

Spikes & Spasms

The TremorAction.org Newsletter

APRIL 2007

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WELCOME TO THE APRIL ISSUE!

In tandem with the 59th Annual Meeting of the American Academy of Neurology, Experience the Progress, The TremorAction.org Newsletter features new and updated articles from our sponsors: Boston Life Sciences, Cleveland Medical Devices, Solstice Neurosciences, Vivacare and Allsup Inc.

Tremor Action Network connects "the bench to the tremor patient" through innovative clinical trials, studies, therapeutic, diagnostic, biopharmaceutical and assistive technology products, and other services.

TAN supports and promotes research in an effort to help find the cause, treatment, and cure for essential tremor and related movement disorders.

We thank our sponsors for their generous support, and we encourage you to visit their websites and those sponsors exhibiting at the AAN Meeting in Boston, April 30 through May 3, to learn more about them.

Enjoy reading the April issue brought to you by **Life In Motion** coalition member **Tremor Action Network**.

BOSTON LIFE SCIENCES

Parkinson's or Essential Tremor

There are approximately 1.5 million people in the U.S. who currently have been diagnosed with Parkinson's disease, and as many as 10 million people afflicted by Essential Tremor, a disorder that is often mistaken for Parkinson's disease, especially in its early stages. According to a report in 2002 in the European Journal of Neurology, there is a 20 to 30 percent misdiagnosis rate by neurologists in the early stages of Parkinson's disease. Boston Life Sciences Inc. is currently testing whether their molecular imaging agent, ALTROPANE®, can offer a more accurate distinction between tremors caused by Parkinsonian Syndrome and those associated with other disorders

The BLSI trials involve Single Photon Emission Computed Tomography (SPECT) scans using ALTROPANE as an imaging agent. The imaging agent binds to the dopamine transporter protein found on the surface of dopamine-producing neurons, making it visible during SPECT. Because Parkinson's-related syndromes usually have a decreased number of dopamine-producing cells, research demonstrates that patients with these syndromes would also have fewer dopamine transporter proteins. Therefore, BLSI believes that ALTROPANE allows them to see whether tremors are associated with Parkinson's-related diseases or other disorders.

The Phase III, POET-I (Parkinson's or Essential Tremor) trial for the ALTROPANE molecular imaging agent was completed in March of 2006. In September 2006, Boston Life Sciences reported statistically significant. The POET-I trial was designed to assess whether ALTROPANE imaging is more accurate than the clinical diagnosis of primary care physicians (PCP) to distinguish between

tremors caused by Parkinsonian Syndrome and those associated with other disorders, as judged by comparison to a definitive diagnosis by Movement Disorder Specialists (MDS). ALTROPANE scans showed statistically significant superiority over the diagnosis of PCPs on measures of both specificity and sensitivity, the Primary Endpoint of the trial. Based on data analyzed to date, with the exception of one "possibly-related" urinary tract infection that resolved after treatment, there were no drug-related serious adverse events.

BLSI is expected to meet with the FDA in the spring of 2007 to discuss the path towards approval for ALTROPANE. Following the FDA discussions, BLSI is planning to initiate the POET-2 trial by the end of 2007. BLSI is also planning to meet with regulatory authorities in Europe to discuss initiating clinical development in select European countries.

BLSI believes if doctors can better differentiate Parkinsonian tremors from non-Parkinsonian tremors, they

can get a headstart in providing the proper treatment for patients.

For more information about the POET trial, please visit the POET web pages at:

<http://www.bostonlifesciences.com/poet/index.asp>

Or e-mail BLSI at trials@bostonlifesciences.com

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About the Author

Boston Life Sciences, Inc. (BLSI) is a biotechnology company engaged in the research and clinical development of novel diagnostic and therapeutic solutions for central nervous system (CNS) disorders.

ALTROPANE is a registered trademark of Boston Life Sciences, Inc.

More Accurate Tools for Researching, Diagnosing and Treating Movement Disorders

By Joseph Giuffrida, PhD and Maureen Phillips



Imagine you are going to the doctor for a routine movement disorders exam. You go through the usual manual tasks, such as finger tapping, touching your nose or opening and closing your hand, and the clinician watches and evaluates your performance. According to the doctor, your symptoms

seem to be the same as your last visit, but to you, they feel worse. You also may have just taken your medication. By the time you get to the doctor, your symptoms are under control, and there is no way to show how your symptoms change throughout the course of a normal day. You refer to your symptom journal or simply try to explain what is getting worse and how it feels, but it's not that easy to do.

At CleveMed, our Division of Movement Disorders is working to provide clinicians a more complete picture of how Parkinson's symptoms fluctuate throughout the day, without adding much additional burden to the patient. In the TAN newsletter from September 2005, CleveMed included an article introducing ParkinSense, a small, wireless device for monitoring the upper extremity symptoms of Parkinson's disease, such as tremor and bradykinesia (slowed movements). ParkinSense is worn on the finger and wrist of the patient and monitors the motion of the hand to help determine the severity of Parkinson's disease symptoms. The device sends data to a computer over a wireless link where it is displayed and analyzed in the ParkinSense software. The software also includes videos to guide subjects through upper extremity motor tasks. Ultimately, CleveMed's goal is to use ParkinSense for

detecting subtle differences in symptoms from visit to visit, or even over the course of a day, week or month. This way, the doctor will then be able to adjust medication dosage and timing to better suit each individual person's needs.

Each day, CleveMed is moving closer and closer to providing a portable, wireless system to continuously monitor Parkinson's disease motor symptoms. The hardware unit was significantly upgraded last fall to include a push button diary on the wrist worn component, which allows the patient to indicate when they have taken their medication and when their symptoms are severe. The radio was upgraded to simplify setup and improve wireless communications. We are also in the process of completing a study with 60 Parkinson's subjects in which we are comparing the quantitative data collected by ParkinSense to the qualitative Unified Parkinson's Disease Rating Scale (UPDRS) for tremor and bradykinesia. Preliminary results indicate that the ParkinSense system can output similar clinical scores for

CleveMed's Division of Movement Disorders is focused on systems that record movement, restore control and enhance function.

tremor and bradykinesia as a movement disorder specialist would. Once this clinical study is complete, there are still many challenges to producing a clinical product. First, we plan to submit peer-reviewed publications to demonstrate the efficacy of ParkinSense. Additionally, CleveMed will demonstrate the benefits to insurance companies so that reimbursement may be provided for ParkinSense. CleveMed is also seeking FDA clearance to market the clinical version of the ParkinSense device. With these new upgrades and the completion of clinical trials, ParkinSense is well on its way to being a useful tool for doctors and patients alike.

A new addition to CleveMed's movement disorders line of products is KinetiSense. KinetiSense was actually developed using the same motion sensing technology as ParkinSense. After receiving clinical feedback on ParkinSense for a little over a year, we realized that there



is a very large movement disorders market, outside of Parkinson's disease, that this technology could be useful for. The KinetiSense system is similar to ParkinSense in that it monitors complete three dimensional motion using tiny sensors called accelerometers and gyroscopes as well as muscle activity called electromyography. The difference is that KinetiSense provides a system that can be targeted toward a broader range of movement disorders and rehabilitation applications. For example, a researcher could use the system to perform gait analysis for individuals who have Huntington's disease, ALS, cerebral palsy or other disorder that affects the way a person walks. KinetiSense could also be used for essential tremor monitoring, biomechanics, or exercise physiology. In any of these applications, one of the biggest benefits is the wireless technology of the system. KinetiSense gives subjects the ability to move freely about a research lab, ultimately creating more natural movements unavailable through more traditional tethered designs. If researchers are equipped with better, more precise, more accurate tools to investigate these disorders, then better treatments may soon follow.

CleveMed's Division of Movement Disorders is focused on quantifying movement disorder symptoms and providing home based therapy aimed at restoring function through systems that record movement, restore control and enhance function. Using our small, lightweight, wireless technology, we hope to provide multiple clinical products for diagnosis, treatment and assistance for the millions of people currently living with movement disorders.

To find out more about CleveMed, The Division of Movement Disorders or our products, please visit our

website at www.CleveMed.com or call us at 1-877-CleveMed (253-8363).

About the Author

Joseph P. Giuffrida, PhD is the Director of the Division of Movement Disorders at Cleveland Medical Devices, Inc. in Cleveland, Ohio. His research focuses on developing clinical products for movement disorders including Parkinson's disease, stroke and cerebral palsy. Dr. Giuffrida can be reached by email: jgiuffrida@clevedmed.com or phone: (216) 619-5904.

Maureen Phillips is a Biomedical Applications Specialist in the Division of Movement Disorders at Cleveland Medical Devices, Inc. in Cleveland, Ohio. Her responsibilities include organizing clinical studies, obtaining clinical feedback, marketing, and sales. Ms. Phillips can be reached by email: mphillips@clevedmed.com or phone: (216) 619-5918.

CleveMed's movement disorders research is supported by Small Business Innovation Research grants from the National Institute of Child Health and Human Development (1R43HD047086-01A1) and the National Institute of Neurological Disorders and Stroke (5R44NS043816-03, 1R43NS053032-01, 1R43NS046976-01A1).

A Room with a Solstice View

By Kathleen Welker

Jerry Judd Pryde, MD, Los Angeles based medical director for Solstice Neurosciences, visited the Blackhawk Room last Fall as guest speaker for San Ramon Regional Hospital's affiliated movement disorders support group. Tremor Action Network invited Dr. Pryde who arrived to a packed-filled room of individuals who were attentive and asked numerous questions. The group members, individually and collectively, were recipients of an excellent presentation by Dr. Pryde, who presented fair and balanced information. TAN is sharing "excerpts" from the two hour event with our Spikes & Spasms readers to gain a better understanding of the therapeutic uses of botulinum toxin; in particular, cervical dystonia.

FDA requires disclosure that botulinum toxin is indicated only for cervical dystonia, but there are many off-label uses for botulinum toxin including the treatment of facial wrinkles, spasticity, migraine headaches, bladder and bowel syndromes.

Cervical dystonia is an involuntary contraction of the muscles in the neck that cause the face and head to tilt in an involuntary direction. The treatment of choice is injection into the muscles that are spastic, which temporarily diminishes the muscle spasms and helps the face and head to move into a more normal position. The treatment is temporary. Studies indicate the variable from patient to patient effect lasts about 12 to 16 weeks. The injection may hurt a little, lasting for a fraction of a second. The pain or burning sensation may have more to do with the injection technique than the medication.

An evaluation determines the pattern for the injection into the affected muscles. A spastic muscle is identifiable with an EMG computer. The medication with a small needle is injected into the muscles and the delivered medication

stays in the muscles, causing the nerves that control the muscles to recognize the medication as a compound that the nerve thinks it needs. The nerves absorb the medication out of the muscles and the medication temporarily blocks the nerves for 3 months, as the nerves can no longer send impulses to the muscles specifically injected. The muscles relax which impedes the muscle contractions.

There are two botulinum toxin strains to choose from. Toxin A Botox® is manufactured by Allergan, and toxin B Myobloc® is manufactured by Solstice Neurosciences. The studies that have been done indicate each toxin is pretty identical, statistically equal in efficacy, safety, injection site pain, but not so equal in side effects.

**Toxins are fascinating,
and we are on the verge
of tremendous
treatments with toxins in
the future.**

Side effects with Myobloc® include dry mouth and difficulty in swallowing, which is from the dry mouth. Out of 100 people 30 reported mild dry mouth. In long term studies the dry mouth tends to go away, even with the increase in dosage. The 30 people out of 100 were able to swallow safely, and this side effect is temporary as well.

Dose escalating studies indicate botulinum toxin strains at super high dosages, triple the recommended dosage for cervical dystonia, can cause temporary side effects such as weakness in a limb, weakness in muscles other than the muscles being injected, blurry vision, constipation, and difficulty in urinating.

The guidelines for the medication are to start with the lowest dose possible, and not be injected more frequently than every 12 weeks, because the medication has protein in it and the immune system may recognize the protein and develop antibodies against the medication. The immune system can recognize that the medication doesn't belong in the body, and the immune system binds to the medication and makes the medication inactive. Studies conducted

show resistance to one strain doesn't necessarily develop resistance to another. Managing the dosage and not injecting more frequently than every 3 months, minimizes the immune system risk. However, each patient's immune system is different, and the guidelines may not prevent individual patients from becoming immune to the medication.

There are 7 strains of botulinum toxin, A through G. At this time some of the strains are only in the lab and may not make it to the marketplace. There is Dysport® that is licensed in Europe. Dysport is a slight variation of the toxin strain A. If patients switch from one toxin to another, the toxin Units cannot be converted. As a matter of safety patients have to start over because of the potential for an overdose.

Dr. Pryde cautions not to switch from one toxin strain to another "just because," emphasizing that patients should continue with the toxin that is effective until the patient develops resistance. Botulinum toxin is safe but is not effective if a physician is not using it well. Over exposing a patient with overdoses can increase the patient's risk of not being able to use a drug that is very effective. Dr. Pryde trains physicians how to use the drug effectively.

Dr. Pryde's clinical experience, separate from an employee of Solstice Neurosciences and not yet proven studies, is to choose Myobloc® in treating cervical dystonia and forms of dystonia that are painful, because patients with significant pain tend to get better relief with Myobloc®, which in turn betters the patient's quality of life. Myobloc® is designing toxin studies for pain relief.

To a rousing applause of appreciation, Dr. Pryde's presentation ended with an encouraging statement that "Toxins are fascinating, and we are on the verge of tremendous treatments with toxins in the future!"

About the Author

Kathleen Welker is a movement disorders advocate, who along with individuals diagnosed with essential tremor, cervical dystonia, and tremor related neurological movement disorders founded Tremor Action Network. Kathleen's advocacy passions include the development and implementation of various programs to promote movement disorders awareness.

Spikes & Spasms encourages you to visit <http://www.solsticeneuro.com> for Myobloc® details.

Why You Need Vivacare

By Sarah Brown

Over 63% of American adults have Internet access and 80% of them seek health information online at search engines and sites like WebMD. However, most patients prefer to get the information directly from their own physician. Are you one of them?

In most doctor offices, the typical patient education process relies on information given to you in person at the end of the appointment, and supplementing verbal instructions with paper-based handouts. During these visits, we are often confronted with new medical terms, complex concepts and a long list of to dos. ("Be sure to do A, B and C, but don't do X, Y and Z"). Because of these many factors, it's easy to see why many of us tend to forget most of what we are told within 6 minutes of walking out the door.

What is a person to do? In most cases, we are left going to the Internet. Look up a term on Google, and research the disease on health specific Websites. Unfortunately, this can lead to a different set of problems, including misleading Websites, and patient confusion.

Vivacare was founded to help bridge this "information gap" by offering neurologists with a wide variety of patient education tools that are designed to help you better

understand your medical condition and treatment plan, in the place you're already looking, online.

Vivacare's most used service is the practice branded Online Patient Education Library, guiding you, the patient, to a resource that contains trusted and comprehensive educational information selected by your doctor for you. The library contains over 1500 neurological titles organized by topic, including focal dystonia, Parkinson's disease, and tremor. Information comes from credible sources, such as the Parkinson's Disease Foundation and Tremor Action Network. Your neurologist can also publish his/her own handouts to further personalize the service.

Additionally, patients can opt-in to enroll for "personal updates" which provide ongoing messages with self-care advice and medication reminders.

Finding trusted and informative content about your condition from the source you trust most, your doctor, couldn't be easier. Vivacare services give people with neurological conditions and their families' easy access to information and tools that are consistent with the recommendations of their own doctor.

To see if your neurologist offers a patient education library, please visit <http://www.seeyourneurologist.com>. If you are a physician interested in providing a practice branded Online Patient Education Library for your patients, please go to <http://www.vivacare.com/neurology> to learn more and enroll.

About the Author

Sarah Brown is part of Vivacare's management team that understands the complexities of practice management and patient care.

SSDI: You Have Questions, We Have Answers

Allsup Inc. specializes in Social Security Disability Insurance (SSDI) applications. And because we are so specialized we hear many, many questions. Two of the most popular are "Am I eligible for benefits?" and "When will I get paid?"

Am I Eligible?

Calendar quarters, qualifying quarters, fully insured and currently insured. These are some of the many technical terms you may hear as you begin the SSDI application process. Understanding them will allow you to have a more solid footing as you apply for the benefits you need - and have already paid for.

One of the first questions Allsup Inc. is asked by their customers is "Am I eligible for benefits?"

The answer to that question comes in two parts. The first is "Have you worked long enough and recently enough?" The second is "Are you disabled?"

Allsup's experts are trained to determine not only if you meet the basic qualifications, but also whether your condition, or conditions, could meet the standards the Social Security Administration (SSA) is looking for when they make a disability award.

Whether your disability meets the SSA standards can only be determined one a case-by-case basis, but the more basic qualifications are easier to explain.

In order to fulfill the basic qualification in applying for SSDI you must be both "currently insured" and "fully insured."

Let's explain what "currently insured" means first.

Vivacare's most used service is the practice branded Online Patient Education Library, a resource that contains trusted and comprehensive educational information selected by your doctor for you.

If you earned \$1,000 in 2007, you have just "bought a quarter." You can get up to four quarters in each calendar year. For you to be "currently insured" you must have 20 quarters in the past 10 years. A simple way to explain this is working five out of the last 10 years. You would also be "currently insured" if you earned two quarters each year for the last 10 years.

Additionally, if you are under age 31 when you become disabled, it is possible to be "currently insured" with less than 20 quarters of coverage. To gain this "special insured status" you must have earned half of all possible quarters in the period between reaching age 21 and becoming disabled. For example, a 25-year-old would probably qualify as "currently insured" with only eight quarters of coverage.

Bottom line -- you can only earn four quarters a year and you need 20 quarters in the last 10 years to be "currently insured." If you are under age 31 when you become disabled, Allsup's experts would be able to help you determine how these rules affect your eligibility.

In addition to being "currently insured" you must also be "fully insured" to be able to apply for disability benefits.

There are two ways to determine if you are "fully insured."

The first is "Do you have 40 quarters of coverage?" (Remember you can earn up to four quarters a year.) If you do, then you are "fully insured."

The second way to be "fully insured" is to have six quarters of coverage plus one quarter of coverage for each year after the year you reach the age of 21. For example, the same 25-year-old we discussed earlier would probably only need 10 quarters of coverage to be "fully insured".

So to be able to be considered for SSDI, you must be both

"currently insured" and "fully insured." Allsup's SSDI experts are always available to help you figure all this out.

Where Is My Money?

Another common question is "How long will it be from the time I get my award and when I get a check from the government?"

For a majority of claimants, the time between being awarded and actually seeing a check is 60-90 days. In a small percentage of cases, we have seen payments as quickly as 1-2 weeks. This is typically for simple cases awarded at level one or two in the claims process.

Our extensive experience with the Social Security's Payment Centers shows that they typically need at least 60 days to process an award.

There are many reasons why awards are delayed.

In California for example, Social Security offsets (reduces) your

disability benefits by how much you receive from state disability. This adds time to the process as SSA has to determine the amount of the offset, and thus you have a delay.

In most other states, SSA offsets your disability benefits by how much you receive from workers' compensation benefits. Again, this delays payment. A similar situation occurs if you have ever received Supplemental Security Income (SSI).

There are also delays that can be inadvertently be caused by you.

Once an award is made, SSA has to verify citizenship through original copies of birth certificates or naturalization documents. Allsup knows this and follows up with SSA to see if any of these documents are needed. If

We hear many, many questions. Two of the most popular are "Am I eligible for benefits?" and, "When will I get paid?"

you are applying by yourself you will probably have to wait for a letter instructing you to bring these documents to the local SSA office. This may be months after you have been awarded.

Additionally, if you have a large amount of retroactive benefits (back pay) coming to you, SSA needs multiple signatures before releasing the check, which delays payment. It is also possible on large awards for the payments to arrive in multiple checks over a period of a few months.

As a general guideline, however, don't expect anything before 60 days after you are awarded. But prepare yourselves for a longer wait. SSA personnel are over-worked, over-loaded, under-budgeted and under-staffed. They are working as hard as they can, but delays are inevitable, and can be lengthy, especially if you are applying by yourself.

Remember, Allsup is always here to help you through the process. It is all we do, and we have helped tens of thousands of people just like you get the benefits they deserve. You stay at home. We do the work.

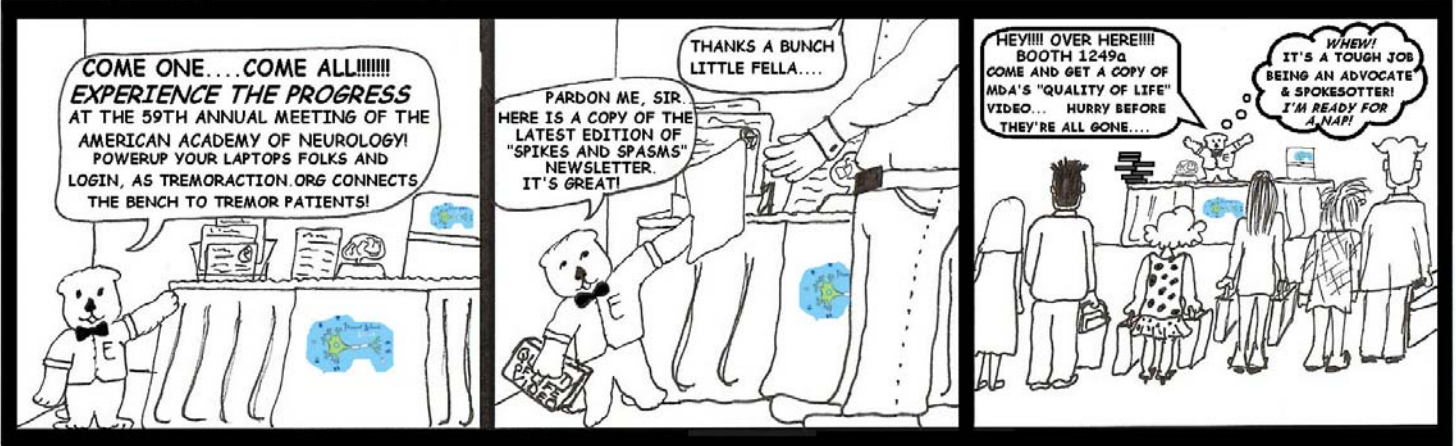
About the Author

Founded in 1984, Allsup Inc. is the nation's premier provider of Social Security Disability benefits.

For more information on how Allsup Inc. can help you file for Social Security Disability Insurance benefits, visit www.allsup.com/TAN/.

ROMBERT the Essential Otter
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Created by Aleah Mahan
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