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

**Consolidation (2 cycles)**
Cytarabine+sorafenib

**Follow-Up:**
1. Geriatric Assessment
2. Global QOL survey (EORTC QLQ-30)

**Maintenance (12 cycles)**
Sorafenib

**Survival +“QOL” outcomes every 6 months**
- Days hospitalized
- Oncology clinic visits
- Admission to nursing home/hospice

Analysis Underway: Anticipate completion summer 2016
Intergroup trial: Non-intensive

- Target population: age $\geq 60$ years, “unfit” for intensive therapy
- Multi-arm phase 2/3 trial testing “novel therapeutics” versus azacitididine 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

Co-PIs: Michaelis and Walter
Intergroup trial: Intensive

- Target population: age ≥ 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

PI: Uy