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|--|---|
| Sending institution (please stamp here) Phone _____ | Patient data (including birth name and date of birth) |
|--|---|

GHSG Studienzentrale
 Uniklinik Köln
 50924 Cologne
 Germany

Phone +49 221 / 478 - 88166
 Fax +49 221 / 478 - 88188

Serious Adverse Event Report

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|--|--|--|
| | | |
|--|--|--|

Day Month Year

SAE

AVD-Rev
03/10 V1.0

| | |
|----------------------|-----------------------|
| Trial AVD-Rev | CRF ID Case ID |
|----------------------|-----------------------|

Initial Report Follow up Report Treatment Cycle No. _____

Start of Adverse Event

| | | |
|-----|-------|------|
| | | |
| day | month | year |

 Investigator was informed on

| | | |
|-----|-------|------|
| | | |
| day | month | year |

Stop of Adverse Event

| | | |
|-----|-------|------|
| | | |
| day | month | year |

 Stop unforeseeable

Description, course and treatment of serious adverse event *(please specify)*

Event is serious due to *(please check where applicable, multiple answers possible)*

Death
 Life-threatening
 Hospitalisation / Prolongation of Hospitalisation / Intensive Care

Secondary Neoplasia
 Persistent or significant disability or incapacity

Congenital Anomalia / Birth Defect
 Other _____ *(Please specify)*

Medical Report
 attached
 will be sent a.s.a.p.

Relevant primary and concurrent diseases

Changes in laboratory values associated with the SAE

| Trial medication | Dose | Start of relevant Cycle | Last administered | Discontinued <input type="checkbox"/> No <input type="checkbox"/> Yes | | | | | | | | | | | | | | | | |
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| 1. Adriamycin | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">mg/m² BSA</td></tr> </table> | | | | mg/m ² BSA | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year |
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| 2. Dacarbazine | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">mg/m² BSA</td></tr> </table> | | | | mg/m ² BSA | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year |
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| 3. Vinblastin | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">mg/m² BSA</td></tr> </table> | | | | mg/m ² BSA | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year |
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| 4. Lenalidomide | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">mg abs.</td></tr> </table> | | | | mg abs. | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year | <table style="display: inline-table; border-collapse: collapse;"> <tr><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td><td style="border: 1px solid black; width: 20px; height: 15px;"> </td></tr> <tr><td style="font-size: 8px;">day month year</td></tr> </table> | | | | day month year |
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| Supportive medication | Dose / Day | Start of relevant Cycle | Last administered | Discontinued <input type="checkbox"/> No <input type="checkbox"/> Yes | | | | | | | | | | | | | | | | |
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| SAE is assumed to be associated with trial medication: <input type="checkbox"/> Individual agent _____ (enter No. of trial medication from page 1) <input type="checkbox"/> AVD-Rev | Causality <input type="checkbox"/> certain <input type="checkbox"/> probable <input type="checkbox"/> possible <input type="checkbox"/> improbable <input type="checkbox"/> not associated <input type="checkbox"/> not assessable | | | | | | | | |
| SAE is assumed to be associated with supportive medication: _____ _____ | Causality <input type="checkbox"/> certain <input type="checkbox"/> probable <input type="checkbox"/> possible <input type="checkbox"/> improbable <input type="checkbox"/> not associated <input type="checkbox"/> not assessable | | | | | | | | |
| Outcome of SAE <input type="checkbox"/> Recovered <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Lasting damage <input type="checkbox"/> Unknown <input type="checkbox"/> Death Date of Death <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td></tr><tr><td style="font-size: 8px; text-align: center;">day</td><td style="font-size: 8px; text-align: center;">month</td><td style="font-size: 8px; text-align: center;">year</td><td></td></tr></table> Cause of Death _____ | | | | | | day | month | year | |
| | | | | | | | | | |
| day | month | year | | | | | | | |
| Date <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td></tr><tr><td style="font-size: 8px; text-align: center;">day</td><td style="font-size: 8px; text-align: center;">month</td><td style="font-size: 8px; text-align: center;">year</td><td></td></tr></table> Place _____ Signature of Investigator _____ | | | | | | day | month | year | |
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| day | month | year | | | | | | | |

**Please fax without delay to GHSG Studienzentrale, 50937 Köln, Fax +49 / 221 / 478 - 88188
In addition, please send a detailed medical report to the GHSG Studienzentrale within 3 days !**

| | | | | | | | | | | |
|---|---|------|---|--|-----|-------|------|-------|---|--|
| <u>Please do NOT complete the following fields. They will be completed by the sponsor.</u> | | | | | | | | | | |
| Name and Address of Sponsor Universität zu Köln Albertus Magnus-Platz 50923 Köln | Name and Address of the Trial Chairman (Representative of the Sponsor) Prof. Dr. A. Engert Klinikum der Universität zu Köln Klinik I für Innere Medizin Kerpener Str. 62 50937 Köln | | | | | | | | | |
| Trial Code _____ EudraCT No. _____ | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;"> Assessment of Causality corresponds with Trial Site Assessment <input type="checkbox"/> Yes <input type="checkbox"/> No </td> </tr> </table> | | Assessment of Causality corresponds with Trial Site Assessment <input type="checkbox"/> Yes <input type="checkbox"/> No | | | | | | | |
| Assessment of Causality corresponds with Trial Site Assessment <input type="checkbox"/> Yes <input type="checkbox"/> No | | | | | | | | | | |
| Date of Receipt of SAE Report: <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td></tr><tr><td style="font-size: 8px; text-align: center;">day</td><td style="font-size: 8px; text-align: center;">month</td><td style="font-size: 8px; text-align: center;">year</td><td></td></tr></table> | | | | | day | month | year | | Evaluation of the Event Serious <input type="checkbox"/> Yes <input type="checkbox"/> No Unexpected <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| | | | | | | | | | | |
| day | month | year | | | | | | | | |
| Do any safety aspects result from the event that influence the so far assumed risk-benefit-ratio? <input type="checkbox"/> No <input type="checkbox"/> Yes Do any safety aspects result from the event that necessitate changing the trial protocol? <input type="checkbox"/> No <input type="checkbox"/> Yes Do any safety aspects result from the event that necessitate terminating the trial protocol? <input type="checkbox"/> No <input type="checkbox"/> Yes | | | | | | | | | | |
| Date <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td></tr><tr><td style="font-size: 8px; text-align: center;">day</td><td style="font-size: 8px; text-align: center;">month</td><td style="font-size: 8px; text-align: center;">year</td><td></td></tr></table> _____ <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Place / Signature of reporting physician of GHSG Stamp of GHSG Studienzentrale </div> | | | | | | | day | month | year | |
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| day | month | year | | | | | | | | |