



## Bringing New Medicines to Market: The Development Process

Before a new medicine is marketed, it must undergo extensive testing and be approved by relevant regulatory agencies. The first stage in the development process is pre-clinical research, during which the product is tested in animals, generally over a one- to three-year period. If the results indicate that it is safe for human testing, the product then undergoes a series of clinical tests in humans. Human clinical trials generally consist of four phases, starting on a small scale to assess safety and then expanding to larger trials to test efficacy.

**Phase I** Phase I trials involve testing the product on a limited number of healthy individuals, typically 20 to 80 people, to determine its basic safety and pharmacological data. This phase lasts an average of six months to one year.

**Phase II** Phase II trials involve testing a small number of volunteer patients, typically 100 to 200 people who suffer from the targeted disease or condition, to determine the product's effectiveness and dose response relationship. This usually takes one to two years.

**Phases IIIa-b** Phase IIIa trials involve testing large numbers of patients, typically several hundred to several thousand persons, to verify efficacy on a large scale as well as safety. Phase IIIa trials are focused on regulatory approval issues and involve numerous sites and generally last two to three years.

After the successful completion of Phase IIIa, the sponsor submits a registration dossier containing all pre-clinical, pharmacologic, efficacy, and safety data; information about the product's composition; and the sponsor's plans for producing, packaging and labeling. The regulatory review process can take up to 30 months or longer, depending on the country, type of product and other factors.

Phase IIIb trials usually begin after submission of the registration dossier and prior to regulatory approval. These studies, which also involve large numbers of patients, generally focus on issues such as the product's cost-effectiveness or its relative efficacy compared with approved medicines in the same therapeutic class or those that are used to treat the same disease.

**Phase IV** Phase IV trials begin after regulatory approval and typically are used to prove safety and efficacy in new indications (uses); to test new dosage strengths and formulations, e.g., a sustained release capsule or a flavored solution for children; to confirm certain extraclinical benefits such as cost-effectiveness or improved quality of life; and to collect and analyze long-term safety data on patients treated with the product in normal practice.