ACRIN 6665

Malignant GI Stromal Tumors: Treatment Monitoring with PET

CRF Set

TA

ACRIN

PET Imaging/Primary and Recurrent Operable Malignant GIST Technical Assessment Form

If this is a revised or corrected form, indicate by checking box.

ACRIN Study 6665

Case #

PLACE LABEL HERE

Institution

Institution No.

Patient's Name

Patient's I.D. No.

Instructions: The TA form is to be completed by the Technologist at the ACRIN site for each time point specified in the protocol, i.e., question 1 on the form. The completed form is <u>faxed</u> to R. Badawi, Ph.D., Dana Farber Cancer Institute. The <u>original</u> paper form is mailed to the ACRIN Headquarters. PET images are to be transmitted as defined in Appendix VIII. Please see attached instructions (page 3) for image transfer and data submission address. All dates must be reported as mm-dd-yyyy. All time fields must be reported in military format, i.e., 1:00pm = 13:00 hrs. Code all questions unless otherwise specified.

(page 3) for image transfer and data submission address. Alin military format, i.e., 1:00pm = 13:00 hrs. Code all question	Il dates must be reported as mm-dd-yyyy. All time fields must be reported ns unless otherwise specified.
PET TIME-POINT INFORMATION	(10)
1. Protocol Imaging time point (if Q1 is code 4, complete Q4 and sign and date form) 1 Baseline PET (pre-Gleevec therapy) 2 Week 1 PET (at 24 hrs to 7 days post-initiat of Gleevec therapy) 3 Week 4 or week 8 PET (prior to surgery) 4 PET imaging not done, specify time point an complete item 4 (i.e., baseline, week 1, week 4 or week 8	1 Stomach 2 Small Intestine 3 Colon 4 Other, specify {11} PET Data Acquisition and Pre-processing (Patient's weight /height are measured on the day of imaging, not verbally relayed by the patient)
2. Date of PET imaging dd yyyy	7. Patient voided immediately pre-imaging? 1 No 2 Yes 8. 13 Patient voided immediately post-imaging?
3. Date of PET image transfer mm dd yyyy	1 No 2 Yes
4. System Was PET imaging completed? 1 No* 2 Yes 99 Unknown (6)	9. Duration of patient fasting pre-PET imaging 14
5. Selection of injection site 1 Right antecubital 2 Right wrist 3 Left antecubital 4 Left wrist 5 Right foot 6 Left foot 7 Other, specify {9} 99 Unknown	13. Any radiotracer infiltration at injection site noted? 0 None 1 Minor (estimated to be less than 20% of dose) 2 Severe (estimated to be more than 20% of dose) 14. Dose assay mCi 15. Time of dose assay (military time) (20) :

TA Revision	ACRIN Study 6665 Case #
17. [22] Number of bed positions scanned	PLACE LABEL HERE
The state of the s	Institution No.
17a. [23] mm Overlap of bed positions	Patient's Name Patient's I.D. No.
18. IF INTERLEAVED EMISSION-TRANSMISSION SCANS USED: 18a. [24] Minutes duration of transmission scan per bed	25b. [42] Filter properties 1 Hann 2 Shepp 3 Gaussian
18b. [25] Minutes duration of emission scan per bed	4 Ramp
19. IF NON-INTERLEAVED EMISSION-TRANSMISSION	5 Other, specify <u>{43}</u> 25c. Filter cutoff <u>{44}</u>
SCANS USED: 19a. [26] Minutes duration of transmission scan	25d. 45 Cutoff units 1 Pixel -1
20. Emission scan 27	2 Nq 3 FWHM (mm) 4 Other, specify 46} 26. 47 Scatter Correction applied?
21. Emission scan dead time correction applied 1 No 2 Yes 22. Transmission scan processing used 1 Segmentation 2 Emission-subtraction	1 No* 2 Bergstrom 3 Model-based 4 Energy-window 5 Tail-fit 6 Other specify,{48} If No*, specify reason{49}
3 Segmentation and emission subtraction 4 Other, specify {31} 23. Emission acquisition mode 1 2D 2 3D	27. Random Correction applied? 1 No* 2 Delayed window subtraction 3 Tail fit 4 Other specify, _{51} If No*, specify reason_{52}
24. Reconstruction algorithm used (complete all that apply) {33}□ 1 FORE {34}□ 2 RAMLA: Number of iterations:{35}} {36}□ 3 OSEM: Number of iterations:{37}} Number of subsets:{38}} {39}□ 4 3DRP {40}□ 5 FBP	28. Pixel size of reconstructed images 53 mm 29. Slice thickness of reconstructed images mm
25a. Filter used for reconstruction 25a. Filter dimensions 1 2D filter 2 3D filter	

TA	Revision	ACRIN Study	6665 Case #
		Institution	Institution No.
F-18-F	DG Procurement	Patient's Name	Patient's I.D. No.
30.	F-18-FDG Source 1 Synthesized 2 Purchased If synthesized*, complete Q31, if F-18-FDG is purchased**, complete 32.		
31. *I	f F-18-FDG is synthesized, provide the following		
31a.	Method {56}		
31b. 5	Pyrogen test result 1 Passed 2 Failed 98 Not done		
31c. R	adiochemical purity test result: \[\langle 58 \rangle \]. \[\langle % \] Not done		
32. **!	f F-18-FDG is purchased, provide the name of the p	pharmacy licensed to provid	le F-18-FDG
COMME	NTS:{61}		
	52}		{63} <u> </u>
PRINT N	AME OF PERSON COMPLETING FORM		DATE FORM COMPLETED

TA	Revision	PLAC	ce LABEL HERE
		Institution	Institution No.
		Patient's Name	Patient's I.D. No.
Image trans	mission via internet:	(attent's Name	ratients i.b. No.
named 66 name. Un the ACRII from the f should be be sent to	365. A sub-folder must be created un nder this subfolder, individual subfolder N case number. Do not send compre- file header and/or image. If identificate sent in an e-mail to the designated ro o ACRIN headquarters specifying the	s and procedures must be observed. The der 6665 with the institution acronym or a sers must be created for each case to be a seed or encrypted files. All patient identifion or clinical information needs to be serview site. When images (PET, CT) are case number sent, the institution it was sering@phila.acr.org and copied to rweet	ACRIN institution number as the folde submitted, with the folder name being fying information must be scrubbed in the folder purposes of image review, it transmitted via FTP, an e-mail should sent from, and the number of images
ETD imo	age via internet to:		
Host:	ges via internet to: ftp://xray.acrin.	org or ftp://206.137.103.34	
Userid:	6665		
Passwor	d gist		
2. Data For	m and CT Scan Reports Submission		
A.	Fax completed TA form to: R. Badawi, Ph.D. Dana-Farber Cancer Institute Fax: 617-632-3581 The patient identifiers (initials) should appear in the header	ould not appear on the form. The ACRIN	Case #, protocol #, Institution # and
В.	Mail the completed TA form and C	CT Scan Reports to:	
	ACRIN 6665 Data Management American College of Radiology 1101 Market Street, Suite 1400 Philadelphia, PA 19107 The data form should have <u>all</u> ider initials.	ntifiers marked: ACRIN Case #, Institutio	on name, Institution # and patient

ACRIN PET Imaging/Primary and Recurrent Operable Malignant GIST Core Lab PET Semi-Quantitative **Assessment Form**

1	ACRIN	Study 6	665
PLAC	CE I	ABEI	HERE

TENCE BILDER HERE			
Institution	Institution No		
Participant Initials	Case No		

f this	is	a	rev	isec	or	corre	cted	
orm.	inc	lic	ate	by	che	ckina	box.	

Instructions: Form is to be completed by the Core Lab Reader and sent to the ACR office. All dates must

PE	TIMAGING REVIEW INFORMATION			
1.	Dates of PET images reviewed Baseline PET {1}	2. 3.	Reader ID {5} [] [] [] Reader Name: {6} (print)	_
	If one or more PET studies not done, specify time point(s) (i.e., baseline, week 1, week 4 or week 8) [4]		(ріші)	

Part III Semi-Quantitative Assessment

4. PET FDG uptake analysis (completed for baseline only)

Lesion Number	ROINumber (1 = lesion, 2-5 = background)	Image Plane	Number of Pixels	Min(SUV) Simple — — · —	Max (SUV) Simple	Mean (SUV) Simple	Standard Deviation (SUV) Simple
1	1	{8}	{9}	{10}	{11}	{12}	{13}
	2	{15}	{16}	{17}	{18}	{19}	{20}
	3	{22}	{23}	{24}	{25}	{26}	{27}
	4	{29}	{30}	{31}	{32}	{33}	{34}
	5	{36}	{37}	{38}	{39}	{40}	{41}
2	1	{43}	{44}	{45}	{46}	{47}	{48}
	2	{50}	{51}	{52}	{53}	{54}	{55}
	3	{57}	{58}	{59}	{60}	{61}	{62}
	4	{64}	{65}	{66}	{67}	{68}	{69}
	5	{71}	{72}	{73}	{74}	{75}	{76}
3	1	{78}	{79}	{80}	{81}	{82}	{83}
	2	{85}	{86}	{87}	{88}	{89}	{90}
	3	{92}	{93}	{94}	{95}	{96}	{97}
	4	{99}	{100}	{101}	{102}	{103}	{104}
	5	{106}	{107}	{108}	{109}	{110}	{111}

0	7
U	
-	

Revision

ACRIN Study 6665 PLACE LABEL HERE

Institution	Institution No		
Participant Initials	Case No		

Complete the following question for 1 week time point.

и					
ч	1	1		١i	ı
-1	-	-1	- 2		?
•	•	•		-1	

Have new lesions been visualized since baseline imaging?

- 1 No
- 2 Yes***

5a. PET FDG uptake analysis (at 1 week time point)

Lesion Number	ROI Number (1 = lesion, 2-5 = background)	Image Plane	Number of Pixels	Min(SUV) Simple	Max (SUV) Simple	Mean (SUV) Simple	Standard Deviation (SUV) Simple
1	1	{114}	{115}	{116}	{117}	{118}	{119}
	2	{121}	{122}	{123}	{124}	{125}	{126}
	3	{128}	{129}	{130}	{131}	{132}	{133}
	4	{135}	{136}	{137}	{138}	{139}	{140}
	5	{142}	{143}	{144}	{145}	{146}	{147}
2	1	{149}	{150}	{151}	{152}	{153}	{154}
	2	{156}	{157}	{158}	{159}	{160}	{161}
	3	{163}	{164}	{165}	{166}	{167}	{168}
	4	{170}	{171}	{172}	{173}	{174}	{175}
	5	{177}	{178}	{179}	{180}	{181}	{182}
3	1	{184}	{185}	{186}	{187}	{188}	{189}
	2	{191}	{192}	{193}	{194}	{195}	{196}
	3	{198}	{199}	{200}	{201}	{202}	{203}
	4	{205}	{206}	{207}	{208}	{209}	{210}
	5	{212}	{213}	{214}	{215}	{216}	{217}
4***	1	{219}	{220}	{221}	{222}	{223}	{224}
	2	{226}	{227}	{228}	{229}	{230}	{231}
	3	{233}	{234}	{235}	{236}	{237}	{238}
	4	{240}	{241}	{242}	{243}	{244}	{245}
	5	{247}	{248}	{249}	{250}	{251}	{252}
5***	1	{254}	{255}	{256}	{257}	{258}	{259}
	2	{261}	{262}	{263}	{264}	{265}	{266}
	3	{268}	{269}	{270}	{271}	{272}	{273}
	4	{275}	{276}	{277}	{278}	{279}	{280}
	5	{282}	{283}	{284}	{285}	{286}	{287}
6***	1	{289}	{290}	{291}	{292}	{293}	{294}
	2	{296}	{297}	{298}	{299}	{300}	{301}
	3	{303}	{304}	{305}	{306}	{307}	{308}
	4	{310}	{311}	{312}	{313}	{314}	{315}
	5	{317}	{318}	{319}	{320}	{321}	{322}

^{***}If yes, record new sites visualized during follow-up imaging in table 5a as lesion #4, 5, and 6 as necessary.

	7	7
9		-
	Q	QZ

Revision

ACRIN Study 6665

Institution _____ Institution No. __

PLACE LABEL HERE

	Charles and Arthurs
Participant Initials	Case No.

Complete the following question at 6. pre-surgery time point.

> Have new lesions been visualized since week 1 imaging?

- 1 No
- 2 Yes***

***If yes, record new sites visualized during follow-up imaging in table 6a as lesion #4, 5, and 6 as necessary.

Lesion Number	ROI Number (1 = lesion, 2-5 = background)	Image Plane	Number of Pixels	Min(SUV) Simple	Max (SUV) Simple	Mean (SUV) Simple	Standard Deviation (SUV) Simple
1	1	{325}	{326}	{327}	{328}	{329}	{330}
	2	{332}	{333}	{334}	{335}	{336}	{337}
	3	{339}	{340}	{341}	{342}	{343}	{344}
	4	{346}	{347}	{348}	{349}	{350}	{351}
	5	{353}	{354}	{355}	{356}	{357}	{358}
2	1	{360}	{361}	{362}	{363}	{364}	{365}
	2	{367}	{368}	{369}	{370}	{371}	{372}
	3	{374}	{375}	{376}	{377}	{378}	{379}
	4	{381}	{382}	{383}	{384}	{385}	{386}
	5	{388}	{389}	{390}	{391}	{392}	{393}
3	1	{395}	{396}	{397}	{398}	{399}	{400}
	2	{402}	{403}	{404}	{405}	{406}	{407}
	3	{409}	{410}	{411}	{412}	{413}	{414}
	4	{416}	{417}	{418}	{419}	{420}	{421}
	5	{423}	{424}	{425}	{426}	{427}	{428}
4***	1	{430}	{431}	{432}	{433}	{434}	{435}
	2	{437}	{438}	{439}	{440}	{441}	{442}
	3	{444}	{445}	{446}	{447}	{448}	{449}
	4	{451}	{452}	{453}	{454}	{455}	{456}
	5	{458}	{459}	{460}	{461}	{462}	{463}
5***	1	{465}	{466}	{467}	{468}	{469}	{470}
	2	{472}	{473}	{474}	{475}	{476}	{477}
	3	{479}	{480}	{481}	{482}	{483}	{484}
	4	{486}	{487}	{488}	{489}	{490}	{491}
	5	{493}	{494}	{495}	{496}	{497}	{498}
6***	1	{500}	{501}	{502}	{503}	{504}	{505}
	2	{507}	{508}	{509}	{510}	{511}	{512}
	3	{514}	(515)	{516}	{517}	{518}	{519}
	4	{521}	{522}	{523}	{524}	{525}	{526}
2	5	{528}	{529}	{530}	{531}	{532}	{533}

COMMENTS: (534)

{535}

ACRIN Case # **ACRIN Study 6665** PET Imaging/Primary and Recurrent PLACE LABEL HERE Operable Malignant GIST Supplemental PET Technical Institution Institution No. Assessment Form If this is a revised or corrected Patient's Name Patient's I.D. No. form, indicate by checking box. Instructions: Form is to be completed by R. Badawi upon receipt of TA form, CT images PET images and CT report. The completed form is mailed to the ACRIN data management center for each time point. Dates are reported as mm-dd-yyyy. PET TIME-POINT INFORMATION If image quality suboptimal or inadequate, 1. [1] Protocol Imaging time point (if Q1 is coded 4, complete the following complete Q4 and sign/date form) Baseline PET (pre-Gleevec therapy) 2 Week 1 PET (at 24 hrs to 7 days post-initiation Originating site contacted of Gleevec therapy) No 1 3 Week 4 or week 8 PET (prior to surgery) 2 Yes 4 PET imaging not done, specify time point and complete item 4 Contact date (i.e., baseline, week 1, week 4 or week 8) dd mm уууу Originating site contact person {14} 2. Date of PET imaging dd уууу CT IMAGING INFORMATION 3. Date of PET image transfer mm dd уууу CT imaging performed 1 No PET IMAGING DATA QUALITY ASSESSMENT 2 Yes* (*If yes, complete 7, 8 & 9) Image quality (If image quality is suboptimal, or inadequate code reason) Date of CT imaging Adequate 2 Suboptimal* mm dd уууу {6} Entire study not complete CT report received 2 Noisy images No 3 Patient motion Yes Radiotracer infiltration 4 5 TA form incomplete SUVs cannot be calculated CT image received in following format (specify reason) Not received 1 Digital, DICOM Other, specify [8] Digital, not DICOM 3 Inadequate Hardcopy {9} Entire study not complete 2 Noisy images 3 Patient motion 4 Radiotracer infiltration 5 TA form incomplete SUVs cannot be calculated (specify reason) {10} Other, specify {11} COMMENTS: {19} {20} SIGNATURE (PERSON COMPLETING FORM) DATE FORM COMPLETED



If this is a revised or corrected form, indicate by checking box.

ACRIN PET Imaging/Primary and Recurrent Operable Malignant GIST Core Lab PET Imaging Evaluation Form

ACRIN Study 6665

Case #

PLACE LABEL HERE

Institution Institution No. **Patient's Name** Patient's I.D. No.

Instructions: Form is to be completed by the Core Lab Reader(s) and sent to the ACR office. All dates must be reported as mm-dd-yyyy. All time fields must be reported in military format [i.e. 1:00pm = 13:00 hrs]. Code all questions unless otherwise specified. PET IMAGING REVIEW INFORMATION 2. [5] Reader ID 1. Dates of PET images reviewed 3. [6] Reader Name Baseline PET {1} Annick D. Van den Abbeele, M.D. {2} Week 1 PET 2 Barry A. Siegel, M.D. {3} Week 4 or week 8 PET 3 Other, specify {7} If one or more PET studies not done, specify time point(s) (i.e., baseline, week 1, week 4 or week 8) Part I (Blinded Qualitative Assessment) Date PET images reviewed at Core Lab Uptake scale * Change in uptake scale**(compare to baseline) Change in lesion volume*** 0 No uptake 0 Lesion borders not visible, cannot evaluate 0 Not imaged, cannot evaluate Definitely normal 1 Marked decrease in uptake 1 Marked decrease in lesion volume 1

- Probably normal
- Indeterminate
- Probably abnormal 4
- Definitely abnormal

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

4. Primary tumor and metastatic disease uptake assessment as visualized on PET imaging only

LESION #	ANATOMIC SITE 1 Stomach 2 Small Intestine 3 Colon 4 Mesenteric nodes 5 Retroperitoneal nodes 6 Liver 7 Other, specify*	BASELINE UPTAKE SCALE* (0 TO 5)	WEEK1 UPTAKE SCALE* (0 TO 5)	WEEK 1 CHANGEIN UPTAKE SCALE** (0 TO 5)	WEEK 1 CHANGE IN LESION VOLUME*** (0 TO 5)	PRE-SURGERY UPTAKE SCALE* (0 TO 5)	PRE-SURGERY CHANGEIN UPTAKE SCALE** (0 TO 5)	PRE-SURGERY CHANGEIN LESION VOLUME*** (0 TO 5)
<u>(9)</u>	{ <u>10</u> } * {11}	<u>{12 }</u>	{ 13 }	<u>{14</u> }	{ <u>15</u> }	<u>{16</u> }	{ <u>17</u> }	{18}
{19}	{20} * {21}	<u>{ 22 }</u>	{23 }	{24}	{ 25 }	{26}	{ <mark>27</mark> }	{28}
{29}	{30}*_{31}	{32 }	{33} }	{ <u>34</u> }}	{35 }	{ <mark>36</mark> }	{ <u> 37 </u> }	{38}
{ 39 }	{40} * {41}	{42}	{ 43 }	{44}	{45}	{ 46 }	{47}	{48}
{49 }	{50} * {51}	{ 52 }	{ <u> 53</u> }	{54 }	{ 55 }	{56}	{ <u>57</u> }	{ 58 }
{59}	{60} * {61}	<u>{ 62 }</u>	{ 63 }	{ <u>64</u> }}	{ [65] }	<u>{ 66 }</u>	{ <u> 67 </u> }	<u>{68</u> }
{69 }	{ 70 } * { 71 }	{ 72 }	{73}	{ 74 }	{ 75 }	{[76]}	{ <mark>77</mark> }	{ 78 }
{ 79 } }	{80} * {81}	<u>{ 82 }</u>	{ <mark>[83</mark>]}	{ 84 }	[85]	{ <u>86</u> }	{ <mark>87</mark> }	{ <u>88</u> }

COMMENTS:	{89}	

IM	Rev	ision				PLACE	6665 Case LABEL HI	
Part II (l	Jnblinded Qualit	ative Ass	sessment)	2070	stitution atient's Nam	ne	Institut	ion No. 's I.D. No.
Uptake s 0 1 2 3 4 5		ot evaluate I	Change i	n uptake scale**(c) No uptake Marked decrease Slight decrease No change in u Slight increase Marked increase	compare to base ase in uptake e in uptake uptake in uptake se in uptake	eline) Change 0 L 1 N 2 S 3 N 4 S 5 N	in lesion volume* esion borders not vilarked decrease in light decrease in lo change in lesion light increase in learked increase in	** isible, cannot evaluat n lesion volume lesion volume n volume esion volume
LESION #	ANATOMIC SITE 1 Stomach 2 Small Intestine 3 Colon 4 Mesenteric nodes 5 Retroperitoneal nodes 6 Liver 7 Other, specify*	BASELINE UPTAKE SCALE* (0 TO 5)	WEEK1 UPTAKE SCALE* (0 TO 5)	WEEK1 CHANGEIN UPTAKE SCALE** (0 TO 5)	WEEK1 CHANGEIN LESION VOLUME*** (0 TO 5)	PRE-SURGERY UPTAKE SCALE* (0 TO 5)	PRE-SURGERY CHANGEIN UPTAKE SCALE** (0 TO 5)	PRE-SURGERY CHANGEIN LESIONVOLUME*** (0 TO 5)
90	91 * {92}	93	94	95	96	97	98	99
{ <u>100</u> }	{101} * {102}	{103}	{ <u>104</u> }	{105}	{ <u>106</u> }	{ <u>107</u> }	{ 08 }	{ <u> 109</u> }
{ 110 }	{111} * {112}	{ <u>113</u> }	{ <u>114</u> }	{ <u>115</u> }	{ <u>l16</u> }	{ <u>117</u> }	{ <u>118</u> }	{ <u> 119</u> }
{ <u>120</u> }	{ 21 } * {122}	{123}	{124}	{ <mark>125</mark> }	{[26]}	{ <u>127</u> }	{128}	{ <u>129</u> }
{ <u>130</u> }	{[131]} * {132}	{[133]}	{134}	{ <u>135</u> }	{136}	{ <u>137</u> }	{ <u>138</u> }	{ <mark>139</mark> }
{ <u>140</u> }	{[141]} * {142}	{ 143 }	{[144]}	{ 145 }	{146}	{ <u>147</u> }	{ 148 }	{ <u> 149</u> }
{150}	{ 151 } * {152}	{ <u>153</u> }	{154}	{155}	{156}	{ <u>157</u> }	{158}	{ 159}
{160}	{161} * {162}	{163}	{164}	{165}	{1 <u>66</u> }	{[67]}	{168}	{ <mark>169</mark> }
{170} {171} {172} {173}	2	CT image	<u>s</u> reviewed for t	he unblinded qua	alitative ass	essment.		
{176}	ITS: {175}	IPLETING	FORM)				{177} DATE FOR	-
© 2	003					ACRIN 66	65 (vB) IM	10-01-03 2 0