**Patient Population**
See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years
- Must have previously untreated AML and be candidates for intensive induction chemotherapy; patients are allowed to have had prior hydroxyurea
- Must not have acute promyelocytic leukemia (APL) and must not have evidence of t(15;17)(q22;q21)
- ECOG PS 0 - 3 (restricted to PS 0 - 2 if age > 70 years)
- Must have LVEF > 45% or within institutional normal limits
- Must be able to lie still for a 1.5 hour PET scan
- Must not have a history of allergic reaction attributable to compounds of similar chemical or biologic composition to $^{18}$F-fluorothymidine
- Must not weigh more than the maximum weight limit for the PET/CT table for the scanner(s) to be used at each center
- The patient is participating in the trial at an institution which has agreed to perform the imaging research studies, completed the ECOG-ACRIN defined scanner qualification procedures and received ECOG-ACRIN approval as outlined in Section 9.4
- Women must not be pregnant or breast-feeding; all females of childbearing potential must have a blood test or urine study within 2 weeks prior to registration to rule out pregnancy

**Treatment Plan**
See Section 5.0 for Complete Treatment Details

- The overall goal of this study is to evaluate the Negative Predictive Value (NPV) of post-treatment FLT uptake parameters for complete remission (CR) in patients with AML
- Patients with AML who are candidates for induction chemotherapy will be enrolled in this prospective imaging trial
- Participants will receive an anthracycline (IV days 1-3 x 1-2 cycles) plus infusional cytarabine (100-200 mg/m², IV days 1-7 x 1-2 cycles)-based regimen
- All participants will receive one imaging study according to study protocol: mandatory post-treatment FLT PET/CT within three days before or after the nadir bone marrow biopsy (between Days 10-17 of treatment)
- Pre-treatment FLT PET/CT is optional
- Eligible participants will be actively involved in the trial until remission bone marrow biopsy results are available
- Patients will be followed for survival outcomes for up to 1 year beyond the end of study accrual period
- The injectable activity of FLT for most studies will be ≤ 0.07 mCi/kg of Fluorine - 18, not to exceed 5 mCi with a specific activity greater than 200 Ci/mmol at the time of injection. The amount of injected drug is ≤ 6.1 µg (≤ 25 nmol per dose) of FLT. FLT is administered to subjects by intravenous injection of ≤ 10 mL
- Patients enrolled on this imaging trial also may be enrolled in a cooperative group AML treatment study, with an understanding of data sharing between the groups to ensure the data requirements for the EAI141 project are available

**Patient Enrollment**
All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**
ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!
EAI141

**EAI141 Available Through ECOG-ACRIN Cancer Research Group**

*Early Assessment of Treatment Response in AML using FLT PET/CT Imaging*

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**Schema**

1. **PRE-REGISTRATION**
   - Bone Marrow Aspirate Submission

2. **REGISTRATION**
   - Baseline Imaging (optional)
   - [F-18] FLT PET/CT

3. **INDUCTION CHEMOTHERAPY**
   - Nadir Bone Marrow
   - Post-Treatment Imaging
   - [F-18] FLT PET/CT

4. **REMISESSION CHEMOTHERAPY**
   - Remission Bone Marrow

5. **FOLLOW UP**

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1. Pre-treatment bone marrow aspirate or peripheral blood should be sent for central review.
2. Optional imaging must be done within 1 week prior to initiation of therapy.
3. Post-Treatment imaging is mandatory and must be completed 10-17 days after initiation of first induction cycle and prior to reinduction.
4. Nadir Bone Marrow should be completed 7-10 days after completion of induction therapy. Remission Bone Marrow should be completed 28-35 days after initiation of first induction therapy.
5. Remission bone marrow aspirate should be sent for central analysis.
6. Participants will be followed for up to 1 year beyond the end of the accrual period.

**Accrual = 83 patients**