

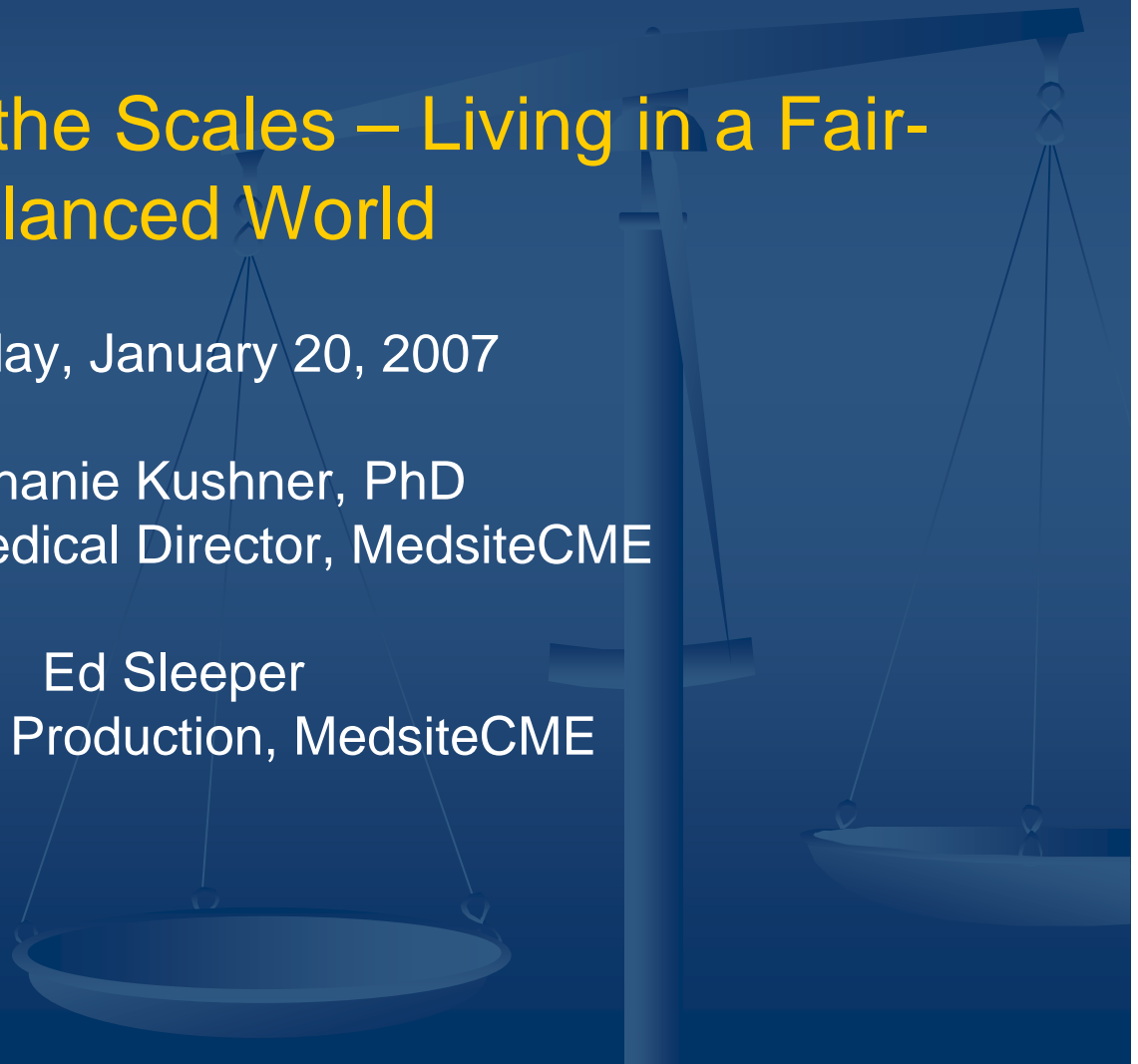
Alliance for CME
32nd Annual Meeting - January 17-20, 2007

Trying Not to Tip the Scales – Living in a Fair-
Balanced World

Saturday, January 20, 2007

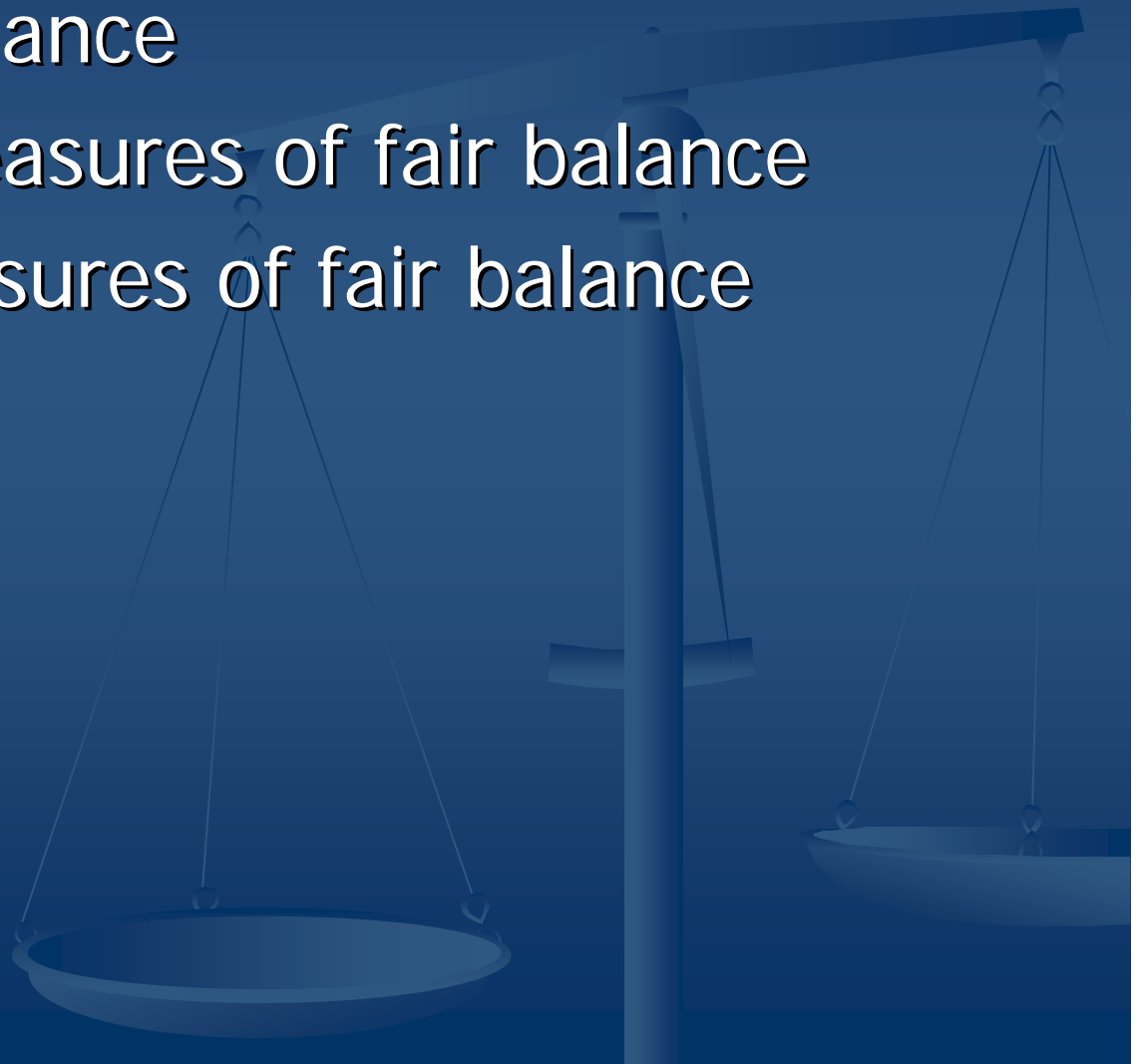
Stephanie Kushner, PhD
Associate Medical Director, MedsiteCME

Ed Sleeper
Director of Production, MedsiteCME



Agenda

- Defining fair balance
- Quantitative measures of fair balance
- Qualitative measures of fair balance
- Communication
- Discussion



Defining Fair Balance

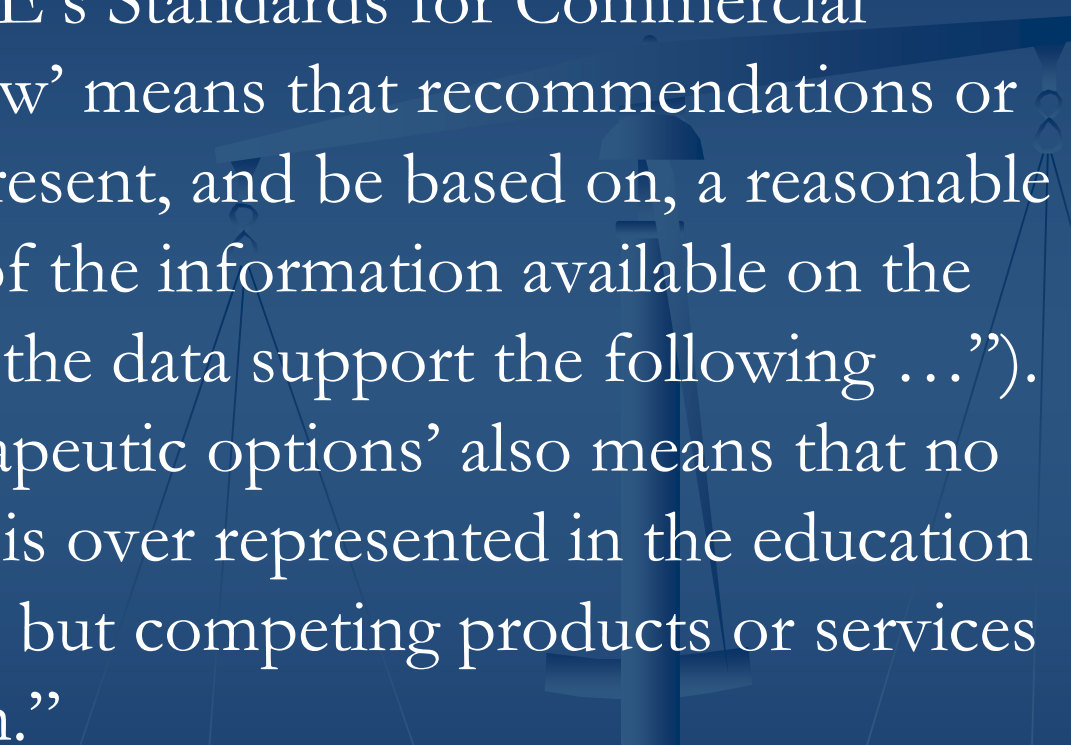
A faint, stylized image of a balance scale is visible in the background. The scale is positioned on the right side of the frame, with its horizontal beam extending towards the left. Two pans are suspended from the beam by thin lines. The entire image is rendered in a light blue color, matching the background. The scale is a classic symbol of justice and balance.

How Do You Define Fair
Balance?



ACCME Statement on Fair Balance

According to the AACME's Standards for Commercial Support, "a 'balanced view' means that recommendations or emphasis must fairly represent, and be based on, a reasonable and valid interpretation of the information available on the subject (eg, "On balance the data support the following ..."). A 'balanced view of therapeutic options' also means that no single product or service is over represented in the education activity when other equal but competing products or services are available for inclusion."



Two Key Elements of Fair Balance

- No single product or service is over-represented when other equal but competing products are available for inclusion – represents a quantitative measure of fair balance
- Recommendations must represent and be based on a reasonable and valid interpretation of the available information on the subject – represents a qualitative measure of fair balance

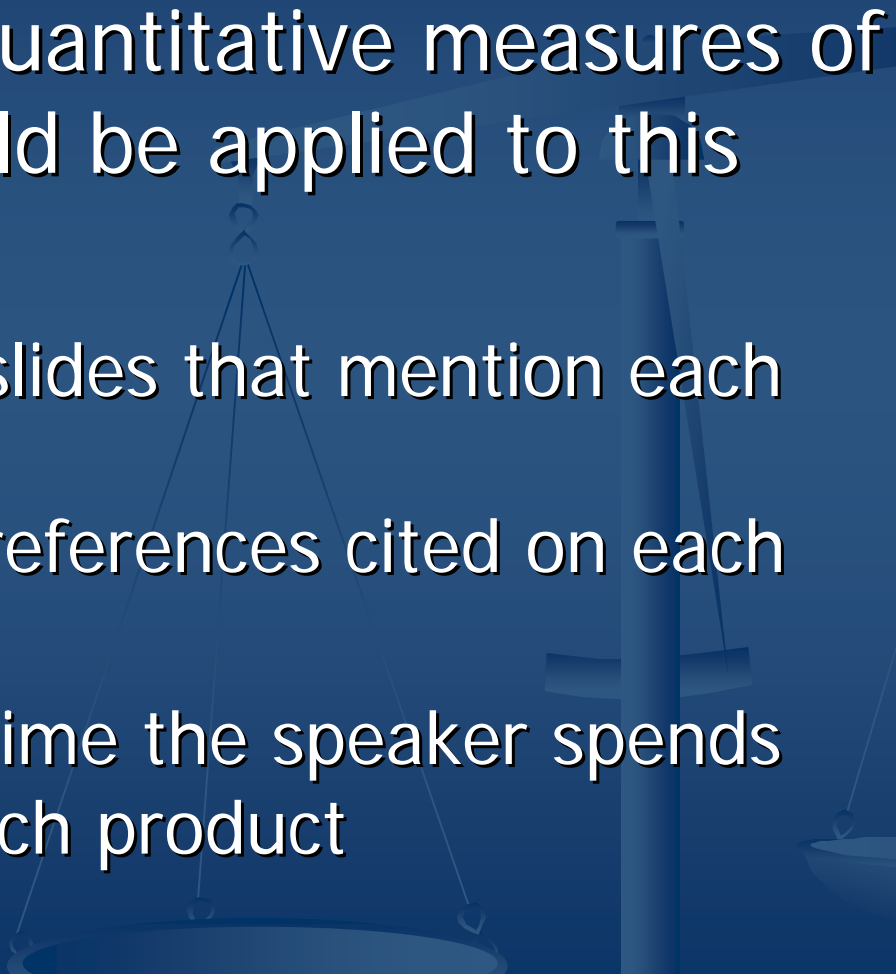
Quantitative Measures of Fair Balance



Case Study: Quantitative Measures for Slide Decks

- Commercially supported satellite symposium at a major congress
- Presentations will be given by three speakers – each presentation is 30 minutes long
- There are approximately 30 slides per presentation
- There are 4 commercially available products for the therapeutic area that is being discussed

Case Study: Quantitative Measures for Slide Decks (cont'd)

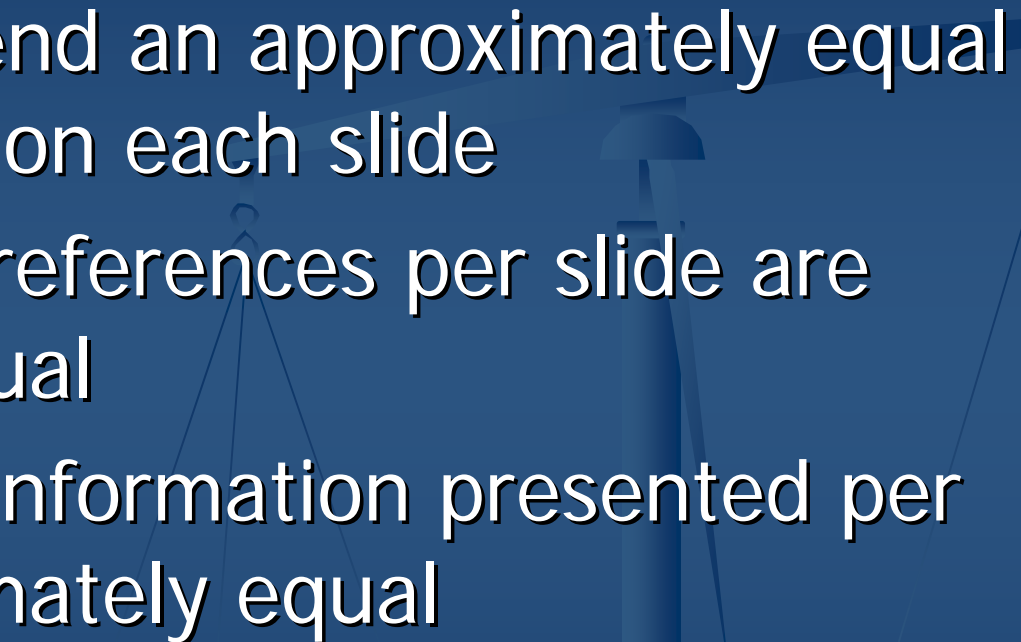
- What types of quantitative measures of fair balance could be applied to this program?
 - The number of slides that mention each product
 - The number of references cited on each product
 - The amount of time the speaker spends talking about each product
 - Other?
- 

Quantitative Measures: Number of Slides

- Overall, there are 96 slides presented at the symposium
- Forty of the slides focus on pharmacotherapy with the 4 commercially available products
- Each commercially available product is mentioned in 10 slides

Does this scenario represent a fair balanced program?

Equal Number of Slides: Assumptions

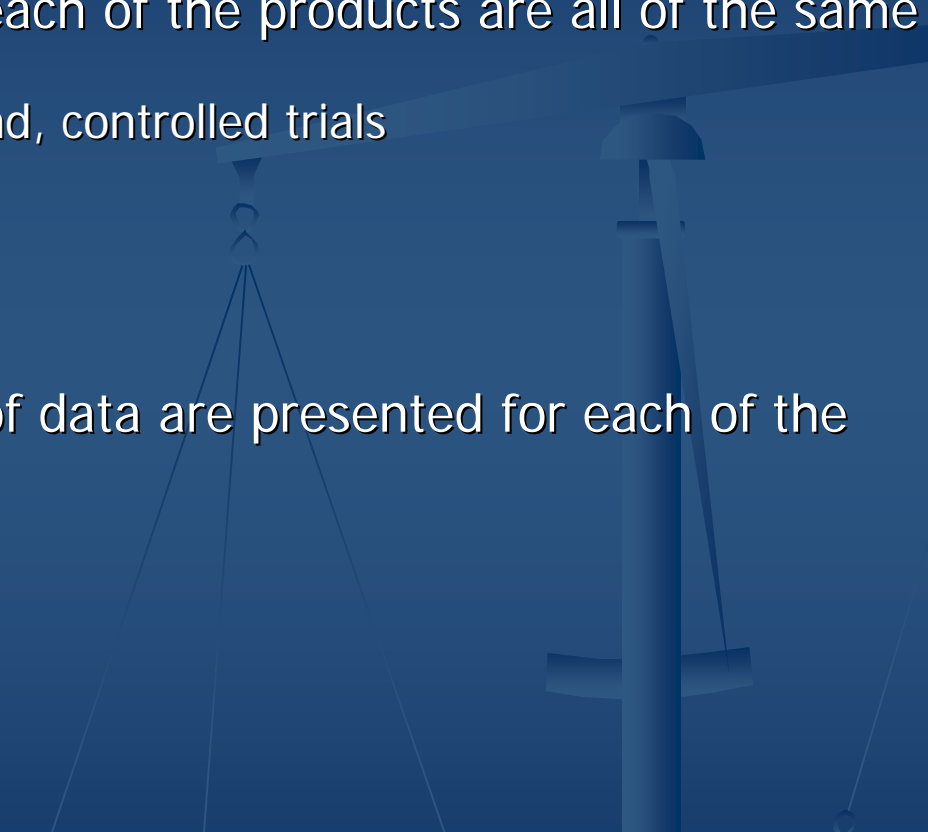
- Speaker will spend an approximately equal amount of time on each slide
 - The number of references per slide are more or less equal
 - The amount of information presented per slide is approximately equal
- 

Quantitative Measures: Number of References Cited per Product

- 96 slides presented in the symposium containing a total of 40 unique references
- Twelve of the references focus on data regarding the 4 commercially available products
- There are 3 unique references for each of the 4 commercially available products

Does this scenario represent a fair-balanced program?

Equal Number of References Cited: Assumptions

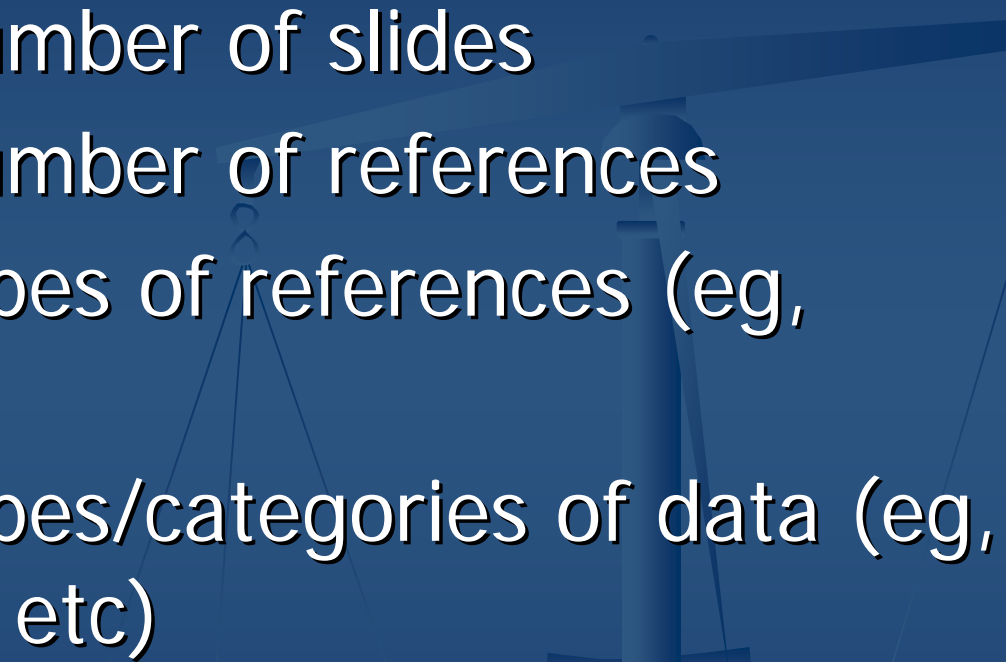
- The references cited for each of the products are all of the same type (if available)
 - Randomized, double-blind, controlled trials
 - Open-label studies
 - Meta-analyses
 - Review articles
 - Others
 - Similar types/categories of data are presented for each of the products (if available)
 - Efficacy
 - Safety
 - Tolerability
 - Monotherapy
 - Polytherapy
 - Others
- 

Quantitative Measures: Amount of Time Devoted to Each Product

- Each of the 3 presentations is 30 minutes long
- Each speaker spends 20 of the 30 minutes discussing pharmacotherapy
- Each speaker devotes 5 minutes to each of the 4 commercially available products

Does this scenario represent a fair-balanced program?

Equal Amount of Time Devoted to Each Product: Assumptions

- Same/similar number of slides
 - Same/similar number of references
 - Same/similar types of references (eg, RCTs)
 - Same/similar types/categories of data (eg, efficacy, safety, etc)
- 

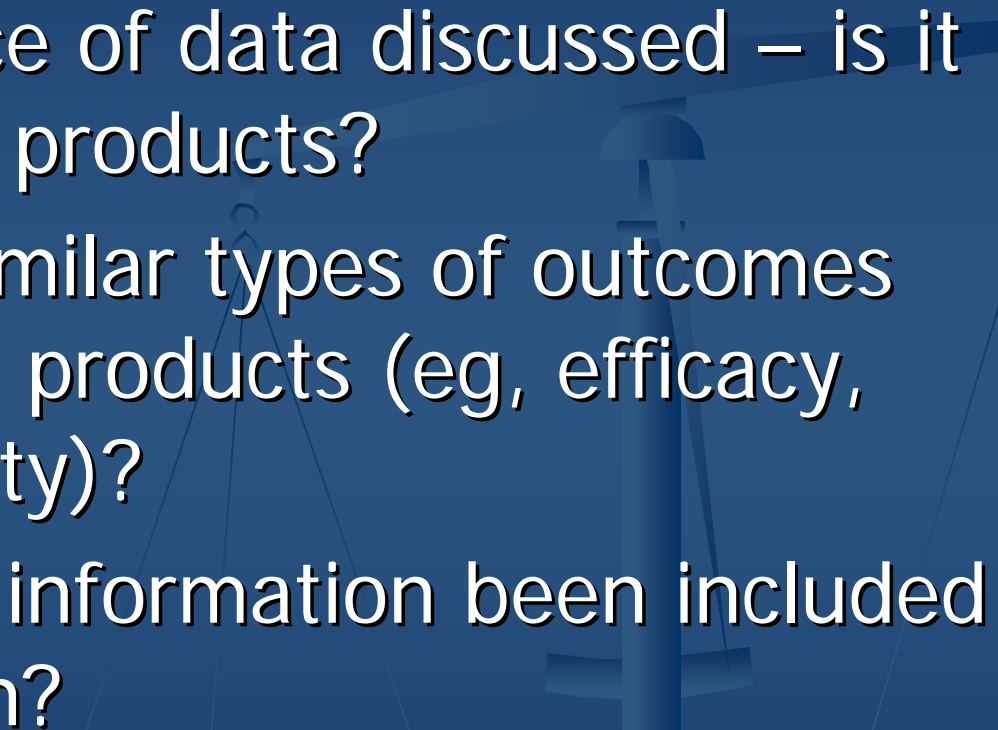
Quantitative Measures of Fair Balance: Important Considerations

- Slide decks are often reviewed and accredited based on a visual review
 - Number of slides and references can be determined
 - Amount of time can only be estimated – speaker may spend more time on some slides than others
- It is important to utilize more than one quantitative measure when evaluating a program for fair balance

Qualitative Measures of Fair Balance

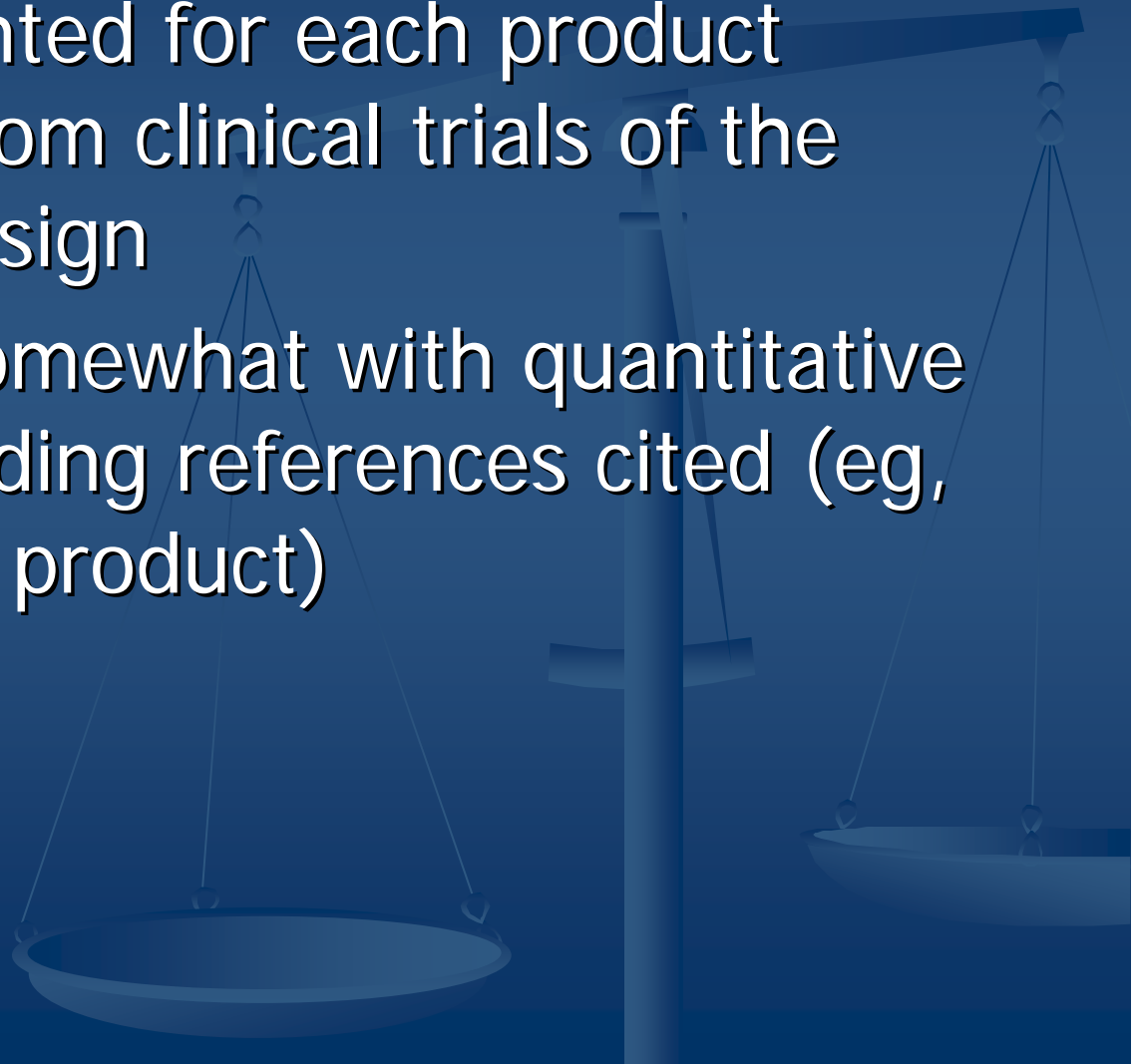


Types of Qualitative Measures

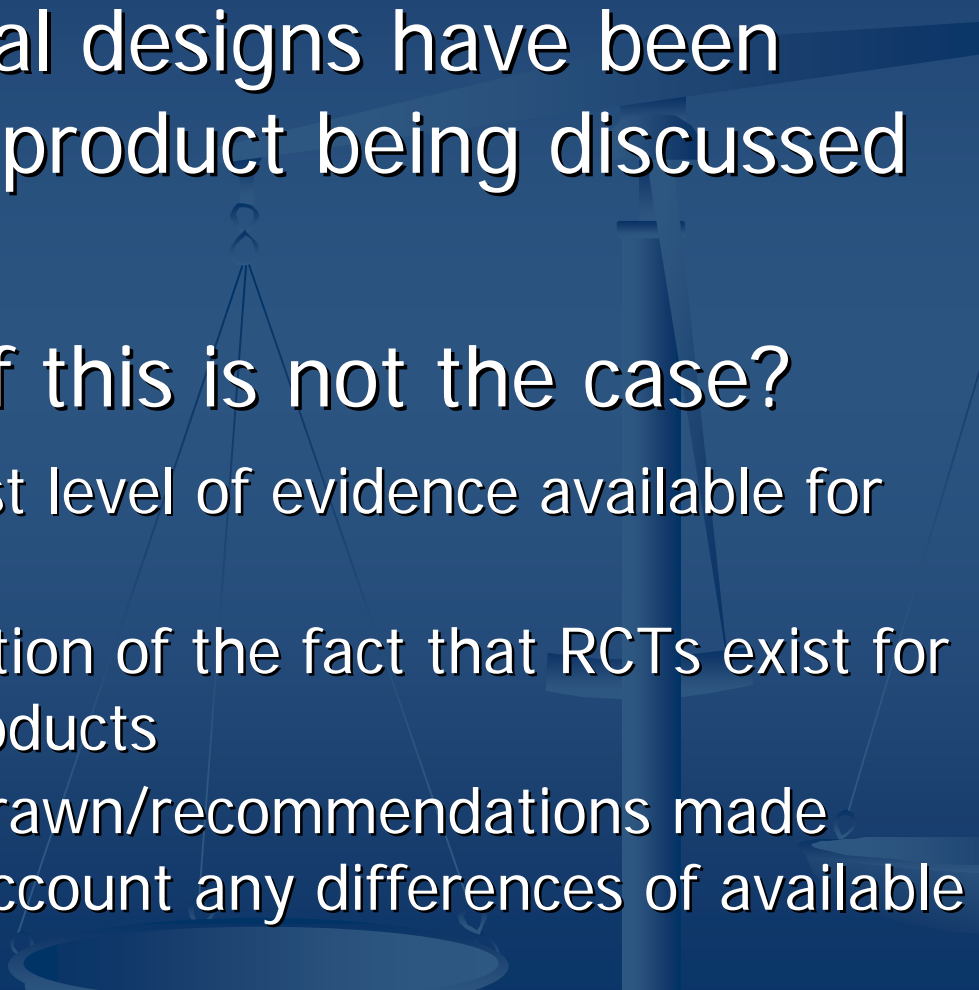
- Level of evidence of data discussed – is it the same for all products?
 - Are the same/similar types of outcomes discussed for all products (eg, efficacy, safety, tolerability)?
 - Has all relevant information been included in the discussion?
- 

Qualitative Measures: Level of Evidence

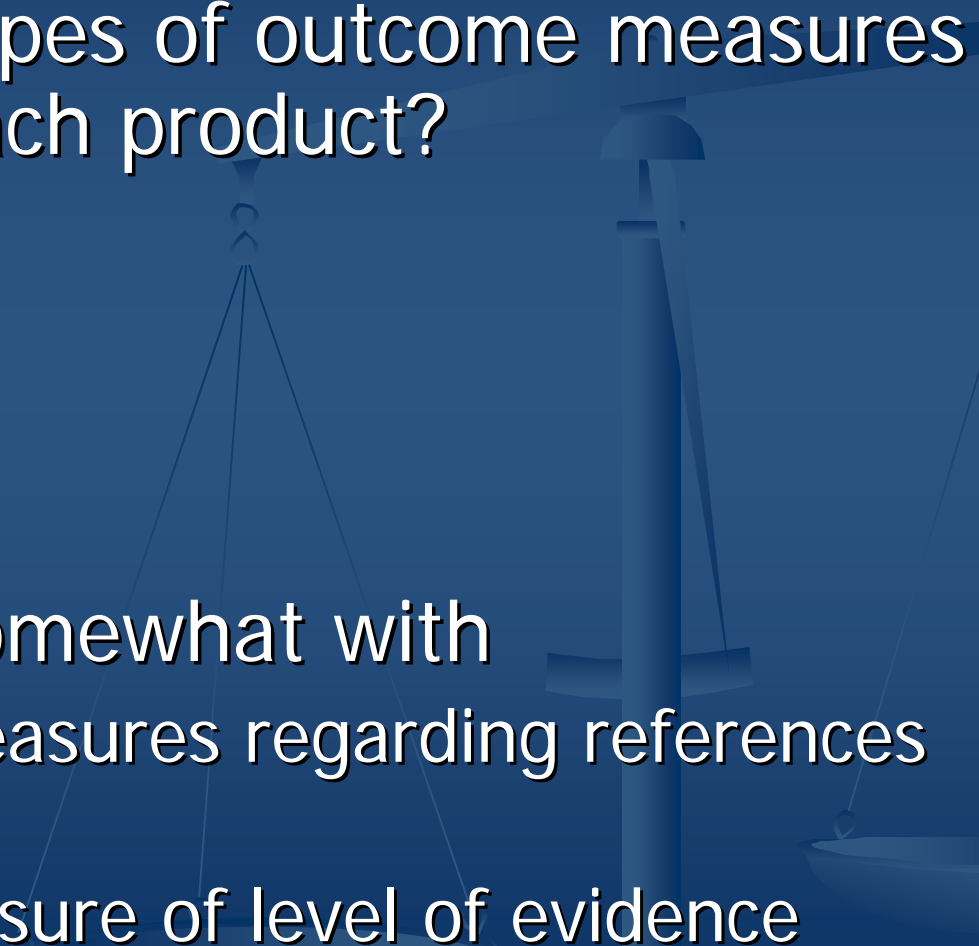
- The data presented for each product should derive from clinical trials of the same/similar design
- This overlaps somewhat with quantitative measures regarding references cited (eg, 1 RCT cited per product)



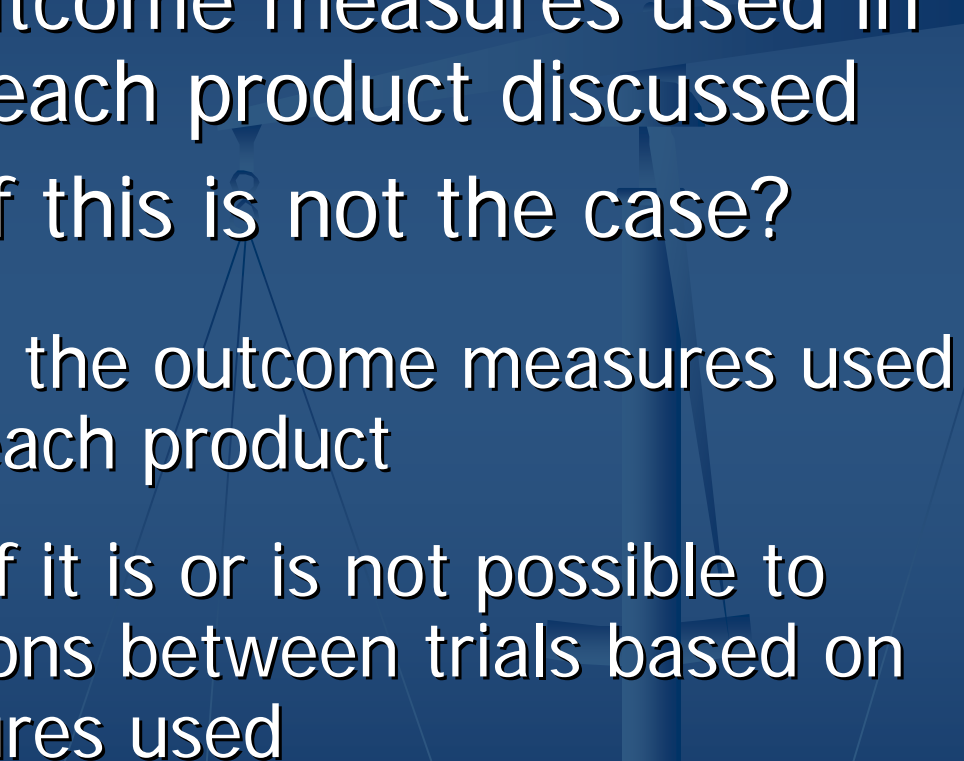
Level of Evidence: Assumptions

- Same/similar trial designs have been applied to each product being discussed (eg, RCTs)
 - What happens if this is not the case?
 - Discuss the highest level of evidence available for each product
 - Make explicit mention of the fact that RCTs exist for only 3 of the 4 products
 - Any conclusions drawn/recommendations made should take into account any differences of available level of evidence
- 

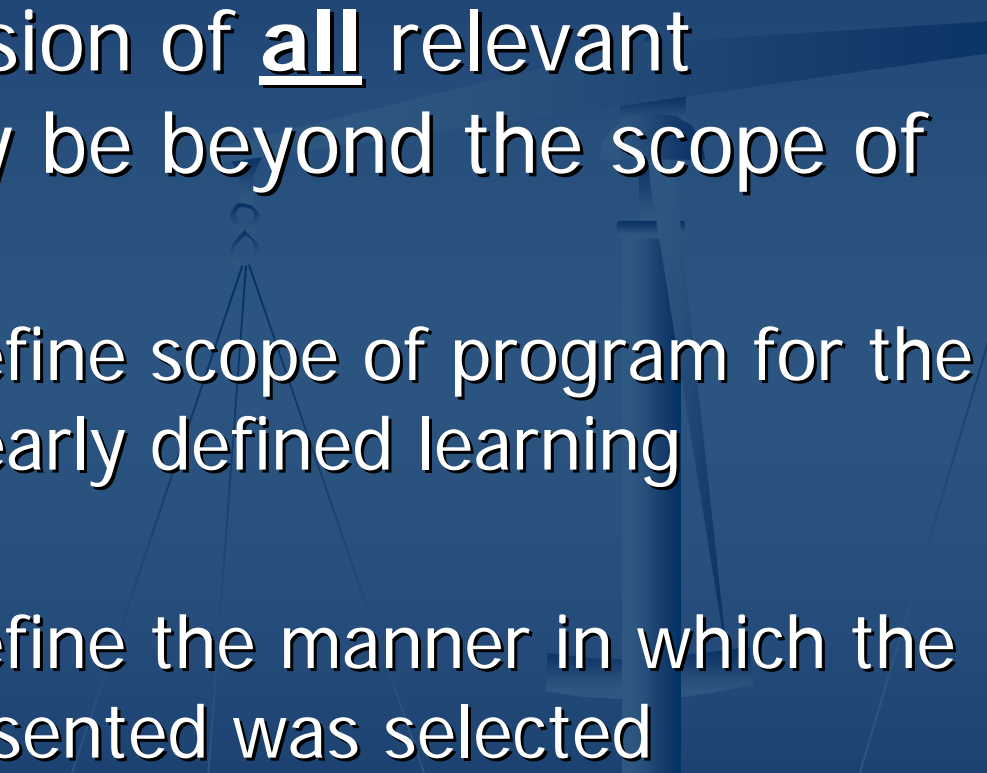
Qualitative Measures: Types of Outcome Measures Discussed

- Are the same types of outcome measures discussed for each product?
 - Efficacy
 - Safety
 - Tolerability
 - Quality of life
 - This overlaps somewhat with
 - Quantitative measures regarding references cited
 - Qualitative measure of level of evidence
- 
- A faint, stylized image of a balance scale is visible in the background of the slide. The scale is positioned on the right side, with its vertical pillar and horizontal beam extending across the middle. The two pans are visible, hanging from the beam. The image is semi-transparent and serves as a decorative element.

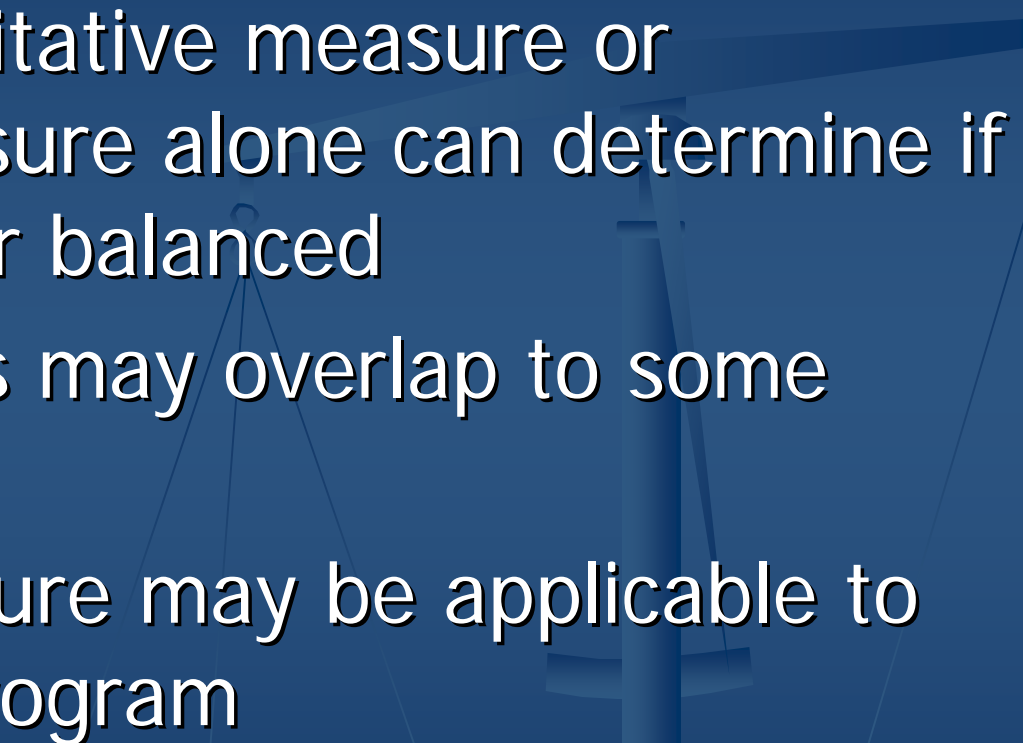
Types of Outcome Measures: Assumptions

- Same/similar outcome measures used in clinical trials of each product discussed
 - What happens if this is not the case?
 - Clearly describe the outcome measures used in the trials of each product
 - Explicitly state if it is or is not possible to make comparisons between trials based on outcome measures used
- 

Qualitative Measures: Inclusion of All Relevant Information

- Often, the inclusion of all relevant information may be beyond the scope of the program
 - Important to define scope of program for the participants (clearly defined learning objectives)
 - Important to define the manner in which the information presented was selected
- 

Key Points to Keep in Mind

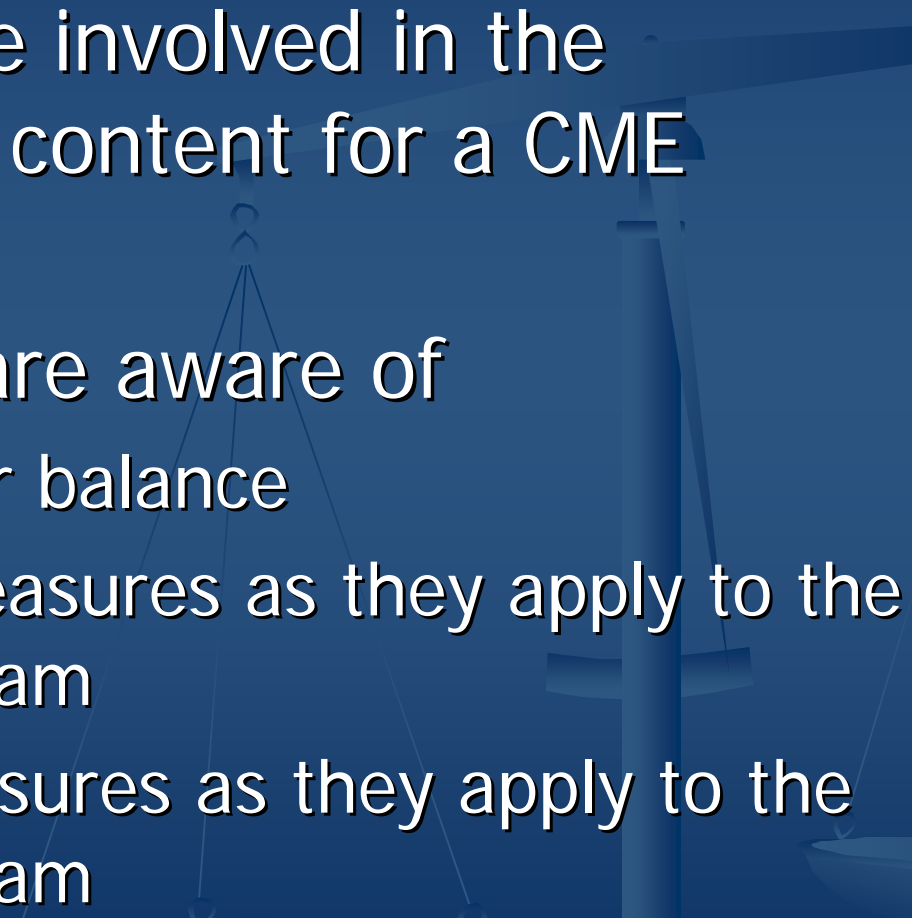
- No single quantitative measure or qualitative measure alone can determine if a program is fair balanced
 - These measures may overlap to some degree
 - Not every measure may be applicable to every type of program
- 

Communication

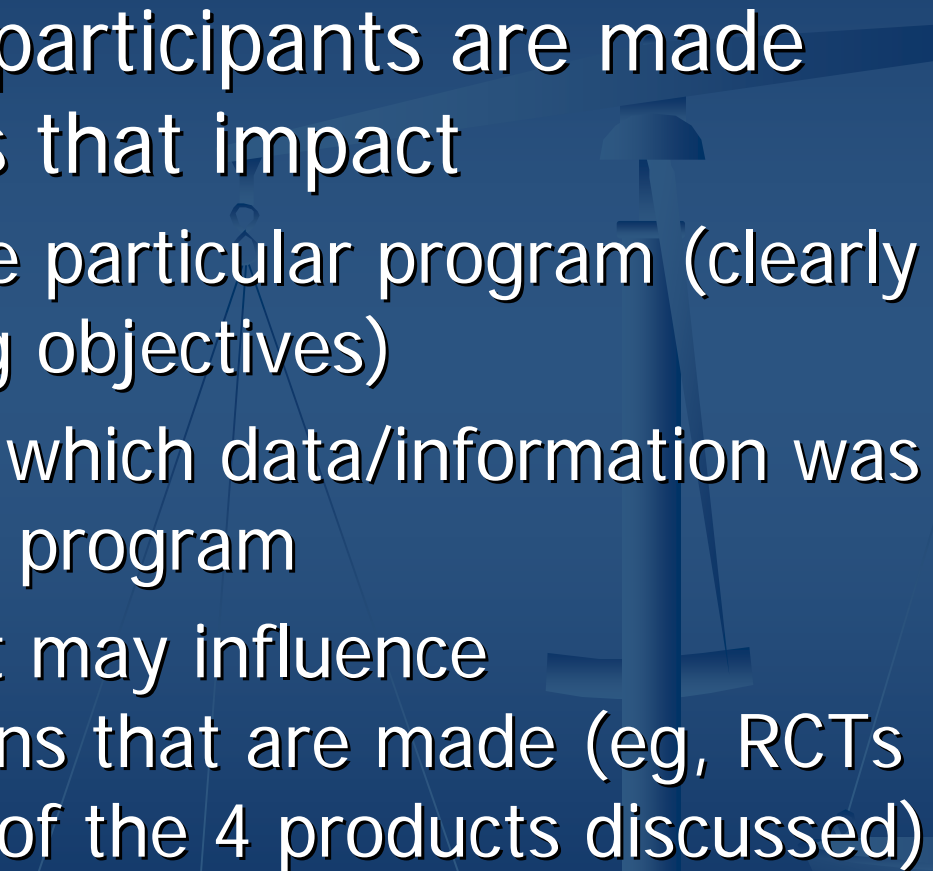


Why is it so important?

Keep Everyone “On the Same Page”

- Many parties are involved in the development of content for a CME program
 - Ensure that all are aware of
 - Definition of fair balance
 - Quantitative measures as they apply to the particular program
 - Qualitative measures as they apply to the particular program
- 

Keep Everyone “On the Same Page” (cont’d)

- Make sure that participants are made aware of factors that impact
 - The focus of the particular program (clearly defined learning objectives)
 - The method by which data/information was selected for the program
 - Any factors that may influence recommendations that are made (eg, RCTs exist for only 3 of the 4 products discussed)
- 

Perception



Can a program appear fair
balanced to some and biased to
others?

Discussion

