Beat AML Master Trial

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BEAT AML STUDY DESIGN
PHASE 2, NEWLY DIAGNOSED AML

Patient Registration
Bone Marrow Sample
Genomic Screening
< 1 Week (7 days)
Marker Positive
Marker Negative

Assign Treatment by Marker

Targeted Agent or Combination
Primary Endpoint: CR; CRi
Novel Agent

Diagnostics Assessed:
• Cytogenetics-locally with central review (Dr. N. Heerema)
• Broad NGS genomic analysis (Foundation Medicine)
• FLT3 ITD and TKD (PCR based assay, Invivoscribe)

Treatment Assigned: Centrally (JCB, RL, BD)
- November 2016
- 16 clinical sites
- 7 Pharmaceutical Companies
- 11 Sub-studies
- Over 600 patients
CHALLENGES

Start Up
- Pharmaceutical commitment
- Diagnostic Assay
- Clinical Trial Culture
- Design of database, TMF, etc.

Operations
- Data, data, data
- Monitoring
- On-going safety reporting
- Maintaining a “pipeline”
- Pharmaceutical commitment