1. Reporter Details		☐Initial ☐Follow-up
Reporter Name:		E-mail:
Contact address:		Telephone number:
		Fax number:
Type:	☐ Physician (Specialty): _____	☐ Consumer or other non healthcare professional
	☐ Pharmacist	☐ Other (Specify) _____

If reporter is a consumer, have they informed their physician of the exposure? ☐ Yes ☐ No

Has the consumer provided permission to contact their healthcare professional? ☐ Yes ☐ No

If yes, please provide healthcare professional contact details:

Name:	Type:	Telephone:
Address:		Email:

2. Patient Details			
Date of birth (Day/Month/Year)	Age Yrs/mo.	Height cm	Weight kg

3. Company Drug Section

	Name	Strength	Dose	Route	Indication	Treatment start date (day/month/year)	Treatment end date (day/month/year)	Lot	Expiry
1.									
2.									
3.									

4. Details of Adverse Event

Adverse Event	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
			☐ Yes ☐ No *If yes, provide dates of hospitalization.*	☐ Recovered / Resolved ☐ Recovered / Resolved with Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown	☐ Related ☐ Not Related ☐ Unknown

Site of Infection

☐ Bone	☐ Genitourinary	☐ Prostate
☐ Blood	☐ Hepatobiliary	☐ Respiratory
☐ Cardiovascular	☐ HEENT	☐ Skin
☐ CNS	☐ Joint	☐ Other, specify :
☐ Gastrointestinal	☐ Kidney	

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5. Were there any complications caused by the infection?
If yes, please provide details.

6. Treatment
Treatment provided for event: Action taken with Company Drug in response to event:

7. Diagnostic Tests					
Biopsies: Yes / No	Date:	Location:	Findings:		
Cultures: Yes / No	Date:	Location:	Findings:		
Radiographic Studies: Yes / No	Date:	Location:	Findings:		
CSF Analysis: Yes / No	Date:	Cell count:	Culture:	Staining:	PCR:
Cytology:					
Other diagnostic test results (e.g. complete blood cell count):					

8. Concomitant Drugs & Therapies

9. Medical History
Patient's concomitant conditions, relevant medical history, known risk factors, relevant tests, laboratory data. *(Include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy e.g. alcohol, smoking, other substance consumption, hypertension, eclampsia, diabetes including gestational, infections during pregnancy, environmental or occupational exposure that may pose a risk factor).*

10. Completed By		
Name:	Signature:	Date (day/month/year):