



Mitchell Schnall, MD, PhD,
ACRIN Network Chair

Gratitude for 10 Years of NCI Support

by Mitchell Schnall, MD, PhD

ACRIN could not have successfully achieved the 10-year imaging research milestones it now celebrates without the unequivocal and ever-resourceful support of NCI, and specifically the Cancer Imaging Program (CIP) within the Division of Cancer Treatment and Diagnostics (DCTD). The "big science" of ACRIN clinical trials requires a diversity of expertise and a large team of members willing to roll up their sleeves and get dirty. The top-down complete commitment within the DCTD to the use of imaging as a tool in therapeutics served as a guiding force for this team from day one.

Financial Support

The core grant covering the basic science of ACRIN clinical trials is provided through the NCI U01 (Research Project Cooperative Agreement) funding mechanism. Unlike many other similar grants, this one actually operates like the cooperative partnership the category label implies. NCI representatives participate in the ACRIN Steering Committee as well as disease site and experimental science committees.

Research projects of mutual interest that do not fit into the core grant mission and are proposed by either NCI or ACRIN also receive ancillary funding from NCI. These include those trials too large to conduct without additional funding and support, such as the study of dynamic contrast MRI (DCE-MRI) as a marker of response of renal cell carcinoma to targeted therapy in collaboration with ECOG. The National Lung Screening Trial (NLST), the Digital Mammographic Imaging Screening Trial (DMIST), and the National CT Colonography Trial are other examples. A second category of ancillary projects include trials in focus areas that NCI targets with set-aside funds. These projects, which help to provide infrastructure supporting ACRIN core imaging laboratories, include the Virtual Imaging Evaluation Workspace (VIEW).

NCI has been amenable to searching through its available funding mechanisms, even pursuing competitive grants when necessary. This has been important, actually critical, to the success of ACRIN. Most recently, NCI has been instrumental in securing funds for ACRIN research through the American Recovery and Reinvestment Act (ARRA) of 2009.

Nonmonetary Support

Just as important as the budgetary support is the value-added assistance NCI has extended to ACRIN since the beginning of the partnership. This includes efforts to identify appropriate scientific collaborators, manage difficult regulatory issues, identify and obtain information technology resources, lend its broad expertise in clinical cancer care, and manage dissemination of results for large trials with media interest.

Past Key Supporters

Numerous NCI professionals made contributions to ACRIN's development over the last 10 years, including several who are no longer involved with the program. Daniel Sullivan, MD, as

(continued on page 4)

ACRIN Fall Meeting Highlights

Many exciting sessions and presentations are scheduled for this year's 2009 ACRIN Fall Meeting that are reflective of ACRIN's leadership in medical imaging. Several highlights are listed below and more meeting information is available at <https://registrations.acr.org/acrin/>.

Researcher's Workshop

Wednesday, September 30, 1:00 - 4:30 pm:

This two-part workshop will include presentations on quantitative medical imaging for clinical research and practice, and imaging in industry-sponsored clinical trials and will be followed by a panel discussion. Workshop components include "Introduction to Quantitative Imaging as a Biomarker in Clinical Trials" and "Imaging in Industry-Sponsored Clinical Trials."

ACRIN Research Associates Education Session

Wednesday, September 30, 9:00 - 5:00 pm:

This session is a great start to receiving basic research associate training and a great way to establish strong relationships with others working to support clinical trials. This session will include presentations and discussions on lung cancer pathology, imaging and treatment, sensitivity in recruiting the terminally ill, trials utilizing IND imaging agents, and various protocol and departmental round tables.

(continued on page 4)

NCI-ACRIN Partnership Celebrates Anniversary

In the Beginning

This year marks the 10th anniversary of a historical milestone in the evolution of medical imaging. In March 1999, a \$22 million grant was awarded to ACRIN by the National Cancer Institute (NCI) to pursue the development of a network capable of conducting rigorous, multi-center, interdisciplinary clinical trials in cancer imaging. ACRIN represented one of the largest grants by the National Institutes of Health (NIH) targeting medical imaging. Although one might say "the rest is history," what better time to learn more about the programs and individuals at NCI currently supporting and guiding ACRIN research efforts.

ACRIN's NCI grant is administered within the Division of Cancer Treatment and Diagnosis (DCTD) by the Cancer Imaging Program (CIP). Originally established in 1996 as the Diagnostic Imaging Program, CIP encourages coordination and collaboration among experts in basic, translational, and clinical research to advance the understanding of cancer imaging and to create better diagnosis and treatment options for patients. A recent focus of investigation has been the role of molecular imaging in the development of more effective cancer therapies.

In the midst of heightened activity surrounding the American Recovery and Reinvestment Act, several NCI staff members found a few moments to share their unique perspective regarding ACRIN's past successes and future challenges.

NCI Perspectives

James Tatum, MD brought a wealth of imaging experience to his 2 years of directing the Cancer Imaging Program (CIP), including a career as a diagnostic radiologist with board certification in nuclear medicine and nuclear cardiology, and serving as chief of several imaging departments while at Virginia

Commonwealth University Medical School. In addition to the CIP branches mentioned earlier, Tatum oversees the NCI's Clinical Trials Branch,



James Tatum, MD

under which ACRIN clinical trials are administered through staff collaboration across branches. According to Tatum, "CIP oversees all trials that involve imaging as it relates to cancer, with the exception of early exploratory phase 1 trials."

Tatum states "For ACRIN to come from where it was 10 years ago to be a well-respected clinical cooperative group, of equal stature to other such groups, some in existence for decades, is truly remarkable."

"For ACRIN to come from where it was 10 years ago to be a well respected clinical cooperative group, of equal stature to other such groups, some in existence for decades, is truly remarkable."

— James Tatum, MD

Although all clinical trials conducted before ACRIN's inception included imaging, he recalls that these studies were thought of as "add-on, ancillary components whose findings were not considered significant to the research."

Tatum likens ACRIN's efforts to educate clinicians about how imaging can help them better meet their patient care goals, as "a Paul Revere-type of ride." He adds that, in its decade-long experience, ACRIN has shown how large multicenter trials demonstrate imaging's benefits across a broad population of patients.

"Few organizations have shown comparable capacity for conducting the studies necessary to convince regulatory agencies of the value of medical imaging, making ACRIN the go-to group for implementing imaging into research questions," States Tatum. In describing the role that imaging research can play in broadening the range of therapeutic options available, Tatum refers to a "magic moment, in which a researcher, after identifying a gap in currently provided medical care, determines a question that, if answered, could change the course of treatment, reduce morbidity, and provide a better outcome for the patient."



Paula Jacobs, PhD

Having provided contracted clinical research support to CIP since 2006 with a focus on investigational new drug (IND) management for radiotracer imaging agents and ferumoxtran-10

(Combidex®) MRI, Paula Jacobs, PhD recently assumed the position as deputy associate director in the CIP program. Professionally educated as a chemist, she completed a postdoctoral fellowship in radiology and worked with magnetic resonance contrast agents for 20 years with Advanced Magnetics. She is especially passionate about her participation in the ACRIN Experimental Imaging Sciences Committee (EISC), which she describes as "cool, because it involves fun, new scientific stuff."

Jacobs describes the staff of ACRIN as "educated, hardworking, and performing good science." As an example, she references the ACRIN Digital Mammographic Imaging Screening Trial (DMIST) which "has changed medical practice. Since the publication of DMIST results, many more women now have access to digital mammography. Using imaging to find cancer earlier and detect recurrence is important. At the end of the day, improving the lives of patients is the real goal." Acknowledging the logistical difficulties involved in large, multicenter trials, Jacobs describes ACRIN as "absolutely unique in its ability to handle the image data management."

Jacobs anticipates that ACRIN will be continually challenged to recruit and maintain good performing sites to obtain data sufficient to answer the research questions. "As ACRIN moves into more complex trials that

"As ACRIN moves into more complex trials that involve several types of imaging methods, extensive coordination will be required to carry all the steps efficiently."

– Paula Jacobs, PhD

involve several types of imaging methods, extensive coordination will be required to carry all the steps efficiently."



Lalitha Shankar, MD, PhD

Lalitha Shankar, MD, PhD has served as medical officer and advisor to the CIP associate director for 6 years. In her role as acting chief of the NCI's Clinical Trials Branch, Shankar's interests center on the evaluation and approval of imaging meth-

"ACRIN is particularly well suited for phase 2 and 3 trials because of the strength of its data collection, review, and analysis methods."

– Lalitha Shankar, MD, PhD

ods to optimize their use in cancer patient care. With medical fellowships in nuclear medicine and radioimmunology, and a PhD in imaging science, Shankar is involved in formulating trial research questions, evaluating available imaging methods to determine those appropriate for specific trials, distinguishing between therapeutic and imaging goals, and identifying new agents and methods for parallel studies of agents in standard use. "ACRIN is particularly well suited for phase 2 and 3 trials because of the strength of its data collection, review, and analysis methods," states Shankar. She also credits the EISC for ACRIN's ability to effectively address feasibility issues in designing trials of new imaging methods.

The increased wealth of imaging methods, agents, and molecular-targeted treatments to be studied, while positive in its ultimate potential to affect cancer treatment, says Shankar, comes with "the challenge to develop a short list of those most useful for clinical trial investigation."

A nurse practitioner and nuclear medical technologist, Barbara Galen, MSN, CRNP has served in various capacities at NIH since 1978, including Chief Technologist in the Nuclear Medicine Department, Clinical Center, NIH. For the last 8 years, she has served as a program director at CIP, administering the program aspects of grants, including the ACRIN linked U01s. Galen is impressed with how successfully ACRIN has tackled the difficult task it was presented 10 years ago. "Not only did they have to develop a functional organization with a relevant scientific plan," says Galen, "but they also had to address barriers to con-

"It will be important for ACRIN to articulate the critical role that imaging technology plays in enabling oncologists to achieve the goal of personalizing patient treatment."

– Barbara Galen, MSN, CRNP

ducting clinical trials within the imaging community." Galen describes ACRIN as a cooperative partner, one that "actively collaborates with NCI rather than relating to NCI as merely as a funding source."



Barbara Galen, MSN, CRNP

According to Galen, the challenges faced by ACRIN in the future are similar to those it has faced from its inception. They include the need to continue educating the medical and imaging communities as to the benefits that imaging can offer. She notes, "It will be important for ACRIN to articulate the critical role that imaging technology plays in enabling oncologists to achieve the goal of personalizing patient treatment."

New this Year: Informatics Committee and Imaging Core Laboratory Offer Combined Session

The ACRIN Informatics Committee and Imaging Core Laboratory are joining efforts to provide an exciting half-day program on Friday, October 2 from 1:00 to 5:00 PM. All attendees are welcome to join the combined meeting that will feature:

- Andrew Buckler, MS of Buckler Biomedical LLC providing an introduction to the Quantitative Imaging Biomarkers Alliance (QIBA)
- Richard L. Wahl, MD, director of nuclear medicine/PET and vice chair of New Technology and Business Development in the Russell H. Morgan Department of Radiology and Radiological Science, presenting "Evolving Considerations for PET Response Criteria in Solid Tumors"
- An overview of Core Laboratory activities by ACRIN deputy co-chair and chair of the ACRIN PET Core Laboratory Barry Siegel, MD and an update on new laboratory software and hardware tools by Core Laboratory operations administrator, Mehdi Adineh, PhD
- A breakout session for the PET and MRI/CT working groups will include:
 - PET Core Laboratory: PET qualification presentations and discussions
 - MRI/CT Core Laboratory: Informatics and AIM (Annotated Imaging Mark up) initiatives presented by chair Daniel Rubin, MD, PhD, and an overview of new MRI/CT laboratory initiatives by chair Mark Rosen, MD, PhD

Gratitude for 10 Years of NCI Support

(continued from page 1)

Associate Director of CIP starting in 1997, was the initial architect of ACRIN who ran the program in its early days. Ed Staab, MD, now deceased, was a branch chief who was always supportive of the ACRIN mission. Another former branch chief, Carl Jaffe, MD, developed the information technology infrastructure necessary for standardization of ACRIN multisite imaging data.

Ongoing Key Supporters

Barbara Galen, MSN, CRNP; James Tatum, MD; and Paula Jacobs, PhD, all interviewed in this issue, continue to facilitate and champion the clinical research conducted by ACRIN. Galen has been a true partner from the beginning. The new leadership by Associate Director Tatum brought a different vision of ACRIN's role of imaging research as well as a focus on the development of imaging markers. Years of scientific experience in industry with radiotracers has enabled Jacobs to play a unique, although indirect, supportive role.

Special Advisor to the CIP Associate Director, Gary Kelloff, MD, has contributed his focus on pathology and the role of imaging techniques as biomarkers to be used diagnostically. Although not as well known for his involvement with ACRIN, James Doroshow, MD, the Director of DCTD since 2004, has developed and validated new cancer treatments through his work in the Laboratory of Molecular Pharmacology. In addition to demonstrating an ongoing commitment to exploring the role of imaging in clinical cancer care, he has been of assistance to me personally in my responsibilities as ACRIN Network Chair.

(ACRIN Fall Meeting Highlights continued from page 1)

Plenary Sessions

Thursday, October 1, 8:30 - 10:00 am:
Presentations during this session will include the "State of ACRIN" by Mitchell Schnall MD, PhD, ACRIN network chair, and Constantine Gatsonis, PhD, director of ACRIN Biostatistics Center as well as presentations on ACRIN protocols 6654, 6657, 6664, 6673, and PA 4001.

Friday, October 2, 8:30 - 10:00 am:
ACRIN awards will be presented during this session and a presentation will be given on "Defining the Clinical Development Pathway for ACRIN Trials."

2009 ACRIN Fall Meeting
Wednesday, September 30
through Saturday, October 3
Ritz-Carlton Pentagon City
Arlington, VA
For more information please
visit our Web site at www.acrin.org

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

American College of Radiology
Imaging Network
Administrative Headquarters
1818 Market Street, Suite 1600
Philadelphia, PA 19103

Telephone: 215-574-3150

Mitchell Schnall, MD, PhD
Network Chair
University of Pennsylvania

Denise Aberle, MD
Deputy Co-chair
UCLA

Barry Siegel, MD
Deputy Co-chair
Washington University

Constantine Gatsonis, PhD
Director
ACRIN Biostatistics Center
Brown University