Corrona ♥ their Participants!
Clinical Research and You

Joint Effort: The Corrona Pharmacovigilance Program

The Importance of the Follow-Up Visit

The Practice of Mindfulness
People with RA may have more options for treatments. This year, the FDA (Food and Drug Administration) has approved three biosimilar therapies, for use in the treatment of moderately to severely active RA: Inflectra, Amjevita, and Erelzi. Inflectra (infliximab-dyyb) is the biosimilar equivalent to Remicade (infliximab), Amjevita (adalimumab-atto) is the biosimilar to Humira (adalimumab) and Erelzi (etanercept-szzs) is the biosimilar to Enbrel (etanercept). You might be familiar with Humira, Remicade, and Enbrel, but what are biosimilars, and how do they stack up against their biologic counterparts?

Biologics are products made from living organisms such as cells and tissues and are used to treat various medical conditions. Whereas conventional drugs (e.g. aspirin) are made from defined, chemical “recipes”, biologics are manufactured using unique and complex compositions that are not easily identified. In rheumatoid arthritis and other chronic, auto-immune diseases, biologics target the proteins in cells that cause inflammation. Biosimilars are manufactured with a similar mixture to its biologic counterpart, though the compound is not the same. In order for a drug to be classified and approved as a biosimilar, it must:

- Not indicate any significant clinical difference to the biologic
- Demonstrate the same level of safety and effectiveness as the biologic
- Utilize the same route of administration
- Have the same dosing and strength

Though biosimilars had already been approved for use in the European Union (EU) for several years, the first biosimilar drug ever to be approved in the U.S was in 2015 for Zarxio. Zarxio (filgrastim-sndz), a biosimilar to Neupogen (filgrastim), is a therapy used in the treatment of cancer and other diseases. As more patents for biologics expire, the market for biosimilar drug products may continue to surge.

Clinical Research and You: Why are Volunteers Important to Clinical Research?

Kimberly Gottfried, RN, MS

Everyday clinical research volunteers help researchers and clinicians explore promising new medical treatments targeting the cause of many illnesses. Every person’s decision to participate is different, but the end cause is the same: improve the treatment options, relieve symptoms, and hopefully, improve the human condition.

If you were diagnosed in 1999 with chronic myeloid leukemia (CML), you probably would not be alive today. Only 30% of patients survived five years after diagnosis back then, and you would have had two treatment options: a risky bone marrow transplant or daily injections of interferon. Given the same diagnosis today, you can take a daily pill that targets the cancerous cells directly, causing fewer side effects and contributing to higher rates of remission than in 1999. This same success story has been repeated in many disease areas; HIV/AIDs deaths have fallen by 70%, new blood pressure medications have prevented millions of hospitalizations, and the rates of heart attack and heart failure have been cut in half.

How did we get here? Through the efforts of patients, like you, who through voluntary participation in clinical trials make new medicines a reality. Anyone can volunteer to participate, as long as you meet the trial’s eligibility requirements. And, with more than 4,000 experimental drugs and therapies and over 80,000 clinical research studies conducted annually, there are many opportunities to participate and contribute to the process. There are many different types of research trials: experimental drugs, collection of tissue samples, behavior studies, survey studies, and of course, those like the one your physician’s office has chosen to participate in – observational, non-interventional registry studies.

On behalf of Corrona’s researchers and staff, we thank the thousands of you who have already chosen to participate in the Corrona registries and have given unselfishly year after year, your time and efforts to help advance the collective health of patients with rheumatic disease.

If you want to help make a difference, talk to your physician today about joining Corrona’s mission in improving health care options for patients with rheumatic and autoimmune diseases everywhere.

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~FOCUS–The Practice of Mindfulness~

Judith Ellen Tauriac, BA

Mind your manners. Mind your own business. Be mindful of oncoming traffic. Mind over matter. Through the course of your life, you may have heard or seen these phrases, or you may have spoken these words to someone else. Mindfulness, once a catchall of our common lingo, now has become a movement and a way of life. You may be surprised to learn that something which seems “out there” can be well within your grasp and a useful tool in developing greater self-awareness.

Chances are, you’ve been practicing mindfulness without realizing it. When you are diligently crafting an email to a client or going for a morning run, you could be in the practice of mindfulness. Simply put, mindfulness is the act of being present or aware of the present moment. On the other hand, if you’re like most humans, you have the tendency to send a text, wipe down the countertops, and watch TV all at the same time! All that multi-tasking can seem like an art form, but it is counter-productive and decreases our ability to focus and complete tasks. Mindfulness offers us a way to tune into whatever it is we are doing and find a connection.

What it looks like. You may have an image of a person sitting cross-legged, eyes shut with a peaceful demeanor. Perhaps you conjure a statue of the Buddha nestled in a garden or among shrubbery. Depictions of mindfulness are not necessarily that of serenity and quiet. Athletes who perform at their most optimal level are said to be “in the zone”—a place where they fully concentrate on their physical goals amid a cheering crowd. Thich Nhat Han, a well-known peace activist and Zen Buddhist Monk, says that washing dishes can be an act of mindfulness by placing your thoughts on what your hands do when they are washing the dishes. Thus, mindfulness can occur in an exertion (running, catching a ball) and also in a somewhat meaningless and every day task. The difference is in taking on an observer’s role while you are performing what you are doing.

What if feels like. Anecdotally, many people have experienced the benefits of the practice such as, having less stress, enjoying more wholehearted involvement in leisurely activities and possessing an overall better outlook on life. If mindfulness can alter a person’s perspective, are there other tangible elements to the practice? Researchers have sought out answers to this question in an effort to measure the effects of mindfulness on the body. In one study examining a mindfulness practice and its effect on pain management, Dr. Mary C. Davis and colleagues at Arizona State University found that subjects who were trained in mindfulness-based techniques experienced a decrease in stress levels that were related to the fatigue and pain symptoms of RA.1 A study conducted in New Zealand demonstrated that subjects with RA who practiced a form of mindfulness called MBSR (Mindfulness-Based Stress Reduction), showed a decrease in disease activity and improvement in morning stiffness well after the intervention concluded.2

How it works. Consider this simple approach: imagine a snow globe. In its stillness, the white flakes and glitter cover its floor, but when you shake it up, a flurry ensues. One way to quiet or focus the mind is to visualize your thoughts as the scattering snowflakes drifting to the bottom of the globe. It doesn’t happen all at once, but each thought, like the individual snowflake, takes its time to find its place. If you have a snow globe handy, give it a shake and observe the crisscrossing path of the flakes falling to the bottom. Another approach is known as RAIN: Recognize the thought, Allow the thought, Investigate where the thought comes from, and be Non-judgmental about it. By following our thoughts as a kind of interested bystander, we may better understand our thought processes. These examples provide ways to approach mindfulness, as there is no one right way to reap the benefits of the practice. For further exploration, visit these websites: www.mindful.org and http://www.umassmed.edu/cfm/stress-reduction/.


The Importance of the Follow-Up Visit

Tanya Sommers, MS ANP-BC

Participating in regular follow-up visits with your Rheumatologist is not only an essential part of maintaining your optimal health and well-being, but is crucial when taking medication to manage your RA disease process.

As health care professionals, we recognize how Rheumatoid Arthritis disease affects the body. We know the broad scale of treatments available, and we know the potential medication side effects. The key to successful treatment and management is your ability to communicate the pieces we do not know--your day to day life, how you are feeling, how your body is responding to the medications administered, and more specifically, how your body is tolerating the treatment regime being used.

Patients with many types of arthritis, like RA for example, can experience symptoms that may be a sign that there is something more serious happening, and often times, these are not something that is anticipated or can be predicted by your physician.

The Corrona RA Registry is designed to capture these critical elements at routine follow-up visits with your provider that occur in a time frame that is practical and relevant in capturing the changes your body may be experiencing. These office visits can offer a bigger picture as to what is working, what is not, and what needs to be monitored more closely.

RA isn't just a disease that affects the joints, it's a disease that affects the body, the individual, and the families of the person affected. Communication with your rheumatologist during routine follow-up visits and completion of the Corrona Subject Questionnaires are tools for routine health and safety information which assist in the monitoring necessary in maintaining your optimal state of a health. The time spent completing the follow up visit is invaluable in helping your provider understand your current health status to determine whether any of your symptoms are serious and if any action should be taken immediately or in the near future.

The patient-reported data you provide by completing the Corrona Follow-up Questionnaires becomes essential to the care you receive. It not only captures disease specific information, but it allows you and your rheumatologist to be able to discuss, develop, and maintain a more thorough plan of care that assesses your physical needs and disease progress and optimizes your health outcome. So, be diligent and be sure to Follow-up!

Joint Effort: The Corrona Pharmacovigilance Program

Rene White, MA

Pharmacovigilance is one of those dazzling words that’s fun to say and can definitely impress your friends at a party, but in case you are reading this before your first cup of coffee, we will also refer to it as “drug safety”. Pharmacovigilance is done to monitor and understand safety or “effects” of drugs or biologics, typically after a medication has been approved for human use. The goal is to minimize risk of harm to patients by ensuring that medications are of good quality, effective, and safe. Drug safety monitoring is an important function of Corrona registries. Patients, physicians, researchers, and regulators (e.g. U.S. Food and Drug Administration) are interested in better understanding the safety of drugs, including medicines specifically used for the treatment of RA. Corrona’s long-term, real-world registries collect data to help support research discoveries and guide treatment decisions made by patients and physicians.

You, as the patient, play a vital role in reporting this important information so that it can be put to good use. Perhaps at this point you are asking, “How?! (Or, you are still repeating “pharmacovigilance” in your head because it’s that fun to say)!

Here’s how! Your rheumatologist or a member of their staff will ask you about the occurrence of any adverse events or medical problems that have newly occurred since your last registry visit. It is important to let them know of any new medical diagnoses or conditions that may be new or occurred since the last time you completed questionnaires at your rheumatologist’s office.

It is also always important that you let the doctor or nurse know right away (even in between clinical visits) if you experience any of the following:

* Hospitalization
* A life threatening medical event
* A new medical problem that results in disability
* Any new pregnancy
* Any congenital anomalies or birth defects diagnosed in your baby

If you are not sure if you’ve experienced an event that meets the serious criteria, and needs to be immediately reported, please ask your rheumatology healthcare provider. They can reach out to the Corrona Drug Safety team, if needed.

As you can see, the relationship among patients, providers and the Corrona Drug Safety team is an interdependent and important one. Thank you for participating in the Corrona RA Registry and remember, drug safety reporting is a joint effort!