Adverse Drug Reaction Report

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Patient	
Initials	Date of Birth
Gender	Pregnancy
☐ f ☐ m	. month
Weight	Height
kg	cm

Adverse Reaction	
Start date . .	Duration

Drugs (Trade name or active substance / dosage form/ Batch.-No.)	Application	Dosage	Duration of treatment start	end	Indication
1					
2					
3					
4					
5					

Suspected causality with drug No. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Please tick at least one drug

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

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

Measures and treatment of adverse reaction

Outcome of the Adverse Reaction

☐ Death (autopsy: ☐ yes ☐ no)
☐ life threatening
☐ hospitalization or prolonged hospitalization
☐ complete recovery
☐ not yet recovered
☐ permanent injury or disability
☐ unknown

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:
Address / Institution:

Phone number:
Email:

Date:

_____
Signature