

# ACRIN NEWSLETTER

Advancing Clinical Care Through Imaging Research

American College of Radiology Imaging Network

September 2007



## Network Chair's Column

by Bruce J. Hillman, MD

I recently had the pleasure of attending the NCI site visit associated with our application for renewal of funding for the 2008-2012 period. It was a pleasure from several perspectives. First, for the only time since ACRIN's founding, I was not the one responsible for putting together the program. The new chair designate, Mitch Schnall, and Constantine Gatsonis, director of the Biostatistics Center, did that. They also held the primary responsibility for responding to the request for application and will be the principal investigators of the linked grants that comprise ACRIN when the expected renewal comes through in January 2008. They did a spectacular job.

I mostly sat and watched in awe at what ACRIN has become. It was only a vision in 1998 when we were awarded the initial grant. As late as our renewal site visit four years ago, it was evident that we were still struggling with both organizational issues and the direction of our science. ACRIN is now a mature organization with a unique role to play in the imaging and cancer research communities. The level of participation and personal investment on the part of ACRIN investigators and staff is something remarkable to behold. We are well recognized by and linked to the cancer research community. We have numerous accomplishments to our credit that were well recognized by the esteemed site visit team. Although such proceedings always are a little tense (some misstep might lie just around the corner; some canny reviewer might be laying an unseen trap), I perceived a congratulatory air. Having little to do but relax in the back and observe what was going on, I must admit to succumbing toward the end to a sense of satisfaction at how ACRIN has progressed. That feeling was validated by the high score we received from the reviewers and their assessments reflected on the "pink sheets."

I took great pleasure (and a little pride) in watching Mitch direct the site visit. He has served as Deputy Chair for nine years, and it's now his turn to lead. More than that, it's time for new ideas, and both Mitch and Constantine seem to have plenty of them. There is still much to be done. I have enormous confidence that it will happen. Mitch and Constantine already are planning additions and changes to the organization. Working with other ACRIN leaders, they have plotted an ambitious research program for the next five years. I invite you to continue to participate and to urge your colleagues and associates to join you.

## ACRIN PA Trials Explore Cutting-Edge Imaging Research

When the Commonwealth of Pennsylvania received millions of dollars from the Tobacco Settlement Act in 2001, legislators allocated nearly 20% of the money for health-related research in Pennsylvania. The Commonwealth Universal Research Enhancement (CURE) Program made grants of nearly \$300 million to fund the state's cutting-edge medical research. ACRIN applied for and received research funding through the program, which enabled the development of the ACRIN PA (Pennsylvania) Network. The ACRIN PA Network will perform imaging studies of early phase technology at Pennsylvania academic medical centers to advance the role of imaging in the detection and/or treatment of disease.

Currently, the ACRIN PA Network plans to conduct three trials:

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## Morales To Lead ACR Image Metrix



Pharmaceutical industry veteran Michael J. Morales has been named general manager of ACR Image Metrix, the contract research organization (CRO) established earlier this year as a for-profit subsidiary of the ACR.

Morales is responsible for the strategic, tactical, and financial operations of ACR Image Metrix. He is former president and CEO of Dimensional HealthCare, Inc., which provided pharmaceutical companies an avenue to collect, evaluate, and report on the use of drug treatments in large patient populations. Morales holds a degree in business management from Pepperdine University.

Headquartered in the College's Philadelphia office, ACR Image Metrix will leverage the ACR's 30 years of experience in coordinating large-scale clinical research to accelerate advances in radiologic care and fund future research. Revenue from the various research projects carried out by ACR Image Metrix will help fund future studies by ACRIN, Radiation Therapy Oncology Group (RTOG), and Quality Research in Radiation Oncology (Q-RR0).

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## New Informatics Developments to Enhance Imaging Research

When a participant enrolls in an ACRIN trial, he or she generates many pieces of data, such as registration information, images from one or more modalities, and follow-up medical information. ACRIN has become a leader in web-based data collection, with a rich electronic data repository of over 76,000 patients and well over 17 million images. "ACRIN has been very successful in developing and implementing clinical trials that have resulted in a wealth of information," says Mitchell Schnell, MD, PhD incoming Network Chair. "The next step is making all those pieces of information easily accessible to our researchers and the broader cancer research community." The initiatives

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**Mitchell Schnell, MD, PhD**

described below all support that significant next step.

### Clinical Trial Data Warehouse

In the past, information generated by ACRIN trials has been rigorously analyzed on a trial-by-trial basis, but there has been no easy way to compare and share information across trials and within the larger community of cancer researchers. Now, a major initiative is well underway to develop a clinical trials data warehouse (CTDW) that will organize image and clinical data from all ACRIN clinical trials into a searchable resource. The CTDW effort is coordinated by ACRIN's Biomedical Imaging Informatics Committee and funded by the

American College of Radiology (ACR). According to Brenda Young, ACR senior director of clinical trials informatics, "We're constructing the building blocks for the future. The goal of the CTDW is to make data available for researchers that will expedite their work and, subsequently, the development of new treatments

**"This vastly improved access to image and clinical data will ultimately benefit the cancer patient."**

**Brenda Young, BA**

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### Common Data Elements for Imaging

Images provide a particular challenge for data collection and analysis. In some ways, an image is like a tissue specimen: it is a rich source of data if properly analyzed, but it is not a data element on its own. In order to generate useable data, images must undergo human or computerized interpretation. However, no standard vocabulary to describe the output of image interpretation has been defined, and the lack of a common vocabulary has been a major limitation for the use of images in clinical research.

To address this lack of a standardized imaging vocabulary, ACRIN has been awarded a contract to map imaging-specific common data elements (CDEs) into the NCI's Cancer Data Standards Repository intended to collect patient information for clinical trials or for cancer care. "Common data elements allow us to ensure that terms are always used with the same intent and same meaning," says Sophia Sabina, data standards administrator. "In the past, five different studies might have asked for the date of an imaging exam five different ways.

Using common data elements will allow us to standardize the question so that it will be asked the same way for every ACRIN study." At this point, most of the potential common data elements for imaging have been identified and reviewed by ACRIN's scientific committees and NCI. Upon final approval, the CDEs will be uploaded into the Cancer Data Standards Repository.

Pam Harvey, ACRIN's director of data management, is looking forward to the project's next phase: "After obtaining sign-off from ACRIN leadership, the next step is to standardize the electronic case report forms using the CDEs." Pam's enthusiasm stems from the prospect of not having to "recreate the wheel" for each form used in an ACRIN study, but rather selecting forms from an inventory of standardized electronic forms. "This effort will have a huge impact on reducing the trial start up timeline. With standardized e-forms, we will not need to redo the form schema and logic for every study and many forms will

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**Pam Harvey, M Mgt**

already be 'Web-entry' ready," explains Pam.

### Cancer Biomedical Informatics Grid

Both of the ACRIN projects described above fit nicely with a new NCI initiative called caBIG (short for Cancer Biomedical Informatics Grid). This project will coordinate informatics standards across research groups and allow collaboration and data sharing in biomedical research. As the largest group focused on cancer imaging studies, ACRIN has assumed a leadership role in oncology imaging informatics.

According to Robert Greenes, MD, PhD, chair of ACRIN's informatics committee, work on caBIG has been a natural progression for ACRIN. "Over the years, ACRIN's information technology and image management methodologies have moved beyond tools for specific immediate needs to much more well engineered and robust suites of tools and applications," he says. "Participation in the caBIG imaging workspace activities will help align ACRIN's development efforts for its operational needs with caBIG's work on specifying and developing standards-based generic approaches that can be used in multiple settings. ACRIN is serving both as a use case for those efforts and as a potential early adopter/test site for them. As a result, ACRIN's infrastructure is, and will continue to be, in the forefront of electronic clinical trial and image management solutions available anywhere."

Over the next several years, all of these informatics projects will help researchers at ACRIN and other research groups by making the information generated by ACRIN trials easily accessible. Says Mitchell Schnell, "We are proud to be assuming a leadership role in caBIG and other projects to standardize data collection and sharing. These efforts will enable us both

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**Robert Greenes, MD, PhD**

to work towards ACRIN's research objectives and to work with other groups in the fight against cancer."

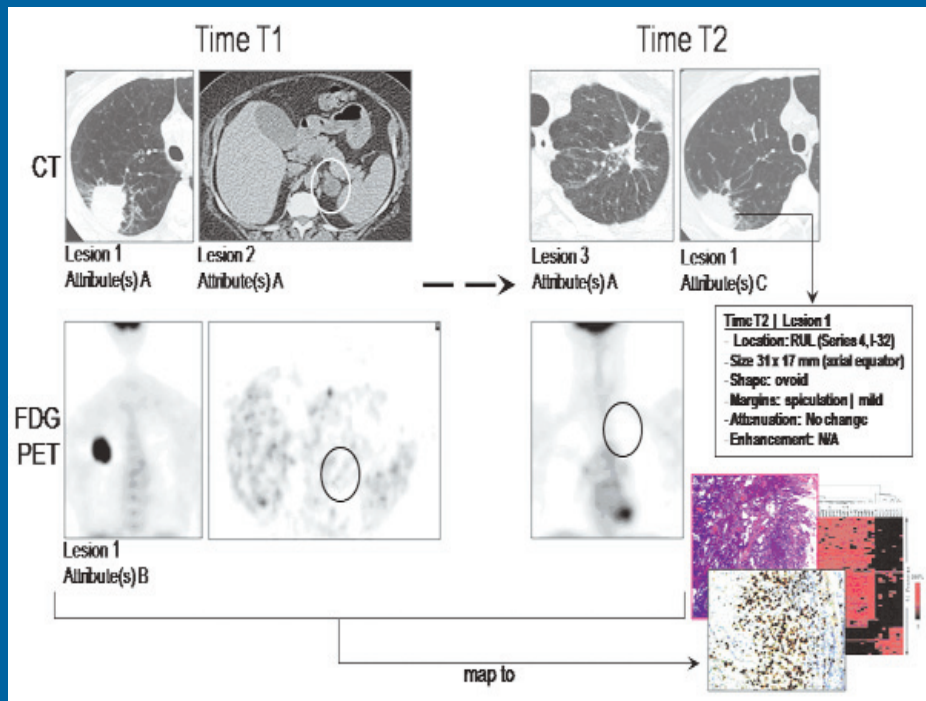
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**PA 4001: A Multi-Center Trial on MR Image Markers of Knee Articular Cartilage Damage in Osteoarthritis** is open and accruing participants. The study will identify and develop techniques to minimize systematic errors that decrease precision of magnetic resonance imaging (MRI) evaluation of knee cartilage; it will also assess the reproducibility of the newly identified MRI techniques in measuring the cartilage morphometry and structure. Future research built on this work may help in the development of disease-modifying osteoarthritis (OA) drugs.

Trial Principal Investigator Timothy Mosher, MD, says, "From a public health standpoint, chronic diseases such as osteoarthritis are very important—they affect a lot of people and consume a lot of dollars. Addressing chronic disease is an important overall research goal for the country, and radiologists have a big role in this research."

A second study is led by Mark Rosen, MD, PhD – **PA 4002: Angle Interleaved Projection Reconstruction with K-Space Weighted Image Reconstruction for Dynamic Contrast MRI of Cancer Therapy Response**. Currently, nearing the end of the development phase, this Phase II, multi-institution study of patients with metastatic colon cancer will image the liver to evaluate tumor vascularity as measured by dynamic contrast enhanced MRI in patients receiving FOLFOX chemotherapy plus bevacizumab.

For the third trial, researchers at the University of Pennsylvania and the University of Pittsburgh have developed a protocol concept involving PET and SPECT to investigate the efficacy of imaging agents for evaluating Alzheimer's disease. Pittsburgh Compound B, an established imaging agent, will be compared against newer imaging agents that are in development at the two institutions.



Example of an ontology mapping specific imaging findings of a participant across imaging modalities and time, preserving the specific attributes of these objects.

These data map to other clinical, pathologic and molecular data and must be queryable across trials, diseases, sites, participants and modalities.



## Advocate Brings Personal and Professional Perspectives

Peggy Anthony became an ACRIN advocate after working as a nurse for over two decades. She says, "As a nurse, I see the professional perspective, but I see the patient and caregiver's perspective too."

Peggy's husband was diagnosed with Stage IIIA lung cancer in 1999. "Having sat there as the wife of somebody undergoing treatment," she says, "I started to really understand the importance of imaging. Today as an advocate, one thing I'm very excited about is being able to look at new ways to get people into appropriate

treatment faster. Radiology is the beginning point for a lot of people—how they get diagnosed, how their treatment is determined. The advocates help ACRIN researchers see what they need to do to help patients."

Peggy, who works as a nurse manager at the Medical University of South Carolina, has been involved with ACRIN 6668 and the National Lung Screening Trial (NLST). She has participated on conference calls, read protocols and informed consent forms, and reviewed marketing materials. When a different group released results about CT scans for lung cancer screening that seemed related to NLST, Peggy's personal and professional perspectives came in handy. She says, "We wanted to do a lot of work so that patients and families would understand both sides of the story and not jump to conclusions. We didn't want people abandoning NLST, because there's very important research that has yet to come out." Using her credibility as a patient advocate, she spoke out locally about the importance of NLST.

Recently, Peggy attended a conference in Dallas with the Coalition of Cancer Cooperative Groups. "The part I found most interesting," she says, "was at the end of the program, when people talked about the role of patient advocates in enhancing accrual for lung cancer trials. That was quite a lively discussion. We talked about access to trials; for example, lots of people in rural areas don't have transportation. Some insurance companies don't cover people on clinical trials, and some states, such as South Carolina, don't require insurance coverage for even standard of care for patients on clinical trials." She is chair of a work group for the South Carolina Cancer Alliance that is seeking a means to protect cancer patients enrolled in clinical trials from denial of payments for standard of care services.

Peggy also thinks that cancer advocacy sometimes focuses too much on the negative. "The face that we put on lung cancer tends to be fatal," she says. "We don't necessarily celebrate the successes—we're not talking about the positive things."

Anthony knows about the positive things from personal experience: thanks to treatment, her husband has been cancer-free for 8 years. She is glad that her work with ACRIN allows her to keep moving cancer research forward. "I think ACRIN has a great patient advocate group," she says. "The advocates are knowledgeable people and they're very passionate about what they do."

## New Contacts for Reporting Expedited Adverse Events

As of October 1, 2007, Technical Resources International (TRI), a contract office for the National Cancer Institute's Cancer Imaging Program, will manage all reporting of expedited adverse events (AEs) and serious adverse events (SAE) for both the 24-hour telephone reports and AdEERS written reports.

When an AE or SAE is reported, TRI will document, track, and review the reports and, if necessary, contact site personnel for additional information. The ACRIN AE and SAE reporting procedures remain the same.

**TRI-staffed 24-hour phone number:**  
301-897-1704  
Mon. - Fri., 7:30 AM - 7:30 PM (EST)  
Leave a message if calling after hours.

**Paper submissions fax number:**  
301-897-7402

**E-mail for general questions:**  
CIPSAEReporting@tech-res.com

**For AdEERS related questions:**  
301-897-7497

**Go to [www.acrin.org](http://www.acrin.org) for details.**

**The ACRIN Newsletter is published by ACRIN Headquarters and distributed to participants and others interested in the Network.**

**ACRIN is supported by the National Cancer Institute Grant CA80098**

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