

Biomedical research methods

What are biomedical research methods?

- An integrated approach using chemical, mathematical and computer simulations, in vitro tests, whole animal models, and human epidemiological studies and clinical trials is currently the best approach to advance science, develop new products and drugs, and treat, cure and prevent disease.

Breaking it down...

- Chemical, mechanical, mathematical and computer simulations prove most useful in the preliminary stages of research where they can stimulate ideas about new research directions
- These are effective research models but they cannot replace laboratory testing. ***
- Computer simulations are an effective research tool because they increase speed and efficiency of existing data. ***

- **In vitro tests** (meaning “in glass”***) are experiments **performed in laboratory***** containers using tissues or cells. These tests are most useful during the early and intermediate research stages to study a single effect of a substance in isolation.
- ***An example of a limitation to in vitro studies would be that cultures cannot tell us how a substance affects a complex animal system.
- In vitro studies are critical to the study of viruses that can only grow in living cells. ***

- **Nonhuman animal models** provide the most reliable and complete data on the functioning of a living system, and they offer the best indicator of how humans will react to a new drug or medical procedure.
- Animals provide the best surrogate for humans in the lab. ***
- Animals share the same structures (cells, tissues organs) as humans. ***
- People with concerns about animals in research should be aware that the use of animals is governed by federal regulations ***

- **Human studies** involve taking laboratory data on the safety and effectiveness of new vaccines or medicines and evaluating them in carefully staged clinical trials using informed human volunteers.
- When humans are used in biomedical research studies, drugs are usually what is being tested.***

3 main phases of human clinical trials:

- In *Phase I* clinical trials, researchers determine a drug's interaction with the human system, including how it is absorbed, distributed, metabolized and excreted, and the likely duration of its therapeutic effect. **This phase involves a small number of healthy volunteers***** and takes approximately one year.

Phases (cont)

- *Phase II* trials use controlled tests that help determine a drug's effectiveness. These studies involve 100 to 300 volunteer patients. Simultaneous animal and human tests are also conducted at this stage as researchers continue to assess the safety of the drug. This phase takes approximately two years.