

# Learning about CLINICAL TRIALS

The importance of viewpoint BY WHITNEY QUESENBERRY



**S**ometimes the most important things you hear in a usability session sneak up on you. It starts with a single comment, and then grows into one of those big “ah-ha” moments that come along every once in a while when you are doing user research.

This project was user-centered research into how cancer patients and their families look for information about cancer and its treatments, as well as how to search for clinical trials. It was part of ongoing work to improve the U.S. National Cancer Institute (NCI) website (<http://www.cancer.gov/>).

One of NCI's goals is to increase participation in clinical trials, as part of a broad mission to improve understanding, treatment, and prevention of cancer. Clinical trials provide patients access to up-to-date and new treatment options and contribute substantially to the knowledge of, and progress against, cancer. Both patients and researchers benefit from clinical trials: patients, from early access to additional treatment options; medical researchers, from a larger pool of patients and the data each contributes. A central feature of the site is the clinical trials search feature, which lets the general public and healthcare professionals search a large database of over 5,000 active trials.

We prepared for exploratory usability sessions with a literature review and comparative audit of more than a dozen cancer-related websites. The literature review included journal articles on patient attitudes towards clinical trials and interviews with cancer information specialists, oncology nurses, and research managers about how they talk to patients about the possibility of participating in a clinical trial. The audit reviewed websites that provide information about clinical trials, many using the same national database of clinical trials as the NCI website.

From these two efforts, we identified three issues that might show up when we watched patients, friends, and family members use the Web to search for clinical trials that would be a good fit for them:

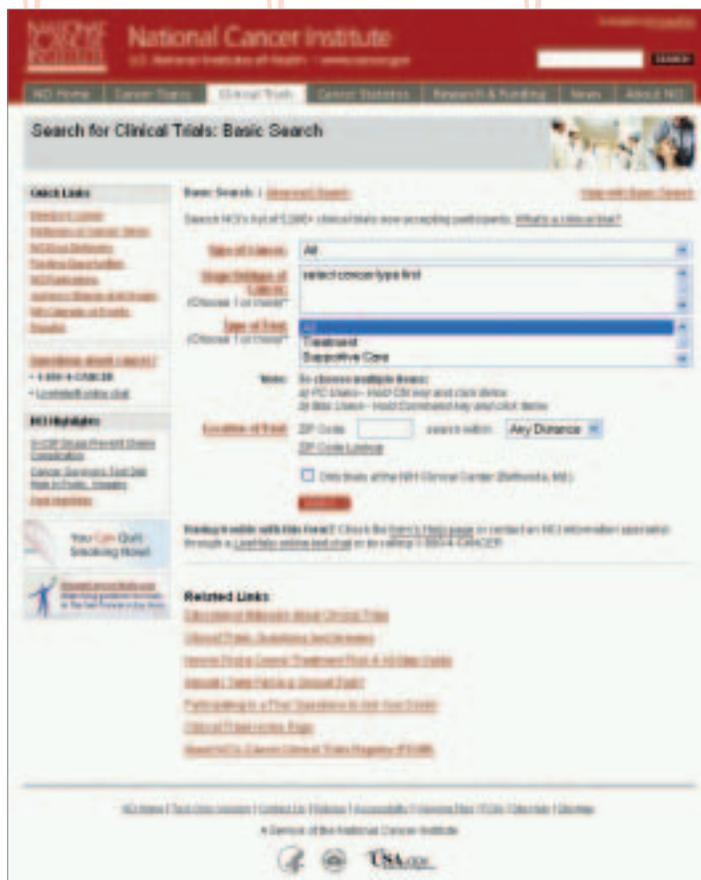
- General barriers to participation. There is a rich literature on the reasons why people are unwilling to join a clinical trial, including the fear of being an experimental "guinea pig."
- The challenges of medical terminology. Clinical trials are tests of treatments that often have those long, polysyllabic tongue twister names. They involve difficult concepts like randomization, and come in phases. (Or is that "stages?"). Even the term "clinical trial" is part of a specialized medical vocabulary.
- Access and eligibility. Clinical trials are carefully controlled experiments, so participation is limited to people who meet strict eligibility criteria. Also, they are conducted at specific geographic locations which might not be convenient for the patient.

All of these issues (and more) showed up in our usability sessions. But so did a single, overwhelming user need that we had not anticipated—our "ah ha" moment. Cancer patients are not looking online for information out of general interest. They have a deep, personal, urgent need for the information. They are, not to mince words, worried that they might die. They want information that will help them, that is about them, that speaks directly to their condition and their lives.

We talked to one patient about her experiences investigating clinical trials, as part of her search for treatment when her adrenal cancer recurred and spread to her lungs. She was well-educated, actively involved in her treatment, and had learned a lot about her type of cancer. This is how she described one experience:

*"I had actually contacted one person. It was very interesting speaking to him on the phone because even as he was talking to me, the patient, he was saying, 'Well, you know, statistics we've had,' (he was really excited) 'One person it*

*worked completely but she still died. But then we had one other person who had partial remission and then some surgery and she's been living for four years and that is great for adrenal cancer.' He's talking about this all excited as a researcher and I'm going, 'I'm sorry, I'm about to start breathing into a paper bag. I realize this is exciting research for you but I'm the patient on the phone.' It was good I was able to contact him, but he wasn't exactly warm and fuzzy."*



In the basic search interface, users can search by types and stages of cancer, type of clinical trial, and by ZIP code to find trials in specific geographical locations.

## Stages and Phases

**Cancers are classified into stages, which define the extent of a cancer within the body. Staging is usually based on the size of the tumor and whether the cancer has spread from the original site to other parts of the body. The higher the stage, the more serious the disease.**

**Clinical trials are classified into phases, which identify a series of steps for testing a new treatment in humans, from Phase I to Phase IV. As the first step in testing, Phase I trials are the most experimental and usually include only a small number of patients who have not been helped by other treatments. Phase IV trials continue testing after a treatment has been approved and is in general use, and usually involve thousands of participants.**

Definitions from the Dictionary of Cancer Terms, <http://www.cancer.gov/dictionary/>

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We need to know what you think of our trials database. Please click on Contact Us at the top of any page to tell us.

**Clinical trial search results**

Narrow your search

Your search retrieved 43 clinical trials. Trials 1 - 10

**Trilostane (Modrena) for pre-menopausal women with advanced breast cancer (BIOV 211)**

Doctors often treat breast cancer that is oestrogen receptor (ER) positive with hormone therapy such as tamoxifen. Sometimes tamoxifen doesn't work very well and the cancer starts to grow again. If this happens, women can have other hormone treatments such as goserelin (Zoladex). Or one of a group of drugs called **aromatase inhibitors** such as anastrozole (Arimidex), letrozole or exemestane.

Aromatase inhibitors are usually used to treat women with post-menopausal breast cancer. But they can be useful for women who were pre-menopausal when they were diagnosed with breast cancer, but have temporarily stopped having periods because of other treatments such as goserelin.

Trilostane (Modrena) is already used to treat some women with advanced post-menopausal breast cancer. But we are not yet sure how well it works for pre-menopausal breast cancer.

In this trial, they are looking to see if trilostane is useful for pre-menopausal women with breast cancer that has continued to grow despite having tamoxifen, goserelin and an aromatase inhibitor.

The aims of the trial are to see how well trilostane works for pre-menopausal breast cancer. And to find out more about the side effects.

[More information about this trial](#)

Match to trials

Clinical Trial Description

**Next Title: A Breast Cancer Trial (Phase II) of RPR108891 versus Capecitabine (Relora) in Male or Female Patients With Advanced Breast Cancer (I)**

**Background:** All patients in this trial will receive either the investigational drug or capecitabine (Relora), a chemotherapy drug that is already approved to treat your disease. These drugs prevent tumor cells from dividing, so they may stop growing or die.

**Purpose:** The purpose of this clinical trial is to determine if the investigational drug is a better treatment than capecitabine for advanced breast cancer in patients that no longer benefit from standard anti-breast treatment.

**Treatment:** The investigational drug in this clinical trial is a steroid hormone drug given through the vein once every three weeks. Patients who receive capecitabine will receive this drug by mouth for 14 days, every 21 days.

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It sounded obvious at first. After all, guidelines for writing for the Web tell us that good writing speaks directly to readers, using plain language and concepts and terminology that are meaningful to them. Good health communication works hard at this, trying to present information that is accurate, authoritative, and usable. But, when you look at clinical trials information (and perhaps most medical websites) from this new perspective, it's easy to find the mismatch: they talk about the statistics, the research, and the details of the disease. What this patient wanted was information that would help her make a decision about her medical condition.

## How to Describe a Clinical Trial

One of the biggest differences between the sites we reviewed was how they presented the description of the clinical trial. Two sites, EmergingMed.com (<http://www.emergingmed.com>) and CancerHelp UK (<http://www.cancerhelp.org.uk>) use short, easy to read text. CancerHelp

## Radiation Therapy in Preventing CNS Metastases in Patients With Non-Small Cell Lung Cancer

### What is the purpose of this trial?

This clinical trial is for people with non-small cell lung cancer, who have recently completed treatment.

The purpose of this trial is to see the good and bad effects radiation therapy to the head works in preventing a tumor which started in the lung, called non-small cell lung cancer, from spreading to the central nervous system (CNS metastases).

Radiation therapy uses high-energy x-rays to damage tumor cells. It is not yet known if giving radiation therapy to the head is effective in preventing CNS metastases in patients who have stage III non-small cell lung cancer.

This is a Phase III clinical trial. Phase III trials compare the results of participants taking an experimental drug with the results of participants taking the standard treatment or another experimental treatment for their type of cancer. "Standard treatment" means the treatment commonly used for this disease.

### How is this trial conducted?

In this study, you will be randomly assigned to receive either radiation therapy or simply be observed. Your quality of life will be assessed for up to 4 years.

This is a randomized study. Randomized means that you will be randomly assigned to one of the two treatment groups. You will have an equal chance of being placed in either group, much like the flip of a coin. Neither you nor the researcher will make the choice; a computer places you in one of the two groups. This study is being done because better treatments are needed for this type of cancer.

### What treatment do participants receive?

If you are eligible and choose to participate, you will be randomly assigned to one of the two treatment groups ("A" or "B").

- Patients in group one will undergo radiation therapy to the head 5 days a week for 3 weeks.
- Patients in group two will undergo observation. Quality of life will be assessed periodically for up to 4 years.

### The first page of the "narrative" prototype

UK is careful to define not only medical terms, but to explain the goals and other facts about the clinical trial in simple, clear text. We expected participants to prefer this format. They didn't.

In the usability sessions, we asked participants to use the clinical trials search feature on several different sites. Then, at the end of the session, we showed them three different paper prototypes of a clinical trial description. They were a blend of good features we identified in the comparative review:

- A short narrative style written in clear, basic English with terms (such as "randomized") defined in the text
- A version that used terse, professional language, and presented the information in a structured list.
- A simplified medical style for the main text with a quick reference section at the top and structured headings.

We used a real clinical trial description, selecting the order and format for the information. Because many web sites have access to the same database, we were able to find different writing styles to use.

Surprisingly, few people preferred the first version. They felt that they had to "work too hard" to find key information in the text, and had trouble telling whether they might be eligible to join the trial. Participants strongly preferred the two versions structured with bullet points—even the one with more professional medical terminology. They said that this format seemed shorter and more succinct. We were also surprised that even people who struggled with the terminology sometimes preferred the professional version. Possibly, having fewer words to read—even if those words are more difficult—is part of the advantage.

One reason they liked the more professional version is that it listed the eligibility criteria up front. For many of the participants, the most important thing is to be able to quickly determine the goals of the trial and whether it might be a treatment option for *them*. As one participant put it, "Well, this [first prototype] is a nice clear explanation. But, I do love having the eligibility criteria."

### Radiation Therapy in Preventing CNS Metastases in Patients With Non-Small Cell Lung Cancer

Phase III Randomized Study of Prophylactic Cranial Irradiation in Patients With Stage IIIA or IIIB Non-Small Cell Lung Cancer

First published 11/1/2002 Last modified 02/9/2005

**About this Trial**

Phase: Phase III  
Type: Treatment  
Status: Active  
Sponsor: NCI

**Protocol IDs**

- RTOG-0214
- NCT00449997
- EOCG-RTOG-0214

**Who Is Eligible?**

**Disease Characteristics**

- Diagnosis of stage IIIA or IIIB non-small cell lung cancer
- No progressive disease
- No extracranial distant metastatic disease
- No suspicion of CNS metastases by MRI or CT scan

**Prior/Concurrent Therapy**

- No more than 16 weeks since prior therapy
- No previous radiation therapy to the head
- Recovered from all prior therapies
- No concurrent enrollment on any other phase III study that has progression-free, disease-free, or overall survival as an endpoint

**Patient Characteristics**

- 18 years and over
- No other malignancy within the past 3 years except non-melanoma skin cancer
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception

**Objectives**

1. Determine whether prophylactic cranial irradiation improves survival after effective locoregional/systemic therapy in patients with stage IIIA or IIIB non-small cell lung cancer.
2. Determine the neuropsychologic impact of this therapy in these patients.
3. Assess quality of life of patients receiving this therapy.
4. Determine the impact of this therapy on the incidence of CNS metastases in these patients.

The first page of the "structured" prototype

## How to Read a Clinical Trial Search Results List

This focus on their own medical details and situation worked well for patients reading the clinical trial descriptions, but it worked against them when scanning a list of clinical trial results. No matter how good or poor their grasp of medical terminology, participants tended to know the medications and treatments they had experienced. Some had cheat sheets. Some could not pronounce the words, but they all *recognized* their own medications.

These words become anchors for patients. As they read, they scan the pages for those words. This strategy works well in most situations, such as looking up information about a newly prescribed medication. In searching for clinical trials, however, it works against them because prior use of a medication or treatment often disqualifies them from the trial. This is more than a problem with the user-interface design—it's a mismatch of mental models. In real sites and in our mockups of search results, the more clearly the treatment being tested is identified, the more likely participants were to pick trials for which they were not eligible.

One solution, used by several sites, is to change the entire concept from *searching* a database to *finding* a match. These sites ask patients to fill out detailed medical questionnaires, and use this information to identify clinical trials for which they might be a match. Patients accepted this, and were willing to complete long forms, as long as they didn't have to reveal personal information that did not seem relevant. Unfortunately this solution relies on good algorithms (or human intervention) for useful results. In the case of rarer cancers, they can often return either no options or options with no obvious connection to the patient's medical situation. They also fail to meet the goal of many long-term cancer patients and survivors—to see the breadth of research being done on *their* cancer.

From this project, we learned that patients have real, personal concerns about their health, and that medical information only becomes compelling to them when it directly answers their questions and enables them to make decisions. It is not enough to simply present the right information to patients;

**50 Clinical Trials found for:**

- Lung cancer (non-small cell, all types)
- Within 20 miles of zip code 08629
- All trial types
- All trial phases

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Title of Trial	Agents	Trial Phase	Cancer Stage	Type of Trial
<a href="#">Carboplatin, Paclitaxel, and Radiation Therapy With or Without Thalidomide in Treating Patients With Stage III Non-Small Cell Lung Cancer</a>	Carboplatin Paclitaxel Thalidomide Radiation	Phase III	Stage III	Treatment
<a href="#">Carboplatin Plus Gefitinib As Treatment of Stage III/IV Non-Small Cell Lung Cancer (M5710)</a>	Carboplatin Gefitinib	Phase II	Stage IIB or IV	Treatment
<a href="#">Docetaxel and Cisplatin in Treating Patients With Stage III or Stage IV Non-Small Cell Lung Cancer</a>	Docetaxel Cisplatin	Phase II	Stage IV	Treatment
<a href="#">Docetaxel With or Without Infliximab in Treating Stage I, II, or IIIA, and Patients in Patients with Unresectable Non-Small Cell Lung Cancer</a>	Docetaxel Infliximab	Phase III	Stage I, II or IIIA	Supportive Care Treatment
<a href="#">Erlotinib in Treating Patients With Stage III, Stage IV, or Recurrent Non-Small Cell Lung Cancer</a>	Erlotinib	No Phase Specified	Stage IIB or IV	Treatment
<a href="#">Erlotinib in Treating Patients With Early-Stage Non-Small Cell Lung Cancer</a>	Erlotinib	Phase II	Stage I, II or IIIa	Treatment
<a href="#">Radiation Therapy in Preventing CNS Metastases in Patients With Non-Small Cell Lung Cancer</a>	Radiation	Phase III	Stage III	Treatment
<a href="#">Radiation Therapy and Stereotactic Radiotherapy With or Without Tamoxifen as Options in Treating Patients With Brain Metastases Secondary to Non-Small Cell Lung Cancer</a>	Tamoxifen Erlotinib Radiation Radiotherapy	Phase III	Not Specified	Treatment
<a href="#">Selenium in Preventing Tumor Growth in Patients With Previously Resected Stage I Non-Small Cell Lung Cancer</a>	Selenium	Phase III	Stage I	Prevention
<a href="#">Tadalafil Plus Radiation Therapy After Concomitant Chemotherapy in Treating Patients With Stage III Non-Small Cell Lung Cancer</a>	Tadalafil Radiation	Phase I	Stage III	Treatment

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One mockup of a list showing the results of a search of a clinical trials database. We looked for a design that would make the list easier to scan and help patients avoid confusing trial *phases* and cancer *stages*.

medical information must also have the right tone, recognizing the gravity of the patient's situation, and must present the information in the right format, so patients may quickly find it and act upon it. **UX**

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**DEDICATION:** *Laura Snyder, my friend and colleague, contributed to this project. Although her participation was intended only as a pilot session, her insights proved to be key to the project. Laura was diagnosed in 2002 and died in July 2007. She never gave up the fight. To the end, she maintained that "life is good."*

## ABOUT THE AUTHOR



**Whitney Quesenberg** is a user-researcher and usability specialist with a passion for clear communication. She works with companies around the world to improve their websites and software applications. She is a past-president of UPA, and serves on two U.S. federal advisory committees, helping create voting systems standards and updating the Section 508 accessibility regulations. She is the author of a chapter on storytelling and narrative in *The Personas Lifecycle*. She's also proud that her chapter "Dimensions of Usability" in *Content and Complexity* turns up on so many course reading lists. She can be contacted at [whitneyq@wqusability.com](mailto:whitneyq@wqusability.com).