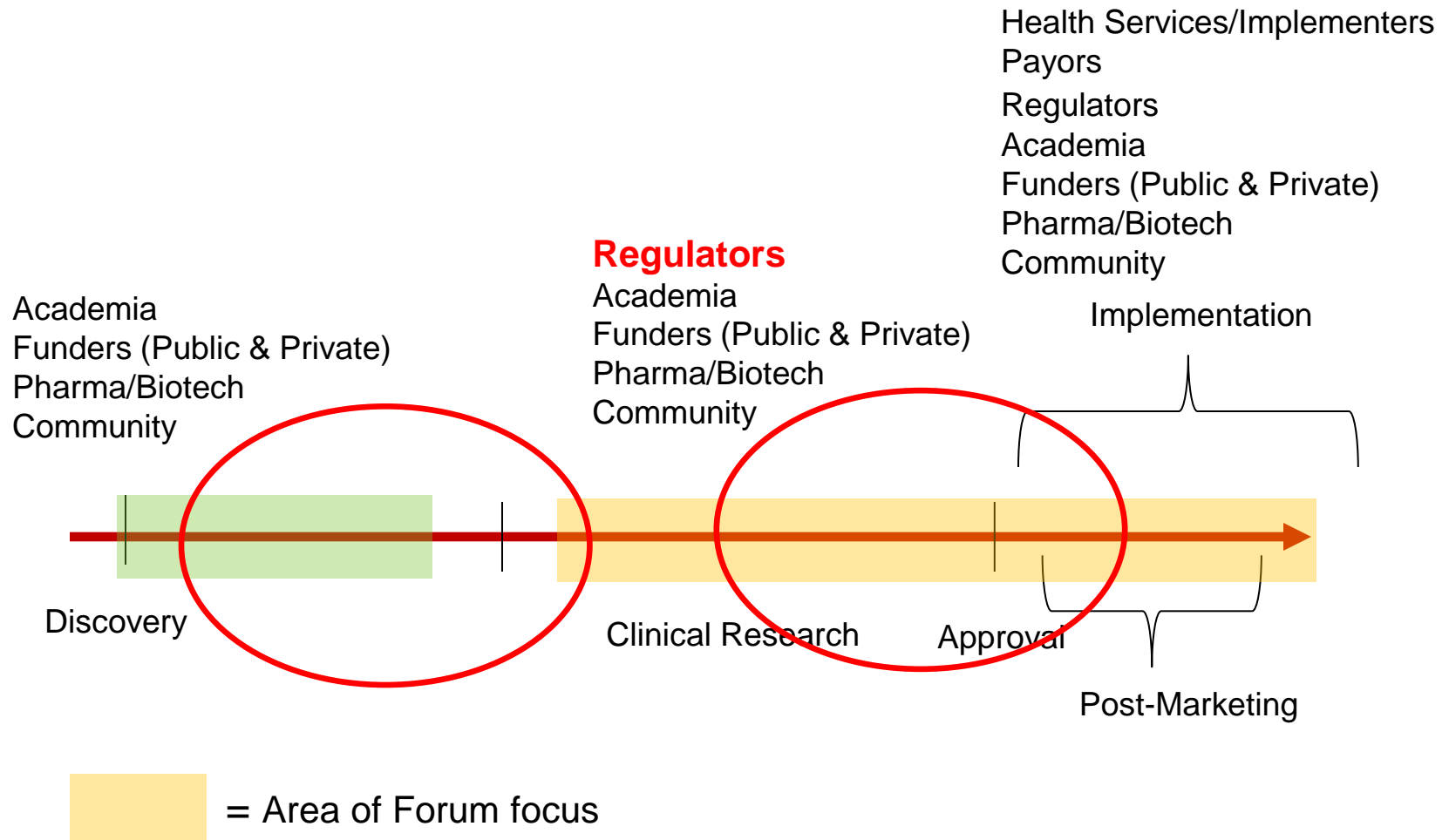




**Needed Collaborations:**  
*One-size does not fit all*

**Structure & Chaos**  
**EFFICIENCY**

# Translational Science/Medicine



- Stakeholder engagement driven deliberative process
  - Neutral, independent – safe -- space
  - Ongoing process
- Co-evolution of science and regulatory guidance
  - Mechanism to act on new science in real time
  - Input from patient community on acceptable benefit-risk

- Increased efficiency of development
  - All parties in the room vs. one-one
- Sign **Information Democracy** move ahead
  - Recruitment of new partners and collaborators
- Support and synergize with other ongoing efforts

# Working with FDA and EMA

- HIV
- HCV
- CMV/transplantation
- Fatty Liver Diseases/Fibrosis
- HBV



# Current/Future Focus on:

- Role of animal models in regulatory process
  - Proof-of-concept
  - Validation
- Regulatory requirements for long-term safety follow-up
- Endpoints for immune-based interventions