METIS CONSULTING SERVICES - TRAINING COURSE SAMPLE PAGE

ICH E8



- •First published in 1998
- •General Considerations for Clinical Trials
- •Describe the internationally accepted principles and practices in design and conduct
- •Guidance on consideration of quality in design and conduct
- •Overview of types of studies during the product lifecycle Principles:
 - Protection of clinical study participants -
 - Scientific Approach to design, planning, conduct, analysis, and reporting
 - Patient input