# FOURIER OLE

NCT02867813

**Principal Investigator:** Dr. John Collins, MD (S. Washington Office)

**Condition:** Dyslipidemia

**Biological:** Evolocumab

**Official Title:** Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk Open-label Extension

**Sponsor:** Amgen

**Purpose:** The primary clinical hypothesis is that long-term exposure of evolocumab will be safe and well tolerated in subjects with clinically evident atherosclerotic cardiovascular disease (CVD).

**Inclusion Criteria:**

- Subject has provided informed consent before initiation of any study-specific activities/procedures
- Subject has completed FOURIER (Study 20110118) while still receiving assigned investigational product.

**Exclusion Criteria:**

- Investigational product was permanently discontinued during FOURIER for any reason, including an adverse event or serious adverse event
- Subject is currently receiving treatment in another investigational device or drug study, or ended treatment on another investigational device or drug study(ies) within less than 4 weeks. Other investigational procedures while participating in this study are excluded
- Subject is not likely to be available to complete protocol-required study visits or procedures and/or to comply with required study procedures to the best of the subject's and investigator's knowledge
- Subject has a history or evidence of any other clinically significant disorder, condition, or disease that, in the opinion of the investigator or Amgen physician, if consulted, would pose a risk to subject safety or interfere with the study evaluation, procedures, or completion
- Subject has a known sensitivity to any of the active substances or excipients (eg, carboxymethylcellulose) to be administered during dosing
- Female subject is pregnant or breastfeeding or is planning to become pregnant or planning to breastfeed during treatment with evolocumab and within 15 weeks after the end of treatment with evolocumab
- Female subjects of childbearing potential who are not willing to use an acceptable method(s) of effective birth control during treatment with evolocumab and for an additional 15 weeks after the end of treatment with evolocumab are excluded

**Source:** https://clinicaltrials.gov/ct2/show/NCT02867813
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