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DID YOU KNOW?

Clinical Trials: Advancing Medical Knowledge

Did you know developing a new medicine, on average, takes at least 10 years and costs 2.6 billion dollars? In order to develop a new medicine, researchers must prove safety and effectiveness through clinical trials before the medicine is approved by regulatory agencies, such as the Food and Drug Administration. In order to complete the required clinical trials, researchers must find enough volunteers to participate. This is also one of the biggest obstacles.

Learn more about some of the common myths and facts about the clinical trial process and why increasing awareness and participation in clinical trials is essential for the timely development of innovative new medicines for the patients that need them.

MYTH: Clinical volunteers are merely human guinea pigs.
FACT: Strict guidelines are in place to ensure clinical trial volunteers are treated fairly and ethically. Before an investigational drug can be given to people who volunteer to participate in clinical trials, scientists must complete a rigorous screening and preclinical testing process, which can take up to six years to complete. Additionally, every clinical trial also has a thorough informed consent process to help protect participant's rights, including the right to leave the trial at any time.

MYTH: Clinical trials are dangerous because they use new practices and medicines.
FACT: Clinical trials are designed for research purposes, and as a result, some level of risk is involved. However, investigational drugs are given to clinical trial participants only after the drugs have gone through a rigorous testing process and scientific evidence indicates that the drug is likely to be effective and safe for use in humans. In addition, all clinical trials are reviewed before they start by an institutional review board (IRB), a committee made up of doctors, scientists and community members who have the responsibility to protect clinical trial participants.

MYTH: Informed Consent is just reading and signing a piece of paper.
FACT: Informed consent is an ongoing, interactive discussion – not a one-time informational session – and it involves two essential parts: a *document* and a *process*. The informed consent *document* includes all the information a patient needs to help make a decision about taking part in the clinical trial, including all the known information about the safety and potential efficacy of the investigational drug being studied in the trial. The informed consent *document* also describes the purpose of the clinical trial, explains the visits and procedures to be done and includes the possible risks and benefits of participating in a way that is easy to understand. The

informed consent *process* provides participants with ongoing explanations to help volunteers make educated decisions about whether to begin or continue participating in a trial.

MYTH: Even after joining a clinical trial a volunteer might get a "sugar pill" or placebo instead of a real drug.
FACT: A placebo is a product that looks exactly like the investigational drug but does not cause harm or good. The decision about whether to use a placebo in a clinical trial is based on how serious the illness is, whether an existing treatment is available and other considerations that ensure a high standard of ethics. When conducting research on serious or life-threatening diseases, the best available treatment (called "standard of care") will be used instead of a placebo.

MYTH: Some people who try to volunteer for a clinical trial are told by the research team they are not eligible to be in the trial. The process seems unfair.
FACT: Every clinical trial has a protocol, which is a plan describing what will be done during the trial, how the trial will be conducted and why each part of the trial is necessary. The protocol for the clinical trial also includes eligibility criteria and guidelines for who can and cannot take part in the trial. Common eligibility criteria include age, gender, having a certain type or stage of cancer, having received (or not received) certain medicines in the past, medical history and current health status. It is important to note that eligibility criteria are not used to reject you personally. These guidelines are used to identify the people most likely to benefit from the clinical trial. The criteria are also necessary to help ensure researchers will be able to answer the research questions about the investigational drug they plan to study.

MYTH: Being in a clinical trial will be painful or unpleasant.
FACT: Like all medical interventions, clinical trials have potential benefits and risks, such as side effects or pain. Processes and procedures can be different for each clinical trial. Some, like in general medical care, may be unpleasant or carry risks. However, providers talk to participants about what to expect and procedures and risks are listed in the informed consent document a patient gets when deciding whether or not to participate. The IRB will also ensure the benefits and risks are carefully weighed and the trial is reviewed for unnecessary harm or discomfort before it starts.

MYTH: Being in a clinical trial won't help.
FACT: Before deciding to participate in a clinical trial, it is important to speak with a doctor or the research team about the trial design and the possible risks and benefits of participating. One potential benefit is that volunteer participants may have the opportunity to receive an investigational drug that is not available to people outside the trial. The clinical trial research team also closely monitors participants, perhaps even more closely, than a doctor or nurse does during regular office visits. And, because trials have detailed treatment plans (called protocols), participants may get additional tests and lab work that might not be part of usual care. Some trial volunteers also report great personal satisfaction in the fact that they have played a key

role in advancing medical science and helping researchers find new treatments that will help more people live longer, healthier lives.[1]

MYTH: Providers will make their patients aware of clinical trials that might help them.
FACT: Your doctor may not know about all available clinical trials that might benefit a patient. The National Institutes of Health has an online database that consumers and providers can use to search for appropriate trials: www.clinicaltrials.gov. Alternatively, patient advocacy organizations can be good contacts to help navigate the process. Many have tailored services that can help patients with their search and understanding the options.

[1] https://www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-General-Perceptions.pdf