

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

Charles H. Pierce, M.D., Ph.D.
Email - charles@pierce1.net