CARB-X

Xccelerating global antibacterial innovation

A NOVEL NON-DILUTIVE PARTNERSHIP TO PROMOTE INNOVATION AND FOSTER A ROBUST ANTIMICROBIALS PIPELINE

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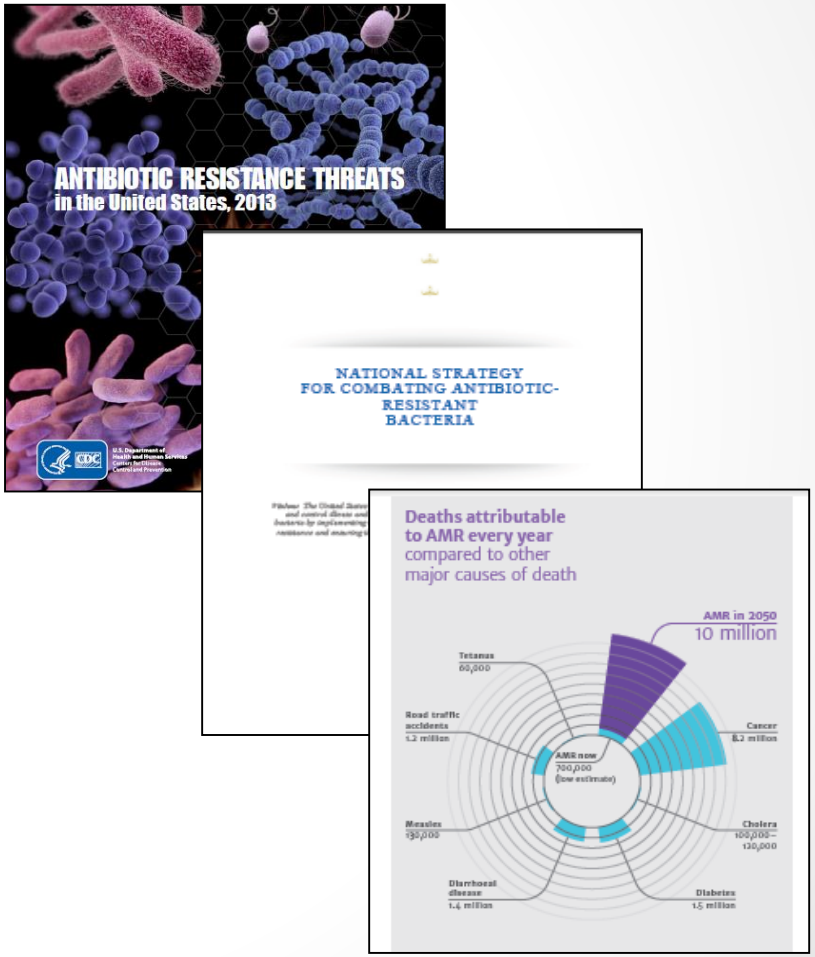
HHS/ASPR/BARDA

Why is BARDA Funding Antibacterial Development?

- Because the pace of drug development has not kept pace with the emergence of antibiotic resistance
- AMR causes 700,000 global deaths each year that will rise to 10,000,000 deaths annually by 2050 with economic cost of $100,000,000,000,000
- To enhance biodefense and public health preparedness
- To meet the requirements in the National Strategy and Action Plan for CARB



BARDA Supported Push and Pull Incentives

Pre-Clinical Development	Clinical Development	Marketing
Pre-IND	Phase I-III	Post Approval

CARB-X

Push Inventive:

Direct Investment via Accelerators into Pre-Clinical Development

Est. 2016

+

BARDA

Push Inventive:

Clinical Stage Public Private Partnerships

Est. 2010

+

CARBi

Pull Inventive:

A new model with market entry Reward & Stewardship

Est. TBD

=

Holistic Set of Incentives to Promote Antibacterial Product Innovation

Note: Includes current and potential BARDA supported push and pull mechanisms. Other USG Agencies have complementary push and pull incentives that are not displayed on this page. CARB-X is co-funded with NIAID

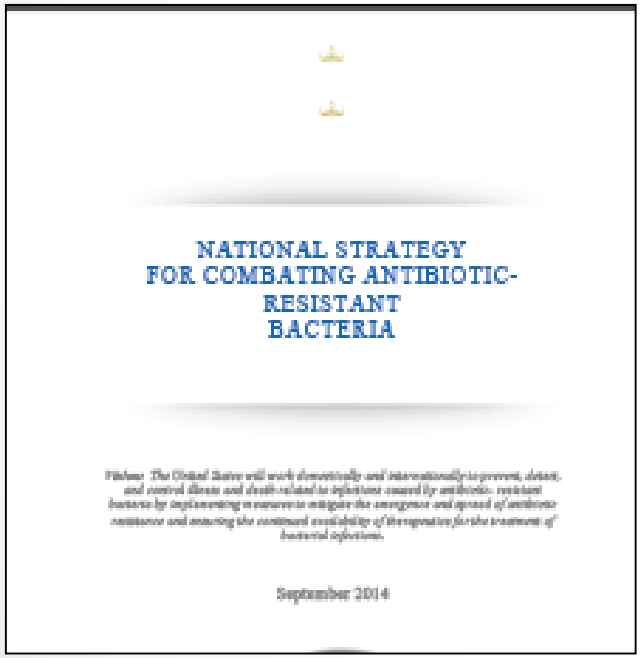
ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

The Power of Non-Dilutive Investments

- Access to funding to support R&D without financial strings attached:
  - No equity positions
  - No loans or convertible loans
  - No requirement for revenue sharing
  - Maintain your IP
- Often overlooked non-financial benefits
  - A committed partner looking at a non-financial value proposition (.e.g. preparedness, etc.)
  - Scientific and Business due diligence
  - Free consulting support
  - Technical oversight
  - Interim milestone funding decisions
  - Access to internal knowledge and industries lessons learned

National Strategy for CARB

"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"


NATIONAL STRATEGY
FOR COMBATING ANTIBIOTIC-
RESISTANT
BACTERIA

September 2014

- **Goal 1:** Slow the Development of Resistant Bacteria and Prevent the Spread of Resistant Infections
- **Goal 2:** Strengthen National One-Health Surveillance Efforts to Combat Resistance
- **Goal 3:** Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria
- **Goal 4:** Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines
- **Goal 5:** Improve International Collaboration and Capacities for Antibiotic Resistance Prevention, Surveillance, Control, and Antibiotic Research and Development

Why do we need an Accelerator?

- Substantial innovation gap in antibacterial drug develop
- No new classes of 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

What to expect from CARB-X

- **Funding**
  - >$350m/5 years
  - >$68m for research Y1
  - Non-dilutive
  - Keep your IP
- **Business**
  - World-class mentoring and business support
  - Prepare for capital markets
- **Pre-clinical**
  - World-class product development support
  - Streamlined access to pre-clinical services from RTI, NIAID & Broad
  - Assistance with CROs
  - Companies free to pick and choose, or use their own

Powered by CARB-X

ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

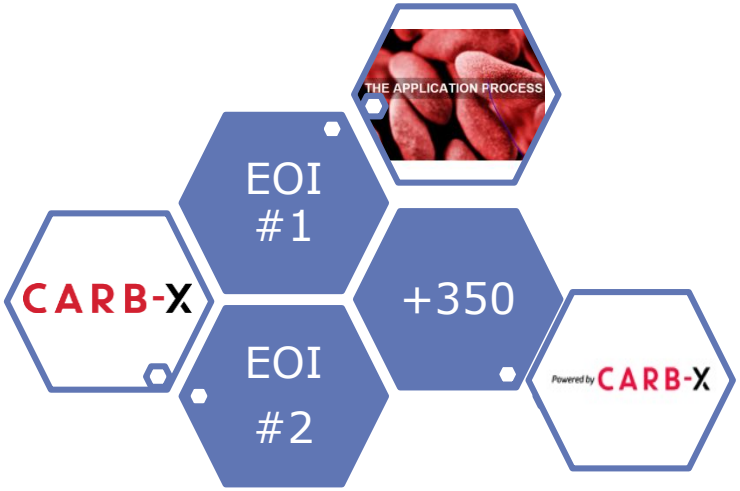
Governance & Scalability

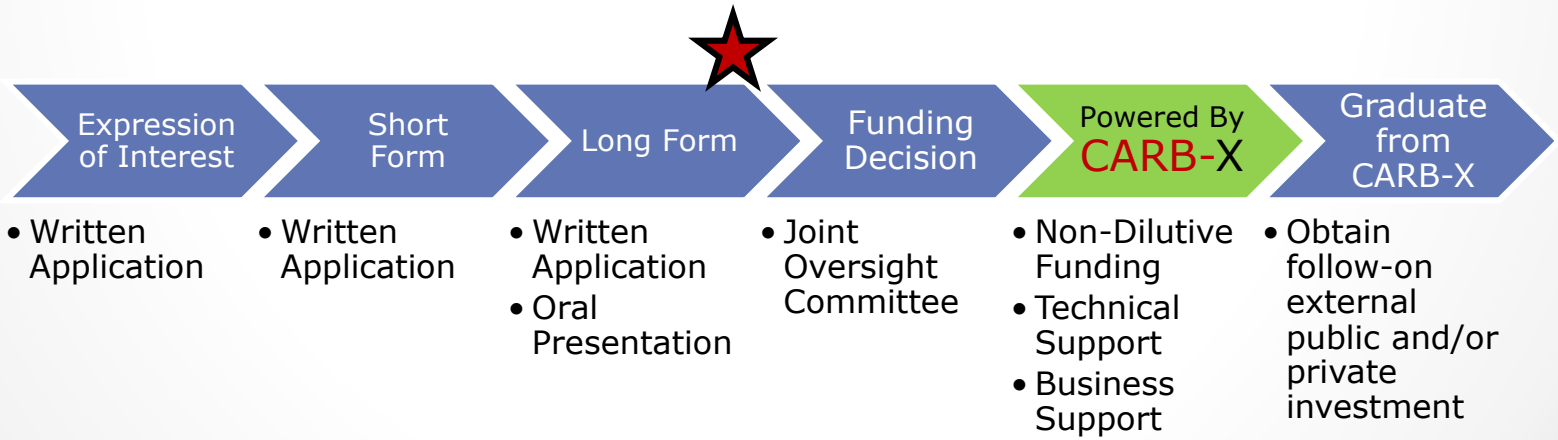
- BARDA sets the strategic priorities for CARB-X
- All decisions for CARB-X are administered through a Joint Oversight Committee (JOC).
- JOC consists of BARDA, NIAID, BU, Wellcome Trust, and AMRC members
- JOC makes decisions on portfolio composition and whether projects remain supported by CARB-X
- 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 for Year#1

- CARB-X's focus is on preclinical development
  - Hit to Lead thru first time in human testing
- Year 1 priorities are novel approaches to treat Gram negative bacteria and non-traditional approaches
- Geographical Scope
  - No geographical limitations
  - CARB-X will fund the best projects, wherever found
- Minimum Criteria
  - Bacteria (not viruses, fungi, mycobacteria or parasites)
  - Listed on the CDC 2013 Urgent or Serious Threat List
  - TRL 3-6
  - Appropriate business structure [Legal entity] to support Pharmaceutical Product Development
  - Funding for basic operations for 12 months

High Level of Interest





For additional info:

www.carb-x.org

www.phe.gov

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Backup

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