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'.
2. All timestamps reflect the timezone of the database server in which the data was collected.
3. Superscripts appear next to fields with overflow.

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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? ☐

ELIGIBILITY CHECKLIST

Checklist # 0 Effective Date 20110921 Waiver # _____

INCLUSION CRITERIA

Sequence	Eligibility Criteria	Criteria Response Y / N / NA
1	Patient has path. conf. breast cancer, is determined to be a candidate for primary sys[1]	○ ○ ○
2	Patient has locally advanced breast cancer, not stage iv, and with a tumor size >= 2cm[2]	○ ○ ○
3	Patient has no obvious contraindications for primary chemotherapy.	○ ○ ○
4	Patient has residual tumor planned to be removed surgically following completion of ne[3]	○ ○ ○
5	Patient is able to lie still for 1.5 hours for pet scanning.	○ ○ ○
6	Patient is age 18 years or older	○ ○ ○
7	Patient has normal organ and marrow function as defined below	○ ○ ○
7A	Leukocytes >= 3,000/ul	○ ○ ○
7B	Absolute neutrophil count >= 1,500/ul	○ ○ ○
7C	Platelets >= 100,000/ul	○ ○ ○
7D	Total bilirubin within normal institutional limits	○ ○ ○
7E	AST(SGOT)/ALT(SGPT) <= 2.5 times the institutional upper limit of normal	○ ○ ○
7F	Creatinine within normal institutional limits OR creatinine clearance >= 30 mL/min/1.7[4]	○ ○ ○
8	If fem., postmeno min. one yr, OR surg sterile, OR not preg, conf by instit SOC preg t[5]	○ ○ ○
9	Patient's ECOG performance status is <=2	○ ○ ○
10	Able to understand and willing to sign a written informed consent document and a HIPAA[6]	○ ○ ○

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ELIGIBILITY CHECKLIST

EXCLUSION CRITERIA

Sequence	Eligibility Criteria	Criteria Response Y / N / NA
1	Patient has received previous treatment (chemotherapy, radiation, or surgery) to invol[7]	○ ○ ○
2	Pat. has uncontrolled inter. illness including, but not limited to, act. Infect., symp[8]	○ ○ ○
3	Patient is medically unstable.	○ ○ ○
4	Patient has a condition requiring anesthesia for PET scanning and/or unable to lie sti[9]	○ ○ ○
5	Patient has a history of allergic reactions attributed to compounds of similar chemica[10]	○ ○ ○
6	Patient is under age 18.	○ ○ ○
7	Patient is pregnant or nursing.	○ ○ ○
8	Patient has had previous malignancy, other than basal cell or squamous cell carcinoma[11]	○ ○ ○
9	Patient is currently on hormone therapy as the primary systemic neoadjuvant therapy.	○ ○ ○

In the opinion of the investigator, is the patient eligible? ○ YES ○ NO ○ X

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COMMENTS

Date	Note

Doc# _____ Status _____ Form ELIGIBILTC (v1, 21-OCT-2011)

Visit# 10 Subevent# _____

Ancillary Information for CRF ELIGIBILITY - C

This page can include any or all of the following:
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-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.

9

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.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

ENROLLMENT

DEMOGRAPHY

Patient Gender ○ Female ○ Male ○ Unknown

Date of Birth ☐

Race: select all that apply

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

Ethnicity ○ Hispanic or Latino ○ Not Hispanic or Latino ○ Unknown ○ Not Reported

Patient Initials ☐

Local Patient ID ☐

Date of Registration ☐

GEOGRAPHY AND GROUP

Patient Subgroup SG1

Registering Group ☐

Registering Institution ☐

Country Code ☐

Postal Code ☐

Method of Payment ☐

Method of payment: 1-Private Insurance, 2-Medicare, 3-Medicare and Private Insurance, 4- Medicaid, 5-Medicaid and Medicare, 6-Military or Veterans Sponsored NOS, 6a - Military Sponsored (incl. CHAMPUS and TRICARE, 6b-Veterans Sponsored, 7-Self Pay (No insurance), 8-No means of payment (no insurance), 98-Other, 99-Unknown

HISTORY

Primary Site ☐

Disease Term ☐

Disease Stage at Entry ☐

CONSENT

Treatment Assignment Code at Enrollment FLT

ECOG Performance Status ☐

Date Informed Consent Signed ☐

Date of Informed Consent Version ☐

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

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BASELINE MEDICAL HISTORY

Obstetric History

PARA ☐ Pregnancies GRAVIDA ☐ Live Births \ ☐ Stil Births ABORTUS ☐ Miscarriages ☐ Abortions

Body System	Medical History If Abnormal
H/E/E/N/T	
NECK	
RESPIRATORY	
CARDIOVASCULAR	
GASTROINTESTINAL	
MUSCULOSKELETAL	
DERMATOLOGIC	
HEMATOPOIETIC/LYM	
ENDOCRINE/METABOL	
URINARY	
GENITALIA	
BREASTS	
PELVIS	
ABDOMEN	
NEUROLOGIC	
PSYCHOLOGIC	
IMMUNE	
OTHER	

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

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

COMMENTS

Section blank? ☐

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

COMMENTS

Date	Note

Ancillary Information for CRF BASELINE MEDICAL HISTORY

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1

Overflow: HEMATOPOIETIC/LYMPH

2

Overflow: ENDOCRINE/METABOLIC

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Visit Name PRE-STUDY Visit Date ______ CRF Blank ☐

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Section blank? ☐

BASELINE SYMPTOMS

Date of Onset	Date Resolved	CTCAE Term	Symptom Description	Grade	Related To Disease Yes	No	Unknown
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○
					○	○	○

Doc# ______ Status ______ Form BASELINE S (v1, 02-MAR-2010)

Visit# 10 Subevent# ______ CRF Page a4.1 of 2

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Study VCU_FLT_8029 Patient 007-010

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COMMENTS

Date	Note

Doc# _____ Status _____ Form BASELINE S (v1, 02-MAR-2010)

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Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

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Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

BREAST CANCER HISTORY

Primary breast cancer diagnosis date _____ *Age at diagnosis* _____

Laterality (Right/Left Side) ◯LEFT ◯RIGHT ◯BILATERAL

Other hormonal therapies ◯ AI ◯ AI + FAS + OS ◯ FAS ◯ NONE
◯ AI + OS ◯ FAS + OS ◯ OTHER (SPECIFY)

Specify: _____

----------Primary Cancer Staging----------

T Stage

◯ Tis (LCIS) ◯ T3
◯ Tis (Paget's) ◯ T4
◯ Tis (DCIS) ◯ T4a
◯ T0 ◯ T4b
◯ T1 ◯ T4c
◯ T1a ◯ T4d
◯ T1c ◯ TX
◯ T1mic ◯ Tis
◯ T2 ◯ T1b

N Stage

◯ PN0 ◯ PN1MI
◯ PN0(I+) ◯ PN2
◯ PN0(I-) ◯ PN2A
◯ PN0(MOL+) ◯ PN2B
◯ PN0(MOL-) ◯ PN3
◯ PN1 ◯ PN3A
◯ PN1A ◯ PN3B
◯ PN1B ◯ PN3C
◯ PN1C ◯ PNX

M Stage

◯ M0
◯ M1
◯ MX

Menopausal Status ◯ Pre-Menopausal ◯ Post-Menopausal ◯ Unknown

LMP Date _____

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

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CHEMOTHERAPY ADMINISTRATION

Start Date	Stop Date	Medication	Dose	Dose Unit	Route
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	
				mg/m2	

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Doc# _____ Status _____ Form CHEMOTHERA (v1, 20-AUG-2009)

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Sample Collection Date ☐ Pathology # ☐

PROLIFERATION INDEX - PRE-TREATMENT

Lesion ID#	Analyzed No	Analyzed Yes	Mitotic Count #	Ki-67 Nuclear Count	Total # of cells
HPF 1	○	○			
HPF 2	○	○			
HPF 3	○	○			
HPF 4	○	○			
HPF 5	○	○			
HPF 6	○	○			
HPF 7	○	○			
HPF 8	○	○			
HPF 9	○	○			
HPF 10	○	○			
			Total		Total

Mitotic Index (%) ☐

Ki-67 Index ☐

Biomarker Name	Analyzed No	Analyzed Yes	% Positive Cells	Staining Grade 0	1	3
Ki-67	○	○		○	○	○

Doc# _____ Status _____ Form PREPROLIF (v1, 10-AUG-2011)

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Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date

Lab ☐ Section blank? ☐

BLOOD CHEMISTRY

Lab Test	Lab Value	---Manual Overrides-- Units	Normal Ranges	-----Centrally stored----- *Units*	*Normal Ranges*	*Range Indicator*	Grade	Clinically Sigificant Yes	No	*Value in Preferred Units*
BUN_SER								○	○	
CREATININE_S								○	○	
SODIUM_SER								○	○	
POTASSIUM_SE								○	○	
BILIRUB_TTL_								○	○	
ALK_PHOS_SER								○	○	
AMYLASE_SER								○	○	
GLUCOSE_NONF								○	○	
ALT_SGPT_SER								○	○	
AST_SGOT_SER								○	○	
LDH_SER								○	○	
ALBUMIN_SER								○	○	

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Visit Name PRE-STUDY Lab Date

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COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date

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Date	Note

Ancillary Information for CRF BLOOD CHEMISTRY

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1

Overflow: CREATININE_SER

2

Overflow: ENDOCRINE/METABOLIC

3

Overflow: BILIRUB_TTL_SER

4

Overflow: GLUCOSE_NONFAST_SER

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Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date _____

Lab ☐ Section blank? ☐

HEMATOLOGY

Lab Test	Lab Value	------Overrides----- Units	Normal Ranges	--Centrally Stored-- Units	Normal Ranges	Range Indicator	Grade	Clinically Significant Yes	No	Value in Preferred Units
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								○	○	
MONO_PC_BLD								○	○	
EOSINOPHIL_P								○	○	
BASO_PCT_BLD								○	○	
NEUT_PC_BLD								○	○	

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? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date

COMMENTS

Date	Note

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

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

OTHER LABS

Lab Test	Value *
BHCG_PREG_SER	

* Expected values are NEG or POS.

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? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date

COMMENTS

Date	Note

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? ☐

Pregnancy Eval

If Urine HcG was done?
- ○ Negative
- ○ Not Applicable
- ○ Not done
- ○ Positive

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Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date

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COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Lab Date

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

Section blank? ☐

PRE-TREATMENT PATHOLOGY

Breast Cancer Location ◯ BILATERAL ◯ LEFT ◯ RIGHT

Type of Specimen ◯ Surgical Biopsy ◯ Core Needle Biopsy

Lesion ID (TA: Target NT: Non-Target)	Status POS / NEG	Diameter 1(cm)	Diameter 2(cm)
TA1	◯ ◯		
TA2	◯ ◯		
TA3	◯ ◯		
TA4	◯ ◯		
TA5	◯ ◯		
TA6	◯ ◯		
NT1	◯ ◯		
NT2	◯ ◯		
NT3	◯ ◯		
NT4	◯ ◯		

Receptor Status

ER ◯ NEGATIVE ◯ POSITIVE ◯ UNKNOWN

PR ◯ NEGATIVE ◯ POSITIVE ◯ UNKNOWN

HER2 ◯ NEGATIVE ◯ POSITIVE ◯ UNKNOWN

Primary cancer type

◯ DCIS ◯ INVASIVE DUCTAL ◯ INVASIVE LOBULAR ◯ MIXED INVASIVE & LOBULAR

◯ MUCINOUS ◯ OTHER (SPECIFY)

Other, specify

Primary Nottingham Grade ◯ 1 ◯ 2 ◯ 3

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

COMMENTS

Date	Notes

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 PRE-STUDY Visit Date _____

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PRIOR TREATMENT SUMMARY

Therapy Type	Any therapy Yes / No	# of Prior Chemo Regimens	Date of Last Dose
CHEMOTHERAPY SINGLE AGENT SYSTEMIC	○ ○		
CHEMOTHERAPY MULTIPLE AGENTS SYSTEMIC	○ ○		
CHEMOTHERAPY (NOS)	○ ○		
HORMONAL THERAPY	○ ○		
SURGERY	○ ○		
DRUG AND/OR IMMUNOTHERAPY	○ ○		
EXTENSIVE RADIATION	○ ○		
LIMITED RADIATION	○ ○		
RADIATION (NOS)	○ ○		
BONE MARROW TRANSPLANT	○ ○		
GENE TRANSFER	○ ○		
PRIOR THERAPY (NOS)	○ ○		
CHEMOTHERAPY NON-CYTOTOXIC	○ ○		
ANTI-RETROVIRAL THERAPY	○ ○		
ANTISENSE	○ ○		
ONCOLYTIC VIROTHERAPY	○ ○		
VACCINE	○ ○		

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

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Tumor Slides Transmittal Form

Part A. Completed by Site RA

Timepoint in study: (select one) ◯ PRE (VISIT 1) ◯ POST (VISIT 5)

Were slides paraffin blocks able to be sent? (select one) ◯ No ◯ Yes

Provide reason unable to send slides paraffin blocks

(complete then intial, sign and date form and send to address listed below along with reports)

◯ Not allowed by institution

◯ Specimen lost

◯ Other, specify

Other, specify ☐

Type of tissue submitted: (check all that apply) ☐ Slides Number of slides ☐

☐ Paraffin block(s) number of blocks ☐

Date of surgical procedure ☐

Before Sending the Slides Blocks and reports, please check to confirm:

ALL study participants' personal identifying information (participant name, medical record number, SS#, etc.) on all of the material is de-identified

Each slide block report is labeled with the study number, site number, patient case number and pre or post timepoint.

The pathology specimens, pathology report, imaging report and this form should be shipped to the central pathology laboratory to:

Megan Quinn
Virginia Commonwealth University Health System
1101 East Marshall Street, Room 4-065
P.O. Box 980470
Richmond, VA 23298-0470
RE: ACRIN 6688 Pathology

Date slides blocks reports Sent to Path Lab ☐

Initials of Person from Site Completing This Form

☐

Date Form Completed ☐

Part B. Completed by VCU Path Lab

Date Slides Blocks Received ☐

Number of slides received ☐

Number of blocks received ☐

Have specimen(s) been received in an acceptable condition? ◯ No ◯ Yes

Initials of Person from Site Completing This Form

☐

Date Form Completed ☐

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name PRE-STUDY Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

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 appear as 'DD-MON-YYYY' Section blank? ☐

COURSE INITIATION

Course# ___

Start Date of Course

Treating Institution

Has patient agreed to use contraception during protocol?

- ◯ N/A, patient is not of reproductive potential
- ◯ No
- ◯ Not Applicable
- ◯ Unknown
- ◯ Yes

Note: This form is for the FLT scan only.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FDG Technical Assessment

Was imaging agent administered? ◯ Yes ◯ No Administration date _____

PET Tracer FDG Lot # _____

Source of agent ◯ Synthesized ◯ Purchased

Method _____ Supplier _____

Injection

Route of administration ◯ IV ◯ Oral

Activity in full syringe before injection _____ Unit _____

Time of assay of full syringe before injection _____

Time of injection _____

Residual activity in syringe after injection _____ Unit _____

Time of assay of residual activity after injection _____

Net activity administered _____ Unit _____

Location of Injection Site

◯ Central Venous Access Device
◯ Right antecubital ◯ Left antecubital
◯ Right foot ◯ Left foot
◯ Right Hand ◯ Left Hand
◯ Right wrist ◯ Left wrist
◯ Unknown ◯ Other, specify

Other Location of Injection Site _____

Any radiotracer infiltration at injection site noted?
◯ NONE
◯ MINOR (less than or equal to 20% OF DOSE)
◯ SEVERE (greater than 20% OF DOSE)

Was imaging exam completed? ◯ No ◯ Yes

If imaging not completed provide reason

◯ Scheduling problem ◯ Medical reason ◯ Progressive Disease
◯ Participant death ◯ Injection site complications ◯ Imaging agent not administered
◯ Equipment failure ◯ Claustrophobia ◯ Adverse event
◯ Participant refusal ◯ Participant withdrew ◯ unknown
◯ Other, specify

Other, specify _____

Date of imaging _____

Weight _____ KGS Height _____ CM *BSA* _____

Fasting ◯ Yes ◯ No

Duration of fasting pre-PET imaging (Hours) _____

Blood glucose before injection of FDG _____ mg/dl

Time blood sample was obtained for glucose measurement _____

Was Foley catheter placed? ◯ No ◯ Yes

If no, Patient voided immediately pre-imaging ◯ No ◯ Yes ◯ Unknown

Patient voided immediately post-imaging ◯ No ◯ Yes ◯ Unknown

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

PET Emission Scan ◯ NOT DONE

Acquisition Mode	# of Bed Position	Time per bed Position	Scan start time	Scan stop time	Type of Scan	Pixel Size (mm)	Thickness (mm)

CT Image Acquisition ◯ NOT DONE

Type of attenuation correction used	Oral contrast used?	Oral contrast type	Amount (ml)	Was IV contrast used?	Amount (ml)	Time of Injection	KVP	mAs	Value origin	Slice thickness of reconstructed images(mm)	transmission scan (minutes)

Scanner specs

☐ Check to confirm scanner is the same scanner used for all previous protocol scans for this participant
(If first scan, check to confirm scanner will be used for future protocol scans for this participant)

Has the scanner used for this study been qualified by ACRIN? ◯ No ◯ Yes

if no, specify reason

if yes provide scanner ID#

Manufacturer

Model Name/or number

Date of last PET scanner SUV validation

Daily scanner QC run on date of study ◯ No ◯ Yes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FLT Technical Assessment

Was imaging agent administered? ◯ Yes ◯ No Administration date _____

PET Tracer FLT Lot # _____

Source of agent ◯ Synthesized ◯ Purchased

Method _____ Supplier _____

Injection

Route of administration ◯ IV ◯ Oral

Activity in full syringe before injection _____ Unit _____

Time of assay of full syringe before injection _____

Time of injection _____

Residual activity in syringe after injection _____ Unit _____

Time of assay of residual activity after injection _____

Net activity administered _____ Unit _____ Other Location of Injection Site _____

Location of Injection Site

◯ Central Venous Access Device

◯ Right antecubital ◯ Left antecubital

◯ Right foot ◯ Left foot

◯ Right Hand ◯ Left Hand

◯ Right wrist ◯ Left wrist

◯ Unknown ◯ Other, specify

Any radiotracer infiltration at injection site noted?

◯ NONE

◯ MINOR (less than or equal to 20% OF DOSE)

◯ SEVERE (greater than 20% OF DOSE)

Was imaging exam completed? ◯ No ◯ Yes

If imaging not completed provide reason

◯ Scheduling problem ◯ Medical reason ◯ Progressive Disease

◯ Participant death ◯ Injection site complications ◯ Imaging agent not administered

◯ Equipment failure ◯ Claustrophobia ◯ Adverse event

◯ Participant refusal ◯ Participant withdrew ◯ unknown

◯ Other, specify

Other, specify _____

Date of imaging _____

Weight _____ KGS Height _____ CM *BSA* _____

Fasting ◯ Yes ◯ No

Duration of fasting pre-PET imaging (Hours) ☐

Was Foley catheter placed? ◯ No ◯ Yes

If no, Patient voided immediately pre-imaging ◯ No ◯ Yes ◯ Unknown

Patient voided immediately post-imaging ◯ No ◯ Yes ◯ Unknown

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

PET Emission Scan ◯ NOT DONE

Acquisition Mode	# of Bed Position	Time per bed Position	Scan start time	Scan stop time	Type of Scan	Pixel Size (mm)	Thickness (mm)

CT Image Acquisition ◯ NOT DONE

Type of attenuation correction used	Oral contrast used?	Oral contrast type	Amount (ml)	Was IV contrast used?	Amount (ml)	Time of Injection	KVP	mAs	Value origin	Slice thickness of reconstructed images(mm)	transmission scan (minutes)

Scanner specs

☐ Check to confirm scanner is the same scanner used for all previous protocol scans for this participant
(If first scan, check to confirm scanner will be used for future protocol scans for this participant)

Has the scanner used for this study been qualified by ACRIN? ◯ No ◯ Yes

if no, specify reason

if yes provide scanner ID#

Manufacturer

Model Name/or number

Date of last PET scanner SUV validation

Daily scanner QC run on date of study ◯ No ◯ Yes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section 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
- ◯ Minimal/Marginal Response
- ◯ Progressive Disease
- ◯ Stable Disease
- ◯ Disease Unchanged

Response Note

Date of Response

Date of Progression

Any Adverse Events in this Course ?

- ◯ Yes
- ◯ No

Note: This form is for the FLT scan only.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

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

Other Imaging

Was a mammogram performed ◯ No ◯ Yes

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

Ultrasound ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

MRI ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

CT scan ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FLT PET/CT: Local Site Image Assessment Form

Reader ID _____ Image Quality Interpretable? ◯ No ◯ Yes

Reason [mark all that apply]

☐ 1 Patient motion
☐ 2 Image artifacts
☐ 3 Incomplete study
☐ 4 Cannot calculate SUV
☐ 5 Radiotracer infiltration
☐ 6 Poor S/N (noisy images)
☐ 7 Incomplete anatomic coverage
☐ 8 Other

Other, Specify _____

Local Site Image Assessment: Torso Survey Scan at 60min

Total number of tumor sites visible ☐

Identify the parameters below for the Primary Tumor (PT1) and any other breast lesions (PT2, PT3 etc.)
from the FLT torso survey scan acquired at 60 minutes after injection

Lesion ID	Local Anatomic Site Description	Indicate FLT PET Slice	FLT SUV Max	FLT Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Section blank? ☐

Identify the parameters below for Other Lesions (LN1, LN2 etc.)

Lesion ID	Anatomic Site Description	Indicate FLT PET Slice	FLT SUV Max	FLT Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FDG PET/CT: Local Site Image Assessment Form

Reader ID _____ Image Quality Interpretable? ◯ No ◯ Yes

Reason [mark all that apply]

- ☐ 1 Patient motion
- ☐ 2 Image artifacts
- ☐ 3 Incomplete study
- ☐ 4 Cannot calculate SUV
- ☐ 5 Radiotracer infiltration
- ☐ 6 Poor S/N (noisy images)
- ☐ 7 Incomplete anatomic coverage
- ☐ 8 Other

Other, Specify _____

Local Site Image Assessment: Torso Survey Scan at 60min

Total number of tumor sites visible ☐

Identify the parameters below for the Primary Tumor (PT1) and any other breast lesions (PT2, PT3 etc.)
from the FDG torso survey scan acquired at 60 minutes after injection

Lesion ID	Local Anatomic Site Description	Indicate FDG PET Slice	FDG SUV Max	FDG Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Section blank? ☐

Identify the parameters below for Other Lesions (LN1, LN2 etc.)

Lesion ID	Anatomic Site Desciption	Indicate FDG PET Slice	FDG SUV Max	FDG Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name BASELINEIMGNFLT1 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COURSE INITIATION

Course# ___

Start Date of Course

Treating Institution

Has patient agreed to use contraception during protocol?

- ◯ N/A, patient is not of reproductive potential
- ◯ No
- ◯ Not Applicable
- ◯ Unknown
- ◯ Yes

Note: This form is for the FLT scan only.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FDG Technical Assessment

Was imaging agent administered? ◯ Yes ◯ No Administration date _____

PET Tracer FDG Lot # _____

Source of agent ◯ Synthesized ◯ Purchased

Method _____ Supplier _____

Injection

Route of administration ◯ IV ◯ Oral

Activity in full syringe before injection _____ Unit _____

Time of assay of full syringe before injection _____

Time of injection _____

Residual activity in syringe after injection _____ Unit _____

Time of assay of residual activity after injection _____

Net activity administered _____ Unit _____

Location of Injection Site

◯ Central Venous Access Device
◯ Right antecubital ◯ Left antecubital
◯ Right foot ◯ Left foot
◯ Right Hand ◯ Left Hand
◯ Right wrist ◯ Left wrist
◯ Unknown ◯ Other, specify

Other Location of Injection Site _____

Any radiotracer infiltration at injection site noted?
◯ NONE
◯ MINOR (less than or equal to 20% OF DOSE)
◯ SEVERE (greater than 20% OF DOSE)

Was imaging exam completed? ◯ No ◯ Yes

If imaging not completed provide reason

◯ Scheduling problem ◯ Medical reason ◯ Progressive Disease
◯ Participant death ◯ Injection site complications ◯ Imaging agent not administered
◯ Equipment failure ◯ Claustrophobia ◯ Adverse event
◯ Participant refusal ◯ Participant withdrew ◯ unknown
◯ Other, specify

Other, specify _____

Date of imaging _____

Weight _____ KGS Height _____ CM *BSA* _____

Fasting ◯ Yes ◯ No

Duration of fasting pre-PET imaging (Hours) _____

Blood glucose before injection of FDG _____ mg/dl

Time blood sample was obtained for glucose measurement _____

Was Foley catheter placed? ◯ No ◯ Yes

If no, Patient voided immediately pre-imaging ◯ No ◯ Yes ◯ Unknown

Patient voided immediately post-imaging ◯ No ◯ Yes ◯ Unknown

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

PET Emission Scan ◯ NOT DONE

Acquisition Mode	# of Bed Position	Time per bed Position	Scan start time	Scan stop time	Type of Scan	Pixel Size (mm)	Thickness (mm)

CT Image Acquisition ◯ NOT DONE

Type of attenuation correction used	Oral contrast used?	Oral contrast type	Amount (ml)	Was IV contrast used?	Amount (ml)	Time of Injection	KVP	mAs	Value origin	Slice thickness of reconstructed images(mm)	transmission scan (minutes)

Scanner specs

☐ Check to confirm scanner is the same scanner used for all previous protocol scans for this participant
(If first scan, check to confirm scanner will be used for future protocol scans for this participant)

Has the scanner used for this study been qualified by ACRIN? ◯ No ◯ Yes

if no, specify reason _____

if yes provide scanner ID# _____

Manufacturer _____

Model Name/or number _____

Date of last PET scanner SUV validation _____

Daily scanner QC run on date of study ◯ No ◯ Yes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FLT Technical Assessment

Was imaging agent administered? ◯ Yes ◯ No Administration date _____

PET Tracer FLT Lot # _____

Source of agent ◯ Synthesized ◯ Purchased

Method _____ Supplier _____

Injection

Route of administration ◯ IV ◯ Oral

Activity in full syringe before injection _____ Unit _____

Time of assay of full syringe before injection _____

Time of injection _____

Residual activity in syringe after injection _____ Unit _____

Time of assay of residual activity after injection _____

Net activity administered _____ Unit _____

Location of Injection Site

◯ Central Venous Access Device

◯ Right antecubital ◯ Left antecubital

◯ Right foot ◯ Left foot

◯ Right Hand ◯ Left Hand

◯ Right wrist ◯ Left wrist

◯ Unknown ◯ Other, specify

Other Location of Injection Site _____

Any radiotracer infiltration at injection site noted?

◯ NONE

◯ MINOR (less than or equal to 20% OF DOSE)

◯ SEVERE (greater than 20% OF DOSE)

Was imaging exam completed? ◯ No ◯ Yes

If imaging not completed provide reason

◯ Scheduling problem ◯ Medical reason ◯ Progressive Disease

◯ Participant death ◯ Injection site complications ◯ Imaging agent not administered

◯ Equipment failure ◯ Claustrophobia ◯ Adverse event

◯ Participant refusal ◯ Participant withdrew ◯ unknown

◯ Other, specify

Other, specify _____

Date of imaging _____

Weight _____ KGS Height _____ CM *BSA* _____

Fasting ◯ Yes ◯ No

Duration of fasting pre-PET imaging (Hours) ☐

Was Foley catheter placed? ◯ No ◯ Yes

If no, Patient voided immediately pre-imaging ◯ No ◯ Yes ◯ Unknown

Patient voided immediately post-imaging ◯ No ◯ Yes ◯ Unknown

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

PET Emission Scan ◯ NOT DONE

Acquisition Mode	# of Bed Position	Time per bed Position	Scan start time	Scan stop time	Type of Scan	Pixel Size (mm)	Thickness (mm)

CT Image Acquisition ◯ NOT DONE

Type of attenuation correction used	Oral contrast used?	Oral contrast type	Amount (ml)	Was IV contrast used?	Amount (ml)	Time of Injection	KVP	mAs	Value origin	Slice thickness of reconstructed images(mm)	transmission scan (minutes)

Scanner specs

☐ Check to confirm scanner is the same scanner used for all previous protocol scans for this participant
(If first scan, check to confirm scanner will be used for future protocol scans for this participant)

Has the scanner used for this study been qualified by ACRIN? ◯ No ◯ Yes

if no, specify reason

if yes provide scanner ID#

Manufacturer

Model Name/or number

Date of last PET scanner SUV validation

Daily scanner QC run on date of study ◯ No ◯ Yes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section 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
- ◯ Minimal/Marginal Response
- ◯ Progressive Disease
- ◯ Stable Disease
- ◯ Disease Unchanged

Response Note

Date of Response

Date of Progression

Any Adverse Events in this Course ?

- ◯ Yes
- ◯ No

Note: This form is for the FLT scan only.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

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

Other Imaging

Was a mammogram performed ◯ No ◯ Yes

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

Ultrasound ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

MRI ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

CT scan ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FLT PET/CT: Local Site Image Assessment Form

Reader ID _____ Image Quality Interpretable? ◯ No ◯ Yes

Reason [mark all that apply]

- ☐ 1 Patient motion
- ☐ 2 Image artifacts
- ☐ 3 Incomplete study
- ☐ 4 Cannot calculate SUV
- ☐ 5 Radiotracer infiltration
- ☐ 6 Poor S/N (noisy images)
- ☐ 7 Incomplete anatomic coverage
- ☐ 8 Other

Other, Specify _____

Local Site Image Assessment: Torso Survey Scan at 60min

Total number of tumor sites visible ☐

Identify the parameters below for the Primary Tumor (PT1) and any other breast lesions (PT2, PT3 etc.)
from the FLT torso survey scan acquired at 60 minutes after injection

Lesion ID	Local Anatomic Site Description	Indicate FLT PET Slice	FLT SUV Max	FLT Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Section blank? ☐

Identify the parameters below for Other Lesions (LN1, LN2 etc.)

Lesion ID	Anatomic Site Description	Indicate FLT PET Slice	FLT SUV Max	FLT Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FDG PET/CT: Local Site Image Assessment Form

Reader ID _____ Image Quality Interpretable? ◯ No ◯ Yes

Reason [mark all that apply]

- ☐ 1 Patient motion
- ☐ 2 Image artifacts
- ☐ 3 Incomplete study
- ☐ 4 Cannot calculate SUV
- ☐ 5 Radiotracer infiltration
- ☐ 6 Poor S/N (noisy images)
- ☐ 7 Incomplete anatomic coverage
- ☐ 8 Other

Other, Specify _____

Local Site Image Assessment: Torso Survey Scan at 60min

Total number of tumor sites visible ☐

Identify the parameters below for the Primary Tumor (PT1) and any other breast lesions (PT2, PT3 etc.)
from the FDG torso survey scan acquired at 60 minutes after injection

Lesion ID	Local Anatomic Site Description	Indicate FDG PET Slice	FDG SUV Max	FDG Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Section blank? ☐

Identify the parameters below for Other Lesions (LN1, LN2 etc.)

Lesion ID	Anatomic Site Desciption	Indicate FDG PET Slice	FDG SUV Max	FDG Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name EARLYTHERIMGFLT2 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COURSE INITIATION

Course# ___

Start Date of Course

Treating Institution

Has patient agreed to use contraception during protocol?

- ◯ N/A, patient is not of reproductive potential
- ◯ No
- ◯ Not Applicable
- ◯ Unknown
- ◯ Yes

Note: This form is for the FLT scan only.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FDG Technical Assessment

Was imaging agent administered? ◯ Yes ◯ No Administration date _____

PET Tracer FDG Lot # _____

Source of agent ◯ Synthesized ◯ Purchased

Method _____ Supplier _____

Injection

Route of administration ◯ IV ◯ Oral

Activity in full syringe before injection _____ Unit _____

Time of assay of full syringe before injection _____

Time of injection _____

Residual activity in syringe after injection _____ Unit _____

Time of assay of residual activity after injection _____

Net activity administered _____ Unit _____

Molar Quantity Injected _____ Unit _____

Location of Injection Site

◯ Central Venous Access Device
◯ Right antecubital ◯ Left antecubital
◯ Right foot ◯ Left foot
◯ Right Hand ◯ Left Hand
◯ Right wrist ◯ Left wrist
◯ Unknown ◯ Other, specify

Other Location of Injection Site _____

Any radiotracer infiltration at injection site noted?
◯ NONE
◯ MINOR (less than or equal to 20% OF DOSE)
◯ SEVERE (greater than 20% OF DOSE)

Was imaging exam completed? ◯ No ◯ Yes

If imaging not completed provide reason

◯ Scheduling problem ◯ Medical reason ◯ Progressive Disease
◯ Participant death ◯ Injection site complications ◯ Imaging agent not administered
◯ Equipment failure ◯ Claustrophobia ◯ Adverse event
◯ Participant refusal ◯ Participant withdrew ◯ unknown
◯ Other, specify

Other, specify _____

Date of imaging _____

Weight _____ KGS Height _____ CM *BSA* _____

Fasting ◯ Yes ◯ No

Duration of fasting pre-PET imaging ☐

Blood glucose before injection of FDG _____

Time blood sample was obtained for glucose measurement _____

Was Foley catheter placed? ◯ No ◯ Yes

If no, Patient voided immediately pre-imaging ◯ No ◯ Yes ◯ Unknown

Patient voided immediately post-imaging ◯ No ◯ Yes ◯ Unknown

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

PET Emission Scan ◯ NOT DONE

Acquisition Mode	# of Bed Position	Time per bed Position	Scan start time	Scan stop time	Type of Scan	Pixel Size (mm)	Thickness (mm)

CT Image Acquisition ◯ NOT DONE

Type of attenuation correction used	Oral contrast used?	Oral contrast type	Amount (ml)	Was IV contrast used?	Amount (ml)	Time of Injection	KVP	mAs	Slice thickness of reconstructed images(mm)	transmission scan (minutes)

Scanner specs

☐ Check to confirm scanner is the same scanner used for all previous protocol scans for this participant
(If first scan, check to confirm scanner will be used for future protocol scans for this participant)

Scanner used qualified for this study by sponsor? ◯ No ◯ Yes

if no, specify reason ☐

if yes provide scanner ID# ☐

Manufacturer ☐

Model Name/or number ☐

Date of last PET scanner SUV validation ☐

Daily scanner QC run on date of study ◯ No ◯ Yes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FLT Technical Assessment

Was imaging agent administered? ◯ Yes ◯ No Administration date _____

PET Tracer FLT Lot # _____

Source of agent ◯ Synthesized ◯ Purchased

Method _____ Supplier _____

Injection

Route of administration ◯ IV ◯ Oral

Activity in full syringe before injection _____ Unit _____

Time of assay of full syringe before injection _____

Time of injection _____

Residual activity in syringe after injection _____ Unit _____

Time of assay of residual activity after injection _____

Net activity administered _____ Unit _____

Location of Injection Site

◯ Central Venous Access Device

◯ Right antecubital ◯ Left antecubital

◯ Right foot ◯ Left foot

◯ Right Hand ◯ Left Hand

◯ Right wrist ◯ Left wrist

◯ Unknown ◯ Other, specify

Other Location of Injection Site _____

Any radiotracer infiltration at injection site noted?

◯ NONE

◯ MINOR (less than or equal to 20% OF DOSE)

◯ SEVERE (greater than 20% OF DOSE)

Was imaging exam completed? ◯ No ◯ Yes

If imaging not completed provide reason

◯ Scheduling problem ◯ Medical reason ◯ Progressive Disease

◯ Participant death ◯ Injection site complications ◯ Imaging agent not administered

◯ Equipment failure ◯ Claustrophobia ◯ Adverse event

◯ Participant refusal ◯ Participant withdrew ◯ unknown

◯ Other, specify

Other, specify _____

Date of imaging _____

Weight _____ KGS Height _____ CM *BSA* _____

Fasting ◯ Yes ◯ No

Duration of fasting pre-PET imaging (Hours) ☐

Was Foley catheter placed? ◯ No ◯ Yes

If no, Patient voided immediately pre-imaging ◯ No ◯ Yes ◯ Unknown

Patient voided immediately post-imaging ◯ No ◯ Yes ◯ Unknown

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

PET Emission Scan ◯ NOT DONE

Acquisition Mode	# of Bed Position	Time per bed Position	Scan start time	Scan stop time	Type of Scan	Pixel Size (mm)	Thickness (mm)

CT Image Acquisition ◯ NOT DONE

Type of attenuation correction used	Oral contrast used?	Oral contrast type	Amount (ml)	Was IV contrast used?	Amount (ml)	Time of Injection	KVP	mAs	Value origin	Slice thickness of reconstructed images(mm)	transmission scan (minutes)

Scanner specs

☐ Check to confirm scanner is the same scanner used for all previous protocol scans for this participant
(If first scan, check to confirm scanner will be used for future protocol scans for this participant)

Has the scanner used for this study been qualified by ACRIN? ◯ No ◯ Yes

if no, specify reason

if yes provide scanner ID#

Manufacturer

Model Name/or number

Date of last PET scanner SUV validation

Daily scanner QC run on date of study ◯ No ◯ Yes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section 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
- ○ Minimal/Marginal Response
- ○ Progressive Disease
- ○ Stable Disease
- ○ Disease Unchanged

Response Note

Date of Response

Date of Progression

Any Adverse Events in this Course ?

- ○ Yes
- ○ No

Note: This form is for the FLT scan only.

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

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

Other Imaging

Was a mammogram performed ◯ No ◯ Yes

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

Ultrasound ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

MRI ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

CT scan ◯ NO ◯ YES

Date of Imaging	Lesion ID	Location	Measurement 1		Measurement 2		Lesion Availability
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	
				mm x		mm	

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FLT PET/CT: Local Site Image Assessment Form

Reader ID _____ Image Quality Interpretable? ◯ No ◯ Yes

Reason [mark all that apply]

- ☐ 1 Patient motion
- ☐ 2 Image artifacts
- ☐ 3 Incomplete study
- ☐ 4 Cannot calculate SUV
- ☐ 5 Radiotracer infiltration
- ☐ 6 Poor S/N (noisy images)
- ☐ 7 Incomplete anatomic coverage
- ☐ 8 Other

Other, Specify _____

Local Site Image Assessment: Torso Survey Scan at 60min

Total number of tumor sites visible ☐

Identify the parameters below for the Primary Tumor (PT1) and any other breast lesions (PT2, PT3 etc.)
from the FLT torso survey scan acquired at 60 minutes after injection

Lesion ID	Local Anatomic Site Description	Indicate FLT PET Slice	FLT SUV Max	FLT Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Section blank? ☐

Identify the parameters below for Other Lesions (LN1, LN2 etc.)

Lesion ID	Anatomic Site Description	Indicate FLT PET Slice	FLT SUV Max	FLT Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

FDG PET/CT: Local Site Image Assessment Form

Reader ID _____ Image Quality Interpretable? ◯ No ◯ Yes

Reason [mark all that apply]

☐ 1 Patient motion
☐ 2 Image artifacts
☐ 3 Incomplete study
☐ 4 Cannot calculate SUV
☐ 5 Radiotracer infiltration
☐ 6 Poor S/N (noisy images)
☐ 7 Incomplete anatomic coverage
☐ 8 Other

Other, Specify _____

Local Site Image Assessment: Torso Survey Scan at 60min

Total number of tumor sites visible ☐

Identify the parameters below for the Primary Tumor (PT1) and any other breast lesions (PT2, PT3 etc.) from the FDG torso survey scan acquired at 60 minutes after injection

Lesion ID	Local Anatomic Site Description	Indicate FDG PET Slice	FDG SUV Max	FDG Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Section blank? ☐

Identify the parameters below for Other Lesions (LN1, LN2 etc.)

Lesion ID	Anatomic Site Desciption	Indicate FDG PET Slice	FDG SUV Max	FDG Uptake Criteria	Largest Diameter on CT (cm)	Visualized?

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name POSTCHEMOIMGFLT3 Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

Surgical Pathology

Date of Surgical Resection ☐

Site ◯ LEFT ◯ RIGHT

Residual Invasive Carcinoma ◯ NO ◯ YES

Residual In Situ Carcinoma ◯ NO ◯ YES

Procedure

◯ Lumpectomy ◯ Simple Mastectomy

◯ Modified Radical Mastectomy ◯ Other

Quadrant ◯ LIQ ◯ LOQ ◯ UIQ ◯ UOQ

Finding ☐

Lesion ID	Status POS / NEG	Diameter 1 (cm)	Diameter 2 (cm)
TA1	◯ ◯		
TA2	◯ ◯		
TA3	◯ ◯		
TA4	◯ ◯		
TA5	◯ ◯		
TA6	◯ ◯		
NT1	◯ ◯		
NT2	◯ ◯		
NT3	◯ ◯		
NT4	◯ ◯		

TA: Target Lesion
NT: Non- Target Lesion

T Stage

◯ Tis (LCIS) ◯ T3
◯ Tis (Paget's) ◯ T4
◯ Tis (DCIS) ◯ T4a
◯ T0 ◯ T4b
◯ T1 ◯ T4c
◯ T1a ◯ T4d
◯ T1c ◯ TX
◯ T1mic ◯ Tis
◯ T2 ◯ T1b

N Stage

◯ PN0 ◯ PN1MI
◯ PN0(I+) ◯ PN2
◯ PN0(I-) ◯ PN2A
◯ PN0(MOL+) ◯ PN2B
◯ PN0(MOL-) ◯ PN3
◯ PN1 ◯ PN3A
◯ PN1A ◯ PN3B
◯ PN1B ◯ PN3C
◯ PN1C ◯ PNX

M Stage

◯ MX
◯ M0
◯ M1

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

COMMENTS

Date	Note

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Visit Name SURGICAL RESECT Visit Date _____ CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

Sample Collection Date ☐ Pathology # ☐

PROLIFERATION INDEX - POST-TREATMENT

	Lesion ID#	Analyzed No	Analyzed Yes	Mitotic Count #	Ki-67 Nuclear Count	Total # of cells
HPF 1		○	○			
HPF 2		○	○			
HPF 3		○	○			
HPF 4		○	○			
HPF 5		○	○			
HPF 6		○	○			
HPF 7		○	○			
HPF 8		○	○			
HPF 9		○	○			
HPF 10		○	○			
				Total		Total

Mitotic Index (%) ☐

Ki-67 Index ☐

Pathologic Response ☐

Biomarker Name	Analyzed No	Analyzed Yes	% Positive Cells	Staining Grade 0	1	3
Ki-67	○	○		○	○	○

Doc# _____ Status _____ Form POSTPROLIF (v1, 10-AUG-2011)

Visit# 70 Subevent# _____ CRF Page e2.1 of 2

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Study VCU_FLT_8029 Patient 007-010

Visit Name SURGICAL RESECT Visit Date _____ CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Note

Doc# _____ Status _____ Form POSTPROLIF (v1, 10-AUG-2011)

Visit# 70 Subevent# _____ CRF Page e2.2 of 2

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

Tumor Slides Transmittal Form

Part A. Completed by Site RA

Timepoint in study: (select one) ◯ PRE (VISIT 1) ◯ POST (VISIT 5)

Were slides paraffin blocks able to be sent? (select one) ◯ No ◯ Yes

Provide reason unable to send slides paraffin blocks

(complete then intial, sign and date form and send to address listed below along with reports)

◯ Not allowed by institution

◯ Specimen lost

◯ Other, specify

Other, specify

Type of tissue submitted: (check all that apply) ☐ Slides Number of slides

☐ Paraffin block(s) number of blocks

Date of surgical procedure

Before Sending the Slides Blocks and reports, please check to confirm:

ALL study participants' personal identifying information (participant name, medical record number, SS#, etc.) on all of the material is de-identified

Each slide block report is labeled with the study number, site number, patient case number and pre or post timepoint.

The pathology specimens, pathology report, imaging report and this form should be shipped to the central pathology laboratory to:

Megan Quinn
Virginia Commonwealth University Health System
1101 East Marshall Street, Room 4-065
P.O. Box 980470
Richmond, VA 23298-0470
RE: ACRIN 6688 Pathology

Date slides blocks reports Sent to Path Lab

Initials of Person from Site Completing This Form

Date Form Completed

Part B. Completed by VCU Path Lab

Date Slides Blocks Received ☐

Number of slides received ☐

Number of blocks received ☐

Have specimen(s) been received in an acceptable condition? ◯ No ◯ Yes

Initials of Person from Site Completing This Form

☐

Date Form Completed ☐

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

Residual Cancer Burden (Surgical Resect time point)

1) Primary Tumor Bed

Primary Tumor Bed Area ____ mm x ____ mm

Overall Cancer Cellularity (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 Burden ____

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name SURGICAL RESECT Visit Date _____

COMMENTS

Date	Note

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name OFF-TREATMENT Visit Date _____

Date will be displayed as 'DD-MON-YYYY'

OFF TREATMENT SUMMARY

Date Off Treatment ☐

Reason Off Treatment
- ◯ Switched to Alternative Treatment
- ◯ Disease Progression before Treatment
- ◯ Death on Study
- ◯ Cytogenetic resistance
- ◯ Late Determination of Ineligibility
- ◯ Disease Progression On Study
- ◯ Refused further Treatment
- ◯ Complicating Disease, Intercurrent Illness
- ◯ Adverse Events, Side Effects
- ◯ Protocol Violation
- ◯ Patient Declined to Participate (before treatment started)
- ◯ No Treatment, per protocol
- ◯ Lost to Further Follow-up
- ◯ Treatment Period Completed
- ◯ PI Discretion
- ◯ Patient Noncompliance
- ◯ Not Treated - Other Reasons, explain
- ◯ Other

Explain 'Other' Reason Off Treatment ☐

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name OFF-STUDY Visit Date _____

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

OFF STUDY SUMMARY

Date Off Study ☐

Reason Off Study
- ○ Study Complete
- ○ Death on Study
- ○ Complicating Disease / Intercurrent Illness
- ○ Toxicity
- ○ Not Treated - Other Reasons, explain
- ○ Lost to Further Follow-up
- ○ Patient Noncompliance
- ○ Other

Explain 'Other' Reason ☐

Date of Disease Progression ☐

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name OFF-STUDY Visit Date _____

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

Section blank? ☐

COMMENTS

Date	Notes

Study VCU_FLT_8029 Patient 007-010 CRF Blank ☐

Visit Name OFF-STUDY Visit Date _____

COMMENTS

Date	Note

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Study VCU_FLT_8029 Patient 007-010

Visit Name CONMED CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

CONCOMITANT MEASURES/MEDICATIONS

Start Date	Stop Date	Agent Name	Procedure	Total Daily Dose	Dose Units	Schedule	Route	Reason

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Study VCU_FLT_8029 Patient 007-010

Visit Name CONMED CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Note

Doc# Status Form CONMED (v2, 23-MAR-2011)

Visit# 100 Subevent# CRF Page h1.2 of 2

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Study VCU_FLT_8029 Patient 007-010

Visit Name AE CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

ADVERSE EVENTS

Date of Onset	Date Resolved	CTC Term	*System Organ Class (SOC)*	AE Description	Expedited Report Filed? Y/ N / U	Grade	Attribution	Y Dose Limiting / N Toxicity	Serious	Action	Therapy	Outcome

Grade:
1 =Mild
2=Moderate
3=Severe
4=Threat
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=Requires Intervention

Action:
1=None
2=Reduced
3=Interrupt
4=Discontinued
5=Interrupt/Reduced

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

Outcome:
1=Recovered
2=Treatment
3=Alive
4=Died

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Study VCU_FLT_8029 Patient 007-010

Visit Name AE CRF Blank ☐

Date of Onset	Date Resolved	CTC Term	*System Organ Class (SOC)*	AE Description	Expedited Report Filed? Y/ N / U	Grade	Attribution	Y Dose Limiting / N Toxicity	Serious	Action	Therapy	Outcome

Grade:
1 =Mild
2=Moderate
3=Severe
4=Threat
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=Requires Intervention

Action:
1=None
2=Reduced
3=Interrupt
4=Discontinued
5=Interrupt/Reduced

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

Outcome:
1=Recovered
2=Treatment
3=Alive
4=Died

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Study VCU_FLT_8029 Patient 007-010

Visit Name AE CRF Blank ☐

Date of Onset	Date Resolved	CTC Term	*System Organ Class (SOC)*	AE Description	Expedited Report Filed? Y/ N / U	Grade	Attribution	Y Dose Limiting / N Toxicity	Serious	Action	Therapy	Outcome

Grade:
1 =Mild
2=Moderate
3=Severe
4=Threat
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=Requires Intervention

Action:
1=None
2=Reduced
3=Interrupt
4=Discontinued
5=Interrupt/Reduced

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

Outcome:
1=Recovered
2=Treatment
3=Alive
4=Died

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Study VCU_FLT_8029 Patient 007-010

Visit Name AE CRF Blank ☐

Note: Dates will appear as 'DD-MON-YYYY' Section blank? ☐

COMMENTS

Date	Note

Doc# Status Form AE (v1, 22-JAN-2010)

Visit# 110 Subevent# CRF Page i1.4 of 4