

Contents

Greetings & Salutations	1
Regulatory Corner	2
Announcements	3
Core Data Set eCRF	
Completion Guidelines	4
Printable English-to-Spanish	
Data Collection Forms	4
In the Pipeline	5
Save the Date	5

Contact Us

General Inquiries

NCTSN@dcri.duke.edu

Ernestine Briggs-King

Director, Data and Evaluation
Program

Ernestine.briggs@duke.edu
919.682.1552, x254

Sarah Ostrowski

Postdoctoral Fellow, Data and
Evaluation Program

sostrowski@psych.duhs.duke.edu
919.682.1552, x223

Bart Evans

Project Leader-Data Core

Bart.evans@duke.edu
919.668.8981

NCTSN

<http://www.nctsn.org>

Greetings & Salutations

On behalf of the Data and Evaluation Program, I extend to all of you greetings and salutations! A very special welcome goes out to the 2008 cohort of grantees. We are pleased to meet the new sites as well as see some familiar faces. Although we have provided updates in the past, this is the first issue of *Data Times*. In future issues, we will continue to include updates about the Data and Evaluation Program and activities, as well as revise the format of the newsletter. Please let us know if you have any suggestions. We welcome your feedback.

The Core Data Set (CDS) is rolling along! As of February 1, 2009, we have data on 10 thousand+ youth who have been served by the Network. Data have come from 50 of the NCTSN sites and affiliates. We used to thank sites individually for their great participation in the CDS, but it's getting cumbersome to list everyone—there are now 41 sites that have included more than 50 youth in the CDS.

There are, however, a few sites that need to be recognized for their stellar participation in the CDS: Kennedy Krieger (1,235), Depelchin (923), Children's Institute International (850), and Chadwick (498). Thanks very much to all of you who are working so hard to gather and enter these data! It is tremendously helpful.

The new enhancements and reporting features are getting lots of positive feedback. Special thanks to the Data Operations Committee for all their time, suggestions, and support throughout this transition.

We will present data from the CDS at the All-Network Conference in March, but I wanted to share a few of the things we've learned so far:

- The Network is doing a great job of providing treatment to a culturally diverse group of youth.
- Youth treated by the Network show a complex set of traumatic experiences (75% of youth have multiple traumas).
- The majority of youth served by NCTSN sites are receiving outpatient services (90%) and Evidence-Based Treatments (96%).
- Clients are showing improvements during treatment. This is particularly true for youth who complete their course of treatment (~70% show positive gains, compared to ~30% of youth who drop out of treatment).

As the CDS continues to grow, it will help us discover crucial things about youth who experience trauma, treatment, and outcomes. **It is ESSENTIAL that everyone who is providing clinical services to youth in the Network completes the CDS on their clients (at both baseline and follow-ups).** We want to use these unique data to increase the knowledge base about youth who experience trauma and effective treatment. Your participation in and support of the CDS will provide important, generalizable data that can help us improve the standard of care for youth and families.

Thanks!!!

Ernestine Briggs-King, PhD



Regulatory Corner

You need to be in frequent communication with your IRB, and be mindful of all federal, state, and local (e.g., IRB-specific) regulations, guidelines and policies, regardless of whether your center is using your local IRB or the Duke University Hospital System (DUHS) IRB as your IRB of record; and whether your center is collecting data locally or your center is participating in the CDS and/or the MACRO Cross-Site Evaluation.

The Data and Evaluation Program regulatory team at the DCRI (**Bart Evans and Julie Gardner**) are always available to assist your center with your regulatory questions such as submitting information to your IRB.

Among the items you may be submitting as part of your IRB application for the NCTSN activities your center has implemented are:

- **Annual Continuing Renewal Application**

This should include updates on enrollment and project progress per your IRB of record requirements. Send a copy of the approvals from these submissions to Bart or Julie via fax or email them as a scanned attachment (see their contact info at the end of this page).

- **Protocol Amendments**

Send these if, for example:

- Your local study staff members change
- Your program decides to add a new local evaluation that will involve treatment or follow-up data collection from clients
- Your program decides to discontinue an evaluation or data collection activity (includes the CDS and MACRO Cross-Site Evaluation)
- Your program submits a waiver of a policy or procedure to your IRB of record
- Your center implements a reimbursement policy for participants

- **Revised Informed Consent Forms (ICFs)**

Depending on the format and information included in your ICF, you may need to update your contact files with any new names and information; or if you add a new evaluation, you may need to revise the section on use of data.

- **Advertisements/Recruitment Materials**

Examples include brochures that address: the data collection for the NCTSN specifically, services offered as a result of participation in NCTSN activities.

- **Safety Events/Deviations or Violations of Protocol**

Submit these to document and gain instruction from your IRB of record if, for example, your center is consenting a participant, and inadvertently uses an older version or a version other than the most current IRB-approved version.

If your center is using the DUHS IRB as your IRB of record, be sure to consult with the DCRI team about all these issues. We will interact with the DUHS on your behalf.

DCRI Data & Evaluation Program Team

If you have any questions or would like to set up a teleconference, feel free to contact us:

Bart Evans
Project Leader
DCRI

bart.evans@duke.edu

- Office Phone: 919.668.8981
- Office Fax: 919.668.8981
- Mobile Phone: 919.724.0703

Julie Gardner
Clinical Trial Assistant
DCRI

julie.gardner@duke.edu

- Office Phone: 919.668.8808
- Office Fax: 919.668.7106



Announcements

InForm/Core Data Set Updates

The **Visit Scheduler** report was launched on November 20, 2008. This report projects visit dates at three-month intervals (from baseline) until treatment ends for patients who are not participating in the Cross-Site Evaluation (CSE) and at twelve-month intervals for patients participating in the CSE.

The report was created in response to requests from centers using InForm. After logging into InForm, the report can be generated by using the following steps:

1. Select the **Reports** button on the left side of the screen.
2. Open the **Core Data Set Administrative Report** folder.
3. Select **Visit Scheduler report**.
4. Specify the **Site, Patient** (or **Patients**), and/or **Date Range**.
5. Click **Finish**.

For each record on the report, the following displays: Patient ID Number, Actual Visit Date, Visit Type, Cross-Site Data Point (if appropriate), Projected Visit Date, and Health Care Provider.

The **InForm Report User Guide** includes a description of other reports available through InForm and instructions for accessing them. To download the guide, go to the **NCTSN Data and Evaluation Program's** intranet site at <http://intranet.nctsn.org/sites/data/default.aspx> and click on **Core Data Set Forms and Resource Library**.

Participants at the Data Strategy Meeting

Thanks to all of you who contributed to a successful meeting!

Lisa Amaya-Jackson, MD
Connie Black-Pond, MA
Ernestine Briggs-King, PhD
Paul Brounstein, PhD
Nikkia Brown, BSN
Brian Deakins, MSW
Shannon Dorsey, PhD
Lori Ebert, PhD
Tonya Elliott
John Fairbank, PhD
John Gilford, PhD, MSW

Robyn Igelman, PhD
Jerry Kirchner, CCRP
Daniel Kleiner, PsyD
Christopher Layne, PhD
Carolyn Malloy
Brian McCourt, CCDM
Megan Mooney, PhD
Robert Murphy, PhD
Mikisha Nation, MPH
Robert Pynoos, MD, MPH
Mark Rains, PhD

Susana Rivera, MA, LPC
Leslie Anne Ross, PsyD
Joseph Spinazzola, PhD
Alan Steinberg, PhD
Carla Stover, PhD
Nick Tise, MPH
Nancy Widdoes, MA
Rebecca Wilgus, MSN
Jane Winsor

Core Data Set eCRF Completion Guidelines

The **Core Data Set eCRF Completion Guidelines** also were released in November. This document is a companion for the Core Data Set (CDS) forms and InForm system training documents. Its purpose is to:

- Define terms and concepts used in the CDS
- Offer additional material to explain/clarify the NCTSN Data and Evaluation Program's expectations and interpretations of the questions in the CDS
- Provide background and contextual information related to the CDS questions/answers

The eCRF Completion Guidelines were written in response to the feedback and questions that the Data and Evaluation Program has received since the inception of the CDS in 2004. The guidelines will be updated periodically as we receive additional questions and feedback.

*NOTE: The document is very large. Since many email systems block messages containing large attachments, we recommend that you download it from the NCTSN Data and Evaluation Program's intranet site. Go to <http://intranet.nctsn.org/sites/data/default.aspx> and click on **Core Data Set Forms and Resource Library**.*

Now Available! PRINTABLE English-to-Spanish Data Collection Forms

Version 2.0 of the **printable** ENGLISH-to-SPANISH Bilingual Core Data Set data collection forms are now on the Data and Evaluation Program intranet site.

The files are available for download individually by Visit Type. These forms may be especially useful for collecting data onsite with Spanish-speaking clients and their caregivers. Then, later, the data can be entered into the Core Data Set InForm system.

To view, download, and print the forms, go to <http://intranet.nctsn.org/sites/data/Standardized%20Assessments%20%20Spanish%20%20Bilingual%20Versi/Forms/AllItems.aspx>: **Standardized Assessments: Spanish & Bilingual Versions.**

Special thanks to staff at the following sites for pilot testing enhancements to the CDS:

Arizona Children Association
Children's Institute International
Clifford Beers
Cullen Center
DSCYF (Delaware)
La Rabida



In the Pipeline...

Several Core Data Set Benchmarking reports are in the works, another project in response to your requests. These reports will put the participation and assessment scores of individual centers in the context of aggregate participation and assessment scores across the Network. Additionally, listings of assessment scores will be provided.

We will continually update you on the progress of these reports and listings as well as provide opportunities for feedback on them.

As always, we welcome your questions and comments about these and any other Data and Evaluation Program initiatives.

Contact us at:

- Phone: 919.668.8182
- Email : NCTSN@dcri.duke.edu

Save the Date

March

All-Network Conference
Florida Hotel and Conference
Center
Orlando, Florida
March 16–19, 2009

Data Operations Meeting
Florida Hotel and Conference Center
Orlando, Florida
March 19, 2009

CONTEST

We will be awarding a
commemorative NCTSN
Knowledge Bank travel mug
to the first 10 centers
who increase their follow-up
participation rate by 10%!