Role of Patients in Research

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2013 Patient and Family Conference:
A Focus on Caregiving

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Basic Cancer Facts

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells.

External risk factors (tobacco) and genetic susceptibilities

One of the most serious public health issues of our country (world)

Anyone can develop cancer
Cancer Burden

• The National Cancer Institute estimates that approximately 13.7 million Americans with a history of cancer were alive on January 1, 2012.
• About 1,660,290 new cancer cases are expected to be diagnosed in 2013.
• In 2013, about 580,350 Americans are expected to die of cancer, almost 1,600 people per day.
• Cancer is the second most common cause of death in the US, exceeded only by heart disease, accounting for nearly 1 of every 4 deaths.
Cancer trends

• The 5-year relative survival rate for all cancers diagnosed between 2002 and 2008 is 68%, up from 49% in 1975-1977.

• Increase reflects improvements in diagnostic technologies (detection) and treatment options accomplished through RESEARCH (basic, clinical and translational)
Medical Research

Evidence-based medicine: Integrating individual clinical expertise with the best available external clinical evidence from systematic research.

• **Systematic research:**
  - e.g. precision of diagnostic tests
  - Safety and efficacy of new drugs
  - Preventive approaches

Provides evidence that replaces previously accepted tests with new ones that are more powerful, more accurate, more efficacious, and safe
Clinical Trials

What is a clinical trial?
Research studies involving people
Final step in the translation of novel discoveries made in the laboratory (bench) to the clinic (bedside)

Intent/Goal:
Find/diagnose cancer, prevent or treat cancer
Manage symptoms of cancer or side effects
Ways to do surgery or give radiation therapy
New drugs or drug combinations
Clinical Trials

**Phases of Clinical Trials**
Trials take place in four phases, each designed to answer different research questions.

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
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<tbody>
<tr>
<td>Number of</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>participants</td>
<td>15-30 people</td>
<td>Less than 100 people</td>
<td>Generally, from 100 to thousands of people</td>
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<tr>
<td>Purpose</td>
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<td>To find a safe dosage</td>
<td>To determine if the agent or intervention has an effect on a particular cancer</td>
<td>To compare the new agent or intervention (or new use of a treatment) with the current standard</td>
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Who conducts clinical trials?

 Majority of cancer research in the US is conducted in National Cancer Institute (NCI)-designated cancer centers, cancer cooperative groups, and community clinical oncology programs (CCOPs).

 The centers, groups, and CCOPs work together in an organized fashion to design new treatment concepts, develop these treatment concepts into treatment strategies, and then incorporate these new strategies into general practice.
Who conducts clinical trials?

60 NCI-designated cancer centers in the United States,

Academic institutions that have demonstrated special qualifications and abilities in cancer research and have passed a rigorous application process.

Together the centers treat approximately 5,000 to 7,000 cancer patients on federally funded trials each year.
Patients in Clinical Trials

Why participate in a clinical trial?
Critical part of the research process
Clinical trials contribute to knowledge of and progress against cancer.

Today’s treatments are a result of past clinical trials
The more people who participate in clinical trials, the faster critical research questions can be answered that will lead to better treatment and prevention options for all cancers.

Opportunity to impact the health of millions
Impact of Patient Participation

Your voice (patient and caregiver) and perspectives drives the research process
- Prioritize research questions
- Design/conduct of research
- Implementing the results in practice
- Influence health policy

You can participate as a clinical research volunteer or as a patient volunteer or consent to provide tissue for research.
Benefits of Patient Participation

- Cancer care provided by top physicians in the field of cancer research.
- Access to new drugs and treatment methods before they are widely available.
- Close monitoring of your health care and any side effects.
- A more active role in your own health care.
- An opportunity to make a valuable contribution to cancer research.
Potential Risks

- New drugs and procedures may have side effects or risks unknown to the doctors.

- New drugs and procedures may be ineffective, or less effective, than current approaches.

- Even if a new approach has benefits, it may not work for you.
FAQs relating to Clinical trials

What is the purpose of the study?
Why do the researchers think the approach being tested may be effective? Has it been tested before?
Who is sponsoring the study?
Who has reviewed and approved the study?
What are the medical credentials and experience of the researchers and other study personnel?
How are the study results and safety of participants being monitored?
How long will the study last?
How will the results be shared?
FAQs relating to Clinical trials

Participation and Care
What kinds of treatment, medical tests, or procedures will occur during the study? How often will patients receive the treatments, tests, or procedures? Will treatments, tests, or procedures be painful? If so, how can the pain be controlled?
How long will participants need to stay in the study? Will there be follow-up visits after the study?
Informed Consent

Informed consent is a process by which people learn the important facts about a clinical trial to help them decide whether to participate.

This information includes details about what is involved, such as the purpose of the study, the tests and other procedures used in the study, and the possible risks and benefits. In addition to talking with the doctor or research nurse, people receive a written consent form explaining the study.
Research Subject Protection

Office of Research Subject Protection:
Advancing responsible and ethical research practices, to ensure that the subject's rights, dignity and welfare of subjects are protected.
Minimize the risks associated with such endeavors in accordance with the Belmont Report, by providing oversight, education and monitoring.
Providing education for investigators, research and administrative staff, and board members.
Promotion and advocacy for research subjects, especially those who are vulnerable and/or susceptible to manipulation and exploitation.
Research Subject Protection

Office of Research Subject Protection:
Providing current and prospective research participants with information in order to make decisions about participation in research studies.
If you are interested in participating in a research study, currently enrolled in a research study, or have questions you would like addressed by someone unaffiliated with a specific research study to:
Discuss problems, concerns and questions.
Obtain information.
Offer input.
Clinical Research

IRB (The Institutional Review Board)
- Group of physicians, scientists and members of the community dedicated to advancing responsible and ethical research practices and to ensure that the rights, dignity and welfare of human subjects are protected.
- Minimizing the risks associated with research by providing oversight, education and monitoring
- Advocating for human rights of research subjects, especially those who are vulnerable and/or susceptible to manipulation and exploitation
- Providing education for investigators, research and administrative staff, and board members
Clinical Research

Conflict of Interest Committee
Determine if a conflict at an individual or institutional level exists that could bias the research we do

Ethics Committee
Guided by ethical values that include the pursuit of truth, excellence, respect, empathy, mutuality, responsibility, integrity and honesty within all relationships between all members of the institute and community.
Act as an advisory and resource to patients, family members or health professionals to address ethical questions

Scientific Review Committee
IACUC (Institutional Animal Care and Use Committee)
Institutional Biosafety Committee
“You are helping yourself. You are helping others. That’s a win-win. I have been there. I have done it and would do it again.”
“People think you only do clinical research studies if you don’t have any other options. I did have choices but the research study was the best choice for me. Because I had that choice, I feel like I am in control of my treatment.”
“At best, the treatment offered by the research study will cure me. At worst, the information they learn from it will help people down the line, like my sons – or anybody’s son”.

Arthur N. Daniels
Resources

www.cancer.gov
Thank you

Any Questions?