



3-Minute GCP Quiz™

Clinical Research Design and Phases

	Answers	Answer
1	Phase 3 studies typically include approximately how many subjects?	more than 100
2	A study that defines the blood levels of a new drug in normal subjects would be considered which phase of clinical investigation?	Phase 1
3	Dose range information in patients is typically defined in which phase of investigation?	Phase 2
4	Which phase of clinical investigation is typically intended to establish the safety and efficacy of a drug in patients?	Phase 3
5	Placebo controlled trials are always double-blind.	False
6	The purpose of stratification in a clinical trial is to ensure that equivalent numbers of subjects are randomized to each treatment.	False
7	The purpose of randomization in a clinical trial is to reduce bias in a study by incorporating an element of chance to determine treatment assignment	True
8	A crossover study design is most appropriate for evaluating treatments of acute diseases.	False
9	Clinical studies with a parallel groups design are restricted to two treatments.	False
10	GCP defines double blind studies as those studies with more than one active treatment group being compared to placebo.	False

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