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Overcoming challenges in pediatric clinical development

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Many of the drugs used in children have never been tested and licensed to use in pediatric population. Therefore, off-label use in the pediatrics is widespread ~ 45% in various settings including lifesaving situations. Medicines tested and developed for adults may not have the same efficacy and safety profile in children, as the pediatric population is not same as adult. Children have different pharmacokinetic and pharmacodynamic profile than adults and they develop different type of adverse drug reactions to the same drugs. Therefore, they need different dosing, formulation and schedule to treat even similar diseases as in adults. Therefore, drugs in children should be thoroughly tested and tried in the appropriate population and indications to get the information on dosing schedule. Lack of appropriate labeling information and formulation may expose children to unwanted side effects and lack of efficacy. In recent years, there has been lot of regulatory and public interest of protecting children through research, leading to early evaluation of medicines in pediatric populations. Current ICH guidelines and FDA [BPCA, PREA, FDASIA and EMA (PIP)] regulations clearly mandate conducting clinical trials in children in order to get the marketing authorizations in adult indications and these regulations are binding to the MAHs. It has been a challenge to the MAHs to conduct clinical trials in children, as the strategies, designing and execution of clinical trials are not same as of the adult clinical trials. In this session, the practical challenges of the pediatric clinical trials will be discussed, along with strategies to overcome the hurdles in designing and execution of such trials.

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