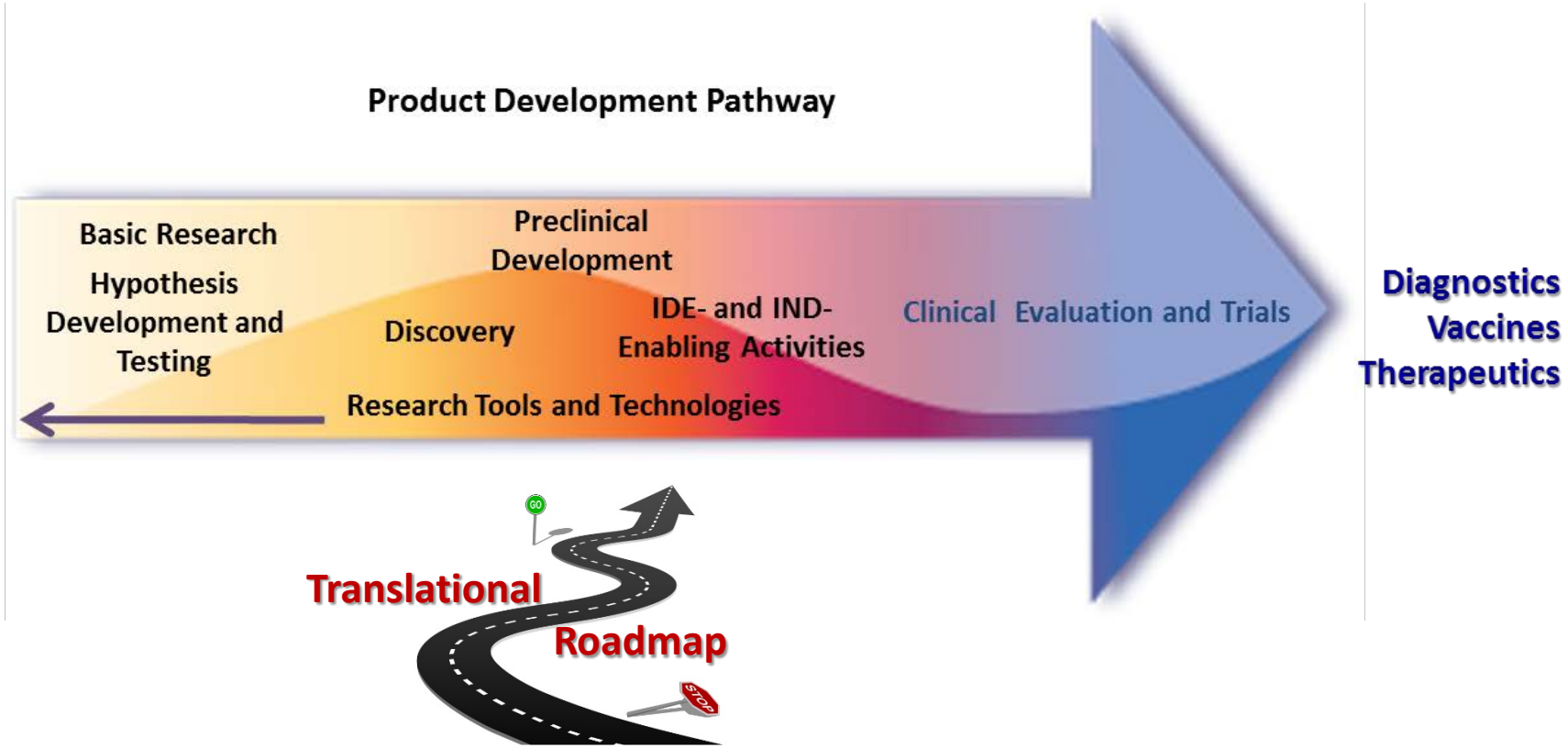
WHY IS THIS WORKSHOP IMPORTANT FOR NIAID

National Institute of Allergy and Infectious Diseases



- 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

Step 1

Breakout groups

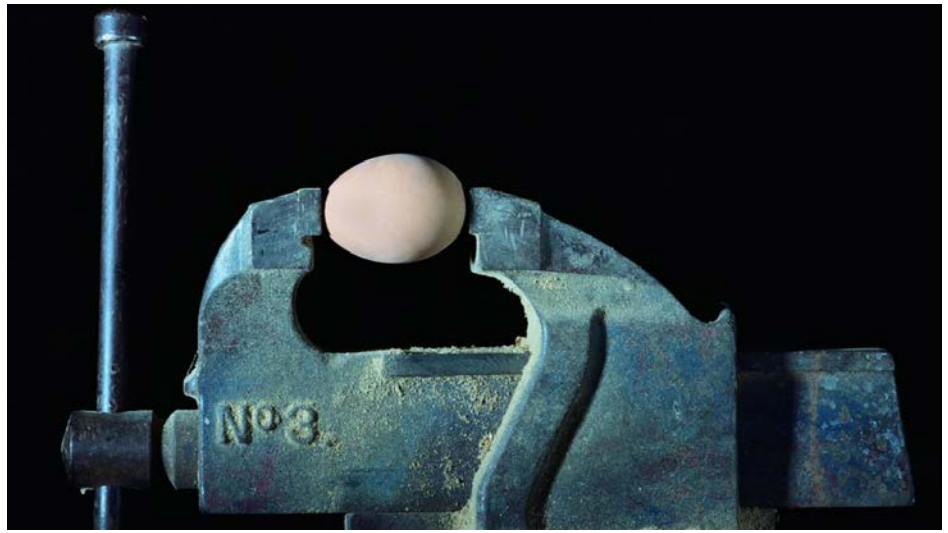
Regimen Development “Simulation”

(Point/Counterpoint Discussion)

Team 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