Clinical Research, part 2

It is obvious we all need improved and safer medical intervention. Medicine is no different from technology in progressing and developing and much more significant as it influences our health and life directly when we get sick.

So how do we know that the drugs we take are safe? In the United States, the safety and development of medicines is controlled and regulated by the Federal Drug Administration (FDA). Other countries have similar institutions but may regulate the drug development through different regulations. More and more often, regulatory institutions from various countries and continents work globally together to allow some processes to become faster and stream-lined for more efficient development.

The rules developed by FDA are published on their website and available to the public. For clinical trials, those rules are combined under GCP, Good Clinical Practice. All clinical investigators who conduct clinical research must follow them. FDA performs audits of research clinics and sites in order to assure integrity of data collected in clinical trials. Doctors who are investigators are directly responsible for that integrity and further, they influence the safety of patients who receive the drugs developed in the process.

Every new medication must go through phases of development: pre-clinical, phase 1, 2, and 3.

Pre-clinical development is associated with animal research and is conducted as a very early stage of discovery of a potential new medicine. Phase 1 usually involves a very small group of patients, who are healthy, and agree to experiment in taking escalating doses of the new medication in order to determine the toxicity of the new drug. Phase 1 trials often take place in a closed hospital setting and require a lot of frequent blood testing, sometimes several times a day.

If the new medicine passes safety limits of the phase 1, it goes to phase 2. Still on a limited basis, 120-200 patients, phase 2 is usually helping to make determination which doses of medications are optimal for patients who suffer from a certain disorder. Often, during phase 2, doctors discover how well the new drug is working, while continuing to monitor safety of it. The level of success is called efficacy.

And finally, phase 3 research studies include a

larger group of patients, sometimes over 1000, and data collected during that final phase is presented to FDA.

For every investigator, safety is always the most significant focus but, I do not deny, observing new medicine showing critical improvement of efficacy is probably the most exciting part of research.

Research team of Dr.Michael Bukhalo Arlington Dermatology (previously known as Altman Dermatology Associates) developed many new drugs showing that critical level of improvement of efficacy. For the last 12 years, we have conducted over 100 clinical trials, many of which brought new drug to the market.

The clinic was visited by FDA twice receiving the most awarding comments of high integrity of data and perfect GCP in patients care. Several hundreds of patients participated in those clinical studies, finding how new drugs are working and receiving optimal medical care in this free of charge option of treatment. Many of those patients returned and keep returning, taking social responsibility for what pharmaceutical companies put on the market. They find the new treatment options altogether with the research team and Dr.Bukhalo.

If you are interested in finding more about clinical research and the studies we run, please call us at 847 392 5440 and ask to talk and meet our research team member. Please, remember that all visits and treatments for clinical research are free of any charges, we do not need any insurance, and we are very flexible with scheduling the day and time. We can meet with you Monday to Saturday, 8-6.

Call us today: Arlington Dermatology (former Altman Dermatology Associates), 1100 W.Central Road, suite 200, Arlington Hts IL 60005