The dual primary endpoint of the study remained the same throughout the trial, and as per protocol v3.0 23/6/2014 the primary endpoint was defined as:

1. The number of patients in whom, by consensus, no further treatment is required.

2. Change in central retinal thickness as measured by Spectralis spectral domain Optical Coherence Tomography

The protocol clarified that "The 'number of patients in whom, by consensus, no further treatment is required' is to be decided with use of 2 study fellows, with Consultant back up as third opinion, looking at all the data collected on any one patient, (including VA, OCT-CRT, morphology, QOL measures etc) and each independently deciding, as is done in clinic all the time, whether a further IVI is required. This will allow the study investigators to make the study more clinically relevant and assess more accurately if this drug will be able to replace Triamcinolone in the uveitis clinic setting. We have chosen to have change in CRT as a further primary outcome."

The primary analysis was conducted by the statistician in line with the approved statistical analysis plan.

The study ended on 18 June 2014 (LPLV). On 3 November 2014 the study database was locked. The statistical analysis plan was signed off on 17 November 2014. On 28 November 2014, the final statistical analysis was agreed by the statisticians. This showed: 3 patients did not require further treatment at 6 months and 5 patients did not require further treatment at 12 months. This information was added to the statistical section of the TMF.

The statement 'no further treatment is required' was not clarified at the study start or throughout the study conduct. After the primary analysis was undertaken it was clear that this statement could be interpreted as either:

- The patient did not respond to the IMP (non-responders) and requires a different treatment or,

- The patient responded to the IMP and did not require further treatment

When the statistical analysis of the study was reviewed, it appeared that a different interpretation of the statement by the study sub-investigator has resulted in inconsistencies in the study data entered into the study database, and therefore upon identification of this perceived inconsistency in the primary outcome definition an "post hoc" analysis was undertaken with review of primary outcome for each patient.

The "post hoc" analysis was based on the clarification of the primary endpoint definition as: 'no further treatment is required' would be interpreted on the basis that there was treatment response, i.e. the patients were classified as responders and further treatment would not be required/warranted. The PI and the study fellow reviewed the patients' records based on the clarified definition and this showed that 6 patients did not require further treatment at 6 months and 9 patients did not require further treatment at 12 months, which differs for the original primary analysis.

The original end of study report uploaded included this "post hoc" analysis, and therefore this further file note was drafted to clarify the results of the study. The EudraCT system has been completed in line with the original analysis as per protocol, and the "post hoc" analysis has also been uploaded.