

Module II: The Trial Landscape Contents

- Why clinical trials?
- Main features of clinical trial design
- The history of clinical trials
- The drug development process
- Phases of clinical trials
- Clinical trial players
- Trial guidelines - GMP, GLP and GCP
- Quality assurance – audits and inspections
- Research ethics
- Risk and benefits of trial participations



Module II: The Trial Landscape Contents of Unit I of Module II

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Why clinical trials? What is a Clinical Trial?

- scientific evaluation of the safety and effectiveness
- medical drug
- medical device
- diagnostic tool
- clinical procedure
- consumer health product



Why clinical trials?
What type of products should be tested?

- drugs/vaccines
- herbs



Why clinical trials?
What type of products should be tested?

- medical devices



Why clinical trials?
What type of products should be tested?

- diagnostic tools – laboratory tests and diagnostic devices



Why clinical trials?

What type of products should be tested?

- surgical procedures



Why clinical trials?

What type of products should be tested?

- medical procedures / prevention studies



Why clinical trials?

What type of products should be tested?

- consumer health products



Why clinical trials?

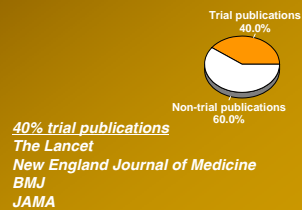
Why are clinical trials important?

- before new research treatments can be made available
- carefully monitored under strict government regulations
- important to ensure safe and effective treatments
- as/more effective or safer than current treatments
- discover new therapeutic uses for currently available medications
- new treatments for conditions that currently have no treatment

Why clinical trials?

How important is trial participation?

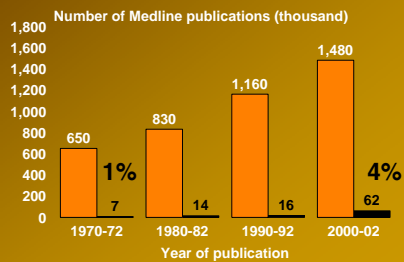
- academic value
- access to new treatment
- revenue
- interaction
- educational



Why clinical trials?

Publication trends

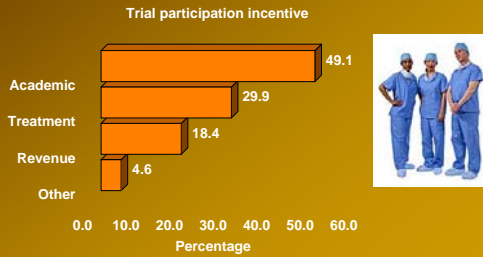
- increase in the proportion of clinical trial publications



Why clinical trials?

Incentives to conduct sponsored clinical trials

- Hong Kong study among 96 active trial investigators (2002)



Conclusion Why clinical trials?

- When new medicines, diagnostic tools and medical devices are to be introduced
- High academic value
