



ASPR

How BARDA Incentivizes Antibacterial Development from Early Development through Marketing Approval

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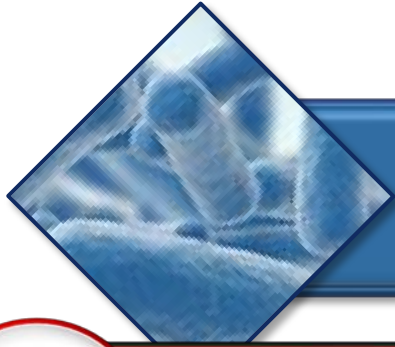
Biomedical Advanced Research and Development Authority

Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development in the US

November 18-19, 2019

UNCLASSIFIED

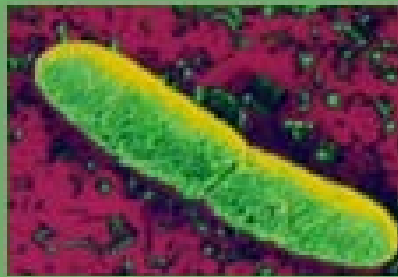
Antibacterials Program



MISSION: Revitalize the antibacterial pipeline through innovative public-private partnerships



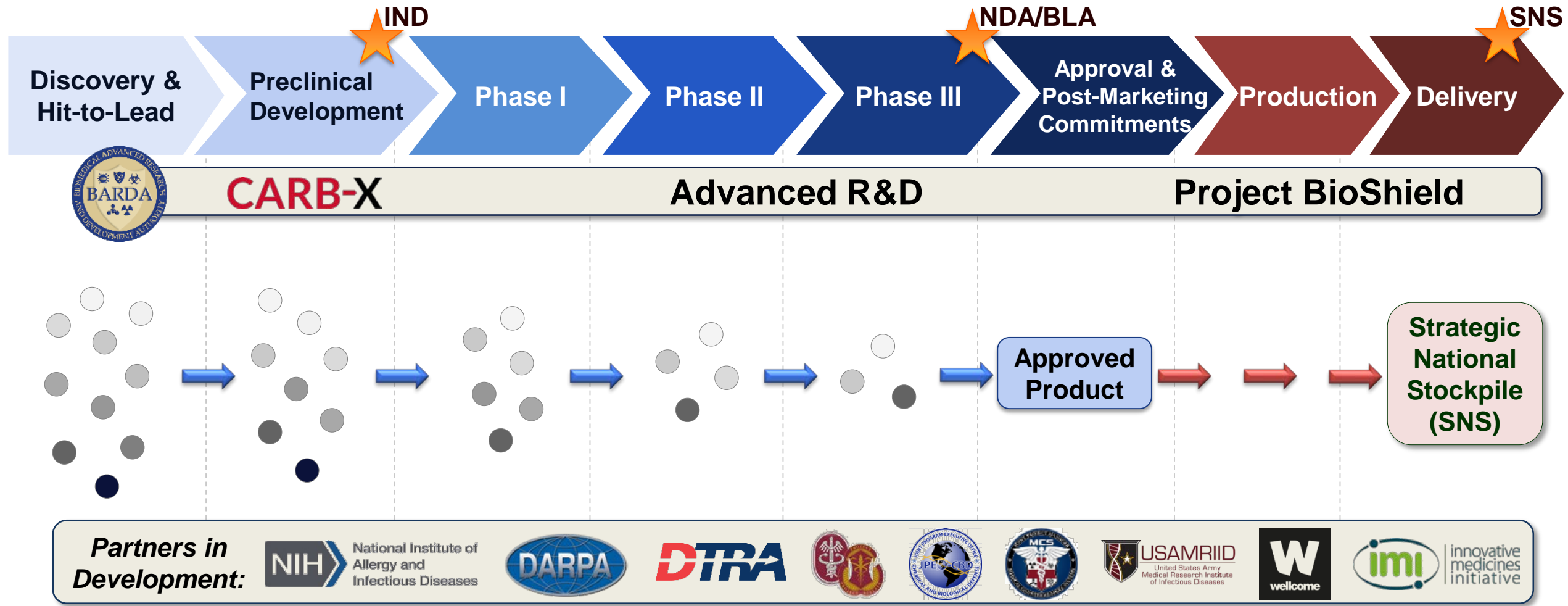
GOAL: Reduce the morbidity and mortality caused by antimicrobial resistant (AMR) bacterial infections following a mass casualty event or a disease outbreak



STRATEGY: Invest in new types of antimicrobials

- Novel mechanisms of action
- Non-traditional antimicrobials
- Host-directed therapeutics
- Small molecules
- Vaccines
- Diagnostics

BARDA's Antibiotic Innovation Partners



CARB-X

as of 6/30/2019

43% of companies indicated not receiving prior USG funding



\$933M

Private Investment since CARB-X Award

\$74.8M

Follow-on government funding (US and other countries)



7
Countries

\$180M BARDA Investment
(2016-2019)

50 Projects | **38** drugs | **6** diagnostics | **3** microbiome | **3** vaccine

Antibacterials Advanced Research and Development (ARD) Program Partners



Recent Approvals to Address Unmet Medical Needs



- Approvals over the last 2 years have been a culmination of 9 years of dedication to the AMR enterprise
- Emphasis on getting drugs to market following established pathways
 - Complicated Urinary Tract Infections & Acute Pyelonephritis
 - Complicated Intra-abdominal Infections
- Operational goal has been to make antibiotics commercially available in pharmacies and hospital formularies while generating biothreat data for Emergency Use Authorization

BRIEF

Achaogen files for bankruptcy protection, seeks asset sale

“BARDA simply cannot continue to provide non-dilutive investment, only to have companies collapse and their newly minted antibiotics shelved or lost completely”

- Rick Bright, BARDA Director

EDITOR'S PICK | 3,775 views | May 10, 2019, 11:41am

Forbes

Building New Models To Support The Ailing Antibiotics Market



The Lab Bench Contributor ©
Science

Perspectives from the cutting edge of science

GUEST POST WRITTEN BY

Dr. Rick Bright

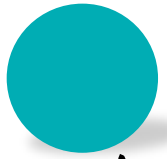
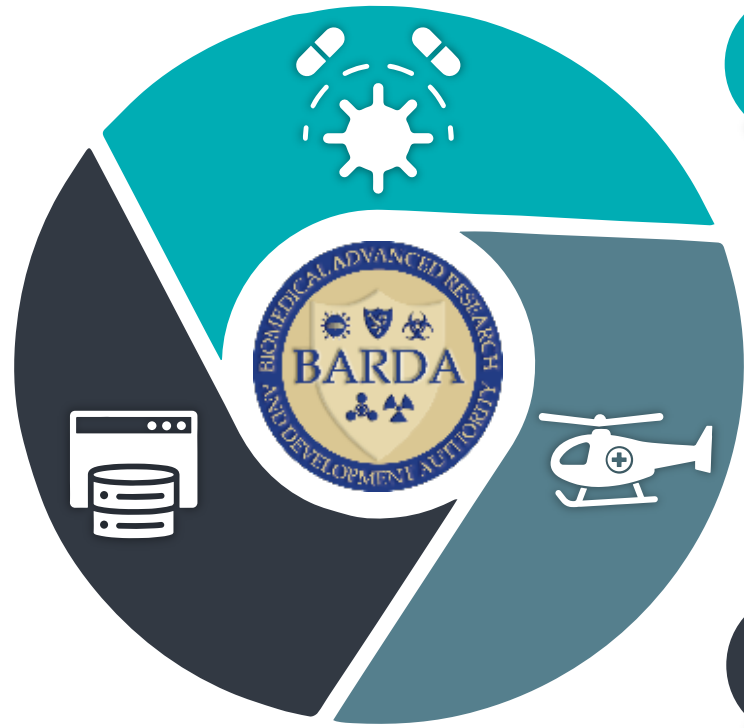
Rick Bright is director of BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services



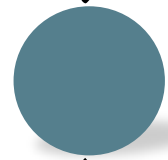
Project BioShield: A First for Antibacterials



CONTRACT PENDING



Biothreat agents may be resistant to antibiotics already in Strategic National Stockpile (SNS)



Emerging antibiotic resistance may complicate a response to any public health emergency



Adding to SNS novel antibiotics that overcome resistance enhances national security, serves as additional market

Clinical Trial Partnership

Global Network to Conduct the Most Challenging Antibiotic Clinical Studies

PROBLEM

- Antibiotics are being approved for easier-to-get indications (e.g. cUTI, cIAI) with little product differentiation
- Priority indications (e.g., pneumonia, bloodstream infections) are challenging to pursue
- Result:
 - Investors focus on low risk, low cost, fast-to-market
 - Clinicians don't know how these drugs will perform at alternative body sites

SOLUTION

- Reduce barriers (cost, risk, time) of clinical trials for critically needed indications
- Establish a global clinical trial capability committed to the AMR space
- *How will this be done?*
 - Cost: provide funding
 - Speed: targeted enrollment for limited populations with specialized investigators
 - Reduced Risk: provide technical support, focus on high resistance rate areas

APPROACH

- Successful Models: Define partnership model incorporating learnings from experiences such as TB Alliance, ACTG, Mycosis Study Group, CARB-X, Oncology, and others
- Core Partners: NIAID/NIH, FDA, BARDA, Industry
- Potential Partners: Wellcome Trust, DOD, UK Government, B&M Gates Foundation, others
- Goal: Enable 4-6 label expansions

Advantages of a Clinical Trial Partnership

Conventional Approach

Pivotal studies are complex and expensive

Inefficient design: One drug = One trial

Sponsor-led oversight: Independent decision-making for each trial, infrequent engagement with regulators, each trial protocol is unique

Each trial requires new start-up, establish CRO, identify clinical sites, initiate trial activities, and dismantle infrastructure at the end of the trial

Patient accrual challenges, rare infections lead to enrollment challenges, cost increases and time delays

Clinical Trial Network Approach

Reduce overall time and costs to completion

Optimize design: Many drugs = one trial

Centralize oversight: Engagement with stakeholders, e.g., FDA and NIAID throughout study planning, execution, and decision-making

Improve start-up: established contracts and data collection systems, established sites with demonstrated patient flow, trained staff reduce risk of trial failure due to conduct issues

More efficient use of patients and resources, “networks could reduce trial size by up to 43%” KOL



Incentivizing and Catalyzing Antibiotic Development



BARDA will continue to leverage its unique authorities to provide innovative business tools that support end-to-end product development, from the earliest stages under CARB-X to commercial procurement via PBS, while at the same time exploring technical solutions to the challenges facing the commercial market.