USE AND FEEDBACK ON THE CV DATA COLLECTION FORMS

Mary Elizabeth Sabol, MD, FACC
Disclaimer

- I am a full time employee of GlaxoSmithKline
- The information presented represents my personal opinion and does not necessarily reflect the opinion or policy of any companies or organizations
Cardiovascular Safety Signals in Non-CV Trials

- CSRC has developed a set of targeted follow-up questions for use in non-CV outcomes trials to collect information as temporally close to the occurrence of an event as possible.
- Purpose: To ensure that information is available in case a CV signal is detected at a later point in time.
Cardiovascular & Death CRFs

- Arrhythmias
- Cerebrovascular Events (Stroke & TIA)
- Heart Failure
- Death
- Deep Venous Thrombosis/Pulmonary Embolism
- Myocardial Infarction
- Peripheral Arterial Thromboembolism
- Pulmonary Hypertension
- Valvulopathy
Summary published on line

- February 12, 2015
Steps in Using CRFs

- Determine how best to incorporate forms into a program
  - E.g., draft text, modular format
- How best to trigger use
- Implement processes to ensure timely completion
- How best to store data until a later date if and when possible adjudication may be needed
Follow up on use

- **Important to work closely with clinical, safety and data managers**
  - Develop best means to trigger the forms
  - Highlight with investigators
    - Information on how process works
    - Overall goals

- **Including in the decision-making process any functional area involved is essential to smoothly incorporating the forms**

- **Expect to have to revise both the forms and the process**
  - Remember, progress is always an evolving process
  - Be flexible and open to suggestions
Summary

- Use of these forms will require each sponsor determining how best to incorporate them into their programs
  - Not mandatory, thus there is flexibility in how best to incorporate
  - Being responsive to team input on a project is key
  - Important to review process in detail at investigator meetings

- Programming can be done so that it is “re-usable” in a modular format

- Benefits of improved data collection can be observed currently on a case by case basis
  - The expectation is that these will aid in any aggregate review in the future