



Combating Antibiotic Resistant Bacteria

CARB-X Funding Rounds for 2018

Supporting innovation to fight drug-resistant bacteria

Kevin Outterson
29 March 2018



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

FUNDERS



PARTNERS





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.

CARB-X

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 28 Projects in 7 Countries*



North America

Forge Therapeutics
San Diego, CA

VenatoRx Pharmaceuticals
Malvern, PA

Cidara Therapeutics
San Diego, CA

Integrated Biotherapeutics
Rockville, MD

Spero Therapeutics
Cambridge, MA

Inhibrx
La Jolla CA

Contrafect Corporation
Yonkers, NY

Visterra Inc.
Cambridge, MA

Amicrobe Inc.
Calsbad, CA

Seres Therapeutics
Cambridge, MA

Tetraphase
Pharmaceuticals Inc.
Watertown, MA

Curza
Salt Lake City, UT

Vedanta Biosciences
Cambridge, MA

Entasis Therapeutics (2)
Waltham, MA

Helixbind
Marlborough, MA

T2 Biosystems
Lexington, MA

Microbiotix Inc.
Worcester, MA

Macrolide Pharmaceuticals
Watertown, MA

MicRx Pharmaceuticals
Hayward, CA

Europe and Asia

Iterum Therapeutics Ltd.
Dublin, Ireland

Antabio
Labège, France

Proteus IRC
Edinburgh, Scotland

Debiopharm International S.A.
Lausanne, Switzerland

Oppilotech Ltd.
London, UK

Bugworks Research India Pvt Ltd.
Bangalore, India

Eligochem Ltd.
Sandwich, UK

Shionogi & Co., Ltd
Osaka, Japan

* As of 29 March, 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 Abs Class	New Non-traditional Product	New Target		CDC	WHO	Hit to Lead	Lead Optimization	Pre-Clinical	Phase I
Amicore	Amicidin-G		✓		Next-generation local antimicrobial	✓	✓	Broad spectrum			
Antibio	PEI		✓	✓	Pseudomonas elastase inhibitor	✓	✓	<i>P. aeruginosa</i>			
BuGen Research	GT100X	✓			β-lactamase inhibitor	✓	✓	Gram-negative activity			
Cellara Therapeutics	CD201		✓	✓	Bi-functional immunotherapy	✓	✓	<i>Acinetobacter</i> + <i>P. aeruginosa</i> + Enterobacteriaceae			
Centrafect	Gram-negative lysins		✓	✓	Recombinant lysin protein	✓	✓	<i>P. aeruginosa</i>			
Curis	CE-02	✓		✓	Novel class Gram-negative	✓	✓	Broad Spectrum			
Debiopharm International SA	Debio1453	✓		✓	Narrow-spectrum inhibitors of PabI	✓	✓	<i>Neisseria Gonorrhoea</i>			
Eligtech	Helical AMP	✓			Helical antimicrobial peptide	✓	✓	Gram-negative activity			
Entasis Therapeutics	ETX0282CPDR				Oral Gram-negative combination	✓	✓	Gram-negative activity			
Entasis Therapeutics	Non-βL PBR	✓			Non-beta-lactam PBR	✓	✓	Gram-negative activity			
Forge Therapeutics	FG-LxC	✓		✓	LxC inhibitor	✓	✓	Gram-negative activity			
Inhibrx	INBRX-111		✓	✓	Multi-specific antibody	✓	✓	<i>P. aeruginosa</i>			
Integrated BioTherapeutics	IBT-V02		✓		Multi-valent toxoid vaccine	✓	✓	<i>S. aureus</i>			
Iterum	Sulopenem				Oral and IV penem	✓	✓	Gram-negative activity			
Microbiotix	T3S5 Inhibitor		✓	✓	Virulence modifier	✓	✓	<i>P. aeruginosa</i>			
Oxiplex	LPS	✓		✓	Targets synthesis of LPS	✓	✓	Gram-negative activity			
Senes Therapeutics	SEN-155		✓		Microbiome - transplant patients	✓	✓	Broad spectrum activity in CD/IBD			
Spars Therapeutics	SPR041			✓	Potentiator	✓	✓	Gram-negative activity			
Tetraphase Pharmaceuticals	TP-6076				Next-generation tetracycline	✓	✓	<i>Acinetobacter</i> + Enterobacteriaceae			
Vedanta	VE303		✓		Microbiome	✓		Colitidis			
VenizipRx	VNRX-PBP	✓			β-lactamase resistant PBP inhibitor	✓	✓	Enterobacteriaceae			
Visterra	VS705		✓	✓	Antibody drug conjugate	✓	✓	<i>P. aeruginosa</i>			

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			

CARB-X

As of Feb 15, 2018

Powered by CARB-X

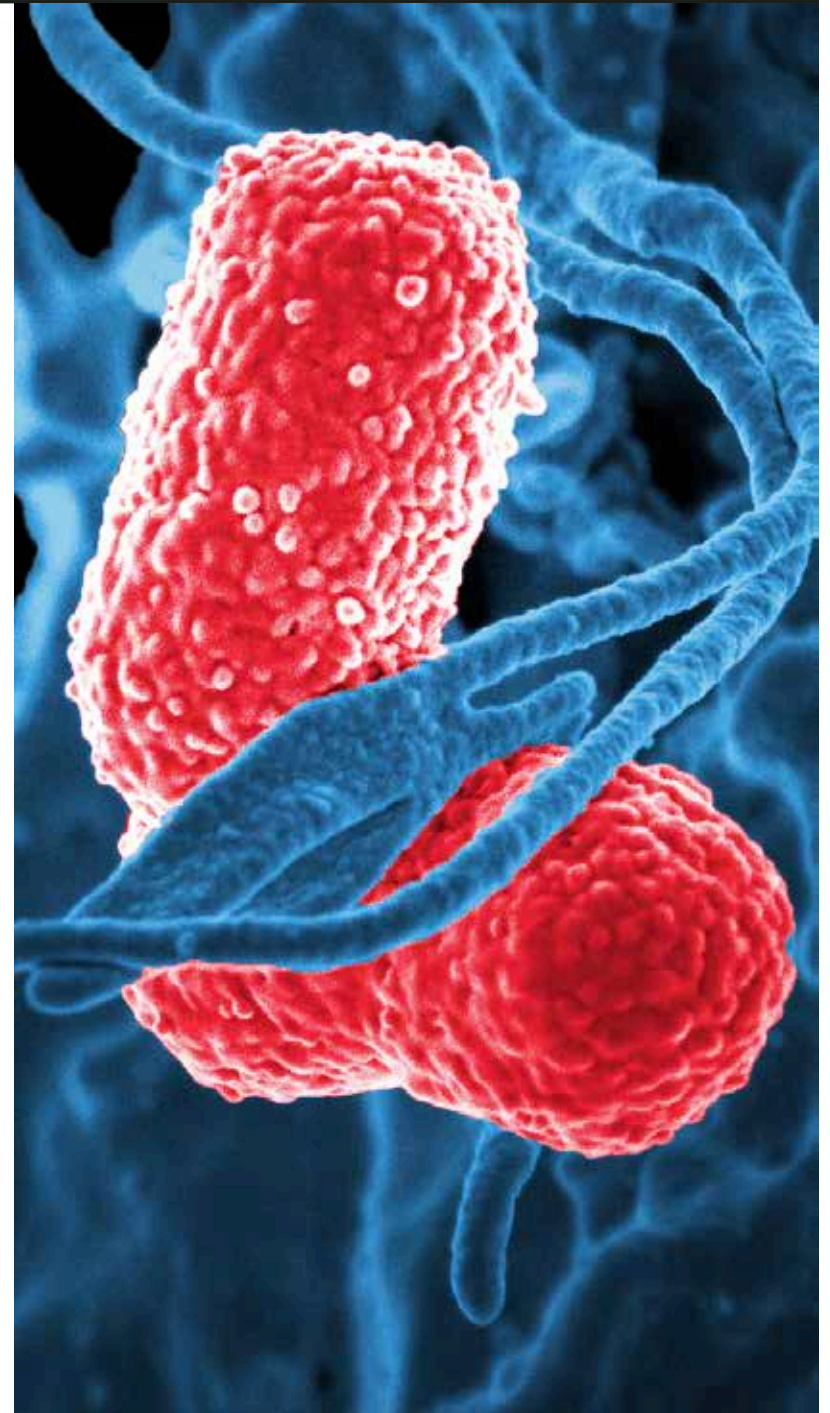
- CARB-X has announced more than \$62 million in awards, plus an additional \$77 million if project milestones are met.
- Many more awards to come in 2018, including a significant number of additional diagnostics

CARB-X Antibacterial Treatment and Prevention Product Portfolio											
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Cellara Therapeutics	CD201		✓	✓	Bi-functional immunotherapy	✓	✓	<i>Acinetobacter</i> + <i>P. aeruginosa</i> + Enterobacteriaceae			
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Entasis Therapeutics	ETX082CPDR				Oral Gram-negative combination	✓	✓	Gram-negative activity			
Entasis Therapeutics	Non-βL PBPi	✓			Non-beta-lactam PBPi	✓	✓	Gram-negative activity			
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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 Funds Projects in Early Development

Therapeutics & Preventatives



Diagnostics & Devices



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 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 cep-R (ESBL+)

Salmonellae spp., fluoroquinolone-R¹

Neisseria gonorrhoeae, 3rd-gen cep-R, fluoroquinolone-R

Shigella spp., fluoroquinolone-R¹

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 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	
<i>Acinetobacter baumannii</i> , carbapenem-R	YES	YES	YES	YES	
<i>Pseudomonas aeruginosa</i> , carbapenem-R	YES	YES	YES	YES	
<i>Enterobacteriaceae</i> , carbapenem-R, 3 rd -gen cephalosporin-R (ESBL+)	YES	YES	YES	YES	
<i>Enterococcus faecium</i> , vancomycin-R	YES	YES	YES	YES	Must also target at least one Gram-negative bacteria listed to be in scope
<i>Staphylococcus aureus</i> , methicillin-R, vancomycin-I/R	YES	YES	YES	YES	Must also target at least one Gram-negative bacteria listed to be in scope
<i>Helicobacter pylori</i> , clarithromycin-R ¹	YES	YES	YES	NO	
<i>Campylobacter</i> spp., fluoroquinolone-R ¹	YES	YES	YES	NO	
<i>Salmonellae</i> spp., fluoroquinolone-R ¹	YES	YES	YES	YES	
<i>Neisseria gonorrhoeae</i> , 3 rd -gen cephalosporin-R, fluoroquinolone-R	YES	YES	YES	YES	
<i>Streptococcus pneumoniae</i> , penicillin-NS	YES	YES	YES	YES	Must also target at least one Gram-negative bacteria listed to be in scope
<i>Haemophilus influenzae</i> , ampicillin-R ¹	YES	YES	YES	NO	
<i>Shigella</i> spp., fluoroquinolone-R ¹	YES	YES	YES	YES	
<i>Clostridium difficile</i>	YES	YES	NO	NO	
Group A Streptococcus	YES	YES	YES	NO	
Group B Streptococcus	YES	YES	YES	NO	

¹Applications 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:

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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 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

CARB-X



How Funding Decisions are Made

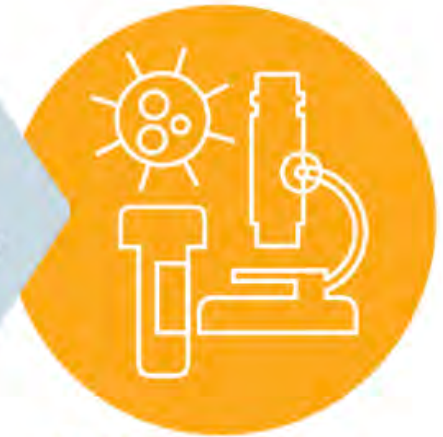


Applications for funding

Received from companies
around the world



Scientific review: Advisory board reviews applications and makes recommendations
Governance: Joint Oversight Committee makes funding decisions






Selected projects

Receive funding &
support

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.

Recap

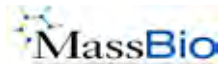
CARB-X 2018 Funding Rounds will open for Expressions of Interest

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](http://www.carb-x.org)

Discussion and questions

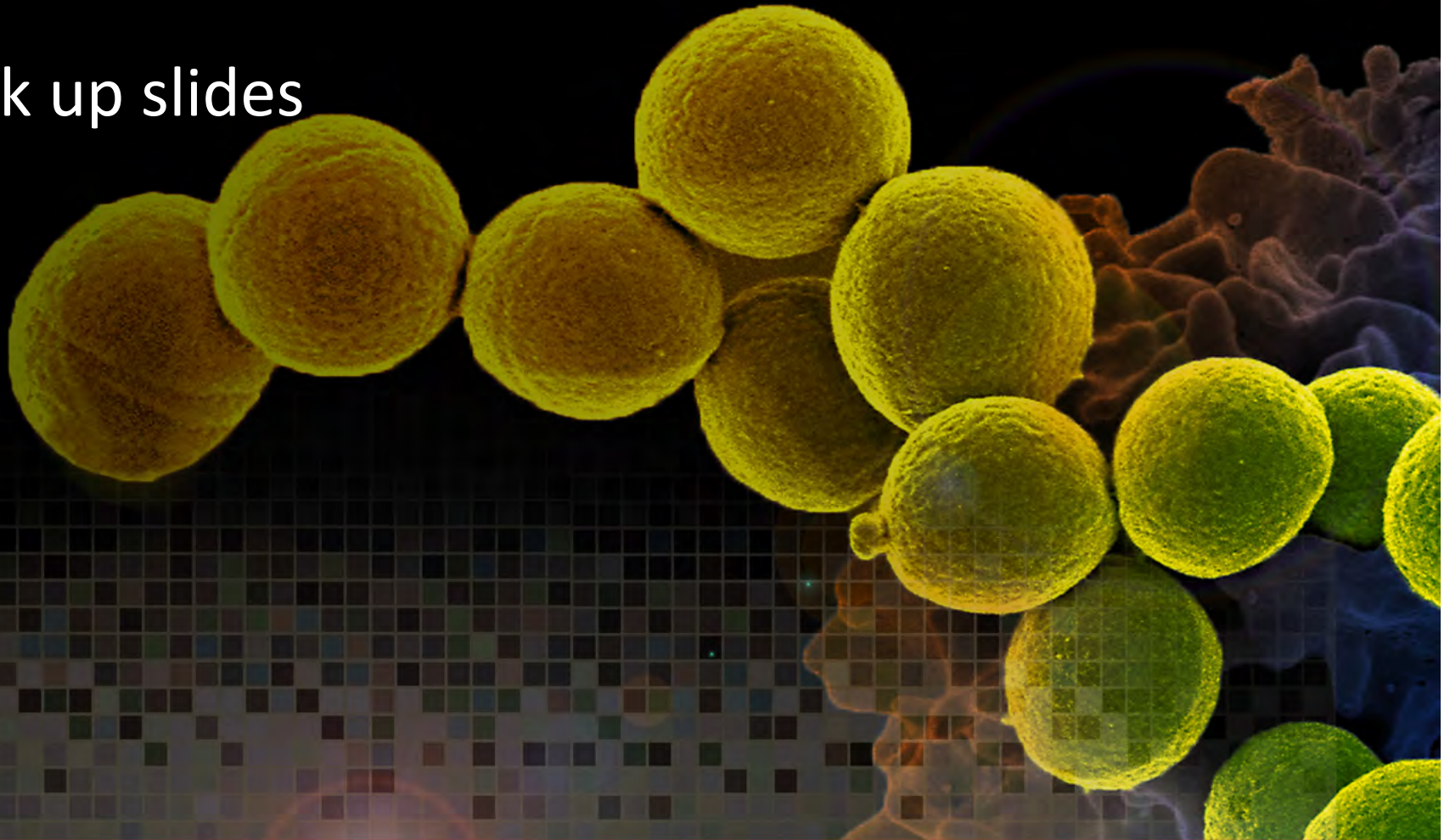


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Combating Antibiotic Resistant Bacteria

Back up slides



Powered by **CARB-X**

Engineering Antimicrobials
AMICROBE

ANTABIO
Developing antimicrobials to end the world's

bugworks

Debiopharm Group

CIDARA
THERAPEUTICS

ContraFect

CURZA

eligochem
SAFER DRUGS BY DESIGN

ENTASIS
THERAPEUTICS
CEPHALOSPORIN PROTECTA, WITH NOVEL ORAL BLI

ENTASIS
THERAPEUTICS
NON-BETA-LACTAM PBPi

FORGE
Therapeutics

INHIBRX

integrated
biotherapeutics

ITERUM
therapeutics

MICROBIOTIX
Inc.

Oppilotech
UNLOCKING RESISTANCE

PROTEUS

SERES
THERAPEUTICS
Leading the Meritclaim Revolution

SPERO
THERAPEUTICS

TETRAPHASE
PHARMACEUTICALS

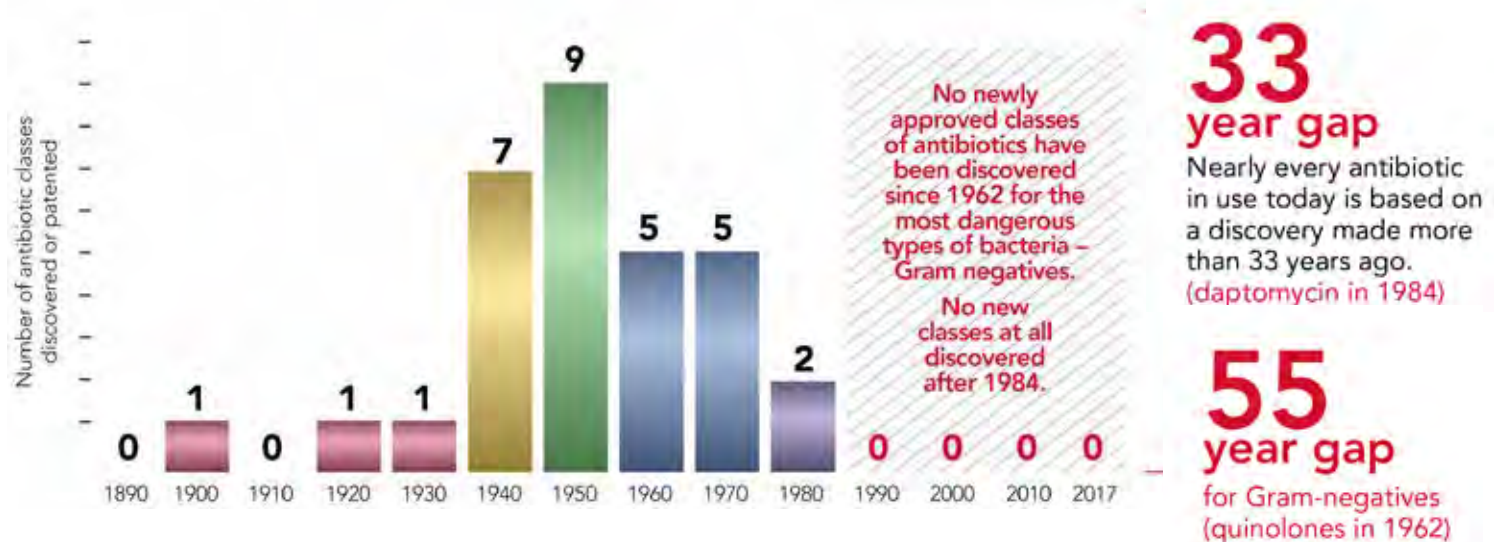
VEDANTA
BIOSCIENCES

VenatorX
PHARMACEUTICALS

Visterra

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 2017¹
- but only 12 in development to treat superbugs on the WHO critical threat pathogen list²
 - Enterobacteriaceae (CRE)
 - *Pseudomonas aeruginosa*
 - *Acinetobacter baumannii*



Only 12 antibiotics in development have the potential to treat WHO's critical threat pathogens.



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.

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.

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Accelerating products to fight drug resistance

With CARB-X support in the past year, 5 projects progressed into the clinic (Ph1)

Powered by **CARB-X**

Phase 1 Progressions - CARB-X Antibacterial Treatment and Prevention Product Portfolio									
Company	Product	Novelty			Description	Development Stage			
		New Abx Class	New Non-traditional Product	New Target		Hit to Lead	Lead Optimization	Pre-Clinical	Phase I
Entasis Therapeutics	ETX0282CPDP				Oral Gram-negative combination	Gram-negative activity			
Iterum	Sulopenem				Oral and IV penem	Gram-negative activity			
Spero Therapeutics	SPR741			✓	Potentiator	Gram-negative activity			
Tetraphase Pharmaceuticals	TP-6076				Next-generation tetracycline	Acinetobacter + Enterobacteriaceae			
Vedanta	VE303		✓		Microbiome	C.difficile			

The above projects are Powered by CARB-X utilizing non-dilutive funding from BARDA, Wellcome Trust, & NIAID. Characterizations of new Abx Class and New Target by CARB-X, following Pew pipeline analysis: <http://www.pewtrusts.org/en/multimedia/data-visualizations/2014/antibiotics-currently-in-clinical-development>. Other characterizations by CARB-X experts and external expert opinion. Abx = traditional small molecule antibiotic. Non-traditional Product = not a traditional small molecule antibiotic.