



ADVERSE EVENT REPORT		CASE NO: (For Celgene use only) _____						
NEW <input type="checkbox"/> FOLLOW-UP <input type="checkbox"/>								
For Celgene use only Date of receipt <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">Day</td> <td style="text-align: center; font-size: 8px;">Month</td> <td style="text-align: center; font-size: 8px;">Year</td> </tr> </table>				Day	Month	Year	Received by: _____ (Name and organization – eg CRO, or company representative)	For Studies Enter: Protocol: _____ Site Number: _____ Patient number: _____
Day	Month	Year						
Source <input type="checkbox"/> Spontaneous <input type="checkbox"/> Compassionate Use <input type="checkbox"/> Literature <input type="checkbox"/> Other, Specify _____								

SUSPECT DRUG						
Drug, Formulation, Strength, Route (eg.capsules,5mg,oral)	Dose & frequency	Lot/Batch no.	Therapy Start date dd.mmm.yy	Therapy Stop date dd.mmm.yy	Drug-Event Causal relationship 1= Not related 2= Related	Indication for use of drug

ACTION TAKEN, SUSPECT DRUG

<input type="checkbox"/> None	<input type="checkbox"/> Unknown	<input type="checkbox"/> Not applicable
<input type="checkbox"/> Dose decreased, specify: _____	<input type="checkbox"/> Permanently discontinued	
<input type="checkbox"/> Dose increased, specify: _____	<input type="checkbox"/> Temporarily interrupted	

PATIENT DATA

Initials:	Date of Birth:	Age:	Weight:	Height:	Gender						
	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">Day</td> <td style="text-align: center; font-size: 8px;">Month</td> <td style="text-align: center; font-size: 8px;">Year</td> </tr> </table>				Day	Month	Year		<input type="checkbox"/> lbs <input type="checkbox"/> kg	<input type="checkbox"/> ft. <input type="checkbox"/> cm	Male: <input type="checkbox"/> Female: <input type="checkbox"/>
Day	Month	Year									

ADVERSE EVENT

Description of Adverse Event (provide diagnosis if available) – symptoms and treatment <div style="border: 1px solid black; height: 150px; width: 100%;"></div>	Event onset date: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">Day</td> <td style="text-align: center; font-size: 8px;">Month</td> <td style="text-align: center; font-size: 8px;">Year</td> </tr> </table> Event stop date: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">Day</td> <td style="text-align: center; font-size: 8px;">Month</td> <td style="text-align: center; font-size: 8px;">Year</td> </tr> </table> OUTCOME OF ADVERSE EVENT <input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae: _____ <input type="checkbox"/> Not recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Death Date of death: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> <td style="border: 1px solid black; width: 20%; height: 20px;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">Day</td> <td style="text-align: center; font-size: 8px;">Month</td> <td style="text-align: center; font-size: 8px;">Year</td> </tr> </table> Cause(s) of Death: _____ <p style="text-align: center; font-size: 10px;">If autopsy is performed please forward report. Please attach relevant clinical laboratory assessments to confirm the event.</p>				Day	Month	Year				Day	Month	Year				Day	Month	Year
Day	Month	Year																	
Day	Month	Year																	
Day	Month	Year																	

Did the event result in hospitalization or prolonged hospitalization? [] Yes [] No	Celgene Corporation 86 Morris Avenue Summit, New Jersey 07901 Telephone (908) 673-9667 Toll Free 1-800-640-7854 Fax: (908) 673-9115 Email: drugsafety@celgene.com
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MEDICAL HISTORY

Current or past relevant medical history (including concurrent illness, allergy, smoking, alcohol abuse)

Yes If Yes, please specify. None Unknown

Large empty box for medical history details.

OTHER MEDICATION (Medication taken during the past 3 months prior to the event)

Drug, Formulation, Strength, Route (eg. Capsules 5mg, oral)	Dose & Frequency	Therapy Start date dd.mmm.yy	Therapy Stop date dd.mmm.yy	Indication for use of drug

Has the patient discussed this event with their health care professional? []Yes []No Unknown[]

If yes, would you please provide their health care professional's contact information?

Name: _____ Country: _____ Fax: _____
Address: _____ Phone: _____
Email: _____

REPORTER: []Physician []Nurse []Pharmacist []Patient []Relative []Other, please specify _____

Name: _____ Country: _____ Fax: _____
Address: _____ Phone: _____
Email: _____

Pharmacy Name (if applicable) _____

DEA or NABP # (US only) _____

Email: _____

Signature: _____ **Date of AE Awareness:** _____