Using an Online Tool to Understand and Improve Clinical Trial Accruals

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The National Cancer Institute (NCI) launched the Community Cancer Centers Program (NCCCP) in 2007 as a three-year pilot, forming a public-private partnership with 16 community hospitals to explore the best methods to enhance access to care—especially for those with healthcare disparities—improve quality of care, and expand research within the community setting.[1] At the conclusion of the pilot period, the network sites collaborated to produce White Paper reports to document their experiences, addressing program deliverables in specific focus areas.

A series about the NCCCP White Papers was first introduced in the January/February 2011 edition of *Oncology Issues*.[2] This month's edition features the Clinical Trials White Paper, divided into the following sections: Using an Online Tool to Understand and Improve Clinical Trial Accruals, Developing the NCCCP Trials Portfolio, Using a Minority Matrix and Patient Navigation to Improve Accrual to Clinical Trials, and Developing the RECIST Criteria Toolkit.

Unfortunately, only three percent of adults with cancer participate in clinical trials. In underserved urban and rural communities, the adult accrual rate is even lower. These groups include populations with disproportionately high cancer rates, so their absence from clinical trials is a significant factor in ongoing healthcare disparities.

To meet its goal of increasing clinical trial accrual—especially among minority or underserved populations—NCCCP formed a Clinical Trials Subcommittee in 2007. Its mission: to enhance NCCCP site access to clinical trials that provide cutting-edge advances and state-of-the-art care, and to help develop new preventatives, diagnostics, and treatments. Today, the Clinical Trials Subcommittee assists NCCCP sites as they continue to work to demonstrate:

- An increased capability to offer multiple types of Phase II and Phase III trials, and to develop protocols for appropriate referral of patients for Phase I trials to NCI-designated cancer centers or academic medical research institutes
- Improved accrual rates of under-represented and disadvantaged patients in all trials
- Enhanced participation in complex clinical trials including multi-modality (i.e., radiation therapy plus surgery) and translational research trials.

The NCCCP Clinical Trials Subcommittee also explored patient and physician barriers to clinical trial enrollment; the infrastructure necessary to perform Phase II and Phase III trials; and mechanisms to increase minority accrual. In addition to the Screening and Accrual Log discussed in this article, NCCCP developed other tools for the network sites, including a clinical trials portfolio, a minority matrix, and the RECIST criteria toolkit.

Screening and Accrual Log

A key step toward increasing clinical trial accrual was the development of the NCCCP web-based Clinical Trials Screening and Accrual Log (Trial Log). The log, designed for the 16 NCCCP pilot sites, allowed collection of real-time enrollment barriers, and created a foundation for developing strategies to overcome these barriers. The log is managed by the NCCCP Trial Log Working Group, enabling real-time, network-driven, trial-specific accrual data.

During the first year of the NCCCP pilot, representatives from all 16 sites worked on developing the Trial Log. The process included:

- Conducting a literature search
- Collecting existing tools used by clinical research programs
- Participating in weekly meetings to develop a comprehensive list of patient and physician accrual barriers, based on barriers most frequently cited in the literature
- Revising the barrier list based on NCCCP input, including webinars, presentations of best practices, and lectures from previous cooperative group conferences and American Society of Clinical Oncology (ASCO) meetings.

Two versions of the log were created. The first version (developed from August 2007 through January 2008) was launched in February 2008, and was used for four NCCCP clinical trials. After data analysis, a second iteration of the log was developed and implemented in March 2009. Nineteen trials were tracked on this log, and the number of trials tracked continues to grow as NCCCP network priorities change. (Version 2 of the Trial Log can be found on pages 54 and 55.)

Due to the extensive changes in the tool from ver-

Screening event held at NCCCP site, The Cancer Program of Our Lady of the Lake and Mary Bird Perkins Cancer Center.

PHOTOGRAPH COURTESY OF NCCCP

sion 1 to version 2, data collected in log versions 1 and 2 remain separate. For example, during development of version 2, the tool was revised to allow for real-time utility and enhanced functionality for data entry, monitoring, and analysis. The log was modified to add data-quality checks and to allow NCCCP sites to review data in real-time to address barriers and to share best practices. Reports were created that allow for evaluating screening versus actual accrual patterns by race, gender, ethnicity, and age. Using these reports, NCCCP sites can monitor the recruitment of under-represented populations, identify strategies, and implement plans to improve recruitment for specific populations. NCCCP Trial Log Working Group leadership also monitors the logs, reviewing data to monitor use, possible trends, and progress.

Key Stakeholder Buy-in

Among all NCCCP sites, the unanimous rationale for participating in the Trial Log project was a commitment to work to increase overall accrual to clinical trials and to reduce disparities in cancer care by making clinical trials more available to the underserved populations. Clinical research staff, support staff, information technology teams, principal investigators, data managers, nurse navigators, and management were all key stakeholders in the Trial Log project.

Information needed for the log came from various places, including private practice physicians, Community Clinical Oncology Programs (CCOPs), patient navigators, and research departments. Accordingly, at NCCCP sites where private practices were the main source of patient referral, practice physicians were also important stakeholders.

Key Success Elements

NCCCP sites found it critical to have someone at each site responsible for providing education about the Trial Log, its purpose, and how to maximize the log's value—both during implementation and on an ongoing basis. While each site had previously captured data regarding difficulties in recruiting underserved populations to clinical trials, this project presented an opportunity not only to analyze barriers to recruitment but also to evaluate different strategies to resolve identified issues. Key success elements included:

The creation of a robust analysis tool. This analysis required personnel, time to perform the literature review, and evaluation of key issues identified by the CCOP sites. NCCCP sites came to the program with a variety of experiences and skill sets. Eight of 16 sites had an existing tool for collecting data, but these tools varied from simple paper to sophisticated databases. Additionally, the amount of information collected was inconsistent and was in itself a barrier to understanding site accrual.

IT support. Information technology (IT) support was critical as it helped operationalize a tool to facilitate collection of data gathered on barriers and challenges and then provided a mechanism to easily analyze desired information and generate reports.

Identification of log owners. The more successful NCCCP sites identified "champions" or "leaders" for the Trial Log. These sites achieved greater participation in the development and implementation processes, and provided ongoing education to key staff members, as well as to all new staff members.

Standardization of trial screening definitions. During development of the Trial Log, NCCCP sites found that trial screening definitions varied from site to site. Standardization of these definitions was important to ensure the accuracy of the information entered into the Screening and Accrual Log. Screening definition examples include:

1. **CALGB 80405 (Colorectal)**: Unresectable locally advanced or metastatic colorectal adenocarcinoma with no prior chemotherapy.
2. **SWOG S0421 (Advanced Prostate CA)**: Hormone refractory metastatic prostate adenocarcinoma to bone and no prior chemotherapy.
3. **CALGB 90601 (Advanced Uroepithelial Neoplasm)**: Locally advanced or metastatic urinary tract transitional cell CA with no prior chemotherapy for metastatic disease.

Time commitment. This element was probably the most pivotal success factor. To make this process work, a significant amount of time was required in developing the Trial Log, assessing and re-assessing what the tool was measuring,

Through the Screening and Accrual Log, the NCCCP was able to better understand specific barriers for enrollment to clinical trials.

refining the tool and the processes involved, and educating and reinforcing the value of the tool. The Trial Log provided insight that was not available through other identified tools.

Implementing the Trial Log

NCCCP sites had varying degrees of success implementing the Trial Log. While the stakeholders involved in implementation were similar to those involved in the development phase, sites found that adding members to the research team, such as clinical research assistants (CRAs), was helpful. The time commitment for the implementation phase was significant. Research staff at each site worked to include the Trial Log into their standard processes. Although all NCCCP sites reported implementation of the Trial Log, actual use of the log varied from site to site. Evidence suggested that a few sites were using the log in real-time, while other sites were using a batching process or retrospective data entry.

Some sites that offered both cooperative group trials and pharmaceutical trials chose to adopt the Trial Log through a local replica Excel spreadsheet or Access database, which allowed for standardizing processes at those NCCCP sites. One NCCCP site created two different site-specific screening logs—one for radiation and one for medical oncology. Specific information was logged weekly, per the oncologist's schedule, on every new or returning consulted patient.

The tool has proven valuable, providing information that is used for internal reports, as well as information required on an ongoing basis for other NCCCP project reports. It also provides physicians with a pre-screening tool that lets them know they will be seeing a patient who is potentially eligible for a study.

Collaboration with other NCCCP sites and participation with NCCCP subcommittees was extremely helpful and important to the implementation process. Conference calls provided a forum to ask questions, share information, solve problems, and receive feedback. The conference calls were also an opportunity to discuss best practices. If a site could not participate in a subcommittee conference call, minutes from the call were reviewed and the site communicated with other NCCCP sites to share information regarding the addition or deletion of trials from the Trial Log. Obtaining and sharing information was key to success.

NCCCP sites found that continued education and reinforcement of processes and goals was essential for appropriate utilization of the Trial Log.

Challenges and Barriers

NCCCP sites identified three major challenges and barriers to successful implementation of the Trial Log. The most common challenge was the time required to complete the steps in the screening and enrollment processes, particularly during the log's initial implementation. NCCCP sites worked to develop strategies and streamline the process for using the log. Second, sites had to develop a process for incorporating the log into their daily workloads. Various staff challenges comprised the third major barrier. Specific challenges and barriers included:

- ***Time.*** Nine of the 16 sites reported time as a challenge and noted a duplication of processes with existing site-specific trial logs.
- ***Log Versions.*** The development of versions 1 and 2 of the log created modest confusion and data overlap that required clarification.
- ***Demographic Data Capture.*** It was sometimes difficult to capture required demographic data (i.e., race, ethnicity, rural); however, NCCCP sites were able to address this barrier by reporting data according to Federal guidelines.
- ***Staff Turnover.*** Change in staff increased the need for ongoing training about how to use the log.
- ***Website Problems.*** The Trial Log website occasionally experienced issues that required IT programming support.
- ***Communication.*** Communication with private practices or practices not located at the NCCCP site was difficult. For the expanded NCCCP network, a recommendation was made that each new site develop a site-specific screening tool that includes the data captured and term definitions used on the NCCCP Trial Log.
- ***Infrastructure and IT Support.*** The level of infrastructure and IT support required enhancement for successful utilization of the tool.

As the NCCCP expands, the ability to house and analyze the data is a challenge that must be met.

Lessons Learned

NCCCP sites found it critical to maintain good communication about the introduction and implementation of the Trial Log with all the key stakeholders—including the NCCCP project coordinator, the site's research manager, and research coordinators.

As with any new tool or project, metrics are needed to help validate the effort. The Trial Log incorporates the appropriate questions needed to collect the data for measurement purposes. By standardizing these questions, the data is useful in understanding which trials do not accrue. However, for reporting to be relevant, all fields must be completed. The use of the Trial Log data collection form improved the process because data could be collected prior to entering it on the website, making sure that all questions were answered before recording online. Additionally, use of the form enabled sites to document the subject's unique

Site Specific Implementation Challenges and Barriers

- At a few of the sites, the limited number of open, NCCCP-endorsed studies reduced the ability to capture data as the ability to contribute screened patients was low.
- The frequent need to change passwords through NCI was another issue. For one NCCCP site, having both data managers and study coordinators access the log as users worked best, because the log asks for information on patients not participating in the trials, as well as those participating; this data must be entered by the study coordinators who originally received the referral. The biggest challenge for this site was staff remembering to enter patients into the log, which only pertains to a limited number of studies. Now, staff use a spreadsheet that lists all referrals. At the end of each month, that spreadsheet is reviewed against the Trial Log to make sure all qualified referrals have been entered into the screening log.
- Another NCCCP site was initially challenged in efforts to gain the support of the two research coordinators charged with using and maintaining the Trial Log. Providing education for staff on the value of the NCCCP project and having IT support in place increased buy-in for the project. The web-based training sessions were essential in learning how to access and use the log. With increased use, the log has become a routine step in screening and enrolling patients. Staff found the Trial Log's design straightforward and easy to use.
- One site faced obstacles trying to come to agreement on the criteria defining a "screened" patient. Once definitions were clarified, documented on the Trial Log, and the tool was further refined, entering screened patients on the log became more routine, and time commitment ceased to be an issue.
- To overcome language barriers, one site developed Spanish and Vietnamese short forms for consenting patients to clinical trials.

identifier in the event a data query was generated that required site clarification.

Implementation and use of the Trial Log allowed NCCCP sites to:

- Track, assess, and compare enrollment and barrier information by population at each site and develop new strategies for clinical trial accrual
- Identify trials required to meet the needs of individual communities served by the site
- Communicate among sites on possible ways to overcome barriers to accrual
- Increase physician input and accountability by discussing barriers to accrual
- Capture data and identify barriers in real-time
- Bring clinical trials to the forefront at their sites.

Through the Screening and Accrual Log, the NCCCP was able to better understand specific barriers for enrollment to clinical trials. For example, the log could reveal common findings among patients screened for a particular trial or it could provide data about when physicians did not participate in a specific trial and why. Also, the Trial Log helped provide a better understanding of characteristics of patients screened and accrued to a specific trial. Best practices were shared among NCCCP sites. In addition, there is now a better understanding of how much has been accomplished as a network to date, and strategies to meet future goals have been identified. Next steps with the Trial Log will be to periodically assess accrual rates across different trials for different populations pre- and post-intervention.

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Additional contributors to this article are acknowledged on page 64.

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This project has been funded in whole or in part with federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. HHSN261200800001E. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U. S. Government.

NCCCP Clinical Trial Screening and Accrual Log, v2.0

Patient Identification Number: _____
(Record the patient ID for your records)

1. Date of patient screening (mm/dd/yy): _____

PATIENT DEMOGRAPHICS

2. Ethnicity (select only one): ☐ Hispanic or Latino ☐ Non-Hispanic or Latino ☐ Unknown

3. Race:
☐ American Indian or Alaska Native
☐ Asian
☐ More than One Race
☐ Not Reported, Data Not Available
☐ Native Hawaiian or Other Pacific Islander
☐ Black or African American
☐ Caucasian
☐ Not Reported, Patient Refused
☐ Unknown, Patient Unsure of Race

4. Gender (select only one) ☐ Male ☐ Female

5. Age (ex. 43)

PROTOCOL SCREENING METHODS

6. Protocol for which the patient was screened (select only one):

☐ ECOG 11505 (Lung)
☐ ECOG E2804 (Renal Cell) Phase II
☐ ECOG E2805 (Adjuvant Renal)
☐ ECOG E5202 (Adjuvant Colon)
☐ PACCT-1 (TAILORx)
☐ NCCTG N0147 (Adjuvant Colon)
☐ NSAPB B-42 (Breast)
☐ NSABP C-10 (Colon) Phase III
☐ CALGB C80405 (Colorectal)
☐ CALGB 50303 (Lymphoma) Tissue Procurement

7. What method(s) were used to identify this patient for protocol screening (select all that apply):

☐ Chart review
☐ Tumor board
☐ Cancer/tumor registry
☐ Patient care rounds
☐ MDC/disease site conference
☐ Review of surgical schedule
☐ Review of clinic schedule
☐ Patient self referral
☐ Physician referral (NCCCP investigator)
☐ Physician referral, within institution
☐ Physician referral, outside institution
☐ Patient navigator
☐ Response to advertisement
☐ Other: _____

8. Was the patient navigator used in identifying the patient for screening: ☐ Yes ☐ No

9. If the patient navigator was involved, indicate how they were involved (select all the apply):
☐ Navigator screened the patient
☐ Navigator obtained consent for treatment
☐ Navigator referred patient to the research team

PROTOCOL SCREENING

10. Did the patient enroll in the protocol: ☐ Yes ☐ No

11. If the patient did not enroll in the protocol, indicate the reason (select only one):

☐ Patient did not meet trial eligibility criteria (skip to question 13)
☐ Patient was eligible but declined participation (skip to question 14)
☐ Patient was eligible but physician declined to offer participation (skip to question 15)
☐ Patient was eligible but started treatment prior to completion of screening (skip to question 12)

12. If the patient was not captured prior to starting treatment, indicate reason why (select only one):

- ☐ Urgency to initiate treatment
- ☐ Patient not referred to research team
- ☐ Recurring patient/Not new patient
- ☐ Insufficient medical records at time of screening
- ☐ Other: _____

13. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply):

- ☐ Performance status
- ☐ Abnormal labs
- ☐ Abnormal organ function
- ☐ Prior therapy
- ☐ Time requirement from surgery or therapy
- ☐ Co-morbidities
- ☐ Insufficient or unavailable pathologic samples for study (include unclear margins)
- ☐ Does not meet genetic testing criteria
- ☐ Patient had progressive disease
- ☐ Other: _____

14. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all the apply):

- ☐ No desire to participate in research
- ☐ Preference for standard treatment
- ☐ Patient preferred another trial
- ☐ Lack of awareness/education about trials
- ☐ Perceived side effects/toxicities too great
- ☐ Cultural/religious issues
- ☐ No insurance coverage
- ☐ Financial concerns/indirect costs (work, etc.)
- ☐ Social issues (housing, childcare)
- ☐ Mistrust of research
- ☐ Family member influenced against trial participation
- ☐ Language barrier/lack of access to interpreter
- ☐ Patient declined to be retested per protocol
- ☐ Refused to have re-biopsy or further tissue collection
- ☐ Insurance company refused to pay for additional testing
- ☐ Insurance company denied coverage
- ☐ Other: _____

15. If the patient was eligible but the physician declined to offer participation, indicate the physician-related reason why (select all the apply):

- ☐ Preferred to offer standard of care
- ☐ Preferred to offer a different trial
- ☐ Medical concerns (age, frailty of patient)
- ☐ Medical concerns (patient tolerating treatment, performance status)
- ☐ Concerns over patient non-compliance/lack of social support
- ☐ Lack of time for physician/research staff to offer patient the trial
- ☐ Lack of physician/research staff time/support to administer trial
- ☐ Lack of knowledge/awareness of the trial by MD/research staff
- ☐ Lack of adequate reimbursement
- ☐ Physician declined to have patient retested per protocol
- ☐ Insurance company refused to pay for additional testing
- ☐ Insurance company denied coverage
- ☐ Refused to have re-biopsy or further tissues collection
- ☐ Language barrier/lack of access to interpreter
- ☐ Other: _____

16. If there was a language barrier, indicate the language spoken (select only one):

☐ Spanish ☐ French ☐ Chinese ☐ Vietnamese ☐ Other:_____