SPRING 2012

More and More Patients and Professionals Discussing the Importance of Clinical Trials

There continues to be growing conversation in the cancer community today regarding the importance of clinical trials in the U.S. The biopharmaceutical industry has long been excited by the increase in the number of "validated candidates" entering clinical trials. As Dr. Richard Schilsky, former President of the American Society of Clinical Oncology, has recently stated "...better understanding of the human genome transforms the development of medicine and allows researchers to more effectively target disease, thereby testing therapies bringing drugs to market",

There is also willingness of patients to discuss their participation in clinical trials. In March, an article in the Detroit Free Press focused on various patient experiences when participating in clinical trials. It is a solid look at the issues patients face when they consider study participation. The article covered some of the reasons why patients ultimately decide to participate in clinical trials. Patients describe participation as empowering (giving them the feeling that they have some control over their disease) or a means by which they can altruistically help future generations who may face a cancer diagnosis. From whichever viewpoint is driving the conversation, clinical trials continue to be on the forefront of the discussion.

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SITE SPOTLIGHT

TRM is happy to welcome 21st Century Oncology to the growing network. 21st Century Oncology is a leading developer and operator of over 98 radiation therapy centers in Alabama, Arizona, California, Delaware, Florida, Kentucky, Massachusetts, Maryland, Michigan, New Jersey, New York Nevada, North Carolina, Rhode Island and West Virginia.

21st Century Oncology and TRM client practices throughout the greater Phoenix area are unifying multiple research interests in the newly formed *Arizona Cancer Research Alliance (ACRA)*. ACRA is being developed to facilitate community oncologist participation in clinical trials with the expectation that access to these studies will enhance patient care and outcomes.

According to Dr. Steven Finkelstein, 21st Century Oncology Director of Oncology Translational Research, "We have always provided cancer patients with access to the most cutting edge radiation therapies. Now working in concert with medical and surgical oncologists throughout the community, it will be possible to test new approaches across these providers and help improve

NEWS

INDUSTRY NEWS

Various media outlets recently reported on the difficulty in using genetic markers in identifying treatments for patients. The following are excerpts from a few of those reporting:

Bloomberg News (3/8, Langreth, Lauerman) reports, *Cancer Scans May Give False Picture of Genes Driving the Disease.* "DNA tests give only a partial picture of the genes driving the disease, according to a study" published in the New England Journal of Medicine (NEJM) "that throws cold water on the idea that scanning may quickly lead to highly effective personalized treatments." Investigators found that "multiple scans on kidney tumors determined that mutations in each portion of the malignancy varied wildly, with only one- third of anomalies found in all parts." Should this finding be "confirmed in other cancer types," it "suggests doctors and companies have only a limited ability to precisely identify individual mutations that can be targeted with drugs, since their tests are typically based on a single biopsy sample."

The Wall Street Journal (3/8, Winslow, Subscription Publication), published *'Personalized Medicine' Hits A Bump* reporting in an accompanying editorial, one of the NEJM's editors suggests that using a tumor's genetic makeup to identify the best treatments with which to treat that tumor may be more difficult than some advocates of personalized medicine have indicated.

outcomes for patients in this more complex treatment environment."

Community based oncology practices are joined by leading cardiology, laboratory, ophthalmology, radiology and interventional providers who will help ensure safety and quality when patients agree to participate in ACRA studies. "You cannot underestimate the importance of involving a core group of leading providers to ensure collection of consistent and high quality data," says Ron Korn, M.D., Ph.D., CEO of Imaging Endpoints Core Laboratory and ACRA participating site, "When patients have scans performed to measure their disease response, they should be confident that the results will be reviewed centrally by experts where accuracy can be guaranteed."

Any cancer providers in the greater Phoenix area who are interested in joining the Arizona Cancer Research Alliance should contact TRM by phone at (424) 208-8866 or email info@trmllc.com.

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STUDY SPOTLIGHT

A Study of MM-121 with Paclitaxel in Platinum Resistant/Refractory Advanced Ovarian Cancers

TRM is now enrolling, at multiple locations, the following study from Merrimack Pharmaceuticals, "A Phase II Randomized Open Label Study of MM-121 in Combination with Paclitaxel Versus Paclitaxel Alone in Patients with Platinum Resistant/Refractory Advanced Ovarian Cancers."

Up to 210 patients will be randomized (2:1) to receive MM-121 plus paclitaxel or paclitaxel alone.

INCLUSION CRITERIA (abbreviated):
• Locally advanced/metastatic or recurrent epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer
• Received at least one prior platinum based chemotherapy regimen
• Platinum-resistant or refractory
• Eligible for weekly paclitaxel
• Adequate liver and kidney function
• 18 years of age or older.

EXCLUSION CRITERIA (abbreviated):
• Evidence of any other active malignancy
• History of severe allergic reactions to paclitaxel or other drugs formulated in Cremophor®EL

For additional information, visit ClinicalTrials.gov or contact TRM directly to refer a patient.

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From the Desk of the CEO

In November 2011, the American Society of Clinical Oncology (ASCO) released a report that articulates the society's vision for a clinical and translational cancer research system. The report, *Accelerating Progress Against Cancer: ASCO's Blueprint for Transforming Clinical and Translational Cancer Research, describes how we can improve our research system by taking full advantage of today's scientific and technological opportunities.* The report boils down to prioritizing targets for therapeutic

COMPANY NEWS

TRM was recently featured in the Arizona Republic for our work in the community and the creation of the Arizona Cancer Research Alliance. To read the full article, visit the Arizona Republic website.

DID YOU KNOW

The first Monday of May each year is the American Academy of Dermatology designated Melanoma Monday. The Academy is raising awareness to encourage early detection as melanoma has a high cure rate when caught early. For more information, visit http://www.melanomamonday.org/.

development, identifying and validating biomarkers early in drug development and overcoming legal, financial, and regulatory barriers in the pursuit of the most promising clinical applications.

I applaud ASCO and its continuing efforts to advance treatments and cures for cancer patients. ASCO is correct in pointing out that with a rapidly increasing understanding but with limited resources we will need to make informed decisions about the best opportunities to pursue in clinical trials. The system could also benefit from an overhaul designed to allow researchers to respond quickly and efficiently to our changing understanding of cancer. What the report lacks is practical guidance to update the system (the report focuses on working groups, public workshops, educational initiatives and advocacy activities).

It is time to recognize that that the legal, financial and regulatory framework we operate in today can accommodate rapid study launch, financial efficiency and compliance with Good Clinical Practice (GCP) requirements. The key is to stop thinking about research as a protocol specific activity and start thinking about sites, investigators and programs as infrastructure that should be utilized for multiple clinical trials. Consider two examples:

> Example 1: In 2008, the NCI and the CEO Roundtable on Cancer issued *Proposed Standardized/Harmonized Clauses for Clinical Trial Agreements*. Part I provided clauses for company-sponsored Clinical Trial Agreements. Proposed language contained in this document would be accepted by all of the TRM client sites. Put in to practice, this would be very productive, however, I rarely see agreements that conform to this standard. As a result, weeks are lost negotiating study specific Clinical Trial Agreements when a single arrangement could cover the needs of multiple studies. In cases where we have negotiated an agreement with one sponsor/CRO we have had to negotiate the agreement again when the same sponsor chooses to work with another CRO.
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> Example 2: Qualification of investigators and the selection of study sites. Today, GCP and sponsor/CRO policies and procedures are frequently cited as justification for qualifying investigators and study sites on a protocol by protocol basis. It is time to qualify investigators and study sites one time and then rely on that qualification for the conduct of multiple studies by multiple sponsors. The qualification process is costly to the sponsors and, in my experience, rarely results in investigator/site disqualification. Centralizing this information and eliminating this cost center would free up resources to pursue additional opportunities for our patients.

I would like to encourage all professionals who participate in the clinical trials process to scrutinize current processes to ensure there is a real legal, financial or regulatory requirement that justifies the action. Embrace all actions that directly protect the rights and/or welfare of a human research volunteer but reject the work you do that is costly, fails to protect study participants and increases the cost and/or timeline of getting new products to patients.

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