

Molecular Imaging News from NCI and the Cancer Imaging Program

The National Institutes of Health (NIH) are suffering from the general budget crunch. As of Newsline press time, a budget has not been approved for federal year 2009. The procedure for operation under a continuing resolution is to spend carefully at a bit below the previous year's level, as a precaution against the possibility of no forthcoming increases. For the National Cancer Institute (NCI), this means funding noncompeting continuing grants and competing applications that scored quite well—all at a reduced level. The usual uncertainty about the budget is heightened in a year like this, with a change in administration and Congressional leadership.

On the grants side, very large changes are being implemented in the application and review process. Most applications are now being received electronically, with Adobe Acrobat as the basis for the documents. This is a 2-step process, going through www.grants.gov to the eRA Commons, all requiring up-front registration by the principal investigator (PI) and his or her institution. Multiple PIs are now permitted and even encouraged. The second change is that after January 2009, only an original submission and a *single* amended submission (not 2 resubmissions as in previous years) will be permitted. In addition, the review process has been changed, and a category of early-stage investigator has been created to improve funding chances for younger investigators. Many of these changes are described on the NIH Web site (<http://enhancing-peer-review.nih.gov/>), with additional details and instructions in a downloadable slide set (http://enhancing-peer-review.nih.gov/training_communication.html). Beginning in January 2010, the maximum allowable length of the R01 research strategy section will be shortened to 12 pages, with 6 more pages allowed to describe clinical trials.

Of particular interest to the nuclear medicine community should be the activities of NCI's Cancer Imaging Program (CIP). The CIP has been creating Investigational New Drug Applications (INDs) for imaging agents in order to engage in multicenter clinical trials of these materials. A subset of the documents filed is being made available to the research community to implement routine synthesis of tracers at their own facilities and to assist investigators with the filing of their own INDs. Four document sets are currently available on the CIP Web site: ^{18}F -fluorothymidine (^{18}F -FLT), ^{18}F -fluoromisonidazole/ ^1H -1-(3-[^{18}F]-fluoro-2-hydroxy-propyl)-2-nitroimidazole (^{18}F -FMISO), $^{16}\alpha$ -[^{18}F]-fluoroestradiol, and, most recently, sodium- ^{18}F -fluoride (Na - ^{18}F). Three major suppliers of ^{18}F -FDG have agreed to supply Na - ^{18}F and to file Drug Master Files to support their products. A series of other radioactive materials continue in various stages of trial, sponsored by the NCI. American College of Radiology

Imaging Network (ACRIN) trial 6668, Lung Cancer: Predicting Treatment Response with PET, has almost completed accrual of 250 patients. ACRIN 6682, Cervical Cancer: ^{64}Cu -ATSM PET/CT Assessment of Tumor Hypoxia, is in development. Information on these and other phase III clinical trial developments is available at www.acrin.org.

The NCI has expanded the activities of the Molecular Imaging Program in its intramural program directed by Peter Choyke, MD. The program has established a small animal imaging laboratory at the NCI Frederick facility, which provides NCI investigators with a state-of-the-art in vivo imaging facility. The NCI Frederick Laboratory, located on the grounds of Fort Detrick, is the site of a large laboratory animal sciences program, as well as many other laboratories focusing on direct research aimed at identifying the causes of cancer, AIDS, and related diseases.

Compounds of interest in cancer therapy and diagnosis arise from many sources. At NCI, imaging in the service of drug development has led to a close relationship between the CIP and the Developmental Therapeutics Program, so that imaging agents can play a large role in preclinical and early clinical trials of new agents. Among agents being investigated are ^{18}F -deoxycytidine, ^{13}N -gemcitabine, ^{11}C -SN-38 (a topoisomerase I inhibitor), ^{124}I -IdUrd, ^{11}C -doxorubicin, ^{11}C -AMT, a comparison of FAU/FMAU/FLT, Na - ^{18}F (NDA filed), continuing studies involving ^{18}F -FLT, ^{111}In -IgG, ^{111}In -herceptin, ^{18}F -Aposense, ^{18}F -lapatinib, and ^{18}F -paclitaxel.

A number of Requests for Application and Program Announcements relating to imaging probe and instrumentation development are available for neuro-nuclear medicine and other areas. A search of the NIH Guide (<http://grants.nih.gov/grants/guide/index.html>) using the keyword "imaging" shows relevant announcements from a number of NIH institutes. The CIP issues a free e-mail newsletter (approximately monthly) with notices of relevant new initiatives, conferences, and notes from the NIH Guide and other sources. To be put on the list to receive the newsletter, send a message to my attention at bc129b@nih.gov.



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