Clinical Events Committees: An FDA Division of Cardiovascular Devices Perspective

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Disclosure Slide

- Bram Zuckerman, MD has no relevant disclosures to report

Clinical Event Committees (CEC)

- Clinical trials should obtain data that are accurate and as free of bias as possible
- CECs can improve endpoint adjudication process by using an independent standardized approach
- Process is quite valuable when endpoints are subjective, require the application of a complex definition, or when the intervention is not blinded

Practical Issues to Consider

- Composition of the CEC
  - Are the designated CEC members independent and qualified for the job?
- Is the general SOP appropriate?
  - Are the proposed definitions valid?
- Does the clinical trial capture the right source data for objective adjudication?
- Will the CEC be able to meet the timeline expectations of the DMC and Sponsor?
- Are appropriate records being kept?