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ASPERGILLUS TECHNOLOGY CONSORTIUM

AsTeC Diagnostic Test Evaluation

Barbara D. Alexander, MD, MHS

AsTeC Co-Principal Investigator

Associate Professor of Medicine and Pathology

Director, Transplant Infectious Disease Services

Head, Clinical Mycology Laboratory

Duke University Medical Center

Durham, North Carolina

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INVASIVE ASPERGILLOSIS ANIMAL MODELS

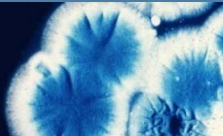
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AsTec Goals:

- Establish & maintain repository of clinical samples from pts at high risk for &/or infected with Invasive Aspergillosis
- Establish a network of laboratories compliant with Good Laboratory Practices to assess new diagnostic assays for Invasive Aspergillosis

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Assessing New Tests for Invasive Aspergillosis:

- ◆ Testing we can do with AsTeC samples

 - Participating laboratories, capabilities, & personnel

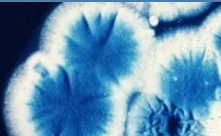
- ◆ Types of test evaluations

 - Reproducibility testing

 - Comparative testing

 - Interference substance testing

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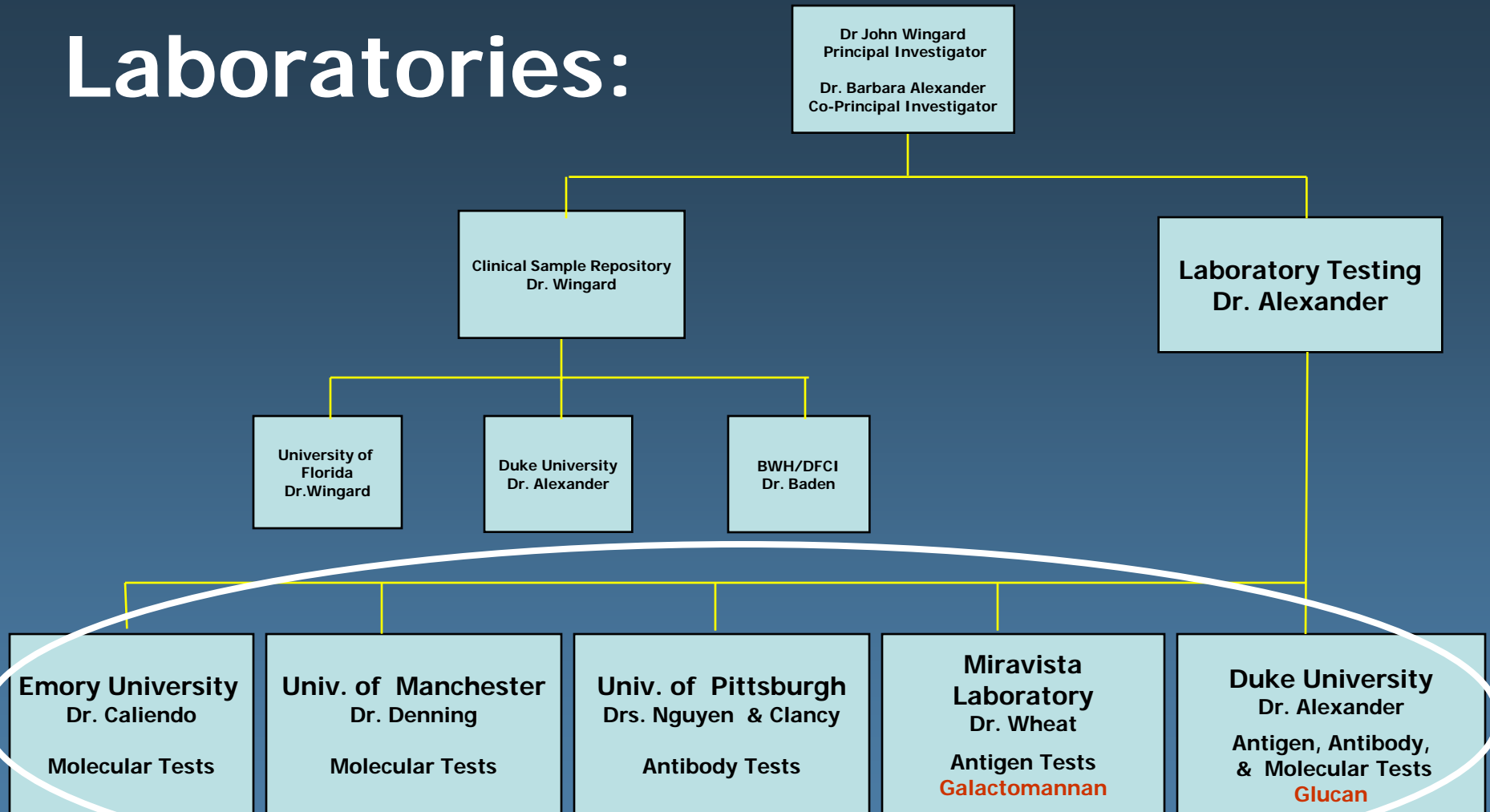
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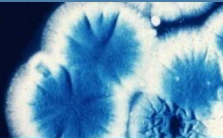
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AsTeC Laboratories:



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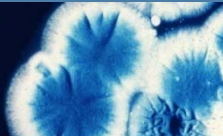
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Evaluating New Tests:

- Manufacturer initiates application process
 - Review of application by AsTeC Review Committee
- Testing will be performed in
 - Consortium laboratories following Good Laboratory Practice guidelines
- Test evaluation based on
 - Clinical Laboratory Standard Institute Reference Procedures
 - FDA Guidance Documents

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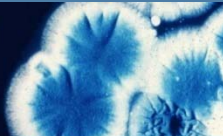
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AsTeC Testing SOPs:

- Test Evaluations
 - Replication (reproducibility)
 - Comparison with predicate devices
 - Interfering medical conditions / substances
- SOPs for different test platforms
 - Antigen, antibody, molecular based assays
- SOPs written to provide flexibility
 - Different sample types (serum, urine, BAL)
 - Individual test's specific testing procedures
- AsTeC template SOPs to be reviewed by FDA

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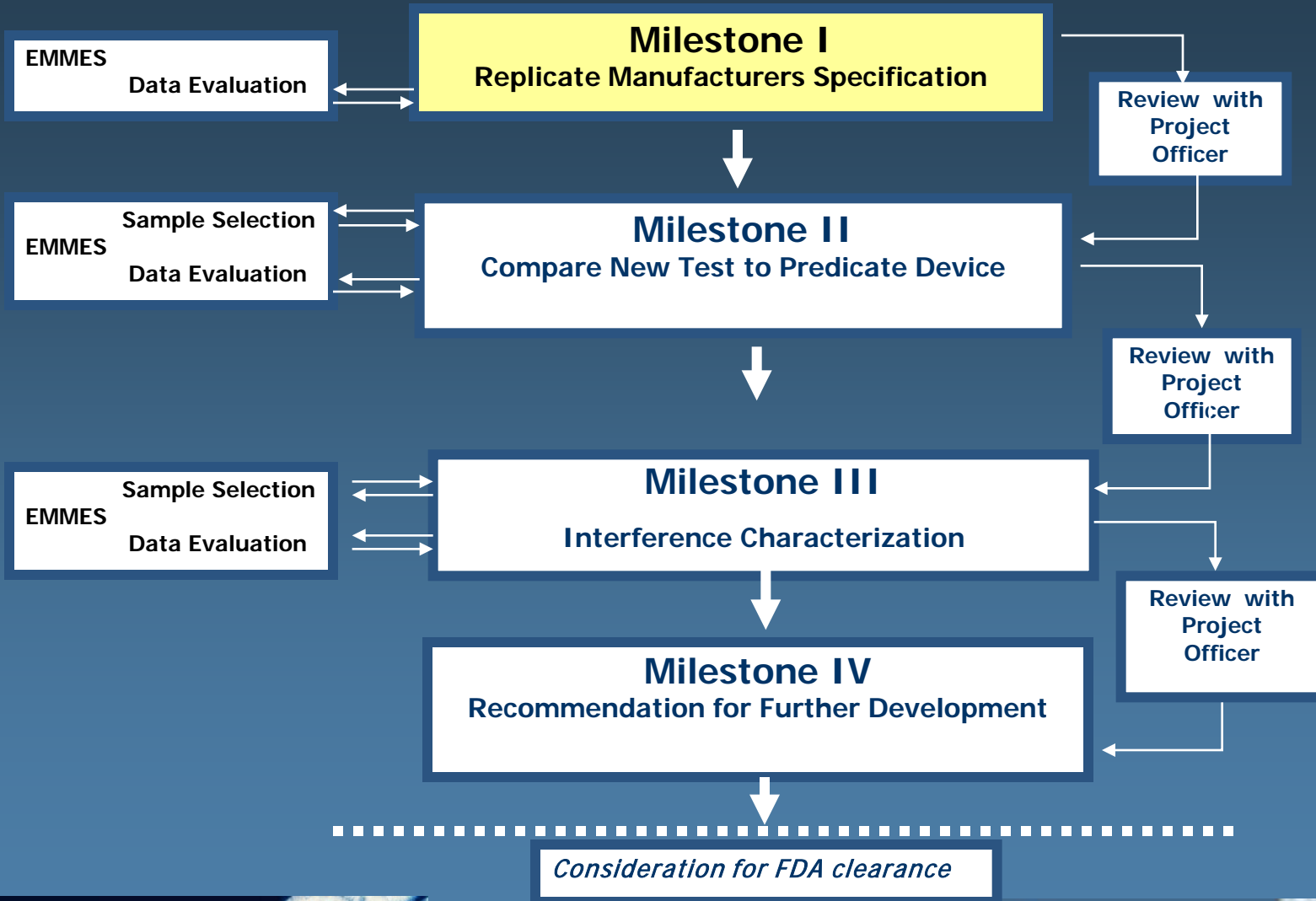


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Testing Milestones:



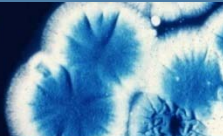
Testing Milestone 1:

Compare consortium laboratory results with manufacturer's claims or literature reports

- Replication (Reproducibility) Studies
 - Initial Repeatability Study
 - Precision
 - Limit of Detection
 - Linear range
 - Accuracy

Using NON-Consortium Specimens

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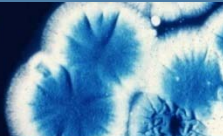
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Data Analysis:

- Data will be transferred to EMMES (Data Management Contractor) for statistical analyses
- Customized reports including graphs and tables produced
- Study Report generated for Project Officer review and the test Manufacturer

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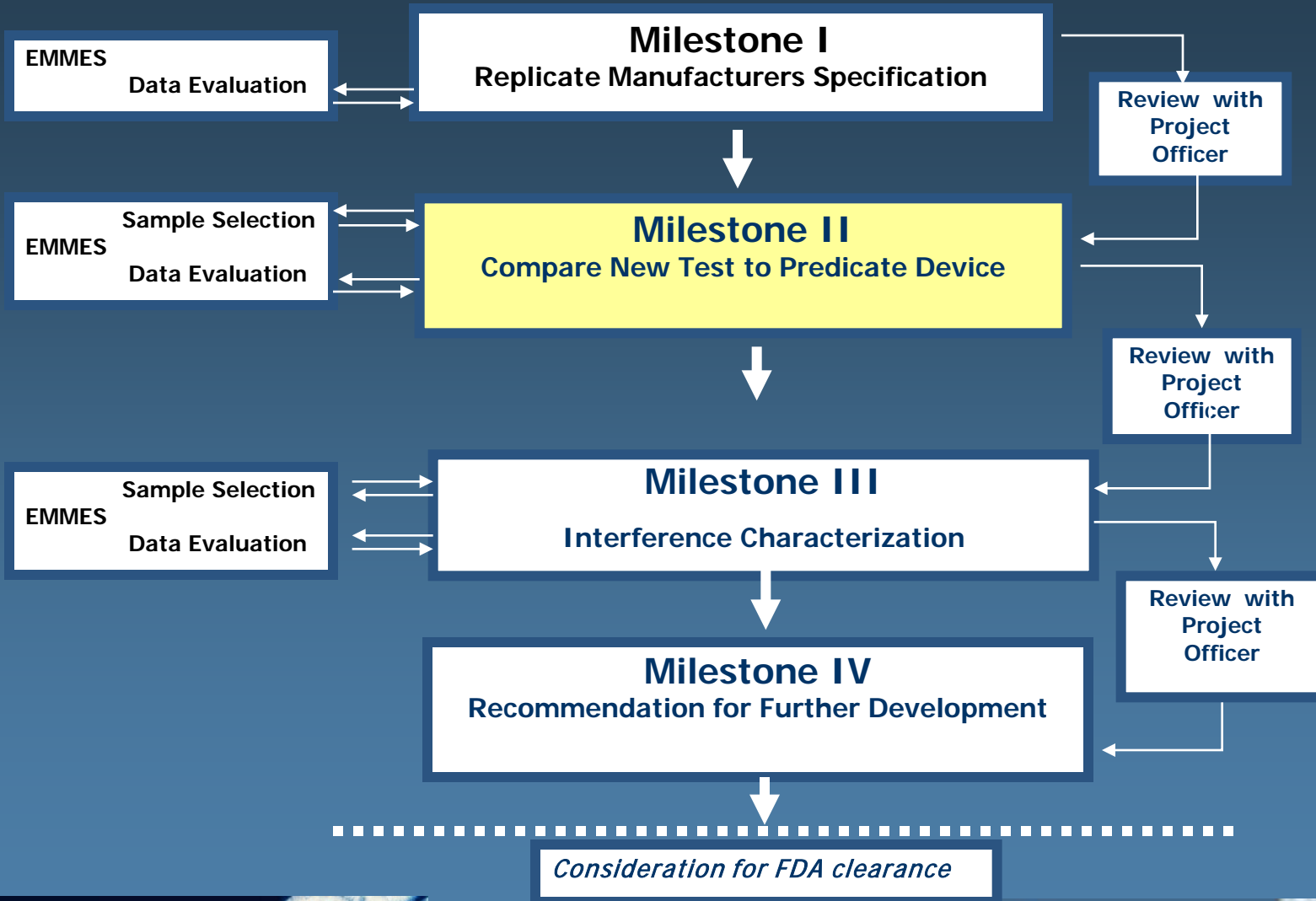
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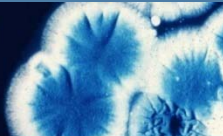
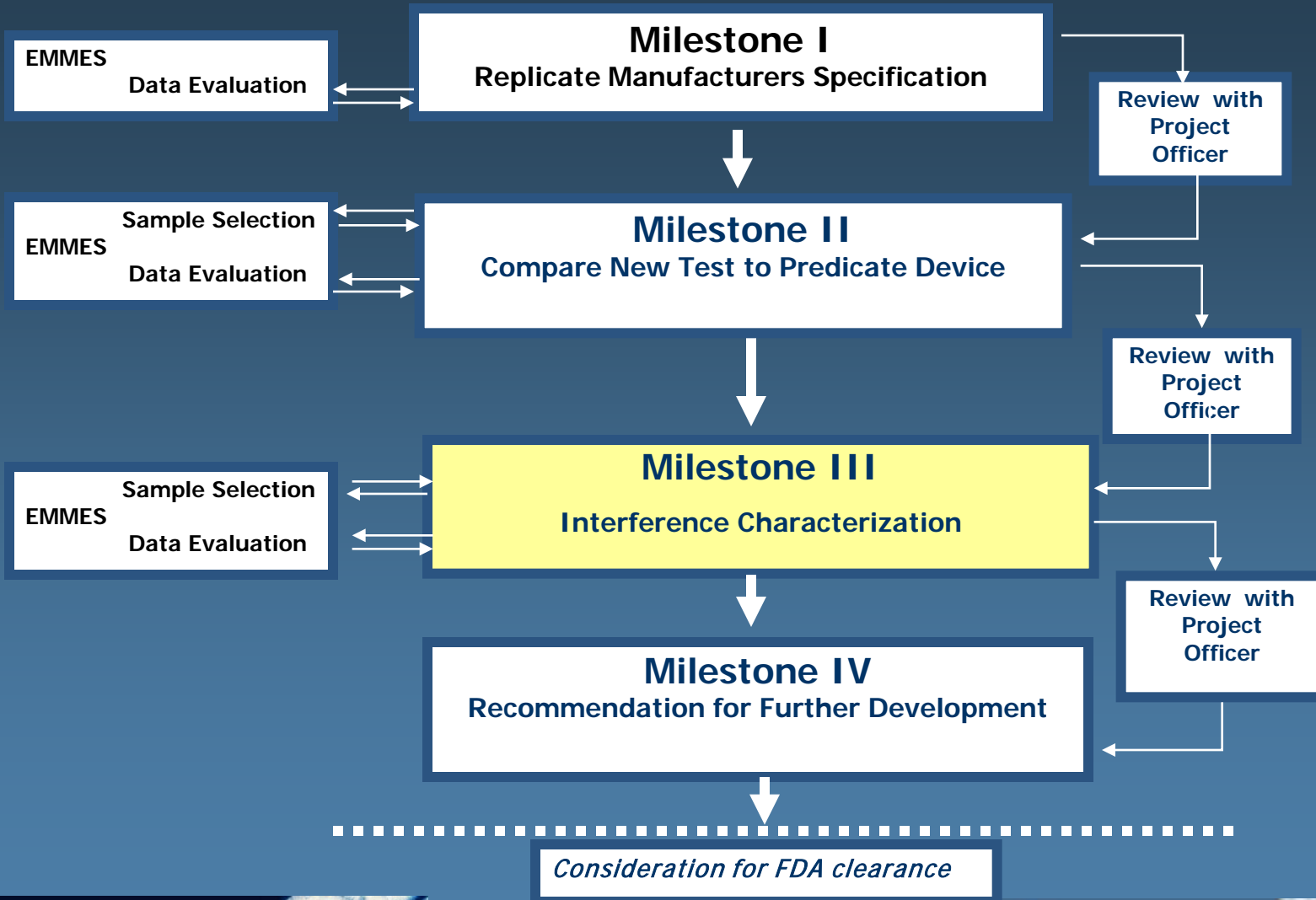
Interpretation & Recommendation:

Recommendation as to proceeding to Comparison Study	Yes	No
TECHNICAL AND PERFORMANCE LIMITATIONS FOR TEST		
Extent to which test reproducibly meets performance		
Level of difficulty in replicating the test		
Suggestions for modifications to improve the test		
Training required		
Description of circumstances that may have affected the quality or integrity of the data		
Potential barriers to commercialization		

Testing Milestones:



Testing Milestones:



Partial list of potentially Interfering Conditions / Substances:

Clinical Assessment

In the preceding 30 days or since the last specimen was collected for repository

Specimen

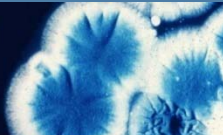
Characterization

At the time sample is processed for repository

- Anitbiotics
- Renal replacement therapy / Plasmapheresis
- Transfusion of blood product / Immunoglobulin
- Plasmalyte / Heparin
- Total Parenteral Nutrition / Enteral hyperalimentation
- Extra Corporal Membrane Oxygenation
- Ventricular assist device / Intra-aortic balloon pump
- Intubation or Continuous Positive Airway Pressure
- Endobronchial stent / Urinary catheter
- Surgical procedure / surgical packing
- Fungal Colonization / mucocutanueous fungal infection
- Diarrhea / Mucositis / Gut GVHD

- Lipemic
- Hemolyzed
- Icteric
- Lot number of collection tube

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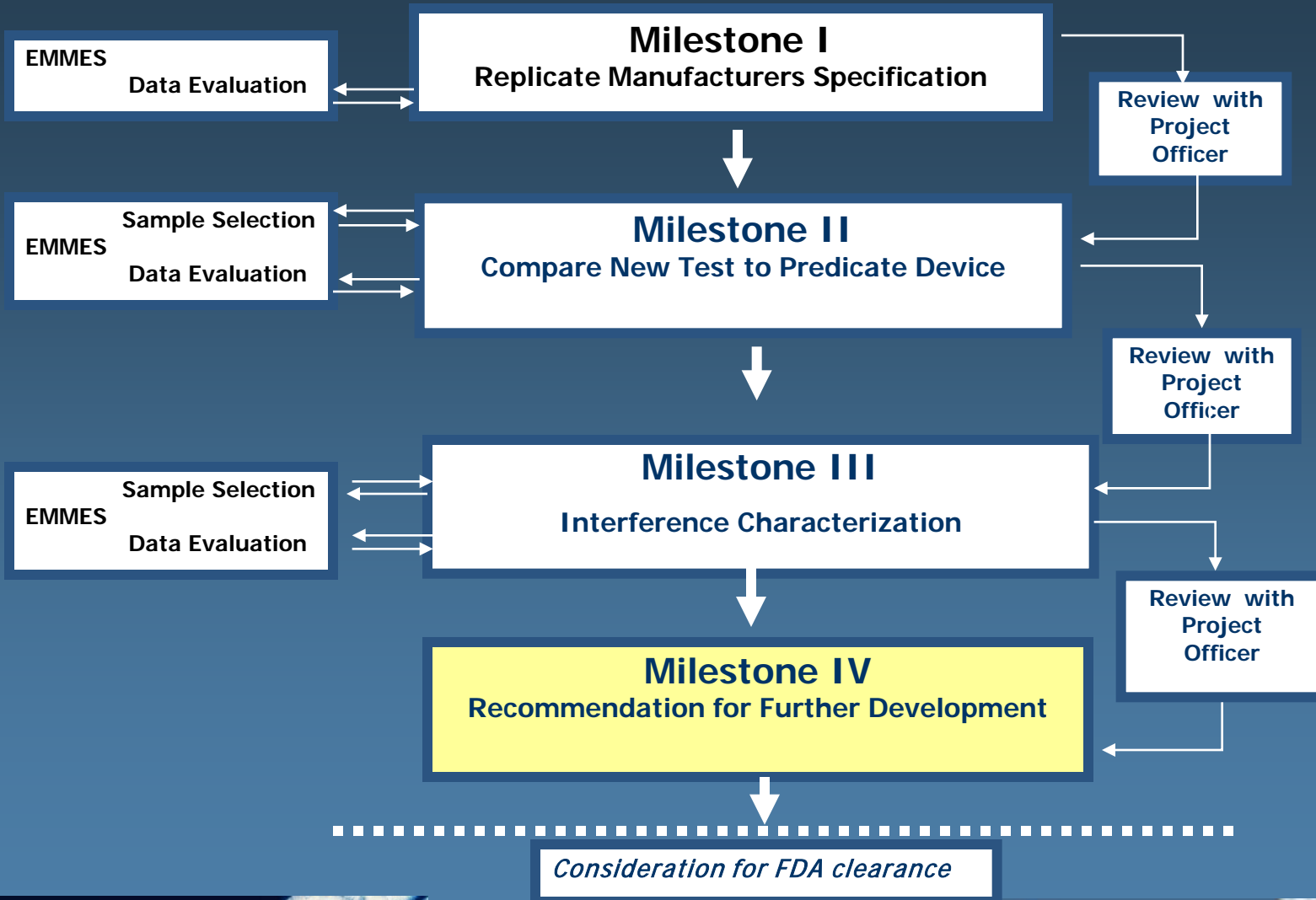
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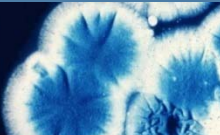
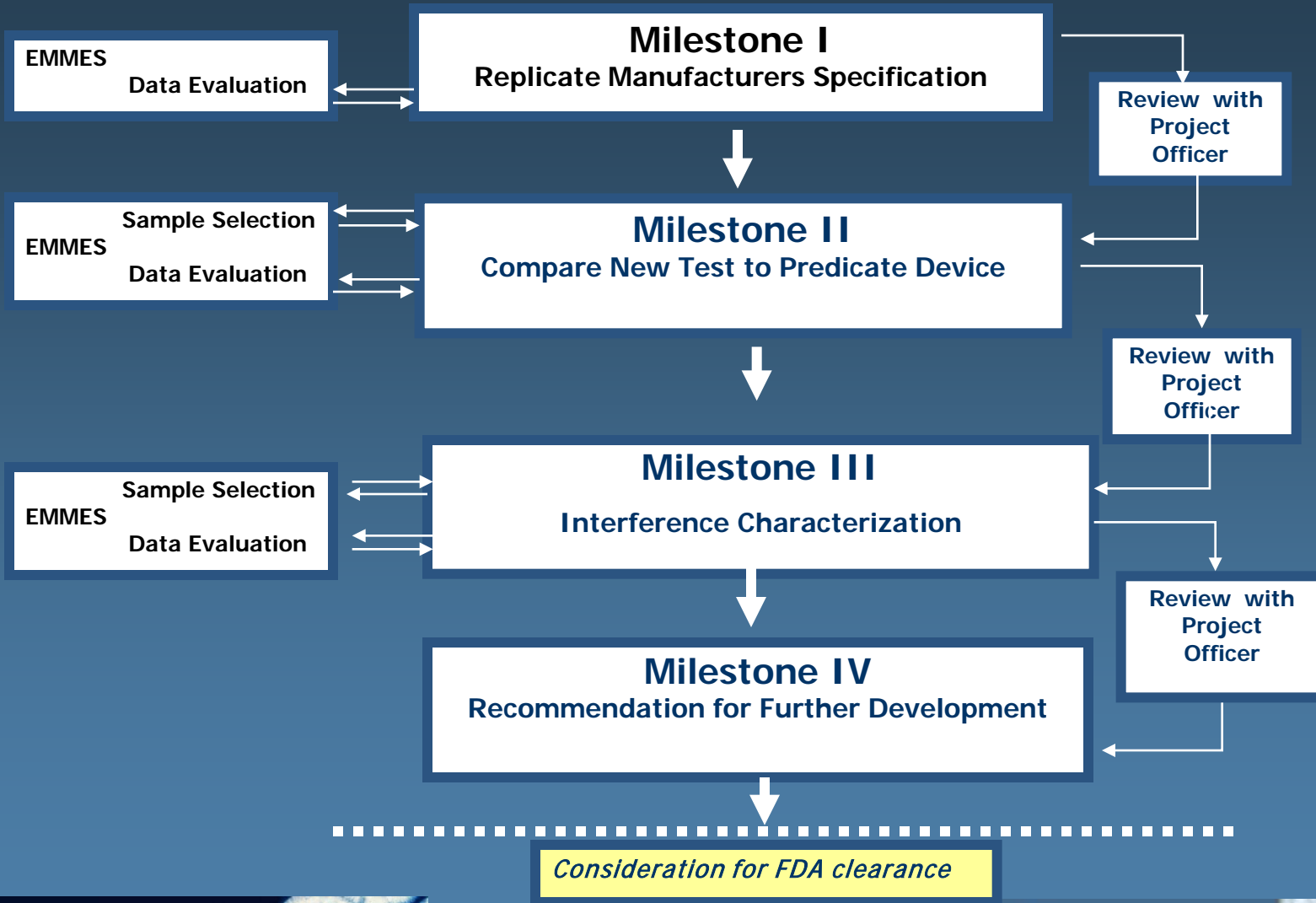
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Testing Milestones:



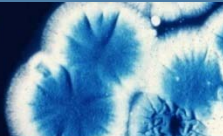
Testing Milestones:



Getting new diagnostic tests for Invasive
Aspergillosis into clinical care sooner.

www.asteccdiagnostics.org

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