

CRF Report for Study 04_C_0121

Report generated by PATRICK CONRAD on 07-JUN-2013 16:26:16

Report on Selected Data

Filter: Patient : 43

Current Patient: 43

Notes:

1. All reported data is current as of the time shown above under 'Report Generated'.
2. All timestamps reflect the timezone of the database server in which the data was collected.
3. Superscripts appear next to fields with any of the following additional information:
 - Overflow
 - An Investigator Comment
 - Audit History if Include Audit History option was chosen
 - Discrepancies if Include Discrepancy Details option was chosen

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Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name SCREENING Visit Date 01-DEC-2004

Intentionally blank? ☐

Gender F Date of Birth 28-JUL-1948 Age at Entry 56.3 Patient Initials MR
Date of Registration 02-DEC-2004 Date from which to Start Including labs 28-OCT-2004

Race: Select all that apply

White ☐ Y
Black or African American ☐
Native Hawaiian or other Pacific Islander ☐
Asian ☐
American Indian or Alaska Native ☐
Race Not Reported ☐
Race Unknown ☐

Ethnicity NONHISPANIC
Registering Institution NCILMB
Local Patient ID 71-30-99-5
Patient Subgroup SG1
Registering Group N/A
Country Code US
Postal Code
Method of Payment 98

Primary Disease Site Blood Disease Term Chronic lymphocyt Disease Stage at Entry IV
Histology/Cytopathology LYMPHOCYTIC LEUKEMIA
Date of Confirmation of Histology 22-OCT-200 Grade of Histology
Date of diagnosis 08-JUN-1999 CDUS Treatment Assignment Code 1
Date Informed Consent Signed 01-DEC-2004 Date of Informed Consent Version 01-JAN-2002

Intentionally blank? ☒

Height (cm) Body Weight (kg) Body Surface Area Performance Status (Zubrod/ECOG)

Intentionally blank? ☒



Study 04_C_0121 Patient 43 CRF Blank ☐
 Visit Name SCREENING Visit Date 01-DEC-2004

COMMENTS

Date	Note
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Ancillary Information for CRF ENROLLMENT

This page can include any or all of the following:

- Overflow
- Investigator Comments
- Discrepancy Detail
- Audit History
- Approval History

Numbers below correspond to superscript(s) appearing with fields in the previous CRF.

1

Overflow: Chronic lymphocytic leukemia stage 4



Study 04_C_0121 Patient 43 CRF Blank ☐

Visit Name SCREENING Visit Date 02-FEB-2007

Section blank? ☐

PATIENT IDENTIFICATION

Institution

NCIMET

□

11/11/2019

Patient Medical Record Number

10-36-04-3



Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name CYCLE 1 Visit Date 02-DEC-2004

Note: dates will appear as 'DD-MON-YYYY'

Section blank? ☐

COURSE INITIATION

Course#
Start Date of Course
Arm
CTEP Treatment Assignment Code
Treating Institution

Section blank? ☒

VITAL SIGNS

Height (cm)	Weight (kg)	BSA	Performance Status Zubrod/ECOG
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>



Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name CYCLE 1 Visit Date 02-DEC-2004

Note: dates will appear as 'DD-MON-YYYY'

Section blank? ☒

COMMENTS

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Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name CYCLE 1 Visit Date 02-DEC-2004

COMMENTS

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Patient 43

Visit Date 02-DEC-2004CRF Blank ☐

Section blank? ☐

STUDY DRUG ADMINISTRATION

[illegible]

Form STUDY MED (v1, 31-JAN-2007)

CRF Page C1.2.1 of 2

Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name CYCLE 2 Visit Date 29-DEC-2004

Note: dates will appear as 'DD-MON-YYYY'

Section blank? ☐

COURSE INITIATION

Course#
Start Date of Course
Arm
CTEP Treatment Assignment Code
Treating Institution

Section blank? ☒

VITAL SIGNS

Height (cm)	Weight (kg)	BSA	Performance Status Zubrod/ECOG
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>



Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name CYCLE 2 Visit Date 29-DEC-2004

Note: dates will appear as 'DD-MON-YYYY'

Section blank? ☒

COMMENTS

Date	Notes
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Study	04_C_0121	Patient	43	CRF Blank	<input type="checkbox"/>
Visit Name	CYCLE 2	Visit Date	29-DEC-2004		

COMMENTS

[illegible]

Patient 43

Visit Date 29-DEC-2004CRF Blank ☐

Section blank? ☐

STUDY DRUG ADMINISTRATION

[illegible]

Form STUDY MED (v1, 31-JAN-2007)

CRF Page C2.2.1 of 2



Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name BLOOD CHEMISTRY Visit Date 29-JUL-2006

Visit Name BLOOD CHEMISTRY Lab DLM
Date 29-JUL-2006 Time 00:00:00 Section blank? ☐

BLOOD CHEMISTRY

Course# 2 Day 578

Lab Test	Value	Units	Report? Y / N	Normal Range (e.g. 1.5-5)	Range Indicator	Grade
BUN	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
CREATININE	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
SODIUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
POTASSIUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
CHLORIDE	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
MAGNESIUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
BICARB_SERUM	<u>25</u>	<u>mmol/L</u>	<input type="radio"/> Y <input type="radio"/> N	<u>21.0-31.0</u>	<u>NORMAL</u>	<u>0</u>
URIC_ACID	<u>3.3</u>	<u>mg/dL</u>	<input type="radio"/> Y <input type="radio"/> N	<u>2.4-5.8</u>	<u>NORMAL</u>	<u>0</u>
BILIRUBIN_TOTAL	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
ALK_PHOS	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
SGOT_AST	<u>190</u>	<u>Unit/L</u>	<input type="radio"/> Y <input type="radio"/> N	<u>9.0-34.0</u>	<u>HIGH</u>	<u>3</u>
SGPT_ALT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
SGGT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
LDH	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
TOT_PROT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
ALBUMIN_SERUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
GLOBULIN	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
CALCIUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
INORG_PHOS	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
GLUC_FASTING	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
GLUC_NONFASTING	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
CHOLESTEROL_TOTAL	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
AMYLASE_SERUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
5_NUCLEOTIDASE	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		
CPK	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>		

Range Indicator: NORMAL, HIGH, LOW, NONNUM, NORANG

Grade: 0 - None, 1 - Mild, 2 - Moderate, 3 - Severe, 4 - Life-Threatening



Study 04_C_0121 Patient 43 CRF Blank ☐

Visit Name BLOOD CHEMISTRY Visit Date 29-JUL-2006

Note: Dates will appear as 'DD-MON-YYYY'

Section blank? ☐

COMMENTS

Date

Note

[illegible]

Doc#	D209802	Status	Batch Loaded	Form	BLOOD CHEM (v1, 30-JAN-2007)
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Visit# 30 Subevent# 0 DCI Date 29-JUL-2006 CRF Page BC1.2 of 3



Study	04_C_0121	Patient	43	CRF Blank	<input type="checkbox"/>
Visit Name	BLOOD CHEMISTRY	Visit Date	29-JUL-2006		

COMMENTS

[illegible]

Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name BLOOD CHEMISTRY Visit Date 01-JAN-2009

Visit Name BLOOD CHEMISTRY.1 Lab DLM
Date 01-JAN-2009 Time 10:05:00 Section blank? ☐

BLOOD CHEMISTRY

Course# Day

Lab Test	Value	Units	Report? Y / N	Normal Range (e.g. 1.5-5)	Range Indicator	Grade
BUN	<u>19</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
CREATININE	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
SODIUM	<u>3</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
POTASSIUM	<u>4</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
CHLORIDE	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
MAGNESIUM	<u>6</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
BICARB_SERUM	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
URIC_ACID	<u>8</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
BILIRUBIN_TOTAL	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
ALK_PHOS	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
SGOT_AST	<u>11</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
SGPT_ALT	<u>12</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
SGGT	<u>13</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
LDH	<u>14</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
TOT_PROT	<u>15</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
ALBUMIN_SERUM	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
GLOBULIN	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
CALCIUM	<u>5</u>	<u>Cells/microL</u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
INORG_PHOS	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
GLUC_FASTING	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
GLUC_NONFASTING	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
CHOLESTEROL_TOTAL	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
AMYLASE_SERUM	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
5_NUCLEOTIDASE	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>
CPK	<u> </u>	<u> </u>	<input type="radio"/> <input type="radio"/>	<u> </u>	<u> </u>	<u> </u>

Range Indicator: NORMAL, HIGH, LOW, NONNUM, NORANG

Grade: 0 - None, 1 - Mild, 2 - Moderate, 3 - Severe, 4 - Life-Threatening



Study	04_C_0121	Patient	43	CRF Blank	<input type="checkbox"/>
Visit Name	BLOOD CHEMISTRY	Visit Date	01-JAN-2009		

Note: Dates will appear as 'DD-MON-YYYY'

Section blank? ☐

COMMENTS

Date

Note

[illegible]



Study	04_C_0121	Patient	43	CRF Blank	<input type="checkbox"/>
Visit Name	BLOOD CHEMISTRY	Visit Date	01-JAN-2009		

COMMENTS

[illegible]

Study 04_C_0121 Patient 43 CRF Blank ☐

Visit Name HEMATOLOGY Visit Date 01-JAN-2009

Visit Name HEMATOLOGY Lab DLM
Date 01-JAN-2009 Time 10:05:00 Section blank? ☐

HEMATOLOGY

Course # Day in Course

Lab Test	Value	UOM	Report Y / N	Normal Range (e.g. 1.5-5)	Range Indicator	Grade
HEMOGLOBIN	<u>10</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
HEMATOCRIT	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
WBC_SERUM	<u>16</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
BANDS	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
NEUT	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
LYMPHOCYTES_SERUM	<u>23</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
BASO	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
MONOCYTES_SERUM	<u>7</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
EOSIN	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
BLAST_CELLS	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
A_LYMPH	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
OTHR_DIFF	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
PLT	<u>2</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
ANC	<u>9</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
RBC_SERUM	<u>25</u>	<u>Cells/microL</u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
RETIC	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
ESR	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
PT	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>
PTT	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>

Range Indicator: NORMAL, HIGH, LOW, NONNUM, NORANG

Grade: 0 - None, 1 - Mild, 2 - Moderate, 3 - Severe, 4 - Life-Threatening



Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name HEMATOLOGY Visit Date 01-JAN-2009

Note: Dates will appear as 'DD-MON-YYYY'

Section blank? ☐

COMMENTS

Date	Note
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Study	04_C_0121	Patient	43	CRF Blank	<input type="checkbox"/>
Visit Name	HEMATOLOGY	Visit Date	01-JAN-2009		

COMMENTS

[illegible]



Study 04_C_0121 Patient 43 CRF Blank ☐

Visit Name HEMATOLOGY Visit Date 03-JUN-2013

Visit Name HEMATOLOGY.1

Lab DLM

Date 03-JUN-2013 Time 08:59:00

Section blank? ☐

HEMATOLOGY

Course # Day in Course

Lab Test	Value	UOM	Report Y / N	Normal Range (e.g. 1.5-5)	Range Indicator	Grade
HEMOGLOBIN	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
HEMATOCRIT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
WBC_SERUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
BANDS	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
NEUT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
LYMPHOCYTES_SERUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
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A_LYMPH	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
OTHR_DIFF	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
PLT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
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RBC_SERUM	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ESR	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
PT	<input type="text"/>	<input type="text"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text"/>	<input type="text"/>	<input type="text"/>
PTT	<u>31.7</u>	<u>sec</u>	<input type="radio"/> Y <input type="radio"/> N	<u>25.3-37.3</u>	<input type="text"/>	<input type="text"/>

Range Indicator: NORMAL, HIGH, LOW, NONNUM, NORANG

Grade: 0 - None, 1 - Mild, 2 - Moderate, 3 - Severe, 4 - Life-Threatening



Study 04_C_0121 Patient 43 CRF Blank ☐
Visit Name HEMATOLOGY Visit Date 03-JUN-2013

Note: Dates will appear as 'DD-MON-YYYY'

Section blank? ☐

COMMENTS

Date	Note
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Study 04_C_0121 Patient 43 CRF Blank ☐
 Visit Name HEMATOLOGY Visit Date 03-JUN-2013

COMMENTS

Date	Note
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Study 04_C_0121

Patient 43

Visit Name ONGOING

CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY'

Section blank? ☐

		Prior Course AE?	ADVERSE EVENTS							Expedited Report filed?	Grade	Attribution	Dose Limiting Toxicity	Serious	Action	Therapy	Outcome
Course#	Day	Y/N	Date of Onset	Date Resolved	CTC Term	CTC Category	AE Description	Y/N/U	Y/N/U	Y/N/U	Y/N/U	Y/N/U	Y/N/U	Y/N/U	Y/N/U	Y/N/U	Y/N/U
<u>1</u>	<u>6</u>	<input type="radio"/> Y <input checked="" type="radio"/> N	<u>07-DEC-2004</u>	<u>08-DEC-2004</u>	<u>Platelets</u>	<u>BLOOD/BONE MAR</u> ¹	<u>Platelets r/t CLL,</u> ²	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>3</u>	<u>3</u>	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>
<u>1</u>	<u>8</u>	<input type="radio"/> Y <input checked="" type="radio"/> N	<u>09-DEC-2004</u>	<u>11-DEC-2004</u>	<u>Hemorrhage, GU</u> ³	<u>HEMORRHAGE/BLF</u> ⁴	<u>Hemmorage r/t LMB-</u> ⁵	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>3</u>	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>
<u>1</u>	<u>9</u>	<input type="radio"/> Y <input checked="" type="radio"/> N	<u>10-DEC-2004</u>	<u>10-DEC-2004</u>	<u>Dizziness</u>	<u>NEUROLOGY</u>	<u>Dizziness r/t LM@</u> ⁶	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>3</u>	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>
<u>1</u>	<u>10</u>	<input type="radio"/> Y <input checked="" type="radio"/> N	<u>11-DEC-2004</u>	<u>15-DEC-2004</u>	<u>Insomnia</u>	<u>CONSTITUTIONAL</u> ⁷	<u>Insomnia r/t nose</u> ⁸	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>2</u>	<input type="radio"/> Y <input checked="" type="radio"/> N <input type="radio"/> U	<u>1</u>	<u>1</u>	<u>2</u>	<u>1</u>	<u>1</u>	<u>1</u>
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<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
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<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
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<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Grade:	Attribution:	Serious:	Action:	Therapy:	Outcome:
1-Mild	1-Unrelated	1-No	1-None	1-None	1-Recovered
2-Moderate	2-Unlikely	2-Threat	2-Reduced	2-Support	4-Died
3-severe	3-Possible	3-Death	3-Interrupt	3-Vigorous	
4-Life-Threatening	4-Probable	4-Disability	4-Discont		
5-Fatal	5-Definite	5-Hospital	5-Interrupt/Reduced		
		6-Anomaly			
		7-Jeopardy			

Doc# R200702

Status Entry Complete

Form ADV EVENT (v1, 31-JAN-2007)

Visit# 50

Subevent# 0

CRF Page 0.1.1 of 4

Study 04_C_0121

Patient 43

Visit Name ONGOING

CRF Blank ☐

<i>Course#</i>	<i>Day</i>	Prior Course AE? Y / N	Date of Onset	Date Resolved	CTC Term	<i>CTC Category</i>	AE Description	Expedited Report filed? Y / N / U	Grade	Attribution	Dose Limiting Toxicity Y / N	Serious	Action	Therapy	Outcome	
—	—	OO						OOO			O	O				
—	—	OO						OOO			O	O				
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Grade:
 1-Mild
 2-Moderate
 3-severe
 4-Life-Threatening
 5-Fatal

Attribution:
 1-Unrelated
 2-Unlikely
 3-Possible
 4-Probable
 5-Definite

Serious:
 1-No
 2-Threat
 3-Death
 4-Disability
 5-Hospital
 6-Anomaly
 7-Jeopardy

Action:
 1-None
 2-Reduced
 3-Interrupt
 4-Discont
 5-Interrupt/Reduced

Therapy:
 1-None
 2-Symptom
 3-Support
 4-Vigorous

Outcome:
 1-Recovered
 4-Died

Doc# R200702

Status	Entry Complete
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Form ADV EVENT (v1, 31-JAN-2007)

Visit# 50

Subevent# 0

CRF Page 0.1.2 of 4



Study 04_C_0121

Patient 43

Visit Name ONGOING

CRF Blank ☐

Course#	Day	Prior Course AE? Y / N	Date of Onset	Date Resolved	CTC Term	CTC Category	AE Description	Expedited Report filed? Y / N / U	Grade	Attribution	Dose Limiting Y / N	Toxicity	Serious	Action	Therapy	Outcome
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Grade: 1-Mild 2-Moderate 3-severe 4-Life-Threatening 5-Fatal	Attribution: 1-Unrelated 2-Unlikely 3-Possible 4-Probable 5-Definite	Serious: 1-No 2-Threat 3-Death 4-Disability 5-Hospital 6-Anomaly 7-Jeopardy	Action: 1-None 2-Reduced 3-Interrupt 4-Discont 5-Interrupt/Reduced	Therapy: 1-None 2-Symptom 3-Support 4-Vigorous	Outcome: 1-Recovered 4-Died
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Doc# R200702

Status Entry Complete

Form ADV EVENT (v1, 31-JAN-2007)

Visit# 50

Subevent# 0

CRF Page O.1.3 of 4



caBIG™ cancer Biomedical
Informatics Grid™

Study 04_C_0121

Patient 43

Visit Name ONGOING

CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY'

Section blank? ☒

COMMENTS

Date	Note

Doc# R200702

Status Entry Complete

Form ADV EVENT (v1, 31-JAN-2007)

Visit# 50

Subevent# 0

CRF Page O.1.4 of 4

Ancillary Information for CRF ADVERSE EVENTS

This page can include any or all of the following:

- Overflow
- Investigator Comments
- Discrepancy Detail
- Audit History
- Approval History

Numbers below correspond to superscript(s) appearing with fields in the previous CRF.

1

Overflow: BLOOD/BONE MARROW

2

Overflow: Platelets r/t CLL, LMB2

3

Overflow: Hemorrhage, GU::Bladder

4

Overflow: HEMORRHAGE/BLEEDING

5

Overflow: Hemmorage r/t LMB-2 CLL INFXN

6

Overflow: Dizziness r/t LM@ CLL LNFXN

7

Overflow: CONSTITUTIONAL SYMPTOMS

8

Overflow: INsomnia r/t nose at night