

Clinical Trials

The Paul-Ehrlich-Institut is the German authority responsible for the evaluation and approval of clinical trials in the field of vaccines and biomedicines. A clinical trial is used to assess the efficacy and safety of medicinal products.

Phase I Trial

A clinical trial in which a medicine is administered for the first time to a few (mostly healthy) people to test the tolerability of the medicine.

Phase II Trial

A clinical trial, often with 100 to 300 participants, to determine the appropriate dose and obtain initial information on the efficacy of the medicinal product against the disease.

Phase III Trial

A clinical trial, usually conducted on a large group of subjects, to gather information about the efficacy and safety of a medicinal product.

Phase IV Trial

A clinical trial to be conducted after authorisation of a medicinal product if necessary.

