


BACKGROUND – THE STUDY QUESTION?	
Background	<ul style="list-style-type: none"> • Provide general background on the topic including why we use this therapy and what current practices are in relation to this therapy and disease state
Previous trials	<ul style="list-style-type: none"> • List Major applicable trials: including reference and citation only • Be prepared to provide details (PIES) of these trials
Why this study?	<ul style="list-style-type: none"> • Explain what this study will provide to clinical practice
GENERAL STUDY OVERVIEW	
Title/Citation	•
Funding	•
Null Hypothesis	•
Trial design	•
Objectives	•
Enrollment	•
Inclusion criteria	•
Exclusion criteria	•
Interventions	•
Endpoints	•
Statistical analyses	•
Monitoring	•
Enrollment	•
Baseline characteristics	•
Primary Outcome	•
Adverse Events	•
Etc	•
	•
	•
AUTHORS' CONCLUSIONS	
<p>Brief description of the authors view and conclusion of the trial and outcomes</p> <div style="display: flex; align-items: center;">  <p>STOP at this point and open the floor to discussion for the following section as you step by step through the PIES method of Critically Evaluating Clinical Trials®</p> </div>	
GENERALIZABILITY/CRITIQUE/DISCUSSION	
P atient Population	<ul style="list-style-type: none"> <input type="checkbox"/> Are there any major differences in patient characteristics that may confound the results <input type="checkbox"/> Evaluate inclusion and exclusion criteria serve as a guide to the patients that the results may be applicable
I ntervention	<ul style="list-style-type: none"> <input type="checkbox"/> Is the intervention being tested representative of current practice or derived from previous well-conducted studies
E ndpoints	<ul style="list-style-type: none"> <input type="checkbox"/> Do the endpoints of the trial truly represent what is claimed as being studied <input type="checkbox"/> Is the endpoint used in the trial clinically significant <input type="checkbox"/> If a surrogate endpoint is used, is it validated for correlation to a hard clinical endpoint

<p>Statistics</p>	<ul style="list-style-type: none"> <input type="checkbox"/> What type of data is being assessed (nominal, ordinal, continuous) <input type="checkbox"/> Are the statistical tests used to evaluate the data appropriate¹ <input type="checkbox"/> Is the effect size clinically relevant <input type="checkbox"/> Evaluate the results in absolute values and calculate number needed to treat (NNT) <input type="checkbox"/> Were subgroups and/or secondary endpoints evaluated? If so what significance can we take from them?
<p>Leader's Conclusion</p>	

*Template message (this is to be deleted for journal club): This is to serve as a template for your journal club handout. This should not exceed one page (front and back) upon completion, as all attendees are to have read the article prior to JC.