



CARB-X

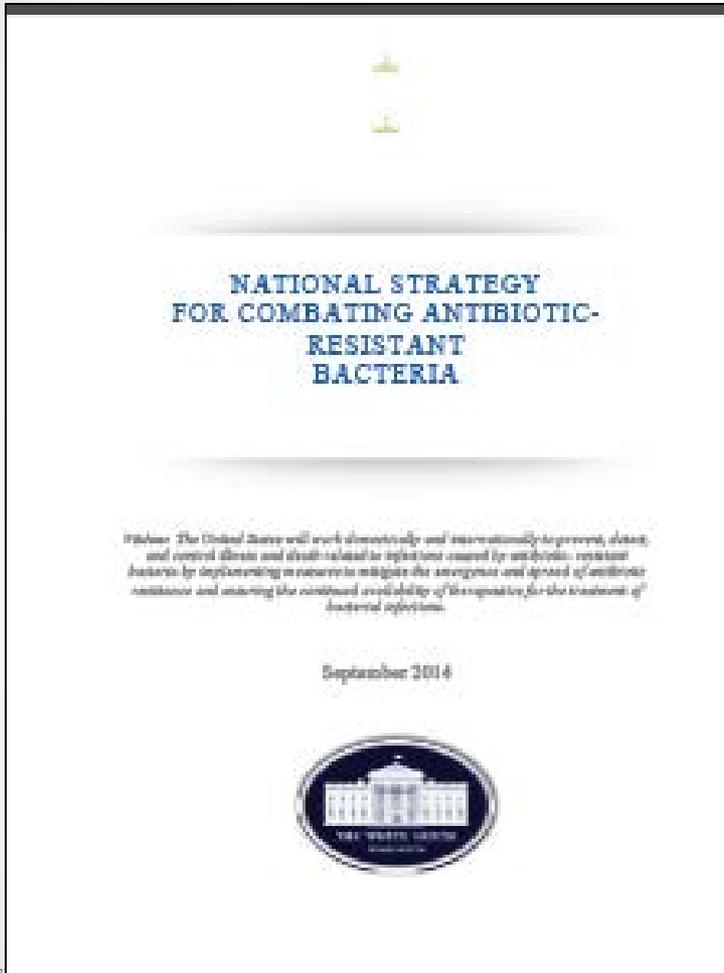
Xccelerating global antibacterial innovation

COMBATING ANTIBIOTIC RESISTANT BACTERIA (CARB) BIOPHARMACEUTICAL ACCELERATOR

Tyler Merkeley, M.S, MBA
BARDA's CARB-X Program Manager
October 18, 2016
HHS/ASPR/BARDA



CARB National Strategy



BARDA and NIAID will create a biopharmaceutical incubator/accelerator—a consortium of academic, biotechnology, and pharmaceutical industry partners—to promote innovation and increase the number of antibiotics in the drug-development pipeline

Why do we need an Accelerator?

- Substantial innovation gap in antibacterial drug development
- No new classes of drugs to treat Gram negative infections in 45 years
- The emergence of antibiotic resistant pathogens has accelerated, given rise to bacterial infections that are untreatable
- Major drug companies have cut back or pulled out of antibiotic R&D. This has left much of the discovery work to small companies with no product on the market limited budgets and R&D capacity
 - An Accelerator will serve as a vital capability for their company to obtain funding and support
- Since BARDA's inception, the valley of death has shifted to earlier stages of development, new innovative public private partnership models are needed to supplement current research programs



CARB-X Overview

- A global antibacterial innovation initiative
- CARB-X brings together BARDA, NIAID, and 4 non-profit life science accelerators to identify, select, and manage a portfolio of early stage antibacterial candidates
- CARB-X will deliver a minimum of 2 antibacterial products to clinical development within 5 years



What is CARB-X?

- BARDA is awarding a 5 year \$250M cooperative agreement (\$30M in year 1) and NIAID is providing in-kind pre-clinical services
- CARB-X partners are matching more than \$100M in funding (\$41M in year 1), for a total potential investment of more than \$350M
- A network of USG agencies, non-profit funders and product developers operating under a common strategic framework to help address a major public health threat of our day
- A component of BARDA's overarching strategy for CARB that augments our existing clinical Antibacterials (AB) Program



CARB-X



A portfolio of
~20 antibacterial
candidates

Private sector
approach to
funding/portfolio
management

A minimum of 2
candidates
progress to
clinical
development



Governance & Scalability

- BARDA sets the strategic priorities for CARB-X
- All decisions for CARB-X are administered through a Joint Oversight Committee (JOC).
- JOC consists of BARDA, NIAID, BU, Wellcome Trust, and AMRC members
- JOC makes decisions on portfolio composition and whether projects remain supported by CARB-X
- CARB-X was designed to accommodate additional accelerators and non-dilutive funding sources
- The lessons learned and success of CARB-X will set the stage for other Accelerators
- How could the Accelerator model be scaled beyond CARB-X?
 - Emerging Infectious Diseases (EID)
 - For CBRN threats



Focus Areas

- CARB-X's focus is on preclinical development
 - Lead optimization thru first time in human testing
- Year 1 priorities are novel approaches to treat gram negative bacteria and non-traditional approaches



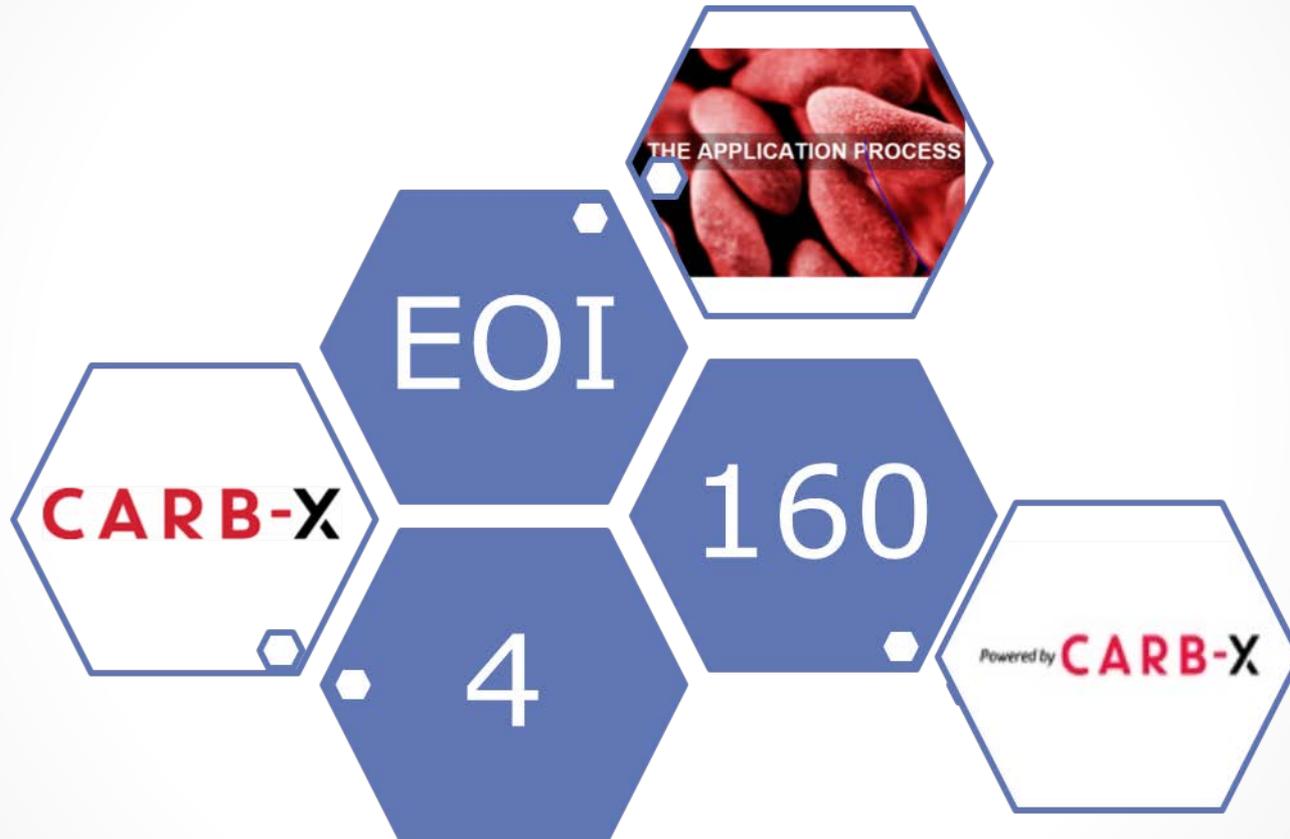
How will we measure the success of CARB-X?

CARB-X's ability to:

- Populate a diverse R&D portfolio of antibacterial candidates
- Develop a network of R&D capabilities and technical support
- Perform the function of an Accelerator
- Progress antibacterial candidates in preclinical development
- Support business needs of innovators



High Level of Interest



For additional info:

www.carb-x.org

www.phe.gov

BARDA's CARB-X Program Manager

Tyler.Merkeley@hhs.gov

202-260-0315

