

**TARDIS - Working Practice Document – No: 045****Title: SAE/Bleeding Events**

All outcomes from the TARDIS trial will be reviewed twice in the first instance. They will be reviewed by independent adjudicators, blinded to treatment allocation and the result of the other adjudication.

When calculating the size of drop in Hb - the baseline Hb will be considered as the starting point, unless there is a more recent blood result that is closer in time to the reported event.

The Hb result after the reported event, or any subsequent lower value (so long as immediately following the event) will be considered.

Clinical details, the timing of the drop and the level of Hb drop will be taken into account when categorising bleeding events.

In cases where there is a disagreement between two adjudicators, a third adjudicator will be approached. If two adjudicators give the same assessment, this will resolve the case. If all three adjudicators have different results, the case will need to be resolved by discussion and case review.

If there is any doubt regarding the categorisation of a bleed, for safety reasons, the highest category of bleed will be reported, so as to avoid under reporting of bleeding events.