Introduction to International Conference on Harmonisation

Leni Mathews, MSN, RN, OCN, CCRC, CCRA
Clinical Research Support Center
What is ICH?

• International Conference on Harmonization Technical Requirements of Registration of Pharmaceuticals for Human Use.

• www.ich.org
Goal

Harmonize regulations across nations
A joint initiative involving regulators and research industry representatives of the European Union, Japan, and United States

WHO-First meeting 1990 in Belgium-
Can you identify this flag?
Quiz

Which of these nations is not a member of the European union?

a. France
b. Turkey
c. Romania
d. Greece
Purpose of ICH

- Safe, Effective and High Quality Medicines are developed and registered in the most efficient and cost effective manner.
- Promote Public Health
- Prevent Unnecessary duplication of clinical trials
- Minimize the use of animal testing without compromising safety and effectiveness
United States Government

International

Sponsors and Contract Research Organizations

Institutional and Departmental
Location of ICH

• No central location
• Meetings are held –rotating between Japan, EU, and US
• Secretariat Offices
  – Geneva, Switzerland
  – Support ICH Steering Committee
  – admin@ich.org
ICH Members

Japan- MHLW and JPMA
- Ministry of Health and Welfare
- Japan Pharmaceutical Manufacturers Association

Europe- EU, EFPIA
- European Union
- European Federation of Pharmaceutical Industries and Associations

USA- FDA and PhRMA
- Food and Drug Administration
- Pharmaceutical Research and Manufacturers of America

Observers- WHO, EFTA, and Canada
- World Health Organization
- European Free Trade Association
- Canada
ICH Structure

- Steering Committee
- Secretariat
- Coordinators
- Working Groups
• Regional Harmonisation Initiatives

APEC
• Asian-Pacific Economic Corporation

ASEAN
• Association of Southeast Asian Nations

GCC
• Gulf Cooperation Countries

PANDRH
• Pan American Network on Drug Regulator Harmonisation

SADC
• South African Development Community
The ICH Process

One of the six parties decides on a topic for harmonisation

Concept paper written

Steering Committee Decides on moving forward and creating a guideline
Products of ICH

- >50 Harmonized Guidelines
International Conference on Harmonization Guidelines

ICH

QUALITY

EFFICACY

SAFETY

MULTIDISCIPLINARY

Good Clinical Practice Guidelines
Four Areas

**Quality** - chemical and pharmaceutical quality assurance
- Stability Testing
- Impurity testing

**Safety** - in vitro and in vivo pre-clinical studies
- Carcinogenicity Testing
- Genotoxicity Testing
- Pre-Clinical Testing

**Efficacy** - clinical studies in human subject
- Dose Response Studies
- Good Clinical Practices
- Clinical Research in Human Subjects

**Multidisciplinary** - cross-cutting Topics which do not fit uniquely into one of the above categories
- MedDRA
Are ICH Guidelines standards?

- Scientific Guidance agreed upon by US, Japan and EU.
- Each regulatory co-sponsor implements according to its national/regional requirements
- Not comprehensive
- To be used in combination with regional requirements
Moving onto ICH GCP

- International Conference on Harmonization
  - Good Clinical Practice Guidelines
  - www.ich.org
Good Clinical Practice Guidelines

- Adopted as law in several countries
- FDA Adopted as Guidance in the United States
Compliance with ICH GCP

- Provides Public assurance that the rights, safety, and well being of subjects are protected
What will we cover?

• Pieces of the ICH GCP
  – The Basics and Terminology
  – Thirteen Principles
  – Institutional Review Board
  – Investigator Responsibilities
  – Sponsor Responsibilities
  – Essential Documents