CLINICAL TRIALS NETWORK (CTN)
TREATMENT EFFECT & ASSESSMENT MEASURES (TEAM) TASK FORCE
RECOMMENDATIONS

(Approved by the CTN Steering Committee on 4/20/2010)

Executive Summary

In November 2008, the CTN Executive Committee approved the formation of an ad hoc task force to address two goals and make a recommendation to the CTN Steering Committee. This document represents the task force's recommendation. (Members of the TEAM Task Force are listed at the end of this document, just before *References*.)

Goal 1:
To recommend a definition for a clinically meaningful outcome on drug use to be used in CTN clinical trials, and a method to capture that outcome.

Recommendation:
If the trial's primary outcome is drug use, it is recommended that it be the number of days of drug use during the last 30 days of the active treatment phase, based on self-report corroborated with qualitative urine drug screening tests. Even if this primary outcome is not used, it is recommended that this information be collected for future cross-study analyses.

In addition to capturing drug use, it is important to evaluate consequences of drug use. Lead Investigators are encouraged to consider two co-primary outcomes: one that captures drug use as defined above, and another that captures well being, functioning, satisfaction, or quality of life. One disadvantage to having 2 co-primary outcomes is the statistical penalty, which increases the sample size, and therefore cost. Alternatively, these measures of consequences can be considered as secondary outcomes.

Goal 2:
To develop a set of key questions that would be common across CTN trials.

Recommendation:
The recommendation is for CTN trials to use the following questions and instruments, realizing that in a few rare cases, some of these questions/assessments will be inappropriate, and therefore would not be used:
1. Timeline Follow-back
2. A standardized qualitative Urine Drug Screening test

3. A standardized demographics form (see Appendix B)
4. The CTN Addiction Severity Index (ASI) Lite (version 10/24/2000) (see Appendix C)
5. A question on primary drug of use
6. A question on age of first use (onset)
7. The World Health Organization's Quality of Life BREF instrument (see Appendix D)

In addition to the above common assessments/questions, treatment retention and functioning were also considered important, but not enough to warrant inclusion in all CTN trials.

Background

As a follow-up to the *Lessons Learned Workshop* at the CTN Steering Committee face-to-face meetings (October 21-23, 2008), the CTN Executive Committee approved during its November 3, 2008 conference call the formation of a CTN Task Force:

1. To recommend a definition for a clinically meaningful outcome on drug use to be used in CTN clinical trials. The outcome needs to be simple, understandable to clinicians and clinically relevant. Also, to recommend a method to capture the outcome. (The goal is *not* to define what is a clinically meaningful difference that makes Treatment A better than Treatment B.)
2. To recommend a set of key questions/instruments that would be common across CTN trials. Demographics and primary drug of use are examples of what could be asked in all future CTN trials.

The CTN Executive Committee asked that the Task Force present its recommendations at the fall 2009 CTN Steering Committee face-to-face meeting. The plan is that the Task Force would disband once the task is completed.

On October 22, 2009, the TEAM Task Force reported its recommendation to the CTN Steering Committee. The Task Force also reported that because of lack of time, it was not able to complete its recommendation on a most appropriate Quality of Life instrument. At that meeting, the Steering Committee requested that the TEAM Task Force (1) complete the Quality-of-Life recommendation; (2) work with the Data and Statistics Center to implement standardization of forms; and (3) report back at the next Steering Committee meeting.

Goal 1 – Primary Outcome

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In addition to capturing drug use, it is important to evaluate consequences of drug use. Lead Investigators are encouraged to consider two co-primary outcomes: one that captures drug use as defined above, and another that captures well being, functioning, satisfaction, or quality of life. One disadvantage to having 2 co-primary outcomes is the statistical penalty, which increases the sample size, and therefore cost. Alternatively, these measures of consequences can be considered as secondary outcomes.

Discussion of Recommendation

Examples of outcome measures that were considered are: abstinence, days of use, time to relapse, severity of relapse, effects of relapse, employment, family functioning, legal problems, acceptability & adherence with treatment, engagement in mutual support programs (recovery), amount of drugs used (severity), methods of use (risk factors such as IV), completion of treatment, and return to treatment (retention). Although it is important to consider domains other than drug use, most CTN trials should remain focused on drug use in terms of their primary outcome.

The primary outcome should also be capable of determining whether a drug was used by the participant for each day during a prescribed period within the study. It is best to determine each day's use by a combination of objective (e.g. urine test) and less objective (e.g. self-report) assessments.

Although complete abstinence is the gold standard, it is virtually impossible to detect for certain all episodes of use for drugs such as cocaine. Reduction in drug use, which is more likely to be detectable, is the silver standard. Drug use reduction is considered as improvement, which may not be reflected in the proportion of complete abstinence. Drug use reduction is also a more practical and realistic goal for the relatively short-term clinical trials typically conducted in the CTN.

How to measure reduction in drug use?

Self-reported drug use administered via Timeline Follow Back or Substance Use Calendar, *and* corroborated with biological measures is the best approach currently available. Although each of self-report and objective biological measures has its own

caveats, they, in combination, reinforce each other: self-report is more precise in terms of providing day-by-day information, and biological measures are more objective and keep participants "more honest" in their self-report.

Which time period should the primary outcome cover?

The focus should be on the last 30 days of the active treatment phase for the following reasons:

- Treatment groups are fairly similar during the time period immediately following randomization, and so including the early part of the active treatment phase in the primary outcome may dilute the treatment effect.
- On the other hand, including any time period *after* the active treatment phase may be problematic in terms of study drop-out rates, which tend to accelerate once treatment ends.
- A time period shorter than 30 days may be too short to produce a robust measure of drug use; and a time period longer than 30 days may start too early to reflect a difference between the treatment arms.
- Drug use during the last 30 days is consistent with the information captured in the Addiction Severity Index ("past 30 days") and SAMHSA's National Survey on Drug Use and Health ("past month") – two widely used and recognized tools in the drug abuse field.

If the active treatment phase is shorter than 30 days, it is recommended that the full treatment phase period be used.

Which biological measure to use?

The vast majority of CTN trials should use qualitative urine drug screening tests. In exceptional cases, deviation from this default recommendation will be necessary. In such cases, alternative options may be used, such us sweat patch, breath analysis (for alcohol or carbon monoxide), quantitative blood and urine tests (for various substances), saliva or hair.

The frequency of urine drug screening tests should be a minimum of twice per week during the last 30 days of the active treatment phase, and a minimum of once per week prior to the last 30 days of the active treatment phase. This is considered to be a practical solution, particularly when participants are typically scheduled to come to the clinic only once a week. In addition, it allows RAs and participants to "practice" the urine test procedure before the last-30-day phase of treatment. Not collecting any urine prior to the last 30 days may create a drastic change in assessing drug use between the prior-to-30-day period and the 30-day period. This drastic change may create unintended consequences in terms of participants' behavior and/or biases for the trial.

How to combine biological measures with self-report?

On days with no urine drug screening (UDS) test, drug use is generally based on self-report. However, when both self-reports and UDS are available, the TEAM Task Force recommends an algorithm that takes into account self-reports from the 2 days prior to the urine drug screening test day. For example, if a participant says that he did not use on Monday, and his urine test administered on Monday was positive, then self-reports from both Sunday and Saturday are examined. If he self-reported that he used on either one of those days, say on Saturday, then the Monday positive urine test is attributed to Saturday's use, and Monday is considered as "no use" based on the self-report. A few additional examples are shown in Appendix A.

The Task Force does not have a recommendation about whether the participant should be challenged in a friendly, non-confrontational way when UDS results and self-reports do not agree. Some believe that it increases accuracy, while others believe that the two results should be kept independent and combined using an objective algorithm such as the one shown in Appendix A. This issue is mentioned here to remind lead investigators to consider the options.

How to operationalize "drug use during the last 30 days"?

The main objective is to avoid asking participants to come back to the clinic a few days *after* their last treatment session in order to cover the "last 30 days of the active treatment phase".

The recommended solution is to define the last contact with the participant during the treatment phase as "the end of the active treatment phase", i.e. as Day 30, and work backwards to determine DAY 1, as long as Day 30 is within the time window for the last session of the active treatment phase (as defined by the protocol). For example, if the active treatment phase is 8 weeks long, and the time window for the last session is any day on Week 8, then Day 30 is the day of the last treatment session during Week 8, whichever day it is. If, however, a participant drops out of the study on Week 6, then a portion of the last 30 days would be considered as missing, and that participant's primary outcome would follow the rule of how missing data are handled.

Further details on how to operationalize urine testing and self-report are left to the Lead Investigator. The goal should be to organize these key data collection procedures in such a way to minimize the possibility of having undetected use.

How does "drug use during the last 30 days" affect analysis strategy?

The recommendation of using the number of drug use days in the last 30 days of treatment is not meant to suggest a specific analysis strategy. The investigative team is free to choose a direct model of predicting the days of use in the last 30 days of

treatment as a function of treatment assignment. The team may also choose to embed drug use in the last 30 days of treatment into a larger repeated-measures model. The difference between treatment arms during the last 30 days of treatment can be specified as a specific contrast within the framework of the repeated measures model. Under most circumstances, the repeated measures approach would give a more powerful test of the difference than the simple model. Either approach to analysis could be specified to include baseline or historical levels of drug use as a control variable.

How to handle missing data?

Although this question was not a focus of the TEAM Task Force, a few suggestions are provided.

The recommendation above on how to operationalize drug use during the last 30 days is based on a full set of 30 non-missing days. Alternatively, ad hoc rules can be implemented that impute a few missing days within the block of 30 days. For example, an imputation rule could be to use multiple imputation methods or the expectation-maximization (EM) algorithm to impute missing days, but only if 5 or fewer days out of 30 are missing. Otherwise, the whole block of 30 days is considered as missing. One should keep in mind that an assumption underlying imputation methods is that the missing data are "missing at random". This assumption may not be reasonable considering the data that are collected as part of the CTN trials.

Another approach is to use percentage of days of use, but only on blocks of 30 days that include 5 or fewer missing days. Otherwise, the whole block of 30 days is considered as missing.

In general, using percent days can lead to misleading results. For example, 2 days of use out of 2 non-missing days is the same as 30 days of use out of 30; or 1 day of use out of 2 non-missing days is the same as 15 days of use out of 30, etc. That is why the *number* of drug-use days, and not the *percent* of drug-use days, is being recommended.

Another approach to handling missing data is to use longitudinal (repeated-measures) statistical models, which allow inclusion of individuals even when some times of assessment are missing. These models use full-information maximum likelihood methods to provide the best estimate of trajectories of drug use given the available data. As pointed out above in the section on analysis strategy, these models can specifically compare treatment conditions based on drug use during the last 30 days of the treatment phase by using specific contrasts.

Use of primary drug or any drug?

If the trial focuses on one primary drug of use, i.e. the experimental treatment is specific to a particular drug of use, the primary outcome should focus on that primary drug of

use. If, on the other hand, the trial accepts all comers, with, for example, a behavioral therapy that targets drug use in general, the primary outcome should include all drugs.

Even if a trial does not focus on a single drug of use, but is interested in reducing use of the participant's primary drug, whichever it is, then the primary outcome should be on the participant's primary drug of use, which would be different for different participants.

The standardization would be for all CTN trials to collect daily drug use for both primary drug and all other drugs. The Lead Investigator can then decide which will correspond to the primary outcome and which to a secondary outcome.

Implementation of the recommendation

To test the applicability of this recommendation, the Task Force reviewed past CTN protocols and discussed whether the information collected in each of these past CTN trials would have allowed the calculation of the primary outcome as recommended in this document. The possible answers were: yes ("Fits"); not exactly as is ("Somewhat Fits"); no ("Does Not Fit"); or not applicable. A total of 26 CTN studies were discussed. As a result:

- 12 studies were labeled as "Fits", i.e. the recommended primary outcome would fit with this protocol.
- 5 studies were labeled as "Somewhat Fits", i.e. the recommended primary outcome would fit, but with some minor modifications to the protocol.
- 1 study was labeled as "Does Not Fit", i.e. the recommended primary outcome could fit the protocol, but only with major design changes.
- 8 studies were labeled as "Not Applicable", i.e. the study was either a survey or was not primarily aimed at comparing drug use.

Another approach to test the feasibility of the recommended primary outcome is to use data from CTN's Public Data Share to examine which variables would be used and what obstacles would be encountered if the recommended primary outcome were to be applied retrospectively. It was decided to analyze data from CTN0007 (MIEDAR in methadone clinics). This CTN0007 data analysis focused on the number of days of use during the last 30 days, assessed at Week 12 (end of treatment phase). It was found that the available data did not provide daily self-reported drug use. It only provided the total number of days of use in the last 30 days as one number. As a result, daily self-reported use could not be corroborated with urine drug screening test results, and the primary outcome as recommended could not be calculated.

Goal 2 – Common Set of Questions

Goal 2:
To develop a set of key questions that would be common across CTN trials.

Recommendation:
The recommendation is for CTN trials to use the following questions and instruments, realizing that in a few rare cases, some of these questions/assessments will be inappropriate, and therefore would not be used:

1. ***Timeline Follow-back***
2. ***A standardized qualitative Urine Drug Screening test***
3. ***A standardized demographics form (see Appendix B)***
4. ***The CTN Addiction Severity Index (ASI) Lite (version 10/24/2000) (see Appendix C)***
5. ***A question on primary drug of use***
6. ***A question on age of first use (onset)***
7. ***The World Health Organization's Quality of Life BREF instrument (see Appendix D)***

In addition to the above common assessments/questions, treatment retention and functioning were also considered important, but not enough to warrant inclusion in all CTN trials.

1. Timeline follow-back

Because the Timeline Follow-back instrument is recommended for collecting drug use regardless of whether it is the primary outcome, a common Timeline Follow-back instrument/CRF should be used across all future CTN trials.

The Task Force also recommends adding to the TLFB instrument the following question: "How many occasions did you use on that day?" (This would be asked only if participants answer "yes" to using drugs on a given day.) In addition to capturing the number of days of use, it will also capture any reduction in frequency of use within a day. For example, a treatment that reduces drug use from daily binging to one use per day should be considered successful.

2. Qualitative Urine Drug Screening Test

Because a qualitative urine drug screening test is recommended for corroborating self-reported drug use, future CTN trials should use a standard Urine Drug Screening (UDS) test (dipstick). All CTN trials may not be interested in each drug on the dipstick, but the same dipstick would be used across CTN trials, and cover the main drugs of interest. This will allow for standardization with regard to results, CRFs, and data.

3. Demographics Form

The simplest version of the CTN demographics form is recommended (see Appendix B). This form represents the minimum set of questions required for all future CTN trials. If necessary, other demographic questions can be added. For example, under Hispanic, the Lead Investigator may ask for additional categories such as Puerto Rican, or Mexican, etc.; under Asian, the LI may ask for Chinese, Japanese, etc.; or under gender, there may be additional questions as well (e.g. in CTN0032-HIV Rapid Test). These additional questions would be protocol-specific, and up to the Lead Investigator. They may be captured on the same or separate CRF.

4. CTN Addiction Severity Index (ASI) Lite

The ASI is one of the most widely used instruments in drug abuse research. It gives a broader look at the effect of drug use in participants' lives, and has been useful for treatment planning.

The CTN ASI-Lite, which has been used in past CTN trials and was part of CTN's old Common Assessment Battery, asks a number of key questions regarding substance use and covers seven important domains (see table below). It asks 142 questions, including all the questions needed to derive a composite score for each domain. On average, it takes 45 minutes to administer, depending on the responses from participants – the more use, the more questions asked. Task Force members agreed that all 7 domains are important and should be captured for consistency, and to facilitate secondary analyses across trials.

One key issue is whether CTN trials need to capture information from all 142 questions. Why not use instead only the 55 questions (39%) that are actually needed to calculate the 7 composite scores? Would this new further-abbreviated ASI-Lite instrument be valid? To answer this question, ASI experts were contacted. Their consensus was that it would be inappropriate to pull questions out of the ASI-Lite and keep only those for the composite scores. The main reason is that one loses the context and the priming questions when one jumps straight to the composite score questions. In other words, the other questions that lead to the composite score questions are just as important as the composite score questions. So the conclusion was that all ASI-Lite questions need to be included in order to preserve the validity of the instrument *and* of the composite scores.

Domain	Total # of questions in CTN ASI-Lite	# of questions needed to calculate the *Composite Score**	Questions needed to calculate the *Composite Score**
General Information	11	0	
1. Medical Status	9	3	M6, M7, M8
2. Employment/Support Status	21	4	E4, E5, E11, E12
3. Alcohol 4. Drugs	29	6 13	D1, D2, D23, D26?, D28, D30 D3-D11, D13, D27, D29, D31
5. Legal Status	29	5	L24, L27, L28, L29, ?
6. Family/Social Relationships	27	13	F3, F18-F26, F30, F32, F34,
7. Psychiatric Status	16	11	P4-P14
Total	**142**	**55**	

* based on the "ASI Composite Scores Manual – 1986".

The recommendation is that at baseline, many of the questions should cover both "the past 30 days" and "in your life", and after baseline, only the former.

To keep the burden on participants to a minimum, Lead Investigators are strongly encouraged to keep the frequency of administering the ASI-Lite to a minimum, once at baseline and only once at follow-up, e.g. six-month follow-up.

5. Primary drug of use

It was suggested to use the ASI (full version) wording to determine "the drug causing the most problems", using a forced-choice model that does not allow for "alcohol and drug" as an answer. While not ideal, it is consistent and probably does the best job of identifying the drug that a participant most wants to reduce or stop.

So a modified version of Question D14, which is included in the full ASI instrument, but not in the ASI-Lite, was selected to identify the substance that causes the most problems. Specifically:

Original question (in full ASI instrument):
D14: Which substance is the major problem? ☐☐
Please code as above or 00-No problem; 15-Alcohol & Drug (Dual addiction); 16-Polydrug; when not clear, ask patient.

Modified question **(recommended)**:
D14: Currently, which substance is the major problem? ☐☐
Interviewer should determine the major drug of abuse (excluding Nicotine use). Please use the substance code 01-12 corresponding to questions D1-D12, and 00 for No Problem. When not clear, ask patient.

Because this question refers to previous questions that are also in the ASI Lite, it is recommended that this question be added to the CTN ASI-Lite, and not be part of a separate instrument/CRF.

6. Age of first use (onset)

Age of onset is a strong predictor of future drug dependence. Capturing this information and reporting it in publications will describe an important characteristic of the sample being studied. It is therefore recommended that the age of first illicit use of substances (alcohol, nicotine, prescribed drugs, or illicit drugs) be collected. This question can be added to the CTN ASI-Lite or be part of a separate instrument/CRF.

7. Quality of Life (QoL)

Why should the CTN capture Quality of Life?
Two main reasons:

1. In their 2009 editorial in Addiction, Miller and Miller stated that the high attrition rate in addiction treatment suggests that what treatments offer is not very attractive, or not relevant to the patients' needs as they see them. So it seems that people are involved in treatments that do not increase their perception that their lives are improving.
2. The CTN should be able to show that successful treatments will not only decrease drug use, but will also improve QoL. Substance abuse treatments should go beyond symptom reduction.

Can the Addiction Severity Index (ASI) instrument, which is on the list of recommended instruments, also be used to get a measure of QoL?
The ASI captures objective quantitative indicators of functionality, but misses what is most relevant to drug users, which is their subjective psychological and physical perception of the impact of what goes on in their lives.
When ASI was compared to the SF-36, Calsyn et al (2004) found that only the ASI medical and psychiatric composite scores measured similar domains as the SF-36 in substance-dependent veterans.
ASI experts were asked whether there is current work on adding quality-of-life questions to the ASI, and the response was that there is no such attempt at this time.

Two instruments that are specific for drug users, i.e. that have been developed for, or tested with substance-dependent individuals were considered:

1. The Injection Drug User Quality Of Life (IDUQOL), which has been used also for non-injection drug users (Brogly et al. 2003).
   Strength: has been psychometrically validated.
   Weakness: is rather complex to administer and time-consuming.

2. The Health-Related Quality Of Life for Drug Abusers (HRQOLDA), which includes 20 five-choice scaled response items (Rojas et al. 2009).
   Strength: has been used and validated with drug abusers, in Spain.
   Weakness: has not been tested in English-speaking population; too new for the US. (An Australian team is in the process of translating it from Spanish to English, and plans to present the translated version at the 2010 CPDD.)

Several QoL instruments (not specific for drug dependents) were also considered:

1. SF series:[1]
   a. SF-6D version 12-1 uses 7 questions from the SF-12 to calculate a score (algorithms are provided at the website).
   b. SF-6D version 12-2, same as (a), but with slightly different questions.
   c. SF-6D version 36-1 uses 11 questions from the SF-36 to calculate a score.
   d. SF-6D version 36-2, same as (c), but with slightly different questions.
   Strength: widely used; tested and used in PROMIS.
   Weakness: the questions in the SF are mostly health-related, and miss the more qualitative aspect of quality of life.
2. EuroQol or EQ-5D, which is a 5-item questionnaire.
   Strength: very brief; widely used by economists and cost effectiveness researchers for deriving Quality-Adjusted Life Years (QALYs). This would standardize cost effectiveness analyses in future CTN trials. Note: there are US weights for calculating results generalizable to the US population.
   Weakness: is mostly about functionality rather than QoL. Misses much of what most individuals feel goes into making up a quality life, and is fairly narrow in what it measures.
3. CDC's HRQOL-4 (Health-Related Quality Of Life), which is a 4-item questionnaire, and is part of CDC's HRQOL-14.
   Strength: is widely used; although not developed specifically for drug abusers, it has been tested with drug abusers (Morgen et al. 2007).
   Weakness: is focused only on health-related issues, and not on other aspects of QoL.
4. World health Organization's QoL-BREF (WHOQOL-BREF), which is a 26-item questionnaire, and which produces a score for each of 4 domains: physical health, psychological, social relationship, and environment.
   Strength: has been extensively validated; has been widely used; has been used with substance dependents, and particularly with alcoholics; QoL for participants in CTN trials can be compared to that of the general population; is in the public domain.
   Weakness: has not been developed specifically for the drug abusing population.

[1] **Background:** RAND Health, a research division within the RAND Corporation, developed a 116-item core survey that measures quality of life, including physical, mental, and general health. This was part of the Medical Outcomes Study (MOS), a two-year study of patients with chronic conditions. Several Short Forms (SF) were also developed from that 116-item survey: SF-36, SF-20 and SF-12.

As far as period covered, the four SF-6D questionnaires and the WHOQOL-BREF ask about the "past 4 weeks". CDC's HRQOL-4 focuses on the past 30 days. All three are thus consistent with the "last 30 days" of the recommended primary outcome. The EQ-5D asks about "your own health state *today*".

After careful consideration of the strengths and limitations of each of these instruments, the recommendation is for the CTN to use the WHOQOL-BREF, and to administer it at baseline *and* at a later time point, e.g. during a 6-month follow-up at the earliest.

The TEAM Task Force debated recommending that the EQ-5D be also used in trials with an important cost-effectiveness component. The rationale is that (1) a standardized cost-effectiveness measure, even though less than ideal, may be preferable to no measure at all; and (2) the EQ-5D would only add 5 questions to participants' response burden. The Task Force however had significant concerns that QALYs generated from the EQ-5D may not be entirely applicable to the population of substance abusers, and thus could be misleading. It thus decided not to add the EQ-5D to the recommendation.

This debate clearly pointed to the need for research designed to create a QoL measure from which QALYs appropriate to the population of substance abusers can be calculated.

How does this recommendation compare to the old CTN Common Assessment Battery (CAB)?

CTN's Old Common Assessment Battery (CAB)	TEAM Task Force Recommendation
Demographic	Demographic
	Time Line Follow-Back (TLFB)
Biological Measures	Urine Drug Screen (UDS)
CTN ASI Lite	CTN ASI Lite + 2 questions
Composite International Diagnostic Interview (CIDI)	
Risk Behavior Survey (RBS)	
	WHO Quality of Life - BREF

How does this recommendation compare to NIDA's data harmonization effort?

A team of representatives from several NIDA divisions is in the process of developing a set of core questions and instruments that would be asked of patients participating in NIDA-funded clinical trials.

How does this recommendation compare to the outcome of the December 15-16, 2009, workshop on clinically meaningful substance abuse treatment outcome for effectiveness trials?

At the December workshop, there was little consensus on any single primary outcome. The general view was that it depends on the study aim, treatment goal, population studied, etc. Two strong candidates did however emerge:

1. Drug use, measured by self-report and biological test
2. Consequences of drug use, e.g. psychosocial functioning, quality of life, criminal justice involvement.

The main recommendations were to:

1. Compare and correlate different outcome measures of drug use
2. Identify short-term predictors of long-term outcomes
3. Develop a decision tree for determining primary outcomes
4. Consider treatment strategies, as opposed to comparing Treatment A to Treatment B
5. Continue discussions with experts to lay out specific proposals

Standardization of forms (CTN Data and Statistics Center)

The Data and Statistics Center 2 has standardized the following Case Report Forms (CRFs):

1. Demographics
2. Timeline Follow-back
3. Urine Drug Screen
4. Adverse Event / Serious Adverse Event
5. Protocol Violation
6. Protocol Termination
7. Fagerström Test for Nicotine Dependence

This means that trials that use the above instruments will be using the corresponding standardized CRFs. If questions need to be added, they will be typically added on separate CRFs.

The plan is to continue this effort of using as many standard forms as possible across CTN trials in the future. Two main benefits will result: shortening the CRF development process, and facilitating cross-studies analyses down the road.

TEAM Task Force members and calls

TEAM Task Force members:

Dennis Daley (co-chair), Appalachian Tri-State Node
Paul Wakim (co-chair), NIDA
Allan Cohen, Pacific Region Node
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The TEAM Task Force was formed in November 2008. It had its first conference call on December 18, 2008, and its second conference call on January 12, 2009. Thereafter, the TEAM Task Force met twice a month, on the first and third Monday of each month. A total of 19 one-hour conference calls and one face-to-face meeting (on March 24, 2009) were conducted. The last conference call before the Task Force's first report was held on October 5, 2009.

The Task Force then reported to the CTN Steering Committee at its face-to-face meeting on October 22, 2009. After the report, the Steering Committee requested that the TEAM Task Force (1) complete the Quality-of-Life recommendation; (2) work with the DSC2 to implement standardization of forms; and (3) report back at the next Steering Committee meeting (spring 2010).

The Task Force resumed its once-every-two-weeks conference calls on January 11, 2010, and held a total of 6 calls.

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Appendix A – Examples on How to Combine Self-Report and Urine Drug Screening Test Results

	1	2	3	4	5
Self Report	—	—	—		
Urine Test			+		
Combined Result	—	—	+		

Correction made on 3rd day, due to positive urine test

	1	2	3	4	5
Self Report	+	—	—		
Urine Test			+		
Combined Result	+	—	—		

Though 3rd day urine test was positive, correction was not necessary. Self report contains positive drug intake within 3 days of positive urine test (1st day).

	1	2	3	4	5
Self Report	+	—	—	—	
Urine Test			+	+	
Combined Result	+	—	—	+	

Correction was not made on 3rd day due to 1st day positive self report. But, Correction was made on 4th day with positive urine test.

	1	2	3	4	5
Self Report	—	+	+	—	
Urine Test				+	
Combined Result	—	+	+	—	

Correction was not made on 4th day due to positive self report on 2nd and 3rd day.

	1	2	3	4	5
Self Report	+	—	—	—	—
Urine Test			+		+
Combined Result	+	—	—	—	+

Correction was not made on 3rd day due to 1st day positive self report. But, correction was made on 5th day with positive urine test.

Appendix B – Demographics Form

Node #: ___ ___ CTP ID #: ___ ___ ___ ___ Participant ID #: ___ ___ ___ ___ Week #: ___ ___ Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___
(month / day / year)

Demographics (DEM)

1 **Date of birth:** ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

2 **Sex:** ☐ 1 Male ☐ 2 Female ☐ 98 Participant chooses not to answer

3 **Ethnicity** *(check only one)*:
- ☐ 1 Hispanic or Latino
- ☐ 2 Not Hispanic or Latino
- ☐ 98 Participant chooses not to answer

4 **Race** *(check all that apply)*:
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Pacific Islander
- ☐ White
- ☐ Other *(specify)*: _____

OR
- ☐ Participant chooses not to answer
- ☐ Unknown

Appendix C – CTN ASI-Lite (version 10/24/2000)

ASI Lite

(double-click on this icon)

Appendix D – World Health Organization Quality Of Life - BREF

WHOQOL-BREF

(double-click on this icon)