MACUSTAR: Development of Novel Clinical Endpoints in Intermediate AMD

Date: 09.02.2024

MACUSTAR Statistical Analysis Plan (SAP):

Publishable Summary SAP Cross-sectional part

The aim of cross-sectional part of the MACUSTAR clinical study is to evaluate the sensitivity, repeatability and discriminant ability of the candidate functional, structural and patient-reported endpoints. Statistical methods will be used to evaluate these parameters across and with respect to the disease stages (no AMD, early AMD, intermediate AMD, late AMD). The MACUSTAR working group statistics and members of the work packages 1 to 4 on the clinical study, functional testing, patient-reported outcomes and imaging have developed a statistical analysis plan for the cross-sectional part of the MACUSTAR study. This statistical analysis plan encompasses descriptive statistics, data exploration, repeatability analyses and correlation analyses, describing the statistical methods intended to be used.

Publishable Summary SAP Longitudinal part

The aim of longitudinal part of the MACUSTAR clinical study is to evaluate the prognostic power of structural, functional and patient-reported markers with regard to progression from iAMD to late AMD (nAMD and GA) and previous structural states. Members of MACUSTAR have developed a statistical analysis plan for the longitudinal part of the MACUSTAR study. This statistical analysis plan encompasses descriptive statistics, primary and secondary endpoints of the longitudinal part and nonconfirmatory analyses. Time-to event methods will be used to assess the associations between markers and progression.