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Analytical software for clinical trials

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Clinical trials often involve patients with specific health conditions who then benefit from receiving otherwise unavailable treatments. Study subjects typically remain on site at the unit for durations of one to 30 nights, and occasionally longer, although this is not always the case. Clinical Trial is conducted to gain insights for design of the clinical trial to follow effectiveness is how well a treatment works in practice and efficacy is how well it works in a clinical trial. The investigators observe the subjects and measure their outcomes & give the research subjects a particular medicine or other intervention.

Clinical trial protocol: Describes the scientific rationale, objective(s), design, methodology, statistical considerations, and organization of the planned trial. Protocol contains a precise study plan for executing the clinical trial, not only to assure safety and health of the trial subjects, but also to provide an exact template for trial conduct by investigators at multiple locations.

Clinical trials involving new drugs are commonly classified into four phases as Phase I, II, III, IV. The drug-development process will normally proceed through all four phases over many years. If the drug successfully passes through Phases 1, 2, and 3, it will usually be approved by the national regulatory authority for use in the general population. The protocol contains a precise study plan for executing the clinical trial, not only to assure safety and health of the trial subjects, but also to provide an exact template for trial conduct by investigators at multiple locations (in a "multicenter" trial) to perform the study in exactly the same way. The protocol also gives the study administrators, the site team of physicians, nurses and clinic administrators, a common reference document for site responsibilities during the trial.

Clinical data management system: CDMS is a tool used in clinical research to manage the data of a clinical trial. The clinical trial data gathered at the investigator site in the Case Report Form are stored in the CDMS. To reduce the possibility of errors due to human entry, the systems employ various means to verify the data. The most popular method being double data entry where two different data entry operators enter the data in the system independently and both the entries are compared by the system. CDMS can perform is the coding of data. Currently, the coding is generally centered around two areas — adverse event terms and medication names.The system can check the data in the CDMS and compare them to the dictionaries. Items that do not match can be flagged for further checking. Some systems allow for the storage of synonyms to allow the system to match common abbreviations and map them to the correct term.

Biography

K Ramesh Kumar has Completed M.Sc. Biochemistry from Osmania University with 72% in the year 2011,I have done project in Preparation of anti human IgG-HRP conjugate and its use in ELISA and western blot. Participated in the poster presentation and quiz at the two day national seminar on “Emerging trends in science.” Organized by NIN Hyderabad. I have participated in poster presentation in “Two-day workshop on immunological and biochemical techniques” organized by the department of bio chemistry.

Personalised nanomedicine

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Personalized medicine aims to individualize chemotherapeutic interventions on the basis of ex vivo and in vivo information on patient- and disease-specific characteristics. By noninvasive visualizing how well image-guided nanomedicines-that is, submicrometer-sized drug delivery systems containing both drugs and imaging agents within a single formulation, and designed to more specifically deliver drug molecules to pathologic sites-accumulate at the target site, patients likely to respond to nanomedicine-based therapeutic interventions may be Preselected. In addition, by longitudinally monitoring how well patients respond to nanomedicine-based therapeutic interventions, drug doses and treatment protocols can be individualized and optimized during follow-up. Furthermore, noninvasive imaging information on the accumulation of nanomedicine formulations in potentially endangered healthy tissues may be used to exclude patients from further treatment. Consequently, combining noninvasive imaging with tumor-targeted drug delivery seems to hold significant potential for personalizing nanomedicine-based chemotherapeutic interventions, to achieve delivery of the right drug to the right location in the right patient at the right time.

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