NEWS RELEASE

CLINICAL TRIALS TRANSFORMATION INITIATIVE

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FDA and Duke Launch Public-Private Partnership to Modernize Clinical Trials

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DURHAM, NC – The U.S. Food and Drug Administration and Duke University Medical Center have begun a collaboration aimed at modernizing the way clinical trials are conducted.

Under an agreement between the organizations, Duke will host a Public-Private Partnership that will include broad representation from government, industry, patient advocacy groups, professional societies, and academia. The participants will work together to develop new standards and identify new methods and technologies that improve safety, boost the quality of information derived from clinical trials, and make the research process more efficient.

"To ensure the safety of clinical trial participants and to improve the health of the public, the clinical research enterprise needs to evolve," said Janet Woodcock M.D., deputy commissioner and chief medical officer. "It needs to be much more streamlined and efficient, and at the same time it needs to be better equipped to answer the pressing questions that confront both patients and health care professionals. Through this collaboration between FDA and Duke, we are going to work with many stakeholders to lay the foundation for achieving these goals."

Woodcock leads FDA's Critical Path Initiative, aimed at facilitating a national effort to modernize the scientific process through which a potential human drug, biological product, or medical device is transformed from a discovery or "proof of concept" into a medical product. The agency has entered into a number of partnerships to address key priority areas of the initiative. This partnership will be chaired by Robert M. Califf, M.D., vice chancellor for clinical research at Duke University and will provide a venue to convene working groups and a national panel of experts. Rachel Behrman, M.D., director of FDA's Office of Critical Path Programs, will co-chair the partnership.

"Society is appropriately demanding more evidence about medical practice," said Califf. "Indeed, there is concern that our research system is falling behind the needs of society to determine the balance of benefit and risk from drugs, devices and surgical procedures. Our system of clinical trials provides the evidence for what the FDA approves and which medical practices are adopted as professional standards. We aim to provide a forum in which the experts in the field can put forward ideas about how to improve the system and then we can do research to inform policy makers about whether suggested changes are likely to have beneficial effects." Among the ideas that the initiative will explore:

- Establishing national standards for a wide range of research functions in order to streamline the current approaches to initiating and conducting clinical trials. There is broad agreement that the process is too slow and unnecessarily complicated. Examples could include the development of standardized electronic forms for collecting data as well as standardized contractual agreements that govern the ways in which individual research sites (such as hospitals and physician practices) interact with research sponsors.
- Exploring alternative models for Institutional Review Boards in order to minimize duplication of effort in multi-site clinical trials and identifying strategies to enhance the process of obtaining informed consent from clinical trial participants.
- Establishing accreditation programs for both clinical investigators and research sites. Currently, research organizations that coordinate large, multi-site clinical trials are required to assess and document the qualifications of each investigator and the quality of each research site participating in a clinical trial. For a large clinical trial the process typically involves several visits to each site, requiring months to complete and often delaying the start of the trial. An accreditation system similar to the one used by hospitals could help research organizations more quickly and efficiently verify the abilities of accredited individuals and sites.
- Extending the use of technology to improve data management. Currently, most of the data collected during clinical trials is recorded on paper. Switching to electronic data management systems would enable researchers to monitor data in real time and help them spot safety problems more quickly. If the electronic systems were standardized across the nation, data from one clinical trial could quickly and easily be compared against data from another.

The initiative will begin by identifying simple measures in areas where there is strong consensus across the clinical research community that better procedures can be established. The complete set of recommendations will take several years to develop.

"This effort is driven by the recognition that the science governing the development of effective drugs, devices, and procedures is advancing rapidly," said Woodcock. "The FDA is looking forward to working with Duke to convene the best talent we can find to inform us about what can be done to improve the clinical trials that form the basis for our regulation of drugs and devices."

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