



# **Update on acute myeloid leukemia (AML) trials in older adults**

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# Outline

- Status update 361006
- Intergroup trials in development updates
  - “Unfit” older adults (SWOG led)
  - “Fit” older adults (Alliance led)

# Study Update for 361006 (intensive)

## Baseline:

1. Geriatric Assessment
2. Global QOL survey (EORTC QLQ-30)

Age ≥ 60 with FLT3 mutated, non-CBF AML

Remission induction  
Daunorubicin+cytarabine+sorafenib

## Follow-Up:

1. Geriatric Assessment
2. Global QOL survey (EORTC QLQ-30)

Consolidation (2 cycles)  
Cytarabine+sorafenib

Maintenance (12 cycles)  
Sorafenib

Analysis Underway:  
Anticipate completion  
summer 2016

Survival + “QOL” outcomes every  
6 months

- Days hospitalized
- Oncology clinic visits
- Admission to nursing home/hospice

# Intergroup trial: Non-intensive

- Target population: age  $\geq$  60 years, “unfit” for intensive therapy
- Multi-arm phase 2/3 trial testing “novel therapeutics” versus azacitidine as control
- Primary outcome: overall survival
- Secondary outcomes: toxicity, remission rates, EFS
- Proposed embedded QOL study (not yet approved):
  - Geriatric assessment
  - Physician/patient decision-making
  - Epidemiology

# Intergroup trial: Intensive

- Target population: age  $\geq$  60 years, “fit” for intensive therapy
- Randomized phase 2 trial testing novel agents (i.e. ulocuplomab, CXCR4 inhibitor) versus daunorubicin/ cytarabine (control)
- Primary outcome: EFS (P2), overall survival (P3)
- Secondary outcomes:
  - Complete remission rates
  - Adverse events
  - Describe the interaction between pretreatment patient and disease characteristics on clinical outcomes
  - Identify geriatric assessment measures associated with outcomes
  - Explore impact of treatment on physical, cognitive, psychosocial factors