

<b>Document #</b>	CRR	MR	IRB	
<b>RADAR IRB STUDY</b>	DRUG: Imatinib Mesylate			
<b>Data Source</b>				
<input type="checkbox"/> IRB SAE Form <input type="checkbox"/> Medwatch Form sent to IRB <input type="checkbox"/> NCI SAE form sent to IRB <input type="checkbox"/> Sponsor Form	<input type="checkbox"/> Cancer Center Clinical Trial Database (NOTIS)	<input type="checkbox"/> Clinical Trial Case Report Form <input type="checkbox"/> Local Mirror of report sent to cooperative group	Medical Record <input type="checkbox"/> Patient Chart <input type="checkbox"/> Imaging study report <input type="checkbox"/> Pathology report <input type="checkbox"/> Clinical chemistry	
<b>Protocol</b>				
<i>Protocol name</i>	<i>Protocol number</i>		<i>Sponsor</i>	
<b>Report Dates:</b>				
<i>To PI</i>	To IRB	To Sponsor	<i>To FDA</i>	<i>SAE Report Numbers</i>
YYYY-MM-DD	YYYY-MM-DD	YYYY-MM-DD	YYYY-MM-DD	
<b>Demographic</b>				
Sex M <input type="checkbox"/> F <input type="checkbox"/>	<i>Age (years)</i>	Weight (kg)	<i>Height (cm)</i>	
<b>Disease</b>				
<b>Tumor Type</b>	<b>Stage</b>	<b>Recurrence</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Tumor Burden</b>	
<b>Drug Administration</b>				
<b>Drug</b>	<b>Start date / Restart</b>	<b>Stop Date</b>	<b>Doses</b>	
Imatinib Meylate				
Other Chemotherapy				
Prednisone				
Methylprednisolone				
Other glucocorticosteroid				
Furosemide				
Torseamide				
Other Diuretic				
Other drugs				

Event date:	_____	_____	_____
	Y Y Y Y	M M	D D
Event time:	_____	_____	
	H H	M M	

<b>Heart Failure</b>	Heart Failure	<input type="checkbox"/> YES	<input type="checkbox"/> NO
	Signs / symptoms:	<input type="checkbox"/> Tachycardia > 90 <input type="checkbox"/> Bradycardia < 50 <input type="checkbox"/> Heart Palpitations <input type="checkbox"/> Chest Pain	<input type="checkbox"/> Weight Gain >2 days / 2 or > lbs in 1 day <input type="checkbox"/> Edema / Effusion <input type="checkbox"/> Face <input type="checkbox"/> Pericardial <input type="checkbox"/> Pulmonary <input type="checkbox"/> Legs <input type="checkbox"/> Ankles <input type="checkbox"/> Other _____ <input type="checkbox"/> Dyspnea (SOB) <input type="checkbox"/> Clubbing of fingers <input type="checkbox"/> Other _____
	Imaging studies:	<input type="checkbox"/> Chest Radiograph	<input type="checkbox"/> EKG <input type="checkbox"/> Echocardiogram <input type="checkbox"/> Other _____

<b>Fracture</b>	Fracture	<input type="checkbox"/> YES If yes, specify: _____	<input type="checkbox"/> NO
	Signs / symptoms:	<input type="checkbox"/> Bone Pain <input type="checkbox"/> Swelling _____ <input type="checkbox"/> Loss of height	<input type="checkbox"/> Other _____
	Imaging studies:	<input type="checkbox"/> X-ray	<input type="checkbox"/> Dexa scan t-score _____ <input type="checkbox"/> Bone scan <input type="checkbox"/> Other _____

<b>Infections</b>	Infections	<input type="checkbox"/> YES If yes, specify site and organism: _____	<input type="checkbox"/> NO
	Signs / symptoms:	<input type="checkbox"/> ANC > 2.0 x 10 <sup>9</sup> <input type="checkbox"/> ANC < 1.0 x 10 <sup>9</sup>	<input type="checkbox"/> Fever > 38.5 C <input type="checkbox"/> Shock, severe acidosis (pH < 7.0), organ failure <input type="checkbox"/> Other _____
	Labs	<input type="checkbox"/> Blood Work <input type="checkbox"/> Blood Cultures _____	<input type="checkbox"/> Other Cultures: <input type="checkbox"/> Other _____
	Treatment	<input type="checkbox"/> IV antibiotic, antiviral or antifungals <input type="checkbox"/> Operation or IV radiology procedure	

Other events:

**Causality**

(Naranjo 2) Did the adverse event appear after the drug was administered?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	UNKNOWN <input type="checkbox"/>
(Naranjo 3) Did the symptoms or signs of the event improve after administration of an agent to treat the event?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	UNKNOWN <input type="checkbox"/>
(Naranjo 4) Did additional events occur with readministration of gefitinib?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	UNKNOWN <input type="checkbox"/>
Were alternative events mentioned in the medical records or by the P.I? If so, please specify: _____ _____	YES <input type="checkbox"/>	NO <input type="checkbox"/>	UNKNOWN <input type="checkbox"/>
(Naranjo 5) Are there alternative causes (other than gefitinib) that could have on their own caused the event?			
(Naranjo 9) Did the patient have the event with previous administration of gefitinib or similar drugs?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	UNKNOWN <input type="checkbox"/>

**Action**

Changes to <b>protocol</b> based at least in part on this event	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Changes to <b>consent form</b> based at least in part on this event	YES <input type="checkbox"/>	NO <input type="checkbox"/>

**Outcome:**

Imatinib Mesylate discontinued?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Agent to treat signs and symptoms Heart Failure/Edema drug given?	YES <input type="checkbox"/> If yes, specify Drug(s) _____ Date(s) _____ Dose _____ Frequency _____	NO <input type="checkbox"/>
Agent to treat signs and symptoms of a Fracture?	YES <input type="checkbox"/> If yes, specify Drug(s) _____ Date(s) _____ Dose _____ Frequency _____	NO <input type="checkbox"/>
Agent to treat signs and symptoms of Infection?	YES <input type="checkbox"/> If yes, specify Drug(s) _____ Date(s) _____ Dose _____ Frequency _____	NO <input type="checkbox"/>

PI Assessment:	<input type="checkbox"/> Probably Related <input type="checkbox"/> Definitely Related <input type="checkbox"/> Possibly Related <input type="checkbox"/> Unrelated <input type="checkbox"/> N/A	Comment:
----------------	--	----------

<b>Data extraction:</b>	
Start time:	
Stop time:	
Initials:	