Registries and Clinical Trial Matching: A Cancer Perspective

Ted Gansler, MD, MBA, MPH
Director of Medical Content
American Cancer Society
Thanks to...

- Katherine Sharpe, MA, MTS. Managing Director, Prevention & Survivorship Strategy
- Katie Dahlquist, MA. NCIC Team Supervisor
- Larissa Comis Tis, MA. Sr. Director, Strategic Partnerships, eviti, Inc.
Is there a need to increase cancer clinical trial enrollment?

“It is estimated that only 3 percent of adults with cancer participate in clinical trials, and people who are members of racial and ethnic minorities, elderly and low-income individuals, and people who live in rural areas remain underrepresented... the trend toward targeted therapy and personalized medicine necessitates larger numbers of patients willing to participate in clinical trials, since these trials are increasingly reliant on stratified populations.”

What % of cancer clinical trials close with insufficient accrual?

“The Institute of Medicine... cited that 40% of trials approved by the National Cancer Institute’s (NCI) Cancer Therapy Evaluation Program (CTEP) close without meeting 100% of target accrual (1)... Among the... phase III trials in this study, 71% were considered as having poor accrual (2)...

We propose defining accrual sufficiency on apparent ability to address primary endpoints (PE) rather than attaining accrual targets. Approximately one third of phase III trials closed with insufficient accrual to address the primary endpoints, primarily due to poor accrual. Defining accrual sufficiency broader than meeting accrual targets represents a fairer account of trial closures.”

Is there a need to increase cancer clinical trial enrollment?

- A substantial proportion (> 1/3?) of cancer trials close with insufficient accrual. It would be nice if the remaining 2/3 filled faster.

- (Some of these trial may have specific protocol “issues” that discourage accrual.)

- The need for patient participation in cancer trials is expected to increase.

- *We must understand and overcome barriers at multiple levels that discourage patient and provider participation. Today, I’ll focus on access to personalized information.*
Some informative survey data...

- Among adults participating in a telephone survey during 2000, only 20% of cancer survivors indicated they were aware that clinical trial participation might have been an option for them (Comis RL, Aldigé CR, Stovall EL, Krebs LU, Risher PJ, Taylor HJ (2000) A Quantitative Survey of Public Attitudes Towards Cancer Clinical Trials. www.cancertrialshelp.org/CTHpdf/308-9.pdf)

- Of the cancer survivors who were aware of clinical trials, where did they obtain that information? Their physicians: 73%, “online”: 5%, from a support/advocacy organization: 3% (Umutyan A, Chiechi C, Beckett LA, et al. (2008) Overcoming barriers to cancer clinical trial accrual: impact of a mass media campaign. Cancer 112(1):212–9)
Some informative survey data...

- Among individuals not diagnosed with cancer, 31% said they would be very willing and 51% would be somewhat willing to participate in a clinical trial, if diagnosed with cancer. (Comis RL, Miller JD, Aldige CR, Krebs L, Stoval E (2003) Public attitudes toward participation in cancer clinical trials. J Clin Oncol 21:830–835)

- 97% of cancer clinical trial participants rated the care they received as excellent or good. (Committee on Cancer Clinical Trials and the NCI Cooperative Group Program, Institute of Medicine: A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program. Washington, DC, The National Academies Press, 2010)
Summary of the situation...

- Patients want information about cancer clinical trials and are very receptive to the idea of participation.
- Most eligible patients do not receive this information from their physicians.
- Very few patients seek this information from voluntary health organizations (“us”).
- Patients trust us more than any other source of medical research information (including their physicians).
Public Trust in Sources of Research Information

There are many sources of information about health and medical research issues. Please indicate how trustworthy you think the information they provide is.

Source: Public Opinion Polls, 1992-2010
“With great power comes great responsibility.”
- Spiderman (2002)
Desired Attributes of a Cancer Clinical Trial Matching Service

- The trial database must contain all public trials and as many private trials as is feasible, and include all open trials in clinicaltrials.gov.
- There must be functionality to narrow the list of trial options based on clinical and geographic information, but without requiring a burdensome degree of clinical data.
- The service should be available online and by phone.
- Results should be presented in an unbiased manner.
- Staff should be available to speak with patients.
The ACS/CCCG Clinical Trial Matching Service

Call ACS National Info Center

Provide clinical & demographic info to Clinical Trial Info Specialist (CTIS)

Discuss list of trials likely to be relevant with CTIS

Discuss other information or patient service needs with CTIS

CTIS send trial information via US mail or e-mail

Visit www.cancer.org

Enter clinical & demographic info

View list of trials likely to be most relevant in a few seconds & send list to your e-mail

CTIS schedules optional follow-up contact to assist with new needs and assess outcomes
American Cancer Society Clinical Trials Matching Service

The American Cancer Society Clinical Trials Matching Service is a free, confidential program that helps patients, their families and health care workers find cancer clinical trials most appropriate to a patient's medical and personal situation. Through a partnership with the eviti, Inc., we can help you find research studies that are testing new drugs or methods to prevent, detect or treat cancer. Read our privacy policy for the clinical trials matching service before you get started.

In just a few minutes, you can learn more about clinical trials that are relevant to your situation. First, log on to our website and complete a online screening questionnaire. The information you provide will be matched against the eligibility requirements for the studies in our database. You will then be able to view the treatment summary and contact information for the clinical trials for which you might be eligible. If you are interested in learning more about a particular study, you can then contact the treatment center directly to speak with a study coordinator. Your search will be saved, so you can come back at any time to review the studies or update your questionnaire.
Set up your ACS Account

1. Email Address (this will become your ACS Account ID)*

2. New Password*
   
   Minimum of 6 characters with at least one number and one letter. Cannot contain special characters.

3. Confirm Password*

4. Choose security question*
   What street did you live on in third grade?

5. Answer*

Security Answer is required.

OR

REGISTER USING ONE OF THE SERVICES BELOW:

[Logos for Google, Yahoo, Facebook, Windows, LinkedIn, and others]

Personal Information

2. First Name* Ted

3. Last Name* Testpatient

4. Check if outside of the U.S.
Signed in using your ACS Account as Testpatient, Ted

EMAIL ADDRESS  
tgansler@yahoo.com

NAME  
Testpatient, Ted

ADDRESS  
Unknown
COCOA BEACH, FL 32931
USA

Update Account Details

SECURITY  
Change your Password
Change your Security Question

My Registered Sites

ACS Account
Edit Preferences
1. What is the patient's gender (optional)
   - Female
   - Male

2. What is the patient's ethnic background? (optional)
   - White

3. What is the patient's date of birth? (optional) (Please enter in MM/DD/YYYY format. Example: 01/31/1950)
   - 01/31/1950

4. What type of insurance does the patient have? (optional)
   - Prefer not to say

5. What is your relationship to the patient? (required)
   - Patient

6. What is the patient's zip code? (required)
   - 32931
1. Which protocol categories would you like to include in the results? (remove checks to limit your search)
   - [x] Treatment
   - [ ] Supportive Care
   - [ ] Prevention
   - [ ] Other

2. What kind of cancer does the patient have? (required)
   - Breast
3. What is the sub-type of cancer that the patient has? (required)
Adenocarcinoma

4. What is the current stage of the disease? (optional)
- Stage 0 (DCIS/LCIS)
- Stage I
- Stage IIA (Negative Nodes)
- Stage IIA (Positive Nodes)
- Stage IIB (Negative Nodes)
- Stage IIB (Positive Nodes)
- Stage IIIA
- Stage IIIB
- Stage IIIC
- Stage IV
- Recurrent Disease

5. What kind of treatment has the patient received? (optional)
- Include all prior therapies
- Diagnostic Biopsy only or local excision of the primary tumor
- Surgical and/or local radiation procedure(s) required to adequately treat the primary tumor(s), no systemic adjuvant treatment (cytotoxic agents)
- Surgical and/or local radiation procedure(s) required to adequately treat the primary tumor(s), with systemic adjuvant treatment < 6 months (from completion of cytotoxic agents)
- Surgical and/or local radiation procedure(s) required to adequately treat the primary tumor(s), with systemic adjuvant treatment > 6 months (from completion of cytotoxic agents)
- No prior systemic treatment for advanced disease with cytotoxic agents
- Prior systemic treatment failure for advanced disease with cytotoxic agents
- Greater than 1 Prior systemic treatment failure for advanced disease with cytotoxic agents
6. How has the cancer affected the patient's daily activity? (optional)
   - 0 - Normal activity (asymptomatic)
   - 1 - Symptoms present but ambulatory without restriction
   - 2 - Confined to bed less than 50 percent of waking hours.
   - 3 - Confined to bed more than 50 percent of waking hours.
   - 4 - 100 percent bedridden due to symptoms related to cancer.

7. To limit your search results to trials involving a specific drug, please select a drug from the list below. (optional)
   - Select

8. Do you want to see Phase I trials?
   - Yes
   - No

What would you like to name your screening?
   - Jan 2013 11:35:52

Would you like to have a link to your screening results emailed to you?
   - Yes
   - No

[Buttons: RESTART SEARCH, CONTINUE]
The American Cancer Society's clinical trial specialists are trained to answer questions about clinical trial participation and to open the door to treatment options available through research studies. They can also provide information about standard treatment options and patient services, including transportation and lodging resources if you decide to participate in a clinical trial away from our home.

To request a call from one of our specialists, Click Here to enter your contact information, even if you are not the patient. One of our specialists will give you a call back within two business days. Please note that we are only able to call people living in the United States or a US territory.

If you are not the patient but think that the patient would benefit the most by talking with us directly, please have him or her call us at 1-800-303-5691.

Treatment

PROTOCOL ID: NCI-2011-02623
Tamoxifen Citrate, Letrozole, Anastrozole, or Exemestane With or Without Chemotherapy in Treating Patients With Invasive RxPONDER Breast Cancer

View Trial Summary View All Locations

PROTOCOL ID: S1007
A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/-Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer

Space Coast Cancer Centers-Titusville
Titusville, FL 32796
1-321-268-4200

Space Coast Cancer Centers-Titusville
490 North Washington Avenue
Titusville, FL 32796
<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Description</th>
<th>Location</th>
<th>Contact</th>
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</thead>
<tbody>
<tr>
<td>CDR0000700069</td>
<td>Higher-Dose Radiation Therapy or Standard Radiation Therapy in Treating Patients With Early-Stage Breast Cancer That Was Removed by Surgery</td>
<td>M.D. Anderson Cancer Center - Orlando, Orlando, FL 32806</td>
<td>321-841-4347</td>
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<tr>
<td>NCI-2011-02572</td>
<td>Chemotherapy With or Without Trastuzumab After Surgery in Treating Women With Invasive Breast Cancer</td>
<td>M.D. Anderson Cancer Center - Orlando, Orlando, FL 32806</td>
<td>321-841-4347</td>
</tr>
<tr>
<td>NSABP-B-49</td>
<td>A Phase II Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer</td>
<td>M.D. Anderson Cancer Center - Orlando, Orlando, FL 32806</td>
<td>321-841-4347</td>
</tr>
<tr>
<td>RTOG-1005</td>
<td>A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation Plus Concurrent Boost Versus Standard Whole Breast Irradiation Plus Sequential Boost for Early-Stage Breast Cancer</td>
<td>M.D. Anderson Cancer Center - Orlando, Orlando, FL 32806</td>
<td>321-841-4347</td>
</tr>
<tr>
<td>MA32</td>
<td></td>
<td>Florida Hospital</td>
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TrialTracker Survey/Questionnaire

Initial Survey Questions

1. How did you hear about the American Cancer Society Clinical Trials Matching Service?
   - □ Referred by the American Cancer Society's National Cancer Information Center (800-ACS-2345)
   - □ Referred by my local American Cancer Society office
   - □ Link on www.cancer.org
   - □ American Cancer Society publication (cancer information document, brochure, etc.)
   - □ Health care professional (doctor, nurse, etc.)
   - □ Family member
   - □ Friend
   - □ Media (news broadcast, article, etc.)
   - □ Other
      ________________  (In case of Other)

2. Why did you contact us about clinical trials?
   - □ I want to find investigational treatments relevant to my medical situation
   - □ I want to try a specific investigational treatment that I have heard of
   - □ I do not want the treatment suggested by my doctor
   - □ My doctor says I would have a poor prognosis with the standard treatment
   - □ My doctor says there is not a standard treatment for my type of cancer
   - □ My doctor suggested a treatment that is not approved for my type of cancer
   - □ My doctor says that I have exhausted my treatment options
   - □ I currently have no evidence of disease but am looking for investigational treatment options in case my cancer recurs
TrialTracker Survey/Questionnaire

Follow-up Survey Questions

3. What is your current interest level in clinical trials?
   - 1 – Very interested
   - 2 – Interested
   - 3 – Undecided
   - 4 – Uninterested
   - 5 – Very uninterested

4. Are any of the following issues preventing you from participating in a clinical trial?
   - I cannot afford treatment-related costs
   - I cannot afford non-treatment-related costs (travel, lodging, time off work, etc.)
   - My insurance will not cover routine costs
   - I do not have insurance
   - I cannot travel to clinical trial site
   - I am afraid of participating in a clinical trial
   - I cannot find a clinical trial using the modality or treatment I want
   - I cannot find a clinical trial in the phase that I want
   - My doctor is unwilling to discuss clinical trials as an option
   - I cannot get copy of medical records
   - I do not have measurable disease or am cancer-free
   - My physical activity level is too low

5. Are you having any insurance-related issues in regards to clinical trials?
   - No – insurance is covering clinical trial costs
5. Are you having any insurance-related issues in regards to clinical trials?
   - No – insurance is covering clinical trial costs
   - No – all clinical trial costs are covered by the study (no need for insurance)
   - Yes – insurance will not cover any clinical trials
   - Yes – insurance will not cover the clinical trial I'm interested in
   - Yes – insurance denied appeal
   - Yes – Medicaid does not cover clinical trials in another state
   - Not applicable – I do not have insurance

6. Did you contact any of the sites to discuss participation in a specific clinical trial?
   - Yes
   - No

7. Did you enroll in a clinical trial?
   - Yes
   - No

8. If you enrolled in a clinical trial, did you find it through our service?
   - Yes
   - No
Summary of Lessons Learned

- 11% of CTMS constituents enrolled.
- About 61% of constituents accessed information via our website only (did not speak with a CTIS).
- In clinical trials for treatment of cancer (unlike some other diseases) eligibility is mostly limited to a short period after diagnosis, before treatment has started. Some patients were initially ineligible, but enrolled months later when their cancer recurred.

Summary of Lessons Learned

- Our CTMS constituent population was skewed toward patients with advanced disease and poor-prognosis types of cancer. Within that population, advanced and recurrent disease predicted greater likelihood of enrollment (OR 1.183; 95% CI 1.001, 1.398). Poor performance status was inversely associated with enrollment (OR 0.650; 95% CI 0.489, 0.866). Many patients (wrongly) viewed clinical trials as an “option of last resort.”
Summary of Lessons Learned

- Many constituents who spoke with CTISs had misconceptions about clinical trials. Individual guidance was very helpful.

- The CTMS trial list was often helpful in stimulating physician/patient discussion regarding clinical trials. (Will this influence physician attitudes or behavior?)

- The CTMS was successful in finding clinical trials for patients whose physicians had not discussed clinical trials as an option.
Summary of Lessons Learned

- The CTMS provided some patients with the sense that they had not overlooked any options.

- The CTMS did not eliminate racial disparities in trial participation. African Americans were less likely than whites to enroll in a trial (OR 0.296; 95% CI 0.107, 0.817)

- The current scale of the CTMS does not meaningfully affect the national rate of cancer clinical trial participation. We are able to help only those patients who ask us for help.
A Road Not Taken

- A electronic medical records company proposed a collaboration with ACS to undertake intermittent EMR data mining to identify patients eligible for cancer clinical trials sponsored by individual pharma clients (but not tell these patients about other trials).

- Why would this not have worked?

- Why would this have been inappropriate even if was possible?
What will (eventually) make a BIG difference?

- Realign physician incentives to encourage (rather than discourage) clinical trial participation.
- Reposition clinical trial participation as an element of clinical quality improvement and not as an academic or regulatory pursuit.
- Link EMRs and clinical trial databases to provide real-time search functionality.
Was this information relevant to you?
Questions to ask yourself...

- Is there a large number of trials for your constituents? How heterogeneous is their disease? Is matching functionality necessary to narrow their list of trial options?

- What providers care for your constituents? Community generalists? Academic subspecialists? What are their incentives/disincentives for clinical research involvement? What is their level of awareness regarding clinical trial options?
Questions to ask yourself...

- Can clinical trials for your constituents be done in a community setting? Is treatment highly intensive? Are specialized facilities required?
- Are your constituents treated mostly as inpatients or outpatients?
- What is your “market penetration” as a provider of information and services to the population of patients with the disease in question?
Was this information relevant to you?

Questions to ask yourself...

- Do any organizations maintain clinical trial databases or lists relevant to your constituents?
- Do any organizations maintain registries of patients with the disease of interest to you?
- At what point in the disease continuum are your patients treated (only at diagnosis, intermittently, continually)? At what points are they eligible for clinical trials? Should matching occur in “real time” at the point of care or intermittently?
Was this information relevant to you?
Questions to ask yourself...

- How serious is the prognosis of patients with the disease of interest to you?
- How effective are current treatment options for patients with the disease of interest to you?
- Add your own questions here...
Thank you!