SITE SELECTION STRATEGIES

Presented on February 8, 2012 by:
Jennifer Sharpe Potter, PhD, MPH
Ro Shauna Rothwell, PhD

Produced by: Liz Butler, NIDA CTN CCC Training Office
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Discussion outline:

• Importance of Establishing site selection criteria
• Coordinating site selection efforts among Lead Team members
• Recommendations for site selection process

ESTABLISHING SITE SELECTION CRITERIA
Increased Average Trial Costs

- Potential Contributing Factors
  - Lack of completion plan
  - Quantity and Suitability of available sites
  - Study complexity
    - Assessment burden
  - Over extension of productive sites
  - Under performing
  - Other

Site Selection Importance

Selection - carefully choosing someone or something as being the best or most suitable

- Site selection in CTN studies has changed over time
- Assumption that a structured site selection process will improve trial performance
- We learn as we go...

Site Selection Impacts

- Site selection impacts:
  - Recruitment and retention of trial participants
  - Timelines
  - Finances
  - Effective, high-quality study implementation
Contributing Site Selection Factors

- Population Needed
- Institutional and Stakeholder Support
- Site Capabilities
- Oversight and Etching
- Site Resources & Limitations
- Cost Share Obligations

Driven by Protocol Design

Determining “Non Negotiable” items

- Evaluate
  - Investigator
    - Qualifications
    - Proximity
  - Research staff
    - What type are needed (counselor, phlebotomist)
  - Research site
    - Accessory facilities (local lab, pharmacy)
  - System as a whole (Time and Events Table)

Site Selection from the Lead Team Perspective (“Making the right choice”)

Lead Team

- Establish a list of non-negotiable items
- Short term interests vs. Long term interests
- Prioritizing protocol needs
  - Staffing
  - Facility
  - Regulatory
- Time & events table (Logistics of achieving study goals)
Contributing Site Selection Factors

Population

• Availability of study population is paramount
• High cost for recruitment challenges
  — Evaluate and demonstrate recruitment capability
  — Engage in the necessary outreach to obtain the target population
• Protocol Design is a big factor
  — Inclusion/exclusion criteria
    • It may pose as a difficulty to some sites recruitment efforts even if the site seems like a good fit
  — Assessment burden

Words of caution

Beware of assumptions!
• B/c good at one study doesn’t mean they are a sure thing for the next study
  — POPULATION availability is huge

Contributing Site Selection Factors

Site Capabilities

• Program’s existing patient population
• Media advertising efforts
• Community recruitment sources
• Program initiative and creativity
  — locate and access to potential participants
• Adhere to timelines and study expectations
• Efficiency
• Regulatory compliance
### Contributing Site Selection Factors

#### Site Resources and Limitations

- Pharmacy
- Local Laboratories
- Number of IRB involved
- Site types
  - VA sites
  - Non profit sites
  - Government sites

#### Oversight and Staffing

- Lead Team and Potential Site Communication is essential for research collaboration as the study moves forward
- Open dialog about expectations, challenges and resources
- Site self assessment is critical
  - Sites review and evaluate their own capabilities
- Organization climate (readiness to engage in new technologies)
- Lead Team proximity to site may impact support

#### Current Site Obligations

- Current Participation in other studies with similar inclusion/exclusion criteria
- Upcoming activities
Contributing Site Selection Factors
Institutional Support

- Institutional support for research and evidence-based practice
- Interference with funding and Standard of Care

Selection Survey Domains and Key Questions:
CTN STAGE-12 & POATS Site Selection Surveys

<table>
<thead>
<tr>
<th>STAGE-12</th>
<th>POATS</th>
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<td>Site program/policy Are there any upcoming changes to policy or procedure changes that could negatively impact the stability of the center or participation in the trial? Did any past or these changes negatively impact the stability of the center or participation in the trial?</td>
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<td>Walk through the intake process from first contact to intake to the intake process is for someone who needs substantial intervention in the range of 15-30 hours per week. Does this intake reflect a single clinic or multiple clinics? If so, how many?</td>
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CTN STAGE-12 & POATS Site Selection Surveys

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<tr>
<td>Facility</td>
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<td>Will you be considering any prior studies held during the course of this study?</td>
<td>Yes, will this study compete for participants?</td>
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<td>Is the proposed budget sufficient enough to support the study at your site?</td>
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<td>Is there a need to locate the participants to see them on a separate computer and internet backlash?</td>
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<td>How many rooms for staff from the SBC, CUG, or RA/SC staff (i.e., office space and treatment rooms)?</td>
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<tr>
<td>Will enough space are you have for study procedures (i.e., a separate office space and treatment rooms)?</td>
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CTN STAGE-12 & POATS Site Selection Surveys

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<td>Staff1</td>
<td>Research staff:</td>
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<td>does office have the PI for the study?</td>
<td>What experience does the PI have in clinical trial research?</td>
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<tr>
<td>What kind of staff does the office have in the area of research?</td>
<td>How many years of experience does the PI have in the area of research?</td>
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<tr>
<td>Does the office have access to the Data and Safety Monitoring Board?</td>
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<tr>
<td>How many therapists do you have in your facility?</td>
<td>Provide details on the access to the Data and Safety Monitoring Board.</td>
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<td>What kind of training would you participating in clinical trials have your therapists?</td>
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<tr>
<td>Will you have additional therapists in the same facility?</td>
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<tr>
<td>Nurse staff</td>
<td>Support staff:</td>
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<tr>
<td>What experience have your RNs provided to your site during the course of the study?</td>
<td>How many therapists do you have in your facility?</td>
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<td>How many personnel, on average, do you have participating in clinical trials this year?</td>
<td>How many years of experience does the PI have in the area of research?</td>
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<td>How many are you expected to participate in clinical trials this year?</td>
<td>Information not requested.</td>
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COORDINATING SITE SELECTION EFFORTS
AMONG LEAD TEAM MEMBERS
Clinical Trial – Pre-Implementation Phase

Where it starts
- NIDA/PRB/IRB Approval (target date)
- Sites Selected (target date)
- Ntnl Trng (target date)
- Sites Endorsed (target date)
- Participant randomized (12-18 after NIDA/PRB/IRB Approval)
- Last Participant’s last visit (data/date)
- Data Lock (data/date)

What it impacts
- Where it starts
- What it impacts

The Causes of the “Kink in the Chain”

- Site (points to ponder before completing the selection survey)
  - Establish realistic capabilities with
    - IRB timelines
    - Staffing
    - Facilities
    - Local regulations

Site Selection Process

Getting started

- Lead Team (Project director, and CPC, CCC, DSC representatives, Lead Node personnel)
  - CCTN & DSMB Approved Site Selection Plan
    (see current CTN Policy and Procedure Guide)
  - Summarize Site requirements
  - Prepare site selection survey
  - Distribute to CTN nodes
    - Forward survey to potential site candidates
  - Sites complete survey for LT consideration
Survey Completion
An opportunity for reflection – verification of fit

• Validate Enrollment Potential
  – If there are doubts about treatment population
    search your site database or logs for admittance
    records that fit the description
  – What are the expected screen failure ratios?
  – Are screen fail ratios comparable to your research
    site enrollment facts?
  – Are there other studies in your institution that
    would compete with the study recruitment at
    your site?

Survey Completion
An opportunity for reflection – verification of fit

• Protocol Considerations
  – Do you have experience with treatment model or
    therapeutic intervention being tested?
  – Do you have previous experience with Lead
    Investigator/Node (Good or Bad)?
  – Are follow up visits reasonable or acceptable? (i.e.
    unrealistic, too frequent)?
  – Are the procedures described in the protocol
    consistent with facility standard of care?
  – Do the procedures described in the protocol
    contradict and/or compromise other funding at your
    facility?

Survey Completion
An opportunity for reflection – verification of fit

• Population Requirements
  – Addressing and providing current trends
  – Avoiding and addressing population drifts
  – Impact on protocol performance
Survey Completion

An opportunity for reflection – verification of fit

- Staff Requirements
  - Consider ancillary staff needs (i.e. pharmacy, local labs)
  - Is there adequate and appropriate support for the trial PI (Sub-investigators)
  - Do you have to hire a substantial amount of staff to conduct the study
    - What is your institutional institution requisition process in relation to the study start timeline?

Survey Completion

An opportunity for reflection – verification of fit

- Facility
  - Adequate Office/clinic space available (i.e. monitoring space, consenting area, require equipment like EKG)
  - Internet/computer access

- Supplies
  - What supplies will be provided by the CCC and the Lead Node?
  - What supplies need to be provided by the research site? Is this feasible for your facility?

Recommended Site Selection Process

Elimination round #1
Lead Team evaluates site survey responses

Elimination round #2
Lead Team holds conference call

Qualification visits determine finalists

Lead Team determines and submits list of final sites selected to the Executive Committee (EC) for review and approval

Lead Nodes announces selection upon EC approval
Site Qualification Visits

• Purpose
  – Determine site ability to conduct the research
  – Site verifies adequate staff, training, education, experience and resources
    • Demonstrate an enthusiasm, capabilities, & readiness
• Structure conducted by the Lead Node (or designee)
  – Facility tour
  – Meet site staff (if available)
  – Discuss and review outstanding tasks
  – Q & A

RECOMMENDATIONS FOR SITE SELECTION PROCESS

Discussing Blinded Site Selection

• Decision based upon facts
  – A look at site raw numbers without the knowledge of accessory information such as node affiliation or specific site staff information
  – Provides anonymity to unknown sites and puts them on a level playing field with well known sites
  – Effective method of site selection
Site Selection Strategies: Investigator Perspectives

- Utilizing national epidemiologic and other existing data
- Review of clinic administrative data
- Collecting prospective data for unique or challenging study population

RECOMMENDATIONS FOR SITE SELECTION PROCESS

Site Selection from the Site Perspective

Site
- Complete Site Selection Surveys
- Appropriate staffing capacity
- Pending policy changes
- Able to handle the tasks of the protocol
  - Current participation in trials that compete with Eligibility criteria
    - CTN & Non-CTN Studies
  - Appropriate
    - facility
    - licenses/registrations
Provide Performance Metrics

Disclosure of site performance expectations

- Key elements of the performance address:
  - Alignment with Study Mission (outcomes)
  - Cost Reduction and/or Protection
  - Risk Management Plan
    - Study and site level
  - Meeting Regulations/Requirements
  - Quality of Study Conduct/Processes
  - Timeline Adherence
  - Buy-in and Engagement
    - Staff
    - Institution
    - Node
    - Participant Engagement

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Potter, Jennifer Sharpe; Donovan, Dennis M.; Weiss, Roger D.; Gardin, John G.; Lindblad, Robert; Wakim, Paul G.; Dodd, Dorian

Upcoming Webinars

<table>
<thead>
<tr>
<th>DATE</th>
<th>WEBINARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEB 29</td>
<td>Getting Started with Social Media</td>
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<tr>
<td>MAY 9</td>
<td>Managing Emotions in Recovery</td>
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<tr>
<td>JUN 13</td>
<td>Biological Measures &amp; Specimen Handling</td>
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<tr>
<td>JUL 18</td>
<td>Co-occurring Disorders: Integrated Treatment of Addiction and Mood and Anxiety Disorders</td>
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<tr>
<td>AUG 15</td>
<td>Personality Disorders and Addiction</td>
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<tr>
<td>SEPT 19</td>
<td>Build Your Team for Research Success</td>
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<tr>
<td>OCT 24</td>
<td>Managing Safety &amp; Crisis Situations</td>
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<tr>
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<td>Practical Statistical Reasoning in Clinical Trials for Non-Statisticians</td>
</tr>
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