AUREUS RESEARCH CONSULTANTS
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RESEARCH NEWS

SUPPLEMENT FOUND TO IMPROVE QUALITY OF LIFE FOR FEMALE CANCER SURVIVORS

A natural nutritional supplement, marketed for the last decade as a sexual aid, has been shown to significantly improve overall quality of life for female cancer survivors, according to researchers at Wake Forest Baptist Medical Center.

The findings were presented at the 2011 American Society of Clinical Oncology (ASCO) annual meeting in Chicago.

Interested in quality of life issues for female cancer survivors, Kathryn M. Greven, M.D., a radiation oncologist at Wake Forest Baptist, first learned of the supplement, called ArginMax for Women™, from a small study conducted at Stanford University that found that it improved sexual function. Sexual dysfunction is prevalent in female cancer survivors, so Greven set out to see if the supplement could produce the same benefit in this population. She found that, while taking the supplement did not result in any improvement in sexual function for female cancer survivors, the supplement did improve their overall quality of life.

With funding from the National Cancer Institute, researchers at the Comprehensive Cancer Center at Wake Forest Baptist, the Derrick L. Davis Forsyth Regional Cancer Center, and multiple other cancer centers across the country recruited 186 female cancer survivors to participate in the study.

To be considered, adult female volunteers had to be at least six months beyond their last active treatment for any kind of cancer, with no current evidence of cancer. Adhering to standard double-blind, placebo-controlled protocol, neither the participants nor the investigators knew who was receiving the supplement and who was receiving a placebo.

The Daily Wellness Company, based in Honolulu, Hawaii, provided materials for the study, including ArginMax™ and placebo pills. Participants received three capsules of either ArginMax™ or placebo twice a day for 12 weeks and were asked to complete two standardized questionnaires that accurately measure sexual function and quality of life. The questionnaires were completed at the start of the study, at four weeks, eight weeks and 12 weeks.

ArginMax™ was originally designed as a sexual enhancement aid, so researchers were primarily looking for improvements in sexual function in this new population. They found no benefit in this area. However, the study findings did reveal an across-the-board boost in measures of overall quality of life for the patients who were randomized to take ArginMax™. The quality of life questionnaires showed improvements in both physical and functional well being among the participants taking the supplement.

"The group taking the supplements experienced significant improvement in overall quality of life, particularly physical well-being," said Greven, the lead investigator on the study. "Bothersome symptoms such as lack of energy, pain, nausea, and sleeplessness were all improved, as were measures of functional well-being, for example the ability to perform normal activities at home or work. Simply, they reported a greater enjoyment of life, without any additional side effects from the supplement."

Edward G. Shaw, M.D., M.A., an oncologist as well as counselor, is principal investigator for Wake Forest Baptist's Community Clinical Oncology Program Research Base and a co-researcher on the study. He explained that cancer survivors can suffer from persistent inflammation, also known as chronic oxidative stress, that can continue for years following treatment of cancer causing fatigue that affects quality of life. He hypothesized that the ingredients in ArginMax™ for Women may be helping to counteract this process.

ArginMax™ is made from a patented formula containing a proprietary blend of L-arginine, ginseng, ginkgo, and 14 vitamins and minerals noted for boosting energy and circulation and optimizing hormonal balance. A separate Men's formula also is available.
"Beyond managing individual symptoms as they appear, the medical community has not been able to offer cancer patients more global symptom relief," he said. "This research is empowering for the community of cancer

survivors. There's been some thought that dietary supplements could offer a potential benefit, but previous studies on other drugs and supplements have had disappointing outcomes. We'd like to see the results replicated in other studies, as they give us renewed hope in this area." Greven said the findings have sparked interest among researchers about whether the supplement could improve quality of life and energy levels for other populations, as well. Future studies are being planned.

"It is very exciting that we've found something that has the potential to affect and improve quality of life for female cancer survivors," Greven said. "We still need to do further work to find an approach that will improve female sexual dysfunction."

(cross posted with permission from Wake Forest)
http://www.wakehealth.edu/News-Releases/2011/Supplement_Found_to_Improve_Quality_of_Life_for_Female_Cancer_Survivors.htm#

REGULATORY CORNER

THE IMPORTANCE OF DOCUMENTATION IN CLINICAL TRIALS *by Alicia Connelly*

As a clinical trials team member, you are likely juggling numerous tasks and all seem to be "top priority". One thing that is consistently a top priority and should not be neglected is documenting the information collected on each patient/subject. This information will not only keep your memory of the interaction with each subject organized, but will keep you compliant with the FDA/GCP regulations. Timely and complete documentation is the only way for the Sponsor to review how the site has implemented the requirements of the protocol. If everything is done per protocol this usually equates to valid data for the study. Every aspect of the trial must be noted in some way. All of your documentation must be clear, complete, and accurate. Below are examples of some areas of the research project that need clear documentation. Just remember the quote, "if it's not documented, it didn't happen".

Informed Consent: You will need to document the Informed Consent process beyond just getting the subject's signature on the form. You will want to note the date, basically what went on in the consenting process and that the subject indicated understanding of what they signed. As with each document, this will be signed and dated by the appropriate study team member.

Study Visits: Take a look at the protocol "calendar of events". You should have clear documentation regarding all procedures required of the protocol. Although documenting the case is not limited to the following, we recommend that it include the following: all contact with the subject, protocol compliance or the "lack thereof" must be clear in your documentation. Any deviations from the protocol including why they occurred must be noted (such as a lab that cannot be drawn for a particular reason such as the subject forgot to fast before a particular test). Other important documentation includes adverse events (serious or not), any changes to baseline, any changes in treatment such as "drug holidays" or dosage changes. Any discussions with the sponsor regarding a particular subjects participation should also be clearly noted. It's best that documentation "given by" the Sponsor "come from" the Sponsor. Proper documentation also includes any phone, texts, or emails from the Sponsor when these represent "significant instruction".

What's also key? Documentation must be signed and dated by the person making the entry, who should also be qualified to evaluate that particular aspect of the trial. For example, a note documenting a change in medical therapy should be signed by a licensed medical professional. (In general, If a person is not qualified to do something in medical practice, they are not allowed to do it in clinical trials either.)

Not only should study visits be documented but missed visits and the reasons for the missed visit should be as well. All attempts to contact the subject regarding the missed visit should be documented. "Why", you ask? This becomes important in explaining why something may be outside of a protocol time point.

What About Missed Doses? Documenting your discussion with the subject regarding the proper use of the study medications is key. If there is a Drug Diary, each time this is reviewed with the subject it should be noted. Many Sponsors also request that any changes made to a "subject diary" be made "by that subject" but clarify this with your protocol and Sponsor. Discussions on the method for collecting concomitant drug therapies must be reported to the Sponsor as directed by the protocol. If the protocol doesn't provide this detail, seek other guidance from your sponsor. As a last resort, you may consider reporting those therapies which may impact study outcomes.

Other key timelines to document include study drug dispensation time-points and drug return. "Where" these time-points are documented again is something that the Sponsor often directs.

Documentation within the CRF…According to ICH/GCP, the CRF is not your considered source documentation for the study unless noted by the Sponsor and outlined in the protocol. What's a common example where this does occur? A subject diary that is directly- transferred to the sponsor. Other common CRF documentation areas include documenting drug dispensation and drug return. Just remember this must also be reflected in the subject-specific documentation and this may also be required in another "log" that is not subject-specific. Duplicate documentation?

Maybe, but often this drug log helps you look at the data from a different perspective or identify drug-supply issues more quickly.

A Closing but IMPORTANT Reminder…We said earlier that "If something isn't documented, it didn't happen". Let's remember this another way too… "Just because it IS documented, doesn't mean that it DID happen!"

Does that last line have you just dying to learn more??? Visit www.aureusresearch.com and read about our new collaboration with Louisiana State University Health Science Center-School of Nursing, 16-topic, online CRC certificate program now

CLINICAL TRIAL CONTRACTS

by Jill Petro, BS, CCRA, CCRC

Whether you are an Investigator, a study coordinator, a site manager, a CRA, or a member of the Contracts and Grants department, you probably have responsibility for some aspects of the contract and budget process. Most of us in these areas have had little, if any, formal legal or financial training. This is unfortunate, because the contract is the critical document that defines the expectations and legal obligations of the Sponsor and Site (and sometimes the CRO).

Now you may say the protocol is more critical, but most contracts have a statement that the agreement supersedes with the protocol merely an attachment to the agreement. Shouldn't we then spend as much effort making sure the contract is good for both parties as we do getting the protocol right? Reviewing contracts and budgets is time-consuming and can be frustrating.

This is NOT our area of expertise, and yet we are expected to negotiate a sound agreement. It is possible to reduce the stress associated with this task if you develop a reasonable process for review. This might include the use of checklists, templates, or spreadsheets.

Checklists: It's not uncommon for Sponsors and Sites to have an "elements of the informed consent checklist" against which the Informed Consent Form for each study is compared to ensure none of the required elements are missing. Most Sponsors and CROs provide sites with a contract for review. The contract has probably already undergone a check of some sort by their legal staff. Wouldn't it be nice for the site to have a "checklist of required elements" to use during the contract review process? This checklist will likely take some time to develop for a site. It should involve input from the Investigator, the Institution, the Site Manager/Study Coordinator, and Lawyer(s). All topics that must be present should be listed and might include:

(A) Who the parties are,

(B) Indemnification,

(C) Subject injury, etc.

Templates: Now that the Site has its list of "required elements in a contract," the group should decide on acceptable and unacceptable language within each topic. These could be your templates when reviewing a contract. If it matches your template (or the intent of your template), everything is fine. If it doesn't, you have some template language which you can suggest as an alternative.

For instance, with regard to the parties, sometimes the contract is between the CRO and the site. If this is the case, your group would have to decide if this is acceptable or if it has to include the Sponsor. Maybe it would be acceptable if it says "CRO on behalf of the Sponsor," but not if it is just says "CRO". When it comes to indemnification, it is almost a universal expectation that the Sponsor will provide indemnity to the Site in some manner. It is likely that this will be a "required element" in the contract. As you discuss this area, your group will probably need to establish expectations on what will and will not be covered by indemnity.

Most Sponsors indemnify for injuries due to study product, but not for injuries caused by negligence. That seems straightforward enough, but what about indemnifying for a procedure that would not have been done except per study requirements? Next, your group will have to carefully check its insurance policies. Most contracts include a statement that the Site will also indemnify the Sponsor. Although some Sites may be able to extend their coverage to another party, many will not be allowed to do that by their insurance carrier. Check this out. If your insurance will not allow this, make sure your checklist includes this "Site indemnifies Sponsor" language in the "unacceptable language."

Subject Safety in Clinical Trials: Our final example is subject injury. Consent forms must explain to the subject what compensation is available in the event of a research-related injury. In my experience, many contracts do not address this issue at all. To ensure all parties agree to their obligations in this area, the contract should include language that mirrors that of the informed consent form. A Site might also want details in the contract that explain how that process will work (how to request and obtain reimbursement).

Did I mention that this was a complex and lengthy process? It will probably take your site some time to develop its checklist and templated language, but it will speed up future negotiations. Why not make it one of your business resolutions for 2011 to bring this issue forward to those involved and try to have the task completed by the end of the year? It will make every contract easier in 2012!

The above article originally appeared in our Newsletter in 2008 and recently on Carl Anderson's "Blog on FDA and GxP Stuff" Jan 16, 2011: http://carl1anderson.wordpress.com

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LAGNIAPPE

Trouble finding dry ice for your specimen shipments? Go to the website listed below and type in your zip code: http://www.dryicedirectory.com/

It is Hurricane Season. Plan your evacuation routes with your pets in mind. This is a link to pet friendly places to stay: http://www.petswelcome.com/

Useful Apps:

FDA Mobile - iPhone-friendly FDA News
http://www.apple.com/webapps/searchtools/fdamobileiphonefriendlyfdanews.html

21 CFR 11 Pocket GuideBy BKP Technologies, Inc.
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Epocrates Essentials: Essential drug, disease, and lab information
http://www.epocrates.com/products/essentials/?CID=PPC-Brand-IMEpocratesPPC-Misspellings-Ess-Hippocrates_OFFICIALSITE2&gclid=CMTOhorUq6kCFQQbKgodmCCZLg

MISCELLANEOUS

STUFF….. GOT TOO MUCH OF IT? RECYCLE IT OR GET RID OF IT AND DO SOMETHING GOOD FOR SOMEONE ELSE OR MOTHER NATURE.

by Elaine Boos , RN, BSN, CCRA, CCRC

Want to do something good for someone else or "mother nature" and never enough time? How about all that stuff at work? The Aureus gang came up with the following:

- How about those pesky left over lab supplies? A shame to waste them, right? Consider donating them to your local public health clinic, HIV clinic, animal shelter, or even your neighborhood veterinarian. Some veterinarians will even put expired tubes to good use. The boxes that each lab kit comes in could be sent to recycling. Gel packs from shipping kits can be put in the freezer and used as handy ice packs to sooth aches and pains or even keep your favorite six pack cold in a cooler.

- Once a study ends, there's often an excess of left over paper. Once it's shredded, bag it up and make a deposit to a recycling bin. You could take the tabbed dividers from the regulatory binders, turn them over, and write new tab information on them. And what about those left over 3 ring binders that take up so much room? Local public schools, senior centers, and free legal clinics might find them useful.

- Some sponsors provide printers and supplies but leave them at sites because it's too costly to have them shipped back to the sponsor. Consider donating the equipment to a school, church, or non-profit organization. And don't forget to recycle your ink cartridges. Some office supply stores will collect them. Some suppliers will include return shipping labels in new cartridge packages so that the used supplies can be returned for recycling.

- Those big bulky boxes that lab and drug supplies are usually shipped in could be broken down and sent to your local organizations that provide meals to the home bound. Food banks are also in need of large boxes. And don't forget to keep a few around at your site for that monitor/CRA who may need them for drug return.

Do you have any helpful tips? We'd love to hear your ideas! Send them to elaineb@aureusresearch.com .

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Aureus Research Consultants, LLC.
Suggestions, Comments, and your contributions are welcomed and appreciated.
Please submit your ideas to
aconnelly@aureusresearch.com or contact her at
504-486-7946

HERE'S TO LIFE

SHARE YOUR QUOTABLE GENIUS!

For centuries, mankind has shared knowledge and experience through quotes. Quotes may cause us to ponder the universe, our soul's journey or simply to provide some humor for the day. Quotes can be used to adjust your perspective on a situation in life, just as a frame on a picture changes the view of the picture. I personally have many favorites which I enjoy and often use to "shift my thoughts" to a more positive outlook.

Here are five of my top favorite quotes:

"Be yourself, everyone else is already taken." Oscar Wilde

"If you look to others for fulfillment, you will never be truly fulfilled." Lao Tzu

"The grass is always greener over the septic tank." Erma Bombeck

"Any intelligent fool can make things bigger, more complex, and more violent. It takes a touch of genius-and a lot of courage-to move in the opposite direction." Albert Einstein

"As you ramble on through life, Brother, whatever be your goal, keep your eye upon the doughnut, and not upon the hole!" Optimist's Creed

Elaine's favorite:

Dear Lord, please help me to be the person that my psychiatrist has medicated me to be.

Here are two quotes from my own experience:

"Commotion without purpose is just commotion." Bruce

"The most important human quality is kindness, for without kindness, nothing else matters." Bruce

If you have a favorite quote from someone or even better, from your own "quotable genius", that is uplifting, encouraging or just plain funny, please send it to me at BruceM@aureusresearch.com and we'll share it with others!

Here's to Life!
Bruce

HAPPY SUMMER