

# Postmarketing Studies Can Be Entree to Research

BY MARY ELLEN SCHNEIDER  
New York Bureau

DALLAS — Becoming an investigator for a phase IV postmarketing study can be a good starting place for dermatologists interested in clinical research, Dr. Fran E. Cook-Bolden told attendees at the annual meeting of the National Medical Association.

But there is a lot expected of physicians who conduct these studies, from allocat-

ing secure storage space to hiring research staff, said Dr. Cook-Bolden of the department of dermatology at Columbia University.

Dr. Cook-Bolden has a private dermatology practice in New York City and is active as well in conducting research for a number of different drug and device companies.

"You really need to enjoy clinical research," she said. "It's really more than just a notion."

Phase IV studies are postmarketing studies that allow researchers to delineate additional information about drugs or devices that have already been approved by the Food and Drug Administration, she said.

"It is an opportunity to talk [about] additional risks, benefits, or optimal use of the drug," Dr. Cook-Bolden said.

A phase IV study, for example, might examine different doses, schedules of administration, different patient populations,

or use of the therapy for different stages of disease.

These studies can be initiated by the drug or device sponsor, but also by physicians, Dr. Cook-Bolden said.

If dermatologists are having success among their patients with an off-label use of a drug, that might be something worth investigating in a study, she said at the meeting.

When pitching an idea for a trial to industry, physicians need to provide the drug or device sponsor with a detailed protocol proposal that includes the background, the rationale for the study, the objective, the design and methodology, the statistical considerations, and the organization of the study. And the proposal should include references. "Industry needs to know that you've done your research," she said.

Companies will also want to know about the physician's previous experience as a principal investigator and their track record in recruiting and retaining patients for a study. There is currently a lot of competition to conduct clinical research, she said.

**Clinical research gives a physician more input on study design and an opportunity to reach out to patients who can't get health care.**

said.

Availability of staff for the clinical study is another key consideration. This type of research can't be done by a physician alone, Dr. Cook-Bolden said. Phase IV studies generally require a physician subinvestigator and a research coordinator in addition to the principal investigator. A pharmacist, a specialist in regulatory documentation, and a nurse are also helpful.

Conducting a research study also requires setting aside some secure storage space. Physicians will need to have locked cabinets to safely store confidential study materials in their offices, and secure, climate-controlled storage for drugs, Dr. Cook-Bolden said. And while it's not essential to set aside clinical exam space for the research, physicians who do a number of studies may find it useful to do so, she said.

Dr. Cook-Bolden said she conducts clinical research because it puts her on the "cutting edge" and allows her to have more input on study design. It can also be an opportunity to reach out to patients who can't get health care, she said.

But physicians shouldn't embark on clinical research as a way to get rich, Dr. Cook-Bolden said. Drug and device sponsors generally pay physicians for the time spent in study activities and cover some overhead, but physicians are still responsible for paying their own research staff and paying the rent for space used in the study.

It generally doesn't make financial sense to conduct just one study, but physicians who are active in clinical research can be successful, she said. ■

*Who's reading your biopsies?*

**PROPATH®**  
DIVISION OF  
DERMATOPATHOLOGY

**PROPATH.** The premier team of highly-trained, board certified dermatopathologists that provides diagnostic expertise and personal service to enhance patient care and fulfill the needs of dermatologists nationwide.

**TERRY L. BARRETT, MD** is director of PROPATH's Dermatopathology Division. Dr. Barrett is a well-respected diagnostician and educator. He is board certified in Anatomic and Clinical Pathology, Dermatology and Dermatopathology, and is a clinical professor of pathology and dermatology. Dr. Barrett speaks throughout the country and internationally on various Dermatopathology and Dermatology topics.

**PROPATH®**  
THE LEADER IN PATHOLOGY SERVICES

Call 1.800.258.1253 or visit [www.propathlab.com](http://www.propathlab.com) to find out more about ProPath.