

# Capstone Project

(Background and Objectives)

BIOSTATISTICS IN CLINICAL TRIALS

# Background

## 1. Background

Indication: Low Back Pain ( LBP)

Parallel, double blind,Multicentric Phase III Clinical Trial ( 4 centers)

Number of treatments: 03

Treatments: Test, Reference and Placebo

Sample Size: n=780

Visits: Day 1( V1), Day 3( V2) and Day 7(V3)

Primary End Point: Visual Analogue Scale (VAS)  
Scale: 0-100 mm

# Study Objectives

## 2. Primary Objectives

1. **Analyze** demographics and baseline characteristics of subjects/patients
2. Compare treatments under study using statistical model  
( Test vs Placebo- Superiority Testing  
Test vs Reference-Equivalence Testing)
3. **Perform sub-group analysis to get more clinical insights**
4. Assess safety parameters such as adverse events

# Data Sets

## 3. Data

The following datasets are available:

1. Randomization
2. Study Populations
3. Patient demographics
4. Baseline Characteristics
5. Vital Signs
6. VAS Data
7. AE data
- 8. Global Assessment**

# Data : Randomization

Patient_ID	Treatment	Center
PID/001	PLACEBO	C1
PID/002	TEST	C3
PID/003	TEST	C2
PID/004	TEST	C1
PID/005	PLACEBO	C1
PID/006	PLACEBO	C4

Columns	Description	Type	Measurement	Possible values
Pateint_ID	Patient ID	Alpha numeric	-	-
Treatment	Treatment given	Factor	-	Placebo, Test and Ref
Center	Study Center	Factor	-	C1, C2, C3 and C4

## Data : Study Populations

Patient_ID	ITT	PP
PID/001	YES	YES
PID/002	YES	YES
PID/003	YES	YES
PID/004	YES	YES
PID/005	YES	YES
PID/006	YES	YES

Columns	Description	Type	Measurement	Possible values
Patient_ID	Patient ID	Alpha numeric	-	-
ITT	Intent to treat population	Factor	-	Yes or No
PP	Per protocol population	Factor	-	Yes or No

Per Protocol population is a subset of Intent to Treat population. Subjects in PP population completed the study without any major pr

# Data :Demographics

Patient_ID	Age	Gender
PID/001	24	Female
PID/002	25	Male
PID/003	22	Female
PID/004	54	Female
PID/005	57	Male
PID/006	22	Male

Columns	Description	Type	Measurement	Possible values
Patient_ID	Patient ID	Alpha numeric	-	-
Age	Age	numeric	-	-
Gender	Gender	Factor	-	Male or Female

## Data : Baseline Characteristics

Patient_ID	Work	Surgery_1Y
PID/001	FT	NO
PID/002	FT	NO
PID/003	FT	NO
PID/004	FT	NO
PID/005	FT	NO
PID/006	FT	NO

Columns	Description	Type	Measurement	Possible values
Patient_ID	Patient ID	Alpha numeric	-	-
Work	Nature of work	Factor	-	FT, PT, No
Surgery_1Y	Any surgery in last 1 year	Factor	-	Yes or No



# Data : Vital Signs

Patient_ID	PR	Pulse rate (beats/min)	RR	Respiratory rate (breaths/min)	SBP	Systolic blood pressure (mmHg)	DBP	Diastolic blood pressure (mmHg)
PID/001	77	BEATS/MIN	16	BREATHS/MIN	110	MMHG	80	MMHG
PID/002	74	BEATS/MIN	17	BREATHS/MIN	122	MMHG	70	MMHG
PID/003	86	BEATS/MIN	14	BREATHS/MIN	120	MMHG	80	MMHG
PID/004	84	BEATS/MIN	16	BREATHS/MIN	124	MMHG	82	MMHG
PID/005	84	BEATS/MIN	15	BREATHS/MIN	110	MMHG	80	MMHG
PID/006	78	BEATS/MIN	17	BREATHS/MIN	118	MMHG	80	MMHG

Columns	Description	Type	Possible values
Patient_ID	Patient ID	Alpha numeric	-
PR	Pulse rate	numeric	-
Pulse rate(beats/min)	Pulse rate units	Character	-
RR	Respiratory rate	numeric	-
Respiratory rate(breaths/min)	Respiratory rate units	Character	-
SBP	Systolic blood pressure	numeric	-
Systolic blood pressure(mmHg)	Systolic blood pressure rate	Character	-
DBP	Diastolic blood pressure	numeric	-
Diastolic blood pressure(mmHg)	Diastolic blood pressure rate	Character	-

## Data : VAS Data

Patient_ID	Day	VAS
PID/001	DAY1	72
PID/002	DAY1	70
PID/003	DAY1	66
PID/004	DAY1	23
PID/005	DAY1	65
PID/006	DAY1	61

Columns	Description	Type	Measurement	Possible values
Patient_ID	Patient ID	Alpha numeric	-	-
Day	Day of measurement	Factor	-	Day 1 to Day 7
VAS	Visual Analogue Scale	numeric	-	0 to 100

## Data : AE Data

Patient_ID	AE	AE_REL	AE_SEVERITY
PID/001	NONE		
PID/002	NONE		
PID/003	NONE		
PID/004	NONE		
PID/005	NONE		
PID/006	NONE		
PID/007	Gastritis	NOT RELATED	MILD

Columns	Description	Type	Measurement	Possible values
Patient_ID	Patient ID	Alpha numeric	-	-
AE	Adverse event	Character	-	
AE_REL	Relation to drug	Factor		Not related, probable, possible, definite
AE_SEVERITY	AE severity	Factor		Mild, moderate, severe, very severe

# Data : Global Assessment

Patient_ID	PGA
PID/001	2
PID/002	4
PID/003	4
PID/004	4
PID/005	1
PID/006	1

Columns	Description	Type	Possible values
Patient_ID	Patient ID	Alpha numeric	-
PGA	Patient Global Assessment 5-point scale	Factor	0 = Worse, 1 = No Change, 2 = Somewhat Better, 3 = Better, and 4 = Much Better