Lung Cancer: Evaluation of Treatment Response with PET

CRF Set

Registration/Eligibility Checklist FDG-PET/CT Tumor Response Patient Outcome - NSCLC

PLACE LABEL HERE		
Institution	Institution No.	
Participant Initials	Case No.	

ACRIN Study 6678

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

Instructions: The eligibility checklist (A0) Part 2 must be completed prior to registration to determine and confirm study eligibility. At time of enrollment, the participant is to review, sign and date the consent. The following questions will be asked at study registration. The date is submitted via the ACRIN website. Submit a paper form only in the event the website is down.				
Part I.	The following	ng questions will be asked at Study Registration:		
	1.	Name of Institutional person registering this case [1]		
	2.	(Y) Has the Eligibility Checklist been completed? [2]		
	3.	(Y) Is the Patient eligible for this study? [3]		
	4.	Date the study-specific Consent Form was signed? (mm-dd-yyyy) (Must be prior to study entry) [4]		
	5.	Patient's Initials (last, first) (L, F) [5]		
	6.	Verifying Physician (Site PI) [6]		
	7.	Participant's ID Number (optional: 999999 may be coded) [7]		
	8.	Date of Birth [mm-dd-yyyy (must be = or > than 18 years)] [8]		
	9.	Ethnicity [9] 1 Hispanic or Latino 2 Not Hispanic or Latino 9 Unknown		
	11.	. Gender _[11] 1 Male 2 Female		
	12.	Participant's country of residence (if other, complete Q18) [12] 1 United States 2 Canada 3 Other 9 Unknown		
	13.	. Zip Code (5 digit code, US residents) [13]		
		Patient's Insurance Status O Other Private Insurance Medicare Medicare and Private Insurance Medicaid Medicaid and Medicare Military or Veteran's Administration Self Pay No means of payment Unknown/Decline to answer		
	15.	 Will any component of the patient's care be given at a Military or VA facility? [15] 1 No 2 Yes 9 Unknown 		

A0	ACRIN 667	8	ACRIN Study 6678 PLACE LABEL HERE	
			Institution	Institution No
			Participant Initials	Case No
	16. Calenda	ar Base Date [= date of registration] _[1]	61	
		registration [randomization] (mm-dd-yy	-1	
		Country, specify (completed if Q12 is co	11	
		(check all that apply) \square =1 No, \boxtimes =2 Y	[]	
		erican Indian or Alaskan Native [19]		
	20. □ Asi	an _[20]		
	21. □ Bla	ck or African American [21]		
	22. □ Nat	tive Hawaiian or other Pacific Islander	[22]	
	23. 🗆 Wh	ite _[23]		
		known _[24]		
	25. Start da	ite of planned chemotherapy treatment	(mm-dd-yyyy) (Group A an	d B only. Enter 99's for Group C) [25]
Part II: Th	e following quest	ions are to determine patient eligibili	ty:	
	26. (Y) Doe	es the participant have histologically or	cytologically proven NSCI	_C? _[26]
		27. (Y) Does the participant have tumor stage IIIB (with malignant pleural effusion), stage IV, or recurrent metastatic disease? [27]		
	NOTE:	28. (Y/NA) Has the participant had a CT or MR scan of the chest? [28] NOTE: If necessary to determine/confirm stage disease, an upper abdomen CT scan (including liver and adrenals) must be performed.		
		. (Y) Has the participant had a history and physical examination within 6 weeks prior to registration? [30]		
		se provide date of physical examinati		[OO]
	32. (Y/NA) H	32. (Y/NA) Has the participant had a CT or MR scan of the brain within 4 weeks prior to registration if there is headache, mental or physical impairment, or other signs or symptoms suggesting brain metastases (Group A and B only) _[32]		
	33. Plea	se provide date of CT or MR [33]		
	34. (Y) Doe: ≥ 2	s the participant have at least one m cm according to Response Evaluation	easurable primary or other	r intrathoracic/supraclavicular lesion RECIST)? [34]
	35. (Y) Doe: Grou	s the participant have a performance sup (ECOG) scale? [35]	status of 0 to 2 on the Eas	tern Cooperative Oncology
	0 1 2 3 4 5	rule provide Performance Status (ECO Fully active, able to carry on all pre-Restricted in physically strenuous ac sedentary nature, e.g., light house we Ambulatory and capable of all selfca more than 50% of waking hours Capable of only limited selfcare, con Completely disabled. Cannot carry of Dead	disease performance without tivity but ambulatory and a ork, office work re but unable to carry out without to bed or chair more n any selfcare. Totally con	ble to carry out of a light or work activities. Up and about than 50% of waking hours fined to bed or chair
-	37. Plea	se provide date the Performance Sta	tus (ECOG) was assessed	^{1.} [37]

A0	ACF	RIN 6678	ACRIN Study PLACE LAB		
		-	Institution	Institution No	
			Participant Initials	Case No.	
	38.	(Y/NA) Is the participant scheduled to be trea administered at 3 weeks intervals? (Gr		nt chemotherapy regimen	
	39.	(Y) Is the participant 18 years of age or older	? [39]		
	40. (Y/NA) Does the participant agree to use medically appropriate contraception if sexually active; women of child bearing potential must not be pregnant or breast-feeding [40]				
	41.	(Y/NA) Has a pregnancy test been done and	shown to be negative? [41]		
	42.	If yes, please provide date of pregnancy to	est. _[42]		
	43.	(Y) Is the participant able to give study specif	ic informed consent? [43]		
	44.	(Y) Is the participant able to tolerate PET imate ACRIN-qualified facility? [44]	ging required by protocol, to be perf	formed at an	
	45.	(Y) Which treatment arm is the participant bei	ng registered to? [60]		
	O Group A O Group B O Group C				
Exclusion C	Criteria:				
	46.	(N) Does the participant have small cell card	inoma histology? [46]		
	47.	47. (N) Does the participant have a pure bronchioloalveolar cell carcinoma histology? [47]			
	48.	48. (N) Has the participant had prior thoracic radiotherapy, lung surgery or chemotherapy within 3 months prior to inclusion in the study? (Radiotherapy or surgery non-thoracic lesions allowed) [48]			
	49.	49. (N) Does the participant have poorly controlled diabetes (defined as fasting glucose level >150 mg/dl) despite medications? [49] (see Section 5.2.4 for details)			
	50.	(N) Has the participant had a prior malignand carcinoma in situ, or other cancer from when the cancer from when the cancer from when the cancer from the cance	y other than basal cell or squamous nich they have been disease free for	s cell carcinoma of the skin, r less than (3) years? [50]	
	51.	(N/NA) Is the participant planning to undergo	chemoradiotherapy? (Exclusion for C	Group A and B only) _[51]	
	52.	(N) Does the participant show clinical or radi	ographic signs of post-obstructive p	neumonia? _[52]	
	53.	(N/NA)Does the participant have symptomatic	brain metastases? (Exclusion for C	Groups A and B only) [53]	
	54. (N/NA) Treatment planned with any targeted or biologic therapy other than bevacizumab or cetuximab? (Exclusion for Groups A and B only) [59]			nab or cetuximab?	
	55.	(N) Is the participant, who is sexually active, u or women who are pregnant or breast-fee	inwilling and/or unable to use medicading? [55]	ally appropriate contraception,	
0	la co				
•	•	, Investigator Designee, or Principal Investiga	itor)		
Signature of	f person	Date tentering data onto the web	form completed	(mm-dd-yyyy) _[58]	



FDG - PET/CT Tumor Response Chemotherapy Assessment Form Cycle 1

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PLACE LABEL HERE

Insti	tution	Institution No.
Parti	cipant Initials	Case No

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

1. Was Chemotherapy given for Cycle 1? $_{[1]}$ CYCLE 1 O No (Complete Q1a then sign and date form) O Yes **Agent Code Table Start Date End Date** Reason for **Total Termination** (mm/dd/yyyy) (mm/dd/yyyy) Dose/ Cisplatin Unit Carboplatin Cycle ended, per protocol Disease Progression Docetaxel Participant withdrew Gemcitabine Participant refused Paclitaxel Change in therapy Vinorelbine Low counts Bevacizumab 88 Other** (specify reason) Cetuximab 88 Other* (specify agent) **Agent Code Reason Code** [6] O mg [9] [3] [4] Oother [7] **Agent Code Reason Code** [10] O_{mg} [11] [17] [12 Oother [15] **Agent Code Reason Code** [18] [22] O_{mg} [19] [25] Oother [23] [20] **Agent Code** Reason Code [26] [30] [32] O_{mg} [27] [33] Oother [31] [28]

 1a. Primary reason chemotherapy not performed O 1 Participant withdrew O 2 Participant refused O 3 Change in therapy 	2. Weight first day this cycle: kg [36]
O 4 Low counts O 5 Death O 6 Referred for supportive care / hospice O 88 Other, specify	3. Serum creatinine at time of cycle:
Signature of Person Responsible for Data	Date form completed (mm-dd-yyyy)
Signature of Person entering data onto the Web	
	Variation 0 0070 04 44 40 00

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FDG - PET/CT Tumor Response Chemotherapy Assessment Form Cycle 2

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Institution	Institution No.
Participant Initials	Case No

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

Was Chemotherapy given for Cyc O No (Complete Q1a then sign O Yes	F. 7		CYCL	.E 2
Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Total Dose/ Unit	Reason for Termination 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
*[3]			O mg O other [7]	Reason Code [8]
*[11]	[12]		O mg O other [15]	Reason Code
*[19]			O mg O other [23]	Reason Code
*[27]			O mg O other [31]	Reason Code
a. Primary reason chemotherant O 1 Participant withdrew O 2 Participant refused O 3 Change in therapy O 4 Low counts O 5 Death O 6 Referred for supportive O 88 Other, specify	ve care / hospice	3. Serum creat	if unknown)	[37] e of cycle: - [38]
ignature of Person Responsible f	or Data		 Date form	 completed (mm-dd-yyyy)
Signature of Person entering data	[42] onto the Web			

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FDG - PET/CT Tumor Response **Chemotherapy Assessment Form** Cycle 3

	PLACE	LABEL	H
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Institution	Institution No.
Participant Initials	Case No.

ACRIN Study 6678

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

CYCLE 3 1. Was Chemotherapy given for Cycle 3? $_{[1]}$ O No (Complete Q1a then sign and date form) O Yes **Agent Code Table** Start Date **End Date** Reason for Total (mm/dd/yyyy) (mm/dd/yyyy) **Termination** Dose/ Cisplatin Unit Carboplatin Cycle ended, per protocol Disease Progression Docetaxel 2 Gemcitabine 3 Participant withdrew Paclitaxel Participant refused Vinorelbine Change in therapy Bevacizumab Low counts Cetuximab 88 Other** (specify reason) 88 Other* (specify agent) **Agent Code Reason Code** O mg [3] [9] [4] Oother [7] **Agent Code Reason Code** [10] O mg [11] [17] [12 [13] Oother [15] **Agent Code Reason Code** [22] O_{mg} [19] Oother [23] [20 **Agent Code** Reason Code [26] [30] O mg [33] Oother [31] [29] [28] 1a. Primary reason chemotherapy not performed $_{[34]}$ Weight first day this cycle: O 1 Participant withdrew ☐ (Check if unknown) [37] O 2 Participant refused 0 3 Change in therapy 0 4 Low counts 3. Serum creatinine at time of cycle: 0 5 Death O 6 Referred for supportive care / hospice O 88 Other, specify_ [35] ☐ (Check if unknown) [39] [40] Date form completed (mm-dd-yyyy) Signature of Person Responsible for Data

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[42]

Signature of Person entering data onto the Web



FDG - PET/CT Tumor Response Chemotherapy Assessment Form Cycle 4

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Institution	Institution No.
Participant Initials	Case No

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

O No (Complete Q1a then sign and date form) O Yes				
Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Total Dose/ Unit	Reason for Termination 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
*[3]		<u></u>	O mg O other [7]	Reason Code
*[11]			O mg O other [15]	Reason Code
*[19]	[20]	[21]	O mg O other [23]	Reason Code
*[27]			O mg O other [31]	Reason Code [32]
O 1 Participant withdrev O 2 Participant refused O 3 Change in therapy O 4 Low counts O 5 Death O 6 Referred for suppor O 88 Other, specify	tive care / hospice	3. Serum creat	if unknown)	[37] e of cycle: - [38]
Signature of Person Responsible	for Data [40]		Date form	completed (mm-dd-yyyy)

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[42]

Signature of Person entering data onto the Web



FDG - PET/CT Tumor Response Chemotherapy Assessment Form Cycle 5

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Institution	Institution No
Participant Initials	Case No.

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

Was Chemotherapy given for Cycle 5? [1] O No (Complete Q1a then sign and date form) O Yes			CYCLE 5		
Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Total Dose/ Unit	Reason for Termination 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 8 Other** (specify reason)	
Agent Code[2] *[3]			O mg O other [7]	Reason Code [8]	
*[11]			O mg O other [15]	Reason Code	
*[19]			O mg O other [23]	Reason Code [24]	
*[27]			O mg O other [31]	Reason Code [32]	
A. Primary reason chemother O 1 Participant withdre O 2 Participant refused O 3 Change in therapy O 4 Low counts O 5 Death O 6 Referred for suppo O 88 Other, specify	w rtive care / hospice	3. Serum creat	if unknown)	[37] e of cycle: - [38]	
Signature of Person Responsible	e for Data		Date form		

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[42]

Signature of Person entering data onto the Web



FDG - PET/CT Tumor Response Chemotherapy Assessment Form Cvcle 6

Cycle 0		
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If this is a revised or corrected form, please	√box.	

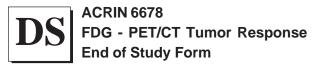
ACRIN Study	6678
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PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Total Dose/ Unit	Reason for Termination 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
*[3]			O mg O other [7]	Reason Code [8]
*[11]			——[14] O mg O other [15]	**
*[19]		[21]	O mg O other [23]	**
Agent Code[26] *[27]			O mg O other [31]	Reason Code [32]
a. Primary reason chemothera O 1 Participant withdrev O 2 Participant refused O 3 Change in therapy O 4 Low counts O 5 Death O 6 Referred for suppor O 88 Other, specify	tive care / hospice	3. Serum creat	if unknown)	[37] e of cycle: - [38]
ignature of Person Responsible	[40]		Data form	 completed (mm-dd-yyyy)



ACRIN Study 6678 PLACE LABEL HERE

		Institution	Institution No	
lf 1	this is a revised or corrected form, please \sqrt{box} .	Participant Initials	Case No	
	structions: For each registered participant, please submit this for scontinuation, including death.	m within two (2) weeks of str	udy completion or premature	
١.	End of Study status: [1] O 1 Protocol specific criteria and follow-up complete (sign of 2 Premature discontinuation (complete Q2 and Q2a) O 3 Participant death (skip to Q3 and Q3a)	and date form)		
2.	Date of premature discontinuation:	(<i>mm/dd/yyyy</i>) _[2]		
	2a. Primary reason for premature discontinuation: (check O Adverse events/side effect/complications (also specification) O Participant explicitly withdraws from further study participant explicitly withdraws from further study participant or protocol violation O Did not meet baseline criteria O Lost to follow-up (unable to obtain contact with the participant of the part	fy on the Adverse Event form rticipation		
5.	Date of death (<i>mm/dd/yyyy</i>) [4] 3a. Cause of death [5]			
	O Disease progression O Other	(specify cause of death) [6]		
C	OMMENTS:			_
Sig	gnature of person responsible for the data	 Date form compl		7]
Si	gnature of person entering data onto the web			

F1 ACRIN 6678 FDG - PET/CT Tumor Response 3 Month Follow-up (F/U) Form

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If this is a revised or	corrected form, please	√box.	

ACRIN Study 6678

PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No

3 MONTH FOLLOW-UP

INSTRUCTIONS: The Research Staff will complete this form following contact with the participant's treating physician. Please submit this form within 2 weeks of the three month evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This is the date on which the participant's treating physician was contacted for information pertaining to disease progression and vital status. For question 5, please refer to Appendix VII (section 3.2) which summarizes the categories of response status.

1.	Timepoint for this follow-up [1]	7.		articipant receive any Radiation Therapy
	o 3 month follow-up		not previ	ously reported? [15]
			o 1	No
	1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation [2]		o 2 o 99	Yes (specify location and provide date) Unknown
			7a.	Anatomic location of Radiation Therapy:
				[16]
2.	Was the follow-up evaluation completed? [3]		76	
	o 1 No (complete Q2a, sign and date form)		7b.	Date of Radiation Therapy: [17]
	o 2 Yes (skip to Q3)			(mm-dd-yyyy)
	2a. Reason not completed: (check all that apply)	8.	Did the pa	articipant have surgery not previously reported? [18]
	☐ =1 Not Marked, 🗹 = 2 Marked		o 1	No
	☐ Scheduling problem [4]		o 2 o 99	Yes (specify location and provide date) Unknown
	☐ Patient refusal [5]		8a.	Anatomic location of surgery:
	☐ Medical reason (define reason in comments) _[6]		oa.	Anatomic location of surgery.
	☐ Withdrew consent (submit the end of study form (DS)) _[7]			[19]
	Other, _[8] specify		8b.	Date of surgery: [20]
3.	Date of last contact between the treating physician			
	and the participant _[10]			(mm-dd-yyyy)
		9.		articipant have any non-protocol
	(mm-dd-yyyy)		chemoth	erapy not previously reported [21]
4.	Participant's vital status at the time of this follow-up [11]		o 1 o 2	No Yes (specify and provide date)
	o 1 Alive			Unknown
	o 2 Dead (submit the end of study form (DS))			
	o 99 Unknown		9a.	Type of non-protocol chemotherapy:
5.	Response status at this assessment (see Instructions) [12]			[22]
	o 1 Complete response (CR)		9b.	Date of non-protocol chemotherapy: [23]
	o 2 Partial response (PR)			
	o 3 Stable disease (SD) o 4 Progressive disease (PD)			(mm-dd-yyyy)
	o 99 Unknown	10.	_	articipant receive any other non-protocol treatmen
				ously reported [24]
	5a. Date the response status was determined $_{[13]}$		o 1 o 2	No Yes (specify and provide date)
	(mm-dd-yyyy)			Unknown
	(<i>IIIIII-</i> uu-yyyy)		10a.	Type of treatment:
6.	Did the participant develop a first progression [14]			7,600
	o 1 No			[25]
	o 2 Yes (submit the progression form (PF)) o 99 Unknown		10b.	Date of non-protocol treatment: [26]
	0 99 OHNHOWH			
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ACRIN 6678 FDG - PFT/CT Tumor Response

ACRIN Study 6678

3 Month Follow-up (F/U) Form	PLACE LABEL HERE			
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Institution Institution No Participant Initials Case No			
	3 MONTH FOLLOW-UP			
Comments:				
	[27]			
Signature of Person responsible for the data	Date form completed (mm-dd-yyyy)			
Signature of Person entering data onto the web				

ACRIN 6678 FDG - PET/CT Tumor Response 6 Month Follow-up (F/U) Form

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If this is a revised of	corrected form, please	√box.	

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No

6 MONTH FOLLOW-UP

INSTRUCTIONS: The Research Staff will complete this form following contact with the participant's treating physician. Please submit this form within 2 weeks of the six month evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This

1.	Timepoint for this follow-up [1]	7.	Did the p	participant receive any Radiation Therapy	
	o 6 month follow-up			iously reported? _[15]	
			0 1	No [15]	
	1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation [2]			Yes (specify location and provide date) Unknown	
	(mm-dd-yyyy)		7a.	Anatomic location of Radiation Therapy:	
2.	Was the follow-up evaluation completed? [3]			[16]	
	o 1 No (complete Q2a, sign and date form)		7b.	Date of Radiation Therapy: [17]	
	o 2 Yes (skip to Q3)			(mm-dd-yyyy)	
	2a. Reason not completed: (check all that apply)	8.	Didthon		
	☐ =1 Not Marked, ☑ = 2 Marked	0.	0 1	articipant have surgery not previously reported? [1] No	8]
	☐ Scheduling problem [4]		o 2 o 99	Yes (specify location and provide date) Unknown	
	☐ Patient refusal [5]		8a.	Anatomic location of surgery:	
	 ☐ Medical reason (define reason in comments)_[6] ☐ Withdrew consent (submit the end of study form (DS))_[7] 				
				[19]	
	Other, specify		8b.	Date of surgery: [20]	
3.	Date of last contact between the treating physician and the participant _[10]			(mm-dd-yyyy)	
	[10]	9.	Did the p	articipant have any non-protocol	
	(mm-dd-yyyy)			nerapy not previously reported [21]	
4.	Participant's vital status at the time of this follow-up [11]		0 1	No	
₹.	o 1 Alive		o 2	Yes (specify and provide date) Unknown	
	o 2 Dead (submit the end of study form (DS))		0 00		
	o 99 Unknown		9a.	Type of non-protocol chemotherapy:	
5.	Response status at this assessment (see Instructions) [12]			[22]	
	o 1 Complete response (CR)		9b.	Date of non-protocol chemotherapy: [23]	
	o 2 Partial response (PR)			• •	
	o 3 Stable disease (SD) o 4 Progressive disease (PD)			(mm-dd-yyyy)	
	o 99 Unknown	10.		participant receive any other non-protocol treatm	en
				iously reported [24]	
	5a. Date the response status was determined $_{\left[13\right]}$		o 1 o 2	No Yes (specify and provide date)	
	(mm-dd-yyyy)			Unknown	
	(///// dd yyyy)		10a.	Type of treatment:	
6.	Did the participant develop a first progression not			71	
0.	previously reported [14]			[25]	
		1			
	o 1 No		10b.	Date of non-protocol treatment:	
	o 1 No o 2 Yes (submit the progression form (PF)) o 99 Unknown		10b.	Date of non-protocol treatment: [26]	

F2 ACRIN 6678 FDG - PET/CT Tumor Response 6 Month Follow-up (F/U) Form

ACRIN Study 6678 PLACE LABEL HERE

6 Month Follow-up (F/U) Form	1		CE LABEL HERE
If this is a revised or corrected form, please $\sqrt{\text{box.}}$		I	Institution No
			ONTH FOLLOW-UP
Comments:			
			[27]
Signature of Person responsible for the data	[—] [28]		
Signature of Person entering data onto the web	[—] [29]		

ACRIN 6678 FDG - PET/CT Tumor Response 9 Month Follow-up (F/U) Form

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ACRIN Study 6678

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Institution	Institution No.	
Participant Initials	Case No	

9 MONTH FOLLOW-UP

 $\textbf{INSTRUCTIONS:} \ \textit{The Research Staff will complete this form following contact with the participant's treating physician. Please submit this form within the participant of the par$ 2 weeks of the nine month evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This

	fer to Appendix VII (section 3.2) which summarizes the categories of res			
1.	Timepoint for this follow-up [1]	7.	_	articipant receive any Radiation Therapy
	o 9 month follow-up		not previ	iously reported? _[15] No
	1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation [2]		0 2	Yes (specify location and provide date) Unknown
	(mm-dd-yyyy)		7a.	Anatomic location of Radiation Therapy:
2.	Was the follow-up evaluation completed? [3]			[16]
	o 1 No (complete Q2a, sign and date form) o 2 Yes (skip to Q3)		7b.	Date of Radiation Therapy: [17]
				(mm-dd-yyyy)
	2a. Reason not completed: (check all that apply)	8.	Did the p	articipant have surgery not previously reported? [18]
	☐ =1 Not Marked, ☑ = 2 Marked ☐ Scheduling problem [4]		0 1 0 2	No Yes (specify location and provide date)
	☐ Patient refusal [5]		o 99 8a.	Unknown Anatomic location of surgery:
	 ☐ Medical reason (define reason in comments)_[6] ☐ Withdrew consent (submit the end of study form (DS))_[7] 			[19]
	Other, _[8] specify		8b.	Date of surgery: [20]
3.	Date of last contact between the treating physician and the participant [10]		D' Lu	(mm-dd-yyyy)
	(mm-dd-yyyy)	9.		earticipant have any non-protocol nerapy not previously reported _[21]
			0 1	No
4.	Participant's vital status at the time of this follow-up [11] o 1 Alive		o 2 o 99	Yes (specify and provide date) Unknown
	o 2 Dead (submit the end of study form (DS)) o 99 Unknown		9a.	Type of non-protocol chemotherapy:
5.	Response status at this assessment (see Instructions) [12]			[22]
	o 1 Complete response (CR) o 2 Partial response (PR)		9b.	Date of non-protocol chemotherapy: [23]
	o 3 Stable disease (SD) o 4 Progressive disease (PD)	40	District	(mm-dd-yyyy)
	o 99 Unknown	10.	not previ	participant receive any other non-protocol treatmen iously reported [24]
	5a. Date the response status was determined $_{\left[13\right]}$		o 1 o 2	No Yes (specify and provide date)
	(mm-dd-yyyy)			Unknown Type of treatment:
6.	Did the participant develop a first progression not			
	previously reported [14]			[25]
	o 2 Yes (submit the progression form (PF)) o 99 Unknown		10b.	Date of non-protocol treatment: [26]
	o oo onkhown			(mm-dd-yyyy)

ACRIN 6678 FDG - PET/CT Tumor Response 9 Month Follow-up (F/U) Form

Comments: _

ACRIN Study 6678 PLACE LABEL HERE

9 Month Follow-up (F/U) Form				
this is a revised or corrected form, please $\sqrt{\text{box}}$.	Institution	Institution No		
this is a revised of corrected form, please V box.	Participant Initials			
	9 MONTH FOLLOW-UP			

	[27]
[28]	[30]
Signature of Person responsible for the data	Date form completed (mm-dd-yyyy)

Signature of Person entering data onto the web

ACRIN 6678 FDG - PET/CT Tumor Response 1 Year Follow-up (F/U) Form

If this is a revised or corrected form, please $\sqrt{\text{box}}$.	
ii iiiis is a revised or corrected form, please v box.	

ACRIN Study 6678

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Institution	Institution No.
Participant Initials	Case No

1 YEAR FOLLOW-UP

INSTRUCTIONS: The Research Staff will complete this form following contact with the participant's treating physician. Please submit this form within 2 weeks of the one wear evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of following cycle two of chemotherapy. Question 1a, is considered the date of following cycle two of chemotherapy.

1. Timepoint for this follow-up [1]			7. Did the participant receive any Radiation Therapy					
	o 1 year follow-up			iously reported? _[15]				
			o 1	No [15]				
	1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation [2]			Yes (specify location and provide date) Unknown				
	(mm-dd-yyyy)		7a.	Anatomic location of Radiation Therapy:				
2.	Was the follow-up evaluation completed? [3]			[16]				
	o 1 No (complete Q2a, sign and date form)		7b.	Date of Radiation Therapy: [17]				
	o 2 Yes (skip to Q3)			(mm-dd-yyyy)				
	2a. Reason not completed: (check all that apply)							
	□=1 Not Marked, ☑=2 Marked	8.	Did the p	articipant have surgery not previously reported? [18]				
	☐ Scheduling problem [4]		0 2	Yes (specify location and provide date) Unknown				
	☐ Patient refusal [5]		8a.	Anatomic location of surgery:				
	 ☐ Medical reason (define reason in comments)_[6] ☐ Withdrew consent (submit the end of study form (DS))_[7] 							
	Other, [8] specify			[19]				
	[9]		8b.	Date of surgery: [20]				
3.	Date of last contact between the treating physician			(mm-dd-yyyy)				
	and the participant [10]	9.	Did the p	articipant have any non-protocol				
	(mm-dd-yyyy)			perapy not previously reported [21]				
4	Participantly vital status at the time of this follow up		0 1	No				
4.	Participant's vital status at the time of this follow-up [11] o 1 Alive		0 2	Yes (specify and provide date) Unknown				
	o 2 Dead (submit the end of study form (DS))		0 99	OTIKTIOWIT				
	o 99 Unknown		9a.	Type of non-protocol chemotherapy:				
5.	Response status at this assessment (see Instructions) [12]			[22]				
	o 1 Complete response (CR)		9b.	Date of non-protocol chemotherapy: [23]				
	o 2 Partial response (PR)			·				
	o 3 Stable disease (SD) o 4 Progressive disease (PD)			(mm-dd-yyyy)				
	o 99 Unknown	10		participant receive any other non-protocol treatmen				
				iously reported [24]				
	5a. Date the response status was determined $_{[13]}$		o 1 o 2	No Yes (specify and provide date)				
	(mm dd ynny)			Unknown				
	(mm-dd-yyyy)		10a.	Type of treatment:				
6.	Did the participant develop a first progression not			.) [-]				
	previously reported [14]			[25]				
	o 1 No		10b.	Date of non-protocol treatment: [26]				
	o 2 Yes (submit the progression form (PF)) o 99 Unknown							
	o 99 Unknown							

F4 07-17-07 "Copyright 2007" 6678 1 of 2

F4 ACRIN 6678 FDG - PET/CT Tumor Response 1 Year Follow-up (F/U) Form

ACRIN Study 6678
PLACE LABEL HERE

1 Year Follow-up (F/U) Form		LIDEE HERE
If this is a revised or corrected form, please $\sqrt{\text{box.}}$		Institution No
		FOLLOW-UP
Comments:		
		[27]
Signature of Person responsible for the data	⁻ [28]	_[30] Date form completed <i>(mm-dd-yyyy)</i>
Signature of Person entering data onto the web	⁻ [29]	

FDG-PET/CT Tumor Response **Patient Outcome - NSCLC Initial Evaluation Form**

	/	
If this is a revised or corrected form, plea	ise √box.	

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No

If this is a revised or corrected form, please √box.	Participant initials Case No
Instructions: Complete this form at the time of patient's entry on registration date. All forms must be signed and dated as indicate	study. Submit the I1 via the Acrin web site within one week of study ed.
STAGING 1. Date of initial diagnosis of NSCLC	5. Prior systemic chemotherapy? [7] (within 3 months prior to study enrollment) o No
(mm-dd-yyyy) _[1]	o Yes (if yes, provide date in Q5a) o Unknown
2. Clinical Stage (select only one) [2] o IIIB (not recurrent) o IV (not recurrent) o Recurrent o IIIA (not recurrent)	 5a. Date last systemic chemotherapy administered ————————————————————————————————————
PRIOR TREATMENT	o No
3. Prior Surgery to the study site? [3] (within 3 months prior to study enrollment) o No o Yes (if yes, provide date in Q3a) o Unknown	o Yes (If yes, provide dates in Q6a/Q6b and dose in Q6c) o Unknown 6a. Start date of Brain XRT
3a. Date of Surgery (<i>mm-dd-yyyyy</i>) [4]	6b. End date of Brain XRT
 4. Prior Thoracic radiotherapy? [5] (within 3 months prior to study enrollment) o No o Yes (if yes, provide date in Q4a) o Unknown 4a. Date XRT completed	6c. Total Dose (Gy) [17] DIAGNOSTIC WORK-UP 7. Blood glucose level [9] (performed within 4 weeks prior to registration)
COMMENTS:	
	[10]
Signature of person responsible for the data	Date form completed (mm-dd-yyyy)
Signature of person entering data onto the web	

ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group A

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	Institution	Institution No. ————
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No.
Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.		
1. Date of Central PET Interpretation (mm-dd-yyyy) 2. Reader ID		

3. Table 1: Record the date and the overall quality of each image

	Timepoint 1	Timepoint 2	Timepoint 3
Date of PET Imaging			
Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)	O No O Yes	O No O Yes	O No O Yes
Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below)	O Adequate O Suboptimal	O Adequate O Suboptimal	O Adequate O Suboptimal
Reason images cannot be interpreted or image quality suboptimal (check all that apply)	O Injection time unknown O Scan start time unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose > 150 mg/dL) O Uptake time < 45 mins O Uptake time > 80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV < 1.5 or > 4.0 O Uptake time > 70 mins and < 80 mins O Uptake time > 70 mins and < 80 mins O Uptake time for the baseline and follow-up scan varies by > 10 mins, but less than 15 mins O Other, specify	O Injection time unknown O Scan start time unknown O Injected dose unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >=45 mins and < 50 mins O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify	O Injection time unknown O Scan start time unknown O Injected dose unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time por the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >=45 mins and < 50 mins O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify

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ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group A

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

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Institution	Institution No.
Participant Initials	Case No

4. Table 2: Record the following for each image. For 'unknown' code 999.

		Timepoint 1					Timepoint 2					Timepoint 3						
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver																		
Target Lesion																		
Additional Lesion 1																		
Additional Lesion 2																		
Additional Lesion 3																		
Additional Lesion 4																		
Additional Lesion 5																		
Additional Lesion 6																		

Tumor Location

- 1 Right upper lobe
- 2 Right middle lobe
- 3 Right lower lobe 4 Left upper lobe/ lingula
- 5 Left lower lobe
- 6 Right Mediastinal lymph node 14
- 7 Right hilar lymph node
- 8 Left Mediastinal lymph node 16 Brain
- Left hilar lymph node Subcarinal lymph node
- 11 Supraclavicular / scalene nodes 88

17

18

Skin

Spleen

Other, specify

- Pleura 12
- 13 Liver
- Adrenals 15 Bone

Change in Uptake Scale (compared to baseline)

- 0 No Uptake
- 1 Marked decrease in uptake
- 2 Slight decrease in uptake
- 3 No change in uptake
- 4 Slight increase in uptake
- 5 Marked increase in uptake

ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group A

ACRIN Study 6678 PLACE LABEL HERE

If	this is a revised or corrected form, please $\sqrt{\text{box}}$.	Institution	Institution No
		Participant Initials	Case No
5.	Compared to baseline PET, has there been an increase in OR decrease in the total number of to increase O 2 stable O 3 decrease	tumor lesion(s)?	
	Compared to baseline PET, has there been an overall increase in OR decrease in the FDG upta O 1 increase O 2 stable O 3 decrease Compared to baseline PET, has there been an increase OR decrease in the size of tumor lesio O 1 increase O 2 stable O 3 decrease		
8.	Overall post treatment metabolic response: (metabolic response criteria defined below: indicated of the complete Metabolic Response (CMR): Complete resolution of all metabolically active tumor lesions: O 2 Partial metabolic Response (PMR): One or both of the following must occur: (indicate response): Target lesions: 20% or greater decrease in maximum SUV from baseline. No unequivocal metabolic lesions: decrease in total number of non-target lesions, without complete resolution of metabolically Stable: Does not qualify for CMR, PMR or Metabolic Progression. O 3 Metabolically Stable: Does not qualify for CMR, PMR or Metabolic Progression. O 4 Metabolic Progression: One or more of the following must occur: (indicate response): Unequivocal development of one or more new metabolically active lesion(s). Target lesions: 20% or greater increase in maximum SUV from baseline. Other tumor lesions: unequivocal increase in FDG activity within other tumor lesions on PET. Unequivocal increase in size of index or other tumor lesions on PET.	tabolic progression of other tumor lesions ar	ons. Ind no unequivocal new lesions.
C (DMMENTS:		
lni	itials of person entering data		Date form completed (mm-dd-yyyy

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ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

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	Institution	Institution No. ————
If this is a revised or corrected form, please √box. □	Participant Initials	Case No.
Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.		
1. Date of Central PET Interpretation (mm-dd-yyyy) 2. Reader ID		

3. Table 1: Record the date and the overall quality of each image

	Timepoint 1	Timepoint 2	Timepoint 3								
Date of PET Imaging											
Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)	O No O Yes	O No O Yes	O No O Yes								
Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below)	O Adequate O Suboptimal	O Adequate O Suboptimal	O Adequate O Suboptimal								
Reason images cannot be interpreted or image quality suboptimal (check all that apply)	O Injection time unknown O Scan start time unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify	O Injection time unknown O Scan start time unknown O Injected dose unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >=45 mins and < 50 mins O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify	O Injection time unknown O Scan start time unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify								

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ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

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Institution	Institution No. ————
Participant Initials	Case No.

4. Table 2: Record the following for each image. For Group B, visit B1 and B2 scans must be read before visit B3 scan is read. For unknown code 999.

		Timepoint 1						Timepoint 2					Timepoint 3					
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver																		
Target Lesion																		
Additional Lesion 1																		
Additional Lesion 2																		
Additional Lesion 3																		
Additional Lesion 4																		
Additional Lesion 5								_										
Additional Lesion 6																		

Tumor Location

- 1 Right upper lobe
- 2 Right middle lobe
- 3 Right lower lobe
- 4 Left upper lobe/lingula
- 5 Left lower lobe
- 6 Right Mediastinal lymph node 14
- 7 Right hilar lymph node
- 8 Left Mediastinal lymph node 16 Brain
- Pleura 12

11

13 Liver Adrenals

Left hilar lymph node

Subcarinal lymph node

Supraclavicular / scalene nodes 88

17

18

Skin

Spleen

Other, specify

- 15 Bone

Change in Uptake Scale (compared to baseline)

- 0 No Uptake
- 1 Marked decrease in uptake
- 2 Slight decrease in uptake
- 3 No change in uptake
- 4 Slight increase in uptake
- 5 Marked increase in uptake

ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

ACRIN Study 6678 PLACE LABEL HERE

If th	is is	s a revise	ed or corrected form, please $\sqrt{\text{box.}}$	Institution	Institution No
				Participant Initials	Case No
Time	poi	int 2: Co	mplete questions 5-8		
5. C	0	pared to increase 2 stable 3 decrea		sion(s)?	
6. C	0	pared to 1 increas 2 stable 3 decreas		n the tumor lesion(s)?	
7. C	0	pared to 1 increas 2 stable 3 decreas			
8. C	ver	all post	treatment metabolic response: (metabolic response criteria defined below: indicate the ov	rerall metabolic response as pr	compted comparing to baseline)
			lete Metabolic Response (CMR): Complete resolution of all metabolically active tumor lesions, and no I metabolic Response (PMR): One or both of the following must occur: (indicate response)	interval development of new lesion	ons.
			Target lesions: 20% or greater decrease in maximum SUV from baseline. No unequivocal metabolic pro	ogression of other tumor lesions ar	nd no unequivocal new lesions.
			Other lesions: decrease in total number of non-target lesions, without complete resolution of metabolica > 50% of the lesions. No unequivocal new lesions.	ally active disease, or unequivocal	decrease in degree of FDG activity within
	0	3 Metab	olically Stable: Does not qualify for CMR, PMR or Metabolic Progression.		
	0	4 Metab	polic Progression: One or more of the following must occur: (indicate response)		
			Unequivocal development of one or more new metabolically active lesion(s).		
			Target lesions: 20% or greater increase in maximum SUV from baseline.		
			Other tumor lesions: unequivocal increase in FDG activity within other tumor lesions on PET.		
			Unequivocal increase in size of index or other tumor lesions on PET.		

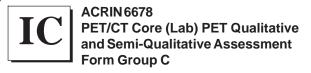
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ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

ACRIN Study 6678 PLACE LABEL HERE

If this	is a revised or corrected form, please $\sqrt{\text{box}}$.	Institution	Institution No
	·· —	Participant Initials	Case No
<u>Timer</u>	point 3: Complete questions 9-12		
9. C	ompared to baseline PET, has there been an increase in OR decrease in the total number of tumor le	sion(s)?	
(O increase O 2 stable O 3 decrease		
10. C	ompared to baseline PET, has there been an overall increase in OR decrease in the FDG uptake within	n the tumor lesion(s)?	
	O 1 increase O 2 stable O 3 decrease		
11. C	ompared to baseline PET, has there been an increase OR decrease in the size of tumor lesion(s)?		
(O 1 increase O 2 stable O 3 decrease		
12.	Overall post treatment metabolic response: (metabolic response criteria defined below: indicate the o	verall metabolic response as	prompted comparing to baseline)
	1 Complete Metabolic Response (CMR): Complete resolution of all metabolically active tumor lesions, and no i 2 Partial metabolic Response (PMR): One or both of the following must occur: (indicate response)	nterval development of new lesion	ons.
	☐ Target lesions: 20% or greater decrease in maximum SUV from baseline. No unequivocal metabolic prog		•
	Other lesions: decrease in total number of non-target lesions, without complete resolution of metabolicall > 50% of the lesions. No unequivocal new lesions.	y active disease, or unequivocal	decrease in degree of FDG activity within
	3 Metabolically Stable: Does not qualify for CMR, PMR or Metabolic Progression.		
	4 Metabolic Progression: One or more of the following must occur: (indicate response)		
	☐ Unequivocal development of one or more new metabolically active lesion(s).		
	☐ Target lesions: 20% or greater increase in maximum SUV from baseline.		
	Other tumor lesions: unequivocal increase in FDG activity within other tumor lesions on PET.		
	☐ Unequivocal increase in size of index or other tumor lesions on PET.		
COMI	MENTS:		
Initial	s of person entering data		Date form completed (mm-dd-yyyy

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	Institution	Institution No	
If this is a revised or corrected form, please √box.	Participant Initials	Case No	
Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protoc	ol.		
1. Date of Central PET Interpretation (mm-dd-yyyy) 2. Reader	ID		

3. Table 1: Record the date and the overall quality of each image

	Timepoint 1	Timepoint 2	Timepoint 3
Date of PET Imaging			
Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)	O No O Yes	O No O Yes	O No O Yes
Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below	O Adequate O Suboptimal	O Adequate O Suboptimal	O Adequate O Suboptimal
Reason images cannot be interpreted or image quality suboptimal (check all that apply)	O Injection time unknown O Scan start time unknown O Injected dose unknown O Patient body weight unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >=45 mins and < 50 mins O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify	O Injection time unknown O Scan start time unknown O Injected dose unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose > 150 mg/dL) O Uptake time < 45 mins O Uptake time > 80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV < 1.5 or > 4.0 O Uptake time > 245 mins and < 50 mins O Uptake time > 70 mins and < 80 mins O Uptake time for the baseline and follow-up scan varies by > 10 mins, but less than 15 mins O Other, specify	O Injection time unknown O Scan start time unknown O Injected dose unknown O Injected dose unknown O Patient body weight unknown O Scanner not or incorrectly calibrated O Related to patient preparation (blood glucose >150 mg/dL) O Uptake time < 45 mins O Uptake time >80 mins O Uptake time for the baseline and a follow-up scan varies by > 15 minutes O Beam hardening artifacts on CT O Patient movement O Misregistration of PET and CT involving the target lesion O Difference in liver SUV from baseline to follow-up scans > 1.0 O Liver SUV <1.5 or > 4.0 O Uptake time >=45 mins and < 50 mins O Uptake time >70 mins and <= 80 mins O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins O Other, specify

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ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group C

If this is a revised or corrected form, please √box.

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Institution	Institution No. ————
Participant Initials	Case No

4. Table 2: Record the following for each image. For 'unknown' code 999.

		Timepoint 1				Timepoint 2						
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver												
Target Lesion												
Additional Lesion 1												
Additional Lesion 2												
Additional Lesion 3												
Additional Lesion 4												
Additional Lesion 5												
Additional Lesion 6												

Tumor Location

- 1 Right upper lobe 12 Pleura
 2 Right middle lobe 13 Liver
 3 Right lower lobe 14 Adrenals
 4 Left upper lobe/ lingula 15 Bone
 5 Left lower lobe 16 Brain
 6 Right Mediastinal lymph node 17 Skin
 7 Right hilar lymph node 18 Spleen
 8 Left Mediastinal lymph node 88 Other, specify
- Change in Uptake Scale (compared to baseline)

10 Subcarinal lymph node11 Supraclavicular / scalene nodes

- 0 No Uptake
- 1 Marked decrease in uptake
- 2 Slight decrease in uptake
- 3 No change in uptake
- 4 Slight increase in uptake
- 5 Marked increase in uptake

COMMENTS:	
Initials of person entering data	Date form completed (mm-dd-yyyy)

ID

ACRIN 6678 PET/CT Imaging Post-treatment Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form

ACRIN Study	y 6678
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It this is a revised or corrected form, please \$\sqrt{box}\$. Participant Initials		Semi-Qualitative Assessment Form	Institution	Institution No	
1. Protocol Time point of PET/CT Imaging (check only one): O Post-treatment after Cycle 1 (Group A and Group B) O Post-treatment after Cycle 2 (Group B only) 2. Was the quality of the PET/CT images adequate for interpretation? O No (complete Q2a and 3, then sign and date form) O Yes 2a. Reason image not interpreted: O Entire study not complete O Noisy images O Patient motion O SUV's cannot be calculated; specify reason: O Other, specify 3. Date of PET exam	If t	this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No	
O Post-treatment after Cycle 1 (Group A and Group B) O Post-treatment after Cycle 2 (Group B only) 2. Was the quality of the PET/CT images adequate for interpretation? O No (complete Q2a and 3, then sign and date form) O Yes 2a. Reason image not interpreted: O Entire study not complete O Noisy Images O Patient motion O SUV's cannot be calculated; specify reason: O Other, specify 3. Date of PET exam	In	structions:			
O No (complete Q2a and 3, then sign and date form) O Yes 2a. Reason image not interpreted: O Entire study not complete O Noisy Images O Patient motion O SUV's cannot be calculated; specify reason: O Other, specify 3. Date of PET exam	1.	O Post-treatment after Cycle 1 (Group A and Group B)			
O Entire study not complete O Noisy Images O Patient motion O SUV's cannot be calculated; specify reason: O Other, specify 3. Date of PET exam	2.	O No (complete Q2a and 3, then sign and date form)	tation?		
3. Date of PET exam		O Entire study not complete O Noisy Images O Patient motion			
4. Date of PET interpretation	•				
 6. Is the pre-treatment PET scan available for post-treatment PET/CT interpretation? O No O Yes 7. Is the pre-treatment CT scan available for post-treatment PET/CT interpretation? O No O Yes 8. How was the post-treatment PET scan interpreted with the post-treatment CT scan? O Software fusion 			dd/yyyy)		
O No O Yes 7. Is the pre-treatment CT scan available for post-treatment PET/CT interpretation? O No O Yes 8. How was the post-treatment PET scan interpreted with the post-treatment CT scan? O Software fusion	5.	Reader ID			
O No O Yes 8. How was the post-treatment PET scan interpreted with the post-treatment CT scan? O Software fusion	6.	O No	PET/CT interpretation?		
O Software fusion	7.	O No	ET/CT interpretation?		
	8.	O Software fusion	post-treatment CT scan?		

1 of 5



ACRIN 6678 PET/CT Imaging Post-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment Form

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No

9.

	Compared to Baseline Only			Post Treatment		
Target Lesion Tumor Number (number should correspond to pre-treatment tumor)	Uptake Scale	Change in Uptake Scale	Local Regional Assessment	Metastatic Disease	Progression based on proximity of the site(s) to local regional assessment	SUV (max)
T1						
T2						
Т3						
T4						
Т5						
Т6						
Т7						
Т8						
Т9						
T10						

Uptake Scale

- 0 Not imaged; cannot evaluate
- 1 Definitely not tumor
- 2 Probably not tumor
- 3 Indeterminate
- 4 Probably tumor
- Definitely tumor

Metastastic Disease

- 0 Not Applicable
- Definitely no metastatic disease
- Probably no metastatic disease
- 3 Indeterminate
- 4 Probably Metastatic disease
- 5 Definitely metastatic disease

Change in Uptake Scale (compared to baseline)

- 0 No Uptake
- 1 Marked decrease in uptake
- 2 Slight decrease in uptake
- 3 No change in uptake
- 4 Slight increase in uptake
- 5 Marked increase in uptake

Proximity

- 1 Not applicable
- 2 In-field
- 3 Marginal
- 4 Remote

Local Regional Response (compared to baseline)

- 0 (CR) Complete Response
- 1 (PR) Partial Response
- 2 (ND) No Response
- 3 (PD) Progressive Disease

2 of 5



ACRIN 6678 PET/CT Imaging Post-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment Form

ACRIN Study 6678

	Institution	Institution No. ———
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No.

10.

Compared to Baseline Only					Post Treatment	
Non- Target Lesion Tumor Number (number should correspond to pre-treatment tumor)	Uptake Scale	Change in Uptake Scale	Local Regional Assessment	Metastatic Disease	Progression based on proximity of the site(s) to local regional assessment	SUV (max)
S1						
S2						
S3						
S4						
S5						

Uptake Scale

- 0 Not imaged; cannot evaluate
- 1 Definitely not tumor
- 2 Probably not tumor
- 3 Indeterminate
- 4 Probably tumor
- 5 Definitely tumor

Metastastic Disease

- 0 Not Applicable
- Definitely no metastatic disease
- 2 Probably no metastatic disease
- 3 Indeterminate
- 4 Probably Metastatic disease
- 5 Definitely metastatic disease

Change in Uptake Scale (compared to baseline)

- 0 No Uptake
- 1 Marked decrease in uptake
- 2 Slight decrease in uptake
- 3 No change in uptake
- 4 Slight increase in uptake
- 5 Marked increase in uptake

Proximity

- 1 Not applicable
- 2 In-field
- 3 Marginal
- 4 Remote

Local Regional Response (compared to baseline)

- 0 (CR) Complete Response
- 1 (PR) Partial Response
- 2 (ND) No Response
- 3 (PD) Progressive Disease



ACRIN 6678 PET/CT Imaging Post-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment Form

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No. ————
Participant Initials	Case No

11. Indicate any Lymphadenopathy

Anatomic Site	Confidence in presence of disease
Supraclavicular	
Ipsilateral hilar	
Contralateral hilar	
Ipsilateral upper medialstinal	
Contralateral upper medialstinal	
Ipsilateral lower medialstinal	
Contralateral lower medialstinal	
Other, Specify	

12. Indicate any distant Metastasis with PET findings

Anatomic Site	Confidence in presence of disease
Supraclavicular	
Ipsilateral hilar	
Contralateral hilar	
Ipsilateral upper medialstinal	
Contralateral upper medialstinal	
Ipsilateral lower medialstinal	
Contralateral lower medialstinal	
Other, Specify	

Confidence Scale

- 1 Definetly no metastasis
- 2 Probably no metastasis
- 3 Possibly no metastasis
- 4 Probably metastasis
- 5 Definetly metastasis

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ACRIN 6678 PET/CT Imaging Post-treatment Core (Lab) PET Qualalative and

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Semi-Qualitative Assessment Form f this is a revised or corrected form, please √box.	Institution	Institution No. ————
	Participant Initials	Case No
PFT Assessment		

- What is your overall confidence in the Prense or Absence of Stage IV disease as seen with PET?
 - O Definitely not present
 - O Probably not Present
 - O Indeterminate
 - O Probably present
 - O Definitely Present

ate form completed

Version 0.2 6678 ID 04-10-09 5 of 5 "Copyright 2009"

ACRIN 6678 PET/CT Imaging Pre-treatment Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form

ACRIN Study 6678 PLACE LABEL HERE

	Semi-Qualitative Assessment Form	Institution	Institution No
lf	this is a revised or corrected form, please \sqrt{box} .	Participant Initials	Case No
to al	estructions: Please record the requested information for all target a maximum of 5 lesions per organ and 10 lesions in total to foll non-measurable disease as non-target disease. The same tested for all required subsequent disease assessments.	ollow as target lesions record	I any remaining measurable lesions and
1.	Protocol Time point of PET/CT Imaging (check only one): O Pre-treatment (Within 2 weeks after registration visit: Gro O Pre-treatment (Within 1 weeks prior to 1st Chemotherap)		o B)
2.	Was the quality of the PET/CT images adequate for interpre O No (complete Q2a and 3, then sign and date form) O Yes	tation?	
	 2a. Reason image not interpreted: O Entire study not complete O Noisy Images O Patient motion O SUV's cannot be calculated; specify reason: 		
	O Other, specify		
3.	Date of PET exam (mm/dd/yyyy)		
4.	Date of PET interpretation (mm/s	(dd/yyyy)	
5.	Reader ID		

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ACRIN 6678 PET/CT Imaging Pre-treatment Core (Lab) PET Qualalative and **Semi-Qualitative Assessment Form**

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Institution	Institution No. ————		
Participant Initials	Case No		

6.

Target Lesion	Tumor Location	Tumor Size in Diameter (cm)	Uptake Scale	SUV (max)	Primary Tumor
T1					O No O Yes
T2					O No O Yes
Т3					O No O Yes
Т4					O No O Yes
Т5					O No O Yes
Т6					O No O Yes
Т7					O No O Yes
Т8					O No O Yes
Т9					O No O Yes
T10					O No O Yes

Tumor Location

- Right upper lobe
- 2 Right middle lobe
- Right lower lobe
- Left upper lobe 4
- 5 Left middle lobe
- Right Mediastinal lymph node Right hilar lymph node
- 8 Left Mediastinal lymph node
- Left hilar lymph node
- 10 Subcarinal lymph node

Uptake Scale

- 0 Not imaged; cannot evaluate
- 1 Definitely not tumor
- 2 Probably not tumor
- 3 Indeterminate
- Probably tumor
- 5 Definitely tumor



ACRIN 6678 PET/CT Imaging Pre-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment Form

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	Institution	Institution No. ————
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials	Case No.

7.

Non- Target Lesion	Tumor Location	Tumor Size in Diameter (cm)	Uptake Scale	SUV (max)	Primary Tumor
S1					O No O Yes
S2					O No O Yes
S 3					O No O Yes
S4					O No O Yes
S5					O No O Yes

Tumor Location

- 1 Right upper lobe
- 2 Right middle lobe
- 3 Right lower lobe
- 4 Left upper lobe
- 5 Left middle lobe
- 6 Right Mediastinal lymph node
- 7 Right hilar lymph node
- 8 Left Mediastinal lymph node
- 9 Left hilar lymph node
- 10 Subcarinal lymph node

Uptake Scale

- 0 Not imaged; cannot evaluate
- 1 Definitely not tumor
- 2 Probably not tumor
- 3 Indeterminate
- 4 Probably tumor
- 5 Definitely tumor

ACRIN 6678

PET/CT Imaging Pre-treatment Core (Lab) PET Qualalative and

ACRIN Study 6678 PLACE LABEL HERE

Semi-Qualitative Assessment Form	Institution	Institution No
If this is a revised or corrected form, please $\sqrt{\text{box.}}$		Case No
Comments:		
Signature of Nucelar medicine MD		Date form completed
Signature of person entering data onto the web		

Version 0.2 6678 "Copyright 2009" IM 04-10-09 4 of 4

ACRIN 6678 PET/CT Core (Lab) PET Qualitation and Semi-Qualitative Assessment Form Merck	tive ent
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If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Merck ID:	- [200]			
Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.					
1. Date of Central PET Interpretation(mm-dd-yyyy) [1]	2. Reader ID [2]				

3. Table 1: Record the date and the overall quality of each image

	Timepoint 1	Timepoint 2	Timepoint 3
Date of PET Imaging	[3]	[4]	[5]
Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)	O No [6] O Yes	O No O Yes	O No O Yes
Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below	O Adequate O Suboptimal	O Adequate [10] O Suboptimal	O Adequate O Suboptimal
Reason images cannot be interpreted or image quality suboptimal (check all that apply)	□ Injection time unknown [12] □ Scan start time unknown [13] □ Injected dose unknown [14] □ Patient body weight unknown [15] □ Scanner not or incorrectly calibrated [16] □ Related to patient preparation [17] □ Uptake time < 45 mins [18] □ Uptake time >80 mins [19] □ Uptake time for the baseline and a follow-up scan varies by > 15 minutes [20] □ Beam hardening artifacts on CT [21] □ Patient movement [22] □ Misregistration of PET and CT involving the target lesion [23] □ Difference in liver SUV from baseline to follow-up scans > 1.0 [24] □ Liver SUV <1.5 or > 4.0 [25] □ Uptake time >=45 mins and < 50 mins [26] □ Uptake time >70 mins and <= 80 mins [27] □ Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins [28]	□ Injection time unknown [31] □ Scan start time unknown [32] □ Injected dose unknown [33] □ Patient body weight unknown [34] □ Scanner not or incorrectly calibrated [35] □ Related to patient preparation [36] □ Uptake time < 45 mins [37] □ Uptake time < 80 mins [38] □ Uptake time for the baseline and a follow-up scan varies by > 15 minutes [39] □ Beam hardening artifacts on CT [40] □ Patient movement [41] □ Misregistration of PET and CT involving the target lesion [42] □ Difference in liver SUV from baseline to follow-up scans > 1.0 [43] □ Liver SUV < 1.5 or > 4.0 [44] □ Uptake time >=45 mins and <= 80 mins [46] □ Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins [47]	□ Injection time unknown [50] □ Scan start time unknown [51] □ Injected dose unknown [52] □ Patient body weight unknown [53] □ Scanner not or incorrectly calibrated [54] □ Related to patient preparation [55] □ Uptake time < 45 mins [56] □ Uptake time >80 mins [57] □ Uptake time for the baseline and a follow-up scan varies by > 15 minutes [58] □ Beam hardening artifacts on CT [59] □ Patient movement [60] □ Misregistration of PET and CT involving the target lesion [61] □ Difference in liver SUV from baseline to follow-up scans > 1.0 [62] □ Liver SUV <1.5 or > 4.0 [63] □ Uptake time >=45 mins and < 50 mins [64] □ Uptake time >70 mins and <= 80 mins [65] □ Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins [66]

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MC	ACRIN 6678 PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment
	Form Merck

		/
If this is a revised	or corrected form, plea	ase √box.

4. Table 2: Record the following for each image. For 'unknown' code 999.

		Timepoint 1					Timepoint 2					
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver						[69]						[70]
Target Lesion	[72]	[73]	[74]	[75]	[76]		[77]	[78]	[79]	[80]	[81]	
Additional Lesion 1	[87]	[88]	[89]	[90]	[91]		[92]	[93]	[94]	[95]	[96]	
Additional Lesion 2	[102]	[103]	[104]	[105]	[106]		[107]	[108]	[109]	[110]	[111]	
Additional Lesion 3	[117]	[118]	[119]	[120]	[121]		[122]	[123]	[124]	[125]	[126]	
Additional Lesion 4	[132]	[133]	[134]	[135]	[136]		[137]	[138]	[139]	[140]	[141]	
Additional Lesion 5	[147]	[148]	[149]	[150]	[151]		[152]	[153]	[154]	[155]	[156]	
Additional Lesion 6	[162]	[163]	[164]	[165]	[166]		[167]	[168]	[169]	[170]	[171]	

Tumor Location

- 1 Right upper lobe2 Right middle lobe 12 Pleura 13 Liver 3 Right lower lobe 14 Adrenals 4 Left upper lobe/ lingula 15 Bone 5 Left lower lobe 16 Brain 6 Right Mediastinal lymph node 17 Skin 7 Right hilar lymph node 18 Spleen 8 Left Mediastinal lymph node 88 Other, specify 9 Left hilar lymph node 10 Subcarinal lymph node

Change in Uptake Scale (compared to baseline)

- 0 No Uptake
- 1 Marked decrease in uptake

11 Supraclavicular / scalene nodes

- 2 Slight decrease in uptake
- 3 No change in uptake
- 4 Slight increase in uptake
- 5 Marked increase in uptake

COMMENTS:		

Date form completed (mm-dd-yyyy)

[183]

ACRIN 6678 FDG - PET/CT Tumor Response Off Study Criteria

ACRIN Study 6678 PLACE LABEL HERE

		Institution	Institution No	
lf t	his is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials_	Case No	
eli	structions: Participants who meet any of the following criteria, p gible participants. Participants going off study will not undergo ar aging, nor will the study follow-up visits continue. An End of Study	ny additional FDG/PET	scans or CT scans for tumor volumetric	
l.	Was the participant removed from the study for any of the fol O No (Sign and date form) O Yes (Complete Q1a; complete an End of Study Form (DS)		ecified in section 8.5 of the protocol? [1]	
	1a. Select from the following off study criteria (check all tha	at apply) □=1 Not Mark	.ed,	
	$\hfill\Box$ The baseline SUV of the tumor (measured at the first F	PET/CT study) is less the	nan 4.0. _[2]	
	☐ There are significant protocol variations or image artifa (Appendix VI), which result in an unrepeatable and inaction			
	☐ Participant receives less than 2 cycles of first-line chem	notherapy due to drug t	oxicity. [4]	
	☐ Participant undergoes the baseline pre-chemotherapy	FDG-PET/CT scan(s) a	after the initiation of chemotherapy. [5]	
	☐ Participant undergoes the post-chemotherapy cycle 1 F	FDG-PET/CT scan after	r initiation of chemotherapy cycle 2. [6]	
	☐ Participant refuses the FDG-PET/CT scan(s) at the stu	udy imaging visits and/o	or refuses study follow-up visits. [7]	
Si	gnature of person responsible for the data	Date form	completed (mm-dd-yyyy)	
Si	gnature of person entering data onto the web			

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P1

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A1 - Pre-Chemotherapy (Within 14 days of Registration)

ACRIN Study 6678

PLACE LABEL HERE

Institution No. —

Institution _____

	(Within 14 days of Registration)	Participant Initials	Case No	
lf	this is a revised or corrected form, please $\sqrt{\text{box.}}$			
NS	STRUCTIONS: This form is to be completed by the Radiologist for the FDG	-PET/CT performed at this timep	oint.	
ı.	Time point of PET/CT [1]	\	/ISIT: A1	
	o Pre-chemotherapy (Group A within 14 days after registration	on)		
2.	Was the FDG PET/CT interpretation completed? [2]			
	o No (Complete Q2a, then sign and date form) o Yes (Skip to Q3)			
	2a. Reason images cannot be interpreted: (check all that app	oly) \Box =1 Not Marked, $⊠$ = 2	: Marked	
	Related to SUV calculation injection time unknown [3] scan start time unknown [4] injected dose unknown [5] patient body weight unknown [6] scanner not or incorrectly calibrated [7] Related to patient preparation (Blood glucose level Related to the uptake time (time between injection and Uptake time < 45 minutes [9] Uptake time > 80 minutes [10] Uptake time for the baseline and a follow-up scan Related to beam hardening artifacts on CT [12] (Beam hardening artifacts are overlying all possible Patient movement [13] Misregistration of PET and CT involving the whole match target lesion as defined on PET) and no other	start of scan) varies by > 15 minutes [11] e target lesions in the ches target lesion (i.e. target lesi	on as defined on CT does not	
3.	Date of FDG PET/CT exam (mm-dd-y	<i>(УУУ)</i> _[15]		
١.	Date of FDG PET/CT interpretation	(mm-dd-yyyy) _[16]		
5.	Reader ID [17]			

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ACRIN 6678 FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A1 - Pre-Chemotherapy (Within 14 days of Registration)

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678

Institution	Institution No.
Participant Initials	Case No.

	VISIT: A1
6.	Is the overall quality of the FDG PET/CT acceptable [18]
	o Adequate (skip to Q7) o Suboptimal (provide reason in Q6a, then sign and date form)
	6a. Reason suboptiomal (check all that apply) □=1 Not Marked, v = 2 Marked
	☐ Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
	Related to the whole body distribution of FDG
	☐ Difference in liver SUV from the baseline to the follow-up scan > 1.0 [20]
	☐ Liver SUV < 1.5 or > 4.0 [21] Related to uptake time (time between injection and start of scan)
	☐ Uptake time >=45 minutes and < 50 minutes [22]
	☐ Uptake time > 70 and <= 80 minutes [23]
	Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes [24]
	Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [25]
	☐ Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
7.	Record MAX SUV measurement of target lesion (refer to Appendix VI section 6 for details; if max SUV is less than 4.0, complete the (O1) Off Study Form) ———————————————————————————————————
8.	Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
	·[28]
9.	Location of Target Lesion in the Chest (choose only one) [29]
	o Right upper lobe
	o Right middle lobe
	o Right lower lobe
	o Left upper lobe / lingula
	o Left lower lobe
	o Right mediastinal lymph node
	o Right hilar lymph node
	o Left mediastinal lymph node
	o Left hilar lymph node
	o Subcarinal lymph node
	o Supraclavicular/scalene nodes

P1

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A1 - Pre-Chemotherapy (Within 14 days of Registration)

ACRIN Study 6678

(Within 14 days of Registration)			
If this	is a revised or corrected form, please $\sqrt{\text{box}}$.	Institution	Institution No
		Participant Initials	Case No
		V	/ISIT: A1
10.	Are there any metastatic lesions to report? [30]		
	o No		
	o Yes (complete Q10a)		
	10a. Indicate anatomic location (check all that apply,) □=1 Not Marked, ☑= 2 Marked	
	Hilar nodes [31]	,	
	☐ Medialstinal nodes [32]		
	☐ Supraclavicular/scalene nodes [33]		
	☐ Ipsilateral lung [34]		
	Contralateral lung [35]		
	Pleura [36]		
	Liver [37]		
	Adrenals [38]		
	☐ Bone _[39]		
	☐ Bone marrow [40]		
	☐ Brain _[41]		
	☐ Skin [42]		
COMM	MENTS:		
			[44]
Dadial	[45]		Date form completed (mm-dd-yyyy)
radio	logist responsible for data		Date Ioffit completed (mm-dd-yyyy)
Dozas	n entering data ento the web		
rerso	n entering data onto the web		

PF ACRIN 6678 FDG - PET/CT Tumor Response Progression Form

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

INSTRUCTIONS: Submit this form when signs of progression occur. Please specify the site of progression by placing an X in the box next to the anatomical part. Report all signs of progression. For each site, record the method of evaluation and date of evaluation in the subsequent columns. Dates are recorded as mm-dd-yyyy. If more than one method of evaluation is used, provide the most definitive method of evaluation used to determine progression. Repeat for all sites of progression.

EVALUATION (most definitive) y 5 Ultrasound 6 Bone Scan 7 Physical Exam 88 Other (specify in commer (check all that apply) GRESSION □=1 Not Marked, ☑= 2 Marked oper lobe [1] iddle lobe [4] wer lobe [7] oer lobe / lingula [10] rer lobe [13] dediastinal lymph node [16]	METHOD OF EVALUATION [2] [5] [8] [11] [14]	DATE OF E	VALUATION (mm	n-dd-yyyy)
pper lobe [1] iddle lobe [4] wer lobe [7] per lobe [13] rediastinal lymph node [16]	[2] [5] [8] [11] [14]	DATE OF E	VALUATION (mm.	[3]
wer lobe [4] wer lobe [7] per lobe / lingula [10] ver lobe [13] mediastinal lymph node [16]	[5] [8] [11] [14]			[6]
wer lobe [4] wer lobe [7] per lobe / lingula [10] ver lobe [13] mediastinal lymph node [16]	[5] [8] [11] [14]			[6]
wer lobe [7] per lobe / lingula [10] per lobe [13] pediastinal lymph node [16]	[11]			
per lobe / lingula [10] ver lobe [13] nediastinal lymph node [16]	[11]			
ver lobe [13] nediastinal lymph node [16]		_ _		[12
ediastinal lymph node [16]	[[[[[[[[[[[[[[[[[[[[[15
	L [17]			[18
ilar lymph node [19]	[20]			[21
diastinal lymph node [22]	[23]			[24
ar lymph node [25]	[26]			[27
nal lymph node [28]	[29]			[30
avicular/scalene nodes [31]	[32]			[33
[34]	[35]			[36
57]	[38]			[39
is [40]	[41]			[42
3]	[44]			[45
arrow[46]	[47]			[48
9]	[50]			[51
2]	[53]			[54
[55] specify [56]	[57]			[58
i 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ar lymph node [25] inal lymph node [28] lavicular/scalene nodes [31] [34] [37] Is [40] larrow[46] [49] [2] [55] specify [56]	[29] [29] [32] [34] [35] [35] [38] [44] [44] [47] [47] [50] [53]		[29] - -

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A1 - Pre-Chemotherapy and Visit C1 Pre-Treatment

ACRIN Study 6678

	Visit A1 - Pre-Chemotherapy and Visit C1 Pre-Treatment	Institution	Institution No
	and visit of Fie-Heatilielit	Participant Initials	Case No
lf	this is a revised or corrected form, please \sqrt{box} .		
NS	STRUCTIONS: This form is to be completed by the Radiologist for the FDG	G-PET/CT performed at this timepo	pint.
	Time point of PET/CT [1]	VIS	SIT: A1/C1
	o Visit A1/C1 (Groups A & C within 14 days of registration)		
2.	Was the FDG PET/CT interpretation completed? [2]		
	o No (Complete Q2a, then sign and date form) o Yes (Skip to Q3)		
	2a. Reason images cannot be interpreted: (check all that ap	<i>ply</i>) □=1 Not Marked, $\stackrel{\checkmark}{\square}$ = 2	Marked
	Related to SUV calculation		
	injection time unknown [3] scan start time unknown [4] injected dose unknown [5] patient body weight unknown [6] scanner not or incorrectly calibrated [7] Related to patient preparation (Blood glucose level) Related to the uptake time (time between injection and [9] Uptake time < 45 minutes [9] Uptake time > 80 minutes [10] Uptake time for the baseline and a follow-up scan Related to beam hardening artifacts on CT [12] (Beam hardening artifacts are overlying all possib Patient movement [13] Misregistration of PET and CT involving the whole	varies by > 15 minutes [11]	
	match target lesion as defined on PET) and no other		
	Other	- [14	I
	☐ Other, _[48] specify	[49]	
-	Date of FDG PET/CT exam(mm-dd-	уууу) _[15]	
١.	Date of FDG PET/CT interpretation	(mm-dd-yyyy) _[16]	
j.	Reader ID [17]		

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A1 - Pre-Chemotherapy and Visit C1 Pre-Treatment

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No.

	VISIT: A1/C1
6.	Is the overall quality of the FDG PET/CT acceptable [18]
	o Adequate (skip to Q7)
	o Suboptimal (provide reason in Q6a, then sign and date form)
	6a. Reason suboptiomal (check all that apply) $\square = 1$ Not Marked, $\stackrel{\checkmark}{\square} = 2$ Marked
	Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
	Related to the whole body distribution of FDG
	☐ Difference in liver SUV from the baseline to the follow-up scan > 1.0 [20]
	☐ Liver SUV < 1.5 or > 4.0 [21]
	Related to uptake time (time between injection and start of scan)
	 □ Uptake time >=45 minutes and < 50 minutes [22] □ Uptake time > 70 and <= 80 minutes [23]
	☐ Uptake time 5 76 and 12 66 minutes [23] ☐ Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes [24]
	☐ Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [25]
	Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
	Other
	☐ Other, _[50] specify
8.	Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
	·[28]
9.	Location of Target Lesion in the Chest (choose only one) [29]
	o Right upper lobe
	o Right middle lobe
	o Right lower lobe
	o Left upper lobe / lingula
	o Left lower lobe
	o Right mediastinal lymph node
	o Right hilar lymph node
	o Right fillar lymph houe
	o Left mediastinal lymph node
	o Left mediastinal lymph node

ACRIN 6678 FDG-PET/CT Tumor Response PET/CT Local Interpretation Form Visit A1 - Pre-Chemotherapy

and Visit C1 Pre-Treatment

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No. ————
Participant Initials	Case No

f this is a revised or corrected form, please ✓ box	Participant Initials Case No
	VISIT: A1/C1
O No O Yes (complete Q10a)	
Hilar nodes (31) Hilar nodes (31) Medialstinal nodes (32) Supraclavicular/scalene nodes (33) Ipsilateral lung (34) Contralateral lung (35) Pleura (36) Liver (37) Adrenals (38) Bone (39) Brain (41) Skin (42) Other, (52) specify COMMENTS:	Not Marked,
	[44]
Radiologist responsible for data	Date form completed (mm-dd-yyyy)
Person entering data onto the web	

ACRIN 6678

FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A2 and B1 - Pre-Chemotherapy and Visit C2 Pre-Treatment

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Visit A2 and B1 - Fre-Chemotherapy		Institution	Institution No
	and Visit C2 Pre-Treatment	Participant Initials	Case No
lf t	his is a revised or corrected form, please $\sqrt{\text{box.}}$		
INS	TRUCTIONS: This form is to be completed by the Radiologist for the FDC	G-PET/CT performed at this time	point.
1.	Time point of PET/CT [1]	VISIT:	A2/C2 AND B1
	o Visit A2/C2 and B1 (Groups A and B within 1-7 days before	the start of Chemotherapy (Cycle 1; Group C pre-treatment)
2.	Was the FDG PET/CT interpretation completed? [2]		
	o No (Complete Q2a, then sign and date form) o Yes (Skip to Q3)		
	2a. Reason images cannot be interpreted: (check all that ap	oply) □=1 Not Marked, 🗹=	2 Marked
	Related to SUV calculation		
	☐ injection time unknown [3]		
	scan start time unknown [4]		
	injected dose unknown [5]		
	patient body weight unknown [6]		
	scanner not or incorrectly calibrated [7]		
	Related to patient preparation (Blood glucose leve	els > 150 mg/dL) _[8]	
	Related to the uptake time (time between injection and	d start of scan)	
	☐ Uptake time < 45 minutes [9]		
	☐ Uptake time > 80 minutes [10]		
	☐ Uptake time for the baseline and a follow-up scan	varies by > 15 minutes [11]	
	☐ Related to beam hardening artifacts on CT [12]		
	(Beam hardening artifacts are overlying all possible	le target lesions in the ches	st)
	☐ Patient movement [13]		
	☐ Misregistration of PET and CT involving the whole		
	match target lesion as defined on PET) and no ot	her target lesion available [1	4]
	Other		
	Other, [48] specify	[49]	
3.	Date of FDG PET/CT exam(mm-dd-	<i>-уууу)</i> _[15]	
4.	Date of FDG PET/CT interpretation	(mm-dd-yyyy) _[16]	
5.	Reader ID [17]		

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A2 and B1 - Pre-Chemotherapy

and Visit C2 Pre-Treatment		
If this is a revised or corrected form, please $\sqrt{\text{box}}$.		

	ACRI	N St	udy o	00/	O	
PLA	CE	LA	BEI	[,]	HER	RE

Institution	Institution No.
Participant Initials	Case No

VISIT: A2/C2 AND B1

	VISIT. AZ/CZ AND BT
6.	Is the overall quality of the FDG PET/CT acceptable [18]
	o Adequate (skip to Q7) o Suboptimal (provide reason in Q6a, then sign and date form)
	6a. Reason suboptiomal (check all that apply) □=1 Not Marked, ☑=2 Marked
	☐ Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
	Related to the whole body distribution of FDG
	\Box Difference in liver SUV from the baseline to the follow-up scan > 1.0 $_{[20]}$
	\Box Liver SUV < 1.5 or > 4.0 [21]
	Related to uptake time (time between injection and start of scan)
	☐ Uptake time >=45 minutes and < 50 minutes [22]
	 □ Uptake time > 70 and <= 80 minutes _[23] □ Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes _[24]
	☐ Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [24]
	☐ Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
	Other
	Other, [50] specify[51]
8.	Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
	·[28]
9.	Location of Target Lesion in the Chest (choose only one) [29]
	o Right upper lobe
	o Right middle lobe
	o Right lower lobe
	o Left upper lobe / lingula
	o Left lower lobe
	o Right mediastinal lymph node
	o Right hilar lymph node
	o Left mediastinal lymph node
	o Left hilar lymph node
	o Subcarinal lymph node
	o Supraclavicular/scalene nodes

ACRIN 6678 FDG-PET/CT Tumor Response PET/CT Local Interpretation Form Visit A2 and B1 - Pre-Chemothe

ACRIN Study 6678
PLACE LABEL HERE

31 - Pre-Chemotherapy		
Pre-Treatment	Institution	Institution No. ————
ed form, please $\sqrt{\text{box}}$.	Participant Initials	Case No

and Visit C2 Pre-Treatment	Institution	Institution No	
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No	
	VISIT: A	A2/C2 AND B1	
10. Are there any metastatic lesions to report? [30] o No (Skip to Q11) o Yes (Complete Q10a)			
Hilar nodes [31] Medialstinal nodes [32] Supraclavicular/scalene nodes [33] Ipsilateral lung [34] Contralateral lung [35] Pleura [36] Liver [37] Adrenals [38] Bone marrow [40] Brain [41] Skin [42] Other, [52] specify			
COMMENTS:			
		[44]	
[45] Radiologist responsible for data			
Person entering data onto the web			

ACRIN 6678

FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A3 and B2 Post-Chemotherapy Cycle 1
(Within 3 days before Cycle 2)

ACRIN Study 6678

	Visit A3 and B2 Post-Chemotherapy Cycle 1 (Within 3 days before Cycle 2)	Institution Participant Initials	Institution No	_
lf	this is a revised or corrected form, please $\sqrt{\text{box.}}$			
NS	STRUCTIONS: This form is to be completed by the Radiologist for the FDG-	-PET/CT performed at this timep	pint.	
	Time point of PET/CT [1]	VISIT	: A3 and B2	
	o Post-chemotherapy Cycle 1 (Group A and B within 3 days b	pefore Cycle 2)		
) <u>.</u>	Was the FDG PET/CT interpretation completed? [2]			
	o No (Complete Q2a, then sign and date form) o Yes (Skip to Q3)			
	2a. Reason images cannot be interpreted: (check all that app	oly) □=1 Not Marked, =2	Marked	
	Related to SUV calculation			
	\square injection time unknown $_{[3]}$			
	scan start time unknown [4]			
	☐ injected dose unknown [5]			
	☐ patient body weight unknown [6]			
	scanner not or incorrectly calibrated [7]			
	☐ Related to patient preparation (Blood glucose level	r-1		
	Related to the uptake time (time between injection and	start of scan)		
	Uptake time < 45 minutes [9]			
	Uptake time > 80 minutes [10]			
	Uptake time for the baseline and a follow-up scan	varies by > 15 minutes [11]		
	\square Related to beam hardening artifacts on CT $_{[12]}$			
	(Beam hardening artifacts are overlying all possible	e target lesions in the ches	i)	
	☐ Patient movement [13]			
	☐ Misregistration of PET and CT involving the whole			
	match target lesion as defined on PET) and no oth	er target lesion available [14	1	
	Other			
	☐ Other, _[48] specify	[49]		
3.	Date of FDG PET/CT exam (mm-dd-y	'YYY) _[15]		
١.	Date of FDG PET/CT interpretation	(mm-dd-yyyy) _[16]		
j.	Reader ID [17]			

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A3 and B2 Post-Chemotherapy Cycle 1 (Within 3 days before Cycle 2)

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678

Institution	Institution No.	
Participant Initials	Case No.	

	Participant Initials Case No
	VISIT: A3 and B2
6.	Is the overall quality of the FDG PET/CT acceptable [18]
	o Adequate (skip to Q7) o Suboptimal (provide reason in Q6a, then sign and date form)
	6a. Reason suboptiomal (check all that apply) □=1 Not Marked, ☑= 2 Marked
	☐ Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
	Related to the whole body distribution of FDG
	☐ Difference in liver SUV from the baseline to the follow-up scan > 1.0 _[20]
	☐ Liver SUV < 1.5 or > 4.0 [21]
	Related to uptake time (time between injection and start of scan)
	☐ Uptake time >=45 minutes and < 50 minutes [22]
	☐ Uptake time > 70 and <= 80 minutes [22]
	☐ Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes [24]
	☐ Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [25]
	☐ Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
	Other
	Other specify
	[51]
8.	Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
	·[28]

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit A3 and B2 Post-Chemotherapy Cycle 1 (Within 3 days before Cycle 2)

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678 PLACE LABEL HERE

Institution	Institution No. ————
Participant Initials	Case No.

ir this is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials	Case No
	VISIT:	A3 and B2
 Are there any new metastatic lesions not previously reported No Yes (complete Q10a) 	? [30]	
9a. Indicate anatomic location (check all that apply) = 1 N Hilar nodes [31]		
		[44]
Radiologist responsible for data		Date form completed (mm-dd-yyyy)
Person entering data onto the web		

ACRIN 6678

FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit B3 - Post-Chemotherapy Cycle 2
(Within 3 days before Cycle 3)

ACRIN Study	6678
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PLACE LABEL HERE

Institution No. —

Institution _____

	(Within 3 days before Cycle 3)	Participant Initials	Case No
lf	this is a revised or corrected form, please $\sqrt{\text{box}}$.		
INS	STRUCTIONS: This form is to be completed by the Radiologist for the	e FDG-PET/CT performed at this timepoint	
1.	Time point of PET/CT [1]	VIS	SIT: B3
	o Post-chemotherapy Cycle 2 (Group B within 3 days b	efore Cycle 3)	
2.	Was the FDG PET/CT interpretation completed? [2]		
	o No (Complete Q2a, then sign and date form) o Yes (Skip to Q3)		
	2a. Reason images cannot be interpreted: (check all th	at apply) $\square = 1$ Not Marked, $\cancel{\square} = 2$ Ma	arked
	Related to SUV calculation		
	injection time unknown [3]		
	scan start time unknown [4]		
	☐ injected dose unknown [5]		
	patient body weight unknown [6]		
	☐ scanner not or incorrectly calibrated [7]	- levels - 450 m = (dl.)	
	Related to patient preparation (Blood glucose		
	Related to the uptake time (time between injection	n and start of scarry	
	 □ Uptake time < 45 minutes [9] □ Uptake time > 80 minutes [10] 		
	☐ Uptake time for the baseline and a follow-up	scan varies by > 15 minutes	
	☐ Related to beam hardening artifacts on CT [1]		
	(Beam hardening artifacts are overlying all po		
	☐ Patient movement [13]		
	Misregistration of PET and CT involving the w	vhole target lesion (i.e. target lesion a	as defined on CT does not
	match target lesion as defined on PET) and r	no other target lesion available [14]	
	Other	1. 1	
	Other, [48] specify	[49]	
3.	Date of FDG PET/CT exam (mr	m-dd-yyyy) _[15]	
4.	Date of FDG PET/CT interpretation	(mm-dd-yyyy) _[16]	
5.	Reader ID [17]		

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ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Interpretation Form Visit B3 - Post-Chemotherapy Cycle 2 (Within 3 days before Cycle 3)

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678

Institution	Institution No.
Participant Initials	Case No.

	ils is a revised of corrected form, please V box.	Participant Initials	Case No
			VISIT: B3
ô.	Is the overall quality of the FDG PET/CT acceptable [18]		
	o Adequate (skip to Q7) o Suboptimal (provide reason in Q6a, then sign and date for	rm)	
	6a. Reason suboptiomal (check all that apply) \square =1 Not Mark	ed, ☑ = 2 Marked	
	$\hfill \square$ Related to patient preparation (participant fasted for I	ess than 4 hours, but	blood glucose levels < 150 mg/dL) [19]
	Related to the whole body distribution of FDG		
	☐ Difference in liver SUV from the baseline to the follow	/-up scan > 1.0 _[20]	
	\Box Liver SUV < 1.5 or > 4.0 [21]		
	Related to uptake time (time between injection and start of	of scan)	
	☐ Uptake time >=45 minutes and < 50 minutes [22]		
	☐ Uptake time > 70 and <= 80 minutes [23]		
	Uptake time for the baseline and a follow-up scan va		
	Related to beam hardening artifacts on CT (beam ha		
	☐ Participant movement (misregistration of PET and CT	in the area of the targ	get lesion by more than 3 axial slices) [26]
	Other		
	☐ Other, _[50] specify	[5	1]
3.	Record the mean SUV measurement in normal liver tissue (r	efer to Appendix VI sec	etion 5)
	·[28]		

ACRIN 6678 FDG-PET/CTTumor Response PET/CT Local Interpretation Form Visit B3 - Post-Chemotherapy Cycle 2 (Within 3 days before Cycle 3)

ACRIN Study 6678

Institution	Institution No. ————
 Participant Initials	Case No

If this is a revised or corrected form, please √ box	Participant Initials	Case No.
	VISIT	
9. Are there any new metastatic lesions not previously reported o No o Yes (complete Q10a)	? [30]	
9a. Indicate anatomic location (check all that apply) Hilar nodes [31] Medialstinal nodes [32] Supraclavicular/scalene nodes [33] Ipsilateral lung [34] Contralateral lung [35] Pleura [36] Liver [37] Adrenals [38] Bone [39] Bone marrow [40] Brain [41] Skin [42] Other, [52] specify COMMENTS:		
		[44]
Radiologist responsible for data	Date	
Person entering data onto the web		

ACRIN 6678 FDG - PET/CT Tumor Response **PET/CT Local Technical** Assessment Form

Visit A1 - Pre-Chemotherapy and Visit C1 - Pre-Treatment

If this is a revised	or corrected form, please	√box.	
	or corrected form, produce	4 DOM:	

PLACE LABEL HERE Institution _____ Institution No. ___

ACRIN Study 6678

Participant Initials _____ Case No. __

	tructions: This form is to be completed, by the Radiologist or Technoges are to be transmitted to ACRIN as detailed in the study protocol. All	ologist, for the protocol-specified PET scan performed at this timepoint. All I times must be reported in military format (i.e., 2:45pm = 1445 hours).
Pa	art I: Exam Data	VISIT: A1/C1
1.	Protocol time point [1] O Visit A1/C1 (Groups A & C within 14 days of registration)	7. Participant height cm [9] 8. Full activity in syringe before injection
2.	Was PET imaging completed? O No* (complete Q2a, then sign and date form) O Yes (proceed to Q3 and continue with form) 2a. *If No, provide reason: [3] O Scheduling problem O Equipment failure O Participant refusal O Medical reason O Injection site complications O Claustrophobia O Blood glucose level (per protocol specifications) O Participant withdrew consent O Progressive disease	8a. Residual activity in syringe after injection mCi [52] 9. Time of dose assay (military time) 10. Time of injection (military time) 11. Location of injection site 0 Right antecubital 0 Right wrist 0 Left antecubital 0 Left wrist
2	O Participant death O Other, specify: O Unknown Date of PET imaging: [5]	O Rightfoot O Leftfoot O Other, specify:
	(mm-dd-yyyy)	12. Any radiotracer infiltration at injection site noted? O None O Minor (estimated to be less than 20% of dose) O Severe (estimated to be more than 20% of dose)
	Duration of participant fasting pre-PET imaging: [6] hours (up to time of FDG injection; if unknown record 99)	13. Participant voided immediately pre-imaging? _[16] O No O Yes O Unknown
5.	Blood glucose at start of PET imaging [7] (record value measured before FDG injection) mg/dl	14. Participant voided immediately post-imaging? O No O Yes O Unknown
6.	Participant weight (measured on day of scan) [8] kg	

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form Visit A1 - Pre-Chemotherapy and Visit C1 - Pre-Treatment	ACRIN Study 6678 PLACE LABEL HERE Institution Institution No
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials Case No
Part II: Image Acquisition	VISIT: A1/C1
Transmission Scan	PET Emission Scan
15. Type of transmission scan (check one) [18] O CT (complete Q16 thru 19, then skip to Q21) O Interleaved (go to Q20) O Non-interleaved, PET emission first (go to Q20) O Non-interleaved, transmission first (go to Q20)	22. Emission start time: [28] (military format) 23. Emission stop time: [29]
16a. Was Oral contrast used? [19] O No O Yes, define below [20] O Positive contrast O Negative contrast	(military format) 24. Number of bed positions scanned [30] 25. Emission acquisition mode [31] 0 2D 0 3D
16b. Was IV contrast used? [21] O No O Yes	26. Pixel Size of Reconstruction image
17. kVp	Part III: Scanner / F-18-FDG Procurement
18. mAs [23]	28. PET or PET/CT Scanner used for this exam:
19. Slice Thickness mm [24]	Vendor
20. Minutes duration of transmission scan per bed position? minutes [25]	29. Date of last PET scanner calibration:(mm-dd-yyyy) [36]
21. Transmission scan processing used: O Segmentation O CT O Segmentation and emission subtraction O Other, specify:	30. Daily scanner QC run on date of study? (check one) [37] O No O Yes 31. Has the scanner used for this study been qualified by ACRIN? O No O Yes, provide date: ———————————————————————————————————

FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form		PLACI	RIN Study 6678 E LABEL HERE
Visit A1 - Pre-Chemotherapy and Visit C1 - Pre-Treatment		Institution	Institution No.
If this is a revised or corrected form, please	box.	Participant Initials	Case No
		VI	SIT: A1/C1
32. F-18-FDG Source [38]			
O Synthesized (If synthesized, composite of purchased)O Purchased (If purchased, complete)		and c)	
32a. Method:		[39]	
32b. Pyrogen test result [40]			
O Passed			
O Failed			
O Not done			
32c. Radiochemical purity test result			
	[41]		
<u> </u>			
3. Purchased: name of licensed pharma	acy providing I	18-FDG:	
		[42]	
4. Are there any adverse events related	l to imaging to		[43]
O No (Sign and date form)		report for this timepoint?	[43]
		report for this timepoint?	[43]
O No (Sign and date form)O Yes (Complete Q34a and submit a	adverse event re	report for this timepoint?	[43]
O No (Sign and date form)	adverse event re	report for this timepoint?	[43]
O No (Sign and date form)O Yes (Complete Q34a and submit a34a. Does this event meet the criteria	adverse event re	report for this timepoint?	[43]
O No (Sign and date form)O Yes (Complete Q34a and submit a34a. Does this event meet the criteriaO No	adverse event re	report for this timepoint?	[43]
 O No (Sign and date form) O Yes (Complete Q34a and submit a 34a. Does this event meet the criteria O No O Yes 	adverse event re	report for this timepoint?	[43]
 O No (Sign and date form) O Yes (Complete Q34a and submit a 34a. Does this event meet the criteria O No O Yes 	adverse event re	report for this timepoint?	[43]
 O No (Sign and date form) O Yes (Complete Q34a and submit a 34a. Does this event meet the criteria O No O Yes 	adverse event re	report for this timepoint?	[43]
O Yes (Complete Q34a and submit a 34a. Does this event meet the criteria O No	adverse event re	report for this timepoint?	[43]

⁻ [46]

[48]

Signature of person entering data onto the web "Copyright 2010"

Signature of person responsible for the data

Date form completed (mm-dd-yyyy)

⁻ [45]

ACRIN 6678 FDG - PET/CT Tumor Response **PET/CT Local Technical** Assessment Form

Visit A2 and B1 - Pre-Chemotherapy and **Visit C2 Pre-Treatment**

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If this is a revised or corrected form, please $\sqrt{\text{box}}$.

PLACE LABEL HERE		
Institution	Institution No	
Participant Initials	Case No	

ACRIN Study 6678

		nologist, for the protocol-specified PET scan performed at this timepoint. All times must be reported in military format (i.e., 2:45pm = 1445 hours).	
Pa	art I: Exam Data	VISIT: A2/C2 AND B1	
1.	Protocol time point [1] O Visit A2/C2 and B1 (Groups A and B within 1-7 days before the start of Chemotherapy Cycle 1; Group C pre-treatment)	 7. Participant height (measured on the day of scan) 8. Full activity in syringe before injection 	
2.	Was PET imaging completed? O No* (complete Q2a, then sign and date form) O Yes (proceed to Q3 and continue with form) 2a. *If No, provide reason: O Scheduling problem O Equipment failure O Participant refusal O Medical reason O Injection site complications O Claustrophobia O Blood glucose level (per protocol specifications) O Participant withdrew consent O Progressive disease O Participant death O Other, specify:	8a. Residual activity in syringe after injection mCi [52] 9. Time of dose assay (military time) [11] 10. Time of injection (military time) [12] 11. Location of injection site [13] O Right antecubital O Right wrist O Left antecubital O Left wrist O Rightfoot O Leftfoot O Other, specify:	
	O Unknown	O Unknown	
	Date of PET imaging: [5] (mm-dd-yyyy) Duration of participant fasting pre-PET imaging: [6]	 12. Any radiotracer infiltration at injection site noted? [15] O None O Minor (estimated to be less than 20% of dose) O Severe (estimated to be more than 20% of dose) 13. Participant voided immediately pre-imaging? [16] 	
5.	hours (up to time of FDG injection; if unknown record 99) Blood glucose at start of PET imaging [7] (record value measured before FDG injection)	O No O Yes O Unknown	
6.	mg/dl Participant weight (measured on day of scan) [8]	 14. Participant voided immediately post-imaging? [17] O No O Yes O Unknown 	

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form Visit A2 and B1 - Pre-Chemotherapy and Visit C2 Pre-Treatment If this is a revised or corrected form, please \(\sqrt{box}. \)	ACRIN Study 6678 PLACE LABEL HERE Institution Institution No Participant Initials Case No
in this is a revised of corrected form, piedse V box.	T -
Part II: Image Acquisition	VISIT: A2/C2 AND B1
Transmission Scan	PET Emission Scan
15. Type of transmission scan (check one) [18] O CT (complete Q16 thru 19, then skip to Q21) O Interleaved (go to Q20) O Non-interleaved, PET emission first (go to Q20) O Non-interleaved, transmission first (go to Q20)	22. Emission start time: [28] (military format) 23. Emission stop time: [29]
16. CTtransmission scan:	
16a. Was Oral contrast used? [19] O No O Yes, define below [20] O Positive contrast O Negative contrast	24. Number of bed positions scanned [30] 25. Emission acquisition mode[31] O 2D O 3D
16b. Was IV contrast used? [21] O No O Yes	26. Pixel Size of Reconstruction image
17. kVp [22]	Part III: Scanner / F-18-FDG Procurement
18. mAs [23]	28. PET or PET/CT Scanner used for this exam:
19. Slice Thickness mm [24]	Vendor
20. Minutes duration of transmission scan per bed position? minutes [25]	29. Date of last PET scanner calibration:
21. Transmission scan processing used: [26] O Segmentation O CT O Segmentation and emission subtraction O Other, specify:	30. Daily scanner QC run on date of study? (check one) [37] O No O Yes 31. Has the scanner used for this study been qualified by ACRIN? [49] O No O Yes, provide date:

ACRIN 6678 FDG-PET/CTTumor Response PET/CT Local Technical **Assessment Form** Visit A2 a

ACRIN Study 6678

reatment	
or corrected form, please $\sqrt{\text{box.}}$	Case No

C2 Pre-Treatment	mstitution mstitution no.
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials Case No
	VISIT: A2/C2 AND B1
32. F-18-FDG Source [38]	VIOLITATION DI
O Synthesized (If synthesized, complete Q32a, b, a	and c)
O Purchased (If purchased, complete Q33)	,
32a. Method:	[39]
32b. Pyrogen test result [40]	
o Passed	
O Failed	
O Not done	
32c. Radiochemical purity test result: [41]	
33. Purchased: name of licensed pharmacy providing l	F-18-FDG:
	[42]
34. Are there any adverse events related to imaging to	report for this timepoint?
O No (Sign and date form)	[43]
O Yes (Complete Q34a and submit adverse event re	eporting form (AE))
34a. Does this event meet the criteria of a serious	adverse event? [44]
O No	
O Yes	
COMMENTS:	
COMMENTS.	
	[45
[46]	
Signature of person responsible for the data	Date form completed (mm-dd-yyyy)
[48]	
Signature of person entering data onto the web	

T3

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form Visit A3 and B2 - Post-Chemothera

ACRIN	Study	6678
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Visit A3 and B2 - Post-Chemotherapy Cycle 1 (Within 3 days before Cycle 2)	Institution No
, ,	Participant Initials Case No
If this is a revised or corrected form, please √box.	
	gist or Technologist, for the protocol-specified PET scan performed detailed in the study protocol. All times must be reported in military
Part I: Exam Data	VISIT: A3 and B2
Protocol time point O Post-chemotherapy Cycle 1 (Group A and B, within 3 days before Cycle 2) Was PET imaging completed? O No* (complete Q2a, then sign and date form) O Yes (proceed to Q3 and continue with form) 2a. *If No, provide reason: O Scheduling problem O Equipment failure O Participant refusal O Medical reason O Injection site complications O Claustrophobia O Blood glucose level (per protocol specifications) O Participant withdrew consent O Progressive disease O Participant death	6. Participant weight (measured on day of scan) [8] kg
O Other, specify: ———————————————————————————————————	O Other, specify: O Unknown
Data of DET impurious	
Date of PET imaging: [5]	 12. Any radiotracer infiltration at injection site noted? [15] O None O Minor (estimated to be less than 20% of dose) O Severe (estimated to be more than 20% of dose)
hours (up to time of FDG injection; if unknown record 99)	13. Participant voided immediately pre-imaging?_[16]O NoO YesO Unknown
i. Blood glucose at start of PET imaging [7] (record value measured before FDG injection) mg/dl	14. Participant voided immediately post-imaging? [17]O NoO YesO Unknown

ACRIN Study 6678 PLACE LABEL HERE Institution Institution No	
Participant Initials Case No	
VISIT: A3 and B2	
PET Emission Scan	
22. Emission start time: [28] (military format)	
23. Emission stop time: [29] (military format)	
24. Number of bed positions scanned [30] 25. Emission acquisition mode[31] 0 2D 0 3D	
26. Pixel Size of Reconstruction image mm [32]	
Part III: Scanner / F-18-FDG Procurement	
28. PET or PET/CT Scanner used for this exam:	
Vendor[34]	
Model name and/or number	
29. Date of last PET scanner calibration:	
30. Daily scanner QC run on date of study? (check one) [37] O NO O Yes 31. Has the scanner used for this study been qualified by ACRIN? [49] O NO O Yes, provide date: ———————————————————————————————————	

T3

ACRIN 6678

FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form

ACRIN Study	6678
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Visit A3 and B2 - Post-Chemotherapy Cycle 1 (Within 3 days before Cycle 2)	Institution	Institution No	
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials	Case No	
O Synthesized (If synthesized, complete Q32a, b, O Purchased (If purchased, complete Q33)	_	A3 and B2	
32a. Method:	[39]		
32b. Pyrogen test result [40] O Passed O Failed O Not done 32c. Radiochemical purity test result: [41]			
33. Purchased: name of licensed pharmacy providing	յ F-18-FDG:		
 34. Are there any adverse events related to imaging to No (Sign and date form) O Yes (Complete Q34a and submit adverse event) 34a. Does this event meet the criteria of a serious O No O Yes 	reporting form (AE))		
COMMENTS:			
			[45]
Signature of person responsible for the data	 Date form complet	 ed (mm-dd-yyyy) [4	7]
Signature of person entering data onto the web			,

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form Visit B3 - Post-Chemotherapy Cycle 2 (Within 3 days before Cycle 3)

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6678

PLACE LABEL HERE

Institution	Institution No.
Participant Initials	_ Case No

Pa	art I: Exam Data		VISIT: B3
	Protocol time point [1] O Post-chemotherapy Cycle 2 (Group B, within 3 days before Cycle 3) Was PET imaging completed? [2] O No* (complete Q2a, then sign and date form) O Yes (proceed to Q3 and continue with form) 2a. *If No, provide reason: [3] O Scheduling problem O Equipment failure O Participant refusal O Medical reason O Injection site complications O Claustrophobia O Blood glucose level (per protocol specifications) O Participant withdrew consent O Progressive disease O Participant death O Other, specify:	10.	Participant weight (measured on day of scan) [8]
	O Unknown		O Unknown
	Date of PET imaging: [5] (mm-dd-yyyy) Duration of participant fasting pre-PET imaging: [6]		Any radiotracer infiltration at injection site noted? O None O Minor (estimated to be less than 20% of dose) O Severe (estimated to be more than 20% of dose)
7.	hours (up to time of FDG injection; if unknown record 99)	13.	Participant voided immediately pre-imaging? _[16] O No O Yes O Unknown
5.	Blood glucose at start of PET imaging [7] (record value measured before FDG injection) mg/dl	14.	Participant voided immediately post-imaging? O No O Yes O Unknown

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ACRIN 6678		
FDG - PET/CT Tumor Response PET/CT Local Technical	ACRIN Study 6678	
Assessment Form	PLACE LABEL HERE	
Visit B3 - Post-Chemotherapy Cycle 2	Institution Institution No	
(Within 3 days before Cycle 3)	But the state of t	
If this is a revised or corrected form, please √box.	Participant Initials Case No	
Part II: Image Acquisition	VISIT: B3	
Transmission Scan	PET Emission Scan	
 15. Type of transmission scan (check one) [18] O CT (complete Q16 thru 19, then skip to Q21) O Interleaved (go to Q20) O Non-interleaved, PET emission first (go to Q20) 	22. Emission start time: [28] (military format)	
O Non-interleaved, transmission first (go to Q20)	23. Emission stop time: [29] (military format)	
16. CTtransmission scan:		
16a. Was Oral contrast used? [19]	24. Number of bed positions scanned [30]	
O No	OF Emission conviction made	
O Yes, define below [20]	25. Emission acquisition mode _[31] O 2D	
o Positive contrast	0 3D	
O Negative contrast	0 35	
16b. Was IV contrast used? [21] O No	26. Pixel Size of Reconstruction image mm [32]	
o Yes	27. Thickness of Reconstructed images	
17. kVp [22]	Part III: Scanner / F-18-FDG Procurement	
18. mAs [23]	28. PET or PET/CT Scanner used for this exam:	
19. Slice Thickness	Vendor	
19. Slice Thickness L. L. mm [24]		
	Model name and/or number	
20. Minutes duration of transmission scan per		
bed position? minutes [25]	29. Date of last PET scanner calibration:	
bed position: minutes [25]	(mm-dd-yyyy) _[36]	
21. Transmission scan processing used: [26]	[50]	
O Segmentation	30. Daily scanner QC run on date of study? (check one) [37]	
o CT	O No	
O Segmentation and emission subtraction	O Yes	
O Other, specify:	24 Has the coopper used for this study been sweliffed	
	31. Has the scanner used for this study been qualified by ACRIN?[49]	
[27]	O No	
	O Yes, provide date:	
	(mm-yyyy) _[50]	

T4

ACRIN 6678

FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form

ACRIN Study 6678

Visit B3 - Post-Chemotherapy Cycle 2 (Within 3 days before Cycle 3)	Institution	Institution No.	_
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials	Case No	_
O Synthesized (If synthesized, complete Q32a, b Purchased (If purchased, complete Q33)		SIT: B3	
32a. Method:	[39]		
32b. Pyrogen test result [40] O Passed O Failed O Not done			
32c. Radiochemical purity test result: [41] % 33. Purchased: name of licensed pharmacy providing	g F-18-FDG:		
	[42]		
34. Are there any adverse events related to imaging			
O No (Sign and date form)	-		
 O No (Sign and date form) O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No O Yes 			
O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No			
O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No O Yes			
O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No O Yes			
O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No O Yes			
O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No O Yes			
O Yes (Complete Q34a and submit adverse event 34a. Does this event meet the criteria of a serious O No O Yes	s adverse event? [44]		[45]

ACRIN 6678 FDG - PET/CT Tumor Response PET/CT Local Technical Assessment Form

ACRIN Study 6678

	ASSESSMENTFORM	Institution	Institution No	_
If th	nis is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No	
ma	tructions: The TA form is to be completed, by the rages are to be transmitted to ACRIN as detailed in the steps the form instructions indicate otherwise. All times mu	udy protocol. For check box	questions, check only one respons	
Pa	art I: Exam Data			
1.	Protocol time point O Pre-treatment (within 2 weeks after registration visit: Group A only)	6. Patient weight (me	1-1	
	 O Pre-treatment (Within 1 week prior to 1st Chemotherapy Cycle: Group A and Group B) O Post-treatment (Post Chemotherapy Cycle 1, Group A and Group B) 	7. Patient height (measured on the day of	of scan) cm [9]	
	O Post-treatment (Post Chemotherapy Cycle 2, Group B only)	8. Dose assay	mCi [10]	
2.	Was PET imaging completed? O No* (If no, complete 2a, then sign and date form) O Yes (go to Q3)	9. Time of dose assa	y (military time)	[11]
	2a. *If No, provide reason: [3] O Scheduling problem O Equipment failure O Patient refusal O Medical reason O Injection site complications O Claustrophobia O Other, specify:	10. Time of injection of the control	on site _[13] oital al	[12]
3.	Date of Imaging: [5](mm-dd-yyyy)	O None O Minor (estima	filtration at injection site noted atted to be less than 20% of dose) nated to be more than 20% of dose	
 4. 5. 	Duration of patient fasting pre-PET imaging: [6] hours (up to time of FDG injection) Blood glucose at start of PET imaging [7] (record value measured before FDG injection) mg/dl	O No O Yes O Unknown	mediately pre-imaging? _[16] mediately post-imaging? _[17]	

ACRIN 6678 FDG - PET/CT Tumor Response PET Technical Assessment Form	ACRIN Study 6678 PLACE LABEL HERE	
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Institution Institution No Participant Initials Case No	
Part II: Image Acquisition		
Transmission Scan	PET Emission Scan	
15. Type of transmission scan (check one) [18] O CT O Interleaved (go to Q20) O Non-interleaved, PET emission first (go to Q20) O Non-interleaved, transmission first (go to Q20)	22. Emission start time: (military format) [28] 23. Emission stop time: (military format)	
16a. Was Oral contrast used? O No O Yes, define below O Positive contrast O Negative contrast	24. Number of bed positions scanned [30] 25. Emission acquisition mode[31] O 2D O 3D	
16b. Was IV contrast used? [21] O No O Yes	26. Pixel Size of Reconstruction image mm [32] Part III: Scanner / F-18-FDG Procurement	
17. KVP [22] 18. MAS [22]	27. Thickness of Reconstructed images mm [33] 28. PET or PET/CT Scanner used for this exam:	
19. Slice Thickness [23]	Vendor	
20. Minutes duration of transmission scan per bed position? minutes [25]	29. Date of last scanner calibration:(mm-dd-yyyy) [36]	
21. Transmission scan processing used: [26] O Segmentation O CT O Segmentation and emission subtraction O Other, specify:	30. Daily scanner QC run on date of study? (check one) [37] O No O Yes	
[27]		

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IA FDG - PET/CT Tumor Response	ACRIN Study 6678	
PET Technical Assessment Form	PLACE LABEL HERE	
	Institution	Institution No
If this is a revised or corrected form, please $\sqrt{\text{box}}$.		
ii tiilo io a revisea or corrected form, piedoc y box.	Participant Initials	Case No
31. F-18-FDG Source [38]		
O Synthesized (If synthesized, complete Q31a, b, an	d c)	
O Purchased (If purchased, complete Q32)	u c)	
31a. Method:	[39]	
	[33]	
31b. Pyrogen test result [40]		
O Passed		
O Failed O Notdone		
O INOLUCITE		
31c. Radiochemical purity test result: [41]		
ore: Radioenermear purity test result. [41]		
%		
32. Purchased: name of licensed pharmacy providing F-	18-FDG:	
	[42]	
COMMENTS:		
-		
		[43]
Signature of parson responsible for the data!	Data form som	
Signature of person responsible for the data ¹	Date form com	рівсьа (піпі-аа-уууу)

[46]

Signature of person entering data onto the web²