

Diabetic Macular Edema

**A Study to Evaluate Efficacy, Safety & Pharmacokinetics of the Port Delivery System (PDS) With Ranibizumab in Participants With Diabetic Macular Edema (DME) Compared With Intravitreal Ranibizumab A Substudy to Evaluate the Safety of Re-Implanting the PDS With Ranibizumab in Participants With DME**

**Trial Status**

Active, not recruiting

**Trial Runs In**

1 Countries

**Trial Identifier**

NCT04108156 GR40550

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*The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.*

***Trial Summary:***

This study will evaluate the efficacy, safety, and pharmacokinetics of the PDS with Ranibizumab in participants with DME when treated every 24 weeks (Q24W) compared with intravitreal ranibizumab 0.5 mg every 4 weeks (Q4W). The substudy will evaluate the safety of re-implanting the updated PDS with ranibizumab and the refill-exchange procedures following re-implantation in participants with DME who were previously enrolled in the main Study, GR40550. Up to 100 participants from the main study will be enrolled and followed for a maximum of 72 weeks post-re-implantation in the substudy.

**Hoffmann-La Roche**

Sponsor

**Phase 3**

Phase

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**NCT04108156 GR40550**

Trial Identifiers

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***Eligibility Criteria:***

**Gender**

All

**Age**

>=18 Years

**Healthy Volunteers**

No

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