Processing of Individual Case Safety Reports

Adverse Event Reporting Form

A. Patient Information

1. Patient Initials: _____

2. Age: _____ **or** **Date of Birth:** _ _/_ _ /_ _ _ _ (dd/mm/yyyy)

3. Sex: ☐ Male ☐ Female

4. Height: ____ cm

5. Weight: ____ kg

6. Country:

B. Adverse Event

7. Seriousness of the event:

☐ Death
☐ Hospitalization- initial or prolonged
☐ Congenital anomaly
☐ Required intervention to prevent permanent impairment/damage
☐ Disability
☐ Life threatening

8. Date of Event: __ __/__ __ /__ __ __ __ (dd/mm/yyyy)

9. Date of this report: __ __/__ __ /__ __ __ __ (dd/mm/yyyy)

10. Describe event or problem:

11. Relevant tests/laboratory data (attach memo, if required):

12. Other relevant history, including pre-existing medical conditions (e.g. allergy, pregnancy, smoking and alcohol use, hepatic/renal dysfunction etc.):

C. Suspect Medication

13. Name (Brand and Generic)	**14. Strength***	**15. Manufacturer***
# 1 _____	# 1 _____	# 1 _____
# 2 _____	# 2 _____	# 2 _____

*** from product label**

16. Daily Dose	**17. Frequency**	**18. Route Used**
# 1 _____	# 1 _____	# 1 _____
# 2 _____	# 2 _____	# 2 _____

19. Therapy dates:

Start Date (dd/mm/yyyy)	**End Date (dd/mm/yyyy)**	**Duration**
# 1 _____	# 1 _____	# 1 _____
# 2 _____	# 2 _____	# 2 _____

20. Batch	**21. Expiry Date**	**22. Indication**
# 1 _____	# 1 _____	# 1 _____
# 2 _____	# 2 _____	# 2 _____

23. Event abated after discontinuation of suspect medication

☐ Yes ☐ No ☐ NA

24. Event reoccurred after reintroduction of suspect medication

☐ Yes ☐ No ☐ NA

25. Concomitant medicinal products:

26. Outcome of the event:

☐ Fatal ☐ Recovered ☐ Other (specify)
☐ Recovering ☐ Unknown

D. Reporter

27. Name and address:

28. Phone: **29. E-mail:** **30. Fax:**

31.Healthcare Professional:

☐ Yes ☐ No

32. Occupation:

33. Also reported to:

☐ Regulatory agencies ☐ Distributor/sales personnel

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CONFIDENTIALITY
Any information related to the identities of the reporter and patient will be kept confidential.

- **Report SERIOUS adverse events. An event is serious when the patient outcome is:**
  - Death
  - Life-threatening (real risk of dying)
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment

  Medical events that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed above shall also be considered as serious events.
- **Report even if:**
  - You're not certain the product caused adverse experience
  - You don't have all the details although point nos. 1, 7, 8, 9, 10, 11, 13 & 27 are essentially required

HOW TO REPORT

- Just fill in the sections that apply to your report
- Attach additional pages if needed
- Use a separate form for each patient and event

WHERE TO REPORT
Mail to:
Global Vigilance – Competence Centre Oncology
Fresenius Kabi Oncology Limited
Echelon Institutional Area,
Plot No. 11,
Sec 32 Gurgaon 122001

Fax: +91-124-3325003

Phone: +91-124-4885000 (Extn. 5163)

E-mail: Covigilancecell.IN_ND@fresenius-kabi.com

Reason for Revision:	1. Scheduled revision 2. To align with current SOP-QA-001