Adverse Event Report Form[*)]	Doc ID: Form PV 004	V04
Case Number: <Will be assigned by biolitec>	☐ Initial report ☐ Follow-up report	

1. Patient Details

Initials	Country	Date of birth	Age	Sex	Weight	Height
☐/☐/☐ First/Middle/Last			☐ years	☐ Female ☐ Male	☐ kg	☐ cm

2. Foscan®

Drug	Batch No.	Indication for PDT-treatment	Dosage regimen	Total dosage	Route of administration
Foscan® (INN: Temoporfin)			☐ mg/kg	☐ mg	☐ Intravenous ☐ Other:

Foscan® injection:

Date: ☐ unk ☐ **Hour** (hh:mm): ☐ **Duration of injection:** ☐ min

Was patient instructed to avoid sunlight?

☐ Yes ☐ No

Illumination:

Date: ☐ unk ☐ **Hour** (hh:mm): ☐ ☐ PDT ☐ iPDT

3. Adverse events (AE)

#	Adverse Event	Description (including signs, symptoms, treatment, relevant lab data)	Start date	End date	Outcome	May have been caused by Foscan®	Other non-drug causes
1			☐ unk ☐	☐ unk ☐ ☐ Ongoing	☐ Recovered ☐ Recovered w sequal ☐ Not recovered ☐ Unknown	☐ No ☐ Unlikely ☐ Possible ☐ Probable ☐ Certain	☐ Yes, specify:
2			☐ unk ☐	☐ unk ☐ ☐ Ongoing	☐ Recovered ☐ Recovered w sequal ☐ Not recovered ☐ Unknown	☐ No ☐ Unlikely ☐ Possible ☐ Probable ☐ Certain	☐ Yes, specify:
3			☐ unk ☐	☐ unk ☐ ☐ Ongoing	☐ Recovered ☐ Recovered w sequal ☐ Not recovered ☐ Unknown	☐ No ☐ Unlikely ☐ Possible ☐ Probable ☐ Certain	☐ Yes, specify:
4			☐ unk ☐	☐ unk ☐ ☐ Ongoing	☐ Recovered ☐ Recovered w sequal ☐ Not recovered ☐ Unknown	☐ No ☐ Unlikely ☐ Possible ☐ Probable ☐ Certain	☐ Yes, specify:

[*)] This form is intended to be used for reporting of adverse events and adverse reactions

4. Other drugs administered during or prior to the adverse event(s) described in Table 3 (including those drugs administered for anaesthesia and peri-PDT treatment)

#	Drug	Indication	Dosage	Start Date	Stop Date	May this drug have caused the AE?
1				unk	unk Ongoing	No Yes, AE #:
2				unk	unk Ongoing	No Yes, AE #:
3				unk	unk Ongoing	No Yes, AE #:
4				unk	unk Ongoing	No Yes, AE #:
5				unk	unk Ongoing	No Yes, AE #:
6				unk	unk Ongoing	No Yes, AE #:
7				unk	unk Ongoing	No Yes, AE #:
8				unk	unk Ongoing	No Yes, AE #:
9				unk	unk Ongoing	No Yes, AE #:
10				unk	unk Ongoing	No Yes, AE #:

5. Seriousness

The adverse event(s) resulted in or was/were …

- Death (due to the adverse event)
- Life threatening (i.e. was at risk of death at time of the adverse event)
- Inpatient hospitalisation or prolongation of existing hospitalisation
- Congenital anomaly/birth defect
- Persistent or significant disability or incapacity
- None of the above; i.e. the case is non-serious

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6. Relevant medical history (diagnostics, allergies, pregnancy etc.)

7. Additional relevant information, e.g. laboratory test results

8. Reporter details			
Name		**Professional status**	
Organization/University		**Unit**	
Address		**ZIP/Postal code**	
City		**Phone number**	
Email		**Fax number**	
If you are the patient, may we contact your health care professional? If yes, please provide details:			
Name		**Professional status**	
Organization/University		**Unit**	
Address		**ZIP/Postal code**	
City		**Phone number**	
Email		**Fax number**	

Date signed:

Reporter's signature: ……..

Send this form to: pv@biolitecpharma.com

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