

High Quality Data for Healthcare to Answer Scientific Questions

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Description

Clinical research may be a branch of healthcare science that determines the protection and effectiveness (efficacy) of medicines, devices, diagnostic products and treatment regimens intended for human use. These could also be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical research is different from clinical practice. In clinical practice established treatments are used, while in clinical research evidence is collected to determine a treatment. The term "clinical research" refers to the complete bibliography of a drug/device/biologic, of course any test article from its inception within the lab to its introduction to the buyer market and beyond. Once the promising candidate or the molecule is identified within the lab, it's subjected to pre-clinical studies or animal studies where different aspects of the test article (including its safety toxicity if applicable and efficacy, if possible at this early stage) are studied.

In the U.S., when a test article is unapproved or not yet cleared by the Food and Drug Administration (FDA), or when an approved or cleared test article is employed during a way which will significantly increase the risks (or decreases the acceptability of the risks), the information obtained from the pre-clinical studies or other supporting evidence, case studies of off label use, etc. are submitted in support of an Investigational New Drug (IND) application to the FDA for review before conducting studies that involve even one human and a test article if the results are intended to be submitted to or held for inspection by the FDA at any time within the future (in the case

of an already approved test article, if intended to submit or hold for inspection by the FDA in support of a change in labeling or advertising)

Clinical research review criteria will depend upon which federal regulations the research is subject to (e.g., (Department of Health and Human Services (DHHS) if federally funded, FDA as already discussed) and can rely on which regulations the institutions take, additionally to any extent further stringent criteria added by the institution possibly in response to state or local laws/policies or accreditation entity recommendations. this extra layer of review (IRB/REB in particular) is critical to the protection of human subjects especially after you consider that usually research subject to the FDA regulation for prior submission is allowed to proceed, by those selfsame FDA regulations, 30 days after submission to the FDA unless specifically notified by the FDA to not initiate the study.

Clinical research is commonly conducted at academic medical centers and affiliated research study sites. These centers and sites provide the prestige of the tutorial institution yet as access to larger metropolitan areas, providing a bigger pool of medical participants. These academic medical centers often have their internal Institutional Review Boards that oversee the moral conduct of medical research. Within the global organization, the EU Medicines Agency (EMA) acts during a similar fashion for studies conducted in their region. These human studies are conducted in four phases in research subjects that give consent to participate within the clinical trials.