

Unscheduled Assessment Summary

63076

Please Use Black Pen To Fill Out Form.

corrfix
Correction

Week # <i>week</i>	Sequence # <i>seqno</i>	Date of Assessment <i>assesdtd</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>
		mm / dd / yyyy	- - -	

Instructions:

Complete this form for patients from all therapy groups with unscheduled visits to the clinic.

Reason for the Visit

1. Is the patient: Hospitalized Outpatient *uahosp*

2.A. Did the patient experience a non-serious adverse event? Yes No *uaae*

B. If Yes, date of the Non-Serious Adverse Event Form: *uaaedtd* / /

3.A. Did the patient experience a serious adverse event? Yes No *uasae*

B. If Yes, date of the Serious Adverse Event Form: *uasaedt* / /

4.A. Was there another reason for the unscheduled clinic visit? Yes No *uaotr*

B. If Yes, specify:

CRA Use Only

Physical Exam

5.A. Was a physical examination clinically indicated at this visit? Yes No *uaphysexm*

B. If Yes, why was a physical exam performed:

Laboratory Data

6. Were laboratory samples drawn? Yes No *ualab*

If No, skip to item 11.

7. Date the samples were drawn: *ualabdt* / /

8. List of tests performed:

A. Hematology: Done Unable to obtain *uahmtotst*

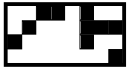
B. Chemistry: *uachemtst*

C. Other: *uaotrtrst*

Signature: _____

Certif. #: *staffid1* -

Unscheduled Assessment Summary



18308

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<i>week</i>	<i>seqno</i>	<i>assesdtt</i> mm / dd / yyyy	<i>idn</i>	<i>letcode</i>

Laboratory Data (Continued)

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9.A. Were there any hematology abnormalities of clinical significance?

Yes No *uahmtoabn*

If No, skip to item 10.

B. Record the primary reason for the abnormality (Choose one):

<input type="radio"/> Due to the disease under study	<input type="radio"/> Reasonable possibility due to other concurrent medication
<input type="radio"/> Due to other concurrent disease	<input type="radio"/> Other
<input type="radio"/> Reasonable possibility due to study drug <i>uahmtoabnres</i>	Specify: _____

10.A. Were there any chemistry abnormalities of clinical significance?

Yes No *uachemabn*

If No, skip to item 11.

B. Record the primary reason for the abnormality (Choose one):

<input type="radio"/> Due to the disease under study	<input type="radio"/> Reasonable possibility due to other concurrent medication
<input type="radio"/> Due to other concurrent disease	<input type="radio"/> Other
<input type="radio"/> Reasonable possibility due to study drug <i>uachemabnres</i>	Specify: _____

Future Visits

11.A. Was the patient placed on untreated follow-up?

Yes No *uauf*

B. If Yes, date of the Therapy Stop/Restart Form:

authrstpdt
mm / dd / yyyy

12.A. Was the patient withdrawn from the study?

Yes No *uawddt*

B. If Yes, date of the Withdrawal/Close-Out Form:

uawddt
mm / dd / yyyy

Signature: _____

Certif. #:

staffid2 - [] [] [] [] [] []