Re-engineering the Clinical Research Enterprise
Clinical Research Workforce Training

Our nation's ability to fully explore the ever-expanding opportunities for medical advances are limited only by our resources, the most important of which is the scientific workforce. To fulfill the promise of 21st century medicine and to make further progress in controlling major human diseases, we must cultivate and train a cadre of clinical researchers with skills that match the increasing complexity and needs of the research enterprise.

The clinical research workforce must be large enough to facilitate bench-to-bedside research, the phased testing of approaches from small to large studies and the translation of proven concepts into medical practice at the community level. Clinicians must be trained to work in the interdisciplinary, team-oriented environments that characterize today's emerging research efforts. Clinical researchers need to be trained in an array of disciplines important to the conduct of clinical studies, including epidemiology, behavioral medicine, and patient-oriented research.

This NIH Roadmap effort envisions several major programs to expand, enhance and empower the clinical research workforce: the establishment of an agency-wide Multidisciplinary Clinical Research Career Development Program, a cadre of National Clinical Research Associates, and a clinical research training program for medical and dental students.

Multidisciplinary Research Career Development Program. The purpose of this program is to support the early career development of clinical researchers from a variety of disciplines, including patient oriented research, translational research, small and large scale clinical investigation and trials, and epidemiologic and natural history studies. The program will fund doctoral level professionals to learn how best to design and oversee research in multidisciplinary, collaborative team settings. As such, these researchers will have a high potential for becoming leaders of various fields of clinical research critical to the NIH mission. Each of the research career development grants will include a broad representation of clinical disciplines and professions (e.g., internal medicine, surgery, pediatrics, obstetrics/gynecology, dentistry, pharmacy, statistics, nursing, psychology) and the various specialties and sub specialties within each of these areas. The programs will include a structured, core didactic component and a practical, training component suited to various aspects of the design, conduct, and analysis of clinical research.

National Clinical Research Associates. The clinical research workforce also must be broad enough to support the testing of ideas in large-scale studies and the translation of proven concepts into medical practice, both at the community level. The National Clinical Research Associates (NCRA) Program will help increase the number of clinical investigators and diversify

the settings in which clinical research is conducted. Community practitioners (physicians, dentists, and nurse practitioners) will be recruited to refer and follow their patients in clinical research. This program is more fully described at: http://nihroadmap.nih.gov/clinicalresearch/ncra/factsheet.asp.

Clinical Research Training in Medical and Dental Schools. To encourage and support clinical research workforce development among physicians, dentists, and nurses, a national meeting was held on May 11–12, 2004 to consult with the extramural community on ways to expand the pipeline of students entering clinical research, train future leaders and other team members, and create a viable career pathway for clinical researchers. Meeting participants discussed specific uses, strengths, and weaknesses of existing clinical research training programs and general medical scientist training programs. NIH staff are now examining how to balance the various options for enhancing the teaching of clinical research. These include short courses, one-year pull-out programs, master's level programs, and modifications of the existing Medical Scientist Training Program.

NIH Clinical Research Training Program. This program, on the NIH campus, was established in 1997 to train medical and dental students in clinical or translational research after completion of their clinical rotations. The size of the program doubled in FY2004 from 15 to 30 students. Through this program, selected medical and dental students obtain stipends and academic and administrative support. The program hosts an annual Clinical Investigator Student Trainee Forum for medical and dental students in clinical research training programs across the country. The goal of these Forums is to enhance the development of a community of emerging clinician-scientists, to feature recent advances in clinical and translational research, to teach networking skills, and to provide career development resources. More information on the NIH Clinical Research Training Program can be found at: http://www.training.nih.gov/crtp/index.asp

Inventory/Evaluation of Clinical Research Training Programs. NIH will conduct an inventory and evaluation of clinical research training programs in the United States, to determine their extent and scope and whether data are available on trainee outcomes. This study will help identify best practices for clinical research training programs, providing models for the future. The inventory will also provide a baseline for Roadmap endeavors in clinical research workforce training, and it will identify gaps and opportunities for new programs.

The URL for the NIH Roadmap web site is nihroadmap.nih.gov. For more information on the Re-engineering the Clinical Research Enterprise Clinical Research Workforce Training initiatives, contact Judith M. Whalen, National Institute of Child Health and Human Development, (301) 496-1877, whalenj@exchange.nih.gov. Further information about NIH can be found at its Web site: www.nih.gov.