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Questions and Answers: Cancer Nanotechnology

Key Points

- **What is nanotechnology?** Nanotechnology is the creation of useful materials, devices, and systems used to manipulate matter at an incredibly small scale -- between 1 and 100 nanometers. (Question 1)
- **Why is nanotechnology an important tool for cancer research?** For cancer researchers, the ability of nanoscale devices to easily access the interior of a living cell affords the opportunity for unprecedented gains on both clinical and basic research frontiers. (Question 3)
- **Is NCI taking steps to ensure that all nanodevices are safe for the individual and the environment?** The NCI is systematically addressing these issues within the purview of its biomedical expertise and its collaborations, primarily through the newly developed Nanotechnology Characterization Laboratory. (Question 10)
- **Are there any real world examples showing the promise of nanotechnology?** The field of nanotechnology has already yielded specific products and proofs of principle demonstrated to be of value in clinical applications including liposomes, first generation nanoscale devices, that are being used as drug delivery vehicles in several products. (Question 13)

1. What is nanotechnology? What is a nanometer?

Nanotechnology is the creation of useful materials, devices, and systems used to manipulate matter at an incredibly small scale -- between 1 and 100 nanometers.

A nanometer is one billionth of a meter - 1/80,000 the width of a human hair, or about ten times the diameter of a hydrogen atom. Such nanoscale objects can be useful by themselves, or as part of larger devices containing multiple nanoscale objects.

Nanotechnology has the potential to enable the translation of molecular-based science into clinical advances, thereby facilitating major progress in the early detection, diagnosis and treatment of cancer.

The emerging field of nanotechnology involves scientists from many different disciplines including physicists, chemists, engineers, material scientists, and biologists. Nanotechnology is being applied to almost every industry imaginable, including, but not limited to electronics, magnetics and optoelectronics, energy, information technology, materials development, transportation, pharmaceuticals, and biomedical applications.

2. What are nanoscale biomedical devices?

Nanoscale devices are the same size as many important biological objects, and therefore can be used to “see” biological activity that the naked eye cannot. They can perform tasks inside the body that would otherwise not be possible. For example, nanoscale devices smaller than 50 nanometers can easily enter most cells, while those smaller than 20 nanometers can move through the walls of blood vessels. As a result, nanoscale devices can readily interact with molecules on both the cell surface and within the cell, often in ways that do not alter the behavior of those molecules.

Nanoscale devices are smaller than human cells, which are 10,000 to 20,000 nanometers in diameter, and cellular components such as mitochondria that are inside cells. Nanoscale devices are similar in size to large biomolecules such as enzymes and receptors -- hemoglobin, for example, is approximately five nanometers in diameter, while a cell’s wall is around six nanometers thick. Larger devices, such as microfluidic chips, are also being developed with nanoscale components for advanced diagnostics applications.

3. Why is nanotechnology an important tool for cancer research?

There are several reasons that nanotechnology could help transform cancer research and clinical approaches to cancer care:

- Most biological processes, including those processes leading to cancer, occur at the nanoscale. For cancer researchers, the ability of nanoscale devices to easily access the interior of a living cell affords the opportunity for unprecedented gains on both clinical and basic research frontiers.

- The ability to simultaneously interact with multiple critical proteins and nucleic acids at the molecular level will provide a better understanding of the complex regulatory and signaling patterns that govern the behavior of cells in their normal state as well as the transformation into malignant cells.

- Nanotechnology provides a platform for integrating research in proteomics -- the study of the structure and function of proteins, including the way they work and interact with each other inside cells -- with other scientific investigations into the molecular nature of cancer.

4. Why is a nanotechnology initiative appropriate now when there are so many competing research priorities?

The timing of this nanotechnology initiative is excellent because of a confluence of several factors. These include:

- An enormous amount of genomic information and basic knowledge about cancer processes has been gained in recent years and now awaits clinical application

- Recent advances in identifying the molecular underpinnings of cancer

- Nanotechnology provides a new approach for understanding complex systems within human cells

- Expanding computer and information technology capabilities for manipulating vast amounts of clinical and biological data

- Advances in nanotechnology itself that make it feasible to develop devices for imaging and delivering drugs

5. What is the promise of nanotechnology for cancer detection and therapy?

The National Cancer Institute (NCI) envisions that over the next five years nanotechnology will result in significant, and perhaps paradigm-changing, advances in early detection, molecular imaging, assessment of therapeutic efficacy, targeted and multifunctional therapeutics, and prevention and control of cancer.

Nanotechnology offers a wealth of tools that are providing cancer researchers with new and innovative ways to diagnose and treat cancer. Already, nanotechnology has been used to create new and improved ways to find small tumors through imaging. Nanoscale drug delivery devices are being developed to deliver anticancer therapeutics specifically to tumors. Work is currently being done to move these new research tools into clinical practice.

In the near future, nanoscale devices could offer the potential to detect cancer at its earliest stage and simultaneously deliver anticancer agents to the discovered tumor. Indeed, nanoscale devices could be the crucial enabling technology that will turn the promise of personalized cancer therapy -- where a patient receives a drug based on the exact genetic and molecular characteristics of his or her particular type of cancer -- into reality.

Nanotechnology provides opportunities to prevent cancer progression. For example, nanoscale systems, because of their small dimensions, could be applied to stop progression of ductal types of breast cancers.

Examples of nanotechnology in cancer research today include the following:

- Nanoscale cantilevers and nanowire sensors can detect biomarkers of cancer from a single cell, which heretofore was unimaginable.
- Nanoparticles can aid in imaging malignant lesions, so surgeons know where the cancer is, and how to remove it.
- Nanoshells can kill tumor cells selectively, so patients don't suffer terrible side effects from healthy cells being destroyed.
- Dendrimers can sequester drugs to reduce systemic side effects, deliver multiple drugs to maximize therapeutic impact, and rapidly discern effectiveness of a drug.
- Biosensors can monitor genetic changes and hyperplasia to prevent cancer progression.

6. What has been NCI's experience in funding cancer-related nanotechnology research and development?

The NCI has been a leader in funding cancer-related nanotechnology research for the past six years. The NCI has funded numerous projects that have demonstrated the potential for nanotechnology to be a major contributor to advances in cancer detection, therapy and prevention.

- NCI has been funding several highly successful cancer nanotechnology research projects via the Unconventional Innovations Program (UIP) (http://otir.nci.nih.gov/tech/uip.html) and the Innovative Molecular Analysis Technologies Program (http://otir.nci.nih.gov/tech/imat.html). The UIP began in 1999 and is targeted to invest $50 million over a ten year period. Applications to the Innovative Molecular Analysis Technologies (IMAT) program have been received in response to a solicitation since August 1998. Some examples of work being conducted by these projects include novel technologies for noninvasive detection, diagnosis, and treatment of cancer, and immunoliposome technology for tumor-targeted drug/probe delivery.

7. What is the NCI Alliance for Nanotechnology in Cancer and how was it developed?

The NCI Alliance for Nanotechnology in Cancer is a comprehensive, integrated initiative encompassing the public and private sectors, designed to accelerate the application of the best capabilities of nanotechnology to cancer. The Alliance will be comprised of researchers, clinicians, and public and private organizations that have joined forces to develop and translate cancer-related nanotechnology into clinical practice. The Alliance will accelerate the transition of molecular-based science into the clinic by enabling cross-disciplinary collaborations within the scientific community and among the public and private sectors.

The NCI Alliance for Nanotechnology in Cancer builds on a strong foundation of science and scientific accomplishments that have been undertaken by NCI over the past six years.

Also, the NCI is supporting regional cancer nanotechnology symposia to foster inter-disciplinary collaborations. These collaborations are resulting in improved communication and coordinated research efforts that capitalize on the expertise of individual researchers. It is anticipated that these collaborations will dramatically reduce the time required to translate novel ideas into products.

Based on input from cancer nanotechnology research experts across the country and within the institute, the NCI has developed a Cancer Nanotechnology Plan. The plan is a strategic model for funding research, integrating interdisciplinary efforts, and accelerating the application of nanotechnology to cancer research.

The Alliance represents a collective group of initiatives that will be implemented by NCI as part of the Cancer Nanotechnology Plan.

8. Are NCI's efforts affiliated with the NIH Roadmap or the National Nanotechnology Initiative?

NCI's Cancer Nanotechnology Initiative is separate from, but coordinated with, both the National Institutes of Health (NIH) Roadmap activity and the National Nanotechnology Initiative (http://www.nano.gov).

The NIH Roadmap is focusing on challenges and opportunities associated with basic research, whereas the majority of NCI's research initiatives are focusing on using knowledge from this basic research and translating it into clinical products. There are several areas where NIH's Roadmap activity and NCI's Cancer Nanotechnology Plan (CNPlan) have provided mutual support. The NIH Roadmap Nanomedicine Implementation Group is planning to fund development awards for Nanomedicine Center development by the end of 2005. The goal of this initiative is to fund Centers using and developing nanotechnology to examine biological processes compatible to the missions of the various NIH institutes. This supports a long term goal of the NIH to support infrastructure development in nanomedicine.

In contrast, the CNPlan capitalizes on past NCI investment in nanotechnology and focuses those efforts on the immediate mission of the NCI. The plan carries a shorter timeline and specific milestones to achieve the NCI goals. The projects initiated under the CNPlan will be integrated, milestone-driven, and product-oriented. The efforts will include targeted objectives and goals, and will use a project-management approach to capitalize on today's opportunities to create the tools that both clinicians and cancer researchers need.

The NCI anticipates continued support and participation with the NIH Nanomedicine Implementation Group, as well as other working groups, where appropriate.
In addition, NCI is developing collaborations with other Federal agencies involved in the National Nanotechnology Initiative that will assist and leverage resources. These partnerships include the National Institute for Standards and Technology (NIST), the U.S. Food and Drug Administration (FDA), and the Department of Defense. For example, NCI has entered into a collaboration with NIST to support technical research on nanoparticles to hasten the development of publicly available information on physical and biological characterization. These steps will help researchers with developing the pathways for clinical trials and commercialization of cancer nanotechnologies.

9. How much will NCI invest in this effort?

Funding of $144.3 million over five years has been approved, which NCI believes is an important step to gain significant clinical advances to reduce suffering and death from cancer. This initiative is one of several which NCI is funding to further the knowledge and understanding of ways to detect, diagnose, and treat cancer at earlier stages of development.

10. Is NCI taking steps to ensure that all nanodevices are safe for the individual and the environment?

Concerns have been voiced that nanotechnology, specifically biomedical nanotechnology, may be advancing too fast, and regulatory agencies are not able to adequately address potential safety concerns. The NCI recognizes the importance of advancing our knowledge and understanding of the technology, while also ensuring that the technology is safe and effective. The success of efforts in the field is contingent upon scientific excellence in research and development that is both ethical and safe for the body and the environment. The NCI is systematically addressing these issues within the purview of its biomedical expertise and its collaborations, primarily through the newly developed Nanotechnology Characterization Laboratory. The NCI has partnered with the National Institute of Standards and Technology (NIST) to help develop criteria to define all the key physical and biological characteristics of nanodevices intended for use in cancer-related nanotechnology research. Furthermore, the NCI is expanding its interaction with the FDA to facilitate smoother transition from bench-to-bedside by ensuring that researchers have sufficient and appropriate data to guide the development of safe and efficient nanodevices.

11. What is the Nanotechnology Characterization Laboratory?

One of the major challenges in life sciences and cancer research at this time is the need to thoroughly delineate the biological and physical characteristics of given nanotechnologies as they are developed so that research knowledge can be shared and built upon as rapidly as possible.

With the vast number of nanodevices being used in cancer research, it is necessary to develop a common lexicon or vocabulary that researchers can use to better understand their test results. This lexicon can also be used by researchers who are beginning new research projects. It will help them avoid initial and time-consuming characterization efforts. This role will be filled by the Nanotechnology Characterization Laboratory (NCL), which the NCI will establish at its NCI-Frederick, Maryland facility. A primary objective of the NCL is to develop data on how nanomaterials and nanodevices interact with biological systems. These research endeavors will chart a common baseline and compile scientific data that will inform research and development as well future regulatory actions involving nanoscale diagnostics, imaging agents, and therapeutics. Moreover, this information will be linked to NCI-supported Cancer Centers and related programs through public databases available through NCI's Cancer Biomedical Informatics Grid (CaBIG).

12. What communities are involved in the cancer nanotechnology initiative? Who did NCI consult with in the development of this plan?

All the key communities involved in cancer research and clinical progress are involved in this cancer nanotechnology initiative, including academic and government scientists, private industry, patient advocacy groups, and other government agencies.

Biomedical nanotechnology involves elements of numerous disciplines, including chemistry, physics, biology, material science and others—disciplines which have not traditionally worked together. Over the past year, NCI solicited input and feedback on the Cancer Nanotechnology Plan from a large cross-section of the cancer community. The plan was developed using a distributed governance model, and its premise is that it will only succeed with widespread participation from multiple disciplines and partners. As a result, the funding mechanisms chosen for the initiative emphasize inter-disciplinary team efforts involving partners from a cross-section of the cancer research and development community.

In planning this initiative, the NCI included input from a wide range of sources. To help facilitate the institute's planning processes, discussions were facilitated by a prominent nanotechnologist. Our discussions included expert consultations with cancer biologists, biomedical engineers, physicists, clinical trialists, and patients. Moreover, a series of regional symposia were held that brought together cancer biologists and engineers to help identify key opportunities and strategies for future research. Solicitations were sought from the research community through a request for information and several symposia at cancer research meetings were sponsored by NCI. Also, detailed discussions were held with officials from other Federal agencies associated with the National Nanotechnology Initiative, including the National Science Foundation, Department of Energy, Department of Commerce, and Department of Defense.

13. Are there any real world examples showing the promise of nanotechnology?

Yes. The field of nanotechnology has already yielded specific products and proofs of principle demonstrated to be of value in clinical applications:

- Liposomes, which are first generation nanoscale devices, are being used as drug delivery vehicles in several products. For example, liposomal amphotericin B is used to treat fungal infections often associated with aggressive anticancer treatment and liposomal doxorubicin is used to treat some forms of cancer.

- Another recent example is work done by researchers at Massachusetts General Hospital, led by Ralph Weissleder, M.D., Ph.D., which has shown that nanoparticulate iron oxide particles can be used with magnetic resonance imaging (MRI) to accurately detect metastatic lesions in lymph nodes without surgery.

- In May 2004, two companies (American Pharmaceutical Partners and American BioScience) announced that the FDA accepted the filing of a New Drug Application (NDA) for a nanoparticulate formulation of the anticancer compound taxol to treat advanced stage breast cancer. Earlier-stage research has shown that nanoparticulate sensors can detect the cell death that occurs when a cancer cell succumbs to the effects of an anticancer drug. Such sensors would be of great value to clinicians, who would no longer have to wait months to determine if a cancer therapy is working before switching a patient to a course of therapy. In addition, such a sensor could greatly accelerate clinical trials of new anticancer agents, again by providing very early signals of efficacy.

14. Where can I find more information about NCI's nanotechnology efforts?

Additional information about the NCI Alliance for Nanotechnology in Cancer can be found at http://nano.cancer.gov .

To view an archived copy of the video Web cast of the NCI press briefing on the Nanotechnology Cancer Alliance, please go to: http://videocast.nih.gov/PastEvents.asp.

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For more information about cancer, please visit the NCI Web site at http://www.cancer.gov or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).