WHY IS THIS WORKSHOP IMPORTANT FOR NIAID

- Identify research gaps/needs
- Generate hypotheses
- Improve value of NIAID model services / leverage resources (e.g. BMGF)
- Identify pragmatic data gaps – Fill through NIAID contract services?
- Better comparability of product candidates – Strategic decision making
Regimen Development “Simulation”  
(Point/Counterpoint Discussion)

“Project Team”  
(Facilitator: Mark Goldberger)

- Pick one hypothetical regimen for clinical development
- Create data driven arguments to support the proposed plan (discussions from day 1)
- Collate biologically relevant information to move into clinical trials
- Identify data that need to be generated to make plan stronger – the “perfect plan”
- Get ready to sell the plan to management

“Management Team”  
(Facilitator: Christine Sizemore)

Prepare for Step 2:
- How to evaluate the preclinical plan
- Consider available resources
- Balance between preclinical and clinical testing
- Iterative testing
- Regulatory considerations

Breakout groups
Regimen Development “Simulation”  
(Point/Counterpoint Discussion)

“Pressure test” the roadmap developed in Step 1
- Are available data convincing?
- Why did you choose a specific model?
- Do they may to human endpoints
- What risks remain?
- When to go into humans?

Goal:
Play devil’s advocate
Challenge dogma & assumptions – but -
Must offer alternative suggestions and convincing counter-arguments