Suspected Adverse Reaction Report Form

Source of report: ☐ spontaneous ☐ post-authorization study ☐ unsponsored study

1. Patient Details & History

Patient initials (First - Last)	**Date of birth** (dd/mmm/yyyy)	**Age at onset of reaction** (years)	**Sex** ☐ female ☐ male	**Weight** ☐ kg ☐ lb	**Height** ☐ cm ☐ in	**Pregnancy** ☐ yes ☐ no ☐ n.a.	**Country of occurrence** (use full name)

Relevant patient history (e.g. diagnoses, allergies, pre-existing medical conditions, smoking & alcohol use, pregnancy with last month of period, etc.)

2. Suspect Medicinal Product Information

Suspect Medicinal Product(s) (include all information available: trade name, generic name, form and dosage)	**Batch number(s)**	**Expiry Date(s)** (dd/mmm/yyyy)
1.	1.	1.
2.	2.	2.

Daily dose (with units)	**Route of administration**	**Rate of infusion** (if applicable) (mL/min)	**Concentration of solution**
1.	1.		
2.	2.	**Time infusion commenced** (if applicable)	**Solvent used for reconstitution of the lyophilized product** (if applicable)

Current therapy dates related to this reported reaction(s) (dd/mmm/yyyy, time)		**Indication(s) for use**
From	*To*	
1.	1.	1.
2.	2.	2.

3. Adverse Reaction Information

Describe adverse reaction(s) (give signs or symptoms, diagnosis, course) **including relevant tests / laboratory data**
(continue on separate page if you need more space)

1.

2.

Please attach de-identified copies of relevant documentation (medical report, results, laboratory findings, expert's report, anaesthetist's report)

Onset of reaction(s) (dd/mmm/yyyy, time)	**End of reaction(s)** (dd/mmm/yyyy, time)

Treatment of adverse reaction(s)

CSL Behring * Pharmacovigilance * P.O. Box 12 30 * 35002 Marburg, Germany * Fax +49-6421-39-4775 * Email: phv.reporting@cslbehring.com
CSL Behring * Pharmacovigilance * Wankdorfstrasse 10 * 3000 Bern 22, Switzerland * Fax +41-31-344-5486 * Email: PVIGI@cslbehring.com
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CSL Limited * Medical Affairs Department * 45 Poplar Road * Parkville, Victoria Australia 3052 * Fax +61-3-9389-1160 * Email pharmacovigilance@csl.com.au

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3. Adverse Reaction Information (continued)

Is the case serious?

☐ Yes ☐ No *(if yes please tick at least one of the following boxes)*

☐ Death _____(dd/mmm/yyyy) Autopsy *(tick if yes)* ☐

Cause of death _____

☐ Life-threatening
☐ Persistence or significant disability/incapacity
☐ Required intervention to prevent permanent impairment/damage
☐ Congenital anomaly/birth defect
☐ Hospitalisation – initial or prolonged
☐ Suspected transmission of an infectious agent

Case Outcome

☐ Recovered _____(dd/mmm/yyyy)
☐ Recovered with sequelae _____(please specify)
☐ Permanently disabled
☐ Died
☐ Not yet recovered
☐ Unknown

Causality Assessment

☐ Highly probable
☐ Possible
☐ Unlikely
☐ Unassessable

Reaction abated after stopping medicinal product?

1. ☐ Yes ☐ No ☐ Not applicable
2. ☐ Yes ☐ No ☐ Not applicable

Reaction reappeared after reintroduction?

1. ☐ Yes ☐ No ☐ Not applicable
2. ☐ Yes ☐ No ☐ Not applicable

Previous therapy with suspect medicinal product?

1. ☐ Yes ☐ No ☐ Not applicable
2. ☐ Yes ☐ No ☐ Not applicable

Suspect medicinal product tolerated in the past?

1. ☐ Yes ☐ No ☐ Not applicable
2. ☐ Yes ☐ No ☐ Not applicable

If yes, therapy dates

_____(dd/mmm/yyyy)

4. Concomitant Medicinal Product(s) (exclude those used to treat reaction)

Concomitant medicinal product(s) (trade name) / dosage and form	**Batch number**	**Daily dose** (with units)	**Route of administration**	**Dates (start/stop) of administration** (dd/mmm/yyyy)	**Indication(s) for use**
1.					
2.					
3.					

5. Reporter Information

This Form also requests some information about you, the reporter/treating doctor. This information will be used by CSL in connection with any follow up investigation of the event by CSL. This information may also be accessed by other members of the CSL Group of companies (some of which are resident overseas) as part of CSL's global adverse event reporting database. If this information is not provided it may adversely effect our investigation. This information will be retained by CSL for as long as it is required for this purpose or as required by law. You can acces this information (to the extent authorised by the Privacy Act 1988 and other applicable laws) by contacting CSL's Privacy Officer at 45 Poplar Road, Parkville, Victoria, Australia 3052

Details of Reporter

(If the reporter is the patient, has the patient given consent to CSL to follow up the adverse reaction report with the healthcare professional?) *yes*☐ *no* ☐

Occupation:
Full Name:
Organisation/Address:
Telephone:
Fax:
Email:
Date & Signature _____

Details of Treating Doctor *(If different from Reporter)*

Full Name:
Organisation/Address:
Telephone:
Fax:
Email:
Date & Signature _____

6. Administrative Information (Internal Use Only)

International (WAVES) case no. _____

CCS Number _____

Date first received by manufacturer (dd/mmm/yyyy)

Report received by

Name _____

Local Affiliate/Country _____

Date & Signature _____

Date first received by Pharmacovigilance (dd/mmm/yyyy)

MR ☐ **BRN** ☐ **KOP** ☐ **BMW** ☐ **PKV** ☐

Initial☐ **Follow-up**☐

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