

Processing of Individual Case Safety Reports

Adverse Event Reporting Form

A. Patient Information			
1. Patient Initials:	3. Sex:	4. Height:	5. Weight:
_____	_____	_____ cm	_____ kg
2. Age: _____	<input type="checkbox"/> Male		
or			
Date of Birth: _____	<input type="checkbox"/> Female		
__/__/____	6. Country:		
(dd/mm/yyyy)			

B. Adverse Event	
7. Seriousness of the event:	
<input type="checkbox"/> Death	<input type="checkbox"/> Required intervention to prevent permanent impairment/damage
<input type="checkbox"/> Hospitalization- initial or prolonged	<input type="checkbox"/> Disability
<input type="checkbox"/> Congenital anomaly	<input type="checkbox"/> Life threatening
8. Date of Event:	9. Date of this report:
__/__/____	__/__/____
(dd/mm/yyyy)	(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	End Date	Duration
(dd/mm/yyyy)	(dd/mm/yyyy)	
# 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		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

24. Event reoccurred after reintroduction of suspect medication		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
25. Concomitant medicinal products:		
26. Outcome of the event:		
<input type="checkbox"/> Fatal	<input type="checkbox"/> Recovered	<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Recovering	<input type="checkbox"/> Unknown	
D. Reporter		
27. Name and address:		
28. Phone:	29. E-mail:	30. Fax:
31. Healthcare Professional:		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	
32. Occupation:		
33. Also reported to:		
<input type="checkbox"/> Regulatory agencies	<input type="checkbox"/> Distributor/sales personnel	

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 Version: 00
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 Approved by: Dr. Rajul Rastogi



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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
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