Phases (cont).

- *Phase III* trials are conducted to confirm the results of earlier efficacy tests and further identify any adverse reactions. Clinical testing at this point is extensive, involving 1,000 to 3,000 volunteer patients in medical clinics and hospitals. This phase takes approximately three years

- After human clinical trials are completed, firms file a New Drug Application (NDA) with the FDA. The NDA is a comprehensive statement of the information on: drug structure, the scientific rationale and purpose of the drug therapy, pre-clinical animal and other laboratory study results, all human clinical testing results, drug formulation and production details and the company's proposed labeling. This takes approximately 2.5 years to complete.
- Currently, it takes approximately 12 years from initiation of animal and other laboratory studies through all phases of clinical trials and submission of data to the FDA for approval. For each new medicine approved, the cost is hundreds of millions of dollars.

Example

- If an experimental drug is currently in phase I of clinical trials, it will be 11 years before it is made available to the public.***

- **Epidemiological studies** are another type of human study. These studies look at occurrence and distribution of disease in a population.

- May be divided into three general types: experimental, descriptive and observational

Experimental epidemiology

- Experimental epidemiology is the human equivalent of animal testing — providing or withholding a substance to determine its toxic or beneficial effects.
- Such studies are greatly limited by ethical and legal considerations as well as the difficulties involved in securing the cooperation of a large number of people.

Descriptive epidemiology

- Descriptive epidemiology analyzes data on the distribution and extent of health problems or other conditions in various populations, trying to find correlations among characteristics such as diet, air quality and occupation.

Observational epidemiology

- Observational epidemiology uses data derived from individuals or small groups. Data are evaluated statistically to determine the strength of association between a particular variable and disease.

Strengths and limitations

- Strengths: Epidemiological studies offer scientists a direct opportunity to study the effects in humans exposed to chemicals and disease-causing organisms.

  These studies are also useful in identifying patterns in disease or injury distribution. These patterns may be traced to causative factors.

- Limitations: A major disadvantage of epidemiological studies is that considerable human exposure can take place before a toxic effect is detectable, particularly in the case of diseases like cancer that take many years to develop.