


Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-xxxx). Do not return the completed form to this address.

Filling out PDF Forms

This PDF form contains “**roll-over** or **double-click** ” help functionality.

This form allows you to enter data directly onto the screen. After completing the form, you are able to print the document so that you can fax/mail the document.

To fill out a form:

1. Select the hand tool. 
2. Position the pointer inside a field, and click to type text.
3. After entering text or selecting a check box, do one of the following:
 - Press tab to accept the form field change and go to the next form field.
 - Press Shift+Tab to accept the form field change and go to the previous form field.
 - Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.
4. Once completed, print the form.

Unsolicited Data Modification Form (UDM)* Protocol: TAILORx/ PACCT-1

INSTRUCTIONS

**The Unsolicited Data Modification Form template is attached to these instructions (2nd page of this document).*

Submit a CTSU Unsolicited Data Modification Form [UDM], accompanied by a CTSU TAILORx Data transmittal Form to update data provided on the original CRF OR to update data previously entered into RDC.

- **DO NOT SUBMIT AMENDED CRFs or COPIES OF CRFs.** Said documents will not be processed.
- **DO NOT SUBMIT A TAILORx UDM TO:** (1) Update the Patient ID, (2) Update the Follow-Up Report Period, (3) Update Reporting Period Start and End dates, (4) Redact patient identifiers on a previously submitted CRF/Report or (5) Respond to a Data Clarification Form (DCF).
- **SPECIAL INSTRUCTIONS TO REQUEST DELETION OF A FOLLOW-UP FORM:** only submit a deletion request for the following 2 reasons, using the standard text as specified, (1) “the wrong Patient ID was specified” OR (2) “the wrong FUP Report Period was specified.”
 1. Complete the UDM form requesting the Follow-Up form to be deleted (see example below).
 2. Submit a NEW Follow-Up form with the correct Patient ID or Follow-Up Report Period specified.

| Form Name Visit / Month | Page Number | Field / Question on CRF | Current Value on CRF | Corrected / Updated Value To |
|------------------------------------|----------------|----------------------------|-------------------------|---|
| <i>FOLLOW-UP FORM MONTH 12</i> | <i>ALL</i> | <i>ALL</i> | <i>ALL</i> | <i>DELETE FOLLOW-UP FORM, the wrong PID was specified OR the wrong FUP Report Period was specified</i> |

Contact the CTSU Helpdesk for questions (888) 823-5923.

Unsolicited Data Modification Form (UDM) Protocol: TAILORx/ PACCT-1

Patient Number: _____ NCI Site Code: _____

Patient Initials: _____ Investigator Name: _____

Submit a CTSU Unsolicited Data Modification Form [UDM], accompanied by a CTSU TAILORx Data Transmittal Form to update data provided on the original Case Report Form OR to update data previously entered into RDC.

- **DO NOT SUBMIT AN AMENDED CRF or COPIES OF CRFs.** Said documents will not be processed.
- **DO NOT SUBMIT A TAILORx UDM TO:** (1) Update the Patient ID, (2) Update the Follow-Up Report Period, (3) Update the Reporting Period Start and End dates, (4) Redact patient identifiers on a previously submitted CRF/Report, or (5) Respond to a DCF.

To be Completed by the Site:

| Form Name Visit / Month | Page # | Field / Question on CRF | Current Value on CRF | Corrected / Updated Value |
|----------------------------|--------|----------------------------|----------------------|---------------------------|
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CRA/ Investigator Signature: _____

Date: _____

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