Blank Patient Casebook Report for Study VCU_FLT_8029, Casebook BOOK AMENDMENT 9, Patient 007-010

Report generated by LILY LIU on 04-NOV-2011 14:28:39

Notes:

- 1. All reported data is current as of the time shown above under 'Report Generated'.
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Study	VCU_FLT_8029	Patient <u>007-010</u>	
Visit Name	PRE-STUDY	Visit Date	CRF Blank
Note: Dates v	vill appear as 'DD-MON-YYYY'		Section blank?
	ELIGIBIL	ITY CHECKLIST	
Checklist #	0 Effective Date 20110921	Waiver #	
	Patient has locally advanced by Patient has no obvious contrained at Patient has residual tumor play Patient is able to lie still in Patient is age 18 years or old Patient has normal organ and result to the Patient has normal organ and resu	institutional limits mes the institutional upper limit of normal itutional limits OR creatinine clearance >= 30 mL/min/1.7 OR surg sterile, OR not preg, conf by instit SOC preg t	Criteria Response Y / N / NA O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O
Doc#	Status	Form E	LIGIBILTC (v1, 21-OCT-2011)
Visit# 10	Subevent#	CRF Page	a1.1 of 3





Study	VCU_FLT_8029	Patient <u>0</u>	07-010	
Visit Name	PRE-STUDY	Visit Date _		CRF Blank
Note: Dates	will appear as 'DD-MON-YYYY' ELIGI	BILITY CHECKLIST		Section blank?
EXCLUSION	ON CRITERIA			Criteria Response
Sequence	Eligibility Criteria			Y/N/NA
1 2 3 4 5 6 7 8 9	Pat. has uncontrolled interest. Patient is medically unstated. Patient has a condition resulted patient has a history of a patient is under age 18. Patient is pregnant or nure. Patient has had previous medical patient is currently on horizontal patient.	quiring anesthesia for PET scann	ning and/or unable to lie sti compounds of similar chemica l or squamous cell carcinoma	000000000
Doc#	Status		Form El	LIGIBILTC (v1, 21-OCT-2011)
Visit# 10	Subevent#		CRF Page	a1.2 of ³





Study	VCU_FLT_8029	Patient 007-010	,
Visit Name	PRE-STUDY	Visit Date	CRF Blank
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Ancillary Information for CRF ELIGIBILITY - C

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: CREATININE_SER

2

Overflow: ENDOCRINE/METABOLIC

3

Overflow: BILIRUB_TTL_SER

4

Overflow: Creatinine within normal institutional limits OR creatinine clearance >= 30 mL/min/1.73 m2 for patients with creatinine levels above institutional normal.

5

Overflow: If fem., postmeno min. one yr, OR surg sterile, OR not preg, conf by instit SOC preg test, and willing to use adeq contracep (hormone or barrier meth birth cont; abstinence) for the duration of study;

6

Overflow: Able to understand and willing to sign a written informed consent document and a HIPAA authorization in accordance with institutional guidelines.

7

Overflow: Patient has received previous treatment (chemotherapy, radiation, or surgery) to involved breast; including hormone therapy.

8

Overflow: Pat. has uncontrolled inter. illness including, but not limited to, act. Infect., sympt. cong. heart failure, unstable A.P., C.A., or psych illness/social sit. that would limit compliance with study.

Overflow: Patient has a condition requiring anesthesia for PET scanning and/or unable to lie still for 1.5 hours.

10

Overflow: Patient has a history of allergic reactions attributed to compounds of similar chemical or biologic composition to F-18 fluorothymidine.

11

Overflow: Patient has had previous malignancy, other than basal cell or squamous cell carcinoma of the skin or in situ carcinoma of the cervix, from which s/he has been disease free for less than 5 years.



Doc#



ENROLLMENT (v1, 18-NOV-2009)

Form

Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	PRE-STUDY	Visit Date		-
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	ENRO	LLMENT		
DEMOGRAPHY				
Ĩ.	Female Date of Birth Male Unknown			
Race: select all that a White Black or African A	apply American or other Pacific Islander or Alaska Native	Ethnic	ity O Hispanic or Lat O Not Hispanic o O Unknown O Not Reported	
Race Unknown Patient Initials Date of Registration	Local Patie	nt ID		
GEOGRAPHY AI	ND GROUP			
5-Medicaid and Medicaid	1-Private Insurance, 2-Medicare, 3-Medicare, 6-Military or Veterans Sponsore red, 7-Self Pay (No insurance), 8-No insurance)	d NOS, 6a - Mi	e Payment Vate Insurance, 4- Melitary Sponsored (incl.	CHAMPUS and TRICARE,
Primary Site		Disease Stage	at Entry	
Disease Term				
CONSENT				
Treatment Assignment Date Informed Conse		ECOG Perfo	rmance Status	

_____ Status CRF Page <u>a2.1</u> of ³ _____ Subevent# ——— DCI Date Visit#





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Visit#





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Visit Name	PRE-STUDY	Visit Date						
	Note: Dates will appear as 'DD-MON-YYYY' Section blank?							
	BASELINE MEDICAL	. HISTORY						
Obstetric Histo	ory							
PARA Pregnancie		ABORTUS Misca	rriages	Abortions				
Body System N	Medical History If Abnormal							
NECK								
RESPIRATORY								
CARDIOVASCULAR								
GASTROINTESTINAL								
MUSCULOSKELETAL								
DERMATOLOGIC								
HEMATOPOIETIC/LYN								
ENDOCRINE/METABOI								
URINARY								
GENITALIA								
BREASTS								
PELVIS								
ABDOMEN								
NEUROLOGIC								
PSYCHOLOGIC								
IMMUNE								
OTHER								
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 Doc#
 Status
 Form
 BASELINE M (v1, 30-MAR-2009)

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Ancillary Information for CRF BASELINE MEDICAL HISTORY

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: HEMATOPOIETIC/LYMPH

2

Overflow: ENDOCRINE/METABOLIC





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Note: Date	es will appear a	as 'DD-MON-YYYY'		Section	on blank?
Date of Onset	Date Resolved	BAS CTCAE Term	Symptom Description	Related To Disease Grade Yes No Unknown O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O O	
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Visit# .	10	Subevent#		CRF F	Page <u>a4.1</u> of ²





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Visit# <u>10</u>		Subevent#		CRF Page a4.2 of ²





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Visit Name	PRE-STUDY		Visit Date								
Note: Dates will appear	as 'DD-MON-YY\	YY'		S	ection blank?]					
	BREAST CANCER HISTORY										
Primary breast cancer diagnosis date Age at diagnosis Laterality (Right/Left Side) OLEFT ORIGHT OBILATERAL Other hormonal therapies OAI OAI + FAS + OS OTHER (SPECIFY) Specify: Specify:											
		Primary Cancer	· Staging								
T Sta	ge	N Sta			M Stage						
O Tis (LCIS) O Tis (Paget's O Tis (DCIS) O T0 O T1 O T1a O T1c O T1mic O T2	O T3	PN0 PN0(I+) PN0(I-) PN0(MOL+) PN0(MOL-) PN1 PN1A PN1A PN1B PN1C	O PN1MI O PN2 O PN2A		O M0 O M1 O MX						
Menopausal Status O	Pre-Menopausal	O Post-Menopau	usal O Unkno	wn							

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 Status
 Form
 BREAST CAN (v1, 31-MAR-2009)

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Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	PRE-STUDY	Visit Date		
Note: Dates will app	ear as 'DD-MON-YYYY'	COMMENTS	Se	ction blank?
Date	Notes			
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Visit# 10	Subevent# DC	I Date		<u>a5.2</u> of ³





Study	VCU_FLT_8029	Patient	007-010	_ CRF Blank
Visit Name	PRE-STUDY	Visit Date		<u> </u>
		COMMENTS		
Date	Note			

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Study VCU_FLT_8029	Patient	007-010	
Visit Name PRE-STUDY	Visit Date		CRF Blank
Note: Dates will appear as 'DD-MON-YYYY'		Section blank?	

CHEMOTHERAPY ADMINISTRATION

Start	Stop					
Date	Date	Medication	Dose	Dose Unit Route		
				mg/m2		
				mg/m2		
				mg/m2		
				mg/m2		
				mg/m2		
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Doc#		Status	Form	CHEMOTHERA (v1,	20-AUG-2009)
Visit#	10	Subevent#	CRF Pag	ge <u>a6.1</u> of	2





Study	VCU_FLT_8029		Patient	007-010			
Visit Name	PRE-STUDY		Visit Date			CRF Blank	
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Doc#		Status			Form CH	EMOTHERA (v1, 20-AUG-2009)
Visit# <u>10</u>		Subevent#			CRF Page	a6.2	of ²





Study VCU_FLT_8029	Patient 007-010	
Visit Name PRE-STUDY	Visit Date	CRF Blank
Note: Dates will appear as 'DD-MON-YYYY'		Section blank?
Sample Collection Date Pathology	#	
PROLIFERATION INDEX - Analyzed Lesion ID# No Yes Mitotic Count # Ki-67 Nu		
HPF 1		Mitotic Index (%) Ki-67 Index
HPF 6		
HPF 10 Total	Total	
Biomarker Name	Analyzed No Yes % Positiv	Staining Grade re Cells 0 1 3
Ki-67		000
Doc# Status		Form PREPROLIF (v1, 10-AUG-2011)
Visit# 10 Subevent#		CRF Page a7.1 of ²





Study	VCU_FLT_8029	Patient <u>007-010</u>	
Visit Name	PRE-STUDY	Visit Date	CRF Blank
Note: Dates	will appear as 'DD-MON-YYYY'		Section blank?
		COMMENTS	
Date	Note		
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	udy <u>VCL</u> t Name	PRE-STU			Patient Lab Date	007-010		CRF Bla	nk 🗌
Lab								Secti	ion blank?
			I	BLOOD	CHEMIS	STRY			
			-		· · · · · · · · ·				
		Manuai	Overrides Normal	Centr	ally stored Normal	Range		Clinically Sigificant	Value in Preferred
Lab Test	Lab Value	Units	Ranges	Units	Ranges	Indicator	Grade	Yes No	Units
BUN_SER								\bigcirc	
CREATININE_S					•			O O	
SODIUM_SER					·			\bigcirc	
POTASSIUM_SE								O O	
BILIRUB_TTL_					•			\bigcirc	
ALK_PHOS_SER					·			\bigcirc \bigcirc	
AMYLASE_SER								O O	
GLUCOSE_NONF.					·			\bigcirc	
ALT_SGPT_SER					<u> </u>	_		\bigcirc	
AST_SGOT_SER								\bigcirc	
LDH_SER					<u> </u>	_			
ALBUMIN_SER								$_{0}$	

Doc#		Status		 Form	BLO	OOD CHEM (v1,	01-APR-2009)
Visit#	10	Subevent#	DCI Date	CRF Page	е	a8.1	of ³





Lab Date	Section blank?
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MMENTS	
Form BLO	OD CHEM (v1, 01-APR-2009)
	Form BLO





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Visit Name PRE-STUDY	Lab Date	

		COMMEN	ГS	
Date	Note			
	Status		Form BLOOD CHEM (v1, 01-API	R-20

Ancillary Information for CRF BLOOD CHEMISTRY

This page can include any or all of the following:

- -Overflow
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- -Audit History
- -Approval History

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

1

Overflow: CREATININE_SER

2

Overflow: ENDOCRINE/METABOLIC

3

Overflow: BILIRUB_TTL_SER

4

Overflow: GLUCOSE_NONFAST_SER





Stu Visit		FLT_8029 RE-STUDY			Patient Lab Date	007-010		CRF	Blank
Lab								\$	Section blank?
			ı	HEMA	ΓOLOGY				
Lab Test HGB_BLD HCT_BLD WBC_NUM_BLD PLATELET_BLD RBC_NUM_BLD MCV_RBC MCH_RBC MCHC_RBC RDW_RBC PMV_BLD LYMPH_PC_BLD		Ov	errides Normal Ranges	Central	Normal Ranges	Range	Grade	Clinically Sigificant Yes No	Value in Preferred Units
MONO_PC_BLD EOSINOPHIL_P BASO_PCT_BLD NEUT_PC_BLD	╡┝───						- - - -	0000	

Doc#		Status		Form	n HE	EMATOLOGY (v	1, 01-APR-2009)
Visit#	10	Subevent#	DCI Date [CRF	Page	a9.1	of ³





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Visit Name PRE-STUDY	Lab Date	
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	COMMENTS	
Date Notes		
Status	Form HI	EMATOLOGY (v1, 01-APR-2009)
10 Subevent# [DCI Date CRF Page	a9.2 of ³





Study VCU_FLT_8029	Patient 007-010 CRF Blank
Visit Name PRE-STUDY	Lab Date

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Date	Note			
	Status		Form HEMATOLOGY (v1, 01-APR-20	9009
10	Subevent#	DCI Date	Form HEMATOLOGY (VI, UI-APR-20	

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Ancillary Information for CRF HEMATOLOGY

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: CREATININE_SER





Study VCU_FLT_8029	Patient 007-010 CRF Blank
Visit Name PRE-STUDY	Lab Date
Note: Dates will appear as 'DD-MON-YYYY'	Section blank?
OTHER LABS	
Lab Test Value *	
BHCG_PREG_SER	
* Expected values are NEC or POS	

 Doc#
 Status
 Form
 OTHER LABS (v1, 13-APR-2009)

 Visit#
 10
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 DCI Date
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Study VCU_FLT_8029	Patient 007-010	CRF Blank
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Visit Name PRE-STUDY	Lab Date

		COMMENT	-s	
Date	Note			
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Visit#	10	Subevent#	_ DCI Date	CRF Pa	ge <u>a10.3</u> of ³





Study <u>VCU_FLT_8029</u>	Patient 007-010 CRF Blank
Visit Name PRE-STUDY	Lab Date
Note: Dates will appear as 'DD-MON-YYYY'	Section blank?
Pregnancy Eval	
If Urine HcG was done? Not Applicable Not done Positive	

 Doc#
 Status
 Form
 PREGNANCY (v1, 01-NOV-2011)

 Visit#
 10
 Subevent#
 DCI Date
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Visit Name	PRE-STUDY	Lab Date			

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Study	VCU_FLT_8029	Patient	007-010	CRF Blank	
Visit Name	PRE-STUDY	Visit Date		Ш	
Section blank?					
	PRE-TREATMENT PA	ATHOLOGY	•		
Type of Specin Lesion ID	tion OBILATERAL OLEFT ORI nen OSurgical Biopsy OCore Nee Status OS / NEG Diameter 1(cm) Diameter OOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOO	GHT edle Biopsy			
Receptor Status ER ONEGATIVE OPOSITIVE OUNKNOWN PR ONEGATIVE OPOSITIVE OUNKNOWN HER2 ONEGATIVE OPOSITIVE OUNKNOWN Primary cancer type ODCIS OINVASIVE DUCTAL OINVASIVE LOBULAR OMIXED INVASIVE & LOBULAR					
Other, specify	OTHER (SPECIFY)				
Primary Nottingham	Grade 01 02 03				

Doc#		Status	Form	PRE PATHOL (v1, 15-OCT-2009)
Visit#	10	Subevent# ——— DCI Date	CRF Pa	ge <u>a12.1</u> of ³



Visit#



Study Visit Name	VCU_FLT_8029 PRE-STUDY	Patient Visit Date	007-010				
	COMMENTS						
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Study	VCU_FLT_8029	Patient	007-010	_ CRF Blank
Visit Name	PRE-STUDY	Visit Date		
		COMMENTS		
Date	Note			
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_____ Subevent# — DCI Date

Visit#





Study <u>VCL</u> Visit Name <u>PRE</u>	J_FLT_8029 E-STUDY	Patient Visit Date	007-010	. CRF Blank
Note: Dates will appear	as 'DD-MON-YYYY'			Section blank?
	PRIOR TRE	ATMENT S	UMMARY	
CHEMOTHERAPY (NOS) HORMONAL THERAPY SURGERY	DTHERAPY DIANT	Any thera Yes / No	apy # of Prior CI Regimens	Date of Last Dose
ONCOLYTIC VIROTHER	PADY	- 00		

Doc#		Status	Form	PRIOR TREA (v1, 04-NOV-2009)
Visit#	10	Subevent# —— DCI Date	CRF Pa	age <u>a13.1</u> of ³





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Doc#

Visit#



Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	PRE-STUDY	Visit Date		
Note: Dates will appear	r as 'DD-MON-YYYY'			Section blank?
	Tumor Sli	des Transmit	tal Form	
	Part A. C	Completed by Si	te RA	
Timepoint in study: (se	lect one) OPRE (VISIT 1) (O POST (VISIT 5)		
Were slides paraffin blo	ocks able to be sent? (select or	ne) ONo OYes		
Provide reason unable	to send slides paraffin blocks			
(complete then intial, si	ign and date form and send to	address listed below a	long with report	s)
Not allowed by instit	ution			
Specimen lost				
Other, specify				
Other, specify				
Type of tissue submitte	ed: (check all that apply)	1	imber of slides	
Date of surgical proced	dure	Paraffin block(s) nu	mber of blocks	
Before Sending the Sli	des Blocks and reports, please	check to confirm:		
ALL study particip	ants' personal identifying infor	mation (participant nan	ne, medical reco	ord number, SS#, etc.) on all
of the material is				
	•			mber and pre or post timepoint.
	ens, pathology report, imaging	report and this form sh	ould be shipped	I to the central pathology
laboratory to:	M	legan Quinn		
		ealth University Health	System	
	-	shall Street, Room 4-0	-	
	P.C). Box 980470		
	Richmon	nd, VA 23298-0470		
	RE: ACR	RIN 6688 Pathology		
Date slides blocks repo	orts Sent to Path Lab			
Initials of Person from	Site Completing This Form			
	<u> </u>			
Date Form Completed				_
Doo#	Status		Form	TUMOR_SLID (v2, 02-SEP-2010)

Form

CRF Page <u>a14.1</u> of ⁴





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	PRE-STUDY	Visit Date		
	Part B. Completed	by VCU Pa	ath Lab	
Date Slides Blocks	s Received			
Number of slides r	eceived			
Number of blocks	received			
Have specimen(s)	been received in an acceptable cond	ition? O No	O Yes	

 Doc#
 Status
 Form
 TUMOR_SLID (v2, 02-SEP-2010)

 Visit#
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 Subevent# — DCI Date
 CRF Page
 a14.2
 of
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Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	PRE-STUDY	Visit Date		
Note: Dates will a	ppear as 'DD-MON-YYYY'			Section blank?
	CC	OMMENTS		
Date	Notes			
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<u>10</u> Subevent# — DCI Date _ ___ CRF Page <u>a_14.3</u> of ⁴



Visit#

_____ Subevent# ——— DCI Date



CRF Page <u>a14.4</u> of ⁴

Study	VCU_FLT_8029	Patient	007-010	_ CRF Blank _
Visit Name	PRE-STUDY	Visit Date	_	
		COMMENTS		
Date	Note			





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		
Note: Dates will a	appear as 'DD-MON-YYYY'			Section blank?
	COURSE IN	ITIATION		
Course#				
Start Date of Cou	irse			
Treating Institutio	n			
Has patient agree	ed to use contraception during protoco	l?		
N/A, patient is	s not of reproductive potential			
O No				
O Not Applicable	e			
O Unknown				
○ Yes				
Note: This f	form is for the FLT scan on	ly.		





Study	VCU_FLT_8029	Patient007-0)10 (CRF Blank
Visit Name		Visit Date		
Note: Dates will a	appear as 'DD-MON-YYYY'	MMENTS	\$	Section blank?
Date	Notes	MINICIATO		
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Doc#	Status		Form COURSE	INI (v3, 13-APR-2010

Subevent# — DCI Date _ ___ CRF Page $\underline{b1.2}$ of 3





Study Visit Name	VCU_FLT_8029 BASELINEIMGNFLT1	Patient Visit Date	007-010	CRF Blank

	COMM	MENTS	
Date	Note		
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]		
 oc#	Status	Form	COURSE INI (v3, 13-APR-2010

Do ______ Subevent# _____ DCI Date _____ CRF Page <u>b1.3</u> of ³ Visit#



_____ Status

_____ Subevent# ——— DCI Date _____

Doc#

Visit#



	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date	
Note: Dates will appear a	as 'DD-MON-YYYY'		Section blank?
Was imaging agent admi PET Tracer FDG Source of agent Synt Method Injection Route of administration (Activity in full syringe before time of assay of full syring time of injection Residual activity in syring time of assay of residual Net activity administered Any radiotracer infiltration	Lot # thesized O Purchased O IV O Oral ore injection Unit nge before injection Unit lactivity after injection Unit Unit Other on at injection site noted? ONONE	Supplier Location of Injection Central Venous Right antecubit Right foot Right Hand Right wrist Unknown Location of Injection Site	S Access Device al OLeft antecubital OLeft foot OLeft Hand OLeft wrist Other, specify
	×	R(less than or equal to 20% C E(greater than 20% OF DOS	•
Was imaging exam comp	0 0	e (groater than 20% or 200	52)
If imaging not completed	provide reason		
Scheduling problem	Medical reason	O Progressive Disease	
O Participant death	O Injection site complications	O Imaging agent not adr	ministered
C Equipment failure	O Claustrophobia	Adverse event	
O Participant refusal	O Participant withdrew	unknown	
		Other, specify	
Fasting Yes No Duration of fasting pre-P Blood glucose before injection of the blood sample was was Foley catheter place. If no, Patient voided imm	ection of FDGmg/dl obtained for glucose measurement ed? ONO OYes nediately pre-imaging ONO OY	es O Unknown es O Unknown	
Davil	Chatria	F	BASE FDG T (v3, 05-MAY-2010)

Form

CRF Page <u>b2.1</u> of ⁴





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		_
PET Emission Sc	•			
Acquisition # of Bed Ti Mode Position P	ime per bed Scan start Scan stop Ty	pe of Scan F	Pixel Size (mm)	Thickness (mm)
Position P	Position time time			
CT Image Acquisi	tion O NOT DONE			
Type of attenuation Oral Or correction contrast coused used? typ	ntrast Amount contrast Amount Time		mAs Value origir	Slice thickness transmission of reconstructed scan (minutes)
Scanner specs				
(If first scan, check to c	canner is the same scanner used for a confirm scanner will be used for future for this study been qualified by ACRIN	protocol scans	for this participant)	articipant
if no, specify reason	or this study been qualified by AONIN	1: 0140 0	163	
if yes provide scanner I	D#			
Manufacturer				
Model Name/or number	r			
Date of last PET scann				
Daily scanner QC run o	on date of study () No () Yes			

 Doc#
 _______Status
 _______BASE FDG T (v3, 05-MAY-2010)

 Visit#
 30
 Subevent# _____DCI Date ______ CRF Page b2.2 of 4





Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date	
Note: Dates will	appear as 'DD-MON-YYYY'	MMENTS	Section blank?
Date	Notes		
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Doc#	Status	Form	BASE FDG T (v3, 05-MAY-201

<u>30</u> Subevent# — DCI Date _ ___ CRF Page <u>b2.3</u> of ⁴



Visit#

_____ Subevent# ——— DCI Date



CRF Page <u>b2.4</u> of ⁴

Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		
		OMMENTS		
Date	Note			



_____ Status

Subevent# —— DCI Date _____

Doc#

Visit#



BASE FLT T (v3, 05-MAY-2010)

CRF Page <u>b3.1</u> of ⁴

Form

Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank		
Visit Name	BASELINEIMGNFLT1	Visit Date			
Note: Dates will appo	ear as 'DD-MON-YYYY'		Section blank?		
FLT Technical Assessment					
PET Tracer FLT Source of agent Statement Stat	Lot #	Location of Injection Location of Injection Central Venout Right antecubit Right Hand Right Hand Right wrist Unknown Location of Injection Site R (less than or equal to 20% of E (greater than 20% OF DOS)	s Access Device tal OLeft antecubital OLeft foot OLeft Hand OLeft wrist Other, specify OF DOSE)		
O Scheduling proble O Participant death O Equipment failure O Participant refusal Other, specify Date of imaging Weight KGS Fasting O Yes O No Duration of fasting pre Was Foley catheter pl If no, Patient voided in	Medical reason	Progressive Disease Imaging agent not ad Adverse event unknown Other, specify es Unknown es Unknown	ministered		





Study Visit Name	VCU_FLT_8029 BASELINEIMGNFLT1	Patient Visit Date	007-010	CRF Blank
PET Emission Sc Acquisition # of Bed T Mode Position F CT Image Acquisi	ime per bed Scan start Scan stop Ty Position time time	pe of Scan F	Pixel Size (mm)	Thickness (mm)
correction contrast co	ral Was IV ontrast Amount contrast AmountTime of pe (ml) used? (ml) Injection	of on KVP	mAs Value origin	Slice thickness transmission of reconstructed scan images(mm) (minutes)
(If first scan, check to Has the scanner used to if no, specify reason if yes provide scanner Manufacturer Model Name/or number Date of last PET scanner leads to the scanner lea	r	protocol scans	s for this participant)	ırticipant

 Doc#
 Status
 Form
 BASE FLT T (v3, 05-MAY-2010)

 Visit#
 30
 Subevent# — DCI Date
 CRF Page
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Study	VCU_FLT_8029	Patient 007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date	
Note: Dates will a	appear as 'DD-MON-YYYY'	MMENTS	Section blank?
Date	Notes		
	_		
Doc#	Status	Form	BASE FLT T (v3, 05-MAY-20

<u>30</u> Subevent# — DCI Date _____ CRF Page <u>b3.3</u> of ⁴





Study Visit Name	VCU_FLT_8029 BASELINEIMGNFLT1	Patient Visit Date	007-010	CRF Blank
	COMN	MENTS		
Date	Note			

Doc#	Status	Form BASE FLT T (v3, 05-MAY-2010)
	Subevent# ——— DCI Date	CRF Page <u>b3.4</u> of ⁴





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		_
Note: Dates will app	pear as 'DD-MON-YYYY'			Section blank?
	COURSE ASSE	SSMENT		
Start Date of Course	•			
-	AC entered on Course Initiation CRF? No Yes, Planned Yes, Unplanned	,		
Course Disposition	○ Unknown○ Completed○ Discontinued			
	ent O Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged			
Response Note Date of Response Date of Progression Any Adverse Events				
Note: This for	m is for the FLT scan only.			

 Doc#
 ______ Status
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 Visit#
 30
 Subevent# _____ DCI Date _____ CRF Page ______ of ____ 3





Study	VCU_FLT_8029		-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		
Note: Dates will a	ppear as 'DD-MON-YYYY'	MMENTS		Section blank?
Date	Notes			
Doc#	Status		Form COL	JRSE ASS (v2, 13-APR-2

Subevent# DCI Date CRF Page $\underline{b4.2}$ of 3





CRF Page <u>b4.3</u> of ³

Study	VCU_FLT_8029		007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		
	Ce	OMMENTS		
Date	Note	_		_
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Visit#





Study	VCU_FLT_8029 BASELINEIMGNFLT1	Patient 007-010 CRF Blank	
Visit Name	DAGELINE IMONIETT	Visit Date	
Note: Dates will appear	r as 'DD-MON-YYYY'		
		er Imaging	
Was a mammogram pe			
Date of Imaging Lesion	n ID Location	Measurement 1 Measurement 2 Lesion Availability	
		mm x mm	
		mm x mm	
		mm x mm	
		mm x mm mm	
Ultrasound NO O	YES		
Date of Imaging Lesion	n ID Location	Measurement 1 Measurement 2 Lesion Availability	
] [
		mm x mm	
		mm x mm	
		mm x mm	
MRI O NO O YES			
Date of Imaging Lesion	a ID I ocation	Measurement 1 Measurement 2 Lesion Availability	
	TID EGGGGGG		
		mm x mm	
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		mm x mm	
CT scan ONO OY	ES		
Date of Imaging Lesion	n ID Location	Measurement 1 Measurement 2 Lesion Availability	
		mm x mm	
		mm xmm	
	O: 1	Form OTHER IMAG (v2, 24-JAN-201	_ 1)
Doc#	Status	Form	,

<u>30</u> Subevent# — DCI Date _____ CRF Page <u>b5</u> of ¹





Study	VCU_FLT_8029	Patient	007-010	_ CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date		_
Note: Dates will appe	ear as 'DD-MON-YYYY' FLT PET/CT: Local S	ite Image	Assessme	Section blank?
Total number of tumo	5 Radiotracer infiltration 6 Poor S/N (noisy image) 7 Incomplete anatomic content of the SUV 8 Other ssessment: Torso Survey Scan at	s) overage 60min and any other		⁻ 2, PT3 etc.)
	tomic Site Description Indicate FLT P	FLT S		Largest Diameter teria on CT (cm) Visualized? Section blank?
Identify the parameter Lesion ID Anatomic S	s below for Other Lesions (LN1, LN2 of the Description Indicate FLT PET	FLT SUV		Largest Diameter ria on CT (cm) Visualized?

 Doc#
 Status
 Form
 IMAGE ASSE (v1, 03-DEC-2010)

 Visit#
 30
 Subevent# — DCI Date
 CRF Page
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Study	VCU_FLT_8029 BASELINEIMGNFLT1	_ Patient	007-010	CRF Blank
		Visit Date		Costion blonk?
Note. Dates will a	appear as 'DD-MON-YYYY' CON	MENTS		Section blank?
Date	Notes			
	Status		Form	IMAGE ASSE (v1, 03-DEC-2010)
Visit# 30	Subevent# DCI Dat	e		e <u>b6.2</u> of ³



Visit#

_____ Subevent# ——— DCI Date



CRF Page <u>b6.3</u> of ³

•	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date	_	
D.		OMMENTS		
Date	Note			





Study Visit Name	VCU_FLT_8029 BASELINEIMGNFLT1	Patient Visit Date	007-010	CRF Blank
Note: Dates will app	ear as 'DD-MON-YYYY'			Section blank?
	FDG PET/CT: Local S	Site Image	Assessment	Form
•	5 Radiotracer infiltration 6 Poor S/N (noisy image dy 7 Incomplete anatomic of the SUV 8 Other Assessment: Torso Survey Scan a	es) coverage	○ No ○ Yes	
Total number of tume	or sites visible ers below for the Primary Tumor (PT1) and any other	breast lesions (PT2. I	PT3 etc.)
	survey scan acquired at 60 minutes af	FDG S	_	Largest Diameter iaon CT (cm) Visualized?
I de a tife de a manage	tors below for Other Leviers (INIA LA	10 -4-)		Section blank?
Lesion ID Anatomic	Site Desciption Indicate FD		S SUV ax FDG Uptake Cri	Largest Diameter iteria on CT (cm) Visualized?

 Doc#
 Status
 Form
 FDG IMAGE (v1, 03-DEC-2010)

 Visit#
 30
 Subevent# — DCI Date
 CRF Page
 b7.1
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Study	VCU_FLT_8029 BASELINEIMGNFLT1		-010	CRF Blank
Visit Name	DASELINEIMGNELTI	Visit Date		
Note: Dates will a	appear as 'DD-MON-YYYY'			Section blank?
	СО	MMENTS		
Date	Notes			
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Doc#	Status		Form FDG I	IMAGE (v1, 03-DEC-2010)

Subevent# — DCI Date _ ___ CRF Page b7.2 of 3





FDG IMAGE (v1, 03-DEC-2010)

Form

Study	VCU_FLT_8029		CRF Blank
Visit Name	BASELINEIMGNFLT1	Visit Date	
	COMM	IENTS	
Date	Note		

Visit# 30 Subevent# —— DCI Date ____ CRF Page $\underline{b7.3}$ of 3

_____ Status

Doc#





LT_8029	Patient	007-010	CRF Blank	
THERIMGFLT2	Visit Date		-	
'DD-MON-YYYY'		Sect	tion blank?	
COURSE INITIATION				
]?			
		THERIMGFLT2 Visit Date S'DD-MON-YYYY' COURSE INITIATION contraception during protocol? eproductive potential	THERIMGFLT2 Visit Date S'DD-MON-YYYY' Sector COURSE INITIATION contraception during protocol? eproductive potential	

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 Status
 Form
 COURSE INI (v3, 13-APR-2010)

 Visit#
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 Subevent# — DCI Date
 CRF Page
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 of
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Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date	
Note: Dates will a	appear as 'DD-MON-YYYY'		Section blank?
	COI	MMENTS	
Date	Notes		
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	Status	Form	COURSE INI (v3, 13-APR-2010)

 $\underline{50}$ Subevent# —— DCI Date _____ CRF Page $\underline{c1.2}$ of 3



_____ Status

Subevent# —— DCI Date

Doc#

Visit#



COURSE INI (v3, 13-APR-2010)

CRF Page <u>c1.3</u> of ³

Form

Study Visit Name	VCU_FLT_8029 EARLYTHERIMGFLT2	Patient 007-010 Visit Date	CRF Blank
	СОММ	IENTS	
Date	Note		
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Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank				
Visit Name	EARLYTHERIMGFLT2	Visit Date					
Note: Dates will appea	r as 'DD-MON-YYYY'		Section blank?				
	FDG Technical As	ssessment					
Was imaging agent ad	ministered? O Yes O No Admin	istration date					
PET Tracer FDG	Lot #						
Source of agent OSy	nthesized Purchased						
Method		Supplier					
Injection		Location of Inject	ion Site				
Route of administration		Central Venou					
Activity in full syringe b			ital OLeft antecubital				
Time of assay of full sy	ringe before injection	Right foot	OLeft foot				
Time of injection Residual activity in syri		Right Hand Right wrist	OLeft Hand OLeft wrist				
	ual activity after injection	Unknown	Other, specify				
Net activity administere		er Location of Injection Site	<u></u>				
Any radiotracer infiltrat	ion at injection site noted? ONONE	_					
	O MINO	R (less than or equal to 20%	OF DOSE)				
	~ ~	RE (greater than 20% OF DO	SE)				
Was imaging exam cor							
If imaging not complete	ed provide reason						
Scheduling probler	m Medical reason	O Progressive Disease					
O Participant death	O Injection site complications	Imaging agent not ad	Iministered				
C Equipment failure	Claustrophobia	Adverse event					
O Participant refusal	Participant withdrew	unknown					
		Other, specify					
Other, specify							
Date of imaging	Height CM BSA	٦					
Weight KGS Fasting Yes No	Height CM BSA						
- 0	DET imaging (Hours)						
•	Duration of fasting pre-PET imaging (Hours) Blood glucose before injection of FDG mg/dl						
-	injection of FDGmg/dl as obtained for glucose measurement						
Was Foley catheter pla	0 0						
•	nmediately pre-imaging \(\int\) No \(\cap \)	Yes O Unknown					
		Yes Ounknown					
		•					
			MIDEDO A OO / O OF MANY COSTS				
Doc#	Status	Form	MIDFDGASS (v3, 05-MAY-2010)				

<u>50</u> Subevent#——DCI Date _____ CRF Page <u>c2.1</u> of ⁴





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
·			<u> </u>	CIXI DIATIK
Visit Name	EARLYTHERIMGFLT2	Visit Date	-	
PET Emission Sc	an ONOT DONE			
Acquisition # of Bed T	ime per bed Scan start Scan stop Ty	pe of Scan	Pixel Size (mm)	Thickness (mm)
Mode Position F	Position time time			
CT Image Acquisi	ition O NOT DONE			
Type of				
attenuation Oral Or	ral Was IV			Slice thickness transmission
correction contrast co	ontrast Amount contrast Amount Time	e of		of reconstructed scan
used used? ty	pe (ml) used? (ml) Inject	ion KVP	mAs Value origii	n images(mm) (minutes)
		_		
Scanner specs				
Check to confirm so	canner is the same scanner used for	all previous pro	otocol scans for this p	articipant
(If first scan, check to o	confirm scanner will be used for future	protocol scan	s for this participant)	
Has the scanner used to	for this study been qualified by ACRII	N? ONo O	Yes	
if no, specify reason				
if yes provide scanner	ID#			
Manufacturer				
Model Name/or numbe	r			
Date of last PET scann	ner SUV validation			
Daily scanner QC run o	on date of study No Yes			





Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date	
Note: Dates will ap	ppear as 'DD-MON-YYYY'		Section blank?
	Co	OMMENTS	
Date	Notes		
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			MIDFDGASS (v3, 05-MAY-201
Doc#	Status	Form	WILDI DGAGG (VS, US-WAT-201)

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_____ Subevent# ——— DCI Date

Doc#

Visit#



MIDFDGASS (v3, 05-MAY-2010)

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Form

Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
	EARLYTHERIMGFLT2	Visit Date	
	COMM	IENTS	
Date	Note		



Doc#

Visit#

_____ Status

_____ Subevent# ——— DCI Date



MIDFLTASS (v3, 05-MAY-2010)

CRF Page <u>c3.1</u> of ⁴

Form

Study	VCU_FLT_8029	Patient 007-010 CRF Blank				
Visit Name	EARLYTHERIMGFLT2	Visit Date				
Note: Dates will appea	ar as 'DD-MON-YYYY'	Section blank?				
	FLT Technical Ass	essment				
Was imaging agent ad	ministered? O Yes O No Adminis	ration date				
Source of agent O Synthesized Purchased						
Method	Su	pplier				
Injection		Location of Injection Site				
Route of administration	n 🔘 IV 🔘 Oral	Central Venous Access Device				
Activity in full syringe b	<u> </u>	Right antecubital OLeft antecubital				
Time of assay of full sy	ringe before injection []	Right foot OLeft foot				
Time of injection Residual activity in syri	ngo ofter injection	Right Hand OLeft Hand Right wrist OLeft wrist				
Time of assay of residual activity after injection Unknown Other, specify Net activity administered Unit Other Location of Injection Site						
Any radiotracer infiltration at injection site noted? ONONE						
•	•	(less than or equal to 20% OF DOSE)				
	OSEVERE (greater than 20% OF DOSE)					
Was imaging exam cor	mpleted? ONO OYes					
If imaging not complete	ed provide reason					
Scheduling probler	m Medical reason	O Progressive Disease				
O Participant death	O Injection site complications	Imaging agent not administered				
C Equipment failure	Claustrophobia	Adverse event				
O Participant refusal	Participant withdrew	Ounknown				
	_	Other, specify				
Other, specify						
Date of imaging						
Weight KGS	Height CM BSA					
Fasting O Yes O No						
Duration of fasting pre	-PET imaging (Hours)					
Was Foley catheter pla	aced? ONo OYes					
If no, Patient voided in	nmediately pre-imaging ONOOYe	s O Unknown				
Patient voided im	mediately post-imaging ONOOYe	s O Unknown				





Study <u>VCU_FLT_8029</u> Visit Name <u>EARLYTHERIMGFLT2</u>	Patient <u>007-010</u> CRF Blank
PET Emission Scan ONOT DONE	
Acquisition # of Bed Time per bed Scan start Scan s	stop Type of Scan Pixel Size (mm) Thickness (mm)
Mode Position Position time time	
CT Image Acquisition O NOT DONE	
Type of	
attenuation Oral Oral Was IV correction contrast contrast Amount contrast Amount used used? type (ml) used? (ml) \[\begin{array}{cccccccccccccccccccccccccccccccccccc	Slice thickness transmission of reconstructed scan Injection KVP mAs Value origin images(mm) (minutes)
Scanner specs	
•	ACRIN? No Yes

 Doc#
 _______Status
 Form
 MIDFLTASS (v3, 05-MAY-2010)

 Visit#
 50
 Subevent# _____ DCI Date
 ______ CRF Page
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Study	VCU_FLT_8029	Patient <u>007</u>	-010	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date		-
Note: Dates will ap	opear as 'DD-MON-YYYY'	OMMENTS		Section blank?
Date	Notes			
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Doc#	Status		Form MIDI	FLTASS (v3, 05-MAY-2010)

<u>50</u> Subevent# — DCI Date _ ___ CRF Page <u>c3.3</u> of ⁴



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Visit#

_____ Subevent# ——— DCI Date



CRF Page <u>c3.4</u> of ⁴

•	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date		_
	CC	OMMENTS		
Date	Note	, <u>-</u>		
	i			
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Note: Dates will appear as 'DD-MON-YYYY' COURSE ASSESSMENT Start Date of Course Dose change from TAC entered on Course Initiation CRF? No Yes, Planned Visit Name Course Disposition Completed Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Minimal/Marginal Response Partial Response Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes No	Study	VCU_FLT_8029	Patient	007-010	CRF Blank
COURSE ASSESSMENT Start Date of Course Dose change from TAC entered on Course Initiation CRF? No Yes, Planned Yes, Unplanned Unknown Course Disposition Completed Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course?	Visit Name	EARLYTHERIMGFLT2	Visit Date		
Start Date of Course Dose change from TAC entered on Course Initiation CRF? No Yes, Planned Yes, Unplanned Unknown Course Disposition Completed Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course? Yes	Note: Dates will app	pear as 'DD-MON-YYYY'			Section blank?
Dose change from TAC entered on Course Initiation CRF? \(\) No \(\) Yes, Planned \(\) Yes, Unplanned \(\) Unknown Course Disposition \(\) Completed \(\) Discontinued Response Assessment \(\) Not Applicable per Protocol \(\) Too Early to assess, per protocol \(\) Not Assessed \(\) Not Evaluable \(\) Complete Response \(\) Partial Response \(\) Partial Response \(\) Minimal/Marginal Response \(\) Progressive Disease \(\) Stable Disease \(\) Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course? \(\) Yes		COURSE AS	SSESSMENT		
O No O Yes, Planned O Yes, Unplanned O Unknown Course Disposition O Completed O Discontinued Response Assessment O Not Applicable per Protocol O Too Early to assess, per protocol O Not Evaluable O Complete Response O Partial Response O Minimal/Marginal Response O Progressive Disease O Stable Disease O Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? O Yes	Start Date of Course	9			
O Yes, Planned O Yes, Unplanned O Unknown Course Disposition ○ Completed ○ Discontinued Response Assessment ○ Not Applicable per Protocol ○ Too Early to assess, per protocol ○ Not Evaluable ○ Complete Response ○ Partial Response ○ Partial Response ○ Minimal/Marginal Response ○ Progressive Disease ○ Stable Disease ○ Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? ○ Yes	Dose change from T	AC entered on Course Initiation C	RF?		
O Yes, Unplanned O Unknown Course Disposition Completed O Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Partial Response O Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes		○ No			
Course Disposition Completed Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Partial Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes		_			
Course Disposition Completed Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Partial Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ?		_			
Completed Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ?		Ounknown			
Discontinued Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course?	Course Disposition				
Response Assessment Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course?		O Completed			
Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Pratial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes		ODiscontinued			
O Too Early to assess, per protocol O Not Assessed O Not Evaluable O Complete Response O Partial Response O Minimal/Marginal Response O Progressive Disease O Stable Disease O Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course? O Yes	Response Assessmo	ent			
O Not Assessed O Not Evaluable Complete Response Partial Response O Minimal/Marginal Response O Progressive Disease O Stable Disease O Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? O Yes		O Not Applicable per Protocol			
Not Evaluable Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes		_	col		
Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes		Ξ			
O Partial Response O Minimal/Marginal Response O Progressive Disease O Stable Disease O Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? O Yes		<u> </u>			
Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes		_			
Progressive Disease Stable Disease Disease Unchanged Date of Response Date of Progression Any Adverse Events in this Course ? Yes		_			
Stable Disease O Disease Unchanged Response Note Date of Response Date of Progression Any Adverse Events in this Course ? O Yes		_			
Response Note Date of Response Date of Progression Any Adverse Events in this Course ? Yes					
Date of Response Date of Progression Any Adverse Events in this Course ? Yes		O Disease Unchanged			
Date of Response Date of Progression Any Adverse Events in this Course ? Yes	Response Note				
Date of Progression Any Adverse Events in this Course ? Yes	response rete				
Date of Progression Any Adverse Events in this Course ? Yes	Date of Response				_
Any Adverse Events in this Course ? O Yes					
O Yes					
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Note: This form is for the FLT scan only.					
	Doc#	Status		Form	COURSE ASS (v2, 13-APR-2010
COURSE ASS (v.2. 13-ARR-2014	<u> </u>				ogo C4.1 of 3
Doc# Status Form COURSE ASS (v2, 13-APR-2010	Visit# <u>50</u>	Subevent# —— DCI Da	ate	CRF Pa	age <u>c4.1</u> of ³





Study Visit Name	VCU_FLT_8029 EARLYTHERIMGFLT2	Patient <u>007-010</u> Visit Date	CRF Blank
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Date	Notes		
Doc#	Status	Form	COURSE ASS (v2, 13-APR-2

 $\underline{50}$ Subevent# —— DCI Date _____ CRF Page $\underline{\underline{c4.2}}$ of 3



<u>50</u>

Visit#

_____ Subevent# ——— DCI Date



CRF Page $\underline{c4.3}$ of 3

Study	VCU_FLT_8029		007-010	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date		
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Date	Note	OMMENTS		
	'			





Study	VCU_FLT_8029	Patient 007-	010 CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date	
Note: Dates will appea		ar Imagina	
Was a mammogram pe	erformed ONo OYes	ner Imaging	
Date of Imaging Lesion	n ID Location	mm x	ment 2 Lesion Availability mm mm mm mm mm mm
Ultrasound NO NO Date of Imaging Lesion			mm
MRI ONO OYES			
Date of Imaging Lesion	n ID Location	mm x r	ment 2 Lesion Availability mm mm mm mm mm mm
CT scan NO NO		Measurement 1 Measure	ement 2 Lesion Availability
		mm x	mm mm mm mm
Doc#	StatusDC	I Date	Form OTHER IMAG (v2, 24-JAN-2011) CRF Page <u>c5</u> of ¹





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date		_
Note: Dates will appe	ear as 'DD-MON-YYYY' FLT PET/CT: Local S	ite Image	Assessmen	Section blank? t Form
Total number of tume Identify the parameter from the FLT torso su	5 Radiotracer infiltration 6 Poor S/N (noisy image dy 7 Incomplete anatomic cute SUV 8 Other	60min and any other ber injection FLT SU	breast lesions (PT2,	Largest Diameter
				Section blank?
Identify the parameter Lesion ID Anatomic S	rs below for Other Lesions (LN1, LN2 of the Description Indicate FLT PET	FLT SUV		Largest Diameter on CT (cm) Visualized?





Study	VCU_FLT_8029 EARLYTHERIMGFLT2		07-010	_ CRF Blank
7.6.() (4.1.6.		Visit Date		Ocetica blendo 🗖
Note: Dates will a	appear as 'DD-MON-YYYY' CON	/MENTS		Section blank?
Date	Notes			
	Chahus		IN	MAGE ASSE (v1, 03-DEC-2010)
Doc#	StatusDCI Dat	re	1 01111	<u>c6.2</u> of ³



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Visit#

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CRF Page <u>c6.3</u> of ³

Study	VCU_FLT_8029		007-010	_ CRF Blank _
Visit Name	EARLYTHERIMGFLT2	Visit Date		
	Co	OMMENTS		
Date	Note			
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Study	VCU_FLT_8029 EARLYTHERIMGFLT2	Patient	007-010	CRF Blank
Visit Name	EARLI ITERIMOFETZ	Visit Date		
Note: Dates will app	ear as 'DD-MON-YYYY'			Section blank?
	FDG PET/CT: Local S	ite Image	Assessment	Form
Total number of tumor ldentify the parameter from the FDG torso s	Image Quality t apply] 5 Radiotracer infiltration 6 Poor S/N (noisy image dy 7 Incomplete anatomic of te SUV 8 Other assessment: Torso Survey Scan a	Interpretable? es) coverage t 60min) and any other ter injection FDG S	○ No ○ Yes breast lesions (PT2, F	PT3 etc.) .argest Diameter
Lesion ID Anatomic S	Site Desciption Indicate FD	•	S SUV ax FDG Uptake Cri	Section blank? Largest Diameter teria on CT (cm) Visualized?

 Doc#
 Status
 Form
 FDG IMAGE (v1, 03-DEC-2010)

 Visit#
 50
 Subevent# — DCI Date
 CRF Page
 <u>c7.1</u> of
 3





Study Visit Name	VCU_FLT_8029 EARLYTHERIMGFLT2	_ Patient <u>007-010</u> _ Visit Date	
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Date	Notes	IMENTS	
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Doc#	Status	Form	DG IMAGE (v1, 03-DEC-2010)

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Visit#

_____ Subevent# ——— DCI Date



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Study	VCU_FLT_8029	Patient 007-010	CRF Blank
Visit Name	EARLYTHERIMGFLT2	Visit Date	
	Co	OMMENTS	
Date	Note		
	<u> </u>		





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date		
Note: Dates will a	appear as 'DD-MON-YYYY'			Section blank?
	COURSE IN	ITIATION		
Course#				
Start Date of Cou	rse			
Treating Institutio	n			
Has patient agree	ed to use contraception during protoco	l?		
N/A, patient is	not of reproductive potential			
O No				
O Not Applicable	e			
Unknown				
Note: This f	orm is for the FLT scan on	ly.		

 Doc#
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 Form
 COURSE INI (v3, 13-APR-2010)

 Visit#
 65
 Subevent# — DCI Date
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Study	VCU_FLT_8029	Patient 007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will a	appear as 'DD-MON-YYYY'		Section blank?
		MMENTS	
Date	Notes		
L			
Doc#	Status	Form	COURSE INI (v3, 13-APR-2010)

65 Subevent# —— DCI Date _____ CRF Page d1.2 of 3





Study Visit Name	VCU_FLT_8029 POSTCHEMOIMGFLT3	Patient 007-010 Visit Date	CRF Blank
	COMM	MENTS	
Date	Note		

Doc#	Status	COURSE INI (v3, 13-APR-2010)
Visit# 65	Subevent# DCI Date	CRF Page <u>d1.3</u> of ³





Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will appea	ar as 'DD-MON-YYYY'		Section blank?
Net activity administered Molar Quantity Injected	Lot #	Supplier Location of Inject Central Venou Right antecubi Right foot Right Hand Right wrist Unknown er Location of Injection Site	s Access Device tal OLeft antecubital OLeft foot OLeft Hand OLeft wrist Other, specify
Was Foley catheter pla	mpleted?	Yes O Unknown	
Doc#	Status	Form	POSTFDGASS (v1, 25-JAN-2010)
Visit# <u>65</u>	Subevent# — DCI Date	CRF Pa	ge <u>d2.1</u> of ⁴





Study	VCU_FLT_8029	_ Patient	007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	_ Visit Date		_
PET Emission Scanner Acquisition # of Bed Time Mode Position Programmed CT Image Acquising Type of Oral	ime per bed Scan start Scan stop Position time time	Type of Scan	Pixel Size (mm)	Thickness (mm) Slice thickness transmission
	st contrast Amount contrast Amoun	t Time of		of reconstructed scan
correction used used?	type (ml) used? (ml)	Injection KVP	mAs	images(mm) (minutes)
Scanner specs				
	canner is the same scanner used for confirm scanner will be used for fut		•	participant
•	for this study by sponsor? \(\int\) No	-	s for this participant)	
if no, specify reason	Tor triis study by sportsor: O're	<u> </u>		
if yes provide scanner I	D#			
Manufacturer				
Model Name/or number	r			
Date of last PET scann	er SUV validation			<u>-</u>
Daily scanner QC run o	on date of study No Yes			

 Doc#
 Status
 Form
 POSTFDGASS (v1, 25-JAN-2010)

 Visit#
 65
 Subevent# — DCI Date
 CRF Page
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 of
 4





Study	VCU_FLT_8029	Patient 007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will a	appear as 'DD-MON-YYYY'	MMENTO	Section blank?
Date	Notes	OMMENTS	

65 Subevent# — DCI Date _____ CRF Page <u>d2.3</u> of ⁴



Visit#

_____ Subevent# ——— DCI Date



CRF Page d2.4 of 4

Study	VCU_FLT_8029		007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date		_
		MMENTS		
Date	Note			



_____ Status

_____ Subevent# ____ DCI Date ____

Doc#

Visit#



Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will appo	ear as 'DD-MON-YYYY'		Section blank?
	FLT Technical As	sessment	
Was imaging agent ad PET Tracer FLT	ministered? Yes No Admin	istration date	
Source of agent OSy	nthesized Purchased		
Method	S	upplier	
Injection		Location of Inject	ction Site
Route of administration	ı		us Access Device
Activity in full syringe b	<u> </u>		Dital OLeft antecubital
Time of assay of full sy Time of injection	ringe before injection []	○ Right foot ○ Right Hand	OLeft foot ○Left Hand
Residual activity in syri	 nge after injection	Right wrist	OLeft wrist
	ual activity after injection	O Unknown	Other, specify
Net activity administere	ed Unit Othe	r Location of Injection Site	
Any radiotracer infiltrat	ion at injection site noted? ONONE		
	ž	R (less than or equal to 20%	
	0 0	RE (greater than 20% OF DC	OSE)
Was imaging exam con			
If imaging not complete		_	
Scheduling probler	•	O Progressive Disease	
Participant death	O Injection site complications	Imaging agent not a	dministered
Equipment failure	Claustrophobia	Adverse event	
O Participant refusal	O Participant withdrew	unknown	
Other energify		Other, specify	
Other, specify Date of imaging			
Weight Kgs	Height CM BSA	٦	
Fasting () Yes () No	Holght	_	
	-PET imaging (Hours)		
Was Foley catheter pla			
•		∕es ∩ Unknown	
		∕es O Unknown	
		•	
Doc#	Status	Form	POSTFLTASS (v2, 05-MAY-2010)

Form

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Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date		_
PET Emission Sca Acquisition # of Bed Ti Mode Position P	me per bed Scan start Scan stop Ty Position time time	/pe of Scan	Pixel Size (mm)	Thickness (mm)
	HOIT O'NOT BOILE			
Type of attenuation Oral Or correction contrast co used used? typ	ntrast Amount contrast AmountTime	of on KVP	mAs Value origir	Slice thickness transmission of reconstructed scan images(mm) (minutes)
Scanner specs				
(If first scan, check to de Has the scanner used for if no, specify reason if yes provide scanner I Manufacturer Model Name/or number Date of last PET scanner		e protocol scan	s for this participant)	articipant

 Doc#
 Status
 Form
 POSTFLTASS (v2, 05-MAY-2010)

 Visit#
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Study Visit Name	VCU_FLT_8029 POSTCHEMOIMGFLT3	Patient Visit Date	007-010	
Note: Dates will a	appear as 'DD-MON-YYYY'	COMMENTS		Section blank?
Date	Notes			
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Doc#	Status		Form	POSTFLTASS (v2, 05-MAY-2010

65 Subevent# — DCI Date _____ CRF Page <u>d3.3</u> of ⁴



Visit#

_____ Subevent# ——— DCI Date



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Study	VCU_FLT_8029		007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date		-
	co	OMMENTS		
Date	Note			
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Study Visit Name	VCU_FLT_8029 POSTCHEMOIMGFLT3	Patient Visit Date	007-010	CRF Blank
Note: Dates will ap	ppear as 'DD-MON-YYYY'			Section blank?
	COURSE ASS	SESSMENT		
Start Date of Cours	е			
Dose change from	TAC entered on Course Initiation CRF No Yes, Planned Yes, Unplanned	?		
	Ounknown			
Course Disposition	Completed Discontinued			
Response Assessm	Not Applicable per Protocol Too Early to assess, per protocol Not Assessed Not Evaluable Complete Response Partial Response Minimal/Marginal Response Progressive Disease Stable Disease Disease Unchanged			
Response Note				
Date of Response Date of Progression Any Adverse Events				
Note: This for	rm is for the FLT scan only	.		
Doc#	Status		Form	COURSE ASS (v2, 13-APR-2010
Visit# <u>65</u>	Subevent# —— DCI Date			ge <u>d4.1</u> of ³





Study	VCU_FLT_8029		CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will a	ppear as 'DD-MON-YYYY'	MMENTO	Section blank?
Doto		MMENTS	
Date	Notes		
			COURSE ASS (v2, 13-APR

65 Subevent# — DCI Date _ ___ CRF Page $\underline{\text{d4.2}}$ of 3





CRF Page $\underline{d4.3}$ of 3

Study Visit Name	VCU_FLT_8029 POSTCHEMOIMGFLT3	Patient Visit Date	007-010	CRF Blank
	cc	MMENTS		
Date	Note			
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_____ Subevent# ——— DCI Date

Visit#





Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will appea			
Was a mammogram pe	erformed ONo OYes	ner Imaging	
Date of Imaging Lesion	n ID Location	Measurement 1 Measurement 2 mm x mm x mm x mm	Lesion Availability
Ultrasound NO NO Date of Imaging Lesion		Measurement 1 Measurement 2 mm x mm	Lesion Availability
MRI ONO OYES			
Date of Imaging Lesion	n ID Location	Measurement 1 Measurement 2 mm x mm x mm x mm	Lesion Availability
CT scan NO NO		Management 4 Management 2	Lacian Augilahilibu
Date of Imaging Lesion	n ID Location	Measurement 1 Measurement 2 mm x mm [mm x mm [mm x mm]	Lesion Availability
Doc#	Status DC	Form I Date CRF Pa	OTHER IMAG (v2, 24-JAN-2011)





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	. Visit Date		_
Note: Dates will appe	ear as 'DD-MON-YYYY' FLT PET/CT: Local \$	Site Image	e Assessme	Section blank?
Reader ID	Image Quality	Interpretable?	○ No ○ Yes	
Reason [mark all that 1 Patient motion 2 Image artifacts 3 Incomplete stude 4 Cannot calcula Other, Specify	5 Radiotracer infiltration 6 Poor S/N (noisy imag) 7 Incomplete anatomic	es)		
· <u></u>	ssessment: Torso Survey Scan a	at 60min		
from the FLT torso su	or sites visible ers below for the Primary Tumor (PT1 urvey scan acquired at 60 minutes af tomic Site Description Indicate FLT	ter injection FLT S	UV	Largest Diameter
				Section blank?
Identify the parameter Lesion ID Anatomic S	ite Description Indicate FLT PE	FLT SU\		Largest Diameter ia on CT (cm) Visualized?





Study	VCU_FLT_8029	Patient <u>0</u>	007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date _		
Note: Dates will a	appear as 'DD-MON-YYYY'			Section blank?
	COMM	IENTS		
Date	Notes			
Doc#	Status		Form	IMAGE ASSE (v1, 03-DEC-2010)

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_____ Status

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Doc#

Visit#



Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date		
COMMENTS				
Date	Note			
Doo#	Ctatus		F	IMAGE ASSE (v1, 03-DEC-2010)

Form

CRF Page <u>d6.3</u> of ³





Study Visit Name	VCU_FLT_8029 POSTCHEMOIMGFLT3	Patient Visit Date	007-010	CRF Blank
Note: Dates will app	ear as 'DD-MON-YYYY'			Section blank?
	FDG PET/CT: Local S	ite Image	Assessment	Form
Reader ID Reason [mark all tha 1 Patient motion 2 Image artifacts 3 Incomplete stu	t apply] 5 Radiotracer infiltration 6 Poor S/N (noisy imaged) 7 Incomplete anatomic of	es)	○ No ○ Yes	
Other, Specify				
Total number of tumor ldentify the parameter from the FDG torso s	assessment: Torso Survey Scan a or sites visible ers below for the Primary Tumor (PT1) arvey scan acquired at 60 minutes af tomic Site Description Indicate FDG) and any other ter injection FDG S	SUV L	argest Diameter
				Section blank?
Lesion ID Anatomic S	ers below for Other Lesions (LN1, LN Site Desciption Indicate FD0	·	S SUV ax FDG Uptake Crit	Largest Diameter teria on CT (cm) Visualized?

Doc#		Status	Form	FDG IMAGE (v1, 03-DEC-2010
Visit#	65	Subevent# —— DCI Date	_ CRF Pag	ge <u>d7.1</u> of ³





Study	VCU_FLT_8029	Patient 007-010	CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
Note: Dates will a	appear as 'DD-MON-YYYY'		Section blank?
Data		DMMENTS	
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Doc#	Status	Form	FDG IMAGE (v1, 03-DEC-2010)
Visit# 65	Subevent# DCI D	ate CRF F	Page <u>d7.2</u> of ³



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Subevent# —— DCI Date _____

Doc#

Visit#



FDG IMAGE (v1, 03-DEC-2010)

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Study	VCU_FLT_8029		CRF Blank
Visit Name	POSTCHEMOIMGFLT3	Visit Date	
	COMM	MENTS	
Date	Note		





Study Visit Name	VCU_FLT_8029 SURGICAL RESECT		Patient Visit Date	007-010	CRF Blank
Note: Dates will appea	r as 'DD-MON-YYYY'				Section blank?
	Sur	gical Path	ology		
Date of Surgical Rese	GHT		Procedure Lumpecton		ple Mastectomy
Residual Invasive Car Residual In Situ Carci Status	noma NO YI	≣S	•	adical Mastecto	my Other OUIQ OUOQ
TA1	Diameter 1 (cm) Dia	ameter 2 (cm)	TA: Target NT: Non- T	Lesion arget Lesion	
T Stage Tis (LCIS) (Tis (Paget's) (Tis (DCIS) (To (T1 (T1a () T3) T4) T4a) T4b) T4c) T4d) TX) Tis) T1b	○ PN0○ PN0○ PN0	(I-)	2 2A 2B 3 3A 3B 3C	M Stage OMX OM0 OM1

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 SURGICAL P (v1, 03-SEP-2009)

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Study	VCU_FLT_8029	Patient	007-010	_ CRF Blank
Visit Name	SURGICAL RESECT	Visit Date		
Note: Dates will ap	pear as 'DD-MON-YYYY'	OMMENTS		Section blank?
Date	Notes			
	Status		Form SI	URGICAL P (v1, 03-SEP-2009)
	Subevent# —— DCI I		CRF Page	<u>e1.2</u> of ³





Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	SURGICAL RESECT	Visit Date	
	COMI	MENTS	
		WIENTS	
Date	Note		
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Doc#	Status	Form St	JRGICAL P (v1, 03-SEP-2009

Subevent# — DCI Date _ ___ CRF Page $\underline{e1.3}$ of 3





Study <u>VCU_FLT_8029</u>	Patient <u>007-0</u>	10
Visit Name SURGICAL RESECT	T Visit Date	CRF Blank
Note: Dates will appear as 'DD-MON	-YYYY'	Section blank?
Sample Collection Date	Pathology #	
PROLIFER Analyzed	ATION INDEX - POST-TREATMEN	NT
HPF 1	Mitotic Count # Ki-67 Nuclear Count Total # of cel	Mitotic Index (%) Ki-67 Index Pathologic Response Staining Grade
Biomarker Name	No Yes % Positiv	
Ki-67		
Doc# St	atus	Form POSTPROLIF (v1, 10-AUG-2011)
Visit# <u>70</u> Su	ubevent#	CRF Page e2.1 of ²





Study	VCU_FLT_8029	Patient 007-010	_
Visit Name	SURGICAL RESECT	Visit Date	CRF Blank
Note: Dates wil	ll appear as 'DD-MON-YYYY'	COMMENTS	Section blank?
Date	Note		
Doc#	Status		Form POSTPROLIF (v1, 10-AUG-2011)
Visit# <u>70</u>	Subevent#		CRF Page <u>e2.2</u> of ²





CRF Page <u>e3.1</u> of ⁴

Study Visit Name	VCU_FLT_8029 SURGICAL RESECT	Patient Visit Date	007-010	CRF Blank
Note: Dates will appear	r as 'DD-MON-YYYY'			Section blank?
	Tumor Slide	es Transmit	tal Form	
	Part A. Cor	mpleted by Si	te RA	
Timepoint in study: (se	lect one) OPRE (VISIT 1) OF	POST (VISIT 5)		
Were slides paraffin blo	ocks able to be sent? (select one)	O No O Yes		
Provide reason unable	to send slides paraffin blocks			
(complete then intial, si	ign and date form and send to add	dress listed below a	along with report	s)
Not allowed by instit	ution			
Specimen lost				
Other, specify				
Other, specify				
Type of tissue submitte	· · · · · · · · · · · · · · · · · · ·		ımber of slides	
Date of surgical proced		araffin block(s) nu	mber of blocks	
Before Sending the Slice	des Blocks and reports, please ch	eck to confirm:		
ALL study particip	ants' personal identifying informat	ion (participant nar	ne, medical reco	ord number, SS#, etc.) on all
of the material is o	de-identified			
Each slide block r	eport is labeled with the study nun	nber, site number,	patient case nur	nber and pre or post timepoint.
The pathology specime	ens, pathology report, imaging repo	ort and this form sh	nould be shipped	I to the central pathology
laboratory to:	Moar	an Quinn		
	Virginia Commonwealth		System	
		III Street, Room 4-0		
		ox 980470		
		VA 23298-0470		
	RE: ACRIN	6688 Pathology		
Date slides blocks repo	orts Sent to Path Lab			
Initials of Person from	Site Completing This Form			
Date Form Completed				
Doc#	Status		Form	TUMOR_SLID (v2, 02-SEP-2010)

_____ Subevent# —— DCI Date

Visit#





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	SURGICAL RESECT	Visit Date		
	Part B. Completed	by VCU Pa	ath Lab	
Date Slides Blocks	a Pagaiyad			
Number of slides r				
Number of blocks				
	been received in an acceptable cond	lition? No	Yes	
Initials of Person f	rom Site Completing This Form	Ü		
Date Form Comple	eted	_	_	_

 Doc#
 Status
 Form
 TUMOR_SLID (v2, 02-SEP-2010)

 Visit#
 70
 Subevent# — DCI Date
 CRF Page
 e3.2
 of
 4





Study Visit Name	VCU_FLT_8029 SURGICAL RESECT	Patient Uisit Date	007-010	CRF Blank
	ppear as 'DD-MON-YYYY'			Section blank?
		OMMENTS		
Date	Notes			

70 Subevent# — DCI Date _____ CRF Page <u>e3.3</u> of ⁴



Visit#

_____ Subevent# — DCI Date



CRF Page <u>e3.4</u> of ⁴

Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	SURGICAL RESECT	Visit Date		
_		COMMENTS		
Date	Note			





Study Visit Name	VCU_FLT_8029 SURGICAL RESECT	Patient Visit Date	007-010	CRF Blank	
Note: Dates will appea	ar as 'DD-MON-YYYY'			Section blank?	
Residual Cancer Burden (Surgical Resect time point)					
1) Primary Tumor Bed	i				
Primary Tumor Bed Ar	reamm xmm				
Overall Cancer Cellula	rity (as percentage of area)]%		
Percentage of Cancer	that is in situ disease%				
2) Lymph Nodes					
Number of Positive Lymph Nodes					
Diameter of largest metastasis mm					
Calculations:					
Residual Cancer Burde	en 🗌				

 Doc#
 Status
 Form
 RESIDUAL C (v1, 11-MAR-2010)

 Visit#
 70
 Subevent# — DCI Date
 CRF Page
 e4.1
 of
 3





Study	VCU_FLT_8029	Patient <u>007-010</u>	CRF Blank
Visit Name	SURGICAL RESECT	Visit Date	
Note: Dates will a	ppear as 'DD-MON-YYYY'		Section blank?
	CC	MMENTS	
Date	Notes		
Doc#	Status	Form	RESIDUAL C (v1, 11-MAR-2

70 Subevent# — DCI Date _____ CRF Page <u>e4.2</u> of ³





Study Visit Name	VCU_FLT_8029 SURGICAL RESECT	Patient Visit Date	007-010	CRF Blank
	COMM	MENTS		
Date	Note			
	<u></u>			
<u> </u>				

Doc#		Status	 Form RESIDUAL C (v1, 11-MAR-2010)
Visit#	70	Subevent# ——— DCI Date	 CRF Page <u>e4.3</u> of ³





Study	VCU_FLT_8029	_ Patient	007-010	CRF Blank			
Visit Name	OFF-TREATMENT	_ Visit Date		-			
Date will be displayed	Date will be displayed as 'DD-MON-YYYY'						
	OFF TREATME	NT SUMMAR	RY				
Date Off Treatment							
Reason Off Treatmen	at O Switched to Alternative Treat	ment					
	O Disease Progression before						
	O Death on Study						
	O Cytogenetic resistance						
	O Late Determination of Ineligib	ility					
	O Disease Progression On Stud	dy					
	O Refused further Treatment						
	O Complicating Disease, Interc	urrent Illness					
	O Adverse Events, Side Effects						
	O Protocol Violation						
	O Patient Declined to Participat	e (before treatme	ent started)				
	O No Treatment, per protocol						
	O Lost to Further Follow-up						
Treatment Period Completed							
O PI Discretion							
O Patient Noncompliance							
	O Not Treated - Other Reasons, explain						
	Other						
Explain 'Other' Reaso	n Off Treatment						

 Doc#
 Status
 Form
 OFF TREAT (v1, 11-MAR-2010)

 Visit#
 80
 Subevent# — DCI Date
 CRF Page
 f1
 of
 1





Study	VCU_FLT_8029 OFF-STUDY	Patient	007-010	CRF Blank	
Visit Name	<u> </u>	Visit Date			
Note: Dates will appea	ar as 'DD-MON-YYYY'		Section bla	ank? 🗌	
OFF STUDY SUMMARY					
Date Off Study					
Reason Off Study O Death on Study Complicating Disease / Intercurrent Illness Toxicity Not Treated - Other Reasons, explain Lost to Further Follow-up Patient Noncompliance O Other					
Explain 'Other' Reas	on				
Date of Disease Progression					

 Doc#
 Status
 Form
 OFF STUDY (v1, 11-MAR-2010)

 Visit#
 90
 Subevent# — DCI Date
 CRF Page
 g1.1
 of
 3





Study	VCU_FLT_8029	Patient	007-010	CRF Blank
Visit Name	OFF-STUDY	Visit Date		<u> </u>
Note: Dates will ap	pear as 'DD-MON-YYYY'	COMMENTS		Section blank?
Date	Notes	JOININE IVIO		
Date	Notes			
Doc#	Status		Form	FF STUDY (v1, 11-MAR-2010)
Visit# 90	Subevent# DC	I Date	CRF Page	g1.2 of ³





Study Visit Name	VCU_FLT_8029 OFF-STUDY	Patient 007-010 Visit Date	CRF Blank
	COMN	IENTS	
Date	Note		

Doc#		Status	Form	off STUDY (v1, 11-MAR-2010)
Visit#	90	Subevent# DCI Date _	CRI	F Page <u>g1.3</u> of ³





Study	VCU_FLT_8029		Patient 007	7-010				
Visit Name	CONMED						C	CRF Blank
Note: Date:	s will appear as 'DD		.NT MEASURES/MI					Section blank?
				Total	Dose			
Start Date	Stop Date	Agent Name	Procedure	Dose Dose		Schedule	Route	Reason
Doc# Visit# 100		Status Subevent#				Form CRF Pa		MED (v2, 23-MAR-2011)





Study	VCU_FLT_8029	Pati	ent <u>007-010</u>	
Visit Name	CONMED			CRF Blank
Note: Dates v	will appear as 'DD-MON-YYYY'			Section blank?
		co	DMMENTS	
Date	Note			
Doc#		Status		Form CONMED (v2, 23-MAR-2011)
Visit# 100		Subevent#		CRF Page h1.2 2





Study	VCU_FLT_8029	Pati	ent <u>007-010</u>	
Visit Name	AE			CRF Blank
Note: Dates will	appear as 'DD-MON-YYYY'			Section blank?
		ADVERSE EVEN		Grade Serious Serious Charles Serious Charles Serious Confirm Therapy
Grade: Attri 1 = Mild 1= U 2=Moderate 2= U 3=Severe 3= P 4=Threat 4= P	Date Resolved CTC Term	1=None 1=N 2=Reduced 2=S 3=Interrupt 3=S 4=Discontinued 4=V 5=Interrupt/Reduced	rapy: Outcome: lone 1=Recovered symptom 2=Treatment support 3=Alive figorous 4=Died	Y/N/U OOO
Doc#		Status		Form AE (v1, 22-JAN-2010)
Visit# <u>110</u>		Subevent#		CRF Page i1.1 4





Study Visit Name		8029	Patie	ent <u>007-010</u>			CRF Blan	< [
Grade: 1 = Mild 2=Moderate 3=Severe 4=Threat 5=Fatal	Date Resolved 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=Requires Inter	Action: 1=None 2=Reduced 3=Interrupt 4=Discontinued 5=Interrupt/Reduced	AE Description Therapy: 1=None 2=Symptom 3=Support 4=Vigorous	Outcome: 1=Recovered 2=Treatment 3=Alive 4=Died		Expedited Report Filed? Y/ N / U OOO	000000000000000000000000000000000000000	Action Therapy Outcome
Doc# Visit#110			Status			Form A		4 of	





Study <u>VCU_FLT</u> Visit Name <u>AE</u>	_8029	Par	tient <u>007-01</u>	0		CRF Bla	nk 🗍	
Date of Onset Date Resolve Grade: 1 = Mild 2 = Moderate 3 = Severe 4 = Threat 5 = Fatal Date Resolve 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=Requires Intervention		Therapy: 1=None 2=Symptom 3=Support 4=Vigorous	Outcome: 1=Recovered 2=Treatment 3=Alive 4=Died		Expedited Report Filed? Y/ N / U OOO	0000000000	Action Action Dutcome
Doc#	_ Stat	event#			Form CRF Page		4 • of	





Study Visit Name	VCU_FLT_8029 AE	Pat	ient <u>007-010</u>	CRF Blank
Note: Dates wil	l appear as 'DD-MON-YYYY'			Section blank?
		C	OMMENTS	
Date	Note			
Doc#		Status		Form AE (v1, 22-JAN-2010)
Visit# 110		Subevent#		CRF Page i1.4 4