REVIEW ON 'DRUG REGULATORY AFFAIRS IN CLINICAL TRIALS'

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ABSTRACT :
Drug Regulatory Affairs is a study of all aspects within the pharmaceutical development process and how they are subject to various degrees of regulation.Clinical trials (CTs) are conducted to discover new methods o f interventions that are better than the existing ones. They are conducted as per the guidelines suggested by the drug regulatory authority of the country where they are being conducted In India; CTs are regulated by Central Drugs Standard Control Organisation (CDSCO) in consultation with Indian Council of Medical Research (ICMR) as per the schedule Y of the Drug and Cosmetics Rules, 1945 and Ethical Guidelines for Biomedical Research on Human subjects.

KEY WORDS : Clinical trials,Regulatory affairs,Irb,Iec,etc.

INTRODUCTION :

Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including; drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments and preventive care. me International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials. It also serves to protect the rights, integrity and confidentiality of trial subjects.

The procedure of introducing a new pharmaceutical drug to the market, after a lead compound has been recognized during the process of drug discovery, is called drug development process.

India with well trained skilled professionals and vast Pharma companies offers unique opportunities for conducting clinical trials. Due to significant cost reduction and increased pace and productivity of all R&D phases has brought considerable growth and impact to the favorable regulatory climate for conducting the clinical trials in India. Various institutions playing a prominent role in guiding the clinical trial in India include DCGI (drugs controller general of India), DBT (department of biotechnology), ICMR (Indian council of medical research, CBN (central bureau of narcotics), RCGM (review committee on generic manipulation) GEAC (genetic engineering approval committee).

DEVELOPMENT OF CLINICAL TRIAL PROTOCOLS:

Every clinical investigation begins with the development of a clinical protocol. The protocol is a document that describes how a clinical trial will be conducted (theobjectives, design, methodology, statistical considerations andorganization of a clinical trial) and ensures the safety of the trial subjects and Integrity of the data collected. The clinical trial should be carried out in accordance with a written protocol agreed upon and signed by the investigator and the sponsor. Any changes subsequently required must be similarly agreed on and signed by the investigator and sponsor and appended to the protocol as amendments.

The protocol, appendices and any other relevant documentation should state the aim of the trial and the procedures to be used. The reasons for proposing that it should be undertaken on humans. The nature and degree of any known risks. The groups from which it is proposed that trial subjects be selected and the means for ensuring that they are adequately informed before they give their consent.

According to the ICH Good Clinical Practice guidelines, a protocol should include the following topics:

- General information
- Background information
- Study objectives and purpose
- Study design
- Selection and withdrawal of participants
- Treatment of participants
- Assessment of efficacy
- Assessment of safety
- Statistics
- Direct access to source data or documents
- Quality control and quality assurance

- Ethics
- Data management
- Financing and insurance
- Publication policy
- Supplements

INSTITUTIONAL REVIEW BOARD/ INDEPENDENT ETHICS COMMITTEE (IRB/IEC):

According to ICH institutional review board (IRB) as a group formally designated to protect the rights, safety and well- being of humans involved in a clinical trial by reviewing a aspects of the trial and approving its start-up. IRBs can also be called independent ethics committees (IECs).

An IRB/IEC reviews the appropriateness of the clinical trial protocol as well as the risk and benefits to study participants. It ensures that clinical trial participants are exposed to minimal risks in relation to any benefits that might result from the research.

An IRB/IEC: Reviews all study-related materials before and during the trial. Must operate in accordance with national and/or local regulations, as well as with ICH good clinical practices (GCPs) guidelines.

Responsibilities of IRB/IEC

- Safeguard the rights, safety, and well-being of all trial subjects.
- Reviews a proposed clinical trial within a reasonable time and document its views in writing.
- Conducts continuing review of each ongoing trial at least once per year.
- Ensures that information regarding payment to subjects (including the methods, amounts, schedule of payment) is set forth in the written informed consent torm and any other written information is provided to the subjects.

Procedures of IRB/IEC

- Determines its composition and authority under which it is established
- Schedules, notifies its members of, and conducts its meetings
- Conducts initial and continuing review of trials
- Specifies that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favorable opinion of the trial
- Specifies the information that the investigator should promptly report to the IRB/IEC (like deviations from the protocol, adverse drug reactions etc.)

Maintenance of records of IRB/IEC

- IRB/IEC retains all relevant records (e.g., written procedures, lists of occupations/affiliations of members, submitted documents, minutes of meetings, etc.) for a period of at least 3 years after completion of the trial and makes them available upon request from the regulatory authority .
- IRB/IEC may be asked by investigators, sponsors, or regulatory authorities to provide copies of its written procedures and membership lists.

REGULATORY AFFAIRS IN CLINICAL TRIALS

Regulatory Affairs is a profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.

The major responsibilities of these professionals are providing regulatory consultation, formulating drug development strategies, product dossiers, conducting gap analysis, submitting reports, communicating with regulatory agencies and providing training related to regulatory affairs.

The RA professional is the primary link between the company and worldwide regulatory agencies such as US Food and Drug Administration (USFDA & Center for Devices and Radiological Health) Medicines and Healthcare Products Regulatory Agency, United Kingdom, (UKMCA), Therapeutic Goods Administration, Australia European Medicines Agency, Organization of Economic Collaboration and Development (OECD) and Health Canada. He also communicates and interprets the seemingly endless mace of laws, regulations and guidelines to the other departments of the company. The RA personnel develops strategies to overcome delays and presents finding of clinical trials to the regulatory bodies so as to get quick clearance thus reducing the time for approval of new molecules. At its core, the RA professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical and health systems and the public. Operationally RA is responsible for assuring that government obligation, market driven demands and evolving scientific conventions are understood and addressed by various stakeholders.

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