Drug Development Challenges. Facilitating collaboration.

Charlene Reed, PhD, CEO
Then
Margaret Chan, the World Health Organization’s director-general told a meeting in Copenhagen in March of 2012:

“If the current trends continue unabated, the future is easy to predict. This will be a post-antibiotic era. In terms of new replacement antibiotics, the pipeline is virtually dry.”
Our mission is to facilitate the discovery and the development of therapies to fight this global pandemic.
Success

* Accelerated discovery, development and regulatory approval of new therapies for antibiotic-resistant microbes
* Equitable global access to those therapies
* Global awareness and advocacy for antimicrobial resistance
Complex problem

* Scientifically
* Clinically
* Financially
* Socially
Traditional HTS mostly fail to identify compounds that inhibit bacterial targets because by design industry’s compound collections are biased toward mammalian targets.

- Mammalian targets are a wide range of proteins.
- Bacterial targets are intracellular proteins and inhibitors of those enzymes likely occupy a different physiochemical space.
Financial

* Industry commitment
  * The business model for antimicrobials needs to be rethought/reworked
* Philanthropic commitment
* Government investments
* Product development partnerships
Social

* Public awareness
  * Resistance
  * Infection
  * Value of Antibiotics
Clinical Development

- Create more favorable environment for drug development
- Overcome obstacles standing in the way to new therapies
- Regulatory guidelines must evolve to support the development paradigm
- Focus on regulatory pathways and tools to support development
Collaborative Coordinating Structure
Unprecedented opportunity

* Work together to keep up the momentum
* Develop the regulatory science and infrastructure needed for this global unmet medical need.
The FCAR

* We are motivated by the victims of antimicrobial drug resistance

* We are dedicated to ensuring that new therapies are developed, adopted, accessible and affordable