Needed Collaborations:

*One-size does not fit all*

*Structure & Chaos*

**EFFICIENCY**
Facilitating Collaborative Research in Drug Development and Health Policy

- 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
Advantages/Contribution

- Increased efficiency of development
  - All parties in the room vs. one-one

- Signal **Information Democracy**
  - 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