Adverse Drug Reaction Report

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A. Patient						
Initials: _____	Date of Birth: _____	Age/Age Group: _____	Gender: ☐ f ☐ m	Pregnancy: _____week	Weight: _____kg	Height: _____cm

B. Reporter	
Healthcare Professional? ☐ yes ☐ no	
If yes, please provide Healthcare Professional details: ☐ Physician ☐ Pharmacist ☐ Others _____ Name: Address: Phone number: E-mail:	If no, please provide consumer/patient details: ☐ Consumer (patient caregiver or other) ☐ Patient Name: Address: Phone number: E-mail:
Consent for Fresenius Kabi to follow-up with consumer/patient for more information? ☐ yes ☐ no ☐ not applicable	
Consent for Fresenius Kabi to follow-up with Healthcare Professional? ☐ yes ☐ no ☐ not applicable Note: please fill the Healthcare Professional contact details above accordingly.	

C. Drug(s) (Trade name or active substance / dosage form)	Batch/Lot No.*	Route of Administration	Dosage (dose and frequency)	Duration of treatment start	Duration of treatment end	Indication
1						
2						
3						
4						
5						

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

*If Batch/Lot no. of Fresenius Kabi suspect drugs is unavailable**,** please fill with appropriate reason(s): "**asked but unknown**", "**unavailable & consent not received for follow-up**" or "**unavailable & follow-up requested**".

D. Adverse Reaction(s) [please describe the reaction(s) and any treatment given]:

Start date:_____ Stop date:_____ Duration:_____

Seriousness Criteria of Reaction(s)	**Outcome:**	**Treatment discontinued due to Adverse Reaction**
☐ Death (autopsy: ☐ yes ☐ no) ☐ life threatening ☐ hospitalization or prolonged hospitalization ☐ permanent injury or disability ☐ important medical event	☐ unknown ☐ complete recovery ☐ recovered with sequelae ☐ not yet recovered ☐ recovering	☐ 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**.

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

F. Relevant Investigations and Laboratory Data (with date and normal range):

G. Form completed/filled by:

Name: Date & Signature: