

## END OF STUDY FORM

**ITCompl = Completion of investigational treatment**

**ReasIIT = Primary reason for not completing investigational treatment**

**BreakRand = Random code broken**

**DatBreakRand = Date of breaking randomization code**

**FormCompl = Completion of study forms**

**ReasNonCompl = Reason not completing study forms**

**DatEndStud = Date of End study participation**

**ReasEndStud = Primary reason for end of study participation**

<b>1. CDE Variable</b>	ITCompl = Completion of investigational treatment ReasIIT = Primary reason for not completing investigational treatment BreakRand = Random code broken DatBreakRand = Date of breaking randomization code FormCompl = Completion of study forms ReasNonCompl = Reason not completing study forms DatEndStud = Date of End study participation ReasEndStud = Primary reason for end of study participation
<b>2. CDE Definition</b>	This module captures important information relevant to protocol experience. It is applicable both to observational studies and to clinical trials. The first section captures general information on study completion, the second is more focused on trials on investigational treatments. The element 'full investigational treatment' describes whether the patient did or did not complete the full course of investigational treatment. Reasons for not completing the full investigational treatment are additionally documented. The element 'BreakRand' documents whether the randomization code was broken at any time at the site during the treatment period. If this happens, the date is recorded under the element 'DatBreakRand' and comments entered as free text. The element 'FormCompl' documents whether all forms required by protocol and case report form have been completed at the end of study duration. If not all the forms have been completed, the primary reason is documented under 'ReasNonCompl'.
<b>3. Recommended instrument for assessment</b>	N/A. Date end of study participation: calendar. Date breaking randomization code: calendar.
<b>4. Description of measure</b>	Binary/categorical; unique entry.

<p><b>5. Permissible values</b></p>	<p><u>Date end of study participation:</u> DD-MMM-YYYY 99-999-9999 if unknown</p> <p><u>Reason for end of study participation:</u></p> <ul style="list-style-type: none"> <li>- Completion of study</li> <li>- Inability to obtain follow-up</li> <li>- Withdrawal from study (by patient or representative)</li> <li>- Adverse event(s)</li> <li>- Decision for DNR* <ul style="list-style-type: none"> <li>+ date: DD-MMM-YYYY, 99-999-9999 if unknown</li> <li>+ time: HH-MM, 99-99 if unknown</li> </ul> </li> <li>- Withdrawal of support <ul style="list-style-type: none"> <li>+ date: DD-MMM-YYYY, 99-999-9999 if unknown</li> <li>+ time: HH-MM, 99-99 if unknown</li> </ul> </li> <li>- Death</li> <li>- Other</li> </ul> <p style="margin-left: 40px;">*DNR = do not resuscitate</p> <p><u>Completion of study forms:</u> no/yes If no, please state primary reason:</p> <ul style="list-style-type: none"> <li>- Consent withdrawn</li> <li>- Violation study conduct</li> <li>- Other _____</li> </ul> <p><u>Completion investigational treatment:</u> no/yes If no, please state primary reason:</p> <ul style="list-style-type: none"> <li>- Death</li> <li>- Withdrawal from study (by patient or representative)</li> <li>- Problems with treatment delivery (e.g. infusion problems, no medication available)</li> <li>- Adverse event(s)</li> <li>- Withdrawal of active treatment</li> </ul> <p><u>Random code broken:</u> no/yes/ Not applicable <u>Date:</u> DD-MMM-YYYY 99-999-9999 if unknown Add comments as free text</p>
<p><b>6. Classification: Basic/Intermediate/Advanced</b></p>	<p>Identical</p>
<p><b>7. Procedure</b></p>	<p>Document all required information as accurately as possible when the patient has completed the study course.</p>
<p><b>8. Comments/Special instructions:</b> Completion of this form is mandatory.</p>	
<p><b>9. Rationale/justification:</b> This form documents essential information relative to study participation.</p>	

**10. References:**

N/A