The Physician as Clinician and Investigator

Doug Peddicord

ACRO

U.S. Department of Health and Human Services
Food and Drug Administration

The Physician as Clinician and Investigator

- Quality clinical trials start with sponsors who ensure:
  - In-depth testing of investigational product prior to first in man.
  - Protocol design aimed at answering the appropriate safety, dosing, and scientific hypothesis
  - Proper accountability and oversight of safety
    - AE/SAE collection and review
    - Data safety monitoring / interim analysis reviews
  - Investigator training
    - Compound overview
    - Primary objectives of protocol
    - Clear Inclusion / exclusion criteria
    - Safety reporting procedures
- IRBs support proper checks and balances contributing to patient safety.
- *But the sponsor is not at the bedside* – ***the physician is the critical link to the patient***

The Physician as Clinician and Investigator

- The physician/investigator acts responsibly by:
  - Only enrolling eligible subjects
  - Conducting proper informed consent
    - Ensuring subject understands risks, benefits, procedures, and responsibilities
  - Watching for and reporting all AE's, SAE's, and Endpoints
  - Review IB / Safety letters to understand risk to your subjects

The Physician as Clinician and Investigator

- The physician/investigator acts responsibly by:
  - Staying involved
  - Following the Protocol
  - Applying good clinical judgment as needed
  - Consulting Sponsor medical consultant if needed
  - Being available to sponsor and or designee

The Physician as Clinician and Investigator

- The physician/investigator acts responsibly by:
  - Hiring and managing qualified staff.
  - Sharing your experiences and participation with colleagues.
  - Maintaining high levels of vigilance for adverse events, understanding that many AEs are ‘unexpected’ in the early phases of the lifecycle of a medicine

The Physician as Clinician and Investigator

- What are sponsors – and patients – interested in?
  - Recruitment/enrollment
  - An Informed Consent that is thorough and fair
  - Adherence to study inclusion/exclusion criteria
  - (A minimum of) protocol deviations
  - Data – producing quality data, promptly entered, that contributes to the study

The Physician as Clinician and Investigator

Final Take away:

Participation in clinical trials can be a rewarding and safe experience for the investigator and subject if you are appropriately attentive to study treatment, evaluations, and adverse events. Remember you are making a valuable contribution to the way we will practice medicine in the future.