The Cooperative Group Bulletin Board

The Organization and Accomplishments of the American College of Radiology Imaging Network: Progress in Its Second Year of Existence

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The ACRIN2 is a new NCI clinical trials cooperative group, founded in March 1999. ACRIN’s principal objective is to conduct multicenter clinical trials of diagnostic imaging and image-guided therapeutic technologies.

ACRIN devolved from a Request for Applications issued by the NCI’s Biomedical Imaging Program in early 1998, a subsequent competition, and the award made to paired Headquarters and Biostatistical and Data Management Center proposals in September of that year. The Headquarters award was made to the American College of Radiology, which also has been the Headquarters for the Radiation Therapy Oncology Group for more than 20 years. In addition, the American College of Radiology handles data management for ACRIN under the direction of the biostatistical center awardee, the Brown Center for Statistical Sciences, and its Director, the Network Statistician, Dr. Constantine Gatsonis (Ph.D., Brown University, Providence, RI). The initial award was for slightly more than $22 million for 1999–2004. Overall responsibility for directing ACRIN is vested in the Network Chair, Dr. Bruce J. Hillman (University of Virginia, Charlottesville, VA), who also was the PI for the Headquarters proposal.

During the interval between the announcement of the award and the initiation of funding, the principals began to develop ACRIN’s organizational structure, write ACRIN’s Constitution and Bylaws and rules for participation, and set in motion the development of the group’s initial protocols. The Steering Committee (consisting of the Network Chair, the Deputy Chair, a number of Vice Chairs, and representatives from Headquarters, the Biostatistical Center, and the NCI Biomedical Imaging Program) began the biweekly conference calls that direct ACRIN to this day. Over this 4-month period, The Steering Committee designated the more than 30 committees, involving more than 200 physicians and methodologists, that would form the workforce for ACRIN’s subsequent activities.

ACRIN’s design, dictated by the initial Request for Applications, is different from that of the other NCI cooperative groups. There are neither member institutions nor individuals. Rather, because of the diverse nature of ACRIN’s technologies, because ACRIN investigates both established and emerging technologies, and because institutions might thus have the capacity to participate in some but not all trials, the goal was to make ACRIN more nimble by the free flow of individuals and institutions in and out of various ACRIN trials. This has worked well in some regards but has left concerns over investigators’ and institutions’ dedication to ACRIN, a problem with which ACRIN continues to wrestle.

ACRIN has accomplished a great deal since its founding. It has, as noted above, developed a complex organizational structure. It has recently completed its informatics backbone that allows it to operate entirely electronically, with patient entry occurring 24 h/day, 365 days/year; patient randomization; and data and image transmission and storage—a first for any clinical trials cooperative group. ACRIN has extensively promoted its existence throughout the imaging community and among other cooperative trials groups through its Web site,3 publications, and presentations at national meetings. It also has initiated development or opened 12 multicenter trials, many in collaboration with the other cancer cooperative groups.

The first clinical trial ACRIN opened was in collaboration with the Gynecology Oncology Group. This clinical trial compares the accuracy of staging cervical cancer by X-ray CT, MRI, and the classical Federation International Gynecological Obstetric criteria. The PI is Dr. Hedvig Hricak (M.D., Ph.D.; Memorial Sloan Kettering Cancer Center, New York, NY). Opened in late 1999, the trial fell behind in its recruitment goals early on but appears to be gaining momentum in recent months.

Another open clinical trial is one in which ACRIN is directing an arm of a Southwest Oncology Group trial. It focuses on the capacity of positron emission tomography to accurately predict prognosis for patients with non-small cell lung cancer receiving chemotherapy prior to surgery. Led by Dr. Anthony Shields (M.D.) of the Southwest Oncology Group and Dr. Alecia Toledano (Ph.D., Brown University, Providence, RI) of ACRIN, the trial has had difficulty accruing patients to date, largely because some major potential recruiting institutions have not been members of participating intergroup cooperative groups. ACRIN recently has moved to allow recruitment for the clinical trial directly through ACRIN in the hopes of improving accrual.

ACRIN also designed and implemented a clinical trial of virtual CT colonography, a technology that uses air insufflation

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2 The abbreviations used are: ACRIN, American College of Radiology Imaging Network; NCI, National Cancer Institute; PI, principal investigator; CT, computed tomography; MRI, magnetic resonance imaging.

of the colon and the reconstructive capabilities of CT to investigate the colon for neoplasia. Using retrospective CT image data from a number of centers and three different proprietary workstations, PI Dr. C. Daniel Johnson (M.D.) of the Mayo Clinic (Rochester, MN) and his colleagues used 18 readers to each view tens of studies. The data are now in analysis. The results will inform the imaging community about optimal formatting and display for virtual colonography and determine whether ACRIN should embark on a major prospective multicenter trial of this technology.

ACRIN has designed two large screening trials: (a) helical CT for lung cancer screening; and (b) a comparison of conventional and digital mammography for breast cancer screening. The former trial is directed by Dr. Denise Aberle (M.D.) of the University of California Los Angeles (Los Angeles, CA) and is to involve 7,000 subjects. Designed as a randomized trial, the purpose is to estimate reduction in mortality associated with CT lung cancer screening in a high-risk population. As an additional benefit, the trial will collect sputum, blood, and urine specimens to be stored for later investigations of potential biomarkers for lung cancer. The protocol is in its final stages of regulatory approval. Dr. Etta Pisano (M.D.) of the University of North Carolina (Chapel Hill, NC) directs the breast cancer trial. Prospective confirmation of an imaging technology ever, the study is expected to recruit 49,000 women volunteering for breast cancer screening and is estimated to cost more than $26 million over 5 years. ACRIN has requested a supplement to its initial funding to conduct this trial and has received both a favorable scientific and administrative review by the NCI. The protocol has passed regulatory approval and only awaits funding for implementation.

Seven other trials listed below are in various stages of development and regulatory review.

(a) Chemoembolization plus chemotherapy versus conventional chemotherapy for colorectal metastases to the liver [PI, Dr. Michael Soulen (M.D.; University of Pennsylvania, Philadelphia, PA)].

(b) MRI prognosis for patients receiving chemotherapy for advanced breast cancer (collaborative study with Cancer and Leukemia Group B; PI, Dr. Nola Hylton (Ph.D.; University of California San Francisco, San Francisco, CA)].

(c) CT volumetric measurements as a prognostic indicator of head and neck cancers [collaborative study with the Radiation Therapy Oncology Group; PI, Dr. Suresh Mukerjee (M.D.; University of North Carolina, Chapel Hill, NC)].

(d) Magnetic resonance spectroscopic imaging for staging prostate cancer [PI, Dr. Jeffrey Weinreb (M.D.; New York University, New York, NY)].

(e) MRI for staging pediatric malignancies [collaborative study with the Children’s Oncology Group; PI, Dr. Marilyn Siegel (M.D.; Washington University, St. Louis, MO)].

(f) Radio frequency ablation of bone metastases for relief of intractable pain [PI, Dr. Damien Dupuey (M.D.; Brown University, Providence, RI)].

(g) Image segmentation for brain tumors [collaborative study with New Approaches to Brain Tumor Therapy (NABTT); PI, Dr. David Hackney (M.D.; University of Pennsylvania, Philadelphia, PA)].

Physicians and scientists can participate in ACRIN in several ways. Any individual or group can submit a summary proposal of a clinical trial idea to be considered by ACRIN. If ACRIN agrees to perform the trial, the submitter can lead the trial as the PI, and ACRIN will provide statisticians and other methodologists as needed for proper performance. Details of how to do this are on the ACRIN Web site. ACRIN also will consider requests to join its committees, and everyone is welcome to attend ACRIN’s annual open meeting, for which there is no registration fee. Further details are available on the ACRIN Web site or by contacting the ACRIN administrator or the Network Chair. As noted above, ACRIN does not have institutional members. Any institution can submit a general qualifying application to participate in ACRIN trials. The general qualifying application is on the Web site. Each individual trial requires separate trial-specific qualification.

ACRIN has made an excellent start. For the first time, medical imaging has a continuing infrastructure to guide the development, conduct, and analysis of rigorous, multicenter clinical trials. The involvement of leading investigators and institutions and ACRIN’s extensive collaborations with other cooperative groups portend an excellent potential for ACRIN to make important contributions to the evidence base for medical imaging in the future. The major outstanding issue is whether ACRIN can recruit patients to its trials. It has major tests of its capabilities in this regard in the coming year that should go a long way toward defining ACRIN’s long-term viability.

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