

Clinical Trials in Asia

Short glimpses from Japan,
China, Thailand, Korea and Taiwan

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ToC

The political picture &
Health issues in general
Global regulatory circumstances
The Intranet as a working tool
Export and Import - extra hurdle
Glimpses from specific countries

The political picture and health issues in general

Asia are many countries with different cultures!
Fragmented picture in a global setting

The availability of medical doctors
The access to hospitals – varies to a large extent

The view on health issues rapidly changing

The political picture and health issues in general

TRIPS & WHO very influential

ICH & US FDA large impact on views

Regulatory and political circumstances often merged

The political picture and health issues in general cont.

Pandemics play a major role a :
AIDS, flu, malaria, dengue fever, tuberculosis

Pollution

Safety problems with food

Counterfit drugs & Controlled substances

The political picture and health issues in general cont.

Global clinical research is now a priority

Asian GCP

Developing countries vs "state-of-the-art research

Ethical considerations

Safety problems with food

Counterfeit drugs & Controlled substances

Global Regulatory Circumstances

Why Clinical Trials in Asia?

Incentives for global clinical trials vs possible barriers ?

Problems with transparency ?

Singapore and Japan as "leaders" –
with China as a "runner up"

The global regulatory aspect
vs national interpretation

Global Regulatory Circumstances

Clinical Trials in general
GMP requirements
Problems with transparency ?
Equipment
Linguistic problems
Ethic Committees

Ask the local agencies for input
Try to get "pre-submission" meetings!

Local assistance necessary

The Intranet as a working tool

Getting there?

Web pages often available and
info in English is increasing

Quality check on the information available

Language "missinterpretations"

Electronic communication with the authorities

Export & Import – an extra hurdle

Export and Import ALWAYS complicated!

Not only in Asia !

Pay extra attention to:

The time frames

The many different forms - sometimes not in English

Different authorities – different "rules"

Make sure your "local guide" is updated

Glimpses from specific countries

Clinical trials in Japan:

Application and approval instructions

- now available in English

New guideline on Clinical Trials (1.7.05) incl

Clinical Trials Registry and disclosure (21 days/1st pat)

Possibility for face-to-face counselling before an CTA

(4 month) NB! different categories

ICH and the US FDA - tremendous impact

Global clinical trials encouraged

Still time consuming to get an approval!

Glimpses from specific countries

Clinical trials in Japan cont.:

What to pay extra attention to?

Difference between "bridging" and global CT

Earlier Phases more difficult

Safety & Ethics extra important

Strict back ground documentation important

Requirements to Ph1- change on it's way

Waiver re repetitions of clinical trials possible

Costly and still timeconsuming

Coloured by ADRs , pricing,lack of transparency

Glimpses from specific countries cont.

Clinical trials in Mainland China and Hong Kong:
What is the difference? Pros and cons

HK: GMP requirements (Australia & Singapore)

Stability of test material (heat and humidity)

China: Application and approval of CT procedure in place,
but..

Length of time until CTA approval (195/155 days vs 10-15
months!)

Restriction regarding export of bio-material

Strict requirements for back ground documentation

Rechecking quality of study material (revision of specs?)

Glimpses from specific countries cont.

Clinical trials in Mainland China cont.

Early phases extra cumbersome

Rapid recruitment and good quality work after approval -
investigators highly motivated

Choice of research sites easier now, but still limited

“bank” of institutions lack paediatricians

Ethics Committees inconsistencies

Comparator drugs not registered in China?

Few laboratories

Glimpses from specific countries cont.

Clinical trials in S. Korea:

Approx 15-20 centres for global clinical trials

What to pay extra attention to:

Not very much information from authorities is available in English

Extra tox documentation often required ("single reports")

Back ground documentation requirements (approx. as in Japan)

Ph IV post approval requirements usual (confirmation of dose/ effect relationship)

Glimpses from specific countries cont.

Clinical trials in Taiwan:

Mostly bridging studies (still?)

What to pay extra attention to:

Relation to Mainland China

US FDA plays a major role

Extra requirements for preclinical documentation

Ethics committee confusions?

eCTD pilot project ongoing

Glimpses from specific countries cont.

Clinical trials in Thailand:

License for import

GMP requirements

What to pay extra attention to:

CMC documentation requirements

Ethics Committees

Equipment at trial centres

Summing up:

Clinical trials in Asia
Only if you want your drug registered

Still cumbersome and time consuming!