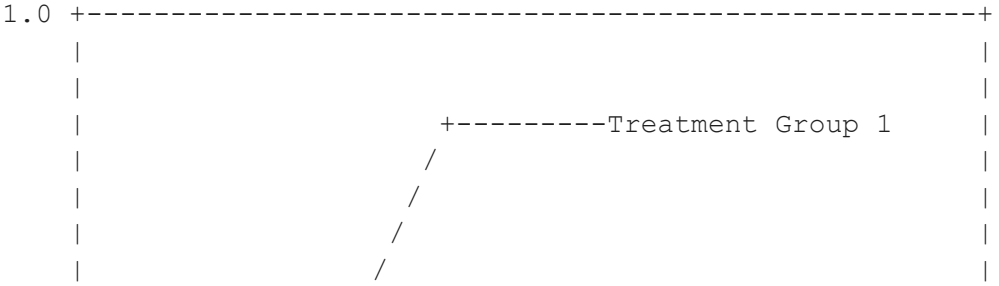
Parameter	Statistic	Treatment Group 1 (N=X)	Treatment Group 2 (N=Y)
Protein (Qualitative)	N		
	Negative	n (%)	n (%)
	Trace		

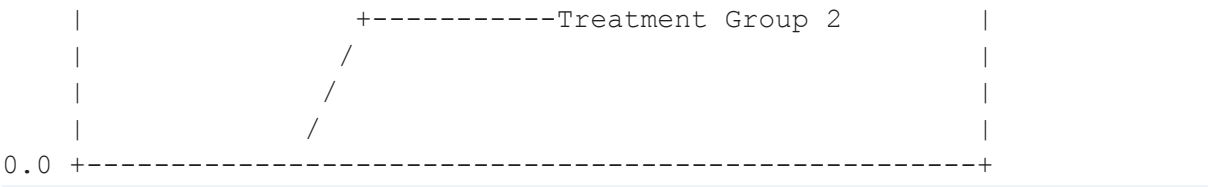
Figure 2.2 Kaplan-Meier Plot for Time to Discontinuation Due to Adverse Event



X-axis: Time (Days)
Y-axis: Probability of No Discontinuation
Description: Kaplan-Meier plot showing the probability of not discontinuing due to an adverse event over time for each treatment group.

Figure 2.3 Kaplan-Meier Plot for Overall Survival





X-axis: Time (Days)

Y-axis: Overall Survival Probability

Description: Kaplan-Meier plot showing the overall survival probability over time for each treatment group.