AE Reporting Form

Date:		Manufacturer Report Number:
Reporter Details Name:	☐ HCP ……. ☐ Pharmacist ☐ Physician ☐ Nurse ☐ Other ☐ Consumer ☐ Other *(state)…*	Address/tel/email/Fax#
Patient Details Patient Initials:	Patient Age/DOB:	Gender: ☐ Male ☐ Female
Adverse Reaction Details	ADR Start Date: ADR Stop Date:	**Outcome**: Resolved ☐ Y Resolving ☐ Y Not resolved ☐ Y Unknown ☐ Y

What is the Diagnosis?

Continue overleaf if required..

Seriousness Criteria: Death ☐ Y ☐ N **Date:**
Is Death Attributed to Event? ☐ Y ☐ N ☐ Unk
Hospitalization ☐ Y ☐ N **Dates: From:** **To:**
Life Threatening ☐ Y ☐ N
Disability ☐ Y ☐ N
Congenital Anomaly ☐ Y ☐ N
Other (Please specify)

AE Treatment, if any:

Suspect Medication Details	**Name and strength with formulation**	**Indication**

Dose/Frequency	Route	Start Date	Stop Date	Lot #/Expiry	
		Discontinued? ☐ YES ☐NO			

Is Event caused due to the Suspect Drug? ☐ Y ☐ N ☐ Unk
Did event abate after stopping drug or Reducing dose? ☐ Y ☐ N ☐ NA
Did the drug reintroduced? ☐ Y ☐ N ☐ NA
Did event reappear after reintroducing the Drug? ☐ Y ☐ N ☐ NA

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Concomitant Medication Details

Name	Dose/Route/Indication	Dates (Start/End)	Suspected?
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

Medical History Details/Allergies

Condition	Date	Current	Past
		☐	☐
		☐	☐
		☐	☐

Lab Details, if any

Other Supporting Details