

UMC SIGNAL DETECTION WORKSHEET

A template for reviewers - all items are optional

ASSOCIATION

Drug _____ ADR _____

IC _____ IC- 2std _____ Year:Quarter _____

<i>The association is:</i>	<i>No</i>	<i>Yes</i>	<i>Source/Country:</i>
Labeled	<input type="checkbox"/>	<input type="checkbox"/>	_____
Expected from the characteristics of the drug	<input type="checkbox"/>	<input type="checkbox"/>	_____
Previously documented (Literature references)	<input type="checkbox"/>	<input type="checkbox"/>	_____ _____ _____

SUMMARY OF CASES

Total number of cases: _____ whereof _____ are single suspect drug reports

Sex distribution: _____ Males _____ Females _____ Not specified

Duplicate reports likely? No Yes, number: _____

Case origin (country):								
Number of cases:								

<i>Is there/ are there any:</i>	<i>No</i>	<i>Yes</i>	<i>Comments:</i>
age group prominence?	<input type="checkbox"/>	<input type="checkbox"/>	_____
characteristic time interval to onset?	<input type="checkbox"/>	<input type="checkbox"/>	_____
characteristics of dose or route of interest?	<input type="checkbox"/>	<input type="checkbox"/>	_____
concurrent ADR(s) of possible interest?	<input type="checkbox"/>	<input type="checkbox"/>	_____ _____ _____

<i>Is there/ are there any:</i>	No	Yes	<i>Comments:</i>
concurrent drug(s) of possible interest?	<input type="checkbox"/>	<input type="checkbox"/>	_____

interaction suspected?	<input type="checkbox"/>	<input type="checkbox"/>	_____
concomitant disease indicators?	<input type="checkbox"/>	<input type="checkbox"/>	_____

FOLLOW UP

<i>Cases with:</i>	<i>Number:</i>		<i>Number:</i>
Positive dechallenge:	_____	Positive rechallenge:	_____

<i>National Centers' causality assessments:</i>			
Certain:	_____	Probable:	_____
Possible:	_____	Unlikely:	_____
Unclassified:	_____	Unclassifiable:	_____

<i>Reported outcomes:</i>			
Recovered:	_____	Recovered with sequelae:	_____
Not yet recovered:	_____	Died - due to ADR:	_____
Died - unrelated:	_____	Died - ADR may be contrib:	_____
Unknown:	_____		

<i>Documentation grading:</i>	0	_____	<i>Trend of the IC value:</i>	<input type="checkbox"/>	increasing
	1	_____			
	2	_____		<input type="checkbox"/>	decreasing
	3	_____			

DISCUSSION
