

Understanding clinical data

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1 Find the dataset names and explain their content

Dataset	Dataset name	Content? What is this data used for? It's significance if any?
AE		
DS		
LB		
QS		
VS		
CM		
DM		
MH		
EX		
QS		
SV		
SE		
ADAE		
ADLBC		
ADLBH		

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Dataset	Dataset name	Content? What is this data used for? It's significance if any?
ADLBHY		
ADSL		
ADTTR		
ADVS		
ADQSCIBC		
ADQSNPIX		

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2 Solve the following questions

2.1 Questions on Baseline, disposition and demography

Sr. no.	Questions	Response
1	Find the total number of patients in the study	
2	Find total number of patients with age > 65 years	
3	Find total number of males and females	
4	How many patients discontinued the trial?	
5	Classify the reason for discontinuation with the no. of patients with the reason.	
6	Classify the no. of patients by the treatment taken.	
7	Did the study have screen failure? If yes then how many?	
8	Classify the patients by their Race and ethnicity	
9	Identify the different doses administered to the patients	

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2.2 Questions on Vital signs

Sr. no.	Questions	Response
1	Find different vital sign parameters captured in the database	
2	Find average of baseline values for supine diastolic blood pressure by different treatment groups	
3	Find average of week 4 values for supine systolic blood pressure after 5 minutes of lying down	
4	Find the units for different vital signs parameters	

2.3 Questions on Concomitant medication

Sr. no.	Questions	Response
1	How many patients took additional medication apart from the drug of interest during the course of the clinical trial?	
2	How many patients started these medications prior to the start of the clinical trial drug?	
3	Find the total number of patients taking drug for Respiratory system.	
4	Find no. of times medication was taken for Respiratory system.	

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Sr. no.	Questions	Response
5	Find the total number of patients taking treatment for ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS?	
6	Find the total number of patients taking alternate medicine other than the study drug during the course of the trial?	

2.4 Questions on Adverse Events

Sr. no.	Questions	Response
1	Find the total number of patients experiencing Adverse Event.	
2	Find the number of patients with Eye disorder by treatment	
3	Find the Adverse events which were severe and serious Which treatment were they related to these?	
4	What are the different types of relationship between study drug and Adverse events?	
5	State the patient ids who has serious Adverse Events and what was the outcome of these Adverse Events	
6	How many patients had Adverse Event starting on Day 24 post the intervention?	
7	Find different Actions taken due to Adverse Events.	

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2.5 Questions on Laboratory data

Sr. no.	Questions	Response
1	Find total number of patients with both baseline and post-baseline “Week 26” information present for the parameter Glucose	
2	Find the total number of patients who had high Creatinine value for baseline and became normal at the End of Treatment visit	
3	Find the number of patients with both baseline and “End of Treatment” non-missing for Hemoglobin values	
4	Find the number of patients with non-missing baseline value for Albumin, classify by treatment	
5	Find the patients with Bilirubin value greater than 1.5XULN	
6	What does “HEM” and “CHEM” stand for in the PARCAT1 variable in the dataset?	
7	Find the total number of patients who had high Basophil counts for baseline and became normal at the End of Treatment visit	