A Culture of Research: Considerations and Lessons Learned from NCI Programs

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Think Tank Webinar
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Objective:
Explore lessons learned and factors that influence research culture from NCI program experience

<table>
<thead>
<tr>
<th>Review</th>
<th>Briefly review clinical trial programs that lie beyond the Consortia within the NCI</th>
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</thead>
<tbody>
<tr>
<td>Assess</td>
<td>Assess site infrastructure/attributes for research</td>
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<tr>
<td>Examine</td>
<td>Discuss strategies to build and support research infrastructure</td>
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DCP has played a significant role in establishing NCI clinical trials networks engaging varied types of sites...community, minority-based, and cancer centers in many national studies, including large prevention trials like STAR for breast and SELECT for prostate.

Experience has shown us that everyone on the team has an important role in creating and supporting the culture of research in your site’s community of practice. Accrual has to be discussed and given time and attention.

The PI is key but so is the newer coordinator! How does the team, engage and create a culture of research....can you draw in and work effectively together?
NCI National Clinical Trials Network (NCTN)

NCI National Clinical Trials Network Structure

LEGEND
- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 30 Lead Academic Participating Sites (LAPS)
- Operations
- Statistics & Data Management
- Tissue Banks
- Member Sites

COG (Pediatric)
ECOG-ACRIN
NRG Oncology
Alliance
Canadian Network Group
SWOG
NCTN Centralized Functions

NCORP Site Participation
Community and Minority-Based Clinical Oncology Programs

Established in 1983 and 1990 respectively

- NCI's initial program supporting increased clinical trial infrastructure and access to cancer clinical trials in community cancer centers.
The NCI Community Cancer Centers Program (NCCCP)
New NCI Program Brings Clinical Research to the Community Setting

NCORP will bring together, and build on the success of, two existing NCI programs: the Community Clinical Oncology Program (CCOP)/Minority-Based Community Clinical Oncology Program (MBCCOP) and the National Cancer Institute’s Community Cancer Centers Program (NCCCP).
The NCI Community Oncology Research Program (NCORP) brings cancer research studies and results to patients in a variety of community settings across the United States.

- **7 Research Bases**
  - Develop and coordinate clinical trials and cancer care research

- **46 Community Sites**
  - To bring NCI approved trials to patients
  - Including

- **900+ Locations**
  - In diverse, community-based hospitals, private practices and more

[NCORP.cancer.gov](http://NCORP.cancer.gov)
Trial Site Minimum Standards for Clinical Research

Compliance with International Conference on Harmonisation (ICH) Good Clinical Practice Guidelines (GCP)
- Defines design, conduct, recording, & reporting of human subjects clinical trials.

Site specific Standard Operating Procedures (SOPs)

Good Clinical Practice training by all investigators and study staff involved in the design and conduct of clinical trials.
Background

“Attributes of Exemplary CT Sites”

Diversification of CT Mix/Portfolio
High accrual activity

Participation in the CT Process (trial input)
Internal QA

Multidisciplinary Involvement
CT Awareness Programs (internal & external)

Formal maintenance of high educational standards
• Board Certification, SOCRA, continuing ed in research

R. Zon, et al., JCO, 2008; JOP, 2011; A. Baer et al., JOP, 2010
The National Cancer Institute–American Society of Clinical Oncology Cancer Trial Accrual Symposium: Summary and Recommendations
Created for community cancer research programs striving to exceed the minimum standards of Good Clinical Practice.
How can this idea of infrastructure assessment be used?

- Program self-assessment, development, and improvement
- Benchmarking program performance and infrastructure
- Program or progress reporting for funders or sponsors
- Planning and communicating with senior leaders about program needs
The CT AIM Tool Attributes

- Quality assurance
- CT portfolio diversity and management
- Physician engagement in CTs
- Participation in the CT process
- Multidisciplinary team involvement
- Education standards
- Accrual activity (includes underserved accrual)
- CT education and community outreach
- CT workload assessment
- Clinical research team/Navigator engagement
**Attribute Example: CT Portfolio Diversity**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Indicator</th>
<th>Pre-Level</th>
<th>Level I</th>
<th>Level II</th>
<th>Level III</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial portfolio phases</td>
<td></td>
<td></td>
<td>In the past year, clinical trial portfolio included active Phase III treatment trials</td>
<td>In the past year, clinical trial portfolio included active Phase III treatment trials and Phase II trials</td>
<td>In the past year, clinical trial portfolio included active Phase III treatment trials, Phase II trials, and either Phase I or Phase I/II trials</td>
<td>None</td>
</tr>
<tr>
<td>Trial portfolio purpose types</td>
<td></td>
<td></td>
<td>In the past year, clinical trial portfolio included cancer treatment and control trials</td>
<td>In the past year, clinical trial portfolio included cancer treatment and control trials, prevention, screening and correlative trials</td>
<td>In the past year, clinical trial portfolio included cancer treatment and control trials, prevention, screening, correlative trials</td>
<td>None</td>
</tr>
<tr>
<td>Trial portfolio disease types</td>
<td></td>
<td></td>
<td>In the past year, clinical trial portfolio included 2-3 disease sites</td>
<td>In the past year, clinical trial portfolio included 4 disease sites</td>
<td>In the past year, clinical trial portfolio included 5 or more disease sites</td>
<td>None</td>
</tr>
<tr>
<td>Trial portfolio review</td>
<td></td>
<td></td>
<td>Clinical trial portfolio diversity was reviewed once in the past year</td>
<td>Clinical trial portfolio diversity was reviewed 2-3 times in the past year</td>
<td>Clinical trial portfolio was reviewed 4 or more times in the past year</td>
<td>None</td>
</tr>
<tr>
<td>Screening log data review</td>
<td></td>
<td></td>
<td>Screening log data was used to assess accrual barriers and the clinical trial portfolio once in the past year</td>
<td>Screening log data was used to assess accrual barriers and the clinical trial portfolio 2-3 times in the past year</td>
<td>Screening log data was used to assess accrual barriers and the clinical trial portfolio 4 or more times in the past year</td>
<td>None</td>
</tr>
</tbody>
</table>
Significant Change in Level III Scoring Over Time for All Attributes Combined (p < 0.0001)

*Significant p-value for change over time (CT Communication, p 0.0281; CT Portfolio, p 0.0228)
Evolution of the CT AIM Tool

• **Expanded Stakeholder input**
  – Community sites
  – ASCO Community Research Forum
  – NCI Advisors cross Division input (DCP, DCTD, DCCPS, CRCHD)

• **Formative Evaluation**
  – Cognitive interviews
  – Principal Investigator/Program Administrator Coordinator pair assessment comparisons
  – Additional field-testing (web-based)
  – Scoring method clarifications
Clinical Trial Assessment of Infrastructure Matrix Tool to Improve the Quality of Research Conduct in the Community

By Eileen P. Dimond, RN, MS, Robin T. Zon, MD, Bryan J. Weiner, PhD, Diane St. Germain, RN, MS, Andrea M. Denicoff, MS, RN, Kandie Dempsey, DBA, MS, RN, Angela C. Carrigan, MPH, Randall W. Teal, MA, Marjorie J. Good, RN, MPH, Worta McCaskill-Stevens, MD, MS, and Stephen S. Grubbs, MD

Michiana Hematology Oncology, South Bend, IN; University of North Carolina (UNC) Chapel Hill; UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC; National Cancer Institute, Bethesda; Leidos Biomedical Research, Frederick National Laboratory for Cancer Research, Frederick, MD; and Helen F. Graham Cancer Center and Research Institute, Newark, DE

Abstract

Purpose: Several publications have described minimum standards and exemplary attributes for clinical trial sites to improve research quality. The National Cancer Institute (NCI) Community Cancer Centers Program (NCCCP) developed the clinical trial Best Practice Matrix tool to facilitate research program improvements through annual self-assessments and benchmarking. The tool identified nine attributes, each with three progressive levels, to score clinical trial infrastructural elements from less to more exemplary. The NCCCP sites correlated tool use with research program improvements, and the NCI pursued a formative evaluation to refine the interpretability and measurability of the tool.

Methods: From 2011 to 2013, 21 NCCCP sites self-assessed their programs with the tool annually. During 2013 to 2014, NCI collaborators conducted a five-step formative evaluation of the matrix tool.

Results: Sites reported significant increases in level-three scores across the original nine attributes combined (P < .001). Two specific attributes exhibited significant change: clinical trial portfolio diversity and management (P = .0228) and clinical trial communication (P = .0281). The formative evaluation led to revisions, including renaming the Best Practice Matrix as the Clinical Trial Assessment of Infrastructure Matrix (CT AIM), expanding infrastructural attributes from nine to 11, clarifying metrics, and developing a new scoring tool.

Conclusion: Broad community input, cognitive interviews, and pilot testing improved the usability and functionality of the tool. Research programs are encouraged to use the CT AIM to assess and improve site infrastructure. Experience within the NCCCP suggests that the CT AIM is useful for improving quality, benchmarking research performance, reporting progress, and communicating program needs with institutional leaders. The tool model may also be useful in disciplines beyond oncology.
There is no one best strategy...
But there are key features of successful CT programs and cultures:

**Physician engagement and outreach**
- Overtly committed and recognized for research efforts
- Educating peers and engaging site leaders (C suite)
- Hiring the right team

**Lead PI/Coordinator relationship**
- Do you strategize on clinic flow, is workload reasonable?
- Talking points for staff to best talk w participants

**Clinical research culture**
- Embedded in site identity?
- Education to do the work well
- Top down/bottom up engagement
- Infrastructure support
- Learning collaborative (across sites)
- Key relationships (pathology, stats, OR staff)
Involvement of the Research Team in Multidisciplinary Team Conferences
Pre-screening and Screening Logs
Reach out
Endoxifen gel vs. placebo in women undergoing breast surgery

Created with the “Mediclub” at Northside College Prep High School in Illinois – a win win for community engagement and increasing trial awareness.
Navigators can introduce the concept of clinical trials

- What is your site's culture around navigators in general and specifically around sharing that clinical research is part of what your center does?
Conclusions

The process of site self-assessment as a research team can potentially improve program function and promote program growth.

CT AIM Tool attributes can continue to evolve to reflect clinical research practice changes and can serve as a model.

A culture of research is created and cultivated over time with dedication and creativity!
Resources/References

• CT AIM Tool
• Exemplary Attributes of CT Sites
• Creating a Culture of Research
• NCI/ASCO Accrual Symposium
• Screening Log
• Accrual Net
• Assessing CT Workload (M. Good)
DISCUSSION
or
QUESTIONS/COMMENTS?