Advancing Clinical Care Through Imaging Research

American College Of Radiology Imaging Network

July 2005

Protocol Summary

Active Protocols

- 6657 Breast - MRI Predictor of Response with CALGB
- 6660 Pediatric Malignancies - Whole Body MRI
- 6661 Bone Metastases - Treatment with RF Ablation
- 6664 National CT Colonography Trial
- 6665 GI Stromal Tumors - PET to Measure Effect of Gleevec with RTOG and ECOG
- 6666 Breast - Screening Breast US
- 6668 Lung - Staging with PET with RTOG

Coming Soon

- 6673 Liver - Treatment with RF Ablation

In Development

- 6671 Cervical - Preop PET/CT and Contrast- Enhanced MRI with GOG
- 6672 Bladder - Contrast- Enhanced MRI for Lymph Node Evaluation
- 6674 Breast - Focused US Ablation and Treatment Evaluation with MRI
- 6675 Melanoma - Treatment Response with FDG-PET with SWOG
- 6676 Kidney - Predicting Treatment Response with DCE MRI with ECOG

Recently Completed

- 6659 Prostate - Cancer Staging with MRI and MRS

Message from the Network Chair

Bruce J. Hillman, MD

There is a great deal of good news to report about ACRIN, as our group continues to develop and expand upon its mission. However, this excitement is sorely tempered by the terrible accidental death of staff member Jo-Ann D’Amato, about which you can read more in this issue of the newsletter. Jo-Ann was not only an enormous contributor to the success we have enjoyed, but in many ways was the sustaining spirit of the outstanding staff who are essential to the enterprise. Jo-Ann's humor, good will, and genuine caring for ACRIN's mission exemplified our striving to accomplish our overall goal of improving the length and quality of the lives of cancer patients.

One major way in which ACRIN hopes to achieve that goal is through collaboration. One of our proudest accomplishments as a research entity is how quickly ACRIN has been able to insert itself as a "player" amidst the cancer research community. More than half of ACRIN's current trials involve major collaborations with other cooperative groups, Special Programs of Research Excellence (SPOREs), internal NCI operations, industry, and the cancer advocacy community. New trials are now being developed with the Gynecology Oncology Group (GOG), Southwest Oncology Group (SWOG), and the Eastern Cooperative Oncology Group (ECOG). ACRIN also is supplying image transmission and archiving services for a number of other cooperative group trials in which it does not have a major design or analysis role. These and previous collaborations have given ACRIN a profile that allows it access to opportunities that were unimaginable just a few short years ago.

2005 Fall Meeting Highlights

Please reserve September 15 - 18, 2005 for the ACRIN 2005 Fall Meeting to be held at the Ritz-Carlton Pentagon City Hotel in Arlington, VA. The scientific programs of ACRIN Disease Site Committees will again be the centerpiece of the meeting. These programs will feature invited speakers, review of the committee's scientific strategy and priorities as well as updates on current protocol activity.

Plenary session highlights include:

- Dr. Gregory Sorenson's presentation about the role of imaging in the field of biomarker research
- A presentation of the DMIST results by Dr. Etta Pisano the trial PI
- Patient Advocate Nancy Roach's introduction to Project IMPACT
- The "state of ACRIN" review by ACRIN leadership.

New! You can now register on line at: https://registrations.acr.org and obtain meeting details.
A Conversation with Barry Siegel

Late last summer, Barry Siegel, MD, director of the Division of Nuclear Medicine at Mallinckrodt Institute of Radiology at Washington University, worked with Ed Coleman and Brian Carey of the Academy for Molecular Imaging (AMI) to discuss ways to persuade the Centers for Medicaid and Medicare Services (CMS) to broaden reimbursement for PET scans. Dr. Siegel drafted the original outline of the plan for a National PET Data Registry, and ACRIN then became involved due to its infrastructure capabilities. Below, Dr. Siegel answers a few questions about the new registry.

What is the National PET Data Registry?

In January, (CMS) announced that it intended to provide reimbursement for PET scans for indications that are currently not covered for Medicare beneficiaries who are enrolled in "certain PET clinical trials, or if the provider and patient are participating in a high quality PET registry." Since a national "high quality PET registry" does not currently exist, members of the Academy of Molecular Imaging (AMI) have been working with CMS to develop one. ACRIN has been asked to provide administrative support and the electronic data collection infrastructure for the registry.

Dr. Bruce Hillner of the Virginia Commonwealth University laid the groundwork for the national registry with a prospective study of 248 patients that assessed changes in intended patient management based on the availability of a PET scan. Dr. Hillner and the National PET Data Registry Working Group have developed the protocol that will be the basis for the registry.

What facilities can participate?

Any PET facility approved to bill Medicare can participate in the registry. Since all communications and data submission will be electronic, the facility will need access to the Internet and an e-mail account that is checked regularly. Facilities will enter the necessary case data and the radiology report via a Web browser.

What will be the per case reimbursement?

We anticipate that Medicare reimbursement to facilities for each case entered on the registry will be the same as that for PET scans performed for covered indications. To cover the data processing fees, the registry will charge the facility a one-time registration fee of $50, as well as $50 for each case registered.

How do I register my facility?

All facilities will be registered via a dedicated registry Web site that will become operational as soon as we have the final approvals from CMS. Copies of the registration form, as well as all of the other registry forms, will also be available on the Web site. Mobile PET providers can participate, but they will need to register separately each site where the mobile unit provides services.

What data will have to be submitted?

The PET facility will register each case prior to treatment via a secure Web site. Before the PET scan, the referring clinician is required to complete a short questionnaire detailing the reason for the PET scan, the patient's cancer type and stage, and the intended management plan. The PET facility will then enter this information into the registry database. After the PET scan is performed, the PET facility will send a copy of the PET report to the database, and the referring clinician will complete a short follow-up questionnaire addressing if or how the information from the PET scan will change the intended plan of patient management. The PET facility will also enter this information into the registry database.

When will the registry open?

As of press time we do not know when the registry will open, though we expect it will be sometime this fall. We are waiting for final clearance from CMS and the Federal Office of Management & Budget (OMB) before we begin accepting registrations.

How can I get more information?

New information about the registry will be posted on the ACRIN Web site (www.acrin.org), and periodic updates will be sent via e-mail to those on our PET Registry Broadcast List.

To register for the broadcast list, send an e-mail containing your name, facility name, facility address, and e-mail address to pet_registry@phila.acr.org.
ACRIN leadership has reviewed a wide range of protocols and protocol concepts during the past six months resulting in significant increase in research activity. The potential research opportunities have been brought forward from the ACRIN Disease Site Committees, other cooperative groups, and from industry. The studies highlighted here have recently begun participant enrollment, received approval from the Cancer Therapy Evaluation Program (CTEP) to proceed with protocol implementation, or are currently undergoing CTEP review. To obtain study protocols and learn about site participation requirements visit: http://www.acrin.org/current_protocols.html.


Summary: Conducted in cooperation with the Radiation Therapy Oncology Group (RTOG), the study’s primary aim is to determine the relationship between the peak SUV of a post-treatment FDG-PET scan and long-term survival. The approximate enrollment will be 250 participants with clinical stage IIB/III non-small cell lung carcinoma who are being planned for definitive concurrent chemoradiation.

Status: Sites are actively being recruited to participate. All sites must carry out the protocol requirements with an RTOG institution. To learn more about the application process, go to http://www.acrin.org/6668_protocol.html or contact Irene Mahon at imahon@phila.acr.org.

ACRIN 6673: Multi-center Feasibility Study of Percutaneous Radiofrequency Ablation of Hepatocellular Carcinoma in Cirrhotic Patients.

Summary: The goal of this feasibility study is to generate sufficient observational data upon which to base and direct future investigations. One hundred and twenty participants will be enrolled onto the trial with the primary aim to estimate the proportion of participants undergoing solitary or repetitive percutaneous RFA treatment sessions whose livers have no identifiable tumor by CT scan at 18 months following.

Status: The protocol was recently approved by the Cancer Therapy Evaluation Program (CTEP) and is available at www.acrin.org/6673_protocol.html. Protocol application materials also will be available at the above link. For more information, contact Donna Hartfeil at dhartfeil@phila.acr.org.

ACRIN 6675: Assessing the Role of PET Imaging as an Early Indicator of Therapy Response

Summary: In a collaborative effort with the Southwest Oncology Group (SWOG) ACRIN will be responsible for coordinating the PET imaging component of the SWOG S0438 trial: A Randomized Phase II Trial of BAY 43-9006 (NSC-724772) With CCI-779 (Temsirolimus; NSC-683864) Or R115777 (Tipifarnib; NSC-702818) In Metastatic Melanoma Melanoma and Assessing the Role of PET Imaging as an Early Indicator of Therapy Response.

The trial's imaging component objectives are to assess the potential role of FDG-PET imaging as: 1) an early indicator of response to therapy; 2) a prognostic indicator; and 3) a correlate for therapeutic response based on molecular characteristics.

Each of the approximately 110 study participants will have a baseline pre-treatment FDG-PET scan. They will then undergo protocol treatment after which they will have a follow-up FDG-PET scan at weeks three and nine. Participants also will have correlative CT or MRI scans at baseline and week nine.

Status: The protocol has been submitted to CTEP and will be available, along with application materials, at www.acrin.org/6676_protocol.html once the protocol has been approved. For more information, contact Donna Hartfeil at dhartfeil@phila.acr.org.

ACRIN 6676: Dynamic Contrast Enhanced MRI

Summary: This is an ancillary study of an ECOG (Eastern Cooperative Oncology Group) trial: The BEST Trial: A Randomized Phase II Study of VEGF, RAF kinase, mTOR, and EGF-R Combination Targeted Therapy with Bevacizumab, Erlotinib, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma.

Dynamic contrast-enhanced MRI (DCE-MRI) utilizes rapid T1-weighted MR imaging during bolus IV administration of small molecular weight gadolinium contrast agents to gauge tumor vascularity. Renal cell carcinoma is a tumor system that has shown itself to be amenable to vascular assessment by DCE-MRI, and may be specifically responsive to therapy targeted at molecular pathways of angiogenesis. This ancillary study provides an opportunity to test the feasibility of a multi-institution trial of DCE-MRI for response assessment to targeted chemotherapeutic agents. One hundred participants from the cohort of participants in the ECOG trial are expected to participate.

Status: Recently submitted to CTEP, the protocol and application materials will be available at www.acrin.org/6676_protocol.html once the protocol has been approved. For more information, contact Bernadine Dunning at bdunning@phila.acr.org.
Jo-Ann D'Amato
ACRIN Senior Research Associate

The following is excerpted from a eulogy that Tom Caldwell, ACR Assistant Executive Director, gave at a memorial service at the ACR Philadelphia Office on June 15, 2005.

It was our privilege to have our friend and colleague Jo-Ann here in our office for four years. In that short time, the impact she had on us and on cancer patients worldwide will be long remembered.

Jo-Ann came to us after a very successful career in radiology. She trained at St. Joseph's Hospital School of Radiologic Technology, in Lancaster, PA, and was certified as a registered radiologic technologist in 1970. In 1992, she gained additional certification in mammography. Her first job was at St. Joseph’s, where she worked for about 10 years. Shortly thereafter, she joined the radiology department at Thomas Jefferson University, where she worked until coming to the ACR in 2001. She was a perfect fit for our staff in ACRIN and the absolute best person I can think of to run the Digital Mammography Screening Trial (DMIST). In this position, she worked closely with the trial Principal Investigator, Dr. Etta Pisano at the University of North Carolina. Dr. Pisano wrote a lovely tribute to Jo-Ann that we share with you here.

In what is an uncanny irony, Dr. Pisano mentioned that she wrote her thoughts about Jo-Ann while she was on vacation with her family in -- where else -- but Paris. And we all know how much Jo-Ann loved Paris, and many of you know how much I love Paris. The only difference between JoAnn and me is that she could speak and pronounce French, and I have been told that I destroy the language. However, I am not that easy to stop, and every time I would see her we would exchange a cheery "Bonjour Madame, Bonjour Monsieur." It always made me feel good and think about the great meals I enjoyed in the French capital. You know, I could see Jo-Ann coming down the hall and just picture her moving down the Avenue Saint-Germain des Prés on the Left Bank. She had that Paris look and feel that makes it such a great city.

Our sudden loss of Jo-Ann reminds us all that we never know what is going to happen in the next week, day, or even the next minute. So we need to be prepared. We need to make right our relationships with all those we love and forgive those who have made for some past difficulties. If we don't do it today, we might not have another chance.

In Tribute

Plans are in development for an award in Jo-Ann's memory. The award details will be made available at the ACRIN 2005 Fall Meeting.

We also are pleased to announce that a Japanese tree lilac (Syringa reticulata, "Ivory Silk") will be planted in Jo-Ann's honor at the corner of 19th and Market Streets in Philadelphia, on the corner where the ACR Philadelphia office is located. The tree grows to 20 feet and blooms reliably in midsummer with large, fragrant, creamy-white flowers.

A Remembrance from Etta Pisano, MD

Jo-Ann D’Amato was a consummate professional who cared deeply about the quality of the work that she and her colleagues at ACRIN did. She always aspired to the highest possible standards for data quality. She worked tirelessly and compulsively for DMIST to assure that our study results would be unassailable. She was dedicated to her profession and to her colleagues. In addition, she was warm, witty, and caring. ACRIN has lost one of its true stars with her death. As we mourn her loss, let us also remember fondly and gratefully her outsized personality and prodigious work ethic. We were all very fortunate to have worked with Jo-Ann. I know how important she considered the work we were doing on DMIST, and I really regret not having the opportunity to drink a toast with her to the study's completion. As we work towards submitting the primary DMIST paper, I can hear her voice in my head in the words that she had begun signing off her emails to me: "Go DMIST!!!" Well, in return let me say, "Well done, Jo-Ann! Au revoir."
Pam McAllister

Pam McAllister, one of ACRIN's patient advocates, was attracted to ACRIN because of the opportunity to be on the "ground floor" when creating the Patient Advocacy Committee's roles and responsibilities. Pam says, "We benefited from the unique situation of working, together with the administration, to develop a group that had no preconceived ideas what we would do or how we would function. This allowed us to take advantage of the unique talents of each member and to create something that others would want to continue and evolve as we finish our terms of service."

As the advocate liaison for the Gastrointestinal Disease Site Committee and related protocols, Pam has been actively involved throughout development and implementation of the National CT Colonography Trial (ACRIN 6664). She says, "This is an important trial because it will help determine if CT colonography will join other established modalities of screening as a sensitive and specific screening tool that can take the burden from endoscopists, who cannot possibly provide colonoscopies to all of our aging population in need of colon cancer screening."

Now that this trial is operational, Pam appreciates the opportunity to observe the effect of various protocol components and recruitment tools on trial accrual. She explains, "We developed educational materials so that all of the pieces needed to successfully complete the trial accrual were in place prior to the start of participant recruitment. Also, accrual is very closely monitored with a plan that was incorporated into the protocol." Pam serves on a committee that monitors site accrual and provides assistance if any participating center falls behind its target goal. "These protocol strategies are not part of most cooperative group trials," she says, "so I'm excited to see if this protocol is more successful in meeting accrual goals." Pam is quick to emphasize the sooner the trial completes accrual the sooner we can learn if CT colonography will prove equal to colonoscopy in a multiple institution study. She says, "This could make it easier to screen the increasing number of over 50 age individuals in the population and thus decrease suffering and death from colon cancer, the second leading cause of cancer death in this country."

As a part of the ACRIN patient advocacy committee, Pam evaluates new trial proposals from the patient perspective and joins the teams of those colon cancer trials that are selected to go forward. She is involved in many other advocacy activities in the cooperative groups, serves on various ASCO committees, and assists the National Cancer Institute as part of CARRA (Consumer Advocates in Research and Related Activities) and PACCT (Program for the Assessment of Clinical Cancer Tests). Most recently, she has been engaged in the development of a national colon cancer group, the Colorectal Cancer Coalition (C3), and serves on its Patient Advisory Board.

A number of important new collaborations are developing. In the past several months, ACRIN leadership has held important discussions with CaBIG, the FDA, and the Coalition for Cancer Cooperative Groups. CaBIG is the NCI-wide initiative to develop an electronic grid in support of cancer research. CaBIG currently has little capacity for medical imaging and lacks essential tools for image transmission, archiving, and manipulation. As a result, CaBIG has announced the initiation of an "imaging workspace," in which ACRIN hopes to play a significant role. The Food and Drug Administration also has announced a new initiative called "critical pathways." FDA recognizes that the time and expense of current protocols for bringing new drugs to market is a disincentive for the very activity FDA needs to support. In response, FDA leadership has proposed the development of new approaches to shorten and reduce the time and cost of drug development, testing, and approval. FDA has acknowledged that imaging will play a significant role, particularly in providing potential intermediate markers (or "biomarkers," in the new vernacular) that presage ultimate patient outcomes. ACRIN hopes to work with FDA and pharmaceutical companies in the standardization and validation of imaging biomarkers that can fulfill this promise. Finally, the Coalition of Cancer Cooperative Groups also has a need for imaging services to complement its current activities in assessing new anti-tumoral pharmaceutical. Drug companies are particularly interested in using molecular and metabolic imaging at an early stage of clinical testing to make "go/no go" decisions about which of their agents has the greatest potential to improve patient care. We are investigating how a collaboration between ACRIN and Coalition member groups could facilitate the development of such services.

ACRIN is progressing from a nascent organization trying to find its direction to a more mature one that plays an important and unique role in the cancer research community. That we have reached this point in our development is a testament to the contributions of hundreds of individuals who believe strongly in the potential of imaging to improve cancer care. Jo-Ann D'Amato was among both the strongest of those believers and those who have made the most important contributions. As we go forward, we will miss her.
2005 ACRIN Outstanding Contribution Awards

The Awards:
ACRIN is seeking nominations for its annual Outstanding Contributions Awards. These Awards are presented to individuals from the following three categories:
- Trial Principal Investigators, Committee Chairs and Committee Members
- Site Investigators and Research Associates
- Headquarters and Biostatistical and Data Management Center Staff

Criteria:
These awards honor individuals who:
- Significantly advanced ACRIN’s scientific goals
- Contributed beyond what is expected in his or her role

Examples of outstanding contributions include: demonstration of exemplary leadership, enhancement of ACRIN policies and procedures, outstanding service to ACRIN’s research community, implementation of novel accrual strategies, and commendable devotion of time, energy and expertise to ACRIN research activities.

Who may Nominate:
Anyone participating in the ACRIN research activities may nominate an individual for an Award. In 500 words or less, nominations must indicate why the nominee is being put forward in as specific terms as possible. Nominators should detail specific examples of how the nominee has made special contributions beyond those expected.

Address and Deadline for Nominations:
Nominations must be in writing and submitted no later than August 5th, 2005. Send nominations by mail, email, or fax, to:

Bruce J. Hillman, MD
Department of Radiology-UVAHS
P.O. Box 800170
Charlottesville VA 22908
Fax: 434-982-0211
Email: bjh8a@virginia.edu

Selection and Presentation:
Selection of awardees will be by a subcommittee of the ACRIN Steering Committee, including representatives of Headquarters and the Biostatistical and Data Management Center. Awards will be presented at the 2005 Fall Meeting’s Annual Awards Luncheon on Saturday, September 17, at the Ritz-Carlton Pentagon City, Arlington, Virginia.

ACRIN Meetings
ACRIN meets twice yearly to set policies, determine its scientific agenda, evaluate its progress, and provide education on clinical trials as they relate to medical imaging. One of these meetings (the Fall meeting) is open to all interested parties, while the other (the Spring meeting) is an invited working group meeting.

Upcoming ACRIN meeting dates and locations are listed below:

- September 15-18, 2005
  Ritz-Carlton Pentagon City, Arlington, VA
  (open to all)

- March 1-3, 2006
  Loews Coronado Bay Resort, Coronado, CA
  (by invitation only)

- October 5-8, 2006
  Ritz-Carlton Pentagon City, Arlington, VA
  (open to all)

- February 27-March 2, 2007
  Ritz-Carlton New Orleans, New Orleans, LA
  (by invitation only)

- September 27-30, 2007
  Ritz-Carlton Pentagon City, Arlington, VA
  (open to all)