

Clinical trial phases with data focus and design features

This slide shows the tabulation of key objectives of multiple phases of the clinical research process. It also provides information regarding factors to be identified while investigating the new drug.

	Phase I	Phase II	Phase III	Phase IV
Objectives	<ul style="list-style-type: none">• Check drug safety and optimal dose• Add text here	<ul style="list-style-type: none">• Check drug efficiency on specific population• Add text here	<ul style="list-style-type: none">• Check drug efficiency on large number of population• Add text here	<ul style="list-style-type: none">• Post approval from FDA monitor drug usage• Add text here
Factors to be Identified	<ul style="list-style-type: none">• Metabolism• Dose proportionality• Add text here	<ul style="list-style-type: none">• Patient safety• Drug - disease interactions• Add text here	<ul style="list-style-type: none">• Efficiency• Risk-benefit information• Add text here	<ul style="list-style-type: none">• Efficiency within large population• Add text here
Data Focus	<ul style="list-style-type: none">• Plasma and serum level• Add text here	<ul style="list-style-type: none">• Dose response• Add text here	<ul style="list-style-type: none">• Side effects• Add text here	<ul style="list-style-type: none">• Add text here• Add text here
Design Features	<ul style="list-style-type: none">• Single, ascending dose tiers• Add Text Here	<ul style="list-style-type: none">• Placebo controlled comparisons• Add Text Here	<ul style="list-style-type: none">• Randomized• Add text here	<ul style="list-style-type: none">• Add text here• Add text here

Presentation Of Clinical Data

Ying-Ying Zheng



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