

Session 1

- CEC provides a systematic process of evaluation of events and reproducibility
- But there is no standard CEC process
- Adjudication does not seem to impact the treatment effect in CV trials but does impact incidence rate of given events
- There is evidence of discordance between PIs and CECs for CV studies on individual event classification but overall the HRs are similar
- How significant is this? Does it impact the assessment of the true estimate? Trial duration and cost?
- Impact of adjudication on trial itself?
- Need for more pragmatic approach to adjudication – CRFs, education of PIs

Session 2

- Adjudication is best done prospectively
- Importance of missed events vs total number of events needed to interpret drug effect to seek truth
- There are potential models to assist with adjudication but will not eliminate the need for CEC which renders a judgment, especially in complex cases
- Need for more proactive approach to identify safety issues during the trial using examination of the database, independent of CEC

Session 3

- Need to prospectively plan what to adjudicate and collect sufficient data to enable effective adjudication by CEC
- Need to define up front the purpose of the CEC
- Adjudication can be performed by an independent committee or by a blinded internal expert, selection of approach may depend on phase of development
- Independence of CEC – define membership qualifications

Session 4

- Quality of data is critical; avoiding errors that affect decision matter
- Determine if adjudication adds value, especially with regards to quality
- Need for framework which indicated benefits and risks of adjudication
- State why we adjudicate