Adverse Drug Reaction Report

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Patient		
Initials	Date of Birth	Age/Age Group
Gender ☐ f ☐ m	Pregnancy (week)	
Weight kg	Height cm	

Adverse Reaction		
Start date:	Stop date:	Duration

Drugs (Trade name or active substance / dosage form/ Batch.-No.)	Application	Dosage	Duration of treatment start	end	Indication
1					
2					
3					
4					

Suspected causality with drug No. ☐ 1 ☐ 2 ☐ 3 ☐ 4 Please tick at least one drug

Medical History and other characteristics
(e.g. underlying and concomitant diseases, other drugs, allergies, smoking, alcohol, liver-/renal deterioration

Relevant Investigations and Laboratory Data (with date and normal range)

Measures and treatment of adverse reaction

Seriousness Criteria of Reaction
☐ Death (autopsy: ☐ yes ☐ no)
☐ life threatening
☐ hospitalization or prolonged hospitalization
☐ permanent injury or disability
☐ important medical event

Outcome of Reaction
☐ unknown
☐ complete recovery
☐ recovered with sequelae
☐ not yet recovered
☐ recovering

Treatment discontinued due to Adverse Reaction
☐ yes ☐ no ☐ no data

Improvement after discontinuation
☐ yes ☐ no ☐ no data

Reappearance after re-challenge
☐ yes ☐ no ☐ no data

In cases of serious Adverse Reactions it may be helpful to attach doctor and/or hospital discharge letter.

Reporter's Name: Date:

Address / Institution:

Phone number:

Email: Signature