2012
Web Seminar Series

SITE SELECTION STRATEGIES

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

Produced by: Liz Buttrey, 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

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ESTABLISHING SITE SELECTION CRITERIA

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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

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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…

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Site Selection Impacts

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

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Contributing Site Selection Factors

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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)*

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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)

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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

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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

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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

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Contributing Site Selection Factors Site Resources and Limitations

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

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Contributing Site Selection Factors 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

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Contributing Site Selection Factors 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

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

	STAGE-12	POATS
Instructions	Programs were asked to provide this information for a 6-month period by admissions per month	Programs were asked to provide site information, administrative data, and collect patient information on key eligibility criteria prospective for 30 days
Site program/policy	Are there any upcoming changes to policy or resource changes that could negatively impact the stability of the center or participation in the STAGE-12 protocol?	Are there any upcoming changes to policy or resource changes that could negatively impact the stability of the program or participation in the POATS?
	Walk through the intake process from first contact to beginning treatment Describe your current treatment schedule for someone who needs outpatient services in the range of 5-15 hours per week	Does this information reflect a single clinic or multiple clinics? If multiple, how many sites?
	Describe how your program incorporates 12- step programs into therapy? What are your community resources for 12-step meetings? Do you have self-help group meetings? Are there many of them/enough?	Does your CTP work with ERs and/or primary care clinics? (Please include both on-site and off-site facilities.) If yes, how many referrals do you receive from the following per month? •Pain clinics •Surgery clinics •Emergency rooms •Primary care clinics For each, how many of these referrals are chronic pain patients?

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

	STAGE-12	POATS
Study Participant Population	Please provide the total number of patients and the number of stimulant abusers admitted to outpatient treatment, providing 5-15 hours per week, who are not being provided housing as part of the treatment program	How many opiate-dependent patients did your facility admit during the prospective time period? •How did you collect this information?
	What is the number of patients currently enrolled in your program receiving 5-15 hours per week?	How many of those patients also meet ALL of the following criteria? •NO lifetime history of heroin injection •NO lifetime history of heroin dependence •In the last 30 days, 4 days or less of heroin use
	What will you do if you are unable to meet the enrollment requirements of the study through your usual patient flow?	How many of these patients, who did not meet the three criteria described above; how many did not because of the following: •Lifetime history of heroin injection •Lifetime history of heroin dependence •In the last 30 days, 5 or MORE days of heroin use •In the last 30 days, 4 days or less of heroin use
	In past studies, have you had to advertise for participants? What methods did you use?	

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

	STAGE-12	POATS
Facility	Will you be conducting any other clinical trials during the course of this study? •If yes, will this study compete for participants?	Are there ongoing or planned trials that would compete with this study for research participants? If yes, please specify
	Is the proposed budget (attached) enough to run the study at your site?	
	Do you have a place to allow the patient to do the assessments with a separate computer and Internet hookup?	
	Do you have room for staff from the DSC, CCC, and Nodes visits possibly lasting more than 1 day?	
	What kind of space do you have for study procedures (i.e. RA/SC office space and treatment rooms)?	

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

	STAGE-12	POATS
Staff	Research staff: Who will be the Site PI for the study? What experience does the PI have in clinical trials research? Will you have the resources to hire and employ research staff this summer? Does the site have an experiences RA or SC available to help with the study?	Does your facility have physicians with buprenorphine experience available to treat study patients with buprenorphine over a 2-year period? If yes, how many?
	Therapeutic staff How many therapists do you have in your facility? What kind of burden could participating in this trial have on your therapist staffing? Do you have an idea on the interest level of your staff to participate in this trial?	Provide details for up to three physicians available for the trial, including for each: usage type (detoxification, maintenance, or both), months of buprenorphine experience, prior drug trial experience
	Node staff What services will your RRTC provide to your site during the course of the study?	Does your facility have staff to provide weekly individual counseling? If yes, how many counselors are available?
IRB	How long has it taken, on average, to get a protocol through your IRB for approval? How many IRBs do you need to go through (i.e. Node, CTP, etc.)?	Information not requested

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COORDINATING SITE SELECTION EFFORTS AMONG LEAD TEAM MEMBERS

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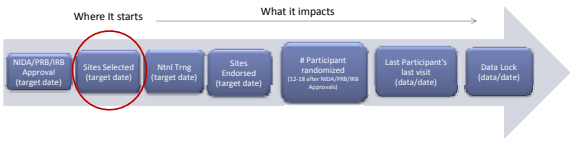
Clinical Trial – Pre-Implementation Phase



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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

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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

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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?

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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?

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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

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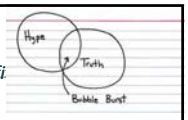
Survey Completion

An opportunity for reflection – verification of fi



- 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?

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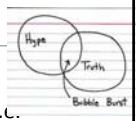
Survey Completion

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?

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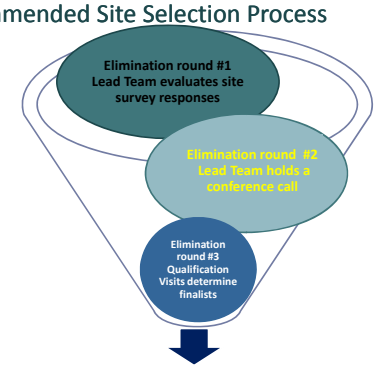
Recommended Site Selection Process



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

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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

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RECOMMENDATIONS FOR SITE SELECTION PROCESS

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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

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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

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RECOMMENDATIONS FOR SITE SELECTION PROCESS

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Site Selection from the Site Perspective

"STAND OUT"

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

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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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A copy of this article and this presentation is available from the Dissemination Library

http://ctndisseminationlibrary.org

Site Selection in Community-Based Clinical Trials for Substance Use Disorders: Strategies for Effective Site Selection.
American Journal of Drug and Alcohol Abuse 2011;37(5):400-407.
[doi: 10.3109/00952990.2011.596975].
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Upcoming Webinars

DATE	WEBINARS
FEB 29	Getting Started with Social Media
MAY 9	Managing Emotions in Recovery
JUN 13	Biological Measures & Specimen Handling
JUL 18	Co-occurring Disorders: Integrated Treatment of Addiction and Mood and Anxiety Disorders
AUG 15	Personality Disorders and Addiction
SEPT 19	Build Your Team for Research Success
OCT 24	Managing Safety & Crisis Situations
NOV 14	Practical Statistical Reasoning in Clinical Trials for Non-Statisticians
DEC 19	Helping Patients with Substance Use Disorders and Pain

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