**Abstract**

**Background:** The French Health Technology Assessment agency requested information on the ranibizumab (RBZ) use and impact in real-world setting.

**Objectives:** To assess the effectiveness and patterns of use of RBZ intravitreal injections (IVI) for patients with visual impairment due to diabetic macular edema (DME) for up to 36-month follow-up.

**Methods:** This is a real-world, post-authorization, observational cohort study in adult patients with RBZ intravitreal injections initiation for best-corrected visual acuity (BCVA) loss due to DME, followed-up for up to 36 months by their ophthalmologist. The primary endpoint was BCVA evolution from baseline to Month 12.

**Results:**
- Overall improvement in BCVA was observed from 3-month follow-up, then mean BCVA remains stable at 6, 9, and 12 months with high variability in patients (Figure 2).
- During the follow-up, the mean BCVA change from baseline was:
  - +6.6 (10.7) letters ([95% CI]: [8.0; 8.2]) at 3-month follow-up (p < 0.05),
  - +6.7 (14.1) letters ([95% CI]: [4.8; 8.7]) at 6-month follow-up (p < 0.05),
  - +6.9 (14.5) letters ([95% CI]: [4.9; 8.9]) at 9-month follow-up (p < 0.05),
  - +7.4 (14.4) letters ([95% CI]: [5.4; 9.4]) at 12-month follow-up (p < 0.05).
- At 12-month follow-up, 36.8% of patients had BCVA above 70 letters (Figure 3).

**Conclusion:** This real-world study of patients with ranibizumab IVI treatment initiation in DME showed an improvement of visual acuity close to the results of the preregistration randomized clinical trial (7.4 letters at 12 months) with a lower frequency of ranibizumab IVI in real-world (5.1 in BOREAL vs 7 injections in RESTORE at 12 months).