

Principles And Practice Of Clinical Trial Medicine

Good clinical practice

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In drug development and production, good clinical practice (GCP) is an international quality standard, which governments can then transpose into regulations for clinical trials involving human subjects. GCP follows the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and enforces tight guidelines on ethical aspects of clinical research.

High standards are required in terms of comprehensive documentation for the clinical protocol, record keeping, training, and facilities, including computers and software. Quality assurance and inspections ensure that these standards are achieved. GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the investigational product are properly...

Clinical trial

supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on dosage, safety and efficacy

Clinical trials are prospective biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on dosage, safety and efficacy. They are conducted only after they have received health authority/ethics committee approval in the country where approval of the therapy is sought. These authorities are responsible for vetting the risk/benefit ratio of the trial—their approval does not mean the therapy is 'safe' or effective, only that the trial may be conducted.

Depending on product type and development stage...

Good laboratory practice

(CTCG) of the Heads of Medicines Agencies released a new recommendation paper on the principles of Good Laboratory Practices (GLP) for clinical trial applications

The Principles of Good Laboratory Practice (GLP) establish rules and criteria for a quality system that oversees the organizational processes and conditions in which non-clinical (non-pharmaceutical) health and environmental safety-or simply toxicology-studies are planned, conducted, monitored,

recorded, reported, and archived. These principles apply to the toxicity testing of chemicals in commerce, to ensure the quality and integrity of the safety data submitted by manufacturers to regulatory authorities globally.

Medicine

Medicine is the science and practice of caring for patients, managing the diagnosis, prognosis, prevention, treatment, palliation of their injury or disease

Medicine is the science and practice of caring for patients, managing the diagnosis, prognosis, prevention, treatment, palliation of their injury or disease, and promoting their health. Medicine encompasses a variety of health care practices evolved to maintain and restore health by the prevention and treatment of illness. Contemporary medicine applies biomedical sciences, biomedical research, genetics, and medical technology to diagnose, treat, and prevent injury and disease, typically through pharmaceuticals or surgery, but also through therapies as diverse as psychotherapy, external splints and traction, medical devices, biologics, and ionizing radiation, amongst others.

Medicine has been practiced since prehistoric times, and for most of this time it was an art (an area of creativity and...

Evidence-based medicine

*decision-making about clinical management. [citation needed]
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teaching the practice of medicine and improving

Evidence-based medicine (EBM), sometimes known within healthcare as evidence-based practice (EBP), is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research." The aim of EBM is to integrate the experience of the clinician, the values of the patient, and the best available scientific information to guide decision-making about clinical management. The term was originally used to describe an approach to teaching the practice of medicine and improving decisions by individual physicians about individual patients.

The EBM Pyramid is a tool that helps in visualizing the hierarchy of evidence in medicine...

Rating (clinical trials)

July 2008). "Chapter 4.5.3: Observer Variability"; Principles and Practice of Clinical Trial Medicine. Elsevier. pp. 72-74. ISBN 978-0-08-055793-9. Hróbjartsson

Within the field of clinical trials, rating is the process by which a human evaluator subjectively judges the response of a patient to a medical treatment. The rating can include more than one treatment response. The assessor is normally an independent observer other than the patient, but the assessor can also be the patient (a patient-reported outcome). Furthermore, some clinical outcomes can only be assessed by

the patient (a "private phenomenon").

Because the evaluation is subjective, this can result in both inter-rater or intra-rater reliability. When conducting clinical trials, ensuring rating consistency is important, but can prove to be quite difficult to obtain. Studies dealing with such indications as pain, mental disease or mood are not able to easily track progress with physical...

Analysis of clinical trials

evaluate the effects of those interventions. The progress and results of clinical trials are analyzed statistically. Randomized clinical trials analyzed by the

Clinical trials are medical research studies conducted on human subjects. The human subjects are assigned to one or more interventions, and the investigators evaluate the effects of those interventions. The progress and results of clinical trials are analyzed statistically.

Good Clinical Practice Directive

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The Good Clinical Practice Directive (Directive 2005/28/EC of 8 April 2005 of the European Parliament and of the Council) lays down principles and detailed guidelines for good clinical practice as regards conducting clinical trials of medicinal

products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

The directive deals with the following items:

Good clinical practice for the design, conduct, recording and reporting of clinical trials:

Good Clinical Practice (GCP)

The Ethics Committee

The sponsors

Investigator's Brochure

Manufacturing or import authorisation

Exemption for Hospital & Health Centres and Reconstitution

Conditions of Holding a Manufacturing Licence

The Trial master file and archiving

Format of Trial Master File...

List of publications in medicine

discovery of contagious diseases, and the introduction of experimental medicine, clinical trials, randomized controlled trials, efficacy tests, and clinical pharmacology

This list of publications in medicine, is organized by field.

Some reasons why a particular publication might be regarded as important:

Topic creator - A publication that created a new topic

Breakthrough - A publication that changed scientific knowledge significantly

Influence - A publication which has significantly influenced the world or has had a massive impact on the teaching of medicine.

The definitive bibliographic source of books and articles demonstrating the history of medicine and identifying the first publications in the field is "Garrison and Morton". (Morton, Leslie T. (Leslie Thomas), Morton's medical bibliography : an annotated check-list of texts illustrating the history of medicine (Garrison and Morton). -- 5th ed. / edited by Jeremy M. Norman. -- Aldershot, Hants, England...

Randomized controlled trial

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A randomized controlled trial (or randomized control trial; RCT) is a form of scientific experiment used to control factors not under direct experimental control. Examples of RCTs are

clinical trials that compare the effects of drugs, surgical techniques, medical devices, diagnostic procedures, diets or other medical treatments.

Participants who enroll in RCTs differ from one another in known and unknown ways that can influence study outcomes, and yet cannot be directly controlled. By randomly allocating participants among compared treatments, an RCT enables statistical control over these influences. Provided it is designed well, conducted properly, and enrolls enough participants, an RCT may achieve sufficient control over these confounding factors to deliver a useful comparison of the treatments...

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