

A Short Review on Step Wise Approaches Involved In History and Development of Clinical Research

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Abstract

The Present Review Article gives u a brief exposure on what is meant by Clinical Research and how it has been evolved and its history of development as an Author I have been searched Standard Text Books, Scientific Journals as well as Official Websites and after cross verifying all I have written this short review which will be useful as reference to future generations who are interested in Clinical Research Field.

Keywords: Clinical Research; Standard Text books; Scientific Journals; history and development; future generations

Clinical Research

The term Clinical Research is defined as a systematic, observational, well planned designed experimental study that is performed in human subjects in order to assess the safety efficacy and extent of toxicity of a particular investigational new drug or combination of drugs, devices, biologics, and vaccines.

History and Development of Clinical Research

- **605-562BC:** The world's first clinical trial is found to be recorded in the Book of Daniel in the Bible which stated that king Nebuchadnezzar was the first person who unintentionally carried the very first clinical trial he ordered all people in his kingdom to eat only meat and to drink only wine but several people objected this later the king Nebuchadnezzar allowed them to eat legumes and water after few months experiment ended ,the vegetarians are found to be well nourished ,

healthier and more vivacious than meat eaters thus the very first clinical trial ended with these results.

- **1537:** A Person named Ambroise Pare who is a Renaissance Surgeon unintentionally carried and experimented a clinical trial that several patients came with wounds he divided entire patients into two groups that to one group he gave treatment with boiling water and to other group he treatment with egg yolk mixed with turpentine oil of rose after that soon he noticed that patients treated with egg yolk mixed with turpentine oil of rose are recovered well whereas patients treated with boiling water remained with swollen and more infected wounds.
- **1747:** This is the period where a very first controlled clinical trial was carried out in this modern era by Dr. James Lind, physician when he was working as a surgeon in a ship he observed high mortality in sailors due to Scurvy then he planned a comparative clinical trial to identify the best standard treatment for Scurvy

.He placed all the patients in two groups with same diet but one group he fed with Cider and Vinegar and other group he fed with lemon juice. Later he found the group fed with lemon juice got recovered well soon within 6 days.

- **1863:** During this year United States Physician named Austin flint planned the first clinical trial with placebo and with active treatment .he treated 13 patients who are suffered with rheumatism with an herbal extract which was advised instead of an established remedy.
- **1923:** It is period where the randomization is introduced to field of Clinical Research.
- **1944:** During this period multi centered clinical trials were introduced and carried out where the trial is conducted in different sites using and following same protocol and methods aiming to get wider testing and better statistical data .The medical research council of UK carried out a trial during 1943-1944binorder to investigate Patulin treatment (extract of Penicillium Patulinum) the common cold.
- **1947:** During this year Nuremberg code was formulated with 10 basic statements for protection of rights of human subjects involving in clinical trial.
- **1962:** This is the year where the “Thalidomide Disaster” took place where Thalidomide a new sleeping pill when tested in pregnant women induced birth defects in thousands of new born babies. After this incident the very first time drug manufacturers are ordered by western European government to submit the data regarding safety and efficacy before manufacturing the drugs to FDA (Food Drug and Administration).
- **1964:** This is the year in which the Declaration of Helsinki came into existence stating the ethical codes for physician and protection of participants in clinical studies all over the world.
- **1977:** In this year bioresearch monitoring program was introduced in order to ensure the quality and

integrity of data submitted to FDA and to protect the rights of human subjects involving in clinical trials.

- **1988:** It is the year in which U.S FDA is provided more authority and accountability in approving the New Drug manufacturing rights to Pharmaceutical Companies.
- **1990:** it is the year in which ICH (international conference of harmonization) assembled in order to eliminate differences in development of new drugs among Europe, Japan, U.S they framed guidelines came into existence for Clinical Trials.
- **2000:** This is the year in which a document named as common technical document (CTD) is developed which acts as dossier used in Europe, Japan and U.S for proposing data gathered in clinical trials to respective governing authorities.

Conclusion

By the Present Review as an Author I hope I have given best brief version and an outer view showing how Clinical Research field has been evolved scientifically. I hope this Short Review will make you easy in understanding the history and developments of Clinical Research.

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