THE ROLE OF A CLINICAL RESEARCH ORGANIZATION

What is drug development and who is Covance?

Researchers are always looking for additional insights into diseases which may allow them to create a new way of preventing or treating the effects of a disease. Once a drug is identified that shows promise, more research needs to be done to understand how this may affect humans, such as how it is absorbed, how it is excreted, what side effects it may have or how it interacts with food or other medications. Only a small number of drugs make it through this early development phase to be tested, either on healthy volunteers or people living with the disease.

Covance is the drug development business of LabCorp and is a clinical research organization (CRO) that supports the pharmaceutical and biotechnology industry in clinical research.

What is the Role of a CRO?

A CRO is a company that is hired by a pharmaceutical, biotechnology or medical device company to manage and lead specific duties related to the development of a new medical treatment. It may also work with academic organizations, charities or the government to perform similar services. These services are outsourced on a contract basis, similar to situations in which an individual arranges for services from an electrician or plumber to support home repairs.

The type of support provided by CROs differs depending on their business focus and the requirements of each customer, but some examples include: clinical research study management, pre-clinical research in the lab or management of laboratory testing in support of a study or research. The CRO can be engaged to provide a range of services for each study, ranging from very specific aspects to managing the full scope.

CROs can be large global organizations, such as Covance, which are able to support studies of multiple diseases, illnesses and clients being conducted almost anywhere in the world, or smaller businesses with niche service offerings based on clinical specialty or geography. An increasingly important part of clinical studies is recruiting doctors and patients to participate in a study. Doctors, who are often referred to as a lead or primary investigator, oversee the patients who are receiving the treatment to make sure the treatment is administered correctly, he/she will also monitor reactions and report back on how each patient handled the treatment. The ability of a CRO to more quickly and precisely identify and recruit investigators and patients can help to accelerate a study, and bring new treatments to the market faster.

CROs provide a cost-effective method for pharmaceutical and biotechnology companies to pursue new medicines or treatments, as it allows the company to focus on the scientific development of products instead of managing every step along the developmental process. Although a pharmaceutical or biotechnology company may transfer study management duties to a CRO, it retains overall responsibility for the quality of the data and oversight of the duties. The

company owns the product and the overall strategy for that product, while the CRO supports the company in meeting its research goals.

Where do I fit in?

If you are a healthy individual but are still interested in supporting clinical research, then you might be interested in learning more about Phase I studies, which are focused on the safety for humans of a potential new treatment; Phase I studies follow pre-clinical studies, in which the treatment is tested in the lab and on non-human subjects to provide an initial safety assessment. In a different topic, we discuss the different phases and what these mean. Phase I studies normally compensate people for their time and participation. The link below will take you to the Covance Phase I unit to learn more about the types of studies currently active.

www.CovanceClinicalTrials.com

If you have been diagnosed with a disease, illness or medical condition, then you may be interested to learn more about Phase II, III or IV studies. These types of studies usually require individuals who have varying degrees of illness or disease, in order to test whether a potential new treatment is effective and could potentially be approved for use with the public.

If you are interested to learn what studies are currently being run in the U.S., go to www.clinicaltrials.gov or opt in on the LabCorp Patient™ portal to receive more information about research to improve lives and to hear more about the studies that Covance is managing.

The role of patients in research

Development of new medical products for humans has been controlled by researchers for many years. However, there is an increasing awareness that those affected by the relevant diseases should have a greater role to play in the development process. This could include participating in a study, supporting family or friends who are participating, joining an advocacy or support group for people with a specific medical condition, writing a blog or posting on social media about your experience with a medical condition or a study or joining a patient advisory panel that might be sponsored by a medical center, managed care organization or biopharmaceutical company. If you or somebody close to you has a medical condition, especially one for which there may not be many effective treatments, and wishes to contribute to clinical research, there are plenty of ways to get involved.

Working with patients to improve health

LabCorp's mission is improving health and improving lives. Its Covance Drug Development business has many opportunities for people to participate in research that can improve the quality of their lives and lives of others. The research can take many forms, including clinical studies, medical device studies and other types of research to develop new healthcare solutions. To make sure you get more information about these studies, including being contacted if you may be eligible to participate in a study, please make sure you have agreed to be contacted through your LabCorp Patient portal account.

OTHER REFERENCES:

https://www.fda.gov/forpatients/approvals/drugs/

http://innovations.bmj.com/content/bmjinnov/early/2017/03/24/bmjinnov-2016-000157.full.pdf

www.clinicaltrials.gov

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