A codification system for the various phases of clinical trials of new technologies.

Note: The system applies mainly to drugs and devices. These trials are part of the development and approval process required by regulatory agencies.

Phase I trial:
A trial usually involving 20 to 80 healthy volunteers to determine a drug's safety, safe dosage range, absorption, metabolic activity, excretion and duration of activity.

Phase II trial:
A controlled trial involving 100 to 300 subjects to determine a drug's efficacy and adverse reactions to the drug (these trials are sometimes divided into **Phase IIa** pilot trials and **Phase IIb** well-controlled trials).

Phase III trial:
A large controlled trial to determine a drug's efficacy and monitor adverse events during longer-term use (these trials are sometimes divided into **Phase IIIa** trials, conducted before the marketing authorization application, and **Phase IIIb** trials, conducted after the marketing authorization application, but before approval).

Phase IV trial:
A post-marketing pharmacovigilance study to monitor a drug's long-term effects and provide additional information on the drug's safety and efficacy, including for patient groups with different dosing regimens.