CLINIGEN Group plc	**ADVERSE EVENT REPORT FORM**	Please fax or e-mail this report to Pharmacovigilance within 24 hours of becoming aware, to Fax: **+44 1283 495034** E-mail: **patientsafety@clinigengroup.com**
DOC/040/v04	Effective Date: 1st June 2015	

Section A – Administrative details

Report ID, if applicable: | **Date you were made aware of the Adverse Event(s):**

Type of the report: ☐ Initial ☐ Follow-up; FU #_____ ☐ Correction to the latest report

Has report been sent to anybody else: ☐ Yes ☐ No

If yes: ☐ Local Regulatory authority; (specify date)_____ ☐ Ethics Committee ☐ Other(specify)_____

Method of Receipt: ☐ Conversation (in person) ☐ Telephone ☐ Fax ☐ Letter ☐ E-mail ☐ Other (specify):

Section B - Patient's details

Patient Initials:	**Date of Birth/Age at the time of event onset/Age group:**	**Gender:** ☐ Male ☐ Female
Weight: kg	**Height:** cm	**For female patients** **Pregnant :** ☐ Yes, exp. delivery date: , ☐ No

Medical history (concomitant and past conditions, including allergies, risk factors, surgical procedures etc.)

Condition/Procedure	**Start date** (DD/MMM/YYYY)	**Stop date** (DD/MMM/YYYY)	**Comment**

Section C – Product details

Suspect Product: **Route of administration:** Batch No. if known: Expiry date:	**Start date** (DD/MMM/YYYY) **:** **Stop date** (DD/MMM/YYYY)**:** **Duration:** days **Frequency :** **Daily Infusion duration:** mins **Dose Administered:** **Unit:**	**Indication:**

If other therapy regimen, please specify:

Concomitant medications

Drug name	**Start date** (DD/MMM/YYYY)	**Stop date** (DD/MMM/YYYY)	**Unit dose**	**Frequency**	**Route of administration**	**Indication**

Do you consider any of above mentioned concomitant drugs to be co-suspects:

☐ Yes; specify _____ ☐ No

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Section D – Adverse Event(s) Information:

Adverse Event(s) Information: (Please provide the description of the reported event(s) as described by the reporter; If applicable, include drugs/procedure given/performed to treat Adverse Event(s); If an adverse event is not reported but a product safety issue is, describe it* and state 'No adverse event'))

* Drug exposure during pregnancy; Exposure to the product via semen; Lactation (breastfeeding), Off label use, Lack of efficacy, Interaction, Suspected transmission of an infectious agent via a medicinal product (Always serious), Overdose, Misuse, Abuse, Unexpected Benefit, Medication Error

Onset Date (DD/MMM/YYYY):	**Resolution Date:** (DD/MMM/YYYY)	**In the reporter's opinion was the event:** ☐ Non-serious ☐ Serious

Please tick all that apply if serious:

- ☐ Death
- ☐ Life-threatening
- ☐ Hospitalisation Initial
- ☐ Hospitalisation Prolonged
- ☐ Disabling/incapacity
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Medically Significant Event

Hospitalisation dates if applicable (DD/MMM/YYYY):

Admission date:

Discharge date:

If **Death**, record:

Date of death (DD/MMM/YYYY):

Cause of death:

Was autopsy performed: ☐ Yes ☐ No

If yes, please provide autopsy results (if known)

Is this Adverse Event(s) Associated with a Product Quality Complaint: ☐ Yes ☐ No

If Yes, describe the PQC in adverse event information above and ensure to request batch number

Due to event (s), the suspect product administration was:

☐ maintained ☐ immediately stopped then resumed

☐ temporarily discontinued ☐ permanently discontinued ☐ unknown

Event abated after the suspect product was discontinued or dose reduced: ☐ Y ☐ N ☐ N/A

Event reappeared after reintroduction of the the suspect product: ☐ Y ☐ N ☐ N/A

Outcome of the Event(s):

☐ Resolved without sequelae ☐ Resolved with sequelae ☐ Resolving ☐ Not Resolved

☐ Unknown ☐ Not Reported ☐ Fatal ☐ Other (specify):

Section E – Reporter's details

Name of Reporter:

Reporter Details:

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other HCP, specify:

☐ Consumer, specify:

Contact details

Permission to contact reporter for additional information ☐ Yes ☐ No

Permission to contact Health Care Professional: (if different from Reporter)

☐ Yes ☐ No

If yes, please provide HCP details:

Name and title of HCP:

Contact details

Relationship of the suspect product administration to the Adverse Event(s) as per reporter:

☐ Highly probable ☐ Probable ☐ Possible ☐ Unlikely ☐ Not related

Name and Title of Person Completing the form: **Contact details Phone/E-mail:**	**Signature of person completing the form:** **Date** (DD/MMM/YYYY)**:**