NCTSN Core Data Set Training Exercises

FOR USE AFTER VIEWING THE ON-LINE NCTSN TRAINING DEMO

Foreword

Prior to completing these exercises, please make sure you have:

1. Watched the web-based demonstration of InForm provided by the Data and Evaluation Team.

2. Practiced using InForm while reviewing the **NCTSN Core Data Set Start-up Manual**. It describes the functions and activities covered by these exercises in detail.

These training exercises are designed to be completed **in the order they appear in this document & according to the instructions provided**. Many exercises will not make sense if those prior have not been completed according to the directions. The page numbers referenced in these Training Exercises correspond to the slide number found in the "Ref.Manual .PPT" or "Ref.Manual .PDF" section of the Start-up Manual.

Explanations for system behaviour are provided in **shaded boxes** throughout the document. Read these explanations carefully to understand how the system works.

Exercise Objectives

Following the completion of these exercises, you will be familiar with the basic functionality of InForm, the EDC system chose for the NCTSN Core Data Set. These exercises provide a concise and comprehensive review of the system. Examples for each of the basic screens and functionality as well as a review of the skills associated with data collection and responding to queries are included.

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General Exercises

Exercise 1 – The Basics

In this section we will be exploring the basic principles required to use InForm.

Please check each item off once completed

1. Type the Username and Password provided by your trainer and click **'Log In'**. (Ref.Manual page 10) ☐
2. Move your mouse very slowly over the buttons in the **Navigation Pane** to view brief information **(Hover Help)** about the button. (Ref.Manual page 19) ☐
3. Click the **'Help'** button in the **Navigation Pane** and click **Inform and Trial Reporting** to view the **'InForm Online Help'**. (Ref.Manual page 16) ☐
4. Click the **'Index'** button at the bottom left hand side of the help window to view an alphabetic listing of all **'InForm Help topics'**. (Ref.Manual page 17) ☐
5. Click the hyperlink letter **'I'** in the index, and then click any hyperlink listed under **'Icons'** to view all standard icons used within **InForm**. Click the Contents tab. ☐
6. Click the Index tab. Click the hyperlink letter **'H'** in the index, and then click any hyperlink to view information about CRF or Online help. ☐
7. Close the **'Help'** menu by clicking the **'Close'** button in the top right hand corner of the **'Inform Online Help'** window. ☐
8. Click the **'Documents'** button in the navigation pane to view the **"Instructions for Completing the NCTSN Core Clinical Data Set Case Report Form".** (Ref.Manual page 21) ☐
9. Click the underlined **'System Screening Information'** in the left pane of the small window to see information about enrolling patients. ☐
10. Click the **'Sample Book'** tab across the top of your screen to view an example of select Core Data Set Forms. ☐
11. Click the **'Return'** button and then the **'Close'** button in the bottom right hand corner of the **'Documents'** window to return to the **'Home Page'** for the study. ☐
12. Click the **'Enroll'** button in the navigation pane to view the **'Screening Log'** The **'Screening Log'** is a list of all clients from your Center. (Ref.Manual page 23) ☐
13. Click the **'Home'** button in the navigation pane to return to the **'NCTSN Core Data Set Home Page'**. (Ref.Manual page 15)

Exercise 1 – The Basics cont.

14. Click the '**Patients**' button in the navigation pane to view the case book listing. This is a list of all clients at the Center for whom case books have been **created.** (Ref.Manual page 24) ☐

15. Click any underlined '**Patient Number'**. ☐

Where does this take you?_______________________________________ *(Ref.Manual page **29)***

16. Click any traffic light icon to view the associated eCRF. ☐

17. Move the mouse slowly over the blue tabs at the top of the screen. ☐

What kind of information is revealed? *(Ref.Manual page 20)*

____

18. Click the **'DEMO'** tab for the **'Demographic'** eCRF. ☐

19. Click the underlined title of the eCRF. ☐

Where does this take you? *(Ref.Manual page 20)*

____

20. Close the open window and click the **'Return'** button in the bottom right hand corner of the screen to return to the **Time and Events Schedule** for the client. ☐

21. Click the **'Queries'** button in the navigation pane to view a list of all queries at the Center. (Ref.Manual page 38) ☐

22. Click the **'Admin'** button in the navigation pane to view information about the Inform system. (Ref.Manual page 56) ☐

23. Click the **'Reports'** button in the navigation pane or click the **'Custom'** tab at the top of the screen to view the titles of NCTSN Core Data Set Reports. ☐

24. Click the **'Home'** button in the navigation pane. (Ref.Manual page 15) ☐

Exercise 2 – Screening and Enrolling a Client for the Core Data Set

In this section you will register a subject into InForm. In order to complete this step, two forms, Screening and Enrollment, must be completed and submitted. Completion of these steps creates the subjects case book, which will allow you to enter study data.

<u>**Please check each item off once completed**</u>

1. Click the **'Enroll'** button in the navigation pane to view the **'Screening Log'**. (Ref.Manual page 23) ☐
2. Click the **'Add Candidate'** button in the bottom right hand corner of the screen. ☐
3. Enter a set of any three initials into the **'Patient Initials'** field. ☐
4. Using the drop down arrows for each field, enter a **'Date of Birth'** where the year is between **'1987** and **1999'.** ☐
5. Enter any **'Gender'.** ☐
6. Enter **'No'** to the question "Has this child been seen at another NCTSN network center(s) for a previous episode(s) of care?" ☐
7. Enter **'Yes'** to the question "Has this child been seen at this center for a previous episode(s) of care?" Then select 'No' and follow instructions. ☐
8. Click the **'Submit'** button in the bottom right hand corner of the screen. ☐
9. Click the **'Enroll'** button to the right of the subject you have just created. ☐
10. Click in the **checkbox** beside **'Please click to continue with screening/enrollment process.'** ☐
11. Click the **'Submit'** button in the bottom right hand corner of the screen. ☐
12. Click the **'Enroll'** button in the bottom right hand corner of the screen. ☐
13. The '**Thank-you for enrolling this patient into the NCTSN Core Data Set'** will appear next. ☐
14. Click **'Go To First Visit'** in the bottom right corner of the screen. ☐

NOTE: The Demographics screen displays. The DEMO tab at the top of the form is yellow.

Where do you need to click to view the data that you entered on the Enrollment Form and the Screening Form?______________________________ (Ref.Manual page 23)

Exercise 3 – Working with Forms, Changing Data and Answering Queries

In this exercise you will work with eCRF's and learn how to resolve data issues that include changing erroneous data and answering queries.

Please check each item off once completed

1. Go to the **Baseline** visit for the patient you created in the last exercise. Enter a visit date of **March 3, 2004**. Complete the remaining questions on the baseline **"DEMO"** screen. Click **Submit** (Ref.Manual page 24,25). ☐

2. Navigate to the **'InsDom'** form by clicking on its tab. (Ref.Manual page 26) ☐

3. Answer 'YES' to item 1 on the **'InsDom'** form & answer item 2 with Other Public, Specify but leave the "Other Public, Specify" box blank . ☐

4. Answer 'YES' to item 3 and "Public, Medicaid" for item 4. Leave item 5 blank. ☐

5. Click the radio button beside "Entire Life" for item 6 (# of months child has lived in this environment) and click **Submit**. Click "OK" that the data has been successfully submitted. ☐

6. Click the **'Queries'** button and review the queries that were just fired for your patient from the **'Queries Listing Screen'**. (Ref.Manual page 38) ☐

7. Click on the first underlined query message hyperlink. Notice the 4 tabs at the top of this page. The "**Queries**" tab should be highlighted yellow. This shows you the incorrect question and the discrepancy message in the reason box. ☐

8. Click the '**Yellow Up Arrow'** in the top left hand corner of the screen. This will take you back to the **InsDom** page. ☐

9. Click the **'Yellow Up Arrow'** again. This takes you to the Time and Events Schedule for that patient. Review the traffic lights for each form. Notice the color of the traffic light. It should be red & yellow. (Ref.Manual page 31) ☐

Remember, the instructions above asked you to leave the 'Other, specify' field blank initially.

The Red Traffic light is InForm's way of telling you there is a query (or question about an item) on that screen.

In this case, InForm tells you that a response needs to be entered in the 'Other Public Insurance, "Specify" field to answer the query. When it's satisfied, the field and traffic light will no longer be red.

Exercise 3 – Working with Forms, Changing Data and Answering Queries cont.

29. Click on the stoplight under **InsDom**. Put your cursor in the "**Other, specify**" box and click once. This takes you to the **Data Value(s) tab**. (Ref.Manual page 41) ☐

30. The answer to question 2, "Type of insurance….": is "Other Public, please specify". Type a brief description into the "**Other, Specify**" field (e.g. Mom&Pop's public insurance). Scroll down the screen & provide the system with a reason why you are changing the field from your original entry (any reason will do!), and then **submit** the information. You may pick a reason off the drop down list or type one of your own into the "Other" text box. (Ref.Manual page 41) ☐

31. Notice how the system closes the query automatically, once the data has been provided. The field is no longer red. ☐

Notice the yellow flag to the right of item 3. It tells you a query was created for that item.

32. Notice the **'Yellow Stack of Papers Icon'** to the right of the item, click on it and review the "**Item Audit Trail**". (Ref.Manual page 43,44) ☐

33. Click the **'Return'** button to return to the **'INSDOM'** page. ☐

34. Click the **yellow arrow up** by the **Visit Ruler Bar**. Note the traffic light for **INSDOM** is now Yellow. ☐

35. Click the Yellow Traffic Light for **INSDOM** & scroll down to question 5. Note the field is also yellow. Answer the question with "Homeless" & click **Submit**. ☐

36. Note the field is no longer yellow. Yellow arrow up to the **Time and Events Schedule** and note the traffic light for **INSDOM** is now Green! ☐

Green lights mean there is no Missing Data and there are no Queries.

Exercise 4 – Comments

This exercise will illustrate how to issue item & form level comments and how to mark items 'Not Done' on an eCRF.

<u>Please check each item off once completed</u>

1. Click the black traffic light on the **Time and Events Schedule** to navigate to the **'INDSEV'** form for your client. Answer questions 1-4 with realistic answers & submit the data. ☐

2. The client refuses to provide the information required for question 5 (Suicidality) at this visit so click on the grey **'Item Level Comment Bubble'** to the right of the item. (Ref.Manual page 45) ☐

3. Enter an explanation why Suicidiality is "Not Done" in the text box, select the **'Not Done'** radio button and **'Submit'** the data. Click "OK" for submitted successfully. (Ref.Manual page 47) ☐

4. Click the **'Return'** button to return to the form. ☐

Notice the grey 'Comment Bubble' for item 5 is now yellow indicating that there is a comment entered in the system for this particular item.

5. The patient changes his mind and tells you later that he sometimes has thoughts of suicidiality. To reactivate this field click on the yellow **'Comment Bubble'** to the right of the item. (Ref.Manual page 45,46) ☐

6. Highlight the comment text with your mouse and use the backspace button on the keyboard to delete it. Use the yellow **'Eraser Icon'** to the right of the item to clear the "Not Done" radio button. **'Submit'** your data. Type a reason explaining why you're making another change into the text box. Click **Submit**. (Ref.Manual page 25,) ☐

7. Click the **'Return'** button to return to the **INDSEV** form. ☐

Notice how the 'Suicidiality" item on the 'INDSEV' form is now yellow again and the comment bubble remains yellow to show comment activity on this item.

8. Enter "Sometimes a problem" as the answer to item 5 (Suicidiality) & click **'Submit'**. ☐

9. Navigate to the **SERREC** form by clicking the tab near the top of your screen. You are unable to determine answers for any questions on this screen. Mark the whole form '**Not Done'** by clicking on the **"Form Level Comment Bubble'** in the top right hand corner of the screen. (Ref.Manual page 45) ☐

10. Input a comment into the text box explaining the reason the form is Not Done. Select the **'Not Done'** radio button to mark the form **Undone**. Click **'Submit'**. ☐

Exercise 4 – Comments cont.

11. Click the **'Return'** button to return to the form. ☐

Notice the Comment icon at the top of the screen is yellow & all the comment icons for the items on this form are yellow. Also note the fields are Gray. The combination of gray fields and yellow comment icons tells you the form will not be completed. On the Time and Events Schedule, the traffic light for SERREC is green.

12. If you determine later that the information for the SERREC form is available, you can remove the **Form Level Comment** to allow for data entry on this form. (Hint: This process is the same as the one you used to change the item level comment in steps 5-8 above.) ☐

Exercise 5 – Dynamic Visit forms

This exercise will review dynamic forms.

Domestic Environment Details, the CBCL, PTSD-RI, TSCC-A and Trauma Detail forms are examples of dynamic forms in the Core Data Set. These forms display when certain conditions are met (e.g., the Sexual Abuse trauma detail form displays only when client has experienced sexual abuse).

Please check each item off once completed

1. Click on **'Trauma' on the Visit Ruler Bar to** navigate to the **Trauma** form. ☐

Count the number of tabs for this form. How many exist? ________________
(Ref.Manual page 48)

2. Enter **'No'** for item 1 "Has child experienced sexual maltreatment & abuse?". ☐
3. Enter **'Yes'** for item 2 "Has child experienced sexual assault/rape?" and enter an age or multiple ages when this occurred. Click **'Submit'** ☐

Notice a 'SexAssault' tab has been created behind the Trauma tab. This screen contains a set of detail questions associated with Sexual Assault/Rape.

Trauma detail forms will be created for each trauma type a child has experienced after the General Trauma Information form is submitted. *(Ref.Manual page 48)*

4. Click the **'SexAssault'** tab to answer the detail questions & click **'Submit'**. ☐
5. Click the **'Trauma'** tab to navigate back to the **Trauma** screen. ☐
6. Use the horizontal scroll bar at the bottom of your screen to scroll over and see the '**Age Unknown'** box at the far right side of the items on the **Trauma Screen**. ☐
7. Click '**Follow-up**' on the **visit ruler bar** to navigate to the **Follow-up form**. Notice the number of tabs for this visit. (Ref.Manual page 55) ☐
8. Answer questions 1- 6 making sure your follow-up visit date is **between the Baseline visit date (March 3, 2004) and today's date.** Answer **item 2, "T**ype of Follow-up Performed" with '**Follow-up for ongoing treatment** '. Answer items 3-6 with realistic answers. Click **'Submit'.**

Exercise 5 – Dynamic Visit forms cont.

Notice new tabs are created for additional sections of the Follow-up Assessment.

9. This client returns for another follow-up visit in the future. To create a new follow-up visit form, click the '**New**' button located at the bottom left corner of **Follow-up Visit** screen to the right of the Visit pulldown box.

   On the new Follow-up Info form, enter a **new follow-up visit date** and indicate that the type of follow-up is **"Followup for ongoing treatment** ". Click **Submit**. (Ref.Manual page 55) ☐

10. Click the arrow on the **Visit Drop Down** list at the bottom of the screen to display a list of **Follow-up Visit Assessments**. How many are listed? ______

Exercise 6 – Common Repeating Forms

This exercise will explore the Breakthrough Series/Learning Collaborative (BSLC) form.

The BSLC form is known as a Common Repeating Form. This form is available in the Baseline Assessment as well as all Follow-up Assessments. This form is different from other forms that display in both visits in that the data entered at baseline displays in the baseline visit as well as in all follow-up visits.

1. Open the **BSLC** form by clicking the **BSLC tab** located to the right of the **Follow-up tab.** ☐

The first question asks *"Is this child/family receiving a treatment from a therapist participating in a breakthrough series or learning collaborative?"* When the answer is **NO**, select **NO** and continue on to the next **eCRF**. When the answer is **YES**, select **YES** and complete a detail record for each initiative in which the child is participating.

2. For training purposes, answer this question with **YES** and click **SUBMIT** to save your response. ☐

The screen turns red and a query message displays. This message reminds you to document details for the BSLC initiative(s). Use the following steps to document the details for each initiative.

3. Click the **Add Entry** button to create a **BSLC detail record.** ☐

4. Enter the information related to the BSLC initiative. ☐
   - Identify the initiative: **Life skills/Life Story**
   - Enter the date this treatment began by using the drop down lists provided: **April 14, 2004**
   - Answer **YES** to: "Did this family member complete the treatment?"
   - Enter **May 14, 2004** as the date treatment was completed.

Notice the BSLC form now displays the answer to question 1 and a table summarizing your responses to questions related to **Life Skills/Life Story**.

Note: For clients who are participating in multiple BSLC initiatives, repeat step 4 for each initiative in which they are participating.

At the beginning of this exercise, you learned that the **BSLC** form is a **Common Repeating Form**, which means that the data entered in one visit displays across the **Baseline** and all **Follow-up** visits for that patient. **Step 5-8** show you how that works:

5. Click the pulldown list at the bottom of the **Follow-up Info** form and select the visit for the date your first **Follow-up visit**. ☐

Exercise 6 – Common Repeating Forms cont.

6. Click the **BSLC tab** and note that the information you entered displays in this visit also. ☐

Now, let's go to the **Baseline Visit** and see that the **BSLC** data entered in the second follow-up visit also displays in the **BSLC** form displayed in the **Baseline Assessment.**

6. To quickly open the Baseline Assessment, click **Baseline Visit** on the visit ruler bar located at the top of the screen beside the **Yellow Arrow Up**. ☐

7. Click the **BSLC** tab to open the form. Notice the data you entered in the **Follow-Up** visit displays. ☐

8. Enter a second **BSLC initiative** with the following details: ☐
   - Initiative: **TF-CBT (Trauma Focused Cognitive Behavioral Therapy)**
   - Date treatment began: **April 15, 2004**
   - Enter **June 15, 2004** as the date the client left treatment.

9. Click **Submit** to save the responses. Note there are now **two** Add Entry records. One for **Life Skills/Life Story** and one for **TF-CBT.** ☐

10. Use the visit ruler bar and return to the **Follow-Up Assessment,** open the **BSLC form** and note that the data you entered in the **Baseline Visit** also displays in **Follow-up Visit.** ☐

12. How many **Add Entry** records display in the list on the **Follow-up BSLC** form? ______

Changing Data on Add Entry Rows

Use the following steps to change (edit) data on an **Add Entry Row:**

1. Click the **underlined number** in the left margin of the row you want to edit. For training purposes, click **2.a** to open the **Add Entry Row** for **Life Skills/Life Story**. ☐

2. Change the date treatment began from **April 14, 2004** to **April 12, 2004**. ☐

3. Use the scroll bar on the right side of the screen to display the **Reason for Change** fields. ☐

4. Enter a reason for change by typing "**This is my reason for the change!"** into the **Reason for Change** text box. ☐

5. Click **Submit** to save your changes. ☐

Exercise 6 – Common Repeating Forms cont.

Deleting Add Entry Rows

If an **Add Entry Row** is created by mistake, it may be deleted. Use the following steps to delete an **Add Entry Row**.

1. Click the underlined row number to open the **Life Skills/Life Story record** (ie **2.a**). ☐

2. Scroll down and enter a **Reason for Change** (i.e. This record was entered by mistake.) ☐

3. Click the **Delete** button on the toolbar at the bottom of the screen. ☐
NOTE: The following confirmation message displays: "Do you really want to mark the item row as deleted?"

4. Click **OK** to confirm that you want to mark the record as "deleted". ☐

NOTE: The Life Skills/Life Story record is deleted (Text with strike-through indicates that the record is 'deleted').

NOTE: **Add Entry** records may be undeleted also. Use the steps outlined above except in # 3, select **"Undelete'** instead of "Delete". The strike throughs are removed from records that have been undeleted.

Use the **Logout** button on the Navigation pane to log out of InForm.

Congratulations! You've completed the training exercises. Notify the NCTSN Support Desk that your training case (provide case # e.g., xxxx-xx-xxxxx) is ready to be checked. The NCTSN Support Desk can be reached at:

1-919-668-8182 or by email at NCTSN@dcri.duke.edu

Thank-you for supporting this NCTSN initiative!