

1 Ethics

Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2 Trial risk vs trial benefit

Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3 Trial participants

The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4 Information on the Medicinal Product

The available non-clinical and clinical information on an Investigational Product should be adequate to support the proposed clinical trial.

5 Good quality trials

Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

6 Compliance with the study protocol

A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

7 Medical decisions

The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

8 Trial staff

Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

13 Quality assurance

Systems with procedures that assure the quality of every aspect of the trial should be implemented.

12 Good Manufacturing Practice

Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

11 Confidentiality

The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

10 Clinical trial data

All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

9 Informed consent

Freely given informed consent should be obtained from every subject prior to clinical trial participation.

13 Principles of Good Clinical Practice

