Recruitment Plan: Development & Execution

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MISSION: To improve care of Kentuckians who suffer from cancer. The Network provides innovative clinical trials, support and education to our research centers and scrupulous quality assurance.
Accrual to clinical trials among adult cancer patients is persistently low.

Only 3-5% of adults with cancer participate in clinical trials.

Through collaboration and leadership among member sites, over 2200 patients throughout Kentucky have had access and participated in KCTN clinical trials!
OBJECTIVES/AGENDA

• Discuss Protocol Accrual Lifecycle

• Review tailored recruitment for oncology investigator-initiated trials
  • Processes & resources necessary to conduct a trial
  • Applying metrics to understand recruitment challenges & identify barriers

• Define characteristics of high-performing sites
Protocol Accrual Lifecycle

Developing
Selecting
Recruiting
Implementing
Evaluating
• Consider stakeholder enthusiasm
  – Scientific interest
  – Level of commitment
  – Competing trials

• Evaluate feasibility
  – Availability of study population
  – Burdens to study participants
  – Recruitment strategies

• Choose sites carefully
  – Recruitment histories
  – Available resources (staffing/facilities)
  – Competing trials
  – Scientific interest & site’s thoughts on feasibility
• Evaluate stakeholder commitment, clinical trial portfolio and participant population
• Assess infrastructure and resources
• Create a “Culture of clinical trials”
• Plan internal processes to conduct study
• Write a comprehensive recruitment and retention plan
  – Integrate recruitment plan with institutional activities
  – Determine how to screen and identify participants
  – Prepare site-specific promotional materials
  – Address diverse and underserved populations
  – Include plans for community outreach
  – Set milestones, metrics, goals
  – Determine methods for tracking accrual progress
• Engage intermediaries to aid accrual
• Identify potentially eligible participants
• Engage participants in the Informed Consent Process
• Consider participant perspective
• Maintain the morale and interest of staff, participants, and their families
• Update participants regarding study-related events and results
“Anything that consumes time, effort, and money should be measured.”

- Monitor trial progress and accrual metrics
- Implement alternative recruitment strategies when accrual milestones are not met
- Communicate consistently with stakeholders and referring physicians
• Analyze the trial’s accrual data for lessons learned
• Report and share accrual experience with others
Realistic, targeted strategic recruitment plans, adequately resourced, implemented and adjusted as needed, are necessary to optimize recruitment and ensure that a clinical trial can be successfully completed.

Investigator-Initiated Oncology Trials:
• Observational
• Therapeutic
TITLE: Attitudes Towards Participation in Clinical Trials Before and After an Educational Session (CARES)

OVERVIEW: Survey procedures used to measure existing attitudes towards clinical trials and determine if an educational session has an effect on these attitudes. Evaluate differences between two participant cohorts.

STUDY POPULATION: ~200 adults
Cohort 1: Cancer patients (receiving treatment or follow-up for cancer)
Cohort 2: Community volunteers (without cancer diagnosis)

STUDY PROCEDURES: Participants attend an educational session. Complete survey before and after session. Participants self-report cancer status based on response to survey question.
Developing:
• Engage patients and caregivers who visit oncology offices as well as internal departments/community groups.
• Study materials (flyers/posters).
• Address burdens to participant.

Selecting: Site Feasibility/Site-Specific Recruitment Plans and Posters
*SITES: 6 KCTN sites selected to participate*

Recruiting:
• Identify and engage participants, caregivers, internal departments, community groups
• Pre-Screen with session specifics
• Reminders the day before
Implementing: Disproportionate accrual with Cohort 2 (community volunteers) 135 to Cohort 1 (cancer patients) 25.

Actions:
1. Cohort 2 closed to accrual.
2. Pre-screen revised to identify Cohort 1 participants.
3. Session time to accommodate patient appointments/clinical operations.
4. Lunch-N-Learn to enhance clinical staff engagement.
5. Additional coordinator recruitment efforts in clinics.

Evaluating:
• Intrinsic and external factors appeared to impact Cohort 1 (cancer patients) attendance more so than community volunteers.
• Patients being “followed for cancer” did not necessarily identify as having cancer.
• Sites welcomed additional support to educate/engage clinical staff in research.
Optimization of Smoking Cessation Strategies Concurrent with Treatment of Tobacco Related Malignancies (MOST Cessation)

BACKGROUND: Smoking Cessation has been shown to:

• Improve the effectiveness of cancer treatment in head and neck cancer, and lung cancer.
• Reduce complications from treatment.
• Reduce the risk of secondary primary tumors that affect patients treated for lung and head and neck cancer.

OVERVIEW: Therapeutic trial assessing the efficacy of smoking cessation strategies for patients receiving treatment for tobacco-related malignancies. All treatments recognized as Standard of Care by US Health & Human Services.

STUDY DESIGN: Based on MOST framework, each patient randomized to receive a combination of each of the following: Counseling, Drug Therapy, and Nicotine Replacement Therapy.

STUDY POPULATION: 180 participants with newly diagnosed or recurrent tobacco-related malignancy
Developing:
- Study Design
- Patient Perspective
- Study materials
  - Flyers/posters
  - Fast Facts
  - Video

**GOAL:** Initiate smoking cessation interventions in conjunction with treatment for cancer
Selecting:

- Site Feasibility
  - Stakeholder commitment
  - Patient population
  - Site team
  - Site Smoking Cessation Processes/Protocols

- Site Recruitment Plan
  - What is your process to identify participants?
  - How is research integrated into clinic?
  - Describe Communications/Outreach?
  - Set milestones, metrics, goals
  - Determine methods for tracking accrual progress

Cancer Diagnosis
- Primary Care, Pulmonology, or Other Provider
- Physical Exam
- Biopsy

Staging
- Imaging Studies (x-rays, CT scans, etc...)
- Laboratory Tests
- Pathologic Assessment

Surgery, if applicable
Oncology Consultation
Treatment Starts
- Radiation Therapy
- Chemotherapy

MOST Introduction
SITES: 9 KCTN/MCCRN sites in KY/WV selected to participate

- Engage intermediaries to aid accrual
- Identify potentially eligible participants
- Engage participants in the Informed Consent Process
- Consider participant perspective
- Maintain the morale and interest of staff, participants, and their families
- Update participants regarding study-related events and results
Identify Participant

Present Study

Consent/Enroll
Present Study

- Passion of PI/Sub-I to introduce study
  - Lays the foundation for a *positive* conversation with coordinator

- Team approach
  - *Cohesiveness* between PI/Study Coordinator

*PI is a champion for smoking cessation... and research!*
- Patient-Centered Approach
  - Establish rapport
  - Flexibility/Convenience
- Tools to assist in following patients
- Resistance to smoking cessation (not study)
  - PI/Clinical Staff Engagement
“Metrics should be used to monitor progress... or lack of progress.”
Screening Outcomes – Site A

- Enrolled: 36%
- Patient Decline: 23%
- Ineligible: 41%

*As of 12Aug2016*
50% of patients started treatment prior to study introduction or stopped smoking closer to cancer diagnosis
Per Feasibility: Projected Accrual 35
Lung cancer 132 (87% smokers)
H&N 108 (69% smokers)

*As of 10 Jul 2015
• Analyze the trial’s accrual data for lessons learned
• Report and share accrual experience with others
• Coordinator Effort
  • Time: Allocated for schedule/chart review
  • Organization: Tools to facilitate screening
  • Follow-Through: Ticklers/Reminders

• Organizational Culture
  • Passion of Investigator
  • Integration of Technology
  • Coordinator Proximity
  • Research Presence/Visibility
  • Clinical Staff Engagement

• Study Promotion
  • Posters/flyers/video/sticky pads/clips
  • Tumor Board
What makes sites successful?

Experience + Availability + Patient Access = High Performing Site
What makes sites successful?
Every patient, every time!
KCTN Coordinating Center:

Tim Mullett, MD, FACS
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Director

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