## 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

## **Table of Contents**

SCREENING	3
ENROLLMENT	3
Ancillary Data Section for ENROLLMENT	6
MEDICAL RECORD NUMBERS	
CYCLE 1	8
COURSE INITIATION	8
STUDY MED ADMIN	11
CYCLE 2	13
COURSE INITIATION	13
STUDY MED ADMIN	16
BLOOD CHEMISTRY	18
BLOOD CHEMISTRY	18
BLOOD CHEMISTRY.1	21
BLOOD CHEMISTRY	
HEMATOLOGY	24
HEMATOLOGY	24
HEMATOLOGY.1	
HEMATOLOGY	27
ONGOING	30
ADVERSE EVENTS	30
Ancillary Data Section for ADVERSE EVENTS	





Study	04_C_0121	Patient	43	CRF Blank				
Visit Name	SCREENING	Visit Date	01-DEC-2004					
Intentionally blank?	]							
Date of Registration  Race: Select all that  White  Black or African An	apply nerican other Pacific Islander	Ethnicity	NONHISE Institution t ID 71-30-9 roup SG1 Group N/A le US					
Histology/Cytopatholo Date of Confirmation of Date of diagnosis	Primary Disease Site Blood Disease Term Chronic lymphocyti 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							
Intentionally blank?		Date of In	formed Consent Ver	rsion 01-JAN-2002				
Height (cm)	Body Weight (kg) Body Surfa	ace Area	Performance State	us (Zubrod/ECOG)				
Intentionally blank?	]							
Doc# R203102	Status Entry Complete		Form ENI	ROLL (v2, 11-JUN-2008)				

Subevent# 0 DCI Date 01-DEC-2004

CRF Page S.1.1

of 3





CRF Page <u>S.1.2</u> of 3

•	04_C_0121	Patient	43						
Visit Nam	ne <u>SCREENING</u>	Visit Date	01-DEC-200	4					
COMMENTS									
Date	Notes								
<u> </u>									
Doc# R203102	2 Status En	try Complete	Form	ENROLL (v2, 11-JUN-2008)					

Subevent# 0 DCI Date 01-DEC-2004





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

Date	Note	Э				
oc# F	R203102	Status	Entry Complete		Form	ENROLL (v2, 11-JUN-2008)
sit# <u>1</u>		_ Subevent#.	0 DCI Date	01-DEC-2004	CRF Pa	age <u>S.1.3</u> of 3

## **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





ANCER Institute					caBIG <sup>™</sup> cancer Biomedical Informatics Grid <sup>™</sup>
Study Visit Name	04_C_0121 SCREENING		Patient Visit Date	43 02-FEB-2007	CRF Blank
					Section blank?
	PATIENT IDE	NTIFIC	ATION		
Institut NCIM		Patient  10-36-	Medical Record	d Number	

R193302 **Entry Complete** MRN (v2, 31-JAN-2007) Status Form Doc#

Subevent# 0 DCI Date CRF Page S.2 of 1 02-FEB-2007 Visit#





HOTTIGIE									
Study	04_C_0121	Patient	43	CRF Blank					
Visit Name	CYCLE 1	Visit Date	02-DEC-2004						
Note: dates will ap	pear as 'DD-MON-YYYY'			Section blank?					
COURSE INITIATION									
Course# Start Date of Cou Arm CTEP Treatment Treating Institutio	Assignment Code ARM B/PROG								
				Section blank?	<u>√</u>				
Height Wei (cm) (kg		S							

 Doc#
 R204502
 Status
 Entry Complete
 Form
 INITIATION (v1, 01-FEB-2007)

 Visit#
 10
 Subevent#
 0
 DCI Date
 02-DEC-2004
 CRF Page
 C1.1.1
 of 3





Study	04_C_0121		Patient	43	CRF Blank
Visit Name	CYCLE 1		Visit Date	02-DEC-2004	<u> </u>
Note: dates will appear	r as 'DD-MON-YY		MENTS		Section blank?
Date	Notes				
	1				
	L				
	<u> </u>				
Doc# R204502	Status	Entry Complete		Form	INITIATION (v1, 01-FEB-2007)
Visit# 10	Subevent#	0 DCI Date	02-DEC-2004	CRF Pa	age <u>C1.1.2</u> of 3





Study	04_C_0121	Patient	43	CRF Blank
Visit N	ame CYCLE 1	Visit Date	02-DEC-2004	

Date	Note
	<u> </u>
	<b>-</b>
# R2045	2 Status Entry Complete Form INITIATION (v1, 01-FEB-2





Study <u>0</u>	04_C_0121	Patient	43			
Visit Name C	CYCLE 1	Visit Date	02-DEC-2004	CRF Blank		
Note: Dates will app	pear as 'DD-MON-YYYY'				Section blank?	П

## STUDY DRUG ADMINISTRATION

				[Pla	anned	-]	[Ac	ctual	]		
Day	Start Date	Time	Medication	Level	Units	Lot#	Dose	Units	Schedule	Duration	Units
1	02-DEC-2004	19:35	LMB-2	40	MCG/KG	112-58	2670	MCG	D1	30	MN
3	04-DEC-2004	19:15	LMB-2	40	MCG/KG	112-58	2670	MCG	D2	30	MN
5	06-DEC-2004		LMB-2	40	MCG/KG	112-58	2670	MCG	D3	35	MN
											Ш
											$\square$
											Щ
											$\square$
									<u> </u>		$\vdash$
											$\vdash$
											Щ

Doc#	R200502	Status	Entry Complete	Form	STUDY MED (v1, 31-JAN-2007)
Visit#	10	Subevent#	0	CRF Pa	age <u>C1.2.1</u> of <sup>2</sup>





Stu	udy <u>04_C_0121</u>		Patien	t <u>43</u>			
Visit Naı	me <u>CYCLE 1</u>		Visit Date	02-DEC-2004	CRF Blank		
Note: Date	es will appear as 'DD-l	MON-YYYY'	COMMENT	S		Section blank?	V
Date	Note						
							_
							$\dashv$
							罝
							_
							_
Doc# F	R200502	Status	Entry Complete		Form STUDY MED (v1, 3	1-JAN-2007)	
Visit# <u>1</u>	10	Subevent#	0		CRF Page C1.2.2	of <sup>2</sup>	





1 STIT GIE				
Study	04_C_0121	Patient	43	CRF Blank
Visit Name	CYCLE 2	Visit Date	29-DEC-2004	
Note: dates will ap	pear as 'DD-MON-YYYY'			Section blank?
	COURSE II	NITIATION		
Course# Start Date of Cou Arm CTEP Treatment Treating Institutio	Assignment Code ARM B	04		
				Section blank?
	VITAL SIGNS			
Height Wei		IS		

 Doc#
 R205102
 Status
 Entry Complete
 Form
 INITIATION (v1, 01-FEB-2007)

 Visit#
 20
 Subevent#
 0
 DCI Date
 29-DEC-2004
 CRF Page
 C2.1.1
 of 3





Study	04_C_0121		Patient	43	CRF Blank
Visit Name	CYCLE 2		Visit Date	29-DEC-2004	4
Note: dates will appea	r as 'DD-MON-YY		IENTS		Section blank?
Date	Notes				
	]				
	<u> </u>				
	<u> </u>				
	]				
	\				
	\ ][				
	J				
	]				
	]				
	1				
	J				
	]				
	]				
	]				
Doc# R205102	Status	Entry Complete		Form	INITIATION (v1, 01-FEB-2007)
Visit# <u>20</u>	Subevent#	0 DCI Date	29-DEC-2004	CRF Pa	age <u>C2.1.2</u> of 3





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

Date	е	Note
oc#	R205102	Status Entry Complete Form INITIATION (v1, 01-FEB-2007
sit#	20	Subevent# 0 DCI Date 29-DEC-2004 CRF Page C2.1.3 of 3





Study <u>04_C_0121</u>	Patient	43	
Visit Name CYCLE 2	Visit Date	29-DEC-2004	CRF Blank
Note: Dates will appear as 'DD-MON-YYYY'			Section blank?

## STUDY DRUG ADMINISTRATION

				[Pla	anned	-]	[Ac	ctual	]		
Day	Start Date	Time	Medication	Level	Units	Lot#	Dose	Units	Schedule	Duration	Units
1	29-DEC-2004	23:55	LMB-2	40	MCG/KG	114918	2710	MCG	D1	33	MN
3	31-DEC-2004	19:54	LMB-2	40	MCG/KG	114918	2710	MCG	D2	30	MN
5	02-JAN-2005	19:48	LMB-2	40	MCG/KG	114918	2710	MCG	D3	30	MN
								<u>                                     </u>			Ш
								l			$\square$
								ļ			$\square$
								ļ			$\square$
								l			$\vdash$
											$\square$
											$\square$

Doc#	R200602	Status	Entry Complete	Form	STUDY MED (v1, 31-JAN-2007)
Visit#	20	Subevent#	0	CRF Pa	ge <u>C2.2.1</u> of <sup>2</sup>





St	tudy	04_C_0121			Patient	43					
Visit Na	ame	CYCLE 2		<u></u>	Visit Date	29-DEC-2004		CRF Blank		]	
Note: Dat	tes will	appear as 'DD-M	ION-YYYY'	С	OMMENTS				Sect	tion blank?	P
Date		Note									
		<u> </u>									_
		][ ][									$\dashv$
		<u> </u>									_
		<u> </u>									<u> </u>
		<u> </u>									_
Doc#	R2006	602	Status	Entry Complete			Form ST	UDY MED (v1, 3	31-JAN	I-2007)	
Visit#	20		Subevent#	0			CRF Page	C2.2.2	of 2		





Study	04_C_0121		Patient	43	CRF	Blank
Visit Name	BLOOD CHEMISTRY		Visit Date	29-JUL-200	06	_
Visit Name BLOOD C	HEMISTRY 2006 Time 00:00:	00	Lab <sub>DI</sub>	LM	] Section	ı blank?
	В	LOOD C	HEMISTRY	•		
Course# 2	<i>Day</i> <u>578</u>					
Lab Test	Value	Units		Report? Y ./ N	Normal Range (e.g. 1.5-5)	Range Indicator Grade
BUN						]
CREATININE						]
SODIUM						]
POTASSIUM						]
CHLORIDE						]
MAGNESIUM						]
BICARB_SERUM	25	mmol/L			21.0-31.0	NORMAL 0
URIC_ACID	3.3	mg/dL			2.4-5.8	NORMAL 0
BILIRUBIN_TOTAL						]
ALK_PHOS						]
SGOT_AST	190	Unit/L			9.0-34.0	HIGH 3
SGPT_ALT						]
SGGT						]
LDH						]
TOT_PROT						]
ALBUMIN_SERUM						]
GLOBULIN						]
CALCIUM						]
INORG_PHOS						]
GLUC_FASTING						]
GLUC_NONFASTING						]
CHOLESTEROL_TOTA	AL					]
AMYLASE_SERUM						
5_NUCLEOTIDASE						
СРК						]
_	MAL, HIGH, LOW, NONN fild, 2 - Moderate, 3 - Sev					
Doc# D209802	Status Batch L	oaded		Form	BLOOD CHEM	(v1, 30-JAN-2007
Visit# 30	Subevent# 0	DCI Date	29-JUL-2006	CRF F	Page BC1.1	of 3



D209802



Study	04_C_0121	Patient	43	CRF Blank
Visit Name	BLOOD CHEMISTRY	Visit Date	29-JUL-2006	
	pear as 'DD-MON-YYYY'  COMM	ENTS		Section blank?
Date	Note			

BLOOD CHEM (v1, 30-JAN-2007) Doc# Subevent# 0 30 \_\_DCI Date 29-JUL-2006 BC1.2 CRF Page Visit#

Form

Batch Loaded

Status





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

Date	Note

 Doc#
 D209802
 Status
 Batch Loaded
 Form
 BLOOD CHEM (v1, 30-JAN-2007)

 Visit#
 30
 Subevent#
 0
 DCI Date
 29-JUL-2006
 CRF Page
 BC1.3
 of 3





Study	04_C_0121		Patient	43	CRF	Blank
Visit Name	BLOOD CHEMIST	RY	Visit Date	01-JAN-2009	9	<u>—</u>
Visit Name BLOOD  Date 01-JAN		:05:00	Lab <sub>D1</sub>	LM	Section	blank?
		BLOOD (	CHEMISTRY	<b>(</b>		
Course#	Day					_
Lab Test	Va	lue Units		Report? Y ./ N	Normal Range (e.g. 1.5-5)	Range Indicator Grade
BUN	19	Cells	microL			<u> </u>
CREATININE				$\supset \circ \circ$		
SODIUM	3	Cells	microL			
POTASSIUM	4	Cells	microL	$\Box$ $\circ$ $\circ$		
CHLORIDE				$\Box$ $\circ$ $\circ$		l
MAGNESIUM	6	Cells	microL	$\Box$ $\circ$ $\circ$		l
BICARB_SERUM				$\Box$ $\circ$ $\circ$		l
URIC_ACID	8	Cells	microL	$\Box$		l
BILIRUBIN_TOTA	L			$\square \circ \circ$		l
ALK_PHOS				$\square \circ \circ$		l
SGOT_AST	11	Cells	microL	$\Box$		l
SGPT_ALT	12	Cells	microL	$\Box$		l
SGGT	13	Cells	microL	$\Box$ $\circ$ $\circ$		l
LDH	14	Cells	microL	$\Box$		
TOT_PROT	15	Cells	microL	$\square \circ \circ$		l
ALBUMIN_SERUM				$\Box$		l
GLOBULIN				$\Box$		l
CALCIUM	5	Cells	microL	$\Box$		l
INORG_PHOS				$\Box$		l
GLUC_FASTING				$\Box$		l
GLUC_NONFASTING	G			$\square \circ \circ$		l
CHOLESTEROL_TO	ral			$\square \circ \circ$		<u> </u>
AMYLASE_SERUM						l
5_NUCLEOTIDASE						l
CPK				$\Box \circ \circ$		l
_	RMAL, HIGH, LOW, Mild, 2 - Moderate,					
Doc# D1077702	Status E	Batch Loaded		Form	BLOOD CHEM	(v1, 30-JAN-200
Visit# 30	Subevent# <u>1</u>	DCI Date	01-JAN-2009	CRF Pa	age <u>BC1.U1.1</u>	_ of 3





Study	04_C_0121	Patient	43	CRF Blank
Visit Name	BLOOD CHEMISTRY	Visit Date	01-JAN-2009	
Note: Dates will app	pear as 'DD-MON-YYYY'  COMM	ENTS		Section blank?
Date	Note			

 Doc#
 D1077702
 Status
 Batch Loaded
 Form
 BLOOD CHEM (v1, 30-JAN-2007)

 Visit#
 30
 Subevent#
 1
 DCI Date
 01-JAN-2009
 CRF Page
 BC1.U1.2
 of 3





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

Date	Note

 Doc#
 D1077702
 Status
 Batch Loaded
 Form
 BLOOD CHEM (v1, 30-JAN-2007)

 Visit#
 30
 Subevent#
 1
 DCI Date
 01-JAN-2009
 CRF Page
 BC1.U1.3
 of 3





Study	04_C_0121	Patient	43	CRF	Blank
Visit Name	HEMATOLOGY	Visit Date	01-JAN-2009		
Visit Name HEMATOL	ogy	Lab D	LM		
Date 01-JAN-		00		S	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	10	Cells/microL			]
HEMATOCRIT					]
WBC_SERUM	16	Cells/microL			]
BANDS					]
NEUT					]
LYMPHOCYTES_SERU	JM 23	Cells/microL			]
BASO					]
MONOCYTES_SERUM	7	Cells/microL			]
EOSIN					]
BLAST_CELLS					]
A_LYMPH					]
OTHR_DIFF					]
PLT	2	Cells/microL			]
ANC	9	Cells/microL			]
RBC_SERUM	25	Cells/microL			]
RETIC					]
ESR					
PT					
PTT					]
Panga Indicator: NOD	MAL, HIGH, LOW, NONNU	IM NORANG			

Range Indicator: NORMAL, HIGH, LOW, NONNUM, NORANG Grade: 0 - None, 1 - Mild, 2 - Moderate, 3 - Severe, 4 - Life-Threatening

 Doc#
 D1077802
 Status
 Batch Loaded
 Form
 HEMATOLOGY (v1, 30-JAN-2007)

 Visit#
 40
 Subevent#
 0
 DCI Date
 01-JAN-2009
 CRF Page
 HM1.1
 of 3





HEMATOLOGY (v1, 30-JAN-2007)

Form

Study	04_C_0121	Patient	43	CRF Blank
Visit Name	HEMATOLOGY	Visit Date	01-JAN-2009	_
Note: Dates will appe	ar as 'DD-MON-YYYY'			Section blank?
Date	Note			
	1			

Visit# 40 Subevent# 0 DCI Date 01-JAN-2009 CRF Page HM1.2 of 3

Batch Loaded

D1077802 Status

Doc#





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

Date	Note

 Doc#
 D1077802
 Status
 Batch Loaded
 Form
 HEMATOLOGY (v1, 30-JAN-2007)

 Visit#
 40
 Subevent# 0 DCI Date
 01-JAN-2009
 CRF Page
 HM1.3 of 3





Study	04_C_0121		Patient	43	CRF	Blank
Visit Name	HEMATOLOGY		Visit Date	03-JUN-2013	3	
Visit Name HEMATOL	JOGY . 1		Lab <sub>DI</sub>	LM		
Date 03-JUN-	2013 Time 08:59:	00			S	Section blank?
		HEM <i>A</i>	ATOLOGY			
Course #	Day in Course					
Lab Test	Value	UOM		Report Y / N	Normal Range (e.g. 1.5-5)	Range Indicator Grade
HEMOGLOBIN						]
HEMATOCRIT						]
WBC_SERUM						]
BANDS						]
NEUT						]
LYMPHOCYTES_SER	UM					]
BASO						]
MONOCYTES_SERUM						]
EOSIN						]
BLAST_CELLS						]
A_LYMPH						]
OTHR_DIFF						]
PLT						]
ANC						]
RBC_SERUM						]
RETIC						]
ESR						<u> </u>
PT						
PTT	31.7	sec			25.3-37.3	
Range Indicator: NOR	EMAL, HIGH, LOW, NONNI	IM NORA	NG	_		

Range Indicator: NORMAL, HIGH, LOW, NONNUM, NORANG Grade: 0 - None, 1 - Mild, 2 - Moderate, 3 - Severe, 4 - Life-Threatening

 Doc#
 D1077902
 Status
 Batch Loaded
 Form
 HEMATOLOGY (v1, 30-JAN-2007)

 Visit#
 40
 Subevent#
 1
 DCI Date
 03-JUN-2013
 CRF Page
 HM1.U1.1
 of 3





HEMATOLOGY (v1, 30-JAN-2007)

Form

Study	04_C_0121	Patient	43	CRF Blank
Visit Name	HEMATOLOGY	Visit Date	03-JUN-2013	
Note: Dates will appea	ar as 'DD-MON-YYYY'	ENTS		Section blank?
Date	Note			

Visit# 40 Subevent# 1 DCI Date 03-JUN-2013 CRF Page HM1.U1.2 of 3

Batch Loaded

Status

D1077902

Doc#





Study	04_C_0121 HEMATOLOGY	Patient	43 03-JUN-2013	CRF Blank
Visit Name	TILIMATOLOGI	Visit Date	03-3014-2013	-
		COMMENTS		
	Note			

1	
1	

 Doc#
 D1077902
 Status
 Batch Loaded
 Form
 HEMATOLOGY (v1, 30-JAN-2007)

 Visit#
 40
 Subevent#
 1
 DCI Date
 03-JUN-2013
 CRF Page
 HM1.U1.3
 of 3





Study	04_C_0121		Patient <u>43</u>		
Visit Name	ONGOING				CRF Blank
Note: Dates will a	appear as 'DD-MON-Y'	YYY'			Section blank?
	Prior Course		ADVERSE EVEN	тѕ	Expedited Grade Serious Serious Artiful Outcome Outcome
Course# Day	AE? Y / N Date of Onset	Date Resolved CTC Term	CTC Category	AE Description	1 / IN / U
<u>1</u> <u>6</u>	07-DEC-2004	08-DEC-2004 Platelets	BLOOD/BONE MAF	Platelets r/t CLL,	
1 8	09-DEC-2004	11-DEC-2004 Hemorrhag	ge, GU 3 HEMORRHAGE/BLE	Hemmorage r/t LMB-2	
1 9	10-DEC-2004	10-DEC-2004 Dizziness	NEUROLOGY	Dizziness r/t LM@ (	
1 10	11-DEC-2004	15-DEC-2004 Insomnia	CONSTITUTIONAL 7	INsomnia r/t nose a	
	. 00				
	.00				
	. 00				
	. 00				
	. 00				
	. 00				
	. 00				
	. 00				
Grade: 1-Mild 2-Moderate 3-severe 4-Life-Threat 5-Fatal	Attribution: 1-Unrelated 2-Unlikely 3-Possible tening 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	1-None 1	Dutcome: I-Recovered I-Died
Doc# R2007	702	Status Ent	try Complete	Form	ADV EVENT (v1, 31-JAN-2007)
Visit# <u>50</u>		Subevent# 0		CRF P	Page 0.1.1 of 4





Study	04_C_0	0121		F	Patient <u>43</u>		
Visit Name	ONGO	ING					CRF Blank
Course# Day  Course# Day  Grade: 1-Mild 2-Moderate 3-severe 4-Life-Threate 5-Fatal	00		Date Resolved CT	Action 1-Not 2-Results 3-Int 4-Dis 5-Int		AE Description  Therapy: 1-None 2-Symptom 3-Support 4-Vigorous	Expedited Report filed? Y/N/U    OOO   OO   OO   OO   OO   OO   OO
Doc# R2007	02		Status	Entry Comp	olete		Form ADV EVENT (v1, 31-JAN-2007)
Visit# <u>50</u>			Subeventa	# 0			CRF Page 0.1.2 of 4





Study <u>04_C_</u>	0121		Patient <u>43</u>		
Visit Name ONGO	ING				CRF Blank
Prior Course AE?  Course# Day Y/N  OO OO OO OO	Date of Onset Date	Resolved CTC	Term CTC Category	AE Description	
00 00 00					
00 00 00					
00 00 00					
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	F	Form ADV EVENT (v1, 31-JAN-2007)
Visit# 50		Subevent#	0	C	CRF Page <u>0.1.3</u> of 4





Study	04_C_0121		Patient 43			
Visit Name	ONGOING				CRF Blank	
Note: Dates will	appear as 'DD-MON-YYYY'					Section blank?
			COMMEN	ITS		
Date	Note					
Doc# R200	702	Status	Entry Complete	Form	ADV EVENT (v1,	31-JAN-2007)
Visit# <u>50</u>		Subevent#	0	— CRF F	Page 0.1.4	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