AsTeC Overview of Progress to Date

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Project Timeline

Where we are now

Phase 1
Setting things up

Phase 2
Sample & data collection

Phase 3
Testing
Progress to date

- Creation of SOPs
  - Sample collection
  - Sample processing
  - Sample storage
  - Sample shipping
  - Inventory management (local & central)
  - Repository backup procedures
  - Quality management program
Progress to date (cont’d)

- Electronic clinical database development (with EMMES)
- Electronic sample tracking system (with EMMES)
- Electronic reporting procedures (with EMMES)
Progress to date (cont’d)

- Validation of procedures/processes
  - Shipping
  - Contamination/stability
    - David Denning
- Staff training
- Patient enrollment
- Sample Collection
Enrollment strategy

- **Group 1**
  - Patients enrolled before treatment or transplant
    - AML, HCT, lung transplant recipients

- **Group 2**
  - Patients enrolled at time of suspected IFI
Clinical annotation of samples

- Demographic information
- Underlying disease
- Disease/ transplant Treatments
- Concomitant medications
- Transfusions

**Goal:**

- Determine pre-test probability of infection
- Potentially interfering medical conditions
Adjudication of cases

- Common scoring of cases
  - Lindsey Baden
Progress to date (cont’d)

- Discussion with FDA to get feedback about our procedures, SOPs, testing strategies
  - Barb Alexander

- Development of calibrator
  - Angie Caliendo

- Manufacturer application process
  - Joe Wheat
Project Timeline

Where we plan to be 1st Quarter 2010

Phase 1
- Setting things up

Phase 2
- Sample & data collection

Phase 3
- Testing