Tracking and Monitoring Trial Progress in NIDA CTN Studies

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Abstract

The National Drug Abuse Treatment Clinical Trials Network (CTN), established by the National Institute on Drug Abuse (NIDA), conducts research to provide a broad and powerful infrastructure for rapid, multi-site testing of promising science-based therapies and the subsequent delivery of these treatments to patients in community-based treatment. A comprehensive set of reports has been developed to use as a management tool to effectively monitor the progress of on-going clinical trials. These reports track the progress of each protocol within the CTN from the date of first enrollment/randomization to final closeout and publication of main results. The content includes areas from all aspects of the clinical trials: source of referral, recruitment rates, CONSORT flow diagram, participant's disposition, tracking and attendance of study participants and post-trial communication. These reports provide both a big-picture view of the NIDA CTN protocols and a very detailed view to meet the needs of the varied audience, which include:

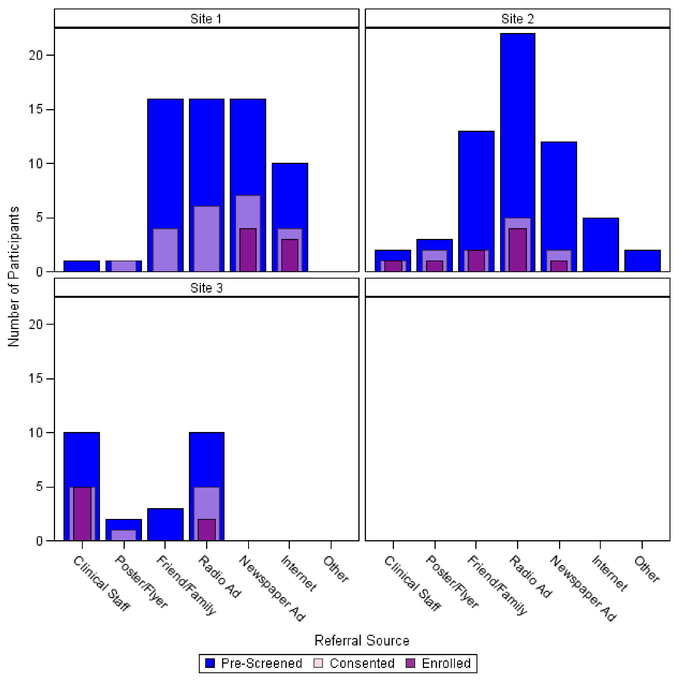
•The sponsor and study leadership to assess the overall progress of multiple on-going protocols.
•The protocol lead teams to monitor their respective protocols in order to identify areas of concern on an individual site level.
•The investigators and staff at each participating community treatment program (CTP) within a protocol to monitor their individual site's performance against other sites.

In this poster, these strategies for tracking and monitoring clinical trial participation and post-trial communication will be presented in the context of a CTN clinical trial.

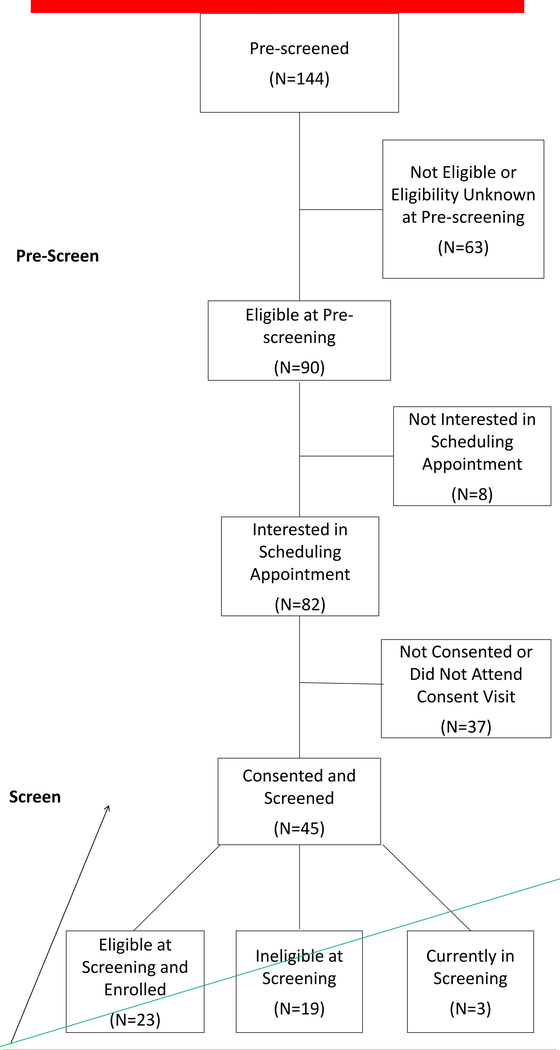
Example of a CTN Study

•A 2-stage, 3 site, single arm study to investigate the effectiveness and safety of a "treatment" as potential pharmacotherapy for methamphetamine disorder.
•Stage 1 will include 20 participants. If stage 1 data documents success in at least 3 "responder" study participants, then stage 2 will include 29 additional participants.
•**Responder**: Participants who provide at least 6 MA-negative urine drug screen (UDS) tests during the last four-weeks of the active medication phase (weeks 5 – 8), including a MA-negative UDS test at the last clinic visit in week 8.
•Following are the examples of reports for this study.
•No real study data are presented in this poster. Data are made up for the purposes of the presentation.

Source of Referral



CONSORT

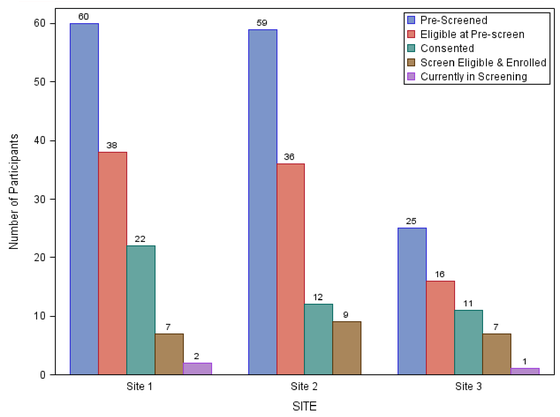


How is the study doing in terms of enrollment? Why were only 23 participants enrolled in the study out of 144 pre-screened? Is this low for this population?

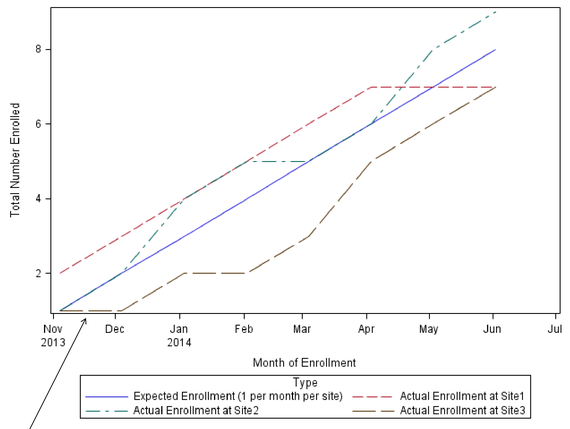
What are the participants sources of referral to the study? Why have Sites 1 and 2 benefited in enrollment because of newspaper and internet advertisements, but not Site 3? Is Site 3 advertising in the newspaper and on the internet or not?

Why Site 3 is pre-screening fewer participants compared to Sites 1 and 2, but the number of enrollments are similar?

Participant's Disposition



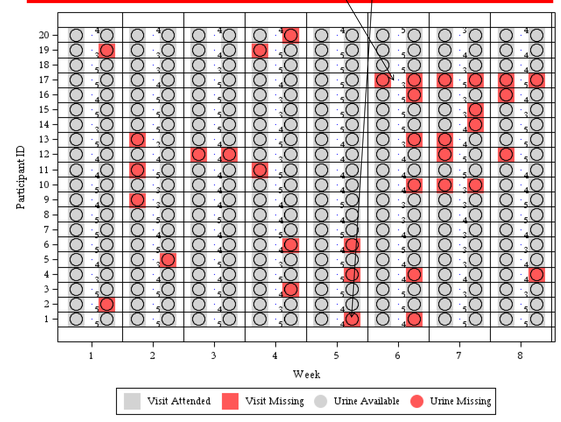
Expected vs Actual Enrollment



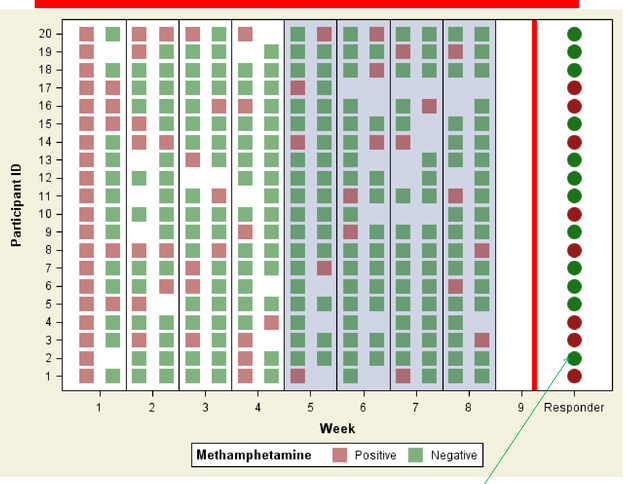
Each site was expected to enroll 1 participant per month (solid blue line). Why is Site 3 consistently enrolling less than expected whereas Site 2 is performing at least as expected and sometimes better? Site 3 has only pre-screened 25 participants (see participant's disposition plot). Could they improve their enrollment rate if they advertised better using newspaper and internet advertisements?

How are attendance and compliance for each participant during the study visits? Each row represents a participant. Each participant is expected to come for 2 visits/week (square), provide 2 UDS/week (circle), and provide 5 self-administration of medication videos per week (numbers in the plot). For example, participant 1 came for all the visits and provided all UDSs except two (one each in weeks 5 and 6). In these weeks, this participant provided 1 less self-administration of medication video. Did participant 17 drop out of the study during week 6? If yes, then how is that participant able to provide the videos? Is this a data entry error?

Visit Tracking and Attendance Info



Results (Fake Data)



What was the result of stage 1? Was it a success? Out of 20 participants enrolled in stage 1, 11 participants were "responders." Participant 1 was not a responder (red circle) whereas participant 2 was a responder (green circle).

Summary

•Reports for tracking and monitoring clinical trial participation and post-trial communication are presented. These types of reports are generated for multiple protocols associated with the National Drug Abuse Treatment Clinical Trials Network. An example of one study is presented in this poster.

•Graphical presentations of participant-level data work well for studies with smaller sample sizes like the study presented here. Larger studies will need to rely more on summary-level data presentations.

•These reports are effective in examining site differences across sites in important study activities like screening, randomizations, and follow-up.

•When developing reports, it is important to consider which reports during study conduct should be broadly shared with Investigators (like source of referral), and which ones should remain limited to internal review only (like study results).

Point of Contact

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