


Title: Individual Case Safety Reports Management	SOP No.: CLA/001/01
ANNEXURE – V	

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
(For Voluntary reporting of Adverse Drug Reactions)

Themis Medicare Ltd. 11/12, Udyog Nagar Industrial Estate, SV Road, Goregaon(W), Mumbai – 400104 Ph: 9805286542, 022-67607080 (Ext-359)	TML ADR yyyy..... <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> Report: Initial / Follow up Report Type: Spontaneous / Clinical Themis Awareness Date: dd/mmm/yyyy: </div> 						
A. Patient Information	<div style="border: 1px solid black; padding: 5px; margin: 5px auto; width: 80%;">12. Relevant tests / laboratory data with dates</div>						
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:15%; padding: 2px;">1. Patient Initials -----</td> <td style="width:15%; padding: 2px;">2. Age at time of Event or date of birth - -----</td> <td style="width:15%; padding: 2px;">3. Sex <input type="checkbox"/> M <input type="checkbox"/> F</td> </tr> <tr> <td colspan="2" style="padding: 2px;">4. Weight ___ Kgs</td> <td style="padding: 2px;">13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)</td> </tr> </table>	1. Patient Initials -----	2. Age at time of Event or date of birth - -----	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F	4. Weight ___ Kgs		13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)	13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)
1. Patient Initials -----	2. Age at time of Event or date of birth - -----	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F					
4. Weight ___ Kgs		13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)					
B. Suspected Adverse Reaction	14. Seriousness of the reaction						
5. Date of reaction started (dd/mm/yyyy)	<input type="checkbox"/> Death (dd/mm/yyyy) _____ <input type="checkbox"/> Congenital anomaly						
6. Date of recovery (dd/mm/yyyy)	<input type="checkbox"/> Life threatening intervention <input type="checkbox"/> Required						
7. Describe reaction or problem	<input type="checkbox"/> Hospitalization-initial permanent or prolonged damage <input type="checkbox"/> Disability <input type="checkbox"/> Other (specify) _____						
	15. Outcomes						
	<input type="checkbox"/> Fatal <input type="checkbox"/> Recovering <input type="checkbox"/> Unknown						
	<input type="checkbox"/> Continuing <input type="checkbox"/> Recovered <input type="checkbox"/> Other (specify) _____						

C. Suspected medication(s)										
S. No	8. Name (brand and /or generic name)	Manufacture (if known)	Batch No. /Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
I.										
II.										
III.										
IV.										
V.										
VI.										
VII.										

Approved By: Head CQA	(Sign/Date)	Page 1 of 2
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Sl. No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
I.										
II.										
III.										
IV.										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (exclude those used to treat reaction)	<div style="border: 1px solid red; padding: 5px;"> D. Reporter 16. Name and Professional Address: _____ _____ Pin code: _____ E-mail _____ Mob/ Tel. No.: _____ Occupation _____ Signature _____ </div>		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">17. Causality Assessment</td> <td style="width: 50%;">18. Date of this report (dd/mm/yyyy)</td> </tr> </table>	17. Causality Assessment	18. Date of this report (dd/mm/yyyy)
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