

1 **Appendix 7: Unblinding Procedure**

2 The study treatment will be unblinded after Database Lock. While the safety of patients should
3 always take priority, maintenance of blinding is crucial to the integrity of a double-blind trial. Before
4 this planned unblinding, the blinding for a specific patient should only be broken when information
5 about the patient's protocol treatment is considered necessary to manage Serious Adverse Events
6 (emergency unblinding). Unblinding procedures should preferably be initiated only after consultation
7 of the principal investigator/coordinating investigator or his/her representative. To initiate an
8 emergency unblinding the pharmacy in charge of the randomisation list should be contacted.
9 Breaking the blinding on a patient will be logged and reported to the coordinating Investigator within
10 24 hours following the unblinding procedure, using the Emergency Unblinding Form. It is considered
11 a major protocol violation, after which the patient goes off protocol treatment (if applicable).