CARB-X

Combating Antibiotic Resistant Bacteria

CARB-X Funding Rounds for 2018

Supporting innovation to fight drug-resistant bacteria

Kevin Outterson

12 March 2018

CARB-X

Combating Antibiotic Resistant Bacteria

A non-profit partnership accelerating the best science from around the world to fight drug resistant infections

FUNDERS

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
BARDA

wellcome

NIH National Institute of Allergy and Infectious Diseases

PARTNERS

BOSTON UNIVERSITY

RTI INTERNATIONAL

CLSI
California Life Sciences Institute

MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

BROAD INSTITUTE

CARB-X funds R&D to combat the rising threat of serious drug-resistant bacteria

Urgent public health need

Antibiotic resistance kills an estimated 700,000 people each year world-wide. No new antibiotic classes for drug-resistant Gram-negative bacteria have been approved in decades.

Investing globally

CARB-X is a non-profit public-private partnership investing $455M in 2016-2021 to accelerate the early development of life-saving antibiotics, vaccines and rapid diagnostics.

Turning science into products

CARB-X provides non-dilutive funding and accelerator support for projects that target Gram-negative resistant bacteria on the WHO and CDC priority lists.

Partnering for results

CARB-X is funded by BARDA and the Wellcome Trust. NIAID provides pre-clinical services. Partners include the Broad Institute of MIT and Harvard, Massachusetts Biotechnology Council (MassBio), California Life Sciences Institute (CLSI) and RTI International. CARB-X is led by Boston University.

Combating antibiotic resistant bacteria

Better stewardship for existing antibiotics

Eliminate inappropriate use of these lifesaving drugs in both humans and animals.

Reduce the need for antibiotics by using alternative and nontraditional approaches to disease treatment and prevention.

Ensure that antibiotics are accessible and available to the people who need them.

Innovation to find new types of antibiotics

Support targeted research initiatives to overcome scientific challenges impeding the discovery of new antibiotics.

Address the complex barriers hindering the development of new treatment options for patients.

Drug-resistant bacteria
Centers for Disease Control and Prevention

Global Reach: CARB-X Funds 23 Projects in 6 Countries*

North America

Forge Therapeutics
San Diego, CA

Cidara Therapeutics San Diego, CA

Inhibrx
La Jolla CA

Amicrobe Inc.
Calsbad, CA

Curza
Salt Lake City, UT

VenatoRx Pharmaceuticals
Malvern, PA

Integrated Biotherapeutics
Rockville, MD

Contrafect Corporation
Yonkers, NY

Seres Therapeutics
Cambridge, MA

Vedanta Biosciences
Cambridge, MA

Spero Therapeutics
Cambridge, MA

Visterra Inc.
Cambridge, MA

Tetraphase Pharmaceuticals Inc.
Watertown, MA

Entasis Therapeutics (2)
Waltham, MA

Microbiotix Inc.
Worcester, MA

Europe and Asia

Iterum Therapeutics Ltd.
Dublin, Ireland

Proteus IRC
Edinburgh, Scotland

Oppilotech Ltd.
London, UK

Eligochem Ltd.
Sandwich, UK

Antabio
Labège, France

Debiopharm International S.A.
Lausanne, Switzerland

Bugworks Research India Pvt Ltd.
Bangalore, India

* As of Feb 15, 2018

CARB-X

Great science knows no boundaries

Powered by CARB-X

- 23 early development projects targeting serious drug resistant bacteria
- 8 new classes of antibiotics
- 10 non-traditional antibiotics
- 11 new molecular targets and a rapid diagnostic

CARB-X Antibacterial Treatment and Prevention Product Portfolio

Sponsor	Product	Novelty			Description	Priority		Development Stage			
		New Abx Class	New Non-traditional Product	New Target		CDC	WHO	Hit to Lead	Lead Optimization	Pre-Clinical	Phase I
Amicrobe	Amicidin-β		✓		Next-generation local antimicrobial	✓	✓	Broad spectrum			
Antabio	PEI		✓	✓	Pseudomonas elastase inhibitor	✓	✓	*P. aeruginosa*			
Bugworks Research	GYROX	✓			Gyrase-topoisomerase inhibitor	✓	✓	Gram-negative activity			
Cidara Therapeutics	CD201		✓	✓	Bifunctional immunotherapy	✓	✓	*Acinetobacter* + *P. aeruginosa* + Enterobacteriaceae			
ContraFect	Gram-negative lysins		✓	✓	Recombinant lysin protein	✓	✓	*P. aeruginosa*			
Curza	CZ-02	✓		✓	Novel class Gram-negative	✓	✓	*Broad Spectrum*			
Debiopharm International SA	Debio1453	✓		✓	Narrow-spectrum inhibitors of FabI	✓	✓	*Neisseria Gonorrhoeae*			
Eligochem	Helical AMP	✓			Helical antimicrobial peptide	✓	✓	Gram-negative activity			
Entasis Therapeutics	ETX0282CPDP				Oral Gram-negative combination	✓	✓	Gram-negative activity			
Entasis Therapeutics	Non-BL PBPi	✓			Non-beta-lactam PBPi	✓	✓	Gram-negative activity			
Forge Therapeutics	FG-LpxC	✓		✓	LpxC inhibitor	✓	✓	Gram-negative activity			
Inhibrx	INBRX-111		✓	✓	Multi-specific antibody	✓	✓	*P. aeruginosa*			
Integrated BioTherapeutics	IBT-V02		✓		Multi-valent toxoid vaccine	✓	✓	*S. aureus*			
Iterum	Sulopenem				Oral and IV penem	✓	✓	Gram-negative activity			
Microbiotix	T3SS Inhibitor		✓	✓	Virulence modifier	✓	✓	*P. aeruginosa*			
Oppilotech	LPS	✓		✓	Targets synthesis of LPS	✓	✓	Gram-negative activity			
Seres Therapeutics	SER-155		✓		Microbiome - transplant patients	✓	✓	Broad spectrum activity vs CRE/VRE			
Spero Therapeutics	SPR741			✓	Potentiator	✓	✓	Gram-negative activity			
Tetraphase Pharmaceuticals	TP-6076				Next-generation tetracycline	✓	✓	*Acinetobacter* + Enterobacteriaceae			
Vedanta	VE303		✓		Microbiome	✓		*C.difficile*			
VenatoRx	VNRX-PBP	✓			β-lactamase resistant PBP inhibitor	✓	✓	Entero-bacteriacae			
Visterra	VIS705		✓	✓	Antibody-drug conjugate	✓	✓	*P. aeruginosa*			

CARB-X Antibacterial Devices and Diagnostic Product Portfolio

Sponsor	Type	Technology	Description			
			Feasibility Demonstration	Optimization and Preparation for Development	Product Development	System Integration and Testing
PROTEUS	Rapid POC Dx	Optical bacterial imaging	POC Diagnostic			

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As of Feb 15, 2018

Powered by CARB-X

- CARB-X has announced more than $62 million in awards, plus an additional $77 million if project milestones are met.
- Many more awards to come in 2018, including a significant number of additional diagnostics

CARB-X Antibacterial Treatment and Prevention Product Portfolio

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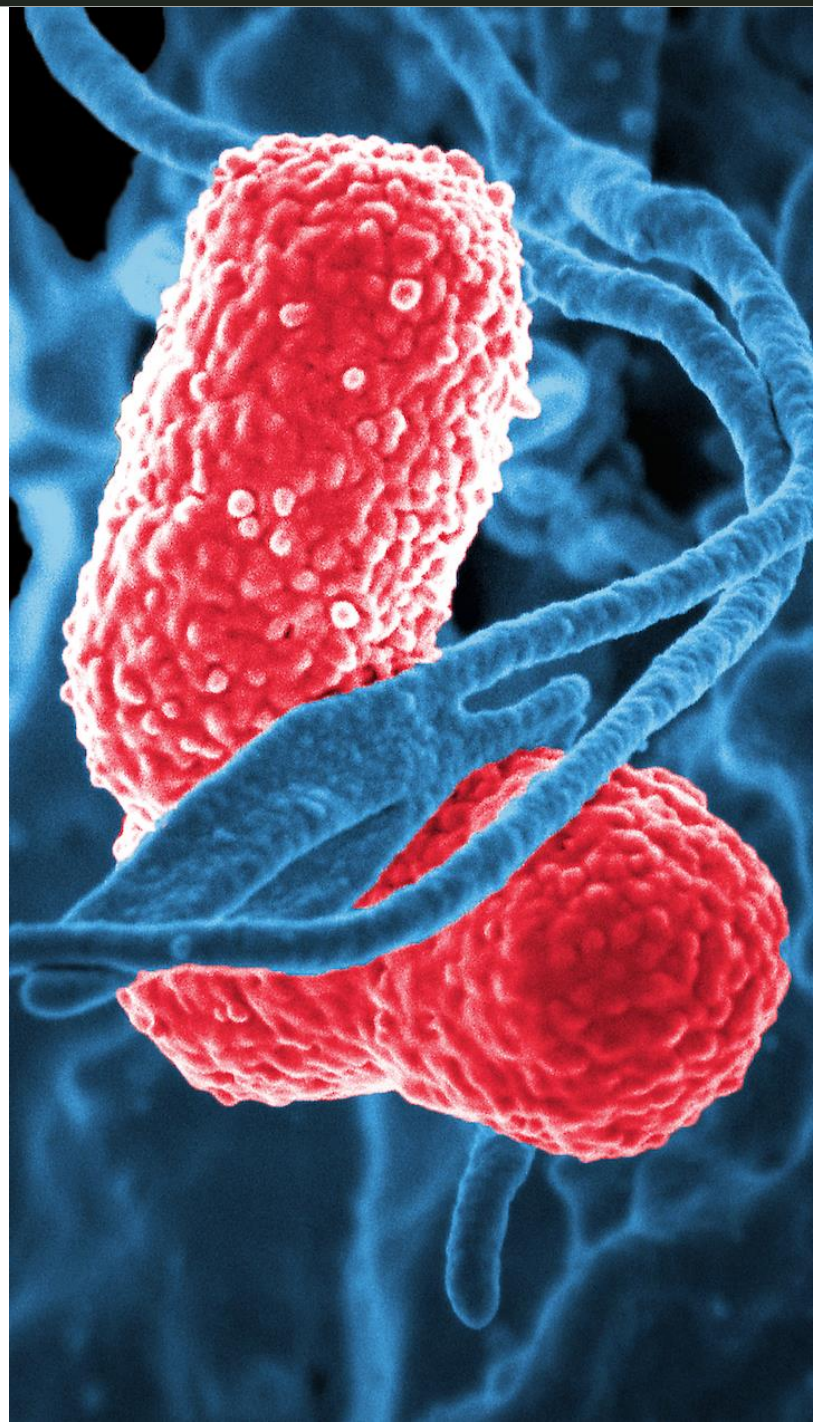
CARB-X

As of Feb 15, 2018

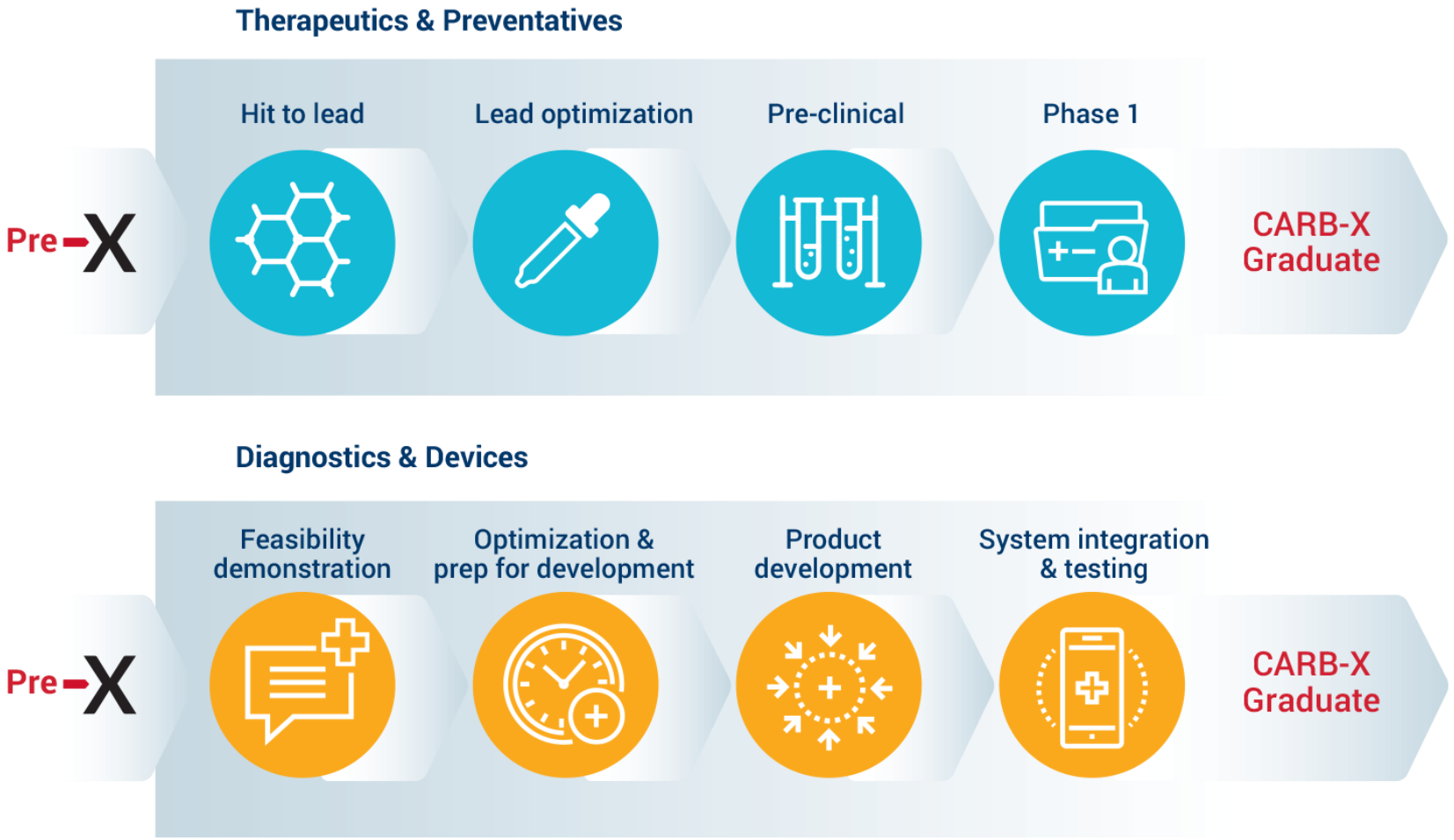
What CARB-X Funds

- Early development projects that address serious bacterial threats
  - antibiotics and therapeutics of all types
  - rapid diagnostics
  - prevention such as vaccines, microbiome, devices
- Projects must target specific 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

CARB-X Funds Projects in Early Development



CARB-X 2018 Funding Round 1

- Scope of Round 1
  - **New classes** of direct-acting small molecule and direct-acting large molecule antibiotics that target certain Gram-negative bacteria
- Expressions of Interest (EOI) accepted on-line only www.carb-x.org/application
- EOI must be submitted March 22 through March 29, 2018, 5 pm EST

Applying for Round 1?
Mark your calendar
March 22 – 29, 2018

CARB-X

CARB-X 2018 Funding Round 1 – Scope

Only projects in scope will be considered for funding by CARB-X. Please consult the tables below carefully.
To be considered, Expressions of Interest for Round 1 must be submitted on-line March 22, 2018 through March 29, 2018, 5 pm EST

2018 Funding Round 1 is restricted to 1) NEW classes of direct-acting small molecule therapeutics and 2) direct-acting large molecule therapeutics targeting the following Gram-negative pathogens
Acinetobacter baumannii, carbapenem-R
Pseudomonas aeruginosa, carbapenem-R
Enterobacteriaceae, carbapenem-R, 3rd-gen ceph-R (ESBL+)
Salmonellae spp., fluoroquinolone-R [1]
Neisseria gonorrhoeae, 3rd-gen ceph-R, fluoroquinolone-R
Shigella spp., fluoroquinolone-R [1]

Please note
These are not considered to be NEW classes and are therefore Out-of-Scope for funding in Round 1

Out of Scope	Out of Scope
β-lactams	Polymyxin
Glycopeptides (vancomycin)	Daptomycin
Quinolones	Pleuromutilin
Aminoglycosides	Nitrofurantoin
Tetracyclines	Trimethoprim
Oxazolidinones	Sulfamethoxazole
Macrolides	Rifampicin
Lincosamides	Mupirocin
Streptogramins	Fosfomycin
Chloramphenicol	Fusidic acid
Metronidazole	Fidaxomicin

NEW class small molecule is defined as a core chemical structure (scaffold) that does not have an antibiotic for human use approved by the FDA or EMA as of March 1, 2018.

Beta-lactamase inhibitors and other potentiators are considered INDIRECT acting and therefore not in scope for Round 1

[1] *Applications for these pathogens should include a discussion of intended/potential routes for sourcing of funding for later stages of clinical development.*

Mode of administration preference guidance

- ***For Enterobacteriaceae offerings:*** If only for ESBL (eg. lacks CRE), PO options are higher priority than IV only
- For ***Salmonellae spp., Shigella spp.*** **and** ***Neisseria gonorrhoeae offerings*** – oral delivery is strongly preferred
- Non-systemic modes of delivery are in-scope generally but would require well-reasoned justification for clinical utility/benefit

CARB-X 2018 Funding Round 2

- Scope of Round 2
  - **Broad scope** of therapeutics, vaccines, diagnostics and devices
- Expressions of Interest (EOI) accepted on-line only www.carb-x.org/application
- EOI must be submitted June 1 through June 8, 2018, 5 pm EST

Applying for Round 2?
Mark your calendar
June 1 - 8, 2018

CARB-X

CARB-X 2018 Funding Round 2 – Scope

Only projects in scope will be considered for funding by CARB-X
To be considered, Expressions of Interest for Round 2 must be submitted on-line June 1 through June 8, 2018, 5 pm EST

Pathogen Scope	Area Scope				Other requirements (if direct Tx)
	Diagnostics	Prevention	Indirect Tx	Direct Tx	
Acinetobacter baumannii, carbapenem-R	YES	YES	YES	YES	
Pseudomonas aeruginosa, carbapenem-R	YES	YES	YES	YES	
Enterobacteriaceae, carbapenem-R, 3rd-gen ceph-R (ESBL+)	YES	YES	YES	YES	
Enterococcus faecium, vancomycin-R	YES	YES	YES	YES	Must also target at least one Gram-negative bacteria listed to be in scope
Staphylococcus aureus, methicillin-R, vancomycin-I/R	YES	YES	YES	YES	Must also target at least one Gram-negative bacteria listed to be in scope
Helicobacter pylori, clarithromycin-R [1]	YES	YES	YES	NO	
Campylobacter spp., fluoroquinolone-R[1]	YES	YES	YES	NO	
Salmonellae spp., fluoroquinolone-R[1]	YES	YES	YES	YES	
Neisseria gonorrhoeae, 3rd-gen ceph-R, fluoroquinolone-R	YES	YES	YES	YES	
Streptococcus pneumoniae, penicillin-NS	YES	YES	YES	YES	Must also target at least one Gram-negative bacteria listed to be in scope
Haemophilus influenzae, ampicillin-R [1]	YES	YES	YES	NO	
Shigella spp., fluoroquinolone-R[1]	YES	YES	YES	YES	
Clostridium difficile	YES	YES	NO	NO	
Group A Streptococcus	YES	YES	YES	NO	
Group B Streptococcus	YES	YES	YES	NO	

[1]*Applications for these pathogens should include a discussion of intended/potential routes for sourcing of funding for later stages of clinical development.*

Mode of administration preference guidance:
For Enterobacteriaceae offerings: If Tx is only for ESBL (eg. lacks CRE), PO options are higher priority than IV only
For ***Salmonellae spp., Shigella spp.*** **and** ***Neisseria gonorrhoeae*** **offerings** – if Tx(direct or indirect), oral delivery is strongly preferred
Non-systemic modes of delivery are in-scope generally but would require well-reasoned justification for clinical utility/benefit
Tx = therapeutic

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 a legal entity and be considered a going concern – solvent with funding in place for operations 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 from larger or better-resourced companies are encouraged to propose higher amounts of cost share where feasible, as this demonstrates financial commitment to the 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

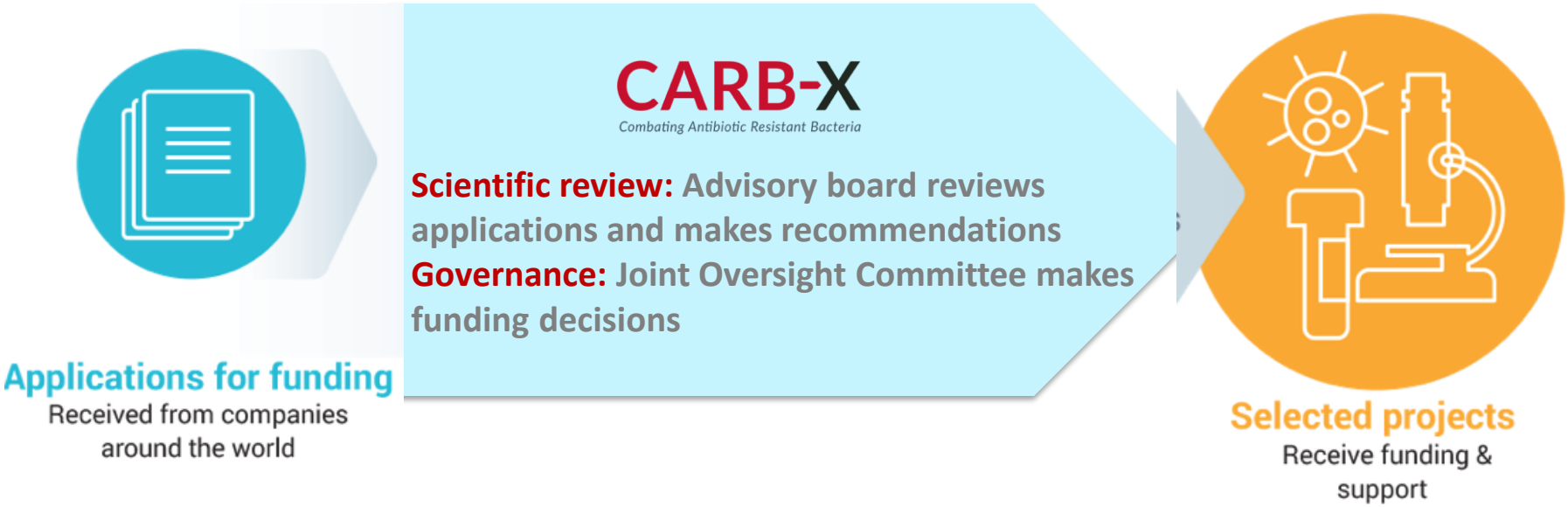
CARB-X Welcomes Applications from Academic and Non-commercial Developers

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 (if IP is controlled by a university, is the project supported by the Technology Transfer office?)
- 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

How Funding Decisions are Made



What to Expect When You Apply

About 8 months from EOI to decision

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.

CARB-X

Recap

CARB-X 2018 Funding Rounds will open for Expressions of Interest
Round 1: March 22-29, 2018
Round 2: June 1-8, 2018

- CARB-X welcomes applications from around the world
- Expressions of Interest applications must be submitted on-line at www.carb-x.org/application
- To qualify for funding and support, projects must be in scope and organizations must meet certain criteria
- The *Powered by CARB-X* portfolio is the world's largest and most scientifically diverse portfolio of early development antibacterial products to respond to the threat of the most serious drug-resistant bacteria and we intend to continue to build the portfolio

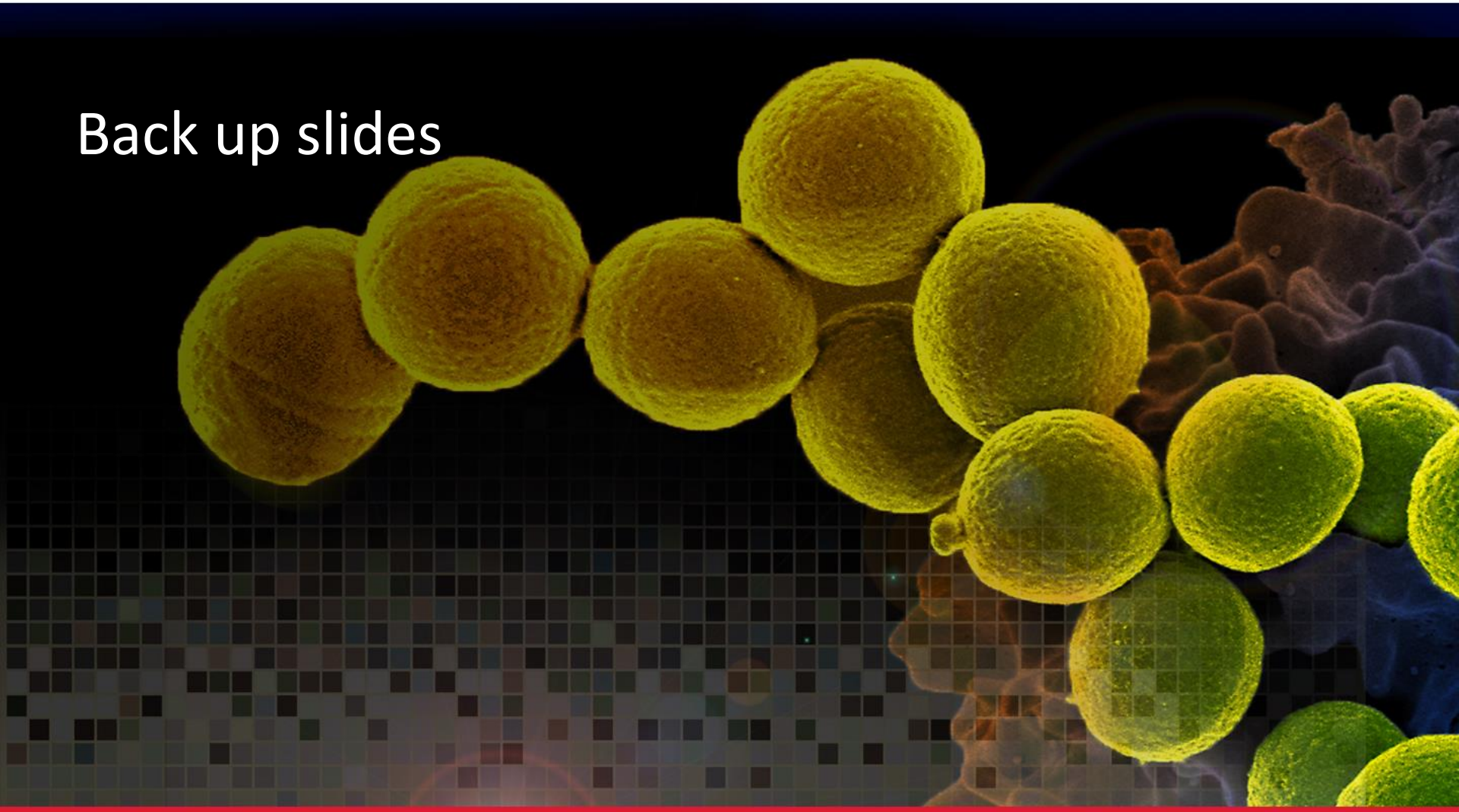
- More information: www.carb-x.org

Discussion and questions

CARB-X

Combating Antibiotic Resistant Bacteria

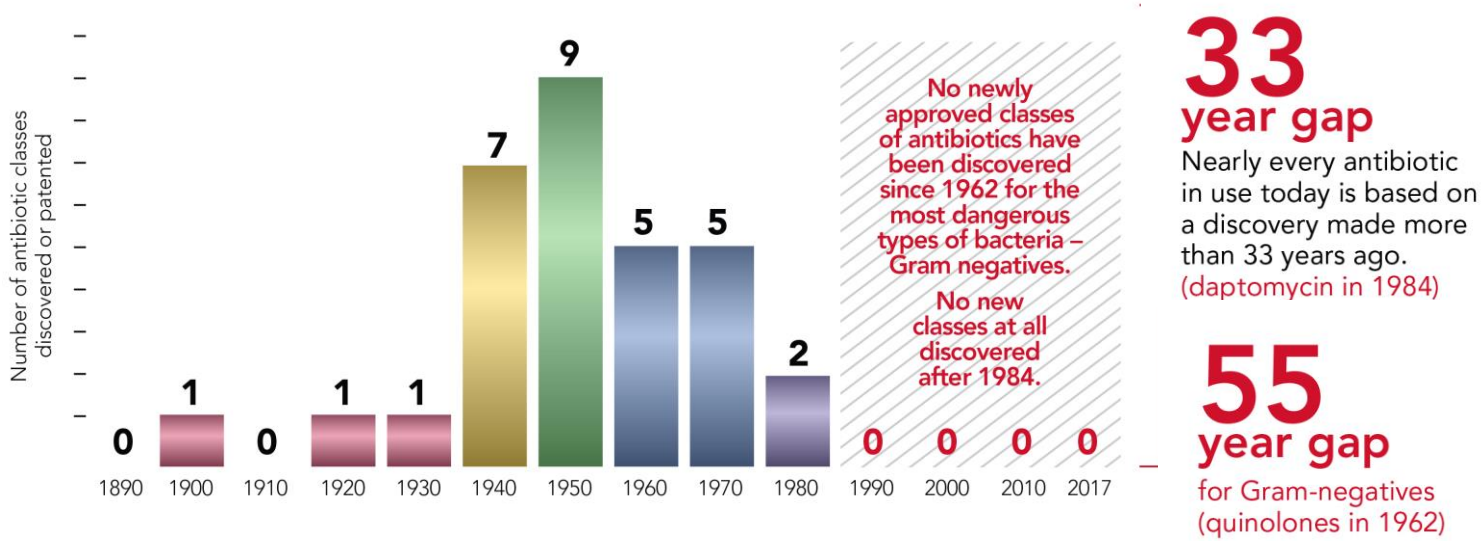
Back up slides



Powered by CARB-X

As of Feb 15, 2018

Discovery of novel antibiotics is not keeping up with emergence of new superbugs



This chart excludes bedaquiline, which is the first drug in a new class to treat tuberculosis.
Source: Pew Charitable Trusts; Deak D, Powers JH, Outterson K, Kesselheim AS. Progress in the Fight Against Multidrug Bacteria?: A Review of FDA Approved Antibiotics 2010-2015. ANNALS OF INTERNAL MED. 2016 MAY 31. DOI:10.7326/M16-0291.

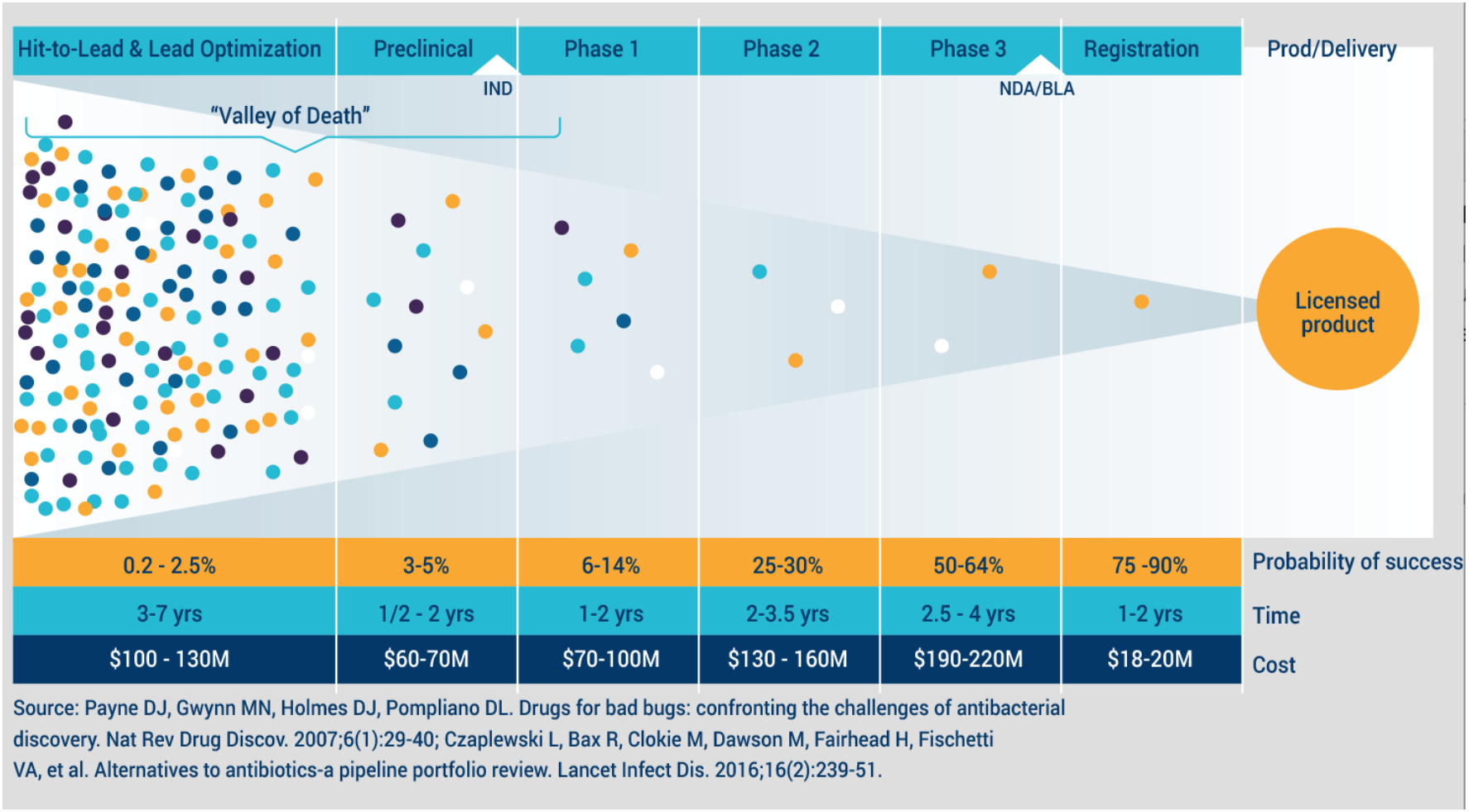
Global antibiotics pipeline is precariously slim

- 48 antibiotics in the global clinical pipeline in September 2017[1]
- but only 12 in development to treat superbugs on the WHO critical threat pathogen list[2]
  - Enterobacteriaceae (CRE)
  - *Pseudomonas aeruginosa*
  - *Acinetobacter baumannii*

1 Pew Charitable Trusts, Dec 2017
2 World Health Organization, "Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics" 2017

Lengthy, risky, and costly

It takes on average 10-12 years and hundreds of millions of dollars to deliver a new drug to market



Source: Payne DJ, Gwynn MN, Holmes DJ, Pompliano DL. Drugs for bad bugs: confronting the challenges of antibacterial discovery. Nat Rev Drug Discov. 2007;6(1):29-40; Czaplewski L, Bax R, Clokie M, Dawson M, Fairhead H, Fischetti VA, et al. Alternatives to antibiotics-a pipeline portfolio review. Lancet Infect Dis. 2016;16(2):239-51.

CARB-X

More than 60 outstanding experts from around the world make up the CARB-X Advisory Board

As of August 2017

CARB-X

Supporting great science

Outstanding experts make up CARB-X's Science Advisory Board (SAB). The SAB ensures the highest scientific standards in evaluating applications for CARB-X funding. Every member of the CARB-X SAB and JOC completes a conflicts of interest process and is excluded from participation in the review or approval of any application with which they have a conflict of interest. We thank them sincerely for their work.

Rosemarie Aurigemma, PhD
Deputy Associate Director, Developmental Therapeutics Program Division of Cancer Treatment and Diagnosis National Cancer Institute, NIH

Maureen J. Beanan, PhD
Program Officer, NIH/NIAID

Keith A. Bostian, PhD
CEO, Institute for Life Science Entrepreneurship

David Boucher, PhD
Health Scientist, ASPR/BARDA

Patricia A. Bradford, PhD
Antimicrobial Development Specialists, LLC

Liliana Brown, PhD
Program Officer, Office of Genomics and Advanced Technologies Division of Microbiology and Infectious Diseases/NIAID/NIH

Karen Bush, PhD
Professor of Practice in Biotechnology, Indiana University

Joseph Campbell, PhD
Program Officer, Research Resources Section Office of Biodefense, Research Resources and Translational Research/DMID/NIAID

Daniel Chelsky, PhD
CSO, Caprion Biosciences Inc.

Thomas Chen
Independent Consultant

Peter Coderre, PhD, MBA
Owner, Antimicrobial Regulatory Consulting LLC

R.D.G. Cooper D.Sc., PhD
Cooper Consulting LLC

Patrice Courvalin, MD, FRCP
Departement de Microbiologie Institut Pasteur

Lloyd Czaplewski, PhD
Independent Consultant Director at Abgentis

Thomas J. Dougherty, PhD
Dept. of Microbiology & Immunobiology Harvard Medical School

Michael N. Dudley, PharmD, FIDSA
Senior Vice President, Head of R&D Co-Lead, Infectious Disease Global Innovation, The Medicines Company

Ann E. Eakin, PhD
Senior Scientific Officer, DMID NIAID/NIH

Paul Eder, PhD
Principal and Senior Medical Diagnostics Advisor Tunnell Government Services, for BARDA

Michael Elisseou, PhD
Contractor, Division of CBRN Countermeasures, BARDA

Ronnie Farquhar, D. Phil.
Morningside Ventures

Anthony Ford-Hutchinson, PhD
Independent Consultant to the Pharmaceutical Industry

Francois Franceschi, PhD
Program Officer, Bacteriology and Mycology Branch NIH/NIAID

Humphrey Gardner, MD
Chief, Medical Oncology, Evelo Biosciences

Steven C. Gilman, PhD
Chairman and Chief Executive Officer Contrafect Corporation

Alan Goldberg
Special Government Employee and SME Drug Development BARDA/ ASPR/ HHS

Mark J. Goldberger, MD, MPH
Independent Consultant Mark Goldberger MD, MPH LLC

Tina Guina, PhD
Program Officer, Drug Development DMID, NIAID, NIH

Raymond D. Harris, PhD
Program Officer Office of Biodefense, Research Resources and Translational Research, DMID/NIAID/NIH

Deborah T. Hung, MD, PhD
Co-Director, Infectious Disease and Microbiome Program Core Institute Member Broad Institute of MIT and Harvard Associate Professor, Department of Genetics Harvard Medical School Associate Professor, Department of Molecular Biology, Massachusetts General Hospital

Randall Kincaid, PhD
Senior Scientific Officer Division of Microbiology and Infectious Diseases, NIAID/NIH

Jane M. Knisely, PhD
Program Officer, NIAID/NIH

Gerald R. Kovacs, PhD
Senior Adviser, CMI Consulting for BARDA

Marina Kozak, PhD
Health Scientist, Division of CBRN Countermeasures BARDA/ASPR/HHS

John S. Lee, PhD
Health Scientist, Diagnostics and Medical Devices Division (DMD) BARDA/ASPR/HHS

Malen Link, PhD, Biologist
Division of CBRN Countermeasures ASPR/HHS/BARD

Frederic J Marsik, PhD
Clinical Microbiology Consultant

Marielena Mata, PhD
Head of Precision Medicine and Companion Diagnostics GSK

Chris Meda, MS
Chief Business Officer, IncellDx Inc. National Sponsorship Chair, Women in Bio, Board Director, Claremont BioSolution

Michael Merchlinsky, PhD
Scientific Program Manager, ASPR/BARDA

Linda A. Miller, PhD
Clinical Microbiologist CMID Pharma Consulting, LLC

Paul F. Miller, PhD
Chief Scientific Officer, Synlogic

Tam Nguyen, PhD
Program Officer, NIAID

Sylvia A. Norman, PhD
President & CEO Sandhill Crane Diagnostics Inc.

David Oldach, MD, FIDSA
Chief Medical Officer Cempra Pharmaceuticals Inc.

Frederick B. Oleson, Jr., DSc
Independent Consultant

Sharon Peacock, MBBS, PhD, FRCP, FRCPath, FMedSci, CBE
Professor of Clinical Microbiology, London school of Hygiene and Tropical Medicine Non-executive Director Addenbrooke's Hospital, Cambridge

Steven J. Projan, PhD, F.A.A.M.
Sr. Vice President R&D, Innovative Medicines Head Infectious Disease & Vaccines, MedImmune

Ryan T. Ranallo, PhD
Program Officer Division of Microbiology and Infectious Diseases NIAID

George Risi, MD, MSc
Senior Medical Adviser Division of Clinical Development, BARDA

Bill Rodriguez, MD
Managing Director Draper Richards Kaplan Foundation

M. Dominic Ryan, PhD
DRI2, LLC

Helen Schiltz, PhD
Program Officer, Drug Development Section, Office of BioDefense, Research Resources, and Translational Research, DMID/NIAID/NIH

Oxana A. Selivanova, PhD
Interdisciplinary Scientist BARDA/ASPR

Karen Joy Shaw, PhD
CSO, Amplyx Pharmaceuticals President, Hearts Consulting Group

Richard Seabrook, PhD, MBA
Independent Consultant Senior Advisor, Translational R&D at Catapult

Anita Sheoran, PhD
Program Officer, Drug Development, Division of Microbiology & Infectious Diseases, NIAID

Nicola Shepherd, PhD
Director, Bellows Consulting Ltd.

David Shlaes
Anti-infectives Consulting, LLC, Retired

Lynn L. Silver, PhD
LL Silver Consulting, LLC

Jared A. Silverman, PhD
Senior Vice President, Research Kaleido Biosciences

Keith Spencer, PhD
Director Academic Liaison, GSK

Jeff Stein, PhD
President & CEO, Cidara Therapeutics

Joyce Sutcliffe, PhD
Independent Antibacterial Consultant

Kimberly L. Taylor, PhD
Project Officer Vaccine Development Section Office of Biodefense, Research Resources and Translational Research/DMID/NIAID

Fred C. Tenover, PhD D(ABMM)
Vice President, Scientific Affairs, Cepheid

Ursula Theuretzbacher, PhD
Antibiotic R&D expert Center for Anti-Infective Agents

Brian N. Tse, PhD
Health Scientist BARDA/ASPR/HHS

Mark Wilcox, MD, FRCPath
Professor of Medical Microbiology University of Leeds Consultant Microbiologist, Head of research and Development in Microbiology at Leeds Teaching Hospitals

Daniel Wolfe, PhD
Health Scientist, BARDA

Neil Woodford BSc PhD FRCPath
Professor Head, Antimicrobial Resistance and Healthcare Associated Infections (AMRHAI) Reference Unit National Infection Service, Public Health England

Lanling Zou, MD, PhD
Bacteriology Program Officer Chief, Translational Sciences Section BMB/DMID/NIAID/NIH/DHHS