

# **Accessibility Evaluation of the ClinicalTrials.gov Web Site**

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*prepared for*

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*by*



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## 1. INTRODUCTION

### 1.1. OBJECTIVES OF THIS REVIEW

The goal of this review is to document accessibility concerns identified in compliance audits and usability testing of the ClinicalTrials.gov Web site. We hope to eliminate significant barriers for individuals with disabilities, particularly those with blindness and low vision, motor disabilities, and cognitive disabilities. Many of our comments focus specifically on issues that may affect use of the site with assistive technologies (hardware and software used by people with disabilities to access electronic and information technology).

### 1.2. ABOUT SECTION 508 COMPLIANCE

Because the U.S. Department of Health and Human Services (HHS) is a Federal agency, it must comply with the Federal accessibility standards established in Section 508 of the U.S. Rehabilitation Act.<sup>1</sup> In addition, the agency has established accessibility standards for its own Web publications,<sup>2</sup> which Macro incorporated into this review.

Section 508 compliance guarantees only a minimum level of accessibility, and a system may be compliant yet still be extremely difficult to use. Macro has, therefore, also documented some lower-priority issues that impact interface usability for assistive technology users. These are derived from guidelines set forth in the Web Content Accessibility Guidelines (WCAG 1.0),<sup>3</sup> developed and published by the World Wide Web Consortium.

Section 508 standards are currently under review, and new standards will go into effect in 2010. The draft for the 508 Refresh<sup>4</sup> includes a number of issues that are not included in the current standards. It may be worth addressing those issues as ClinicalTrials.gov is updated. Macro can provide guidance on the Refresh on request.

### 1.3. CURRENT SYSTEM STATUS

ClinicalTrials.Gov is not compliant with Section 508 of the U.S. Rehabilitation Act. The system will be compliant after the following issues have been addressed:

- Layout table construction must be improved because these tables create problems with tab and reading order and interfere with assistive technology.
- When tables are used to present data, column and row headers must be marked up with the header element TH.
- When more than one level of headers is present in a table, row and column headers must be programmatically associated with table cells.

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<sup>1</sup> <http://www.section508.gov>

<sup>2</sup> <http://www.hhs.gov/od/508policy/index.html>

<sup>3</sup> <http://www.w3.org/TR/WCAG10/>

<sup>4</sup> [http://webaim.org/teitac/wiki/EWG~Draft\\_Jan\\_7.php](http://webaim.org/teitac/wiki/EWG~Draft_Jan_7.php)

- Form controls must be programmatically associated with labels using appropriate markup (LABEL or “title”).
- Skip links must be added to support jumping repetitive navigation links.

## **2. APPROACH**

### **2.1. OUR METHODOLOGY**

Compliance audits incorporate a combination of human and automated testing methods. For this evaluation, we performed the following analyses:

- Hypertext markup language (HTML) and Section 508 validation
- Keyboard testing
- Testing with scripting and style sheets disabled
- Testing in Mozilla Firefox and Microsoft (MS) Internet Explorer (IE) browsers
- Assistive technology testing with a screen reader (JAWS) and magnifier (Windows Magnifier), as appropriate
- Usability testing with users with vision, motor, and cognitive disabilities

Although automated evaluation tools are a useful part of an accessibility evaluation suite, they cannot be relied on as the sole testing method. Human judgment is required to meet many compliance requirements.

### **2.2. PARTICIPANT INFORMATION**

During recent usability testing for the ClinicalTrials.gov Web site, Macro was able to speak with users with a number of disabilities, some of which were age related. One participant, for example, magnified screen text because of age-related low vision problems (cataracts). Another experienced physical disability as a result of long-term, degenerative illness (Parkinson's disease). Another used a screen reader because of vision loss due to retinitis pigmentosa. A final participant discussed how dyslexia and other learning disabilities affected her ability to process spoken and written information. All individuals whose results were included in this evaluation were over the age of 60.

Our findings from these interviews are not comprehensive. Because disabilities are unique, someone else with a cognitive, vision, or motor disability may have a different experience with the system. The screen reader user we interviewed had a great deal of difficulty with the search results interface but said that he was not a frequent user of the screen-reading software (JAWS 9) and that another user might have less difficulty. It should be noted, however, that frequent use of an assistive device or application should not be a requirement if the system is intended for use by the lay public. While the participant with Parkinson's disease experienced moderate physical slowness as a result of the disease, the facilitator did not believe that his disability affected his task completion rates.

### **2.3. ASSESSING PRIORITY**

This report addresses a number of issues that are required for compliance with Federal legislation; these issues will be assigned a "Required" priority rating. If an item created problems during usability testing but is not required for compliance, it will be assigned a "Strongly

Recommended” rating. Any item that is not required for compliance and was not problematic for participants in usability testing but has been shown by research to improve usability for assistive technology users will receive a “Recommended” rating.

### 3. RESULTS BY PAGE

The ClinicalTrials.gov interface uses a fairly simple search engine design, with tabs across the top to select the type of search, a topical index, and a mapping interface. Most features can be operated by keyboard, although tab and reading order are sometimes problematic due to unusual layout table construction.

Many of our comments apply to more than one system screen. In order to avoid redundancies, we have not listed all items on every page. A number of these issues (e.g., problems with tables, forms, skip navigation) apply globally and should be addressed throughout the system.

#### 3.1. BASIC SEARCH

##### 3.1.1. Forms

**Priority Rating:** Required

The Basic Search form includes the “alt” attribute with form controls. “Alt” can be used with input elements that include an image but should not be used with other input elements. In order to explicitly associate a form control with its label, either the LABEL element or the “title” attribute should be used. The following is presented as an example of these issues:

```
<div class="indent1">
  <br/>
  <span class="header2">Enter a word or phrase, such as the name of a medical condition or
intervention.</span><br/>
  <br/>
</div>
<div class="indent2">
  <form name="search" method="get" action="/ct2/results">
    <table cellpadding="3" cellspacing="0" border="0">
      <tr>
        <td class="header3" nowrap>Example: &nbsp; Heart Attack AND Los Angeles</td>
      </tr>
      <tr>
        <td class="header3" align="right" nowrap>
          <input class="header3" type="text" name="term" alt="Search Terms" id="first_focus"
value="" size="60" maxlength="250"/> &nbsp;<br/>
        </td>
        <td class="header3" nowrap>
          <input class="header3" type="submit" alt="Search" value="Search"/> &nbsp;<br/>
        </td>
      </tr>
      <tr>
        <td class="header3" align="right" nowrap>
```

```

        <a href="/ct2/search/advanced" title="Show Advanced Search page">Advanced
Search</a> &nbsp;
    </td>
    <td class="header3" nowrap>
        <a href="/ct2/help/help" title="Show search help"
onclick="openPopupWindow('/ct2/help/help',true); return false;">Help</a>
    </td>
</tr>
</table>
</form>
</div>

```

In order to explicitly associate a form control with its label using the LABEL element, LABEL must include the “for” attribute and INPUT (or SELECT or TEXTAREA) must include the “id” attribute. “Id” values must be unique to a document and must begin with an alphabetical character. The “id” value cannot contain a space, and “id” and “for” values must match exactly. The form control may be contained within LABEL or outside of it, so long as the programmatic association is present.

Explicit association of form controls with labels via LABEL or “title” is required because screen readers sometimes have difficulty associating labels with form controls when they are implicitly associated (e.g., when they are placed next to one another or when INPUT is placed within LABEL, but “for” and “id” are not present). In the example given above, the label (“Enter a word or phrase, such as the name of a medical condition or intervention”) and the form control are separated by a significant amount of markup, including table cells.

Once this association is created, it can be tested as follows: Click on the label for the form control. If focus moves into the element (INPUT, SELECT, or TEXTAREA), the association has been created and is operating correctly. If it does not do this, there is an error. Common errors include invalid or repeated “id” values and mismatched “for” and “id” values.

“Title” may be used with a form control to provide a label when LABEL cannot be used. LABEL cannot be used to associate a form control with multiple labels (e.g., in a form laid out as a data table) and may be difficult to use if no text label is present (although text labels may be hidden using cascading style sheets).

To fix this problem, we recommend that the National Library of Medicine (NLM):

- Use LABEL to associate the label and form control in the Basic Search screen:
  - <LABEL for="search\_terms">Enter a word or phrase, such as the name of a medical condition or intervention.</LABEL>
  - <input class="header3" type="text" name="term" id="search\_terms" value="" size="60" maxlength="250"/>
- Remove the “alt” attribute from INPUT

### 3.1.2. Skip Navigation Links

**Priority Rating:** Required

Users must be given a means of skipping repetitive navigation links via a skip link. On ClinicalTrials.gov, repetitive navigation links include the Home, Search, Study Topics, and Glossary links as well as the tabbed menu in the main search window. The skip link should jump users directly from the beginning of page content to the search feature or other page content.

A skip link may be accomplished in a number of ways. Two of the most common are the following:

- An invisible linked spacer image may be placed in the upper left corner of the page. The GIF image must include a text equivalent stating the target of the link (e.g., alt="skip to main content").
- A text link may be placed in the upper left corner of the page. This link may be hidden using a style sheet.<sup>5</sup>

The skip link must be the first link that users encounter on a page. In order to determine whether the link is operating correctly, tab to the link. Press **Enter** to activate it. Focus should move to the target of the link. Press the tab key again. If focus moves to the first link or form control in the page content, the link is functioning correctly. If focus returns to the top of the page, there is an error. Skip links must be tested in more than one browser. If the link does not pass this test in MS IE, try placing the named anchor in a SPAN element with a width of 100 percent:

```
<span style="width: 100%;"><a name="main"></a></span>
```

### 3.1.3. Headings

**Priority Rating:** Strongly Recommended

The heading element (e.g., H1, H2, H3) is not present in ClinicalTrials.gov pages. The heading element is important for providing structural information on each page. Screen reader users can use the heading element to navigate the page, essentially moving through an outline. Although the heading element is not required for Section 508 compliance, it will be required in the 2010 508 Refresh.

In tests with a screen reader user, we found that one of the first things the participant looked for was page headings: “If I wasn’t sure how big this page was, I might check [headings] . . . Oh, [there are] no headings.” When he encountered a new page or site, he approached it by first looking for headings or tables. If he found neither, he would use the arrow key to attempt to move through the page content. Lack of headings was a significant barrier for him, since they would have allowed him to move through the page content and quickly identify the types of

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<sup>5</sup> See the Skip Navigation page in the Policies and Standards section of the HHS Web site, <http://www.hhs.gov/web/policies/skipnavigation.html>.

information present. This was particularly important in text-heavy pages, such as many of those on the Clinical Trials Web site.

To improve accessibility and usability for screen reader users, we recommend that NLM:

- Use headings (H1, H2, H3) on all system pages
- Use headings appropriately, in ascending order
- Use headings to provide structure to the page and not for presentation alone (e.g., using H4 out of the correct order to get a certain font size)

#### **3.1.4. Primary Language**

**Priority Rating:** Recommended

The primary language of the ClinicalTrials.gov Web site is not specified in HTML. Screen readers are able to determine the primary language of a document and any changes in language that may occur if that information is provided in markup. It is especially important to provide this information when a system contains records from other countries, as this Web site does.

The following tag can be included, for example: `<html lang="en">`.

#### **3.1.5. Plain Language**

**Priority Rating:** Strongly Recommended

ClinicalTrials.gov uses a great deal of medical and research jargon. This creates difficulties for laypeople tasked with locating appropriate studies and places an even greater burden on nonmedical users with disabilities. Individuals with cognitive disabilities encounter difficulties when accessing text-heavy pages or pages that use excessive jargon and/or scientific language. Individuals who use screen readers to access system pages may be at a disadvantage if the reader mispronounces a lengthy scientific term.

During user testing, the blind participant attempted to locate stomach cancer in the by-topic list of diseases. After scrolling through a few cancers, he stated, “I wonder if I want to find stomach cancer, or some scientific word . . . I’m thinking that this might not be where I want to be, because these don’t make sense to me.” When the screen reader read “adenocarcinoma” aloud, he let out an intimidated “Wow.” The scientific language was clearly difficult for him to listen to and made browsing by topic significantly more difficult. Our low-vision participant, who was also a retired physician, spoke at some length about the difficulties health and research jargon would pose for laypeople.

When possible, language should be simplified to facilitate understanding. Plain language will be included as a requirement in the 2010 508 Refresh.

## 3.2. SEARCH RESULTS

### 3.2.1. Complex Layout Table Construction

**Priority Rating:** Required

The search interface, particularly on the Advanced Search and List Results pages, uses complex layout tables. Layout tables do not create accessibility problems unless they interfere with logical reading or tab orders. In the case of the List Results page, the table should be marked up as a data table and simplified.

| ClinicalTrials.gov  |                               | A service of the U.S. National Institutes of Health   |  |
|---|-------------------------------|---|--|
| <a href="#">Home</a> <a href="#">Search</a> <a href="#">Study Topics</a> <a href="#">Glossary</a> |                               | <input type="text"/> <input type="button" value="Search"/>  |  |
| <a href="#">List Results</a>  | <a href="#">Refine Search</a> | <a href="#">Results by Topic</a>  | <a href="#">Results on Map</a>                 |
| Found 901 studies with search of: <b>Japan</b>  |                               |   |  |
| <a href="#">Hide studies that are not seeking new volunteers.</a>                                 |                               |   | <input type="button" value="Display Options"/> |
| 1   | Active, not recruiting        | <a href="#">Randomized Evaluation of Long Term Anticoagulant Therapy (RE-LY) With Dabigatran Etexilate</a>                                |  |
|   |                               | Conditions  | Atrial Fibrillation; Cerebrovascular Accident  |
|   |                               | Interventions   | Drug: Dabigatran etexilate; Drug: Warfarin     |
| 2   | Recruiting                    | <a href="#">Xeloda vs. TS-1 as First-Line Treatment in Unresectable or Recurrent Breast Cancer</a>  |  |
|   |                               | Condition   | Breast Neoplasms                               |
|   |                               | Interventions   | Drug: Capecitabine; Drug: TS-1                 |
| 3   | Active, not recruiting        | <a href="#">Safety Study of Lenalidomide With and Without Dexamethasone in Japanese Subjects With Previously Treated Multiple Myeloma</a> |  |
|   |                               | Condition   | Multiple Myeloma                               |
|   |                               | Interventions   | Drug: lenalidomide; Drug: dexamethasone        |
| 4   | Active, not recruiting        | <a href="#">Adalimumab in Adult Japanese Subjects With Psoriasis</a>  |  |
|   |                               | Condition   | Psoriasis                                      |
|   |                               | Interventions   | Biological: adalimumab; Biological: adalimumab |

Figure 1. Grid view of List Results page

Although the screen reader can read the content in this table, use of table navigation features is complicated by the many blank and spanned cells that have been inserted and by the table's unorthodox structure.

For example, a single record in this table has been structured as follows:

```
<tr valign="top">
  <td class="index" rowspan="3" align="left" nowrap>4</td>
  <td class="spacer" rowspan="3"/>
  <td class="header3" rowspan="3" align="left" style="width:10ex">
    <span style="color: red ">Completed</span>
  </td>
  <td class="spacer" rowspan="3"/>
  <td class="header3" colspan="3" align="left" width="85%"><a title="Show study
NCT00035308: Safety and Efficacy Study of LJP 394 (Abetimus Sodium) to Treat Lupus
Kidney Disease" href="/ct2/show/NCT00035308?term=lupus&rank=4">Safety and
Efficacy Study of LJP 394 (Abetimus Sodium) to Treat Lupus Kidney Disease</a></td>
</tr>
```

```

<tr valign="top" class="body3">
  <td align="right">Conditions:</td>
  <td class="spacer"/>
  <td align="left" width="75%">Immunologic&#160;Diseases; &#160;
Autoimmune&#160;Diseases; &#160; Systemic&#160;Lupus&#160;Erythematosus; &#160;
Lupus&#160;Nephritis; &#160; Lupus&#160;Glomerulonephritis</td>
</tr>

```

```

<tr valign="top" class="body3">
  <td align="right">Intervention:</td>
  <td class="spacer"/>
  <td align="left"
width="75%">Drug:&#160;Abetimus&#160;sodium&#160;(LJP&#160;394)</td>
</tr>

```

When our screen reader user attempted to navigate a record using the arrow keys, he became confused because he could not make sense of the table structure. This was in large part due to the spanned cell in the third column. All the content in the following cells are contained within that spanned TD. Instead of moving across the row as he expected, he ended up in a series of spanned cells (containing title, condition, and intervention). The participant thought he was moving into new columns, when in reality the Conditions and Interventions content was located in the same cell (in terms of visual reading order) as the study title. All the records displayed in the Results List are coded in this way. The table structure is complex and lacks markup that would give users cues to orient themselves.

The table is essentially a data table, but it lacks column and row headers and appropriate associative markup. The user was unable to determine how content below the study title (e.g., Condition, Interventions) related to the study because the cells did not appear to be related in the markup. He could not determine that all the content was in one row because there were a number of spanned cells and no headers. The title itself was also confusing, he said, because the record number (“Show Study NC00519363”) was read before the title (JAWS can be set to prioritize “title” over link text or to prioritize whichever is longest). The titles used jargon he did not understand, which was made even more difficult to decipher by JAWS’s mechanized voice.

Even though all listed results are located in a single table, each result is separated from the others by an empty row that contains a single column, causing the screen reader to announce “end of column” at the end of each result. Instead of moving from cell to cell using table navigation keystrokes, the user must intuit that the table has not ended, move past the shortened empty row, and then move on to the next study row. The screen reader also announces the number of rows in the table. Because the results table is so complex, even when relatively few results are displayed, the screen reader announces a very long table (e.g., “stomach cancer” resulted in a table with more than 200 rows, in response to which our user commented, “Whoa”). This could give an erroneous impression of the number of records listed.

It is worth noting that our screen reading participant did not attempt to use JAWS table navigation keystrokes until the evaluator asked about them, and then he did not remember which keys to use. He instead attempted to move through the tables solely with the arrow keys on the

evaluator’s laptop computer. This suggests that users who do not often browse online for tabular data are likely to be more familiar with layout table navigation than data table keystrokes. It is therefore important that these types of tables are constructed as simply as possible to ensure access for the broadest possible audience.

To simplify this table and add basic data table markup, the following modifications must be made:

- Remove empty cells.
- Eliminate spanned cells.
- Locate all record information in the same cell with the study title or move it to a fourth column (the table structure should mirror the reading order of the table).
- Top each column with a column header and scope="col."

If it is not possible to simplify the table structure, NLM must include column headers (i.e., TH) and programmatically associate each cell containing content with a header (using the “id” and “headers” attributes), which would be a Section 508-compliant solution but may not solve all the problems created by the table structure.

**Table 1. Simplification of Table Structure To Improve Use with Assistive Technology**

| Result Number | Study Status           | Study Name   |
|---------------|------------------------|--|
| 1             | Active, not recruiting | Randomized Evaluation of Long-Term Anticoagulants<br>Condition:<br>Atrial Fibrillation; cerebrovascular accident<br>Interventions:<br>Drug: Dabigatran etexilate, Warfarin |

### 3.2.2. Scripting

**Priority Rating:** Strongly Recommended

Section 508 states that scripted page elements must be readable with assistive technology. The List Results page includes a Display Options feature. JAWS can read the form elements in this feature, and it can be operated by keyboard. Once a checkbox is selected, however, the form is automatically submitted. The page refreshes, and focus moves automatically to the top of the page. This is not an expected behavior: users expect to be able to select more than one checkbox before a form is automatically submitted.

For the screen reader user we interviewed, this was an unexpected event. He found it disconcerting to be abruptly brought back to the top of the screen. Due to the difficulties he was having with the results content, he was unable to determine whether the displayed options had actually changed. Because the refresh occurred immediately after he selected the checkbox, he

was unaware that he could make another selection. Because the content at the top of the page had changed, he was unsure that he was on the same page.

To eliminate this problem, we recommend that automatic submission be eliminated. A button should be provided so that users can submit multiple display options at once and so that the page refresh can be delayed until the user expects it.

### **3.2.3. Display Options Placement**

**Priority Rating:** Strongly Recommended

Our low-vision participant completely ignored the Display Options feature. This was in large part because the link was located at the far right side of the page, where he could not see it without engaging in a significant amount of horizontal scrolling. It took him some time to realize that he was missing content because of the horizontal scrolling issue. Reference links such as “Study Topics” and “Glossary” are not directly related to the operation of the List Results screen and could therefore be placed in a less visible location. The Display Options feature, however, allows users to control the visibility of significant information, so it is important that users see it.

The low-vision users in this study were not using specialized magnification software because their sight was good enough that they were still able to use zoom features in commercial browsers. (It should be noted that this is far more common than use of specialized software,<sup>6</sup> and many low-vision users use a combination of the two.) The problems they experienced, however, would be even more significant for a user who commonly views content at a magnification of 2x or more.

We recommend that features that allow users to control current screen content be placed to the left side of the page so that they will not be missed.

### **3.2.4. Link Targets**

**Priority Rating:** Strongly Recommended

On the List Results page, “title” attributes have been applied to study titles. Unfortunately, the “title” text for all of them reads the study number before the title (e.g., “Show study Show study NCT00582257: Early Onset and Familial Gastric Cancer Registry”). If the user has set his or her screen reader to read “title” text, the screen reader will read this extended title, which is confusing because many users will not understand what the number means.

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<sup>6</sup> Theofanos, M.F. and Redish, J.C., 2005. “Helping Low-vision and Other Users with Web Sites That Meet Their Needs: Is One Site for All Feasible?” *Technical Communication*, 52 (1), February, 9–20.

The study title is a far better indication of the link target than the current “title” value. We recommend that NLM remove the “title” attributes or revise them so that the study title precedes the number. It is not necessary to instruct users to “show” the target of a link. The following is an example of our recommendations:

```
<a title="Early Onset and Familial Gastric Cancer Registry: NCT00582257" href="/ct2/show/NCT00582257?term=stomach+cancer&rank=1">Early Onset and Familial Gastric Cancer Registry</a>
```

### 3.3. REFINE SEARCH

#### 3.3.1. Tab Order

**Priority Rating:** Recommended

In the Advanced Search screen, the tab order is problematic. In most forms, the user expects to tab through all form controls, at which point he or she will have access to buttons for submitting or cancelling data entry. In the Advanced Search screen, however, the **Search** button is placed after the first INPUT element in the page tab order. Because of the way the layout table is structured, users who want to conduct a more specialized search must tab through the **Search** button to enter their criteria and then back up to find it again in order to submit.

|   |   |
|---|---|
| Click on a label to the left for further explanation or read the <a href="#">Help</a> . |   |
| <a href="#">Search Terms:</a>   | <input type="text"/>                                |
| <a href="#">Recruitment:</a>  | All Studies <input type="button" value="Search"/>   |
| <a href="#">Study Type:</a>   | All Studies <a href="#">Basic Search</a>            |
| Targeted Search:  | <input type="text"/> <a href="#">Help</a>           |
| <a href="#">Conditions:</a>   | <input type="text"/>                                |
| <a href="#">Interventions:</a>  | <input type="text"/>                                |
| <a href="#">Sponsors:</a>   | <input type="text"/> <input type="checkbox"/> Exact |
| <a href="#">Study IDs:</a>  | <input type="text"/>                                |

Figure 2. Grid view of Advanced Search page

As figure 2 shows, the **Search** button is located in a TD to the right of the Search Terms INPUT. Tab order follows table structure. If a layout table is present, the tab order will follow the order of table cells, from top to bottom and left to right. Tab order should follow visual reading order or the page’s intended task order.

The placement of the **Search** button appears to be designed so that users can submit their query without having to move through the entire form (a second **Submit** button is placed at the bottom of the page). Since the **Search** button is placed directly after the Search Terms control in terms of tab order, however, the user is encouraged to resubmit his or her original search without exploring the modification options elsewhere on the screen. This can seem counterintuitive because the user visits this page in order to refine his or her search. We recommend that if the

first **Search** button is employed, it should be placed after the top three fields in terms of tab order. The tab and reading order of a page should mirror reading order as it is experienced by sighted users.

### **3.3.1.1. Form Markup**

**Priority Rating:** Required

As noted earlier in this report, form controls must be explicitly associated with labels in markup. This is particularly important with lengthy forms, such as the Advanced Search screen.

## **3.4. RESULTS ON MAP**

### **3.4.1. Redundant Map Links**

**Priority Rating:** Recommended

In the Results on Map section of the Web site, the map image at the top of each screen is clickable. Each country is linked to a list of that country's studies. These clickable areas cannot be activated by the keyboard. A table beneath the map provides redundant links to each country for which data exist, but the user must infer that the "Show map for Central America" link, for example, will lead to a page that includes a text list of studies in specific Central American countries. That is not immediately clear from the link text or "title" value, although the "title" does help to communicate the target of each link. Because of this lack of clarity, the user may not understand that by clicking on the "map" links they can drill down into text-based search results. This is particularly relevant because the map feature's instructions have been placed after the Region Name table in terms of page structure—a screen reader user would encounter the instructions after all the other page content.

Compliance requires that redundant text links be provided for map areas and that column headers be marked up with TH in the listings below the map (see the Data Table section for more information on accessible tables). While the design meets the compliance requirement (i.e., redundant text links are present) and usability testing did not produce results related to this feature, streamlining the design so that relationships between maps and text are clearer will improve accessibility and usability for this audience. NLM may also want to review whether the map image contributes to usability and consider switching to text-based geographical browsing.

If the Results on Map feature is maintained, NLM should:

- Place instructions before the map in terms of reading order
- Provide a link to text-based results before the map image and enable users to choose between graphical or text-based geographical browsing, rather than displaying the map as the default

- Clarify link titles so that users understand that the links will result in a list of studies in that area rather than a “map,” which implies a graphical result that some users may not think they can access (e.g., “Canadian map and studies list”)
- Use data table structure to format text-based regional listings, rather than indicating relationships between regions by presentation (e.g., by indenting country names)

### 3.4.1.1. Data Table

**Priority Rating:** Required

In the Map feature, geographical areas are listed in table format. The table is essentially a data table, with column headers and data, yet it is currently marked up as a layout table.

| Region Name                           | Number of Studies |                           |
|---------------------------------------|-------------------|---------------------------|
| World                                 | 58167             |                           |
| Africa <a href="#">[map]</a>          | 1354              |                           |
| Central America <a href="#">[map]</a> | 1008              |                           |
| East Asia <a href="#">[map]</a>       | 3229              |                           |
| Japan                                 | 901               | <a href="#">[studies]</a> |
| Europe <a href="#">[map]</a>          | 13013             |                           |
| Middle East <a href="#">[map]</a>     | 1944              |                           |
| North America                         | 35760             |                           |
| Canada <a href="#">[map]</a>          | 4752              | <a href="#">[studies]</a> |
| Mexico                                | 769               | <a href="#">[studies]</a> |
| United States <a href="#">[map]</a>   | 33235             | <a href="#">[studies]</a> |
| North Asia <a href="#">[map]</a>      | 941               |                           |
| Pacifica <a href="#">[map]</a>        | 1869              |                           |
| South America <a href="#">[map]</a>   | 1566              |                           |
| South Asia <a href="#">[map]</a>      | 833               |                           |
| Southeast Asia <a href="#">[map]</a>  | 896               |                           |

**Figure 3. Results on Map table**

Column headers (i.e., Region Name, Number of Studies) should be marked up with TH.

Where “studies” links are present, a third column appears that does not include a header. Content within the Region Name column is often indented using nonbreaking spaces (&nbsp;). The indentation is intended to show relationships between regions and countries, but the relationships are only clear to sighted users. In order for this information to be communicated to all audiences, the data table structure must parallel its visual presentation.

To ensure that relationships between data are clear, we recommend that NLM:

- Include a column header for each column
- Use “id” and “headers” to programmatically associate headers with appropriate cell content

- Use table headers rather than indentation to create relationships between data (e.g., a screen reader would not currently recognize that Japan’s studies fall under the East Asia regional header because that relationship is not established in the structural markup)
- Consider eliminating the maps because they do not contribute to the ease of the geographical search’s use and they take up a large amount of screen space

The following example demonstrates one way in which this might be achieved:

**Table 2: Changing the Table Structure to Reflect Data Relationships**

| <b>Region</b>   | <b>Country</b> | <b>Number of Studies</b> | <b>Lists of Studies</b> | <b>Map Search</b>   |
|-----------------|----------------|--------------------------|-------------------------|---------------------|
| World           |                | 58167                    |                         |                     |
| Africa          |                | 1354                     |                         | Africa Map          |
| Central America |                | 1008                     |                         | Central America Map |
| East Asia       |                | 3229                     |                         | East Asia Map       |
|                 | Japan          | 901                      | Japanese Studies        |                     |
| Europe          |                | 13013                    |                         | Europe Map          |
| Middle East     |                | 1944                     |                         | Middle East Map     |
| North America   |                | 35760                    |                         | North America Map   |
|                 | Canada         | 4752                     | Canadian Studies        | Canada Map          |
|                 | Mexico         | 769                      | Mexican Studies         |                     |
|                 | United States  | 33235                    | U.S. Studies            | U.S. Map            |

If NLM cannot change the structure of these tables, it must—at minimum—mark up column headers with TH and associate cell content with headers using the “id” and “headers” attributes.

#### **4. NEXT STEPS**

Because user testing with assistive technologies was performed before retrofitting occurred, we encountered a number of interface issues that prevented task completion. The screen reader user, for example, was unable to complete all tasks in the script because he had so much difficulty with the List Results screen. We recommend, therefore, that NLM conduct a second round of tests with at least one screen reader user in order to verify that problems with the interface have been corrected. Macro has recruited a second screen reader user who is interested in participating in a future evaluation of the site.

## **APPENDIX**

### **ACCESSIBILITY CHECKLISTS**

## CHECKLIST FOR SECTION 508 COMPLIANCE

| Guideline  | Completion Status<br>(Pass, Fail, NA) |
|--|---------------------------------------|
| (a) A text equivalent for every nontext element shall be provided (e.g., via “alt,” “longdesc,” or in element content).  | Pass                                  |
| (b) Equivalent alternatives for any multimedia presentation shall be synchronized with the presentation.   | NA                                    |
| (c) Web pages shall be designed so that all information conveyed with color is also available without color, for example from context or markup.   | Pass                                  |
| (d) Documents shall be organized so they are readable without requiring an associated style sheet.   | Pass                                  |
| (e) Redundant text links shall be provided for each active region of a server-side image map.  | NA                                    |
| (f) Client-side image maps shall be provided instead of server-side image maps except where the regions cannot be defined with an available geometric shape.   | NA                                    |
| (g) Row and column headers shall be identified for data tables.  | Fail                                  |
| (h) Markup shall be used to associate data cells and header cells for data tables that have two or more logical levels of row or column headers.   | Fail                                  |
| (i) Frames shall be titled with text that facilitates frame identification and navigation.   | NA                                    |
| (j) Pages shall be designed to avoid causing the screen to flicker with a frequency greater than 2 Hz and lower than 55 Hz.  | NA                                    |
| (k) A text-only page, with equivalent information or functionality, shall be provided to make a Web site comply with the provisions of this part, when compliance cannot be accomplished in any other way. The content of the text-only page shall be updated whenever the primary page changes. | NA                                    |
| (l) When pages use scripting languages to display content or create interface elements, the information provided by the script shall be identified with functional text that can be read by assistive technology.  | Pass                                  |
| (m) When a Web page requires that an applet, plug-in, or other application be present on the client system to interpret page content, the page must provide a link to a plug-in or applet that complies with § 1194.21 (a)(1-11).  | NA                                    |
| (n) When electronic forms are designed to be completed online, the form shall allow people using assistive technology to access the information, field elements, and functionality required for completion and submission of the form, including all directions and cues.                        | Fail                                  |

| <b>Guideline</b>   | <b>Completion Status<br/>(Pass, Fail, NA)</b> |
|--|---|
| (o) A method shall be provided that permits users to skip repetitive navigation links.   | Fail  |
| (p) When a timed response is required, the user shall be alerted and given sufficient time to indicate that more time is required. | NA  |

## **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REQUIREMENTS**

HHS guidelines incorporate Section 508 standards and the following additional requirements. This list is not comprehensive, as HHS guidelines also cover presentation issues that do not apply to this review.

| <b>Guideline</b>   | <b>Completion Status<br/>(Pass, Fail, NA)</b> |
|--|---|
| You must include a link named “Accessibility” from any Web page that may contain known accessibility barriers or that links to information inside your site that may present accessibility problems for users with disabilities (that is, any information that may not be 100-percent compliant with Section 508 standards). | Pass  |
| Provide file types and sizes for downloadable files.   | NA  |

# **Usability Evaluation of the ClinicalTrials.gov Web Site**

**October 2008**

*prepared for*

**U.S. Department of Health and Human Services  
National Library of Medicine**

*by*



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## **APPENDIXES**

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- B. Subjective Satisfaction Measure Survey
- C. Task Results Matrix for Each User Group
- D. Video Highlights From the Sessions
- E. Summary of Recommendations
- F. Suggested Redesign of Full-Text View Tab
- G. Site Satisfaction Results Matrix for Each User Group

## 1. INTRODUCTION

The National Library of Medicine (NLM) launched a new ClinicalTrials.gov user interface in November 2007, which included new features to help users create and refine queries, introduced topic-based browsing, and provided additional means for users to visualize their results. Macro International Inc. conducted a usability study on the new design to evaluate the quality of users' experiences on the site, gauge the impact of the new features on their target audiences, and identify aspects of the site that can be improved. Based on discussions with NLM staff and a review of the ClinicalTrials.gov site, the following objectives were established for a usability study of the site with representative users. This study addressed the following areas of concern:

- How do the three main user groups (patients/caregivers, health care providers, and clinical researchers) interact with the site? Patients/caregivers need to find relevant trials; health care providers need to find relevant trials for their patients; clinical researchers need to look for other trials being conducted in their area of interest. ClinicalTrials.gov's main focus has been on the patients/caregivers group. More advanced site features should be tested with clinical researchers.
- NLM knows that more than 50 percent of users arrive at the site via Google because both search results pages and individual trial records are indexed by Google. NLM wants to successfully supply context for the users who do not start at the site's home page. Are these users able to locate themselves within the site and navigate the site, or do they get lost?
- For the patients/caregivers group, NLM would like to know whether users understand that ClinicalTrials.gov is a Federal Government-run site and that trial information comes from the sponsors and/or researchers conducting the trials, not from NLM.

## 2. METHODOLOGY

### 2.1. PARTICIPANTS

Between seven and nine participants were recruited for each of the three audience evaluations:

- **Patients/caregivers (nine participants)**—Either potential participants in a clinical trial or caregivers for potential participants
- **Health care providers (seven participants)**—Doctors and other primary health workers who may use clinical trials to aid their patients
- **Clinical researchers (eight participants)**—Individuals engaged in medical research but not involved in providing patient services

Participants were provided with financial incentives to participate. Testing was conducted in accordance with Office of Management and Budget regulations and therefore no clearance was required, as no group had more than 9 participants and different tasks were assigned to each group. The design was reviewed by a Macro institutional review board representative, who determined that there were no risks to participants.

#### 2.1.1. Gender

|                       | Female (N=17) | Male (N=7) |
|-----------------------|---------------|------------|
| Patients/caregivers   | 5             | 4          |
| Health care providers | 4             | 3          |
| Clinical researchers  | 8             | 0          |
| Total                 | 17            | 7          |

#### 2.1.2. Age

|                       | 18–35 yrs. | 35–60 | 60+ |
|-----------------------|------------|-------|-----|
| Patients/caregivers   | 2          | 0     | 7   |
| Health care providers | 2          | 4     | 1   |
| Clinical researchers  | 7          | 1     | 0   |
| Total                 | 11         | 5     | 8   |

#### 2.1.3. Web Experience

|                       | Inexpert <sup>*</sup> | Expert <sup>**</sup> |
|-----------------------|-----------------------|----------------------|
| Patients/caregivers   | 4                     | 5                    |
| Health care providers | 2                     | 5                    |
| Clinical researchers  | 0                     | 8                    |
| Total                 | 6                     | 18                   |

\* Inexpert users may:

- Use Web technologies for limited activities (e.g., some e-mail, using a search engine to find topics of interest) on a semiregular basis
- Rely on a partner or family member to manage more complex online interactions (e.g., banking, patient e-mail lists or newsgroups, unfamiliar searches)
- Pursue little or no health knowledge or management online

\*\* Expert users may:

- Use a variety of Web technologies on a regular (e.g., daily, weekly) basis
- Research health concerns, benefits information, insurance issues, and more online
- Manage health online via various health information services (e.g., Google Health)

#### 2.1.4. ClinicalTrials.gov Experience

|                       | Inexpert <sup>*</sup> | Expert <sup>**</sup> |
|-----------------------|-----------------------|----------------------|
| Patients/caregivers   | 4                     | 5                    |
| Health care providers | 5                     | 2                    |
| Clinical researchers  | 4                     | 4                    |
| Total                 | 13                    | 11                   |

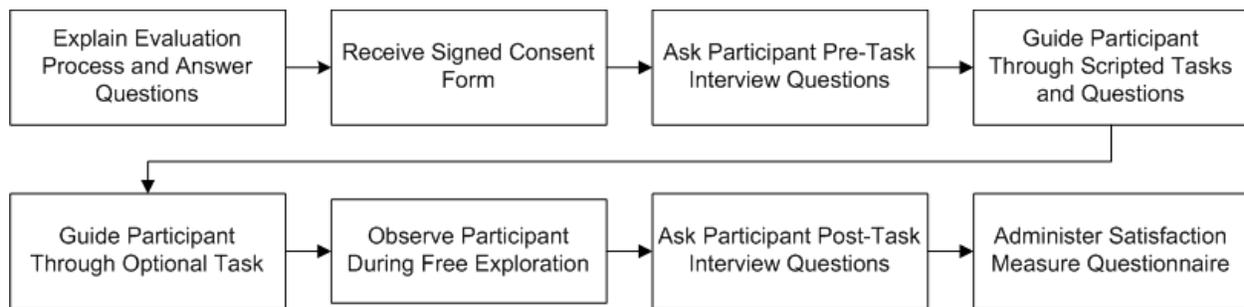
\* Inexpert users may:

- Use ClinicalTrials.gov on a semiregular basis
- Rely on a partner or family member to communicate information from ClinicalTrials.gov
- Pursue little or no health knowledge from ClinicalTrials.gov

\*\* Expert users may:

- Use ClinicalTrials.gov and Web technologies on a regular (e.g., weekly, monthly) basis
- Research health concerns, benefits information, and studies on new medicines online and with ClinicalTrials.gov
- Use ClinicalTrials.gov along with various health information services (e.g., Google Health)

## 2.2. PROCEDURE



### 2.2.1. Tasks

NLM and Macro identified the scenarios most likely to be encountered by each participant group. For example, patients/caregivers are as likely to enter the site via a Google search result link as they are to enter the site via the home page. Clinical researchers are expected to perform more advanced tasks on the site, and health care providers are expected to perform some researcher tasks (as professionals) and some caregiver tasks (as proxies for their patients).

Specific tasks were developed to expose users to aspects of the system that the user scenarios suggested were most important. The specific tasks and questions are included in appendix A. Each participant was asked to complete as many of the tasks as possible during the 1-hour session. A facilitator guided all participants through the session.

### 2.2.2. Apparatus

Twenty participants were tested in the user-testing suite developed by the National Cancer Institute (NCI) in Rockville, MD. This facility offers a desktop computer with a 17-inch CRT monitor for participants and cameras mounted both on top of the computer monitor and more discretely around the room. Techsmith's Morea testing software was used to capture the contents of the screen and transmit this information to a remote observer for behavioral coding. Video footage of the participants was captured separately. One additional participant was tested at the usability testing facilities at the U.S. Department of Health and Human Services offices in Washington, DC. The facilities available there were similar.

Two additional participants were tested in Washington State using a portable usability laboratory that included a laptop and Techsmith software but no camera. A final participant was tested in Bethesda, MD, using a portable usability laboratory and video camera. All participants were provided with a computer mouse for their convenience.

Four participants were tested using Microsoft (MS) Internet Explorer (IE) 7.0 running on Windows XP. Another used Mozilla Firefox 3 on Mac OS X for the testing session. The remainder were tested using Mozilla Firefox 3 on Windows XP. The shift to Mozilla Firefox for testing arose after a number of reliability problems disrupted testing sessions under IE.

### **2.2.3. Initial Impressions**

Each session began with some questions to determine participants' initial impressions of the ClinicalTrials.gov site before using the site. Participants were then provided with the instructions text for each task for their reference. Tasks and questions were also read aloud to the participant.

### **2.2.4. Think Aloud Interviews and Measured Task Performance**

In the Think Aloud protocol<sup>1</sup> participants are instructed to describe what they are thinking as they complete a set of common tasks derived from customer support logs and observed use patterns. In addition to vocalizing their thoughts as they complete the task, participants are prompted to predict the meaning of text and labels and describe the type of information that they expect to find in each section before visiting it. They are asked to identify other features and illustrations on each screen to gauge the comprehensibility of these items.

This phase provides insight into the user's ability to locate, understand, and use interface elements presented in the documents and forms. Problems with terminology, including inappropriate jargon, comprehension, labeling, task flow, and navigation, can be addressed here. For this phase, participants were instructed to describe what they thought as they completed a set of common tasks. The tasks (which defined by NLM & Macro for each participant group) included searching, results selection and examination, and navigation through the site. In addition to vocalizing their thoughts as they completed each task, participants were also prompted to predict the meaning of text/labels (e.g., "Study Topics," "Tabular View") and describe the type of information they expected to find in each section before visiting it. Participants were asked questions to determine their comprehension of the information presented on the site and whether they understood that the content in individual trial records is provided by the research sponsors and not NLM.

For each performance measure, a specific success state was specified for each task in advance and used by observers to determine the success or failure of each participant for the tasks they were given.

### **2.2.5. Free-Form Exploration (Optional)**

After the Think Aloud interviews and measured task performance phase was completed, participants were given the opportunity to explore the ClinicalTrials.gov site and perform personally chosen tasks. Participants were encouraged to use the Think Aloud protocol again during this segment of testing. Less than 50 percent of participants chose to explore the site further when given the opportunity.

---

<sup>1</sup> C. Lewis and J. Rieman, "Task-Centered User Interface Design: A Practical Introduction."

### **2.2.6. Follow-up Interview**

After each participant completed the performance phase of testing and optional free-form exploration, a follow-up interview was conducted. This interview repeated some of the questions from the initial interview to allow for comparisons between users' expectations and their impressions of the site.

Follow-up interview questions covered the participants' opinions on their successes and any problems experienced while using the ClinicalTrials.gov site, appropriate audiences and tasks for the site, important features of the site, and how the site could be improved.

### **2.2.7. User Satisfaction Questionnaire**

After the performance phase of testing and follow-up interview, participants were asked to make retrospective judgments about the site using a satisfaction survey instrument based on the Questionnaire for User Interaction Satisfaction,<sup>2</sup> a commercially available measure of user satisfaction and attitude (see appendix B). Participants provided general impressions related to their satisfaction with the site using a nine-point Likert scale. Due to the technical constraints of the testing environment, this satisfaction survey was administered in paper form.

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<sup>2</sup> Chin, J. P., Diehl, V. A., and Norman, K. L. 1988. *Development of an instrument measuring user satisfaction of the human-computer interface*. Proceedings of SIGCHI '88, (pp. 213–218), New York: ACM/SIGCHI.

### 3. PERFORMANCE MEASURES

Each participant was asked to complete up to 17 tasks during the course of the session, depending on their speed of completion and available time. The majority of tasks presented (51 percent) were either successfully completed by all participants in their audience group or had only one failure. We will therefore focus on the approximately one-third of tasks with success rates below 75 percent. Complete results can be found in appendix C. A complete discussion of these identified problems can be found in section 4.

#### 3.1.1. Patients/Caregivers tasks with success rates < 75%

| Task   | Success Rate* |
|--|---------------|
| <b>Get Help</b><br>If you wanted to ask the people who run this Web site a question, how would you do that?  | 25%           |
| <b>Display Participant Age</b><br>Autism is frequently treated in children. Can you find a way to list which of these trials study children and which trials study adults?   | 38%           |
| <b>Browsing Topics</b><br>Using this Web site, please find clinical trials that are studying treatments for stomach cancer. Do not use the Search function.  | 50%           |
| <b>Understanding of Disease Stages</b><br>Dennis has been told that the cancer is at stage II. Please search in these results for trials that study stage II stomach cancer.   | 56%           |
| <b>Simple Geography</b><br>Since Dennis lives in Baltimore, can you find the trial or trials that are recruiting in Baltimore?   | 56%           |
| <b>Study Contact</b><br>Can you find out who Dennis would contact in Baltimore to participate in or get more information about this trial?   | 63%           |
| <b>Limiting Display by Age</b><br>A lot of the trials listed here study children, and these would not be useful trials for Barbara and John. Can you find a way to remove the trials that only study children? You want to see trials studying people that are John's age. | 67%           |

\* Tasks with higher than a 75-percent success rate are not included here. There were 20 total tasks.

### 3.1.2. Health Care Providers tasks with success rates < 75%

| Task  | Success Rate* |
|---|---------------|
| <p><b>Compound Geography</b><br/>           You have some colleagues in Atlanta and Seattle who you think would be really interested in this type of therapy for their patients. You want to know whether any of these trials are being conducted in Atlanta or Seattle. Please change the search results to show any trials that are being conducted in Atlanta or conducted in Seattle.</p> | 17%           |
| <p><b>Recognizing Ownership of Trial Data</b><br/>           If you found an error on this page, whom would you notify? Who is responsible for the content on this page?</p>  | 57%           |
| <p><b>Identifying RSS Feed</b><br/>           You think this is an interesting area of research. You would like to get updates on any new trials studying virtual reality therapy that are added to this site. Can you find a way to get updates on new trials?</p>   | 57%           |
| <p><b>First Searches</b><br/>           You have come across an article on the use of virtual reality therapy to treat post-traumatic stress disorder. You wonder whether clinical trials are being conducted on this type of therapy. Please search in these results for trials that involve virtual reality.</p>  | 57%           |
| <p><b>Display Options</b><br/>           You would like to see how many patients are being accepted into these trials. Can you change these search results to show the number of patients being accepted?</p>   | 71%           |
| <p><b>Navigating Full-Text View</b><br/>           Please review the information on this page and identify the area or areas of the page that you think best explain the type of treatment Tom would receive if he enrolled in this trial.</p>  | 71%           |

\* Tasks with higher than a 75-percent success rates are not included here. There were 21 total tasks.

### 3.1.3. Clinical Researchers tasks with success rates < 75%

| Task  | Success Rate* |
|---|---------------|
| <p><b>Identifying RSS Feed</b><br/>           You are interested in following this treatment for breast cancer. You would like to get updates on any new trials studying Tamoxifen that are added to the site. Can you find a way to get updates on new trials?</p> | 13%           |
| <p><b>Browsing Topics</b><br/>           Using this Web site, please find clinical trials involving the drug Tamoxifen. Do not use the Search function.</p>   | 25%           |

| Task   | Success Rate* |
|--|---------------|
| <b>Trial Data</b><br>This study has been completed. Can you find any information on results or outcomes of this study?<br>(Successful participants were those who correctly identified that this information was not available.) | 50%           |
| <b>Recognizing Ownership of Trial Data</b><br>If you found an error on this page, who would you notify? Who is responsible for the content on this page?   | 50%           |
| <b>Information Freshness</b><br>You can use any of the information on this page to answer this question. How recent is the content on this page?   | 63%           |
| <b>Display Options</b><br>You would like to see the phases for these Tamoxifen trials. Can you change these search results to show the phase number for these trials?  | 63%           |

\* Tasks with higher than a 75-percent success rate are not included here. There were 19 total tasks.

## 4. EVALUATION RESULTS

Usability deficits were identified across the Web site, most rated as severe in their impact on a user's ability to complete tasks. The majority of issues related to searching and refining search results, navigating long pages, and using individual trial records. Results specific to the three groups included the following:

- The clinical researcher group seemed most comfortable using the site, and many researchers were excited to have learned about new features on the site.
- Health care providers were generally competent users of the site.
- Patients/caregivers had the most usability issues and the most concerns about the accuracy of the site.

See appendix D for user examples and quoted excerpts from the videotaping of the sessions.

### 4.1. GENERAL FINDINGS

#### 4.1.1. Confusion about Purpose and Ownership of the Site

In pretask interviews, all participants understood the purpose of the site to be the study of disease and/or recruitment of volunteers. All reported the National Institutes of Health (NIH) as the owner and maintainer of the site; most read out loud the header text, "A service of the U.S. National Institutes of Health." Only two patients/caregivers mentioned NLM as a site owner or sponsor during pretask interviews. A third patient/caregiver added NLM as a sponsor during the post-task interview but was unsure. Health care providers and clinical researchers identified NLM as a site owner in similarly low numbers; however, participants in both groups did mention the content provided by individual trial sponsors, meaning that they understood that some content was outside the control of the Federal site owners.

Patients/caregivers who were first presented with a search results list or single trial record as opposed to the home page tended to focus on that list or record as representative of the whole site. Patients/caregivers presented with a single record for a lupus clinical trial (NCT00325741) were able to identify the owners of the page as either the National Heart, Lung, and Blood Institute or "investigators from Stanford." The interviews were conducted in an NCI lab, which led one participant to believe that the study and/or the site was administered by NCI and that the study sponsors will present their research to NCI.

#### Recommendations

- Present a stronger branding of the site as owned by NLM in the header or footer on all pages.

#### 4.1.2. Concerns About Accuracy and Currency of the Site

Although NIH and NLM were regarded as trusted brands, many participants felt unqualified to judge the accuracy and currency of the site in pretask interviews. One patient said, “I would assume NLM and NIH would put out stuff that’s accurate, but I’m taking it on faith, really.”

When asked about the currency of the site, participants presented with a single trial record looked for specific dates and were often misled by the processing date at the bottom of the record, which gives a false sense of currency because the processing date is always yesterday’s date. Participants looking at the home page of the site often looked for a date when the content was last updated when asked about the currency of the site; in the absence of a date, they often referred to the number of trials as a possible indicator of recent or complete content. Seeing the status of the studies contributed to a feeling of accuracy and currency when presented with the search results list.

One former patient with more experience looking for potential trials spoke at length on the accuracy of trial information: “I don’t know that there’s a way to judge accuracy based on this page. Without going someplace else for information to validate what’s here, I don’t know that I could do it. I don’t ever do anything without validating. I would Google it for a start to see who has things to say about this type of project. From that, I’d see whose Web site I recognize—mainly from some large [research hospital]—I’d see what they have to say.”

Another former patient said, “If anything, it makes me wonder when they don’t call you back, how well is the study being monitored . . . how serious are they . . . are they really doing it, or they just got a grant. That makes me not be comfortable when someone lists on this official site and they don’t respond.” However, this participant began speaking on the accuracy of the site by saying, “I have no reason to say it’s not—I’m a patient (laughs),” suggesting that some patients may not know what resources are available for finding potential trials other than ClinicalTrials.gov. NLM does not have control over the content of trial records or the responsiveness of investigators, but it can provide more support to patients trying to make choices. For example, the “What should people consider before participating in a trial?” questions are in the middle of the Understanding Clinical Trials page, which can only be linked to from the home page.

#### Recommendations

- Link to guides like the “What should people consider before participating in a trial?” questions from every trial record.
- The home page should indicate how recently the last trial was added as an additional piece of non-static data.
- Provide alternative sources of information on trials.
- Link to other trial databases.

See also the recommendations in Section 4.2, Suggestions for the Home Page.

### **4.1.3. Concerns About Health Literacy Level of Target Audience**

All user groups reported patients and their families as likely users of the site. Only two patients/caregivers mentioned researchers and those involved with conducting trials as users of the site. Only two clinical researchers mentioned health care providers as users of the site. Health care providers were mentioned least overall as users of the site; however, the number of references to health care providers as users did increase in post-task interviews.

Theories on the intended audience for the site were affected by the initial entry page presented to patient/caregiver participants: the home page, a search results list, or a single trial record. The single trial record involved treatment for people with severe systemic lupus erythematosus that was resistant to standard treatment. Patient participants considered that potential volunteers for this trial would be quite knowledgeable about their condition due to their previous experience getting standard treatments for lupus: “The intended audience is medical people. Physicians, nurses. People helping others find treatment. Patients who go online to look for this kind of thing are probably knowledgeable enough to read this kind of thing. It wouldn’t be a new patient because it says ‘patients who are resistant to standard treatment.’ By the time they came to this, they’d have the vocabulary.”

The theme of the educated layperson being the intended user of the site (rather than the public at large) was echoed by health care providers and clinical researchers. One health care provider said that the site’s purpose is “for some relatively sophisticated consumers to enlarge their knowledge about what they may have found elsewhere on the Internet or in other medical publications.” A researcher specifically said that she was changing her pretask response of “subjects or anyone in the research world trying to find out what’s available” as the intended audience: “I’m definitely changing my answer on that. I think it’s more researchers and experts in the field. People conducting clinical research. . . I don’t think it’s a lot with subjects. I’m not sure it’s for the layperson. So I’ll say researchers, research nurses, sponsors, investigators.”

The patients/caregivers with extensive experience searching for trials expressed concern about the volume of information available on the site, which is “probably more than most patients would be interested in.” One user said, “If you know all these things, then yeah, the information is there, but if you come in cold, then it’s not there. And if you . . . provide it for the user who doesn’t know all this stuff, then you’re going to wipe them out. It’s too much information . . . that they don’t need. So the level of information . . . I don’t know. That’s the big problem about this whole thing. The big problem is, who is your customer?”

### **Recommendations**

- See Section 4.2, Suggestions for the Home Page.

### **4.1.4. The Dual-Purpose Site**

There is a fundamental tension between the skills and needs of researchers using the ClinicalTrials.gov site to conduct trials and the skills and needs of patients and their families using the site to find treatment for disease. All participants were asked if the site made it possible for potential volunteers to get the information they need to fully evaluate their options before

volunteering for a trial. One researcher said that she did not see anything that looked like a patient recruitment tool: “I saw a lot of study design, just the nitty gritty, stuff that you see in the protocol. I did not see . . . I will call it a patient recruitment tool where it will tell you in one page what the study is about, where it’s going to be conducted, how many subjects, because subjects don’t need to see that study design and all that stuff. I think it’s going to be a bit overwhelming for volunteers to look through all of that.”

On one level, clinical researchers understood that the medical information presented was highly technical and potentially overwhelming for a sick patient or stressed family member. However, there was also the feeling among researchers that volunteers did not need or perhaps deserve to receive all the information available about their treatment: “I don’t think it’s so important to be able to find results on here, for patients, at least. When patients look at results they tend to form their own opinion of things, you know what I mean?”

The presence of phone numbers and contact information on trial records was often a sign to patients/caregivers that the site had complete information, but one clinical researcher felt that it was “problematic” to have e-mail addresses and phone numbers listed throughout the Web site: “I don’t think most people want their personal information on a Web site like that. I think the way it is is fine. If you really want to find [contact information], you can just look it up or contact the organization.”

The disconnect between clinical researcher and patient/caregiver needs is perhaps best illustrated by the following two quotes:

- Researcher: “You can just type in breast cancer and your State, and some will pop up. It’s quite handy.”
- Caregiver: “What a person needs, for my audience, I need information that will help me select the best chance to save my wife’s life out of a possible 100 choices. Now how do I do that? . . . If you were to ask an oncologist whose wife came down with breast cancer to pick out the top 10 trials that he would like for his wife, and you were to ask that of 10 doctors, I doubt that there would be a lot of overlap.”

Patients and their caregivers clearly need more support in using the site in the form of reference tools, decisionmaking guides, and calls for physician involvement. Recommendations for integrating these resources are discussed in more detail below. Health care providers need a greater presence on the site both as potential users and as resources for potential volunteers. As one patient said: “Because some people can be so desperate . . . I would hope, when anybody applied for these trials, that they would tell that person, have you talked to your physician? I don’t know if that’s a requirement, or if they just take the person . . . This is too catastrophic for the patient to make the only decision.”

However, the same patient pointed out that participating in clinical trials is a significant way of becoming an advocate for one’s health, saying that volunteering is “probably the best way that the pharmaceutical company has for finding new ways for curing chronic conditions. There’s no better way to do it than to have survivors become a part of this . . . Rather than sitting home mad about it, offer your body up.”

## Recommendations

- Further investigate the differing needs of the main audiences for the site.

### 4.1.5. Severity Ratings

The issues identified with the ClinicalTrials.gov site are discussed below, classified into three levels:

- **Severe**—Likely to prevent successful operation on the site or completion of specific tasks
- **Moderate**—Likely to make it difficult for many users to successfully use the site or complete tasks. It may induce recoverable errors requiring some trial-and-error learning.
- **Minor**—Likely to hinder efficient operation of the site or completion of tasks or may induce easily recoverable errors

## 4.2. SUGGESTIONS FOR THE HOME PAGE

Severity Rating: **Minor**

Three patients/caregivers and all health care providers and clinical researchers were presented with the ClinicalTrials.gov home page at the beginning of the evaluation sessions. They were asked to use any of the information on the page to respond to the pretask interview questions. More than half felt that they were unable to judge the accuracy, currency, or completeness of the site's information from viewing only the home page. Two participants pointed to the number of trials (the numbers in red) as the only content that gave some indication of the status of the site. Four participants looked on the home page for a date on which the site was last updated. One health care provider voiced concern that the information was not completely up to date and said that she had had mixed experiences with the information on Government Web sites. Two participants commented on the home page layout, saying that they expected to see the majority of navigation options on the left rather than in a column on the right.

**Page header**—Rather than clicking on the ClinicalTrials.gov logo in the header to reach the home page from elsewhere in the site, all but one participant clicked on the Home link in the right of the header. Less than 33 percent of participants visited the Study Topics link in the header, and no participants clicked on the Search link in the header.

## Recommendations

- Maintain the explicitly labeled Home link in the page header in future redesigns. The header on all pages should include links to Home, Common Terms (formerly the Glossary), a medical dictionary, and Help. See Section 4.2.1, Home Page Resources.

**Page footer**—In the home page footer, which is the standard footer for the site, one participant pointed out that there were five different organizations to contact about the site. When using the Contact Help Desk link, it is not obvious to which organization the question is sent. Depending on the user's screen resolution and browser, the logos in the footer can be difficult to identify.

## Recommendations

- Increase the size of the logos in the page footer and clearly associate each logo image with the corresponding text link.
- Identify the owner of the Contact Help Desk option in the page footer.

### 4.2.1. Home Page Resources

**Search for Clinical Trials**—Patients/caregivers and health care providers used the upper-right search box and the Search for Clinical Trials Basic Search link on the home page in roughly equal numbers. With one exception, clinical researchers always clicked on the Basic Search link and then clicked immediately on the Advanced Search link without completing a search on the Basic Search page. Macro recommends placing a link to the Advanced Search page on the home page.

**Background Information and Understanding Clinical Trials**—Participants who were asked to find some general information on the site about clinical trials and participating in trials chose the Background Information and Understanding Clinical Trials links in roughly equal numbers. Three providers commented that the Understanding Clinical Trials page seemed useful to people new to clinical trials. Macro recommends placing a table of contents at the top of the Understanding Clinical Trials page that lists each question on the page and hyperlinks it to the answer text.

**Glossary**—Two non-native English speakers were unsure of the meaning of the label “Glossary,” and others assumed that the Glossary link would lead them to a comprehensive medical dictionary. Macro recommends relabeling this resource Common Terms and also linking to a medical dictionary, such as the one available on MedlinePlus. In addition, Macro recommends placing a linked alphabetic list at the top of the Common Terms page.

**What’s New**—While completing tasks, only two participants visited the What’s New link on the home page, and those who did viewed the page only briefly. Macro recommends moving the Clinical Alert and Press Release material to the home page in order to add freshness and showcase the latest news in clinical trials.

## Recommendations

- Place a link to the Advanced Search page on the home page.
- Relabel the Glossary as “Common Terms.” Place a linked alphabetic list at the top of the Common Terms page so that users can jump directly to the area of the page containing the word that they want defined.
- In addition to the Common Terms page, link to a medical dictionary such as the one available on MedlinePlus.
- Place a linked table of contents at the top of the Understanding Clinical Trials page that lists each question on the page.
- Move the Clinical Alert and Press Release material from the What’s New page to the home page in order to add freshness.

#### 4.2.2. Audiences for the Home Page

Macro recommends a more standard left-column navigation layout scheme, with the middle and right columns providing resources according to audience, such as:

- Information for patients and their families
- Information for health care providers
- Information for study investigators and sponsors

Help for first-time users of the site could include resources similar to the Evaluating Health Information page on the MedlinePlus Web site (<http://www.nlm.nih.gov/medlineplus/evaluatinghealthinformation.html>) or the tutorial Evaluating Internet Health Information: A Tutorial from the National Library of Medicine (<http://www.nlm.nih.gov/medlineplus/webeval/webeval.html>).

#### Recommendations

- On the home page, present appropriate resources according to audience group.
- Provide tutorials and guides explicitly labeled for first-time users.

#### 4.3. SITE NAVIGATION ISSUES

Severity Rating: **Severe**

**Scrolling**—Many pages on the site require excessive vertical scrolling. For example, the search results list defaults to 50 records per page. This kept some participants from discovering the RSS Feed and Download Options links at the bottom of each search results page. Browsing by condition under the Behaviors and Mental Disorders category for stress disorders requires the user to carefully track the first letter of each entry in a dense vertical list of hyperlinks. Users face a similar challenge when using the Glossary, the list of ClinicalTrials.gov data providers, and the Contacts and Locations tab of a study with hundreds of sites. The Full-Text View tab of a trial record can also be a long page to navigate.

More savvy Web users complained about having to scroll down long pages to find target information; one asked, “I’ve got to scroll down? It’s in alphabetical order. I thought there would be some links by alphabet at the top of the page.” Two older patients were less proficient with using a mouse and the scroll controls in a browser window, and the added scrolling time meant that they found information more slowly.

#### Recommendations

- Whenever possible, alphabetically linked lists should be provided at the top of longer pages to reduce scrolling time for users.
- The default number of search results returned per page should be 20.
- See appendix E for an alternative layout of the Full-Text View tab that provides a linked table of contents and a Study at a Glance table at the top of the page.

**Content below the fold**—Related to excessive scrolling is the issue of links being “below the fold,” or below the area of the screen that can be seen without scrolling down. As mentioned above, the RSS Feed and Download Options links are at the bottom of each search results page, and only the participants who scrolled to the bottom of a page listing up to 50 search results with multiple Display Options potentially checked were able to find them. Approximately one-third of users missed the site owner information in the home page footer and the list of State names on the Results on Map tab because they did not scroll down far enough. We cannot assume that users will carefully read each page they visit on the site.

### **Recommendations**

- Bring important content above the fold, as in the case of the NLM logo or the RSS Feed links, or place a linked table of contents at the top of the page to indicate its structure and content.

**Multiple paths to resources**—Some of the problems with content falling below the fold could be alleviated by giving users more than one path to reach a resource. Many important pieces of content such as the investigator instructions, Download Options link, questions to consider before participating in a trial, and alphabetic Drug Intervention list are linked from only one area or page of the site. Increasing the redundancy of pathways to content will increase the probability that users locate the information they are seeking or happen upon a helpful resource they did not know existed on the site.

### **Recommendations**

- Increase the number of possible paths to important content to enhance findability.

## **4.4. DIFFICULTIES WITH FINDING TRIALS**

### **4.4.1. Searching for Trials**

Severity Rating: **Severe**

Whether they were searching for trials as part of their job or for treatment for a patient, all user groups agreed that using the site search was both the most important task and the most important resource on ClinicalTrials.gov. Participants preferred to search rather than browse for trials in order to save time. Medical professionals and researchers in particular are working under time constraints; as one participant put it, “I’m a rather impatient health care provider, so I’m just going to search [instead of browse].” It is very important, therefore, that site searches produce targeted, useful results.

#### **4.4.1.1. Basic Search**

Participants were highly successful overall in performing basic searches on the site for trials studying a single disease or drug. Patients/caregivers and health care providers used both the Basic Search page and the search box in the page header to perform these searches. Because patients/caregivers and health care providers both relied on the Basic Search, Macro

recommends maintaining this page. One health care provider commented on the Basic Search page: “This is a nice search page. It tells you what to do and gives you an example.”

### **Recommendations**

- Maintain both the Basic Search page and the search box in the page header.

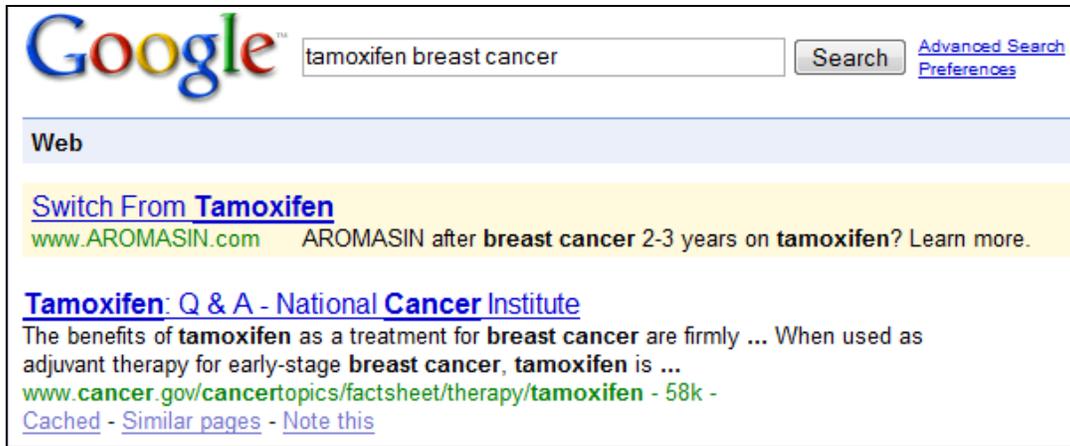
#### **4.4.1.2. Searching Within Results**

Although participants were successful in using the Basic Search, they often had difficulty narrowing down the initial results list to the most appropriate trials for the given task. Only slightly more than half of the patients/caregivers and health care providers who were asked to search within a given results list for a more restricted set of trials were successful. Compared with researchers, patients/caregivers and health care providers were 50 percent more likely to retype their search into the page header search box than to navigate to the Refine Search tab in order to modify a previous search. Even if they knew to navigate to the Refine Search tab, they were not always able to successfully use the advanced search form.

Three participants expected the header search box on the List Results tab to search within the given results; they would enter a new search term, click on the **Search** button, and then lose the results they had previously retrieved. Participants would also lose their results if they accidentally clicked on the **Search** button in the header when the search box was empty, retrieving instead all trial records (roughly 60,000). These hazards were particularly exasperating to one user: “Essentially the frustration comes that you’re always starting over. You have to figure it out yourself unless you are computer-savvy . . . I probably touched something I shouldn’t have.”

The site should give the user as many opportunities as possible to narrow search results. Searches for common diseases such as cancer and diabetes can return thousands of trials. Users need more support to navigate the large amount of information available from the site. Participants unable to successfully refine searches often said that they would simply start going through the retrieved records one by one to find what they were looking for. Often the projected effort involved in weeding out trials manually was so great that these participants reported that they would just give up.

Many Web and site searches provide a basic search box containing the terms just searched on the search results page (see an example from Google, below). This feature allows users to make quick adjustments to searches. Adding a prepopulated search box to the List Results tab would prevent users from making the errors described above and provide some direction to users unaware of or uninterested in using the Refine Search tab.



For example, a search currently represented as Open Studies | “Agranulocytosis” | United States, New York at the top of the Results List page could be presented in a search box as `agranulocytosis status:open state:new york`.

This shows the user the structure of the current search, follows a standard Google-like syntax, and gives the user a local alternative to the Refine Search tab.

### Recommendations

- Add a prepopulated search box to the List Results tab to give the user a local alternative to the Refine Search tab. Give the user as many opportunities as possible to narrow search results.

#### 4.4.1.3. Refine Search (Advanced Search)

When completing tasks, clinical researchers were the only participants who clicked on the Advanced Search link from the Basic Search page. They were 50 percent more likely than those in the other two user groups to go to the Refine Search tab and to succeed in modifying their search results. Some modifications to the Advanced Search form would make it more usable for patients/caregivers and health care providers as well (see below).

The **Search** button on the Advanced/Refine Search page was frequently not responsive. Seven participants (nearly a third of participants) experienced this problem. Furthermore, the red rectangle surrounding the button was confusing—it did not always turn red when fields were modified and looked like an error notice to some participants. In addition, one participant using the Last Updated fields entered an incorrect date, 06/31/2008 (June has only 30 days). The search engine understood this date to be 06/01/1931, and as a result, returned nearly every trial in the system.

### Recommendations

- Make field labels fully descriptive (e.g., “Recruitment Status,” “Trial record first received,” “Trial record last updated”).

- Provide multiple entry fields for the same database field. For example, many researchers were not sure whether they were able to search on the National Clinical Trial (NCT) number. Provide a search field specifically labeled “NCT ID” in addition to the Study ID field. Health care providers were unable to successfully search for trials located in two cities. Provide multiple fields labeled “City.”
- Several participants expected the basic search box in the header to function as a part of the form on this page. Remove the search box from the header for this page and provide a clearly labeled link to start a new search on the Basic Search page.
- Add calendar buttons to the date fields or accommodate invalid entries by using the closest valid date instead.
- Make the State dropdown lists more readable. The prefix “United States” at the beginning of each entry in the list makes it difficult to scan. Consider creating separate dropdown lists specifically labeled “U.S. State,” “Canadian Province,” and “Australian State/Territory.”
- Reorganize the Locations search fields. Participants searching by State often said that they assumed that the search engine would know that the States they were choosing were in the United States and that they could leave the Country fields blank. Consider visually separating the State and country fields.
- Add a ZIP Code search to the location search options. A ZIP Code search is available on the NCI Clinical Trials basic and advanced search pages.
- Do not alter the appearance of the **Search** button on field changes.

#### 4.4.1.4. Search Details Tab

Participants were united in their dislike for the Search Details tab, particularly for searches retrieving no results. Health care providers were given specific tasks involving the Search Details tab, and this may account for their lower satisfaction scores. When participants did intentionally click on the Search Details tab, they were usually exploring all the tabs at the top of the search results list, and they quickly moved on. They only spent time trying to interpret the contents of the Search Details screen when confronted with it as the result of a misspelled search term or a zero-hit search.

Two participants entered misspelled search terms. One participant entered a single-word search (“temodur”), understood what had happened, and was able to quickly select the correct spelling. In another example, shown below, a participant, when correcting a search phrase in which one word was misspelled (“post-traumatiac stress disorder”), paused to read the screen before selecting the corrected phrase.

**Found no studies with search of: post-traumatiac stress disorder**

**Query Suggestions:**

- 1 Unknown word, traumatiac, might be misspelled
  - Change traumatiac to traumatic [post-traumatic stress disorder](#)
  - Change traumatiac to traumata [post-traumata stress disorder](#)
  - Change traumatiac to traumatism [post-traumatism stress disorder](#)
  - Change traumatiac to atraumatic [post-atraumatic stress disorder](#)
- 2 The term, post-traumatiac stress disorder, must be relaxed or trimmed to find documents
  - Trim term to: stress disorder [stress disorder](#)

**Recognized Terms and Synonyms:**

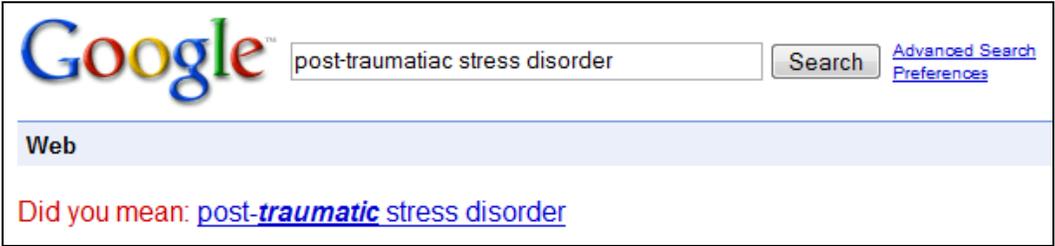
|   |                                   |       |
|---|-----------------------------------|-------|
| 1 | post-traumatiac stress disorder   | 0     |
| 2 | post-traumatiac                   | 0     |
| 3 | disorder<br>diseases<br>disorders | 52684 |
| 4 | stress                            | 1556  |

**No Related Terms**

This screen presents an excessive amount of text to a user who simply wants to search on the correct spelling of “traumatic.”

**Recommendations**

Follow a format more similar to Google’s spelling suggestions, where only the most likely correction is displayed, as shown in the following example:



In general, participants had great difficulty understanding the information on the Search Details screen—what one participant called the “guts” of the search. One health care provider attempted to interpret the Query Suggestions on the screen below and was not successful.

[List Results](#)   [Refine Search](#)   [Results by Topic](#)   [Results on Map](#)   [Search Details](#)

**Found no studies with search of:** **post-traumatic stress disorder | Open Studies | United States, Kentucky | Adult | Phase II III IV**

**Query Suggestions:**

1 No documents are found by all search clauses

- Drop Search Terms clause [Open Studies | United States, Kentucky | Adult | Phase II III IV](#)
- Drop Recruitment clause [post-traumatic stress disorder | United States, Kentucky | Adult | Phase II III IV](#)
- Drop Location clause [post-traumatic stress disorder | Open Studies | United States, Kentucky | Adult | Phase II III IV](#)
- Drop Age Group clause [post-traumatic stress disorder | Open Studies | United States, Kentucky | Phase II III IV](#)
- Drop Phase clause [post-traumatic stress disorder | Open Studies | United States, Kentucky | Adult](#)

He understood that he could choose to drop different search terms but was unsure about what was being dropped. The location clause is included in the Drop Location clause link on this screen, which probably contributed to his confusion. The instructions and options on this screen were not helpful to him; he commented, “That’s an odd term—’clause.’ It’s as if I’m diagramming sentence structures or something . . . this is a little confusing here, quite truthfully.” He was unable to figure out what he could do on this screen, so he gave up on the search task.

The Related Terms section was also confusing to participants. One health care provider asked why phrases such as “university medical center” and “oncology group” were in the Related Terms section for a search on “virtual reality.” Another wanted to know why some links under Related Terms were in bold font and others were not. The different geographic locations that appeared in Related Terms led one participant to believe that she could find studies on her subject in that location simply by clicking on its link; in actuality this simply added that geographic location to her original search with an AND operator.

In order to ensure that all health care provider participants were given the chance to comment on the Search Details page, they were each presented with the following result for a search on “virtual reality” Chicago OR Boston:<sup>3</sup>

<sup>3</sup> The screen image was taken after completion of the evaluation sessions; the number of trials in Chicago and Boston had increased.

[List Results](#)
[Refine Search](#)
[Results by Topic](#)
[Results on Map](#)
[Search Details](#)

**Found 4645 studies with search of: "virtual reality" chicago OR boston**

**Query Suggestions:**

- Arguments of AND in expression, "virtual reality" AND chicago, not found together  
 Drop argument, "virtual reality" [chicago OR boston](#)  
 Drop argument, chicago ["virtual reality" OR boston](#)

**Recognized Terms and Synonyms:**

|   |                 |      |
|---|-----------------|------|
| 1 | virtual reality | 41   |
| 2 | chicago         | 4351 |
| 3 | boston          | 4645 |

**Related Terms:**

Click on a related term to refine your search.  
 This will narrow your search by adding an additional search term.  
 If your search becomes too narrow (finds too few studies), broaden it by removing search terms with the Refine Search page.

|          |                                     |          |                                |
|----------|-------------------------------------|----------|--------------------------------|
| <b>A</b> | <a href="#">alabama</a>             | <b>L</b> | <a href="#">los angeles</a>    |
|          | <a href="#">arizona</a>             |          | <a href="#">louisiana</a>      |
| <b>B</b> | <a href="#">baltimore</a>           | <b>M</b> | <a href="#">massachusetts</a>  |
|          | <a href="#">beach</a>               |          | <a href="#">miami</a>          |
|          | <a href="#">boston</a>              |          | <a href="#">michigan</a>       |
|          | <a href="#">buffalo</a>             |          | <a href="#">minnesota</a>      |
| <b>C</b> | <a href="#">ccop</a>                |          | <a href="#">mississippi</a>    |
|          | <a href="#">chicago</a>             |          | <a href="#">missouri</a>       |
|          | <a href="#">children's hospital</a> | <b>N</b> | <a href="#">new hampshire</a>  |
|          | <a href="#">cleveland</a>           |          | <a href="#">new jersey</a>     |
|          | <a href="#">colorado</a>            |          | <a href="#">north carolina</a> |

The following is a sample of participant comments on page:

- “There are a lot of terms here that don’t seem related to the search. Alabama, Arizona—I don’t know how those refine my search if I’m looking for Chicago or Boston.”
- “Does this mean Chicago is recognized 4,244 times . . . in what? A database somewhere? Are there 4,524 trials on virtual reality in Boston?”
- “‘Drop argument’: I have no idea what that means, whatsoever, and I never did, even back in the dark ages of computers, I never understood ‘arguments.’”
- “What the hell does ‘Arguments of AND in expression’ mean?”
- “I don’t think I’d do much else with this because I don’t think I’d invest the time in trying to figure it out any further. I think I’d work my way back to the Refine Search page and see if I could start again.”
- “I would probably just go out of this site, go to Google, and type in what I want with ‘NIH’ in it, and then it will point to an NIH page, a clinical trials page. This page, I would not use. It’s just not very friendly at all . . . I don’t know anybody who would use it. Nobody in my family would use it. None of my friends would use it. Nobody.”

## Recommendations

- The Query Suggestions section should be rewritten to present options in plain language.
- The Related Terms section can be omitted.

### 4.4.2. Browsing for Trials

Severity Rating: **Severe**

#### 4.4.2.1. Using the Study Topics Link

The lack of intuitive labels and alphabetic browse options rendered the Study Topic lists on this site unusable. Approximately 80 percent of participants who began by using the Study Topics link to complete a task gave up and used a search box instead. When asked specifically to browse for trials on a particular disease or drug, participants were only 50 percent successful in completing the task and often reported that they would rather use the search function.

Clinical researchers were most likely to try browsing by Study Topics to find trials and were the user group most comfortable with the category labels used. However, only one of the clinical researcher participants was able to use Study Topics to find trials involving tamoxifen, a breast cancer drug. Several researchers were confused by the use of the word “neoplasm” (meaning tumor) in the list of studies by condition; they were expecting to find “cancer.” Because the List studies by Drug Intervention link on the home page goes directly to the Select a Drug Intervention Category list, seven out of eight researchers were unaware that an alphabetic list of drugs was also available. They instead needed to be able to identify tamoxifen as an antineoplastic agent. Browsing for this information was beyond the skill level of a participant group with considerable medical training. The one successful researcher able to find the alphabetic list of drugs said of the Select a Drug Intervention Category list, “For someone who is not a specialist, this is bad.”

One health care provider was able to successfully browse drug categories for the drug benicar/olmesartan because she recognized the Antihypertensive Agents category. However, many failed in browsing for post-traumatic stress disorder because they looked under “P,” and the condition is indexed as “Stress Disorders, Post-Traumatic.” Only one provider was patient enough to check under “P,” “T,” and then “S” to complete the task. He noticed that he was only able to get to the alphabetic listing of conditions if he went into a category list and then clicked on **Main Category**, and he said that he would not know in which category to look for post-traumatic stress disorder. Another health care provider commented, “I like the search engine better. I feel like I could be missing something if I [browse].”

Patients/caregivers were also inconvenienced by using the browse function. One participant who was unsuccessful in finding stomach cancer studies by condition resorted to looking by location. Viewing the list of studies in the state of Maryland, he said, “That’s a long way around, I’ll tell you that. That would be an endless task. There’s too many of them.” Another was understandably confused by the term “neoplasm,” saying, “I found a search for stomach neoplasms, but nothing for stomach cancer, unless they mean the same thing.”

## Recommendations

- Use plain English terms when possible, such as “tumor” instead of “neoplasm.”
- Ensure that all inverted terms are also duplicated as uninverted terms (e.g., index not only “Stress Disorders, Post-Traumatic” but also “Post-Traumatic Stress Disorders”).
- Always give the user a choice of browsing by category or by alphabetic list. Do not link directly to one or the other.

### 4.4.2.2. Results by Topic Tab

Participants did not use the Results by Topic tab to refine their searches. When they did click on the tab, they were usually exploring all the tabs at the top of the search results list. None of the participants spent any time on this tab; they moved on to find another resource that would help them complete their task.

## Recommendations

- Modify the Results by Topic tab to provide users with more direction as to how it could help them refine their results.

### 4.4.3. Getting Updates on New Trials

Severity Rating: **Severe**

Health care providers and clinical researchers were asked to find a way to obtain updates on new trials studying specific treatments. To many of these users, this implied finding a place on the site to sign up for e-mail updates. Ten of 15 participants either never located the RSS feed link at the bottom of a search results page or did not recognize RSS as a possible resource for this task. Three participants went to the Refine Search page and tried entering dates into the Last Updated fields as a way to see new trials. No participants used RSS feeds or feed readers.

Of the participants who did view the RSS feed link as the solution for this task, none had an understanding of how RSS feeds work. One health care provider said, “Well, my hopes were up when I saw ‘RSS feed,’ but it sounds like the purpose of that is not what I wanted it for . . . who cares? They’re all right here in the search, I assume. What do I care whether they’ve been received in the last 14 days? What I want to know is if any new ones are registered in the next 14 days.”

A researcher echoed this confusion: “I don’t understand exactly what this is about . . . I lack technical understanding of what an RSS feed is . . . I feel like that would be the past 14 days rather than the future.”

All but one of these participants did click on the RSS link to see what would happen. One participant was using the MS IE browser (version 6.0) for the evaluation session, and when the link took her to a page of raw Extensible Markup Language (XML) code, she exclaimed and

quickly hit the **Back** button. Other participants were using the Mozilla Firefox browser; when they clicked on the RSS link, they were presented with a readable screen that gave different subscription options, including one for MS Outlook. These participants said that they would choose the MS Outlook option, indicating that they were still expecting something in an e-mail format.

Given that no participants were comfortable with subscribing to RSS feeds from the ClinicalTrials.gov Web site, Macro recommends implementing an e-mail update system, possibly similar to the e-mail updates offered by the PubMed.gov site. A quick analysis of ClinicalTrials.gov feeds in the popular Bloglines Web-based feed reader found only 11 trial feeds with more than 1 subscriber, and the maximum number of subscribers was 4. In comparison, 200 PubMed feeds had more than 1 subscriber, and the maximum number of subscribers was 10.<sup>4</sup> RSS feeds may be a more appropriate update mechanism for PubMed users than ClinicalTrials.gov users.

### **Recommendations**

- Implement an e-mail trial update system in addition to the RSS feed option.
- Display the e-mail update option at the top of search results lists.

## **4.5. PROBLEMS SELECTING TRIALS TO REVIEW**

### **4.5.1. Search Results List**

Severity Rating: **Severe**

In general, the search results list was usable for participants, although the default of 50 results per page did require a lot of vertical scrolling. Furthermore, a user who downloaded the 50 trials individually on each Results page pointed out that she had to manually click back to the first page of results, rather than go there directly from the last page of results. However, participants were generally adept at scanning the results and were able to identify the status of trials as “accepting new patients” or “active but not enrolling,” for example.

Participants would have been helped in completing search tasks by seeing different default Display Options in the search results list. For example, participants would search for a particular age group, phase, or NCT number, but the results list would display only the condition and intervention (or whichever display options the user previously selected) for each study. Participants then had difficulty determining how effective the search criterion was, because they had no information on age groups, phases, or the NCT number in the resulting list.

### **Recommendations**

- Automatically update the search results list to show the display options corresponding to search criteria when the user searches on study type, age group, phase, date ranges, or study IDs.

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<sup>4</sup> These numbers were current as of September 25, 2008.

#### 4.5.1.1. Hiding Studies Not Yet Recruiting and Changing Display Options

More than 80 percent of participants were able to use the Hide studies that are not seeking new volunteers link to remove these studies from the search results list. One patient/caregiver familiar with the site called it “wiping out the reds.” However, the location and behavior of this link did cause problems with this task. The plain text link is separate from Display Options and was missed by several participants when first scanning the page; participants asked why it was not a part of Display Options. The link text changes to “Include studies that are not seeking new volunteers” when clicked on, and two participants interpreted the text as a status rather than a command, leading them to click on the link when in fact the results were already in the desired state. As one participant said of this task, “Well, that was easy as long as I took my time to read.”

NLM may want to reconsider how recruitment status is categorized. Two health care providers noticed that studies with the status “Not yet recruiting” were still in the list after they removed the studies not seeking new volunteers. This was puzzling to them. One user said, “I’m looking for something that’s uniform ‘recruiting,’ and then I’m thrown something that is in contrast to that. I can understand why it’s here, but there are trials that never, ever open to recruiting . . . so the fact that it’s here, my reaction was, ‘why am I looking at this?’”

A number of issues were uncovered with the Display Options checkboxes. The location of the Display Options link at the right of the screen kept some participants from noticing it right away. Moving it to the left of the screen and integrating the Hide/Include link would make these options easier to find. The subtle action of the re-display when a Display Options checkbox was checked was disconcerting to three users. They did not necessarily notice that the fields displayed for each record had changed, and looked at first for a button or other command to implement their change. One user said that it “would be nice if there was a blink or something that I circled it and it’s there now.”

The following are additional comments on Display Option labels:

- **Phase**—In a task unrelated to Display Options, patients/caregivers were asked to find trials studying “stage II” stomach cancer. Two were uncertain of the difference between “stage” and “phase,” and one marked the Phase checkbox, saying, “Phase . . . It doesn’t give me a place to say ‘stage II.’”
- **Intervention and Study Type**—The majority of trials registered with the site are interventional studies. One clinical researcher looking mainly at interventional studies remarked that displaying the study type when the Intervention field was already displayed seemed redundant. The Study Type field is generally only informational for observational and expanded-access studies.
- **Size**—Health care providers were asked to change some search results to show the number of patients being accepted into each trial. They did not think that the Size label was informative enough. One remarked, “I have to assume . . . I shouldn’t have to assume . . . that this is the total sample size of the study, or is it the number of patients that still could be recruited?” Another said, “Oooh. Size of what? . . . to a lay person, that could be the size of your shoe.”

- **NCT Id and Other Ids**—Technically, these labels are misspelled and should read “NCT ID” and “Other IDs.” However, the Other IDs label is problematic—if the user does not notice the NCT ID checkbox, “Other” has no context.
- **Sponsor and Funded By**—Both health care providers and clinical researchers were asked to change some search results to show who is responsible for “conducting” the trials. Four of the seven health care providers had issues with the wording of the question. They all succeeded at the task, but many were uncertain of their success, questioning what “conducting” versus “sponsoring” versus “funding” meant. In contrast, no clinical researchers commented on the meaning of “conducting” a trial, and they were satisfied that checking Sponsor displayed the correct answer.
- **Age Group**—Patients/caregivers were asked to find a way to list which of the displayed autism trials studied children and which trials studied adults. More than half the participants failed this task. Participants who did not succeed went to Refine Search and either added words such as “adult” or “child” to the search terms or checked some of the Age Group checkboxes. It was not clear to them that the Age Group Display Option could assist with this task. Some participants also commented that they did not know how many age groups there were or what age ranges applied. This information is only available at the bottom of the Refine Search page.

The distinction between changing display options and refining search criteria was unclear to many participants for a variety of tasks. For example, clinical researchers were asked to change some search results to show the phase number for these trials. The three researchers that failed this task all went to Refine Search and marked some combination of the four Phase checkboxes. Two researchers thought they had succeeded in removing any observational studies from their search results simply by unmarking all Display Option checkboxes except for the Intervention checkbox.

### **Recommendations**

- |  |
|--|
| <ul style="list-style-type: none"> <li>• Use the static text “Hide studies that are not seeking new volunteers” with a checkbox to clearly indicate the status of the results list to the user.</li> <li>• Consider removing studies with the status “Not Yet Recruiting” from the lists of studies seeking new volunteers.</li> <li>• Redesign and conduct further testing of the Display Options interface and the interaction between refining search criteria and changing the results display.</li> </ul> |
|--|

#### **4.5.1.2. Downloading Records**

Clinical researchers were asked to find a way to store the information on a list of trials in order to perform an analysis in the future. Although technically most of them accomplished this task, many were unsure of their success and of the usefulness of the end result. The meaning of “Download Options” was not immediately apparent to all participants. Some were looking for an option called “store records” or “save query.” One researcher said, “I don’t know, maybe I’m downloading what I have here so I can look at it again, but I don’t really know. I don’t really know what all this means. I don’t know what XML is. Is that like an Internet format? . . . This doesn’t look like it’s going to help me very much.”

The file formats available were also confusing to participants. The XML format was not popular, even with those participants who were familiar with it. Another researcher chose XML for the format but said that she was saving the data into an MS Excel file. She had difficulty opening the downloaded Zip file with a Zip extraction application, and when she saw the raw XML, she said, “Oh, that didn’t download very well.” A third researcher wanted to be able to save all the data available in each record but did not realize that “Study XML” was the way to do this. She said, “I see what happens [with Download Options], but I’m not happy with the way it’s offered.” She believed that she would have to go back to the site and open each individual record and said, “This would be a copy and paste job, which I would actually give to my assistant.”

### **Recommendations**

- Link to a Download or Save function from the top of the search results list.
- Clearly label the options for saving records in the Download or Save Search Results function.
- Give users the option to save study records in plain text, not just XML.
- Give users the option to not Zip the downloaded search results file. Make this the default option.

The impulse to save a single study record after viewing it was expressed by participants in all three groups. While viewing a trial record, a health care provider said, “At this point, I would like to save this hit in some way, but I don’t see any way to save it, so what I’m going to have to do is print it . . . it would be nice to have some sort of save feature . . . I suppose I could do a bookmark.”

Because the Download Options feature on the search results list is all-or-nothing, meaning that the user can only download all of the given records or none of them, the site should offer a save option on each trial record page allowing the user to save the study data in plain text format. Furthermore, an E-mail This Trial to a Friend option on each trial record page would also be helpful to users. When asked how they would share the information from particular trial record with a friend or family member, most patients/caregivers said that they would print the Web page or copy the URL of the Web page and e-mail it.

### **Recommendations**

- Offer a save option on each trial record page, allowing the user to save the study data in plain text format.
- Offer an E-mail This Trial to a Friend option on each trial record page.

## **4.5.2. Results on Map Tab**

Severity Rating: **Minor**

An optional task related to finding the State with the most registered trials for a particular treatment was successfully completed by all participants who attempted it. Only two participants were uncertain of the meaning of “Results on Map.” One was not sure whether to expect locations or directions to trial sites; another was expecting a site map. Nearly all participants

thought the Map interface was a helpful feature of the site. Clinical researchers were the most likely to question the value of knowing which State had the most trials.

A number of participants used the links in the table below the map rather than clicking on the map itself. This table should be brought above the fold. Some participants wanted to be able to sort the text list of States by the number of trials. Three out of six patients/caregivers were unable to identify New York on the unlabeled United States map. After clicking on the State, they were able to determine that New York had the most stomach cancer trials registered. None of the maps on the site are labeled, making it difficult to find individual countries in Africa, South America, or Europe and individual States or provinces in the United States and Canada.

### **Recommendations**

- Add labels to the maps for people unfamiliar with the geography of a given region.
- Bring the table of links below the map above the fold.

## **4.6. DIFFICULTIES UNDERSTANDING TRIAL RECORDS**

Severity Rating: **Severe**

### **4.6.1. Full-Text View Tab**

Evaluation sessions uncovered a number of issues with the presentation of the individual trial record, especially for patients/caregivers. NLM cannot directly alter the content of these records; however, NLM can present the various components of the trial record in a more usable manner. A suggested redesign of the Full-Text View tab is included in appendix E. Individual issues are discussed below, in the order they are located on the current Full-Text View tab.

**Who is responsible for the content on the page**—Health care providers and clinical researchers were asked who they would contact if they found an error on a particular trial record. The goal was to have participants identify the given trial sponsors and collaborators, rather than NIH or NLM, as the owners of the page content. Most participants were able to do this; however, only half were able to find a way to report an error. Some wanted to contact a principal investigator, but e-mail addresses and phone numbers were not always supplied in the Contacts and Locations section. Some participants found the Contact Help Desk link in the page footer and said that they would send a message with the subject “Error Found—in a trial.”

**The meaning of medical terms**—Patients/caregivers, who as a group have had less medical training than health care providers or clinical researchers, need support to understand the vocabulary used in trial records. Patients/caregivers were shown the Phase column heading in the Purpose table on a trial for stomach cancer (NCT00052910) and were asked to find more information on what “phase” referred to. All patients/caregivers successfully completed this task, either by clicking on the heading link or going to the glossary and finding “phase.” However, the current site glossary only covers a limited number of terms related to clinical trials. As discussed above, Macro recommends linking to a medical dictionary in addition to the clinical trials glossary.

**MedlinePlus resources**—All health care providers were able to identify the links to MedlinePlus.gov health topic pages as appropriate consumer health information resources for their patients. They either recognized the MedlinePlus brand or associated the name with Medline. Two patients/caregivers had heard of MedlinePlus, but others had not and did not identify it with health information that would be consumer friendly. One guessed that MedlinePlus would provide more information on the same trial or on additional trials. A label clearly identifying these links as consumer health information would make them more transparent to users unfamiliar with MedlinePlus.

**ChemIDPlus resources**—Patients/caregivers were asked for their expectations regarding the ChemIDPlus link and related topics. They generally expected to find information on medicines, including side effects and adverse reactions, resources more akin to the drug information found on MedlinePlus than ChemIDPlus. One caregiver was frustrated with the lack of consumer-friendly drug information on the site, referring to the lengthy list of brand names on the ChemIDPlus menu (see below) and saying, “I was expected to know what the hell that is.” Links to simple, consumer-friendly pages on medicines such as those found on MedlinePlus would be more appropriate for the patients/caregiver audience.

For more information about this substance,  
you may select from the the links below.

**File Locator**

|                                    |                                    |
|------------------------------------|------------------------------------|
| <a href="#">ClinicalTrials.gov</a> | ① NIH ClinicalTrials.gov           |
| <a href="#">DailyMed</a>           | ① NLM/FDA Drug Labelling           |
| <a href="#">MeSH</a>               | ① Medical Subject Headings File    |
| <a href="#">MedlinePlusAll</a>     | ① Search Consumer Health Info      |
| <a href="#">MedlinePlusDrug</a>    | ① Consumer Drug Information        |
| <a href="#">PubChem</a>            | ① PubChem                          |
| <a href="#">PubMed</a>             | ① Biomedical Citations From PubMed |
| <a href="#">PubMed AIDS</a>        | ① AIDS Citations from PubMed       |
| <a href="#">PubMed Cancer</a>      | ① Cancer Citations from PubMed     |
| <a href="#">PubMed Toxicology</a>  | ① Toxicology Citations From PubMed |
| <a href="#">TOXLINE</a>            | ① NLM TOXLINE on TOXNET            |

**Internet Locator**

|                                  |                                 |
|----------------------------------|---------------------------------|
| <a href="#">DrugDigest</a>       | ① Drug Digest                   |
| <a href="#">Drugs@FDA</a>        | ① FDA Drug Database             |
| <a href="#">FDA ConsumerDrug</a> | ① FDA Consumer Drug Information |
| <a href="#">USA.gov</a>          | ① USA.gov Search Engine         |

**Study design and treatment arms**—Health care providers were asked to identify the area or areas of a given trial record that best explain the type of treatment a volunteer would receive. Six

out of eight identified the Arms and Assigned Interventions table as being the best description. One provider said that it provides a level of specificity and resolution not seen previously on the page.

Patients/caregivers were given a task to determine treatment specifics for a trial. This required finding and reading the Arms and Assigned Interventions table. All were successful in completing this task. This particular trial included a placebo arm, and patients/caregivers were also asked whether a volunteer would be guaranteed treatment in order to determine their understanding of placebo-controlled studies. The majority recognized the possibility of receiving a placebo, but two of eight participants said that the volunteer would definitely receive treatment. One participant said that treatment was guaranteed because “that’s the medicine they’re investigating.” Another felt that treatment “is what I would expect to be getting. I wouldn’t expect to be a placebo person . . . I think you have a right to expect it.” This response illustrates well the tension between scientifically rigorous study and patients’ desires to be cured.

**Patient eligibility**—Patients/caregivers were asked to determine whether someone with high blood pressure was eligible to enroll in a trial that excluded patients with “uncontrolled high blood pressure.” All were able to locate the Eligibility section of the record and find the text referring to uncontrolled high blood pressure. However, patients/caregivers with more experience enrolling in trials expressed a general distrust of the eligibility criteria listed in trial records. One participant said: “This whole section caused me a tremendous amount of grief looking at trials for my wife, in that, things seemed to be specified so precisely, but when you called, things got a lot looser . . . I didn’t know how to interpret a lot of these things. It seems to me that this whole section in there should be dealt with in a different way, and what the way is I have no idea . . . When you talked to a person about the trial, [eligibility criteria] weren’t quite so rigid. You really didn’t know where you stood.”

More direction could be given to consumers in this area of the trial record, encouraging them to contact their health care providers and the trial contacts or investigators for help in determining their eligibility.

**How to enroll**—Patients/caregivers and health care providers were asked to identify who should be contacted for more information on participating in a given trial. All health care providers were able to successfully identify contacts and investigators under the Contacts and Locations section of the page as the people a potential volunteer should contact. The task for health care providers was relatively easy in that the trial they were viewing had only two locations in the same city, and the contacts and investigators had e-mail addresses and phone numbers listed.

Patients/caregivers had a more difficult task; they were asked to find contacts local to Baltimore, MD, in a trial record with more than 500 locations. Investigators were listed in the record, but no contact information was given. Five of eight patients/caregivers were able to accomplish this task. For one participant, the only viable link appeared to be the NCI link under Sponsors and Collaborators in the Contacts and Locations section of the page, and she never clicked on the Show 533 Study Locations link that would have led her to the locations in Baltimore. The other two participants were put off by the excessive scrolling required within the long list of locations. One participant gave up, saying, “OK, it’s here somewhere. (laughs) There’s too many of them .

. . you'd have to go through all of these. Dear God.” Another asked why there was no list of links at the top to each State.

One patient/caregiver successfully located the listings for Baltimore but appeared to have difficulty separating the two locations, saying that a volunteer would contact “the Greenebaum Cancer Center . . . at Johns Hopkins” (see screenshot below).

|   |
|---|
| Shore Regional Cancer Center at Memorial Hospital - Easton<br>Easton, Maryland, United States, 21601<br>Contact: Mary S. DeShields, MD 410-819-3332   |
| Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins<br><b>Baltimore</b> , Maryland, United States, 21231-2410<br>Contact: Clinical Trials Office - Sidney Kimmel Comprehensive Cancer Ce 410-955-8804 <a href="mailto:jhccro@jhmi.edu">jhccro@jhmi.edu</a> |
| Greenebaum Cancer Center at University of Maryland Medical Center<br><b>Baltimore</b> , Maryland, United States, 21201<br>Contact: Clinical Trials Office - Greenebaum Cancer Center at Universit 800-888-8823  |

**Finding the results of a trial**—Half of the clinical researchers were asked where they would look for study results on a trial record using the Full-Text View tab. Two researchers located the publication under More Information on the trial record. The other two found the information on outcome measures; one assumed that she had succeeded, and the other said that she was still looking for a “results button.” The remaining clinical researchers were more or less equally successful when using the Tabular View of a record (see section 4.6.2).

Health care providers were asked to find information on a Full-Text View page about recalls of the drug being studied. All were able to locate the Recalls, Market Withdrawals and Safety Alerts link under More Information. Approximately 70 percent were unsure of the meaning of the exit graphic next to this link. Participants understood that they were leaving the page but not necessarily that they were leaving the site. The small size and vague label make this graphic of questionable utility.

**Keywords and terms**—Patients/caregivers were directed to the bottom of a trial record and asked why they thought certain words there and elsewhere on the page were highlighted in different colors. Only 50 percent mentioned search terms or keywords as a possible reason. One health care provider attempted to click on a highlighted word, thinking that it was hyperlinked. No participant groups used the keyword lists at the bottom of the Full-Text View tab.

### Recommendations

A suggested redesign of the Full-Text View tab is included in appendix E.

- Clearly identify MedlinePlus links as consumer health information.
- Link to simple, consumer-friendly pages on medicines such as those found on MedlinePlus for the patients/caregiver audience.
- Encourage potential volunteers to contact their health care providers and the trial contacts or investigators for help in determining eligibility.
- Link to each State at the top of a long list of locations and clearly delineate location entries.

- Require e-mail addresses and phone numbers for contacts and investigators.
- Remove the process date from the bottom of the page because it gives a false sense of currency.
- Maintain the Arms and Assigned Interventions table.
- Consider removing the Exit graphic next to links to other sites and instead indicate the site owner in the link title.

#### **4.6.2. Tabular View Tab**

Half of the clinical researchers were given specific tasks to complete on the Tabular View tab of a trial record, and the remaining researchers completed the same tasks on the Full-Text View tab of the same record. The most conclusive difference between the two groups was the success rate for determining when the trial record was last updated. Both groups were asked to determine how recent the content on the page was. Clinical researchers using the Tabular View tab were able to locate the Last Updated Date cell at the bottom of the page. Clinical researchers using the Full-Text View tab found either the Study Completion date or the Last Updated date, but most were distracted by the process date at the bottom of the page and falsely identified this as the date of the most recent changes to the record. If the process date at the bottom of the Full-Text View tab indicates nothing more than that the page was regenerated the night before, Macro recommends removing this date from the page because it gives a false sense of currency.

Clinical researchers were also asked where they would look for study results on a trial record using the Tabular View tab. Two identified the Medline PMIDs link as a publication on the study results. Two others clicked on the link for “Clinical trial summary from the National Cancer Institute’s PDQ<sup>®</sup> database” where they found another summary of the trial and concluded that results were not available.

Health care providers were asked for their comments regarding the Tabular View tab compared with the Full-Text View tab. Results were inconclusive. About half found the Tabular View easier to read, while others said that it did not match their expectations of finding more tables like the ones found in the Full-Text View.

#### **Recommendations**

- None

#### **4.6.3. Contacts and Locations Tab**

As discussed in section 4.6.1, Macro recommends links to each State at the top of a long list of locations, clearly delineated entries, and required e-mail addresses and phone numbers for contacts and investigators. In addition, because users are unlikely to scroll to the bottom of this page when a large number of locations are listed, Macro also recommends linking to or moving the Sponsors and Collaborators and Investigators sections to the top of the page.

## Recommendations

- Link to or move the Sponsors and Collaborators and Investigators sections to the top of the page.

### 4.6.4. Related Studies Tab

Because the top of the Related Studies tab displays the same study header information shown on the Full-Text View, Tabular View, and Contacts and Locations tabs, participants who visited this page assumed that they were still seeing the same individual study record. One participant said, “It just gives me one study and at a quick glance it looks like it gives me the same study . . . I have to do more work to actually ‘Find Related Studies.’ It doesn’t give me what I expected to find, and I wasn’t expecting to have to do additional search.”

Another participant said, “Is this the same study that I’m looking at? How is it a related study? It looks like the same identical study to me . . . I would much rather have seen here ‘No Related Studies’ . . . [this is] more cognition than I want to engage in.”

## Recommendations

- Test alternative layouts for this page to identify layout elements that would cue users to click on the available links to view studies related to the selected trial record.

## 4.7. ISSUES WITH REGISTERING TRIALS

Severity Rating: **Moderate**

All clinical researcher participants were able to find the Investigator Instructions page or PRS Information page for information on getting started with registration. One researcher commented on the Investigator Instructions page, saying, “For more information, visit another site (laughs). So I would have to go there. Oh, dear. This is not easy.”

All but one researcher were able to find the current list of ClinicalTrials.gov data providers to determine whether a given institution already had an organizational account. However, succeeding at this task required participants to take the counterintuitive step of clicking on the Apply for an organization account link when they had just been asked to verify whether an organizational account already existed. One commented, “I don’t think that link will let me know whether or not one exists, and I would be afraid to click it and start a process.” Another said, “See, this is a trick question, because I’ve done this before.” Researchers mentioned various strategies such as e-mailing [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov) or applying for an account anyway to determine whether it was a duplicate before they found the link to the organization list. All the researchers who found the Getting a PRS Organization Account page immediately focused on the question in bold, “Is your organization on the list?” and had to carefully read to find the organization list link above it. A reorganization of the pages and layouts involved in this process is needed to guide researchers intuitively through each step. Furthermore, the organization list is not usable due to the length of the page.

The pages at <http://prsinfo.clinicaltrials.gov/> and the registration system itself are worthy of further study. One clinical researcher familiar with the process expressed her frustration:

“When investigators are trying to register their trials, I think that whole PRS system needs a lot of help. It’s not as easy, it takes a couple of clicks and going back and forth to try to figure out exactly what you’re doing. It’s very wordy, also. It’s not intuitive, I think. It should just be one button: register your trial. Are you registered [for an account]? Click here to find out. If not, this is how you do it . . . there’s a lot of words, everywhere. (laughs) People don’t like to read things. It slows them down.”

### **Recommendations**

- Reorganize and test the pages and layouts involved in the registration process to guide researchers intuitively through each step.
- Separate the four organization lists, and use alphabetic linked lists to enhance navigation.

## 5. SATISFACTION MEASURES

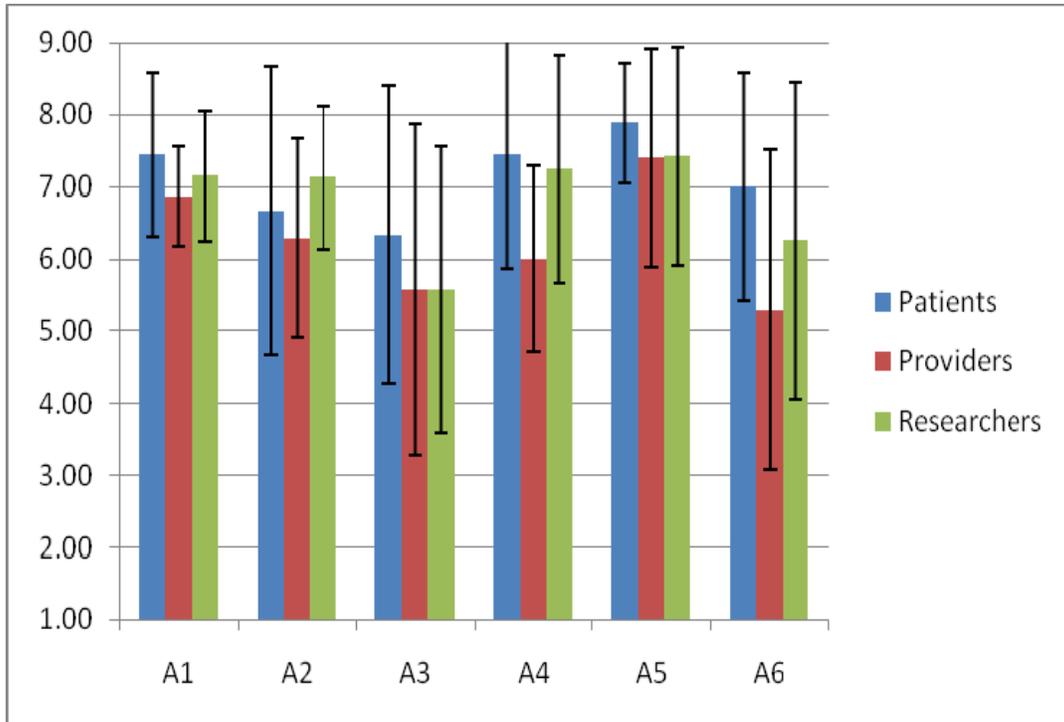
Participants from the three user groups were heterogeneous in terms of their past ClinicalTrials.gov experience and computer experience, leading to a wide variability in responses within groups that makes drawing conclusions from the satisfaction data difficult. Patients/caregivers and clinical researchers were more likely to be familiar with ClinicalTrials.gov and the Internet than the health care providers, leading to slightly higher satisfaction levels, on average. Clinical researchers were generally comfortable with the site and tended to give higher ratings to the site and its interface.

Overall satisfaction results ranged quite high. Given the success rates observed in the performance data, we should consider the possibility that the novelty of the user interface for new users is producing a ceiling effect, which is not uncommon in satisfaction ratings.

The scores to which these graphs refer can be found in the questionnaire text in appendix F. Scores to which less than 50 percent of participants were able to respond have been suppressed in these graphs.

**Table 1. Questions That Measure Overall Satisfaction**

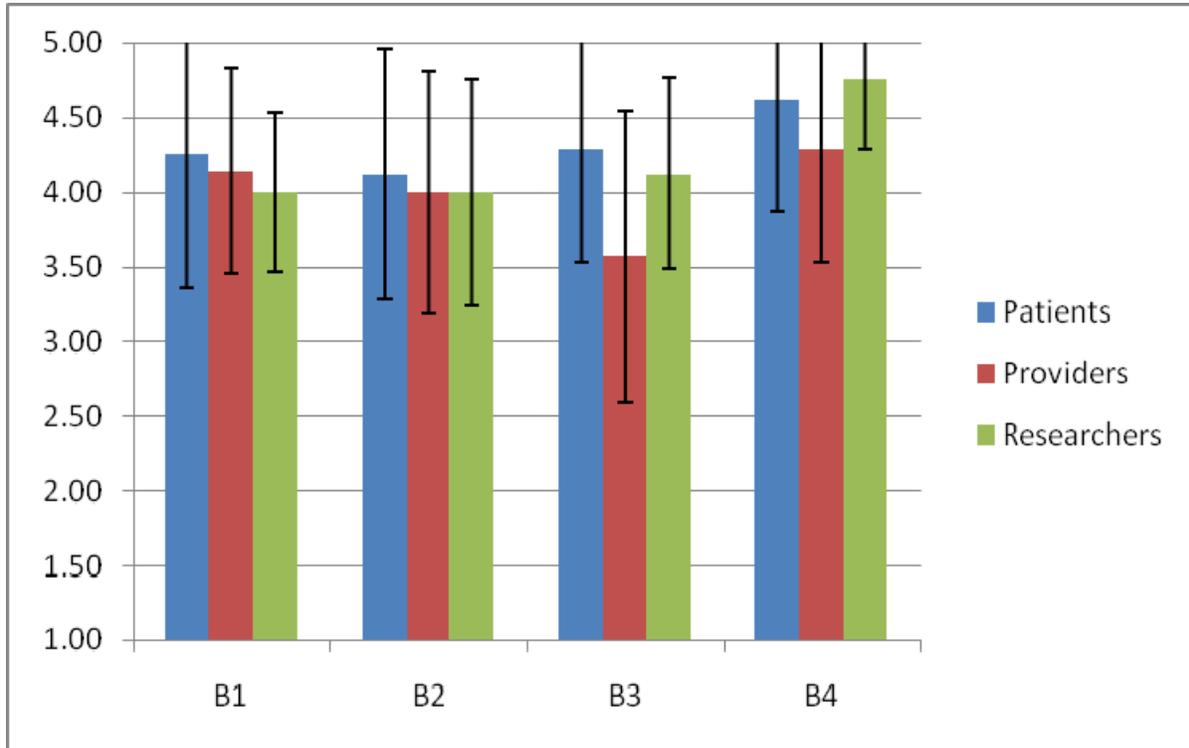
|           | <b>Question</b>                  | <b>Low Term (1)</b> | <b>High Term (9)</b> |
|-----------|----------------------------------|---------------------|----------------------|
| <b>A1</b> | Overall reaction to the Web site | Terrible            | Wonderful            |
| <b>A2</b> | Overall reaction to the Web site | Frustrating         | Satisfying           |
| <b>A3</b> | Overall reaction to the Web site | Dull                | Stimulating          |
| <b>A4</b> | Overall reaction to the Web site | Difficult           | Easy                 |
| <b>A5</b> | Overall reaction to the Web site | Inadequate power    | Adequate power       |
| <b>A6</b> | Overall reaction to the Web site | Rigid               | Flexible             |



**Figure 1. Mean ratings for questions that measure overall satisfaction (Error bars indicate one standard deviation above and below the mean.)**

**Table 2. Questions That Measure User Satisfaction With Site Content**

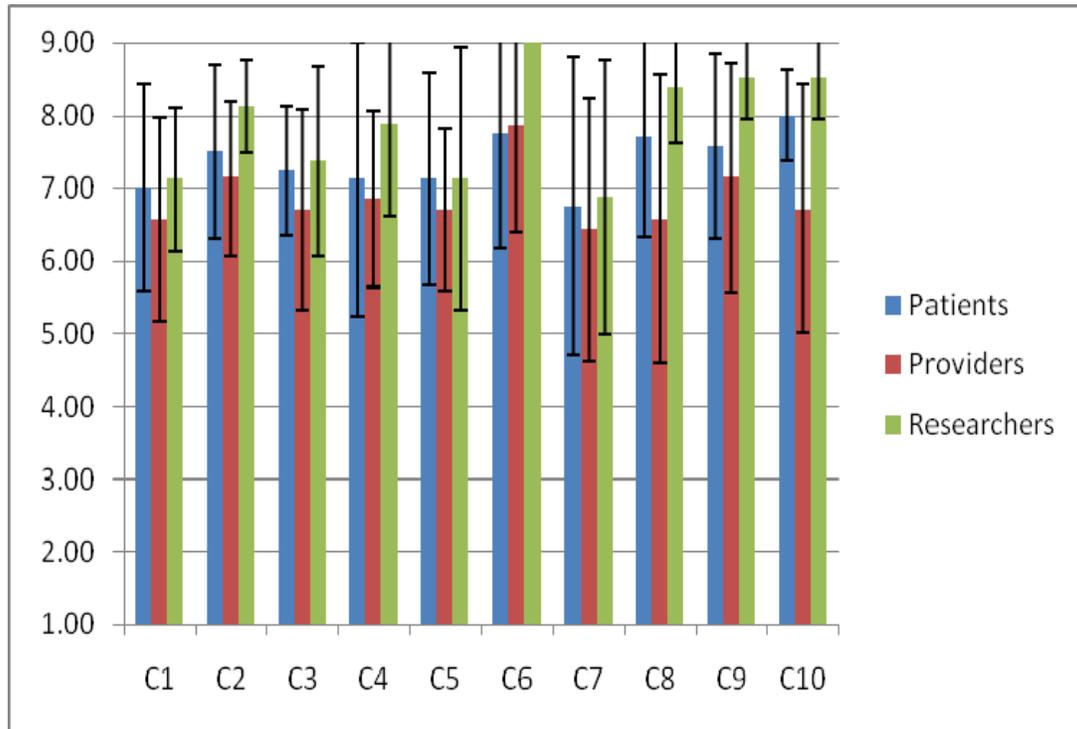
| Question  |   | Low Term (1) | High Term (5) |
|-----------|---|--------------|---------------|
| <b>B1</b> | The information on this site is accurate.                     | Disagree     | Agree         |
| <b>B2</b> | The information on this site is up-to-date.                   | Disagree     | Agree         |
| <b>B3</b> | The information on this site is comprehensive and complete.   | Disagree     | Agree         |
| <b>B4</b> | The information on this site should be recommended to others. | Disagree     | Agree         |



**Figure 2. Mean ratings for questions that measure user satisfaction with site content (Error bars indicate one standard deviation above and below the mean.)**

**Table 3. Questions That Measure User Satisfaction With Site Layout, Navigation, and Terminology**

| Question   |   | Low Term (1)  | High Term (9)  |
|------------|---|---------------|----------------|
| <b>C1</b>  | Screen layouts were helpful.                          | Never         | Always         |
| <b>C2</b>  | Amount of information that can be displayed on screen | Inadequate    | Adequate       |
| <b>C3</b>  | Arrangement of information on screen                  | Illogical     | Logical        |
| <b>C4</b>  | Sequence of screens                                   | Confusing     | Clear          |
| <b>C5</b>  | Next screen in a sequence                             | Unpredictable | Predictable    |
| <b>C6</b>  | Going back to the previous screen                     | Impossible    | Easy           |
| <b>C7</b>  | Progression of work-related tasks                     | Confusing     | Clearly marked |
| <b>C8</b>  | Use of terminology throughout Web site                | Inconsistent  | Consistent     |
| <b>C9</b>  | Medical or trial-related terms                        | Inconsistent  | Consistent     |
| <b>C10</b> | Other terms   | Inconsistent  | Consistent     |

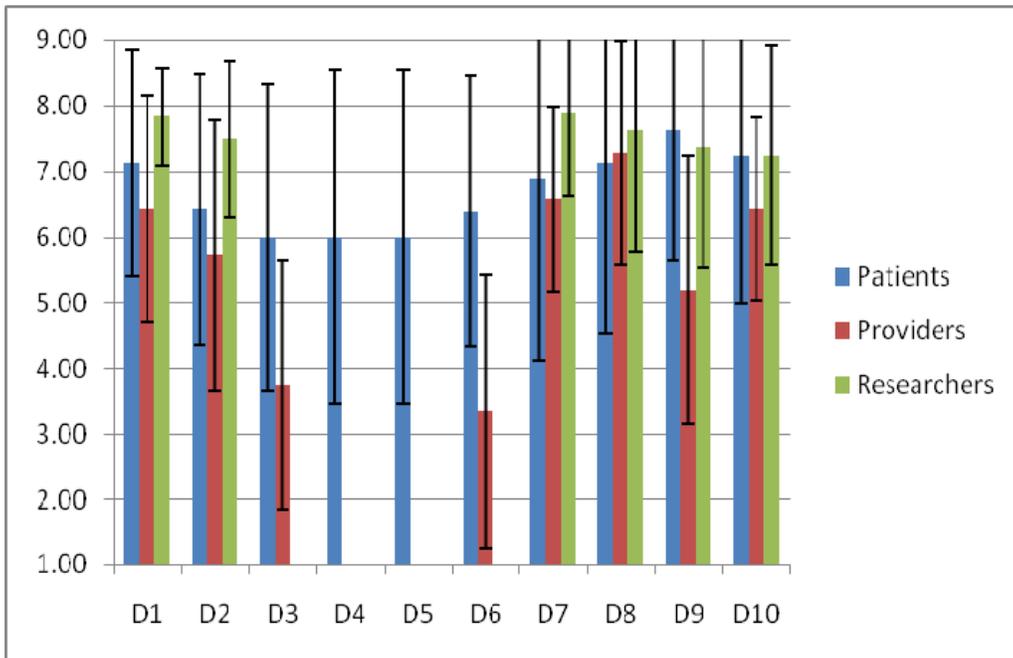


**Figure 3. Mean ratings for questions that measure user satisfaction with site layout, navigation, and terminology (Error bars indicate one standard deviation above and below the mean.)**

**Table 4. Questions That Measure User Satisfaction With System Messages and Feedback**

| Question   |  | Low Term (1) | High Term (9) |
|------------|--|--------------|---------------|
| <b>D1</b>  | Messages which appear on screen        | Confusing    | Clear         |
| <b>D2</b>  | Instructions for commands or functions | Confusing    | Clear         |
| <b>D3*</b> | Instructions for correcting errors     | Confusing    | Clear         |
| <b>D4*</b> | Error messages                         | Unhelpful    | Helpful       |
| <b>D5*</b> | Error messages clarify the problem     | Never        | Always        |
| <b>D6*</b> | Phrasing of error messages             | Unpleasant   | Pleasant      |
| <b>D7</b>  | Learning to use the Web site           | Difficult    | Easy          |
| <b>D8</b>  | Getting started                        | Difficult    | Easy          |
| <b>D9</b>  | Learning advanced features             | Difficult    | Easy          |
| <b>D10</b> | Time to learn to use the Web site      | Slow         | Fast          |

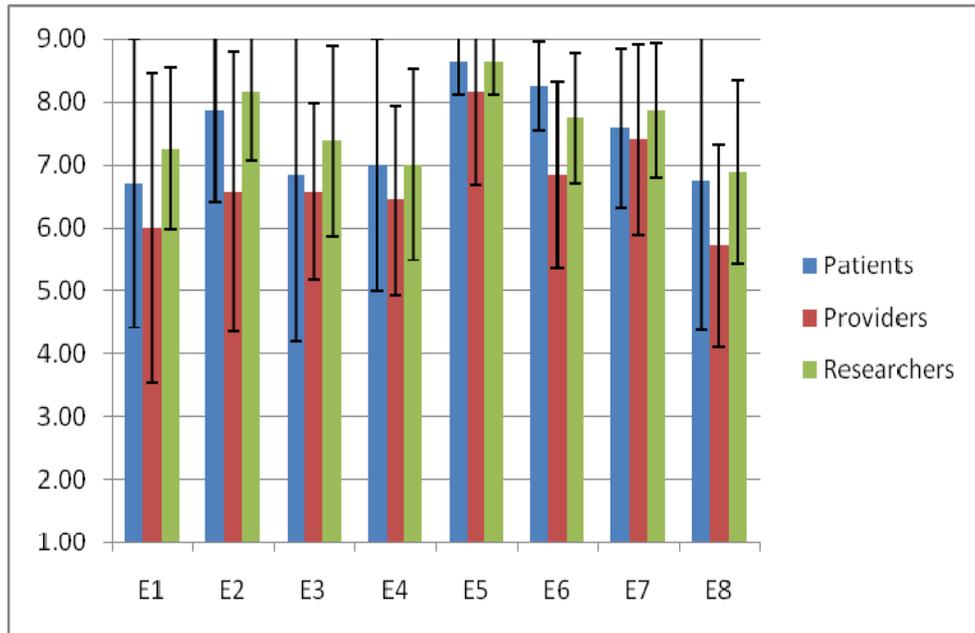
\*The number of responses for some participant groups was less than 50 percent for these questions.



**Figure 4. Mean ratings for questions that measure user satisfaction with system messages and feedback (Error bars indicate one standard deviation above and below the mean.)**

**Table 5. Questions That Measure User Satisfaction With Issues Related to Learning the System**

|           | <b>Question</b>                                     | <b>Low Term (1)</b> | <b>High Term (9)</b> |
|-----------|---|---------------------|----------------------|
| <b>E1</b> | Exploration of features by trial and error          | Discouraging        | Encouraging          |
| <b>E2</b> | Exploration of features                             | Risky               | Safe                 |
| <b>E3</b> | Discovering new features                            | Difficult           | Easy                 |
| <b>E4</b> | Tasks can be performed in a straightforward manner. | Never               | Always               |
| <b>E5</b> | Web site speed                                      | Too slow            | Fast enough          |
| <b>E6</b> | The Web site is reliable.                           | Never               | Always               |
| <b>E7</b> | Correcting your mistakes                            | Difficult           | Easy                 |
| <b>E8</b> | Amount of help given by the Web site                | Inadequate          | Adequate             |



**Figure 5. Mean ratings for questions that measure user satisfaction with issues related to learning the system (Error bars indicate one standard deviation above and below the mean.)**