

Bristol Myers Squibb (make Kenalog): time from drug candidacy to clinical trials down from 20 months to 6;

Lilly: formal development to globalisation reduced from 12.8 years to 7.

Smith-Kline Beecham: clinical development down to 5.5 years.

The cost of getting a drug to registration is US\$500 million!

Phases of development:

- I. First exposure to man (10s of volunteers)
- II. First exposure to patient (100s of patients)
- III. Efficacy and safety studies (1000s of subjects)

Exploratory development is the first part of development in which tolerability, pharmacokinetics (the way the body affects the drug) and pharmacodynamics (the way the drug affects the body) are defined in man. (Posner, 1998)

Human pain models tend to be used.

In the Lancet in December 1999, the following quote was used:

“Experimentation must be done in human beings, because testing a drug on lions or horses might not prove anything about the effect on man.” Avicenna (980-1037)

Animal studies are limited by ethical concerns, interspecies differences and measuring pain.

Healthy volunteers are used because it is quicker and easier (fewer confounding factors, for instance.)

There are, however, two conflicting camps. Rowbotham (from USA, not the speaker at the conference) suggested last year that ethics committees will require volunteer studies, whereas Urban (also in 1999) asserted that volunteer studies are not necessary.