

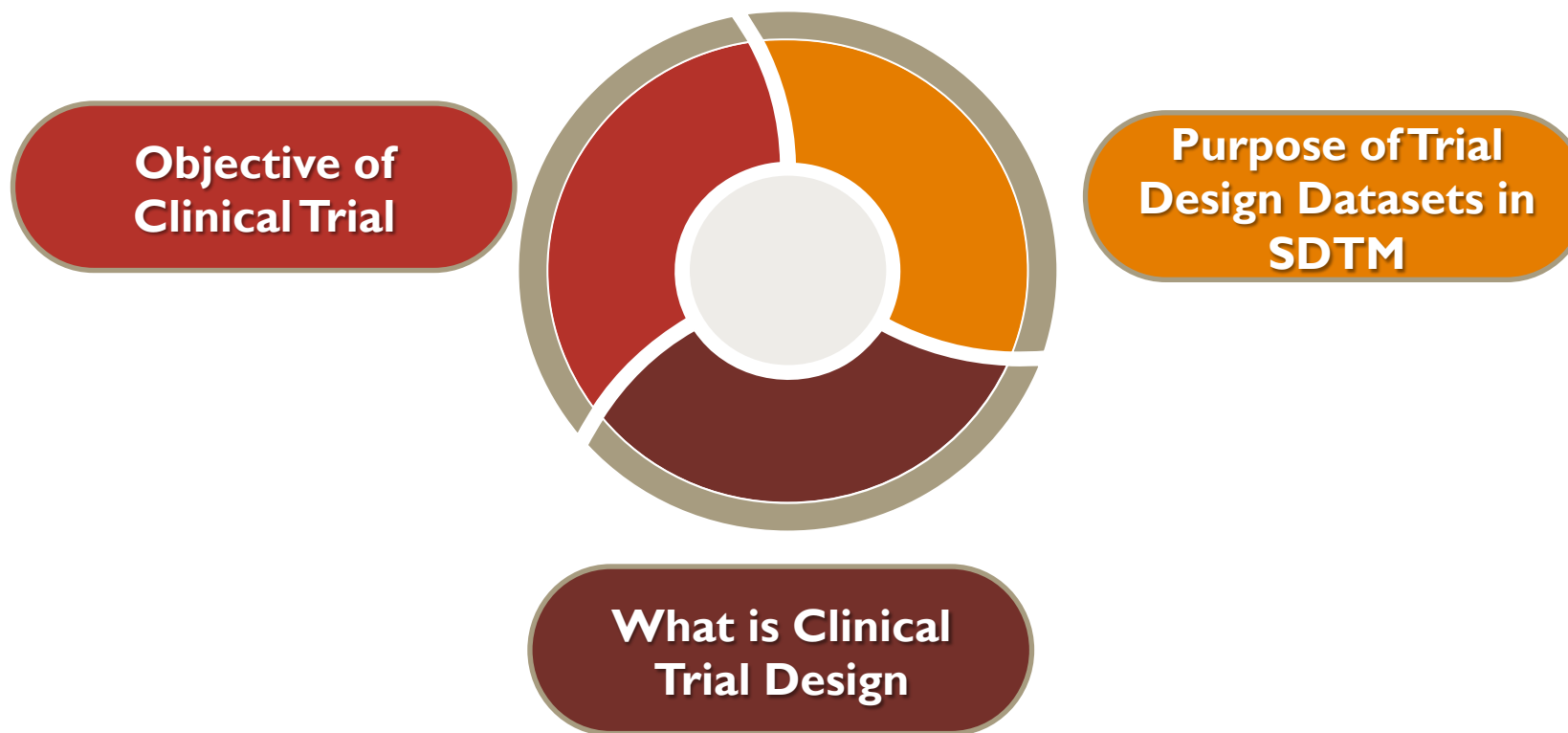
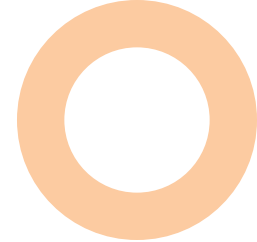
A decorative graphic on the left side of the slide. It consists of a collection of hexagons arranged in a non-uniform, honeycomb-like pattern. Most of the hexagons are white with a thin grey outline. One hexagon, located in the upper-middle part of the pattern, is solid orange. The pattern is more dense on the left and right sides and more sparse in the center.

Decrypting SDTM Trial Design Datasets for Complex Study Designs

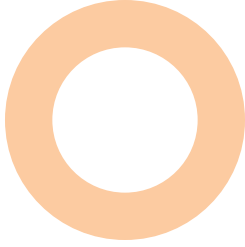
Presented By: **Charumathy Sreeraman**

Date : 09-OCT-2017

Introduction



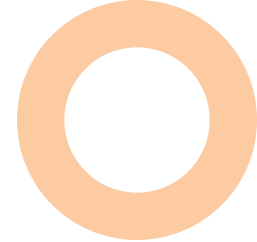
Study Protocol – *its contribution & significance*



- ❑ First document of the clinical trial
- ❑ Contents of protocol
 - *Title*
 - *information about the drug under study*
 - *study objective(s)*
 - *the study design (e.g., blinded, crossover)*
 - *inclusion and exclusion criteria*
 - *a schedule of visits with planned activities at each visit.*

- ❑ Enhancement of scientific integrity of the research
- ❑ Prescribing and initiating the study documentation
- ❑ Increasing the total work effort
- ❑ Serving as strong communication link.
- ❑ The clinical trial protocol provides the design for the study conduct and sets out the endpoints of the study up-front.
- ❑ There is clear guidance on how and when to measure and evaluate the study endpoints.

Study Design



01

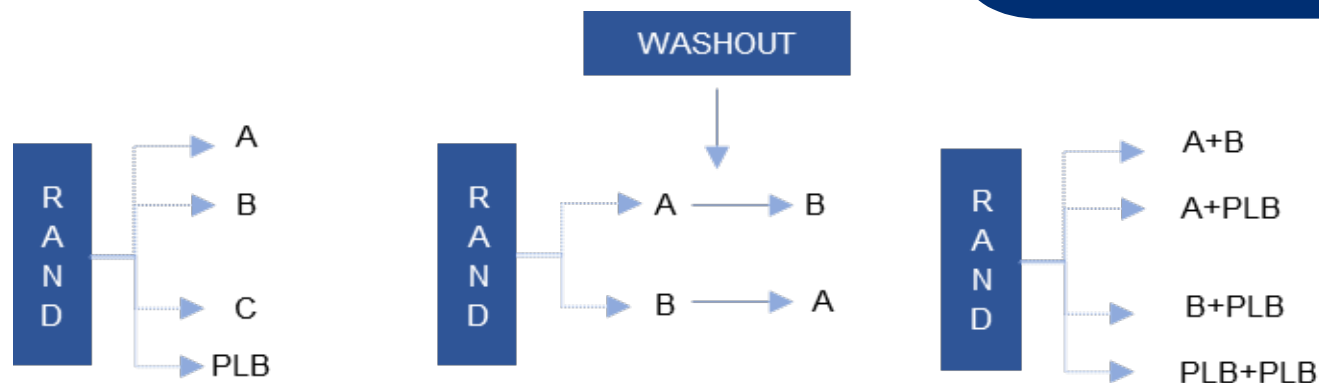
Study Design is a critical activity in the lifecycle of a clinical research study.

02

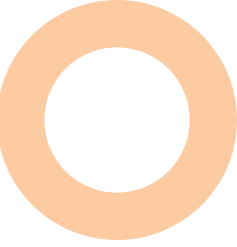
It is the foundational blueprint for the execution of the study, forming the basis for the study protocol.

03

The function of a trial design is to ensure that the evidence obtained enables you to effectively address the research problem logically and as unambiguously as possible.



Trial Design Model Domains



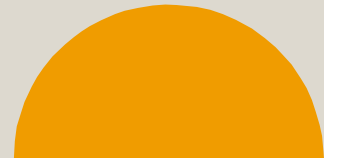
Special purpose dataset



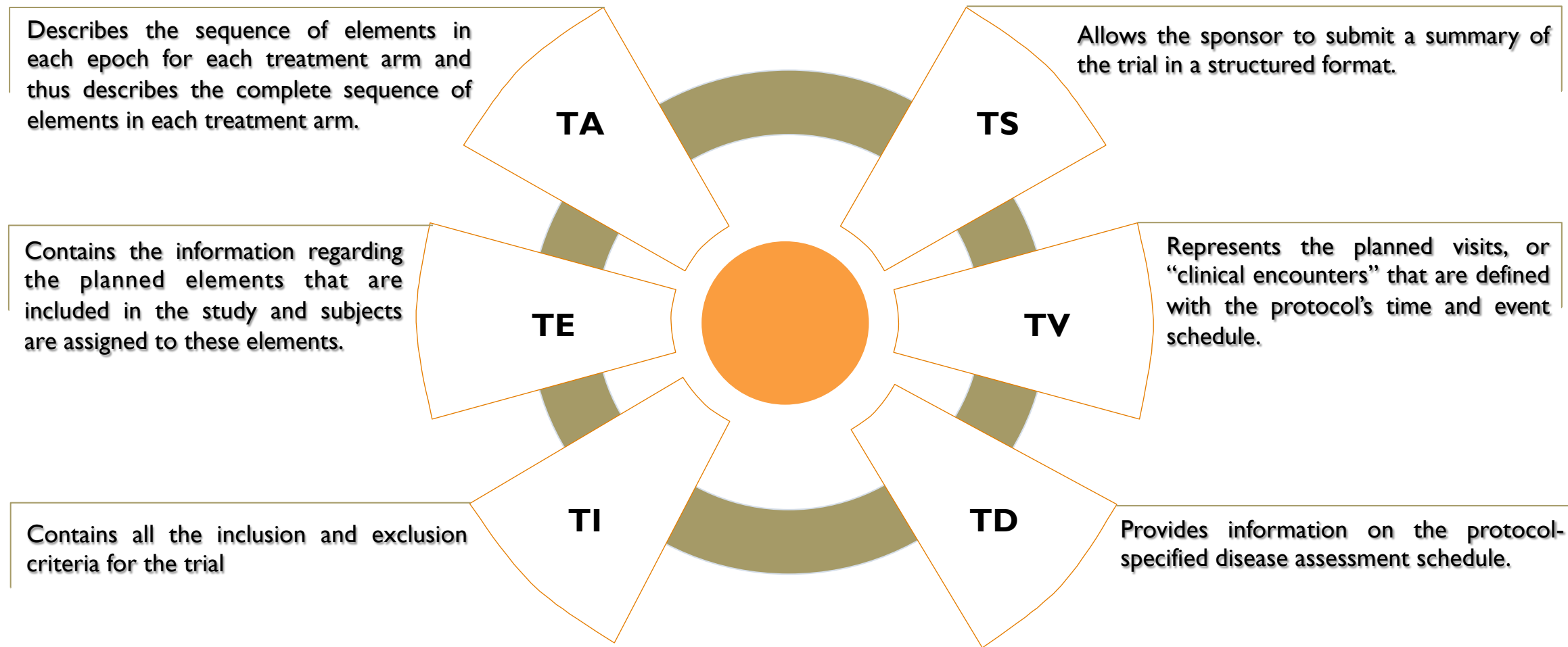
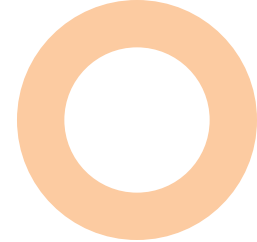
Represents information about the study design but do not contain subject data.



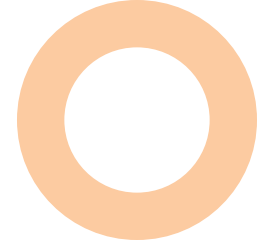
It is to provide the clear description of overall plan and design of the study basically the Clinical study report in the data form.



Trial Design Domains



Trial Design Basics



Element

Building block for creating study cells

An interval of time in the planned conduct of a study during which treatment is constant.

Epoch

Arm

Arm is composed of study cells

These are combination of Arm and Epoch. Each Study Cell represents an implementation of the purpose of its associated Epoch.

Study Cells

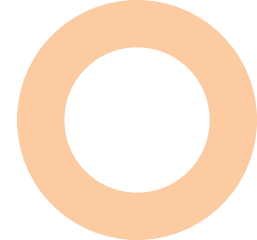
Visit

A clinical encounter that encompasses planned & unplanned trial interventions, procedures & assessments that may be performed on a subject.

An alternative format for representing most of the information in the diagram that shows Arms and Epochs, and emphasizes the Study Cells.

Trial Design Matrix

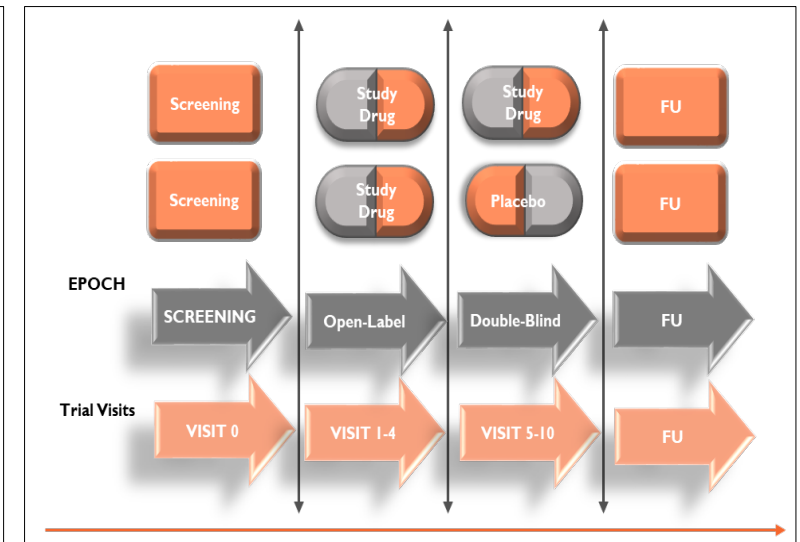
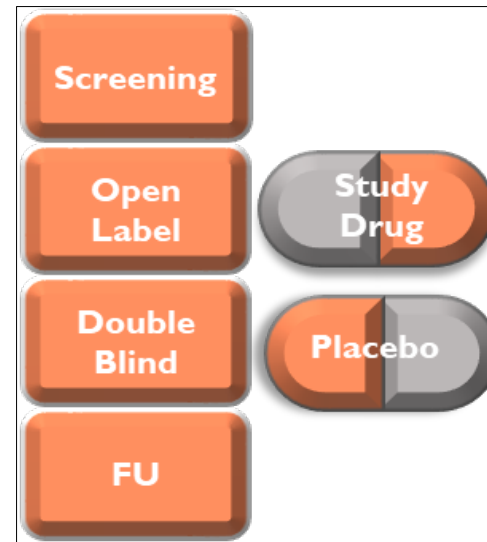
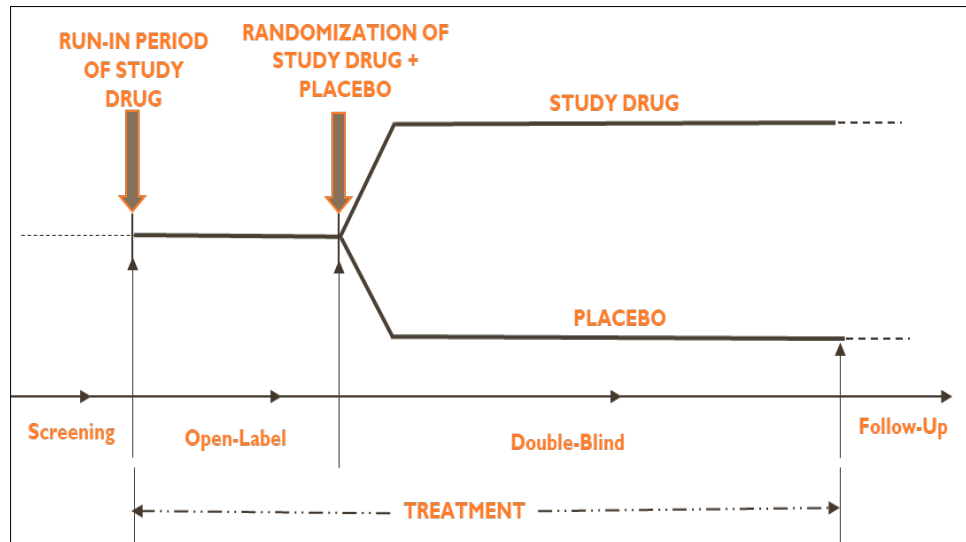
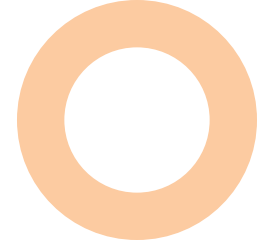
Case Study - TI



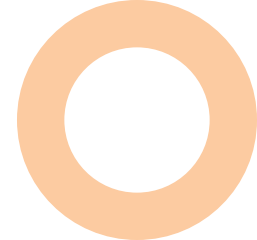
IETEST CD	IETEST	TIVERS
INCL01	The subject is 18 years of age or older.	Version I Amendment 3 dated 08DEC2013
INCL02	The subject agrees to use adequate contraception during the study period and for 12 weeks after the last dose of study therapy.	Version I Amendment 3 dated 08DEC2013
INCL03	The subject has provided signed informed consent.	Version I Amendment 3 dated 08DEC2013
EXCL01	The subject has a concurrent active malignancy other than adequately treated nonmelanomatous skin cancer / in situ neoplasm [Subject with a prior malignancy is eligible being disease-free for > 3 yrs.]	Version I Amendment 3 dated 08DEC2013
EXCL02	The subject has received treatment with agents specifically targeting the CSF-I or CSF-IR.	Version I Amendment 3 dated 08DEC2013
EXCL03	The subject has an active infection; symptomatic congestive heart failure; uncontrolled hypertension; unstable angina pectoris; serious cardiac arrhythmia; active bleeding or any serious medical disorders	Version I Amendment 3 dated 08DEC2013

IETESTCD	IETEST	TIVERS
INCL01	The subject is 18 years of age or older.	Version 7 dated 20APR2015
INCL02A	The subject has CK within normal limits.	Version 7 dated 20APR2015
INCL03A	The subject agrees to use adequate contraception during the study period and for 12 weeks after the last dose of study therapy.	Version 7 dated 20APR2015
EXCL01A	Patient receiving conc trt with other anticancer therapy, including chemotherapy/immunotherapy/hormonal therapy/radiotherapy/chemoembolization/targeted therapy/invest agent <4weeks prior to study entry	Version 7 dated 20APR2015
EXCL02A	The subject has received treatment with agents specifically targeting the CSF-I or CSF-IR including (but not limited to) imatinib, nilotinib, and sunitinib	Version 7 dated 20APR2015
EXCL03A	Subjects with known muscle damage due to a primary, traumatic, or other muscle disease.	Version 7 dated 20APR2015

Case Study - I



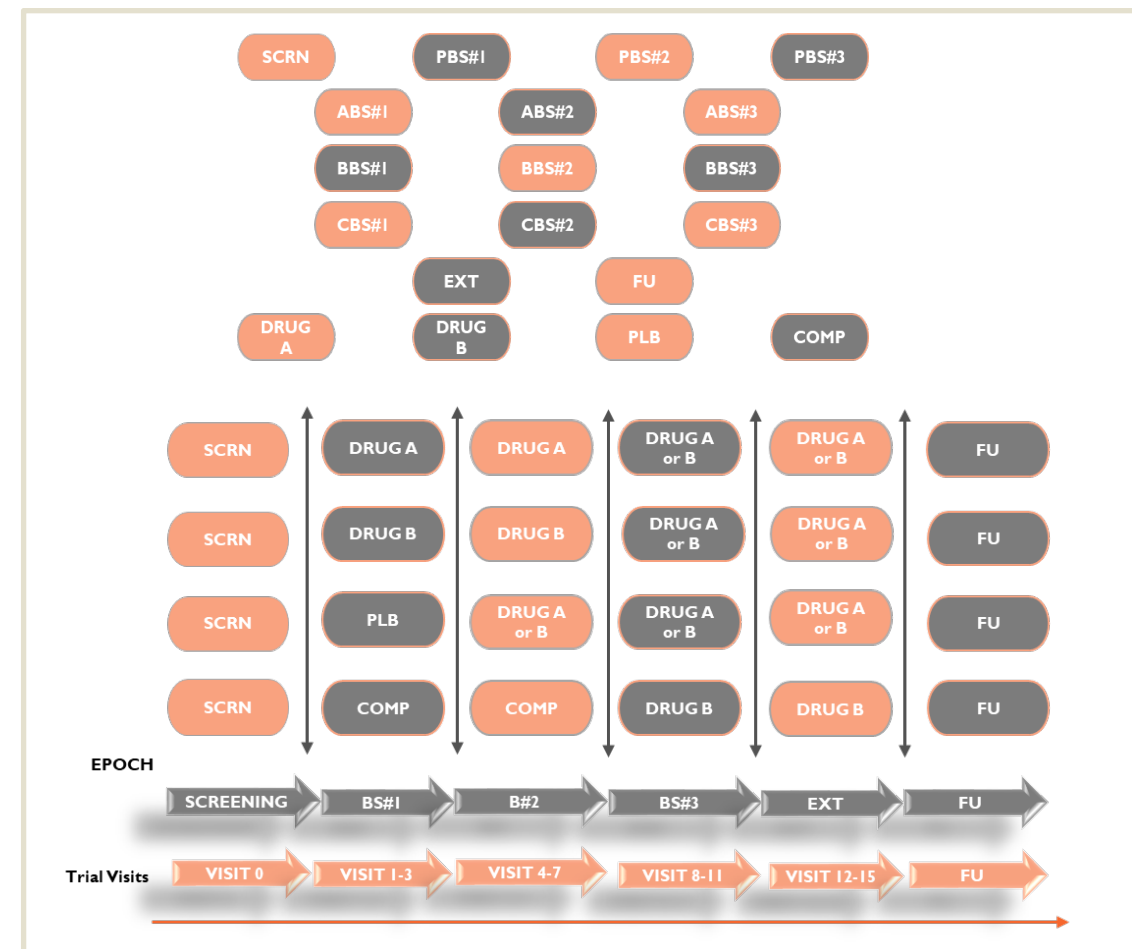
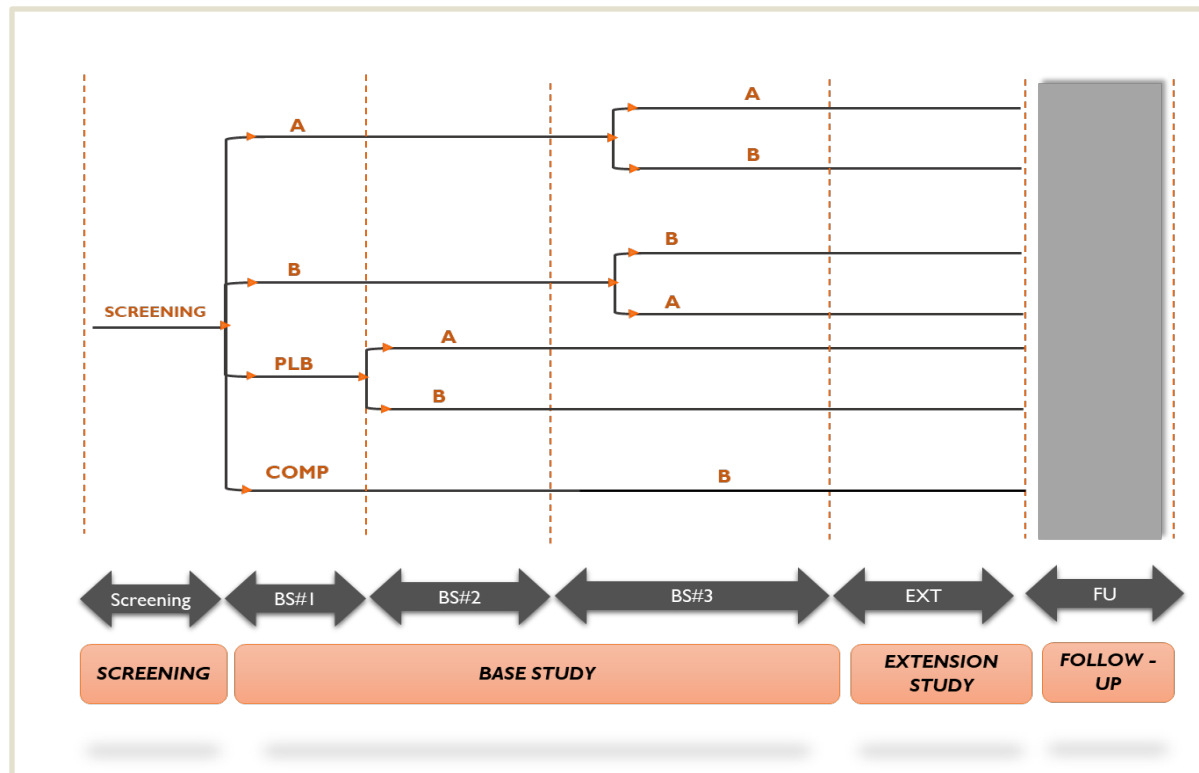
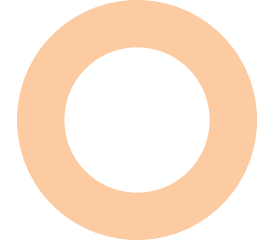
TE & TA Datasets



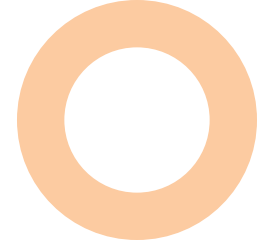
ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
SCRN	SCREENING	Informed consent	5 days after start of the element	P5D
OL	OPEN-LABEL	First dose of study drug	4 weeks after start of the element	P4W
DB	DOUBLE-BLIND	First dose of study drug after randomization	8 weeks after start of the element	P8W
DB	DOUBLE-BLIND	First dose of placebo after randomization	8 weeks after start of the element	P8W
FU	FOLLOW-UP	24 hrs after last dose of study drug/placebo administration	30 days after start of the element	P30D

ARMCD	ARM	ETCD	ELEMENT	TABRANCH	EPOCH
PLB	Placebo	SCRN	Screening		Screening
PLB	Placebo	OL	Open-Label		Treatment
PLB	Placebo	DB	Double-Blind	Randomized to Placebo	Treatment
PLB	Placebo	FU	Follow-Up		Follow-Up
SD	Study Drug	SCRN	Screening		Screening
SD	Study Drug	OL	Open-Label		Treatment
SD	Study Drug	DB	Double-Blind	Randomized to Study Drug	Treatment
SD	Study Drug	FU	Follow-Up		Follow-Up

Case Study - II



TE & TA Datasets



ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
SCRN	SCREENING	INFORMED CONSENT	5 DAYS AFTER START OF THE ELEMENT	P5D
PBS #1	PLACEBO BS PART 1	FIRST DOSE OF PLACEBO	2 WEEKS AFTER START OF THE ELEMENT	P2W
PBS #2	PLACEBO BS PART 2	FIRST DOSE OF STUDY DRUG A OR B AFTER RE-RANDOMIZATION	8 WEEKS AFTER START OF THE ELEMENT	P8W
PBS #3	PLACEBO BS PART 3	CONTINUATION OF THE PREVIOUS ELEMENT	8 WEEKS AFTER START OF THE ELEMENT	P8W
ABS #1	DRUG A BS PART 1	FIRST DOSE OF DRUG A	2 WEEKS AFTER START OF THE ELEMENT	P2W
ABS #2	DRUG A BS PART 2	CONTINUATION OF THE PREVIOUS ELEMENT	8 WEEKS AFTER START OF THE ELEMENT	P8W
ABS #3	DRUG A BS PART 3	FIRST DOSE OF STUDY DRUG A OR B AFTER RE-RANDOMIZATION	8 WEEKS AFTER START OF THE ELEMENT	P8W
CBS #1	COMPARATOR BS PART 1	FIRST DOSE OF COMPARATOR	2 WEEKS AFTER START OF THE ELEMENT	P2W
CBS #2	COMPARATOR BS PART 2	CONTINUATION OF THE PREVIOUS ELEMENT	8 WEEKS AFTER START OF THE ELEMENT	P8W
CBS #3	COMPARATOR BS PART 3	FIRST DOSE OF STUDY COMPARATOR	8 WEEKS AFTER START OF THE ELEMENT	P8W
EXT	EXTENSION PART	CONTINUATION OF THE ARMS FOLLOWED IN BS #3	20 WEEKS AFTER START OF THE ELEMENT	P20W
FU	FOLLOW-UP	24 HRS AFTER LAST DOSE OF STUDY DRUG/PLACEBO/COMPARATOR ADMINISTRATION	30 DAYS AFTER START OF THE ELEMENT	P30D

ARMCD	ARM	ETCD	ELEMENT	TABRANCH	EPOCH
PLB	PLACEBO	SCRN	SCREENING		SCREENING
PLB	PLACEBO	PBS #1	PLACEBO BS PART 1	RANDOMIZED TO PLACEBO	BASE STUDY
PLB	PLACEBO	PBS #2	PLACEBO BS PART 2	RE-RANDOMIZED TO DRUG A OR B	BASE STUDY
PLB	PLACEBO	PBS #3	PLACEBO BS PART 3		BASE STUDY
PLB	PLACEBO	EXT	EXTENSION PART		EXTENSION STUDY
PLB	PLACEBO	FU	FOLLOW-UP		FOLLOW-UP
A	DRUG A	SCRN	SCREENING		SCREENING
A	DRUG A	ABS #1	DRUG A BS PART 1	RANDOMIZED TO DRUG A	BASE STUDY
A	DRUG A	ABS #2	DRUG A BS PART 2		BASE STUDY
A	DRUG A	ABS #3	DRUG A BS PART 3	RE-RANDOMIZED TO DRUG A OR B	BASE STUDY
A	DRUG A	EXT	EXTENSION PART		EXTENSION STUDY
A	DRUG A	FU	FOLLOW-UP		FOLLOW-UP
B	DRUG B	SCRN	SCREENING		SCREENING
B	DRUG B	BBS #1	DRUG B BS PART 1	RANDOMIZED TO DRUG B	BASE STUDY
B	DRUG B	BBS #2	DRUG B BS PART 2		BASE STUDY
B	DRUG B	BBS #3	DRUG B BS PART 3	RE-RANDOMIZED TO DRUG A OR B	BASE STUDY
B	DRUG B	EXT	EXTENSION PART		EXTENSION STUDY
B	DRUG B	FU	FOLLOW-UP		FOLLOW-UP
COMP	COMPARATOR	SCRN	SCREENING		SCREENING
COMP	COMPARATOR	CBS #1	COMPARATOR BS PART 1	RANDOMIZED TO COMPARATOR	BASE STUDY
COMP	COMPARATOR	CBS #2	COMPARATOR BS PART 2		BASE STUDY
COMP	COMPARATOR	CBS #3	COMPARATOR BS PART 3	RE-RANDOMIZED TO DRUG B	BASE STUDY
COMP	COMPARATOR	EXT	EXTENSION PART		EXTENSION STUDY
COMP	COMPARATOR	FU	FOLLOW-UP		FOLLOW-UP

Questions



THANK
YOU!