

NCI and FDA Announce Joint Program to Streamline Cancer Drug Development: Questions and Answers

Key Points

- **What is the purpose of this new NCI-FDA collaboration?** The National Cancer Institute (NCI) and the Food and Drug Administration (FDA) have established this collaboration (which is being formalized through an interagency agreement) to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications and diagnostics. (Question 1)
- **NCI and FDA already work collaboratively on certain areas of study, such as proteomics. How will this relationship change?** As communication is the key to collaborations such as this one, NCI and FDA representatives will meet as a task force to discuss areas such as the proteomics model in which the two agencies might work together. (Question 3)
- **Has the NCI/FDA Oncology Task Force been formed yet?** Yes, the task force has already been formed. The NCI/FDA Task force will be co-chaired by Anna Barker, Ph.D., NCI's deputy director for strategic initiatives, and by Theresa Mullin, Ph.D., FDA's assistant commissioner for planning. (Question 3)
- **Is the aim of this task force to speed drug approvals or to prevent "bad" drugs from reaching the market?** NCI believes that the timely and considered application of science across the continuum of discovery, development and delivery, will optimize and accelerate the delivery of safer, more efficacious drugs to patients. (Question 4)

Question 1. What is the purpose of this new NCI-FDA collaboration?

The National Cancer Institute (NCI) and the Food and Drug Administration (FDA) have established this collaboration (which is being formalized through an interagency agreement) to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications and diagnostics. This new agreement will broaden existing programs and create additional joint programs between these two Department of Health and Human Services (HHS) agencies. The agreement is potentially beneficial to the more than one million Americans who are diagnosed with cancer each year.

Question 2. What led to this joint program?

NCI's mission is to facilitate and support the biomedical and cancer research that will benefit all cancer patients, and the institute recognizes that collaboration is a

vital part of that mission. Discussion about this joint program began immediately after Mark McClellan, M.D., Ph.D., was named commissioner of the FDA. Andrew von Eschenbach, M.D., NCI director, and Dr. McClellan share a common goal in this collaboration -- to combine the expertise of both agencies to inform and speed up the process of discovery and development, including clinical research. NCI anticipates that it will contribute to this process in a wide range of scientific areas such as biomarkers to facilitate drug discovery, proteomics for new diagnostic models, and clinical trials research.

Question 3. NCI and FDA already work collaboratively on certain areas of study, such as proteomics. How will this relationship change?

As communication is the key to collaborations such as this one, NCI and FDA representatives will meet as a task force to discuss areas such as the proteomics model in which the two agencies might work together.

Question 4. Has the NCI/FDA Oncology Task Force been formed yet?

Yes, the task force has already been formed. The NCI/FDA Task force will be co-chaired by Anna Barker, Ph.D., NCI's deputy director for strategic initiatives, and by Theresa Mullin, Ph.D., FDA's assistant commissioner for planning. The members of the task force represent a cross-section of scientific expertise from both NCI and FDA.

Question 5. Is the aim of this task force to speed drug approvals or to prevent "bad" drugs from reaching the market?

NCI believes that the timely and considered application of science across the continuum of discovery, development and delivery, will optimize and accelerate the delivery of safer, more efficacious drugs to patients.

Question 6. How will the two agencies collaborate to address bioinformatics?

NCI and FDA will work together to create a common collection of data standards that can be used to transmit cancer-related clinical research data from investigator to regulator. These efforts will extend and integrate existing standards. The agencies plan to work closely to identify best practices, including those in the private sector and in academia, and the approach has been structured so that organizations can build intellectual property on these standards and systems. It is hoped that pharmaceutical and biotechnology companies will actively engage and contribute to standards and infrastructure. The work developed as part of this bioinformatics effort will be accessible to the entire cancer research community.

NCI also is exploring the formation of government/industry/academic partnership(s) to facilitate the dissemination and application of bioinformatics platforms that will optimize collaboration among sectors. It is envisioned that in such partnerships that groups could contribute software, expertise, and resources to develop information technology efforts across communities.

Additionally, NCI has developed a new Cancer Bioinformatics Grid (ca/BIG) that will be piloted in select NCI cancer centers and in Specific Programs of Research Excellence (SPOREs) across the country. (For more information about SPOREs, go to <http://spores.nci.nih.gov/>.)

Question 7. What about the establishment of biomarkers or surrogate endpoints?

The discovery of biomarkers (substances sometimes found in the blood, other body fluids, or tissues, which may indicate that a certain type of cancer is in the body) has opened up the potential use of these "surrogate (or intermediate) endpoints" in clinical trials. If researchers can demonstrate that there is a direct correlation between biomarkers and specific clinical outcomes, it might be possible to shorten the duration of some research trials - effectively accelerating the process of clinical trials.

NCI and FDA have a mutual goal to review and critique the science that exists for the evaluation of current and proposed biomarkers and endpoints. Through this effort, the two agencies also hope to develop better processes of evaluation for cancer clinical trials.

Genomics and proteomics have pointed to examples where specific endpoints could lead to targeted therapies and preventions. In the future, it may be possible to create drugs to target existing molecular defects in cancer cells and to create new drugs to specifically block the action of these defective proteins. These biomarkers also can be used to improve the outcomes of clinical trials by stratifying patients for specific studies and monitoring ongoing therapy.

Question 8. What are some examples of new NCI programs to advance cancer drug development?

NCI is developing several new programs in drug discovery and development that will provide better tools and technologies in all sectors. Following are some examples:

- A new program to develop tools that will explore molecular targets by focusing on chemical genomics.
- Cancer Molecular Analysis Project (C-MAP), a program that will unify data from different sources to improve the identification of targets for potential new therapies and preventives.

- A new program called the Academic Public/Private Partnership Project (AP4) that will encourage partnerships between cancer centers, academic medical centers and the private sector to develop promising agents.

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To view a press release on this NCI-FDA collaboration, please go to <http://www.cancer.gov/newscenter/pressreleases/NciFdaCollab>.