CLINIGEN Group plc	**Adverse Event Report Form**	Please fax or e-mail this report to Pharmacovigilance within 24 hours of becoming aware, to: **Fax number:** +44(0)1932 824284 **E-mail:** drugsafety@clinigengroup.com

By completing this form, you acknowledge that all personal data provided in this form shall be processed by Clinigen for it to comply with its pharmacovigilance/reporting obligations and for reasons of public health and public interest. Clinigen may share this personal data with competent regulatory authorities, manufacturers of the product identified in this form and its third-party licencing, distribution and pharmacovigilance service providers. All data provided in this form is treated as confidential and will only be shared with third parties where it is necessary to do so for pharmacovigilance purposes.

If you have any further questions about why or how we use the personal data collected in this form and your rights in relation to the personal data, please contact us via the details provided above.

Section A – Administrative Details

Suspect Product:	Click here to enter text.	**Country:**	Click here to enter text.	**Date of Report:**	Click here to enter text.

Report Type: ☐ Initial ☐ Follow Up ☐ Correction to the latest report

Section B – Event(s)

In the reporter's opinion (if a HCP) was the event: ☐ Serious ☐ Non-Serious

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'))

Click here to enter text.

Onset Date: Click here to enter a date. **Resolution Date:** Click here to enter a date.

Serious Criteria:
☐ Hospitalisation ☐ Hospitalisation Prolonged ☐ Disability/Incapacity ☐ Important/Significant Medical Event
☐ Congenital Anomaly/Birth Defect ☐ Life-threatening ☐ Fatal

Hospitalisation Dates
Admission: Click here to enter text.
Discharge: Click here to enter text.

Event Outcome
☐Resolved ☐Resolved with sequelae
☐ Resolving ☐ Not Resolved ☐Fatal ☐ Unknown
☐ Other (specify): Click here to enter text.

Event abated after the suspect product was discontinued or dose reduced: ☐ Yes ☐ No ☐ N/A

Event reappeared after reintroduction of the suspect product: ☐ Yes ☐ No ☐ N/A

If Fatal, Cause of Death: Click here to enter text.
Date of Death: Click here to enter a date.

Post Mortem Performed: ☐ Yes ☐ No
If yes, please provide post mortem results (if known)

Section C- Patient Information*

Patient Initials:	Click here to enter text.	**Date of Birth / Age:**	Click here to enter a date.	**Gender:**	☐ Male ☐ Female	**Ethnicity:**	Choose an item.
Weight:	Click here to enter text.	**Height:**	Click here to enter text.	**If female, Pregnant?**	☐ Yes ☐ No		

Relevant Lab Data	Click here to enter text.	☐ Unknown	☐ None
Relevant Medical History	Click here to enter text.	☐ Unknown	☐ None
History of Allergies	Click here to enter text.	☐ Unknown	☐ None

Section D – Product

Suspect Product:	Click here to enter text.	**Indication:**	Click here to enter text.	**Batch Number:(If Known)**	Click here to enter text.	**Expiration Date:**	Click here to enter a date.
Dose, Units & Route of Administration:	Click here to enter text.	**Frequency:**	Click here to enter text.	**Product Start Date:**	Click here to enter a date.	**Product Stop Date:**	Click here to enter a date.

Action Taken: ☐ Maintained ☐ Temporarily Discontinued ☐ Permanently Discontinued ☐ Dose Increased ☐ Dose Reduced ☐ Unknown

Reporter Causality Assessment: ☐ Definitely Related ☐ Probable ☐ Possible ☐ Not related

	Drug	Dose	Treatment Regimen	Route	Start Date	Stop Date		
Concomitant Meds	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter a date.	Click here to enter a date.	☐ Unknown	☐ None
	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter a date.	Click here to enter a date.		

Section E – Reporter's Details*

Reporter Name: Click here to enter text.
Reporter Position:
☐Physician ☐ Pharmacist ☐ Dentist ☐ Nurse ☐ Paramedic ☐ Other HCP: Specify
☐ Consumer: Specify
Permission to contact reporter for additional information: ☐ Yes ☐ No

Name and title of HCP: Click here to enter text.
Permission to contact Health Care Professional (HCP), if different from Reporter:
☐ Yes ☐ No ☐ Not Explicitly Stated ☐ Reporter is HCP

Tel: Click here to enter text.	**Fax:** Click here to enter text.	**Tel:** Click here to enter text.	**Fax:** Click here to enter text.