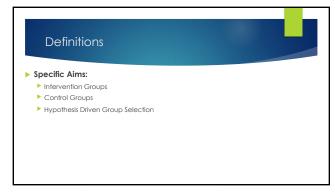






▶ R	CT is Gold Standard Trial Design for Causality
,	Adding to evidence of causality
1	Applying study design procedures to reduce inherent bias
1	Random assignment and blinding procedures
1	The research question needs to be more than exploratory – where is the science?





Response Varia	bles	
Demographics		
Objective Mea	sures	
Subjective Med	sures	
Adverse Events		
Serious Adverse	Events	

Eligibility Criteria

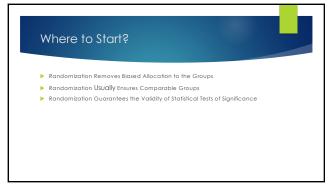
- ▶ Who Are You Recruiting in Versus Screening Out?
 - ▶ Who and Where?
 - ► Flow of Screening to Randomization
 - ▶ Figure 1 in Your Outcome Paper

8

7



Randomizing Procedures	





	Blinding Procedures	
▶ Type	es of Blinding to Remove Bias	
	ingle	
▶ □	ouble	
▶ T	riple	
▶ Blinc	ling Reduces Biases	
▶ K	nown or Unknown	
▶ ∧	Neasurement Error	
> 0	Group Allocation Bias, Selection Bias	

Alternative Trial Designs for the RCT Concurrent Non-Randomized Retrospective Historical Control Observational Cohort Within Group Cross-Over Dosing and Safety Pilot or Feasibility

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Following Up and Tracking Adherence Recruitment Tracking/Adherence to Screening Procedures Visit Documentation/Adherence within Study Visits Retention Tracking/Adherence to Study Visits Treatment Adherence Documentation/Dose Adherence

Questions in General	
16	
Treatment Specific Questions	
	-
17	
Questions Applicable to Your Research	
Research	