

# RELYABLE

**Principal Investigator:**

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**Sponsor:**

Boehringer Ingelheim

**Study Purpose:**

RELY-ABLE long term multi-center extension of dabigatran treatment in patients with atrial fibrillation who completed the RE-LY trial and a cluster randomised trial to assess the effect of a knowledge translation intervention on patient outcomes.

**Objective:**

To establish the long term safety of dabigatran etexilate and to assess the efficacy of a knowledge translation intervention on the prognosis, cardiovascular risk profile and quality of care in patients with atrial fibrillation (AF).

**Inclusion:**

1. Randomization to dabigatran in RE-LY and not permanently discontinued from dabigatran at the time of RE-LY termination visit
2. Patient must require long-term treatment with oral anticoagulation and investigator determines it is clinically appropriate for patient to continue receiving oral anticoagulation.
3. Written, informed consent

**Exclusion:**

1. Need for anticoagulant treatment for disorders other than atrial fibrillation
2. Plan to perform a pulmonary vein ablation or surgery for cure of AF
3. Patients with prosthetic heart valves requiring anticoagulation differing from an INR of 2.0–3.0
4. Symptomatic or endoscopically documented gastroduodenal ulcer disease in the 30 days prior to the start of this trial
5. Severe renal impairment (estimated creatinine clearance  $\leq 30$  mL/min) based upon last results available from RE-LY 1160.26 (should be from within the past year)
6. Anaemia (haemoglobin  $< 100$ g/L) or thrombocytopenia (platelet count  $< 100 \times 10^9$ /L) based upon last results available from RE-LY 1160.26 (should be from within the past year).
7. Uncontrolled hypertension (SBP  $> 180$  mmHg and/or DBP  $> 100$  mmHg)

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8. Active liver disease, including known hepatitis A, B or C
9. Active infective endocarditis
10. Women who are pregnant, lactating or of childbearing potential who refuse to use a medically acceptable form of contraception throughout the study
11. Patients who have received an investigational drug other than dabigatran in the past 30 days or are participating in another drug study.
12. Patients considered unreliable by the investigator concerning the requirements for follow-up during the study and/or compliance with study drug administration (i.e., demonstrated study drug compliance of less than 80% in RE-LY or was noncompliant with study visits in RE-LY), or has any condition which in the opinion of the investigator would not allow safe participation in the study (e.g., drug addiction, alcohol abuse).
13. Current use of quinidine

**Status:**

Follow-up Only!

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.