ASTEC ASPERGILLUS TECHNOLOGY CONSORTIUM

AsTeC Overview of Progress to Date

John Wingard, MD AsTeC Principal Investigator

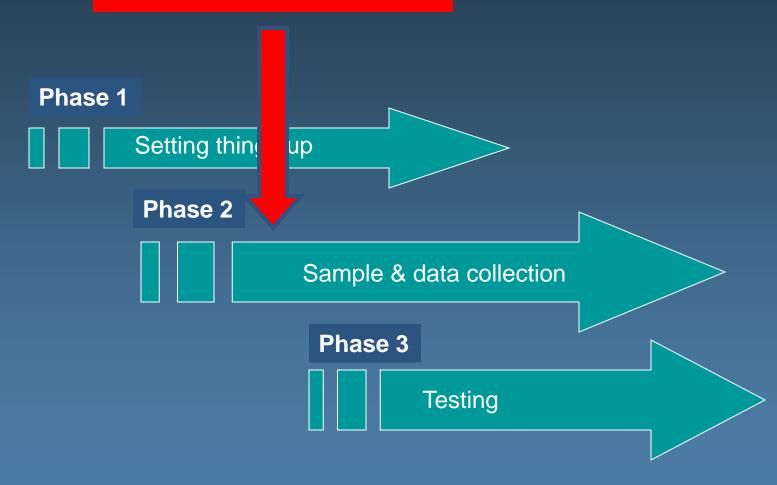
> NIH-NIAID N01-AI-70023 HHSN266200700023C 5/31/07-5/30/14





Project Timeline

Where we are now







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

