



UT Cancer Institute CLINICAL TRIALS NEWS

a bi-monthly newsletter provided by the Clinical Trials Department at the UT Cancer Institute

Results released! The Study of Tamoxifen and Raloxifene, STAR trial, for Breast Cancer Prevention

The National Surgical Adjuvant Breast and Bowel Project released the results of one of the largest breast cancer prevention studies ever conducted. Key Points:

1. Initial results show that raloxifene is as effective as tamoxifen in reducing risk of developing invasive breast cancer, a reduction of about 50%.
2. Those that received raloxifene had fewer serious side effects than those who received tamoxifen, including fewer uterine cancers, blood clots, and cataracts.

We enrolled 60 women in the STAR study with slightly more randomized to receive raloxifene than tamoxifen.



NCI BUDGET CUTS

NCI tells community clinical oncology programs to slow accrual of patients to trials in preparation for budget cuts. There is a proposed \$40 million cut in next year's NCI budget.

Cure for Cancer Worth \$50 Trillion

From 1970 to 2000, gains in life expectancy added about \$3.2 trillion per year to national wealth. Even a 1% reduction in mortality from cancer would be worth \$500 million in social value. The results show that benefits of research are large and worthwhile.
Am.Assoc.Can.Research



FDA Guidance on Patient Reported Outcomes: Discussion, Dissemination, and Operationalization

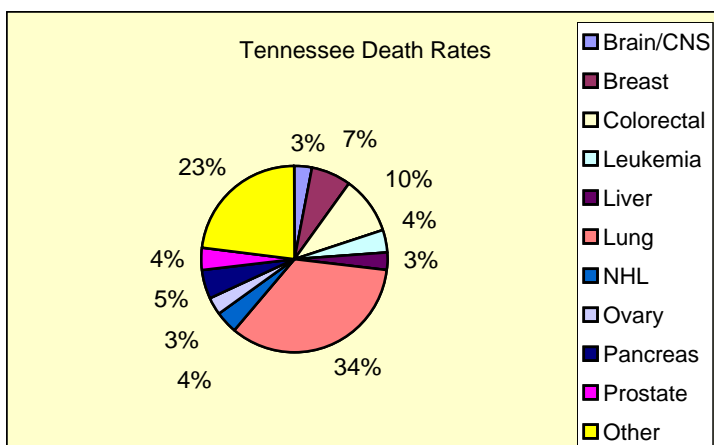
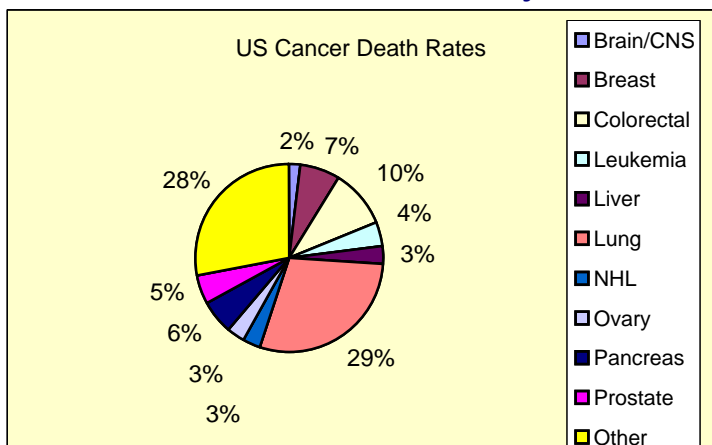
The FDA unveiled its long-awaited draft guidance on patient-reported outcomes (PROs) in Feb. A PRO is any report coming from the study subjects about a health condition and its treatment.

5 Major points of the guidance:

1. PROs should be used in clinical trials because some effects of treatment are known only to the patient.
2. Formal PROs are more reliable than informal interviews with patients.
3. PROs can measure symptoms and the patients' overall condition. They can be general or specific. They can measure the effectiveness of a treatment and side effects.
4. The instrument to measure PROs should be reliable, valid, and easy to interpret.
5. PROs will be designed to the specific needs of the patient population.

Now it's up to the study sponsors to develop PRO instruments and use them for determining outcomes.

Cancer Stats 2006 * American Cancer Society



Benefit of Chemo Depends on ER Status

When it comes to chemo treatment for women whose breast cancer has spread to the lymph nodes, the estrogen status of the tumor matters, according to a JAMA study (April 12). Data was analyzed from 3 CALGB trials with a total of 6,633 patients. They found that chemo works better in breast cancer that is ER negative and doesn't work as well in ER positive cancer as most believe. More ER negative patients receiving chemo were disease-free after 5 years (22% vs. 7%)
Overall survival was 16.7% ER - vs. 4% ER +.

Elderly Patient Recruitment in Clinical Trials

People over 65 years of age are the fastest growing segment of the US population. They also make up the majority of cancer patients. Life expectancy for this group of cancer patients is increasing. However, most clinical trial data come from younger populations. Steps that can be taken to increase elderly enrollees are as follows: 1) educate physicians about the needs of this population, 2) patient education to emphasize benefits of clinical trial participation, 3) broaden funding and scope of clinical trials, 4) have more elderly-specific clinical trials, 5) have inclusion criteria allow more comorbidities.



Featured Protocol

New Antibodies for Lymphoma: Two FDA approved radioimmunotherapy agents, Bexxar (GlaxoSmithKline) and Zevalin (Biogen Idec.), are being studied for relapsed or transformed follicular Non-Hodgkin's Lymphoma. These agents appear to be effective in patients who have become resistant to Rituxan (Genentech) and/or chemo. Key questions to these agents are: Should they be used alone or with other drugs including chemo? Should they be used earlier in the patient's course of treatment? Can they be used in other subtypes of lymphoma? Watch for this study to be open soon!

Questions? Call Barbara Munsey in the Clinical Trials Office at (865) 544-9773

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Brain/CNS	3
Breast	7
Colorectal	10
Leukemia	4
Liver	3
Lung	34
NHL	4
Ovary	3
Pancreas	5
Prostate	4
Other	23

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Ovary	3
Pancreas	6
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