CARB-X
Combating Antibiotic-Resistant Bacteria

BOSTON UNIVERSITY

Funding Efforts to Support Gonorrhea Drug Development

Erin Duffy, PhD
Boston University & CARB-X
FDA-CDC-NIAID Virtual Public Workshop
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CARB-X Accelerates Innovative Products against Drug-Resistant Bacteria

Therapeutics, Preventatives and Diagnostics

Global partnership funds and advances high-risk projects with big-impact potential for patients

- Investing $480 million in 2016-22 to accelerate innovation addressing the global rise of antibiotic resistance
- Targeting the most serious antibiotic-resistant bacteria (CDC, WHO)
- Non-dilutive funding to product developers to drive innovation. Companies assume 10%-20% cost-share
- New rounds possible only after new funding received

56 active PROJECTS* | **$322M** to date | **85** PROJECTS since 2016 | **11** COUNTRIES | **8** project GRADUATES | **2** graduates win contracts with BARDA

World's largest and most scientifically diverse early development portfolio … more to come

- 34 Therapeutics (new classes, novel targets, non-traditional)
- 13 Preventatives (vaccines, antibodies, LBT, phage, small-molecule)
- 9 Rapid Diagnostics

* as of April 21, 2021

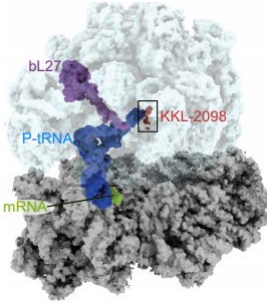
ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE | BARDA | wellcome | NIH National Institute of Allergy and Infectious Diseases | UKaid from the British people | Federal Ministry of Education and Research | BILL & MELINDA GATES foundation

Active Treatment Programs for Gonorrhea

Debiopharm
WE DEVELOP FOR PATIENTS

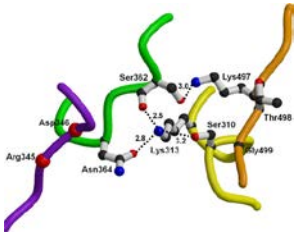
Mechanism: fatty-acid biosynthesis
Molecule: Debio 1453
Stage: Preclinical

MICROBIOTIX Inc.



Mechanism: protein synthesis
Molecule: new class
Stage: Hit-to-Lead

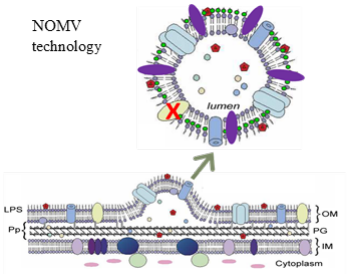
Venatorx
PHARMACEUTICALS



Mechanism: cell-wall synthesis
Molecule: cyclic boronate
Stage: Hit-to-Lead

Active Prevention and Diagnostic Programs for Gonorrhea

THE JENNER INSTITUTE
DEVELOPING INNOVATIVE VACCINES

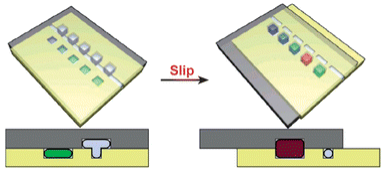


Native Outer-membrane Vesicle Vx
Stage: Lead Optimization

NOVEL MICRODEVICES

Rapid, PoC Molecular Dx, inc AMR
Stage: Feasibility

TALIS



Rapid, PoC ID & AST
Stage: Optimization/Development

CARB-X is More than Funding: Acceleration Themes

- Applicant Support
- Project Specific Acceleration (95+% of active Tx projects are with SMEs, Academia or Institutes)
- **Cross-Project Opportunities for Acceleration**
- Community Development (7 current Accelerators; plans to augment along capabilities and geographies)

CARB-X developed an initial acceleration model in March 2017 in partnership with the funders at the time

The model has been refined based on lessons from the field and based on the evolution of the CARB-X organization

Support via Cross-Project Opportunities

Goal: Identify and fund areas where CARB-X can accelerate the portfolio

- Create efficiencies across multiple funded companies
- Create higher-level understanding of common issues facing developers
- Potentially create funding call around focused areas of innovation/development
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First highest priority areas

- Early evaluation of pre-existing resistance risk (Tx) or antigenic variability (Pv) – *already underway*
- Consistent assessment of key safety risks - *already underway*
- **Improved animal models of infection**
- Improved definition of target patient populations
- Standardization of the assay tools for non-traditional approaches
- Determine optimal sample collection solutions for LRTI

Improved Animal Models of Infection

- There is no empirical model for prediction of the clinical efficacy of treatment of uncomplicated gonorrhea with any antimicrobial agent other than penicillin.
- Can we do better than Moran & Levine's (CID, 1995) "time therapeutic"?
  - Number of hours drug concentrations are ≥ 4X MIC90
- We need model data for clinically-used and –studied antibiotics, including PK, with an emphasis on back-translation.