# ADVERSE EVENT REPORT

NEW ☐
FOLLOW-UP ☐

**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)

For Studies Enter:

Protocol: _____

Site Number: _____

Patient number: _____

Source ☐ Spontaneous ☐ Compassionate Use ☐ Literature ☐ 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

☐ 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

Description of Adverse Event (provide diagnosis if available) – symptoms and treatment

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

Cause(s) of Death:

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

Did the event result in hospitalization or prolonged hospitalization? [ ] Yes [ ] No

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**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 | Indication for use of drug |
|---|---|---|---|---|
| | | | | |
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| | | | | |

**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:** _____ _____



Print form and e-mail to:
drugsafety@celgene.com