USE OF CV ENDPOINT DOCUMENT IN CV & NON-CV TRIALS

(Non-Outcome CV Trials)

Perspective is Key!

Goal: Collect Key Data

- Collect the key basic information necessary to perform adjudication (most often occurring at a later time when an aggregate amount of information has been collected suggesting a potential signal) without undue investigator burden

Implementation Challenges

- Strengths of eCRFs
  - When is it a boon to efficiency?
  - What documentation is consistently lacking/misinterpreted?
- Weaknesses of eCRFs
  - Where are areas of confusion?
  - What information may be lacking/misinterpreted?

Strengths

- Most obvious is CONSISTENCY in KEY information obtained
  - Medical monitors have different perspectives (e.g., regarding essential information as well as essential source documentation)
- Enables subspecialty driven decision-making across a sponsor's portfolio
- Streamlines processes for teams around data collection
  - Not having to "reinvent the wheel"

Weaknesses

- Nature of the project is that non-cardiovascular subspecialists will be most often involved in data collection and review
  - Investigator, medical monitor, safety physician
- Challenge of balancing minimal essential information necessary with scope of variety of programs the eCRFs will be used by (spectrum from pulmonary which may often have subjects with cardiovascular histories to dermatology)
  - What is too little vs too much in terms of requested information?

Implementation Challenges

- Determining which programs will include them
  - Impact of type of program: oncology, pulmonary, dermatology
    - Death eCRF for oncology – should they have a separate form?
- Which types of trials? E.g., NHV, phase I-IV
- Electronic vs paper vs both?
- Will exemptions be allowed?

Implementation Challenges

- Will there be standard templated language?
  - Protocol
  - ICF
  - Study Procedures Manual
  - eCRF guidelines

Implementation Challenges

- How will they be triggered?
  - Automatically, manually, combination of both?
    - Centrally or by the specific teams?
  - How will updates to MedDRA be handled?
  - How will the death eCRF be triggered?

Implementation Challenges

- How will the eCRFs look electronically?
- How will the eCRFs be followed?
- Will source documents be collected?
- Where will the data be stored?
- Who will look at the data?
- Duplicate information, particularly for SAEs

What questions do you have?