ADVERSE DRUG REACTION REPORT

CASE NO: (For Celgene use only) _____

For Celgene use only

Date of receipt

Day	Month	Year

Received by: _____

(Name and organization – eg CRO, or company representative)

Source ☐ Spontaneous ☐ Comp. Use ☐ Lit ☐ Other, Specify_____

For Studies Enter:

Protocol: _____

Site Number: _____

Patient number: _____

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	Indication for use of drug

ACTION TAKEN, SUSPECT DRUG

☐ None
☐ Dose decreased, specify:_____
☐ Dose increased, specify: _____
☐ Unknown
☐ Permanently discontinued
☐ Temporarily interrupted
☐ Not applicable

PATIENT DATA

Initials:	Date of Birth:	Age:	Weight:	Height:	Gender	
	Day / Month / Year		☐ lbs ☐ kg	☐ ft ☐ cm	Male:	☐
					Female:	☐

ADVERSE EVENT

Overall diagnosis of the event

Event onset date: Day / Month / Year

Event stop date: Day / Month / Year

OUTCOME OF ADVERSE EVENT

☐ Recovered
☐ Recovered with sequelae: _____
☐ Not recovered
☐ Unknown
☐ Death
Date of death: Day / Month / Year

Possible cause(s) of Death:

If autopsy is performed please forward report.
Please attach relevant clinical laboratory assessments to confirm the event.

Please provide an assessment of causal relationship of above reported event and the use of Celgene product:

☐ **Related to Celgene product**

☐ **Not related to Celgene product**

☐ **Other cause:**_____

SERIOUSNESS OF THE EVENT (tick all that apply)

☐ Death
☐ Life-threatening
☐ Hospitalization or prolonged hospitalization
☐ Persistent or significant disability or incapacity
☐ Congenital anomaly/birth defect
☐ Other medically important condition or event *
☐ Non-serious

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*** an event not meeting the other serious criteria, but based on medical judgment may jeopardize the patient and require medical or surgical intervention to prevent one of the other serious outcomes.**

CASE NO:_____

MEDICAL HISTORY

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

☐ Yes If Yes, please specify. ☐ None ☐ Unknown

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	Causal relationship 1 = Not related 2 = Related	Indication for use of drug

PRESCRIBER INFORMATION

Name: _____ Country: _____ Fax: _____

Address: _____ Phone: _____

Email: _____

REPORTER

Name: _____ Country: _____ Fax: _____

Address: _____ Phone: _____

Email: _____ **Pharmacy** (if applicable): _____

NOTIFICATION

☐ Initial report ☐ Follow-up report ☐ Final report

Name (PRINT): _____ Title: _____

Signature: _____ Date of AE Awareness: _____

SUBMIT FORM