

CLINICALLY SIGNIFICANT FINDINGS FORM, CSF QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Clinically Significant Findings Form (CSF) is to be completed during the participant's clinic visit. All pertinent test results should be reviewed for abnormal findings. This form is used in order to identify findings that require urgent follow-up and communication by phone or equivalent method with the participant's healthcare team for further evaluation. Other abnormal findings not requiring urgent follow-up should be communicated to the participant or their physician by other methods of communication at the discretion of the local PI/IRB.

Please answer every question on this form. *NOTE: All response options in the paper form may not appear in CDART (e.g., 'Don't know', 'Declines to answer', etc.).* Beside each item input is a small double bracket icon which looks like this: . Clicking this icon displays a field dialogue box in which the "Field Status" selection menu allows you to choose from the following options: 'Refused', 'No response', 'Doesn't know', 'Not applicable', 'Maximum value', 'Minimum value', and 'Missing'. **See MOP 6 – Section 3.2 for additional instructions on how to select a Field Status option.**

Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes (e.g., enter 0.25 rather than .25).

II. INSTRUCTIONS FOR INDIVIDUAL ITEMS

Header Information: Consists of key fields which uniquely identify each subject and recorded occurrence of a form. For the "ID NUMBER", record the 3-character, 6-digit number assigned to the specific participant. For the "Event", record if this is happening at Baseline or another event.

- Item 0a.** Record the date the data was collected or abstracted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 0b.** Record the SOURCE staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SOURCE data, please contact the GIC in order to receive your own individual staff code.
- Item 1.** Select only one option among the two possible choices. If 'No' is selected, go to Item 2.
- Items 1a-1b.** Check all blood abnormalities that apply.
- Item 1c.** Select only one option among the two possible choices.
- If 'No' is selected, go to Item 1c1.
 - If 'Yes' is selected, go to Item 1c2.
- Item 1c1.** Specify why the PI or other study staff did not successfully contact the participant in the space provided.
- Item 1c2.** Record the date the participant was contacted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the data in the space provided.

Item 2. CDART will automatically populate the participant's Hospital Anxiety and Depression Score based on the values entered in the even numbered questions in the HDS form (i.e., HDS 2, 4, 6, 8, 10, 12, and 14). If not entered appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If one or more items (i.e., HDS Items 2, 4, 6, 8, 10, 12, and/or 14) are missing or not entered appropriately, Item 2 will not calculate or auto-populate accordingly.*

NOTE: If the participant's depression score (i.e., even numbered questions) from the Hospital Anxiety and Depression Scale (HADS) is greater than or equal to 15, immediate contact by phone or equivalent is required. If the participant's depression score is less than 15, go to Item 3.

Item 2a. Select only one option among the two possible choices.

- If 'No' is selected, go to Item 2a1.
- If 'Yes' is selected, go to Item 2a2.

Item 2a1. Specify why the PI or other study staff did not successfully contact the participant in the space provided.

Item 2a2. Record the date the participant was contacted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 3. Select only one option among the two possible choices. If 'No' is selected, go to Item 4.

Items 3a-3f. Check all CT findings that apply.

Item 3f1. If Item 3f is checked, specify other finding needing urgent follow-up in the space provided.

Item 3g. Select only one option among the two possible choices. If 'No' is selected, go to Item 4.

- If 'No' is selected, go to Item 3g1.
- If 'Yes' is selected, go to Item 3g2.

Item 3g1. Specify why the PI or other study staff did not successfully contact the participant in the space provided.

Item 3g2. Record the date the participant was contacted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 4. Select only one option among the two possible choices. If 'No' is selected, go to Item 5.

Item 4a.

Items 4a1-4a3. List all other findings that require immediate contact by phone or equivalent in the space(s) provided.

Item 4b. Select only one option among the two possible choices.

- If 'No' is selected, go to Item 3g1.
- If 'Yes' is selected, go to Item 3g2.

Item 4b1. Specify why the PI or other study staff did not successfully contact the participant in the space provided.

Item 4b2. Record the date the participant was contacted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 5. Select only one option among the two possible choices. If 'No' is selected, **Go to End** of the form, and **Save and Close** the form.

Item 5a. Record the PI's electronic signature in the space provided.

Item 5b. Record the date of the PI signature in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Select **Save and Close** at the bottom of the page/screen.