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**
- Cardiac Safety Research Consortium (CSRC): Cardiovascular Safety and Adverse Event Case Report Forms *Therapeutic Innovation & Regulatory Science 216847901456731 9, first published on February 12, 2015 as doi:10.1177/216847901456731 9*

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