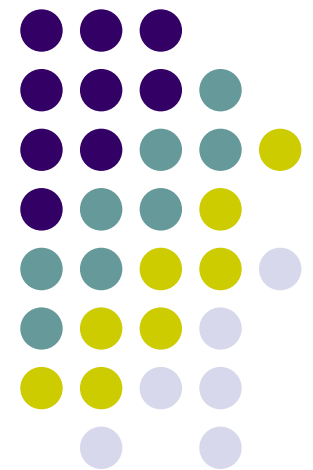


Brief Introduction to the ICH Guidelines

Mario Chen
Family Health International
Biostatistics Workshop
New Delhi, India, March 2007





What is ICH?

- ICH is a joint initiative involving both regulators and research-based industry representatives of the EU, Japan and the US in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines.



Who are the members?

- ICH is comprised of representatives from the six co-sponsoring parties as well as three Observers and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA):
 - Japan: the Ministry of Health & Welfare (MHW) and the Japan Pharmaceutical Manufacturers Association (JPMA)
 - EU: the European Commission (EC) and the European Federation of Pharmaceutical Industries' Associations (EFPIA)
 - USA: the Food & Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers of America (PhRMA)
 - Observers: WHO, EFTA, and Canada



What does ICH stand for?

- The complete name of ICH is the “International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use”.



What is the purpose of ICH?

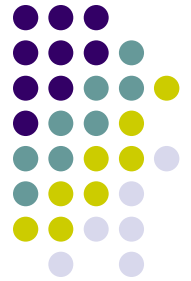
- The objective of ICH is to increase international harmonization of technical requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most efficient and cost-effective manner.

Why are the guidelines important to us?



Where can I get the guidelines?

- Go to the website: www.ICH.org





ICH Guidelines

- ICH has developed over 45 harmonized guidelines
- The ICH Topics are divided into four major categories:
 - Quality (Q), i.e., those relating to chemical and pharmaceutical Quality Assurance
 - Safety (S), i.e., those relating to in vitro and in vivo pre-clinical studies
 - ***Efficacy (E), i.e., those relating to clinical studies in human subject***
 - Multidisciplinary topics (M), i.e., cross-cutting Topics which do not fit uniquely into one of the above categories



Efficacy Topics

- E3: Structure and Content of Clinical Study Reports
- E4: Dose-Response Information to Support Drug Registration
- E6: Good Clinical Practice : Consolidated Guideline
- E8: General Considerations for Clinical Trials
- ***E9: Statistical Principles for Clinical Trials***
- E10: Choice of Control Group and Related Issues in Clinical Trials