

# Global Clinical Trials

## Opportunities and Challenges



**ISCTM**

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### Session 1: ISCTM Summer Meeting

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**ISCTM**

# Conducting CNS Clinical Trials in the Developing World

- **Issue:**
  - Tremendous growth in CNS clinical trial work conducted in sites outside of traditional Western countries

1985

1990

1995

2000

2005

- Prehistory—work between west and east was poorly coordinated

- Increasing amount of primarily safety data gathered from developing world for Western regulatory submissions

- Increasing amounts of efficacy as well as safety data gathered from developing world for Western submissions

# Global Clinical Trials – The Environment

## ■ Regulatory

- Acceptance of foreign data
- Risk evaluation and mitigation

## ■ Pharma

- Patent expiries
- Increased R & D costs
- Cost of clinical trials
- Availability of drug naïve patients

## ■ Healthcare

- Personalised medicine
- Cost containment
- Greater assurance about value

# M Page: Clinical Trials in the Developing World

## Background and Changing Role for CNS trials

- Global clinical development programs make sense
  - Simultaneous registration
  - Cost
- Single integrated data base is more efficient
- Challenge and issues:
  - How to respect cultural diagnostic, gauge pharmacokinetic diversity
  - Managing different outcome measures
- Trend of global development usually goes from West to Developing World
  - what about the reverse?
- Is there a role for WHO in guidelines for regulatory bodies?

# Global Clinical Trials - Pharma

- Regional diversity
  - Healthcare system; patient / doctor relationships
    - Cultural diversity
  - Informed consent – accurate translations
    - Illiteracy
  - Language
- Institutional inexperience
- GCP compliance

# Global Clinical Trials: Implementation GCP Selected Asia Pacific Countries

Country	Year ICH GCP Implemented
Philippines	1993
Taiwan	1996
New Zealand	1996
Hong Kong	1997
Singapore	1998
China	1998
Korea	1999
Malaysia	1999
Australia	2000
Thailand	2000
Indonesia	2001

# Global Clinical Trials: Registries

- WHO Intl Clinical Trials Registry Platform established 2004
  - Single point access for identification and information about clinical trials
- Registries included:
  - Australian, Intl Standard Randomised Controlled Trial Number Register, US NIH ClinicalTrials.gov
- China and India added their National Trials registries in July
- Aims
  - Greater transparency and accountability
  - Improvement ethical conduct and public trust in clinical trials

# Global Clinical Trials -Challenges

## Regulatory

- Foreign data
  - How much / what balance ?
  - Implications for:
    - Understanding drug-drug interactions
    - PK / PD relationship
  - Impact of pharmacogenomics
    - Response / risk

## Global Clinical Trials: Approval times Selected Asia Pacific Countries

Country	EC Approval (weeks)	Regulatory Approval (weeks)	Series or Parallel	Total Time (weeks)
Australia	8-11	CTN:2 CTX:8-14	S	CTN:11-14 CTX:11-25
New Zealand	8-11	8	S	20
China*	6	24	S	46
Hong Kong	4-8	8-12	P	12-14
India	5	13	P	18
Korea	6-8	8-9	P	10-12
Malaysia	8	8	S	16
Singapore	4-8	4-6	P	8-10
Taiwan	14	14	P	16
Thailand	12	16-20	P	20-28

\*Regulatory approval takes into account NICPBP testing of study material

# Global Clinical Trials -Challenges

## Pharmacovigilance

- After thalidomide in the 60's most countries developed national pharmacovigilance systems
  - Spontaneous reports
  - Pharmaco - epidemiological methods
- Not perfect – do provide evidence for regulatory action to protect public health

# Global Clinical Trials -Challenges

## Pharmacovigilance

- WHO programme for international drug monitoring coordinates ADRs at Uppsala Monitoring Centre of the 81 member countries
- Registered members
  - < 27% of middle / low income economies
  - > 96% high income countries
- [www.who-umc.org](http://www.who-umc.org)

# Global Clinical Trials -Challenges

## Pharmacovigilance

- Every country should develop national system that contributes to global database
- Issues:
  - Funding
  - Lack of local expertise
- Possible
  - Public private partnerships (pharma, academia, government)
  - WHO led discussions on funding model for developing countries

# Global Clinical Trials - Conclusions

- Clinical trials ex North America / Western EU
  - Increasingly important
  - Less costly
  - Provide treatment – naïve populations, qualified investigators
- Challenges to CROs / sponsors not insurmountable
  - Local expertise
  - Proactive problem identification / prevention
  - Strong operational models