



WHY CLINICAL TRIALS ARE PART OF THE GREAT LAKES MANAGEMENT SPECIALISTS PRACTICE

by Robert M. O'Bryan, M.D., F.A.C.P.

Clinical trials are based upon understanding of the biology of cancer, knowledge of existing treatments, and evidence that the treatment being tested will be a greater help to a greater number of patients compared with the best known available program. Trials are focused on specific types of cancer and for patients with specific characteristics.

As our discussion indicates, clinical trials mean many things to many people:

Clinical trials bring leading edge treatment to patients through different kinds of trials.

The most common clinical trial is called "Phase III". This trial compares one or more new treatments against the best known standard treatment. The patient entering a Phase III trial is randomized to be



continued on page 2

WELCOME

Great Lakes Cancer Management Specialists is pleased to announce the addition of **Carrie L. Dul, M.D.** to our practice. Dr. Dul began her career in



medicine as an R.N., completing her undergraduate degrees in Psychology, Biology and Nursing Science at the University of Michigan-Dearborn and Wayne State University with highest honors. She attended the University of North Carolina at Chapel Hill Medical School from 1995-1999. Dr. Dul then went on to complete both her Internal Medicine Residency and Hematology and Medical Oncology Fellowship at Oregon Health and Science University in Portland, Oregon. She returned to the Detroit area to join GLCMS.

Dr. Dul is certified by the American Board of Internal Medicine and is board eligible for the specialties of Hematology and Medical Oncology. Her professional memberships include the American Society of Clinical Oncology and the American Society of Hematology.

Dr. Dul has a strong interest in the care of breast cancer patients and women's health in relation to oncology and hematology diagnoses. She completed special clinical training in breast cancer during her fellowship and established an active breast cancer practice. Dr. Dul has participated in clinical trials, written and given review lectures for community oncologists, patients and her academic community in these areas. She has additional training in ethics and has served on the ethics committee during her residency and fellowship. Dr. Dul has taught

continued on back page

A Patient's Story

Experiences of our patients

Vincent Serra

We are pleased to introduce a new segment in our newsletter. Each issue will now feature the story of one of our cancer patients. Our readers will join these patients as they begin what is often the most difficult journey in their lives as they approach the medical and emotional challenges in fighting their cancer. By sharing their experiences, these patients will provide helpful insights and advice to others facing cancer as well as strengthening their resolve through hope and inspiration.

If any of our patients would like to share their cancer treatment experiences with others in our newsletters, we encourage you to contact your GLCMS attending physician. Thank you.

When Vincent Serra, 56, of St. Clair Shores stopped in the office of Luis Barbe, M.D. in July 2004 to make a sales call for his medical supply company, he could not have imagined a more life-changing experience. Vincent started chatting to Betty, one of the nurses, who asked how he had been feeling. Vincent confided that he was having some stomach problems. Betty mentioned this to Dr. Barbe, who scheduled a colonoscopy for him a few days later. A large tumor was found in the ascending colon near the appendix, and lab tests would reveal it to be cancerous.

The news shocked both Vincent and his wife of over thirty years, Mimi. He had been healthy all of his life, never having been hospitalized. Mimi had been diagnosed with thyroid cancer in 1995, but she underwent successful treatment and has remained cancer free. "For the first time, I felt mortal", says Vincent. "Mimi and I had successfully raised our children (Tony, 30 years old and Susan, 25 years old). Life was good and we didn't think too much about our future lives together because we always knew there would be tomorrow. Now we both realized

continued on page 3

CLINICAL TRIALS

continued from front page

treated either with the best known treatment, or with the best known treatment plus the new one. The objective is to learn whether the new one is an advantage. If so, it will eventually become the new standard.

The "Phase II" trial takes a new drug that has been proven to be safe for human use, the doses have been determined, and some preliminary data has suggested which types of cancer might be affected. The new drug is then tested on a limited number of patients and a variety of different cancers. If the drug is as good as or better than existing drugs, it is more widely used, further tested and eventually moved into the Phase III trials.

An "Observational" trial enrolls patients who are already receiving cutting edge treatment, and follows their status for months to years. This allows investigators to "observe" whether there are any additional advantages (or disadvantages) from the treatment that were not seen during the Phase II or Phase III trials. An example of an advantage is the observation that patients who took Tamoxifen in the adjuvant setting for their known breast cancer, had an unexpected 50%-60% decrease in the incidence of new breast cancer occurring in the opposite breast. Tamoxifen was then moved into "risk reduction" and is widely used. An example of a disadvantage is the recently well publicized problem with Vioxx and a similar drug called Celebrex. As a result, a clinical trial testing whether Celebrex would decrease the incidence of colon cancer was discontinued.

Clinical trials network the Great Lakes Cancer Management Specialists with major cancer centers.

The ideas for clinical trials usually originate in the major cancer centers of which there are many around the world. These centers are joined in many ways including regional (for example the

Southwest Oncology Group) by tumor type (for example the National Surgical Adjuvant Breast and Bowel Project) and by type of institution (for example the National Comprehensive Cancer Center Network). The reason for joining together is to share scientific information, help create broad based thinking in order to produce meaningful trials, and have a critical mass of investigators in patients that are large enough to get statistically meaningful results. Great Lakes Cancer Management Specialists are part of this network, actively participating in many such groups. We believe in collaboration. It gives us access to many experts and a range of clinical trials.

After the scientific community approves a trial it is reviewed by a broad based community group called the Institutional Review Board. The Board that reviews the trials we use is at St. John Hospital. The Board includes physicians, nurses, statisticians, social workers, clergy, cancer patients and lay public. They review the trial for its scientific value, protection of human rights, and feasibility. In addition, the board makes sure the consent form is clear and reflects the potential benefits as well as the potential risks of the trial. When the review process is complete and the trial is approved, patients may be enrolled. So a trial is a result of a major collaborative effort.

Clinical trials help win the war against cancer.

The control of cancer is dependent upon prevention through personal life style and community environmental adjustments and early detection through self exam and screening. However, the cornerstone of the war against cancer is the clinical trial. In the United States these efforts are working. The American Cancer Society reports that the death rate from all cancers combined has decreased by 1.5% per year since 1993 for men and by 0.8% per year since 1992 for women. The death rates continue to decrease for

the most common cancers in men (lung, colon and prostate) and women (breast and colon). The relative five year survival rates for female breast cancer had increased from 63% in 1975 to 87% at present and the rates for colon cancer have increased from 46% to 62% over the same timeframe.

The incidence of new cancers within the United States for men is not increasing, and the slight increase in women is due to the finding of more curable breast cancer in more women through better detection. The reason we see so much cancer among us is that as a society we are living longer and there are many more of us getting to the "cancer age". As a rule, the older we get the greater our risk of cancer.

We know that the most important person in a clinical trial is the patient. We know that along with hope, clinical trials create anxiety and many times extra effort on the part of the patient and family. We will discuss clinical trials with you at any time you wish, and will make them as convenient as possible. The patient, along with the Great Lakes Cancer Management Specialists and these collaborative efforts are what the war against cancer is all about. We won't quit until cancer is gone.



CancerExperts MD

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CancerExpertsMD is a internet based service which provides confidential, individualized and convenient cancer case review for patients seeking reassurance that their concerns about their cancer diagnosis, prognosis and treatment have been thoroughly investigated. By simply submitting your case for online review you can access different cancer experts from around the world to comment upon your case.

Go to: www.CancerExpertsMD.com



VINCENT SERRA

continued from front page

that we might not have many tomorrows to spend together.”

Dr. Barbe performed a right bowel resection on Vincent on July 29, 2004. During the surgery, a small portion of the ascending colon on the right side containing the tumor was removed. Some of Vincent's lymph nodes were removed and tested, and Dr. Barbe also examined the surrounding organs. It was determined that the cancer had not spread beyond the colon walls.

Vincent remained hospitalized for ten days. Soon after being released, Dr. Barbe referred him to P. Thomas Porter, M.D. of GLCMS. This was another anxious moment for Vincent and Mimi. Both had heard stories of the difficulty patients often face while undergoing chemotherapy, such as the nausea and extreme fatigue. Vincent was especially worried about his ability to continue working. Dr. Porter was very understanding of their concerns. “When Dr. Porter began to explain the treatment to us, we knew that he understood how scared we were. He did not talk to us in clinical language, but in terms both of us understood. He often paused during his talk with us to ask if we had questions or concerns. I'm sure we asked him more than once about a topic he had already discussed, but he treated us throughout the meeting with patience and compassion.

Dr. Porter explained that Vincent would begin a series of 30 chemotherapy treatments. He would receive a treatment everyday from Monday through Friday, have no treatments the second, third and fourth weeks, then continue the same treatment schedule on the fifth week. This would continue until all 30 treatments were completed. Before Vincent began his treatment, he and Mimi met with Charlotte Cislo of GLCMS, who conducted a “Chemo-Teach” session. Charlotte explained what would happen during each chemotherapy treatment, what side

effects to expect, and what medications he could take to minimize them. Charlotte also told them that should either of them have a question or concern regarding Vincent's treatment, they should call her immediately.

Vincent's treatment began on September 13, 2004. “As a medical supplies salesman, I have dealt with well over a hundred practices in my career. I have never encountered one where everyone is so pleasant, supportive and caring. From my arrival at the Van Elslander Cancer Center, to my signing in at the reception desk, through my treatment session, everyone treats me so well. I feel like I'm getting special treatment, but then I look around and see that all of the patients are treated in this wonderful, compassionate way. The staff adds humor into their conversations, making me laugh while helping to take the edge off during my treatments.”

Vincent was especially impressed by Dr. Porter. “I know he is a busy man, yet on the days that I meet with him he is always smiling, taking time to talk about my progress and filling me with encouragement. I never felt rushed during our meetings and he always had plenty of time to answer my questions. He has helped me feel very positive about my immediate and long-term outlook for recovery”, notes Vincent.

During his six-month chemotherapy period, Vincent was also amazed from the support he received from family and neighbors. “I can't say enough about Mimi. I don't think I would have held up as well as I did without her. I know I was demanding on her both physically and emotionally. She never wavered in her love and support for me, no matter how difficult I was. My son, daughter and neighbors did a lot of work around the house and occasionally took me to my chemotherapy treatments, giving Mimi a much deserved break. Even our yellow Lab, Norton, provided me with constant companionship and loyalty

during my treatment period.”

Vincent completed his chemotherapy on March 11, 2005. His prognosis is excellent, with a less than 10% chance that his cancer will return. Vincent is back to work full time now, watching his diet (eating more fiber), and he and Mimi are celebrating his recovery by doing some home remodeling. Vincent has valuable words of advice for others. “If you are over fifty, get a



Vincent Serra shares a quiet moment at his home with his wife, Mimi, and their dog, Norton.

colonoscopy. You can now drink a powdered prep that is dissolved in Gatorade, and you are completely sedated during the exam. There is absolutely no discomfort during or following the exam.” And for those undergoing chemotherapy, Vincent advises “Always remember that the nurses, medical staff, your family and friends...all are there to help you because they really are concerned and want you to get better. Try to be pleasant with them and never refuse their help. You will find your treatment will go so much better if you follow these simple rules.”

Next Issue:

A Discussion of the Ancillary Services offered at Great Lakes Cancer Management Specialists

WELCOME

continued from front page

medical students about patient communication and end of life care.

Dr. Dul has been recognized by her peers for exceptional compassion in caring for patients and received humanism awards, both in medical school and in residency. She is an advocate for continued research in oncology and participation in clinical trials.

As our practice continues to grow, so does the need to accommodate our patients by expanding the number of hospitals in which we actively attend. Great Lakes Cancer Management Specialists is pleased to announce that our physicians have extended their hospital coverage to include staff privileges at the following hospitals:

St. John Hospital and Medical Center, St. John Macomb Hospital, Bon Secours and Cottage Hospitals and St. Joseph's Mercy of Macomb Hospital.

**GREAT LAKES CANCER MANAGEMENT SPECIALISTS
PHYSICIANS**

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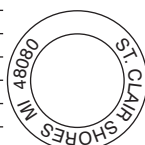
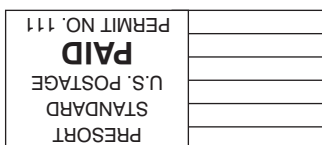
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