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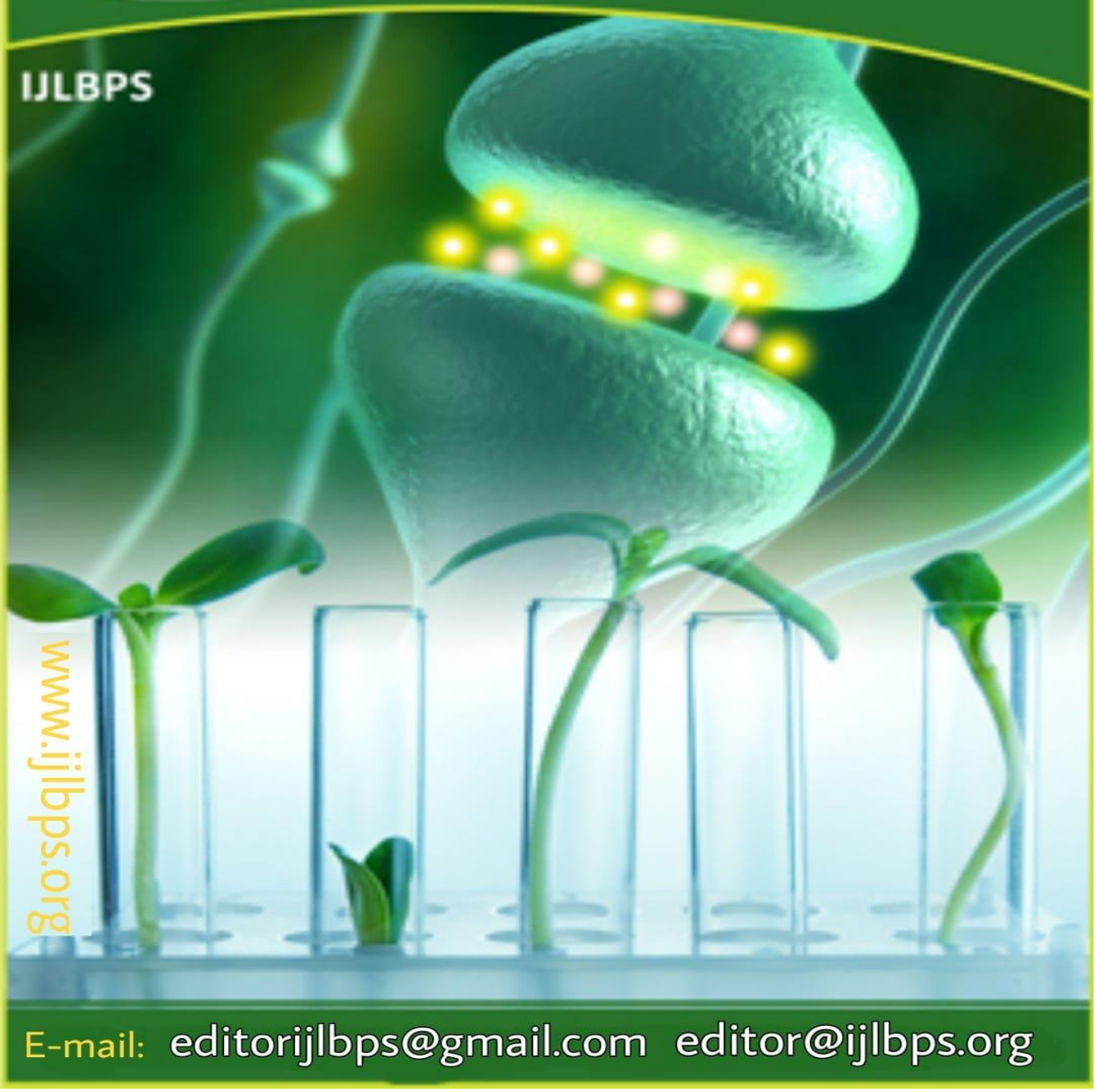

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# Pediatric clinical trials

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## Abstract

The term "clinic" derives from the French word "clinique" and the Greek word "klinike," both of which mean "hospital," and hence allude to the care of the ill at the bedside.To put anything to the test or provide evidence is what the noun trial refers to. Therefore, strictly speaking, a clinical trial is an experiment conducted on ill people. However, in a wide sense, it encompasses any study conducted on humans to ascertain the efficacy of a therapy for the ill or to prevent disease. The FDA has only recently authorized a small number of medications for the treatment of chronic hepatitis B, C, and D in adults. Even fewer are available for kids. Most medications used to treat pediatric patients with liver illness caused by viral hepatitis have only been officially studied in adults. Only two or three medications have undergone comprehensive testing in pediatric clinical trials with children and adolescents aged 0 to 17. Approximately 60% of medications now used in children have not been subjected to rigorous pediatric clinical testing. According to the American Academy of Pediatrics, only a small percentage of drug and biological products marketed in the United States have undergone extensive clinical trials in pediatric population. This includes Ritalin, which is used to treat attention deficit disorder in children, and albuterol nebulizers, which are used to treat asthma in children.

**Key-Words:** Clinical, FDA, Children, Human, Age

## Introduction

Survival rates for kids with cancers including leukemia and solid tumors have increased dramatically because to clinical studies begun after 1960. Many medications are applied to, or used on, children in India. In India, only a handful of the drugs used to treat kids with viral hepatitis-related liver diseases have undergone extensive testing in pediatric clinical trials involving kids as young as infants and as old as 17 years old.

medicines that have only been evaluated and authorized by the FDA for use in adults, including numerous steroidal medicines, are often used in India, particularly in the treatment of children with hepatitis C with significant liver disorders.

## The Start of Pediatric Clinical Trials

Clinical research poses ethical challenges for children's researchers due to the potential dangers participants may experience. In the early stages of clinical research, the highest risk is associated with procedures requiring greater risk, such as chemotherapy and surgery. When is the right time to start studying a drug's effects on children? There are a number of recommendations for incorporating pediatric development into the pharmaceutical registration process in the ICH technical standards document. Children, as study subjects, have unique requirements due to their frailty and developmental quirks.

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Doctors doing research on children have a responsibility to treat the children with dignity and compassion, understand their natural fear of doctors, and recognize the biological differences between children and adults.The importance of doing clinical studies on children The General Assembly of the United Nations adopted the Convention on the Rights of the Child in 1989. It is essential for pharmaceutical research to adhere to the following four principles.No exceptions exist when it comes to youngsters enjoying their human rights.
difference between adults and children
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**The need for clinical research in children**

In 1989 the United Nations general assembly approved a convention on the rights of the child. The following four principles articulated in this declaration are of fundamental importance in pharmaceutical studies.

- ✓ All human rights apply to children without exception.
- ✓ All intervention must have the child's best interest as primary consideration of the highest priority.
- ✓ Children have the right to the highest attainable level of health.
- ✓ Children have right to obtain information and the right to respect of their opinion.

The FDA, EMEA and other authorities state that research in children should be support and encouraged the committee for proprietary medicinal product (CPMP) recommends the following categorization of products to be studies in pediatric clinical trials.

- ✓ Medicinal products for diseases affecting children exclusively such as surfactant in neonates.
- ✓ Medicinal products intended to treat disease occurring in adults and children for which there is currently no treatment.
- ✓ Medicinal products intended to treat diseases that mainly affect children or have a different natural history in children or are of particular gravity in children.
- ✓ Medicinal products to treat a disease occurring in adults and children for which there is insufficient knowledge of toxicity in children.

When a pharmaceutical company develops a new drug it typically spends years developing the compound and testing it in a laboratory setting on human and animal cell. Then the drug is tested on living animals. If these tests are successful the pharmaceutical company provides its data to the FDA and request permission through an investigational view drug in human in clinical trials, also known as medical research or research studies. When it has FDA go ahead clinical testing of experimental drug is conduct in three phases, each phase involves a larger number of people. Once the FDA has granted a view drug approval, pharmaceutical company also conduct post marketing studies.

The FDA is now developing new guideline to force pharmaceutical companies to accelerate drug testing in children to ensure pediatric safety and effectiveness. In India over 75% of medicines used in children are not licensed for use either for the disease states or for the age groups.

During past 22 years medical and legal experts have studied the issue surrounding a child's participation in clinical trials in the eye of the law children 17 and younger are not adults and parent or guardians must grant legal permission for their participation after reviewing all the possible ramifications of the trials. This is called the informed consent process.The reason FDA gives Physicians Latitude in using drug that have been tested only in adults is to hasn't testing of life-saving drug in children and adolescent. Once a drug has been FDA approved any physician can prescribe it, Dr. Brady added it doesn't matter that most drug are approved because of adults trials most drugs used by pediatrician were never tested in pediatric trials. In the case of lamivudine it had a good safety record in kids with HIV, so i was even less hesitant to use it in children with hepatitis B outside thepediatric trials.

Annually about 7500 American children younger than the age of 15 are diagnosed with cancer. An almost equal number of adolescent between 15 to 21 years of age also will be develop cancer consider for example that the year 2000, the European union had about 7.5 million children and 45000 pediatricians but only 12 clinical pediatric pharmacologists. When a clinical trial involves researchers and doctors in several hospitals and research center across the country a data safety monitoring board may be appointed to keep track of the data to ensure participants safety.

**Good Clinical Practice (GCP) issues**

No child should be participating in a study unless a

benefit to children in general will result. The ICH notesthat the benefit to the individual and the benefit to the group must be balanced as follows

"The ethical imperative to obtain knowledge of the effect of the medicinal products in pediatric patient has to be balanced against the ethical imperative to protect the individual child in clinical studies and respect his/her integrity and personal dignity."

GCP helps maintain the balance by ensuring that subjects are properly protected in research studies; studies are based on good science well designed and properly analyzed and study procedure are properly undertaken and documented who take part may be at the risk, the data may be unreliable or unusable and study should be rejected by the ethics committee.

**GCP follows the general principal of medical ethics**

- ✓ Respected for life, human dignity andpersonal autonomy.
- ✓ Beneficence (do some good)
- ✓ Non- maleficiences (do no harm)
- ✓ Justice

From these ethical principles general guideline for good clinical practices in pediatric research can be derived.

**Some ethical issue that would arise in such a trial**

- ✓ What are the pharmacokinetics and pharmcodyanamic of such a dose? Insulin distribution and metabolism would have been studied.
- ✓ Assuming only about 10% of an inhaled dose is absorbed would radio-isotope studies of insulin deposition be required.
- ✓ Are there potential deleterious effects of such a large dose, such as antibody formation?
- ✓ Children with diabetes of 5 to 10 years duration would be very willing to participate. They would likely have a good appreciation ofthe issue involved. They would probably be willing to risk potential side effect in exchange for perceived benefit (absence of injections) would it be appropriated to include children aged 12-16 years in such trials?

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At this time and in the future we can expect pediatric oncologists to play a significant role in translational research to clinical pediatric oncology practices.References

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