

# ENGAGE AF

**Principal Investigator:**

William Felten, MD (Midland)

**Sub-Investigators:**

Robert Genovese, MD

Rodney Diehl, DO

Ed Flattery, Pa-C

**Sponsor:**

DIICHI Sankyo Pharma development

**Study Purpose:**

A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel Group, Multi-Center, Multi-National Study for Evaluation of Efficacy and Safety of DU-176b Versus Warfarin In Subjects With Atrial Fibrillation - Effective Anticoagulation With Factor Xa Next Generation in Atrial Fibrillation (**ENGAGE - AF** TIMI - 48)

**Objective:**

To compare DU-176b to warfarin with regard to the composite primary endpoint of stroke and systemic embolic events.

**Inclusion Criteria:**

- 21 years of age or older; male or female.
- Able to provide written informed consent.
- History of documented AF within the prior 12 months
- A moderate to high risk of stroke, as defined by CHADS2 index score of at least 2

**Exclusion Criteria:**

- Transient atrial fibrillation secondary to other reversible disorders
- Subjects with moderate or severe mitral stenosis, unresected atrial myxoma, or a mechanical heart valve
- Subjects with any contraindication for anticoagulant agents;
- Subjects with conditions associated with high risk of bleeding or have known or suspected hereditary or acquired bleeding disorders
- Females of childbearing potential including the following:
  - Females with a history of tubal-ligation
  - Females less than 2 years post-menopausal

**Status:**

## **ENGAGE AF**

Active enrollment

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.