REQUIREMENTS FOR PRINCIPLE INVESTIGATORS

Design and implementation of a core curriculum
Development of Investigator manuals

Core Content topics

1. Overview of the Drug Development process
    - Description of the Phases and the regulatory requirements of each
2. Study design and Protocol development (the basics based on intended outcome)
    - Bioequivalence
    - First time in man - dose determination
    - Ascending dose tolerance studies
    - CYP450 subset phenotyping
    - Drug Interaction studies
    - When to use Crossover studies
    - Importance of Blinding
3. Review of Statistical methods including:
    - The determination of power and sample size
    - Overview of statistical study designs
4. Study conduct issues - how studies are done
    - What is GCP and how it is applied
    - Subject/Patient safety assurances
    - Reporting of AE's and SAE's
5. Making Protocols conform to the ICH guidelines:
    - The ICH guidelines important to the PI.
6. Review of Pharmacokinetic issues including
    - AUC, Tmax, Cmax, etc
    - Half life and how to use it
7. How to approach studies in special populations (compromised hosts)
    - Renal impaired subjects
    - Hepatic impaired subjects
    - Diabetes - special problems
    - Asthma - special problems
    - Hypertension, etc
8. The IRB process and the expected relationship of the PI to the IRB
9. The Informed Consent - what is required
10. Ethical issues faced by Physicians in Clinical research

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