

ASPERGILLUS TECHNOLOGY CONSORTIUM

AsTeC Overview of Progress to Date

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



ASTEC



ASPERGILLUS TECHNOLOGY CONSORTIUM







INVASIVE ASPERGILLOSIS ANIMAL MODELS

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









