



# BARDA INDUSTRY DAY

## CARB-X

### Global Accelerator for Revitalizing Antibiotic Clinical Pipeline

Tina Guina, PhD  
CARB-X Program Manager, BARDA

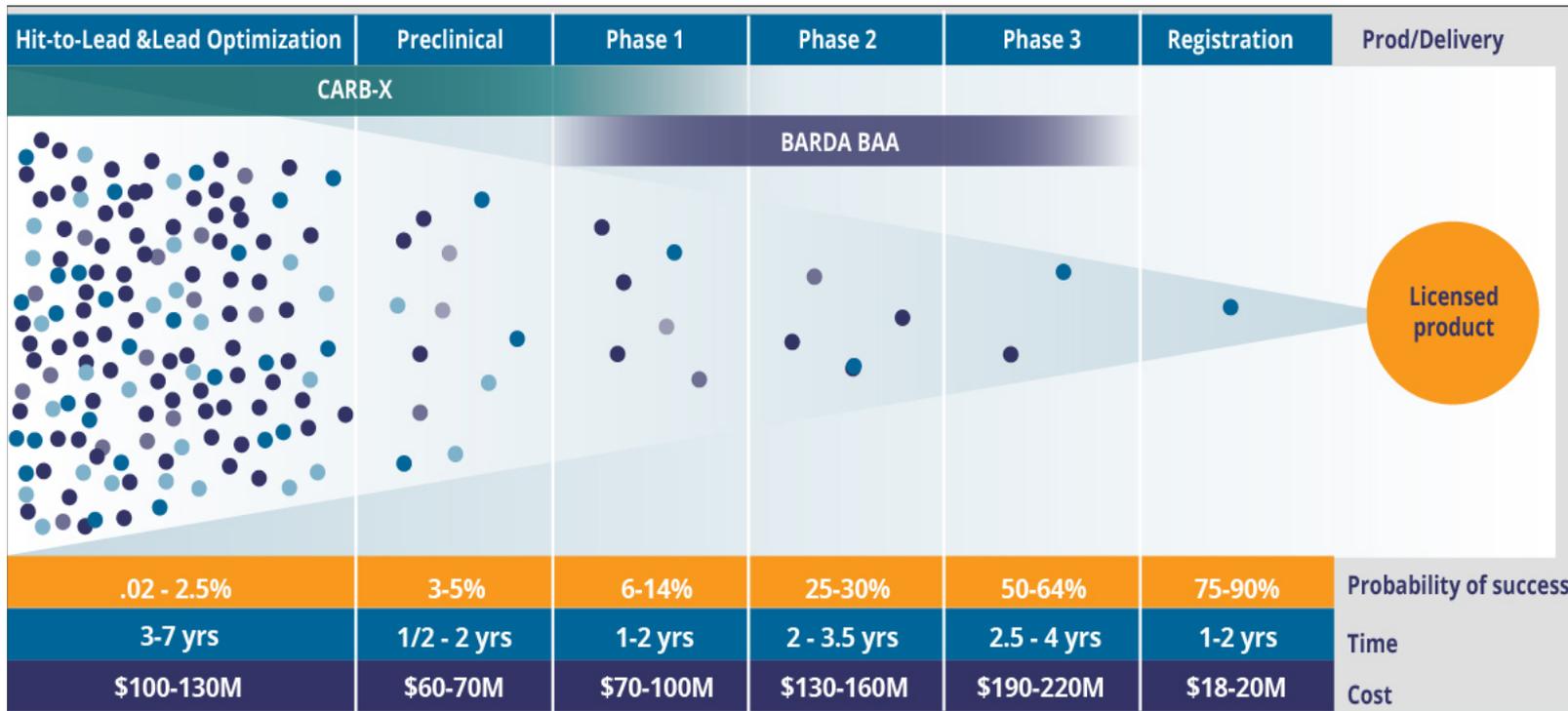
BARDA Industry Day  
*Addressing AMR: CARB-X and Other Models*

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



# Antibiotic Resistance is an Urgent Health Security Threat.

## How Do We Repopulate the Clinical Pipeline?



# CARB-X Accelerates R&D To Combat Antibiotic Resistant Bacterial Infections



Global nonprofit partnership provides non-dilutive funding for antibacterial innovation around the world. CARB-X's network of accelerators provides science & business support to product developers. Investments are leveraged (cost share).

## FUNDERS



National Institute of Allergy and Infectious Diseases



## ALLIANCE PARTNER

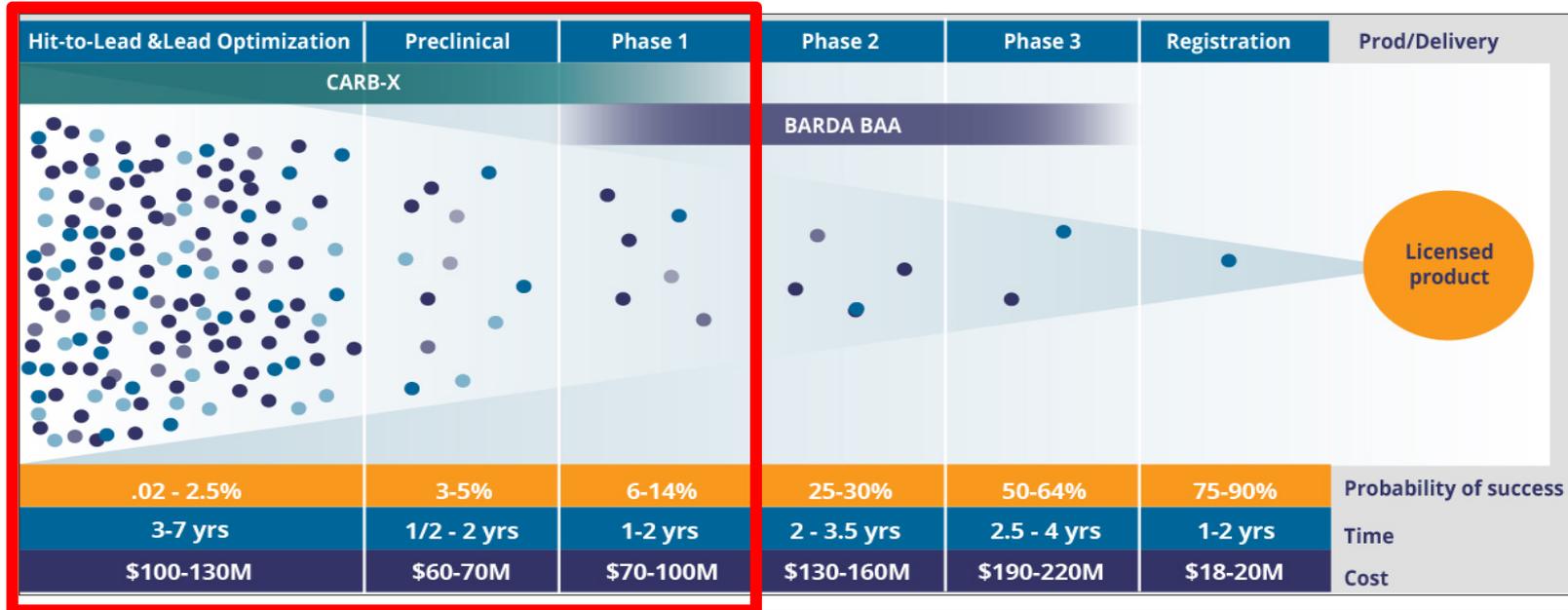
BILL & MELINDA  
GATES foundation

## OTHER PARTNERS & ACCELERATORS



Saving Lives. Protecting Americans.

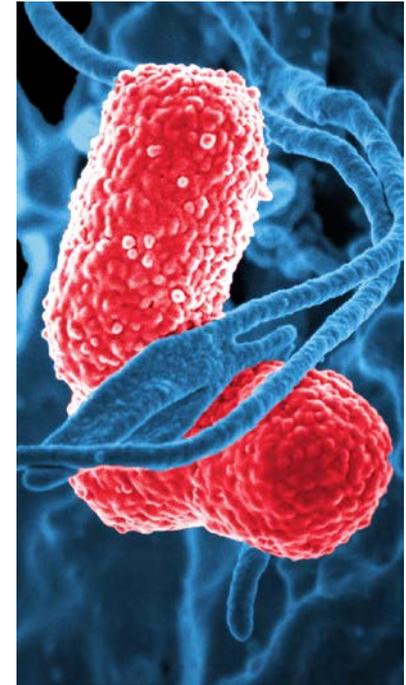
# CARB-X Accelerator Provides Push Incentives in The High-Risk Space



Saving Lives. Protecting Americans.

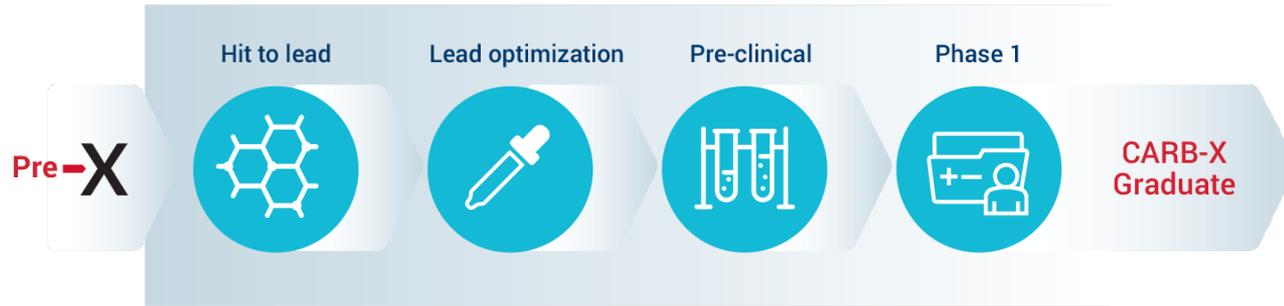
# CARB-X Funds Products that Target Antibiotic Resistant Bacteria

- Products that address serious bacterial threats
  - antibiotics and other therapeutics
  - rapid diagnostics
  - prevention such as vaccines
- Projects must target infections caused by bacteria on the **Antibiotic Resistance Threats** list issued by the Centers for Disease Control and Prevention (**CDC**) in 2013 or on the **Priority Bacterial Pathogens** list published by the World Health Organization (**WHO**) in 2017



# CARB-X Supports Programs in Early Development

## Therapeutics & Preventatives



## Diagnostics & Devices



# CARB-X Welcomes Applications from Around The World

Projects are selected through a competitive process by panels of experts. Funded projects are supported by a network of world-class accelerators.

## Funding & Alliance Partners (\$500 million+ 2016-2021)



## Other Partners & Accelerators (Scientific & Business)



### Applications for funding

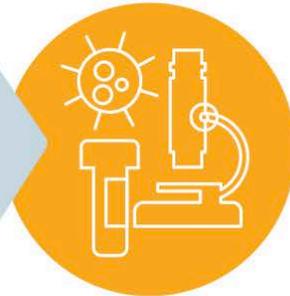
Received from companies around the world

# CARB-X

**Scientific Review:** Advisory Board reviews applications & makes recommendations

**Governance:** Joint Oversight Committee makes funding decisions

**Administration:** Boston University hosts CARB-X



### Selected projects

Receive funding & accelerator support



# Benefits of being *Powered by* CARB-X

- Non-dilutive funding
- CARB-X Support Team established for each company
  - CARB-X Support Team Lead
  - Accelerator support aligned to company profile and needs – business mentoring and scientific expertise
  - Streamlined access to NIAID preclinical services
- Benefits of CARB-X ecosystem

**CARB-X**

Global  
Accelerator  
Network



# Private Investment Followed CARB-X Funding



\* As of June 30, 2018

\*\* Total CARB-X investment announced to June 30, 2018. Does not include obligations to be paid in future periods

Every \$1 that CARB-X invested in *Powered by CARB-X* projects was followed by \$8.7 in private funding

Powered by **CARB-X**





# Ten New Classes of Antibiotics



Gyrase-topoisomerase  
Inhibitor

**GYROX**



Direct-Acting Small Molecule  
Therapeutic

**CZ-02**



Narrow-spectrum Inhibitors  
of FabI

**Debio1453**



Helical AMPS

**Helical AMP**



Direct-Acting Small Molecule  
Therapeutic

**Non-BL PBPI**



Direct-Acting Small Molecule  
Therapeutic

**TOPESKAPE**



LpxC Inhibitor

**FG-LpxC**



Direct-Acting Small Molecule  
Therapeutic

**Pyrrolocytosines**



Direct-acting Small Molecule  
Therapeutic

**SMT-571 Series**



$\beta$ -lactamase Resistant PBP  
Inhibitor

**VNRX-PBP**

Powered by **CARB-X**



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# Eleven Candidates with New Molecular Targets



Pseudomonas Elastase Inhibitor

PEI



Bifunctional immunotherapy

CD201



Recombinant lysin protein

Lysins



Direct-Acting Small Molecule Therapeutic

CZ-02



Narrow-spectrum Inhibitors of FcγRIIIb

Debio1453



LpxC Inhibitor

FG-LpxC



Indirect therapeutic - multi-specific antibody

INBRX-111



Direct-Acting Small Molecule Therapeutic

Pyrrolocytosines



Indirect therapeutic - virulence modifier

T3SS



Direct-acting Small Molecule Therapeutic

SMT-571



Antibody-drug conjugate

VIS-705

Powered by **CARB-X**



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# Twenty Small Molecules

Powered by **CARB-X**

**ACHAAGEN**

Direct-Acting Small Molecule  
Therapeutic

**ANTABIO**  
Developing tomorrow's antibacterials

Pseudomonas Elastase  
Inhibitor



Gyrase-topoisomerase  
Inhibitor



Bifunctional immunotherapy

**CURZA**<sup>®</sup>

Direct-Acting Small Molecule  
Therapeutic



Narrow-spectrum Inhibitors  
of FabI



Helical AMPS



Oral Gram-negative  
combination



Direct-Acting Small Molecule  
Therapeutic



LpxC Inhibitor

**idorsia**

Direct-Acting Small Molecule  
Therapeutic



Oral and IV penem



Direct-Acting Small Molecule  
Therapeutic



Direct-Acting Small Molecule  
Therapeutic

**MICROBIOTIX**  
Inc.

Indirect therapeutic -  
virulence modifier

**MicURx**  
PHARMACEUTICALS

Direct-Acting Small Molecule  
Therapeutic



Direct-Acting Small Molecule  
Therapeutic



Direct-acting Small Molecule  
Therapeutic



Next-generation tetracycline

**VenatoRx**  
PHARMACEUTICALS

$\beta$ -lactamase Resistant PBP  
Inhibitor



**ASPR**  
ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE



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# Ten Nontraditionals and One Vaccine



Direct-Acting Large Molecule  
Therapeutic; Topical

Amicidin- $\beta$



Pseudomonas Elastase  
Inhibitor

PEI



Bifunctional immunotherapy

CD201

ContraFect



Recombinant lysin protein

Lysins



Indirect therapeutic - multi-  
specific antibody

INBRX-111



Vaccine

IBT-V02



Indirect therapeutic -  
virulence modifier

T3SS



Microbiome

SCB-102



Direct-Acting Microbiome-  
based Therapeutic

SER-155



Direct-Acting Microbiome-  
based Therapeutic

VE303



Antibody-drug conjugate

VIS-705

Immunotherapeutics, microbiome, lysin, amino acid copolymers, toxin inhibitor, protein secretion inhibitor

Powered by **CARB-X**



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# Five Diagnostics

HELIXBIND

Direct-from-Specimen  
Diagnostic

Rapid/BSI



PROTEUS

Optical bacterial imaging  
Diagnostic

Optical Bacterial  
Imaging

 SPECIFIC

Diagnostic

SPECIFAST

 T2 Biosystems

Diagnostic

T2MR

 TALIS

POC Diagnostic

POC DX FOR  
NG/CT

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ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE



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# Five Candidates Achieved Clinical Development



Oral Gram-negative combination

Oral BI-BLI combination



Oral and IV penem

Oral and IV penem



Potentiator indirect Therapeutic

\*Antibiotic potentiator



Next-generation tetracycline

Next generation tetracycline



Direct-Acting Microbiome-based Therapeutic

Microbiome therapeutic

\*Completed Phase 1 and graduated from *Powered by CARB-X* portfolio in 2Q2018

Powered by **CARB-X**



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# Pathogens Targeted in Current Portfolio

Pathogens	Therapeutic	Vaccine	Diagnostic
Gram-negative activity	✓		✓
Broad spectrum	✓		
<i>Pseudomonas aeruginosa</i>	✓		
<i>Acinetobacter baumannii</i>	✓		
<i>Neisseria gonorrhoeae</i>	✓		✓
Enterobacteriaceae	✓		
<i>Clostridium difficile</i>	✓		
<i>Staphylococcus aureus</i>		✓	

Powered by **CARB-X**



# CARB-X Partnership is Growing Globally

- UK Government and Bill & Melinda Gates Foundation joined CARB-X partnership in May 2018. New partners expected soon
- CARB-X's global Accelerator Network is expanding to support Powered by CARB-X companies. Stay tuned
- Education and training platforms developed with organizations including GARDP and Pew Charitable Trusts
- 2018 has been a year of exceptional growth – *pipeline has almost doubled* and is growing in size and diversity. New awards to be announced in 2019. Stay tuned



# Acknowledgments



## CARB-X Core (16)

Kevin Outterson  
Diane MacDonald  
Barry Eisenstein  
Karen Gallant  
Rich Lawson

Alexandra Regan  
Alison Haight  
Christina Mercado  
Jason Vo  
Jennifer Robinson

Johnny Sihakhamfong  
Kathleen Chardavoigne  
Merribeth Morin  
Nadia Cohen  
Raj Shetty  
Rose Garson  
Samantha Hirsch  
Sinnamon Tierney  
Su Chiang  
Yelena Greenberg

## Finance and Grants (25)

Diane Baldwin  
Gretchen Hartigan  
Others

## CARB-X Scientific Advisory Board (80+)

## Partners and Accelerators (30+)



BILL & MELINDA  
GATES foundation



***Thank You for Your Attention!***



# Addressing AMR: CARB-X and Other Models Panel Discussion



**Ann Eakin, PhD**  
Senior Scientific Officer  
Concept Acceleration  
NIAID/NIH



**Kevin Outterson, JD**  
CARB-X Exec. Director  
Professor of Law  
Boston University Law  
School



**Lynn Marks, MD**  
Advisor to BARDA  
Ex-SVP Clinical  
Development  
GSK



**Tyler Merkeley, MS, MBA**  
Interim Director  
DRIVE, BARDA

# Audience Q&A

Thank you!

[Tina.Guina@hhs.gov](mailto:Tina.Guina@hhs.gov)



# Backup Slides



# What to Expect When You Apply for CARB-X Funding

Month	1	2	3	4	5	6	7	8
	Cycle begins	Expression of Interest	Review by CARB-X	Short Form	Review by CARB-X	Long form	Final Review	Funding
	CARB-X sets the scope and timing of funding cycle, and opens the application period.	Companies submit Expressions of Interest summarizing the product proposed as a candidate for support. EOIs should not include confidential information.	CARB-X evaluates the application, and selects qualifying projects. CARB-X invites selected applicants via email to provide more detail in a confidential Short Form.	Selected companies submit confidential Short Forms.	CARB-X evaluates the Short Form and invites selected applicants via email to provide more detail in a confidential Long Form.	Selected applicants submit Long Form and a detailed budget.	Long Form applicants are invited to present their project proposals in person to an Advisory Board panel. Applicants undergo due diligence.	Final funding decisions made by CARB-X's JOC. Sub-award negotiations begin on project plan, milestones and budgets. Applicants must agree contractually to certain standards and conditions. Project support begins.
								

# Who Can Apply for CARB-X Funding?

CARB-X welcomes applications from around the world



- Projects must be in scope – CARB-X and specific round
- Applicants must have legal entity and be considered a going concern – solvent with funding in place for at least 12 months
- Applicants must own or have rights to the intellectual property and reasonable expectation of freedom to operate required to carry out the project
- Applicants must be able to contribute at least 30% of the cost of the program/project
- Applicants must have appropriate operations or capabilities in place to support product development, at least through proposed project phases
- Applicants from noncommercial drug development centers or academic institutions must meet additional requirements (next slide)

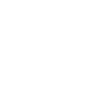
# CARB-X Welcomes Applications from Academic and Non-commercial Developers

Organization must be able to demonstrate R&D/business capabilities, including

- Capabilities similar to those expected of a drug development industry partner, particularly through the development stages in scope for CARB-X.
- Access to and use of relevant experts (internal and/or external) to advance projects toward clinical investigation within the framework of a major regulatory agency, e.g. FDA, EMA, PMDA
- Active management of IP supporting the project
- Well-developed strategy for advancement to human clinical with options for ‘exit strategy’ from organization (e.g. spin out, licensure to biotech)
- Capabilities in commercial (business) development and technology transfer
- Financial commitment and stability to cover cost share of at least 30% of the total cost of the project

**Please note:** CARB-X does not fund basic research/drug discovery including screening for novel targets





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# How to contact BARDA



Medical  
Countermeasures.gov

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.gov/home.aspx)

Portal to BARDA: **Register to request a TechWatch meeting!**



[www.fbo.gov/](http://www.fbo.gov/)  
("FedBizOpps")

Official announcements and info for all government contract solicitations



<https://www.phe.gov/about/BARDA/Pages/default.aspx>

Program description, information, news, announcements



[www.drive.hhs.gov](http://www.drive.hhs.gov)  
*DRIVE questions*

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<https://www.usajobs.gov/>  
*Join the team!*

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Portal to BARDA: **Register to request a TechWatch meeting!**



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[www.fbo.gov/](https://www.fbo.gov/)  
("FedBizOpps")

Official announcements and info for all government contract solicitations



<https://www.phe.gov/about/BARDA/Pages/default.aspx>

Program description, information, news, announcements



[www.drive.hhs.gov](https://www.drive.hhs.gov)

*DRIVE questions*

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