# CANVAS Trial (AFT-28)

**DOACS versus LMWH +/- Warfarin for VTE in Cancer: A Randomized Effectiveness Trial**

**Co-Chairs: Jean Connors MD & Deborah Schrag MD MPH**
**Dana-Farber Cancer Institute, Boston, MA**

ALLIANCE FOUNDATION TRIALS, LLC

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National Blood Clot Alliance

TAP TO RETURN TO KIOSK MENU

rationale
study schema
treatment plan
eligibility criteria
feasibility
follow up

- Cancer patients are at risk for VTE (venous thromboembolism)
- Anticoagulation therapy is necessary to prevent recurrent VTE
- Current practice patterns are a hybrid use of LMWH+/-warfarin
- Recently, the FDA has approved 4 Direct Oral Anticoagulants (DOACs) for VTE based on efficacy trials showing noninferiority to warfarin

Given the myriad exclusion criteria present in efficacy trials, more evidence is needed to inform the **effectiveness of DOACs in cancer**

## RATIONALE

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Enroll eligible participant within 30 days of DVT/PE diagnosis at any site where VTE is Symptomatic or Image-Detected

R 1:1

**Arm 1: Intervention (DOAC)**

MD and patient choose:
• Rivaroxaban • Apixaban
• Edoxaban • Dabigatran

**Arm 2: Usual Care (LMWH +/- Warfarin)**

MD and patient choose:
• Dalteparin • Enoxaparin
• Fondaparinux • Warfarin

**Study Outcomes**

- Recurrent VTE
- Bleeding
- Survival

**Current Accrual: 707**
**Study-wide Accrual Goal: 890**

## STUDY SCHEMA

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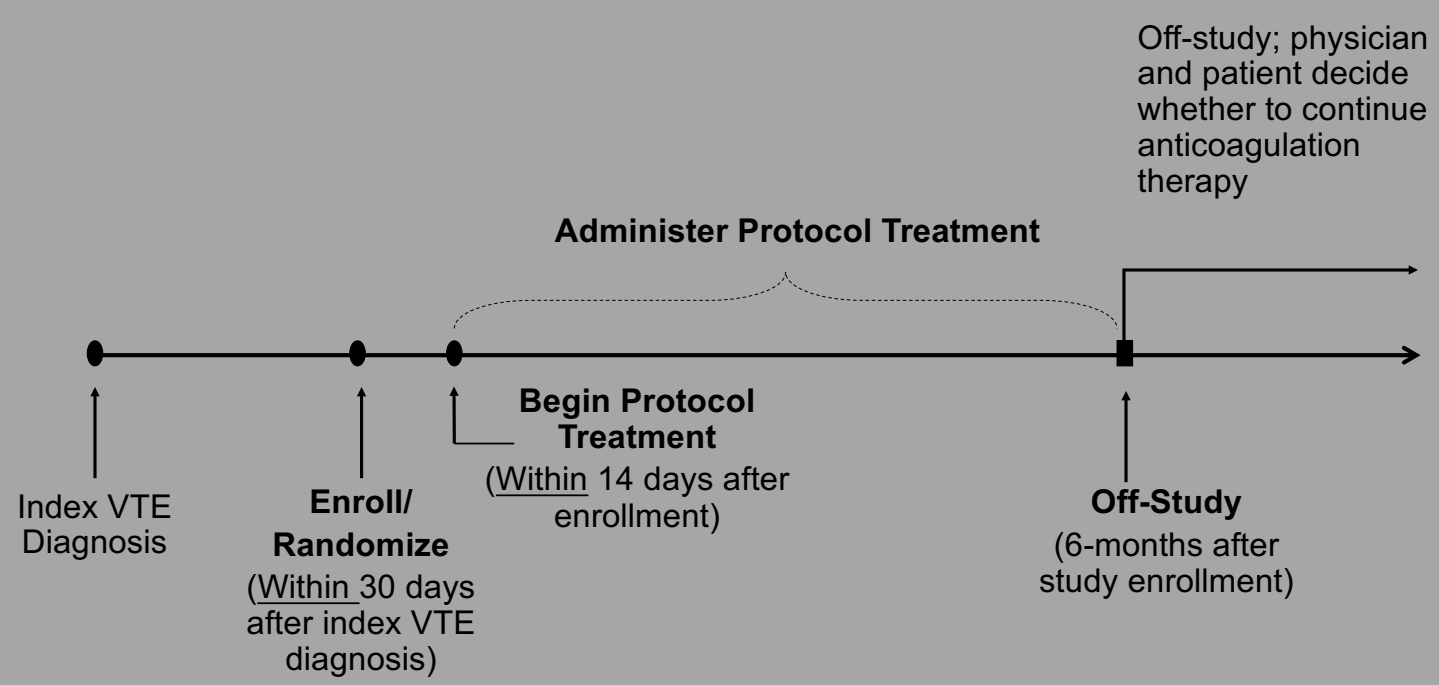


## TREATMENT PLAN

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## Inclusion

- **Cancer Diagnosis**
  - Diagnosis of an **advanced** solid tumor, lymphoma, chronic lymphocytic leukemia (CLL), or myeloma (no time restrictions or limitations) **–OR–** diagnosis of **early** stage solid tumor cancer, lymphoma, chronic lymphocytic leukemia (CLL), or myeloma ≤ 12 months prior to study enrollment.
- **VTE within 30 Days**
  - Diagnosis may be made based on physical exam or imaging studies. Participants with both symptomatic and asymptomatic VTEs are eligible.
  - Any anticoagulation drug/strategy may be used to treat the index VTE; protocol treatment will begin ≤ 14 days after enrollment.
  - Intend anticoagulation therapy for ≥ 3 mo.
- **Age ≥ 18 Years**
- **Platelet ≥ 50,000/mm$^3$** (≤ 7 days prior to enrollment)
- **CrCl ≥ 15 ml/min** (≤ 7 days prior to enrollment)

## Exclusion

- **Acute Leukemia**
- Received or scheduled to receive **alloHSCT**
- Scheduled to receive **autoHSCT**
- Significant **bleeding (**CTCAE **grade 3** or **4)**
- Ongoing **P-gp inhibitor** or **azole antifungals**
- **Pregnant/nursing**

## ELIGIBILITY CRITERIA

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## Investigator Role

- Confirm eligibility
- Consent participant
- Prescribe anticoagulation therapy
- Report SAEs, only if they occur

## Participant Role

- Baseline questionnaire
- 3-month follow up questionnaire
- 6-month follow up questionnaire
- Drug diaries

## CRA Role

- Register & randomize participant
- Administer baseline questionnaire
- Treatment Update Form at 2 weeks
- Record episodes of bleeding and recurrent VTEs from medical record review at 6 months

****No Mandatory Appointments****

**FEASIBILITY**

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## FUNDING SUPPORT

This trial (CANVAS | AFT 28) is funded by an award from the Patient-Centered Outcomes Research Institute (PCORI)

## CONTACT US

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