

Sending institution (please stamp here) Phone: _____	Patient data (including birth name and date of birth)
GHSG Studienzentrale Uniklinik Köln 50937 Cologne Germany Phone +49 / 221 / 478 - 88166 Fax +49 / 221 / 478 - 88188	<h2 style="margin: 0;">Adverse Event Report</h2> <div style="display: flex; justify-content: center; align-items: center; gap: 10px;"> <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;"> </div> </div> <div style="display: flex; justify-content: center; align-items: center; gap: 10px; margin-top: 5px;"> Day Month Year </div> <div style="text-align: right; margin-top: 10px;"> <h1 style="font-size: 2em; margin: 0;">AE</h1> <p style="margin: 0;">AVD-Rev 03/10 V1.0</p> </div>

Trial AVD-Rev	CRF ID Case ID												
<input type="checkbox"/> Initial Report <input type="checkbox"/> Follow up Report Treatment Cycle No. _____													
Start of Adverse Event <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	Investigator was informed on <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year
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day	month	year											
Description, course and treatment of Adverse Event <i>(please specify)</i> <hr/> <hr/> <hr/>													
Medical Report <input type="checkbox"/> attached <input type="checkbox"/> follows													

Relevant primary and concurrent diseases

Changes in laboratory values associated with the AE
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Trial medication	Dose	Start of relevant cycle	Last administered	Discontinued <input type="checkbox"/> no <input type="checkbox"/> yes																								
1. Adriamycin	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table> mg/m ² BSA				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year
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2. Dacarbazine	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table> mg/m ² BSA				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year
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3. Vinblastine	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table> mg/m ² BSA				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year
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4. Lenalidomide	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table> mg abs.				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td><td style="width: 30px; height: 20px;"> </td></tr> <tr><td>day</td><td>month</td><td>year</td></tr> </table>				day	month	year
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Supportive medication	Dose / Day	Start of treatment	Last administered	Discontinued <input type="checkbox"/> no <input type="checkbox"/> yes																								
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AE is assumed to be associated with trial medication:

- Individual agent _____ (enter No. of trial medication from page 1)
- AVD-Rev

Causality

- certain probable possible
- improbable not associated
- not assessable

AE is assumed to be associated with supportive medication:

Causality

- certain probable possible
- improbable not associated
- not assessable

Outcome of AE

- recovered not yet recovered

Date

day	month	year

 Place _____ Signature of Investigator _____

Please send this form together with scheduled documentation forms to the 'GHSB Studienzentrale'.