

(Stempel des einsendenden Instituts)  Telefon: _____  GHSG Studienzentrale Unikliniken Köln  50924 Köln  Tel.: 0221/ 478-88200,- 88163 Fax.: 0221/ 478-88188		Patientendaten (einschl. Geburtsname und –Datum, Geschlecht)       <div style="display: flex; justify-content: space-between;"> <div style="width: 80%;"> <b>Bericht über ein Schweres Unerwünschtes Ereignis</b>  <div style="display: flex; justify-content: center; margin-top: 10px;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: center; margin-top: 5px;"> <span style="margin-right: 10px;">Tag</span> <span style="margin-right: 10px;">Monat</span> <span>Jahr</span> </div> </div> <div style="width: 15%; text-align: center; font-size: 2em; font-weight: bold;">SAE</div> <div style="width: 5%; text-align: right; font-size: 0.8em;">06/08 V1.0</div> </div>		
<b>Studie:</b> PVAG-14 Pilot		<b>Bogen ID:</b> _____ <b>Case ID:</b> _____		
<input type="checkbox"/> <b>Erstmeldung</b> <input type="checkbox"/> <b>Folgemeldung</b> <b>Behandlungszyklus Nr.:</b> ____				
<b>Beginn des unerwünschten Ereignisses :</b>		<b>Kenntnis des Prüfarztes seit:</b>		
<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>		<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>		
<b>Ende des unerwünschten Ereignisses :</b>				
<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>		<input type="checkbox"/> Ende noch nicht absehbar		
<b>Beschreibung, Verlauf und Therapie des unerwünschten Ereignisses (Klartext):</b> <hr/> <hr/> <hr/>				
<b>Ereignis ist schwerwiegend weil (bitte zutreffendes ankreuzen, Mehrfachantworten möglich)</b> <input type="checkbox"/> Tödlicher Verlauf <input type="checkbox"/> Lebensbedrohlich <input type="checkbox"/> Hospitalisierung / Verlängerung der Hospitalisation/ Intensivstation <input type="checkbox"/> sekundäre Malignität <input type="checkbox"/> andauernde körperliche Behinderung/Funktionseinschränkung <input type="checkbox"/> kongenitale Anomalien/Geburtsdefekte <input type="checkbox"/> andere _____ (Klartext)				
<b>Arztbrief:</b> <input type="checkbox"/> im Anhang beigefügt <input type="checkbox"/> folgt innerhalb von 3 Tagen				
<b>Relevante Grund- und Begleiterkrankungen:</b> <hr/>				
<b>Veränderungen von Laborparametern in Zusammenhang mit SAE:</b>				
Studienmedikation	Dosierung / Tag	Beginn des relevanten Zyklus	Zuletzt gegeben am	Abgesetzt <input type="checkbox"/> nein <input type="checkbox"/> Ja
1. Prednison	<div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> mg absolut	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>
2. Vinblastin	<div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> mg/m <sup>2</sup> KOF	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>
3. Doxorubicin	<div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> mg/m <sup>2</sup> KOF	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>
4. Gemcitabin	<div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> mg/m <sup>2</sup> KOF	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>	<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.8em; margin-top: 2px;"> <span>Tag</span> <span>Monat</span> <span>Jahr</span> </div>

