

WORLD **A**NTI-**M**ICROBIAL **R**ESISTANCE CONGRESS **us** | 2016

September 8-9, 2016

Washington Court Hotel, Washington, D.C.

**INNOVATION. COLLABORATION.
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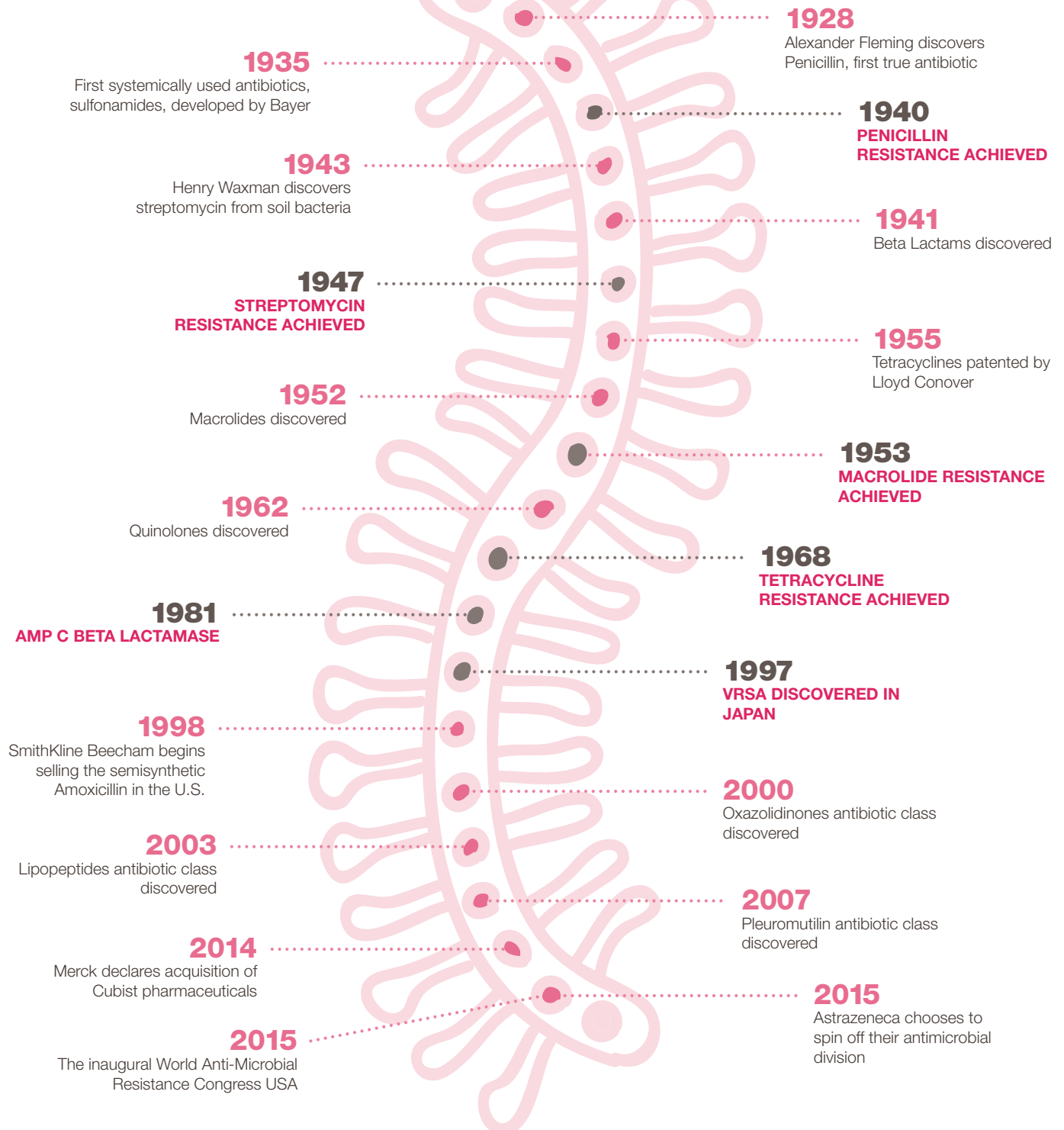
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THE HISTORY OF ANTIBIOTICS



“ ...Failure to battle drug-resistant infections and their causes could result in 10 million extra deaths per year by 2050 at a cost of \$100 trillion to the global economy.

Report commissioned by **UK Prime Minister David Cameron**

”

8:00	Registration and networking breakfast
8:50	Terrapinn welcome remarks
8:55	Chairperson's opening remarks
A GLOBAL CRISIS	
9:00	Leading the fight to resistance: are we reaching a post antibiotic era? - Is bringing new antibiotics to market the solution? - How can we work to prevent the spread of infection through universal access to clean water and sanitation? - Will the World Economic Forum outcomes have a real impact on curbing this global crisis? - Comparing and contrasting needs and priorities in stewardship, hygiene and new antibiotics Dawn O'Connell, Deputy Chief of Staff, United States Department of Health and Human Services
9:20	PANEL SESSION: International collaboration and capacities for antibiotic resistance prevention, surveillance, control and antibiotic R&D - Global efforts to detect new and emerging pathogens, preventing infections and the spread of resistance - How to achieve a globally coordinated surveillance system to gather data and reach early warnings? - Improving antibiotic prescription practices and stewardship - What can be done to spur R&D while making sure essential medicines work? Marcos Espinal, Director, Department of Communicable Diseases and Health Analysis, PAHO/WHO Jean Patel, Deputy Director, Office of Antimicrobial Resistance, CDC Barbara Kerstiens, Deputy Head of Unit, Fighting Infectious Diseases and Advancing Public Health Research and Innovation Directorate-General, European Commission
10:00	Speed networking
10:30	Networking coffee break
ECONOMIC MODELS	
11:00	PANEL SESSION: Will hybrid and delinkage economic models for anti-infectives get more pharma and VC's back into the space? - The goal is developing antibiotics with greater societal value, but why has buy-in been so slow? - Is it fully possible to break the link between sales and volume? - What other incentives are needed to fully foster investment? - How can you coordinate these models globally? How would they work in a post-approval landscape? Kevin Outterson, Professor of Health Law, Bioethics and Human Rights, Boston University School of Law Ankit Mahadevia, Founder and CEO, Spero Therapeutics Chen Yu, Managing Partner, Vivo Capital Anthony McDonnell, Head of Economic Research, Review on Antimicrobial Resistance Jenelle Krishnamoorthy, Executive Director, U.S. Policy and Government Relations, Merck
11:50	Do antimicrobial development and reimbursement models make sense to payers? - What do payers need from industry to justify the high prices of antimicrobials? - What are the main uptake limitations of new drugs when it comes to pricing and reimbursement? - What data is needed to support decision-making? - Are these models helping with innovation? Ed Pezalla, Vice President, National Medical Director for Pharmaceutical Policy and Strategy, Aetna
12:20	Networking Lunch
POLICY AND OTHER INCENTIVES	
Roundtable Sessions	
1:50	ROUNDTABLE 1: QIDP designation - not quite like an orphan drug designation. Is there a real advantage? Barry Eisenstein, Distinguished Physician, Antimicrobials, Merck ROUNDTABLE 2: Patent extensions - Having a few months of patent extensions can mean high profits for big pharma. Should there be a patent wild card? Anthony McDonnell, Head of Economic Research, Review on Antimicrobial Resistance ROUNDTABLE 3: Tax Credits - Will the proposed Antibiotic and Rapid Diagnostic Research and Development Tax Credit Act of 2015 spur clinical development? Stefano Bertuzzi, Executive Director/CEO, American Society for Microbiology ROUNDTABLE 4: Building partnerships - what does pharma need to create non-diluted partnerships, new companies, licensing and M&A in the anti-infectives space? Michael Draper, Senior Director, External Science & Partnering, East Coast, Sanofi ROUNDTABLE 5: Late stage development - What role can private funding sources and the venture capital community play in accelerating and translating academic innovation into new antimicrobial medicines? Aleks Radovic-Moreno, Senior Associate, PureTech Health ROUNDTABLE 6: Antibiotic waste management regulation - Enforceable standards in existing legislation to avoid harmful antimicrobial activity discharge associated with the manufacturing of antibiotics Lucas Wiarda, Director Marketing and Head of Sustainable Antibiotics Program, DSM Sinochem

FUNDING	
Public/Government Funding	
2:30	Funding programs to incentivize <i>pre-clinical</i> development of antibiotics - Supporting the development of therapeutic alternatives to traditional antibiotics to fight antimicrobial resistance (antibodies, phage therapy, microbiome manipulation) - Funding for antimicrobial resistance diagnostics projects - How do these programs align with the CARB goals? Jane Knisely, Program Officer, Bacteriology and Mycology Branch, NIAID, NIH Rosemarie Aurigemma, Chief, Drug Development Section, Office of Biodefense, Research Resources, and Translational Research, NIAID, NIH
2:50	Funding programs to incentivize <i>late-stage</i> development of antibiotics - Stimulating product development through the formation of public-private partnerships - Expanding public-private partnerships to support development of non-traditional approaches - The impact of a clinical trial network to introduce efficiencies in large and complex human clinical studies Christopher Houchens, PhD, Branch Chief (Acting), Antibacterials Program, BARDA
3:10	Combating Antibiotic Resistant Bacteria (CARB) Biopharmaceutical Accelerator Initiative - Novel public private partnership to support R&D and move drugs, vaccines and diagnostics into pre-clinical development - Providing financial, business and drug development guidance - How is the accelerator different from other public-private partnerships? Joseph Larsen, Acting Deputy Director, BARDA
3:30	A Scientific Roadmap for Antibiotic Discovery: could a targeted research initiative jumpstart antibiotic discovery? - Tackling scientific barriers that impede new antibacterial discovery - Generating knowledge, tools, and methodologies to spur innovation - Establishing a framework for sharing information, expertise, and materials across the research community Carolyn Shore, Officer, Antibiotics Resistance Project, The Pew Charitable Trusts
3:50	Networking coffee break
4:20	IMI DRIVE-AB: Driving reinvestment in R&D for antibiotics and advocating their responsible use - How is DRIVE-AB helping reduce antimicrobial resistance through responsible antibiotic use? - Working towards novel business models needed to revive reinvestment in antibiotics - Helping determine future public health needs by estimating the current and future impact of antibiotic resistance on societies Judy Hackett, Global Payer Evidence Director, AstraZeneca, Project Coordinator, Drive-AB
4:40	IMI-ENABLE: A European Antibacterial Drug Discovery Platform - Creating a collaborative drug discovery platform for early stage molecules that have potential to become drug candidates and treat gram-negative infections - How can ENABLE advance the development of potential antibiotics against gram-negative bacteria? - Experiences from working in a public-private partnership such as ENABLE Anders Karlén, Professor, Department of Organic Pharmaceutical Chemistry, Biomedical Centre, Uppsala University, Leader, Managing Entity, ENABLE
5:00	IMI-COMBACTE, developing novel antibacterials in a public private partnership: accomplishments and vision - Developing novel trial designs to deliver safety, pharmacology, and proof of efficacy data for novel agents - Using novel molecules to prevent serious infections and the spread of antimicrobial resistance - Contribution towards global efforts against antimicrobial resistant infections Hasan Jafri, Senior Director, Clinical Research and Development, Infectious Diseases and Vaccines, MedImmune, Director, COMBACTE Magnet
5:20	Private funding for antibacterial drug development - What is the current landscape of VC funding for antibacterial development? - How to balance risk vs. profitability? - How has the GAIN act incentivized private funding? Jens Eckstein, President, S.R. One
5:40	Chairperson's closing remarks and drinks reception
6:40	End of day 1

8:00	Registration and networking breakfast
8:55	Chairperson Opening Remarks
	BIOFILMS
9:00	Biofilm-Associated Antimicrobial Resistance - Diagnostic: susceptibility testing for bacterial biofilm - Therapy: tolerance vs resistance, acute vs chronic infections - Current and future antimicrobial strategies Robin Patel , Director, Infectious Diseases Research Laboratory, Mayo Clinic
9:20	A question of life and death: combatting lung infections in Cystic Fibrosis (CF) patients - Susceptibility testing of <i>Pseudomonas aeruginosa</i> biofilm - Results on clinical samples and cellular models of Cystic Fibrosis - How will rapid detection of biofilm formation impact the disease progression and treatment? François Jehl , Bacteriology Lab manager, Hospital Strasbourg, France, Test coordinator, Antimicrobial Committee, French Society of Microbiology
9:40	Evaluation of Staphylococcus aureus bone and joint infection (BJI) and biofilm formation - Overcoming diagnostic challenges and preventing recurrence - Refining the choice of antibiotics to prioritize in the management of orthopedic biofilm infections - Staphylococcal pathogenesis and results in clinical samples and animal models Frédéric Laurent , Professor of Microbiology, National Reference Center on Staphylococcus, Hospital Lyon, France
10:00	Biofilm and clinical cases - BioFilm Profiling to optimize therapeutic treatment of patients - Preliminary clinical cases - Current and future antimicrobial therapy: not only planktonic but also biofilm! Fabrizio Ensoli , Head, Pathology and Microbiology, Sapienza University of Roma, Italy
	This portion of the program was developed in partnership with our Platinum Sponsor 
10:20	Networking break
	CLINICAL DEVELOPMENT
10:50	Complexities in clinical trials for anti-bacterial drug development: from patient enrollment to the robustness of the data - What do clinical trials for antibacterial drug development look like right now? - How to balance ethical considerations with the need to enroll patients in real-time? - What are the main challenges faced in trial design and data outputs? Larry Tsai , VP Clinical Development, Tetraphase Pharmaceuticals
11:10	Addressing pediatric antibacterial drug development - Overview of the Pediatric Research Equity Act (PREA) to conduct trials in children - Importance of these trials to achieve enhanced knowledge on dosing and effectiveness of drugs - Practical and ethical challenges when studying antibacterial drugs in neonates and infants Sumathi Nambiar , Director, Division of Anti-Infective Products, FDA
11:30	Drug delivery: Development of solithromycin in oral and intravenous dosing formulations for pediatric use - The first pediatric oral drug for respiratory tract infections in 28 years: moving from intravenous to oral formulation - Leveraging the results of adults' trials to develop pediatric drugs - What will be the key elements to achieve approval? Prabhavathi Fernandes , Chief Executive Officer, Cempra
11:50	Late-stage development: A phase III development program for the treatment of Carbapenem-Resistant Enterobacteriaceae - Leading the fight against carbapenem-resistant Enterobacteriaceae (CRE) in a landscape of limited treatment options - Phase 3 study design to treat gram negative organisms non-susceptible to antibiotics - Preliminary results and considerations for the future Michael Dudley , Senior Vice President of Research and Development and Chief Scientific Officer, The Medicines Company
12:10	Networking Lunch

	ROUNDTABLE SESSIONS
1:40	ROUNDTABLE 1: Dermatology – finding alternative treatment options for acne patients to curb antimicrobial resistance in the dermatology field James Del Rosso, DO, FAOCD, FAAD, Adjunct Clinical Professor, (Dermatology), Touro University Nevada ROUNDTABLE 2: Regulatory pathways – new regulatory pathways for bringing antibiotics to market in the U.S. and in Europe Tom Chen, Global Anti-infective Franchise Head, Basilea Pharmaceutica ROUNDTABLE 3: New targets – will Melinta's ESKAPE pathogen platform reach the development of a new antibiotic class? Erin Duffy, Chief Scientific Officer, Melinta Therapeutics ROUNDTABLE 4: Clinical trials – how to go beyond non-inferiority studies to optimize of clinical trials for antimicrobials Scott Evans, Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG), Harvard University ROUNDTABLE 5: Antibiotics Industry self-regulation – Introducing voluntary, transparent and auditable commitments, for the responsible use and manufacturing of antibiotics Lucas Wiarda, Director Marketing and Head of Sustainable Antibiotics Program, DSM Sinochem
2:20	Networking coffee break
	RAPID DIAGNOSTICS
3:00	The Longitude Prize initiative to create a cost effective rapid diagnostic test to facilitate bacterial infections treatment decisions - Encouraging the development of a novel and transformative, point of care diagnostic test to be used globally to fight antibiotic resistance - Enabling a more targeted use of antibiotics, and an overall reduction in misdiagnosis and prescription - The Discovery Awards as a tool to help teams progress their ideas for the prize through small grants - Uncover ways to win the £10m Longitude Prize Tamar Ghosh , Lead, Longitude Prize, Nesta
3:20	NIH/BARDA Antimicrobial Resistance Diagnostic Challenge - Technical criteria and performance characteristics of the diagnostic for which the prize will be offered - What are the appropriate translational requirements for the diagnostic challenge? - How will the prize impact rapid diagnostics development in years to come? Robert Eisinger , Senior Health Science Policy Advisor, Division of Program Coordination, Planning, and Strategic Initiatives, NIH
3:40	FDA Perspective: Methods to detect antimicrobial susceptibility and resistance - FDA initiatives to promote development of new assays - Defining “Rapid”: Aspects of growth-dependent and growth-independent diagnostic assays - Diagnostic assay diversity and utility for patient management, infection control - Role of new assays in antimicrobial drug trials Ribhi Shawar , Branch Chief, Division of Microbiology, CDRH OIVD, FDA
4:00	Rapid diagnostics for an effective transition from broad to targeted antibiotics - Why has innovation and adoption of rapid diagnostics been slow? - Economic incentives to support rapid diagnostics development - What would the perfect rapid diagnostic test look like? If you're interested in sponsoring this session get in contact with André Singer at andre.singer@terrapinn.com or +1 646 619-1797
	NON-TRADITIONAL THERAPEUTICS
4:20	The development of mAbs for the treatment and prevention of infectious disease - What are the clinical and regulatory challenges to the development of mAbs to treat infections? - What are the real and potential advantages of mAbs vs. traditional anti-infectives? - What is the history, current status, and future of mAbs for infections? Dave Mantus , Chief Development Officer, Arsanis
4:40	Lysins as narrow spectrum anti infectives for the treatment of serious drug resistant bacterial infections - Using bacteriophage enzymes to cleave the bacterial cell wall, clear biofilms and prevent resistance - How can lysins be used synergistically with standard of care antibiotics? - Current data and future development plans Steven Gilman , Chairman & CEO, ContraFect Corporation
5:00	Chairperson's closing remarks

CLASS OF 2016



Marcos Espinal
Director of the Department of Communicable Diseases and Health Analysis
PAHO/WHO



Jean Patel
Deputy Director, Office of Antimicrobial Resistance
CDC



Barbara Kerstiens
Deputy Head of Unit, Fighting Infectious Diseases and Advancing Public Health Research and Innovation
Directorate-General
European Commission



Jens Eckstein
President
S.R. One



Robin Patel
Director, Infectious Diseases Research Laboratory
Mayo Clinic



François Jehl
Bacteriology Lab manager
Hospital Strasbourg
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Chen Yu
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Frédéric Laurent
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Fabrizio Ensoli
Head, Pathology and Microbiology
Sapienza University of Roma, Italy



Larry Tsai
VP Clinical Development, Tetrphase
Pharmaceuticals



Anthony McDonnell
Head of Economic Research
Review on Antimicrobial Resistance



Ed Pezalla
Vice President, National Medical Director for Pharmaceutical Policy and Strategy
Aetna



Barry Eisenstein
Distinguished Physician, Antimicrobials
Merck



Sumathi Nambiar
Director, Division of Anti-Infective Products
FDA



Prabhavathi Fernandes
Chief Executive Officer
Cempra



Michael Dudley
Senior Vice President of Research and Development and Chief Scientific Officer
The Medicines Company



Stefano Bertuzzi
Executive Director/CEO
American Society for Microbiology



Michael Draper
Senior Director, External Science & Partnering, East Coast
Sanofi



Aleks Radovic-Moreno
Senior Associate
PureTech Health



James Del Rosso
DO, FAOCD, FAAD, Adjunct Clinical Professor, (Dermatology)
Touro University Nevada



Tom Chen
Global Anti-infective Franchise Head
Basilea Pharmaceutica



Erin Duffy
Chief Scientific Officer
Melinta Therapeutics



Lucas Wiarda
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Jane Knisely
Program Officer, Bacteriology and Mycology Branch
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Rosemarie Aurigemma
Chief, Drug Development Section, Office of Biodefense, Research Resources, and Translational Research
NIAID, NIH



Scott Evans
Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG)
Harvard University



Tamar Ghosh
Lead, Longitude Prize,
Nesta



Robert Eisinger
Senior Health Science Policy Advisor, Division of Program Coordination, Planning, and Strategic Initiatives
NIH



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BARDA



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Chairman & CEO
ContraFect Corporation



Judy Hackett
Global Payer Evidence Director
AstraZeneca
Project Coordinator
Drive-AB



Anders Karlén
Professor, Department of Organic Pharmaceutical Chemistry, Biomedical Centre
Uppsala University,
Leader, Managing Entity
ENABLE



Hasan Jafri
Senior Director, Clinical Research and Development, Infectious Diseases and Vaccines
MedImmune
Director
COMBACTE Magnet



Neil Miller
Chief Scientific Officer
Auspherix



Debabrata Biswas
Assistant Professor, Department of Animal and Avian Sciences
University of Maryland



ATTENDING ORGANIZATIONS INCLUDE



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PITCH YOUR COMPOUND, DRUG OR TECHNOLOGY TO INVESTORS AT WORLD ANTIMICROBIAL RESISTANCE CONGRESS USA – SUBMIT YOUR PROPOSAL TO **ANDRE.SINGER@TERRAPINN.COM**

The World Anti-Microbial Resistance Congress taking place in Washington DC this September 8-9, brings together payers, funding and government agencies, academics, pharma and biotech to discuss ways to further spur investment in the field. If you have a compound/drug in development and would like to have the opportunity to present it to main stakeholders in order to gain visibility, recognition or potential funding, you cannot miss to be at our event.

30+ companies are pitching – don't miss the chance to be one! Submit your proposal **NOW** to **andre.Singer@terrapinn.com**

1. Join the **CDC, PAHO/WHO** and the **European Commission** in their discussion about International collaboration and capacities for antibiotic resistance prevention, surveillance, control and antibiotic R&D
2. Engage in the discussions about delinkage and hybrid economic models to incentivize antibiotic development along with the **AMR Review, Boston University, Spero Therapeutics and Vivo Capital**
3. Hear Aetna discuss whether current antimicrobial development and **reimbursement models** make sense to payers
4. Discuss the significance of incentives for antimicrobial development such as **tax credits, patent extensions** and **QIDP designation**, and whether these will be sufficient to support late stage development
5. Listen to **BARDA, NIH/NIAD, IMI** and the Pew Charitable Trusts detail all the available funding programs for antibiotic development under both U.S and Europe's public-private partnerships and transatlantic collaboration to develop antimicrobials

10 REASONS TO ATTEND

6. Stay abreast of biofilm formation and the link to antimicrobial resistance from leading experts from the **Mayo Clinic, Lyon Hospital, Strasbourg Hospital and Sapienza University, Rome**
7. Address the complexities of clinical development for antibiotics including those surrounding **pediatric trials** with **Cemptra, Tetraphase, Harvard University, The Medicines Company** and the **FDA**
8. Discover global initiatives to develop new **rapid diagnostics** such as the **European Longitude Prize** and the **NIH/ BARDA diagnostic challenge**
9. Explore **non-traditional therapeutics** like the use of monoclonal **antibodies** and **bacteriophages** as alternatives to treat infections and curb resistance
10. Attend our pitch and partner stream and hear **30 biotechs** and **academic institutions** pitch their compounds and technologies to investors to further advance their pipelines and programs

The earlier you book the more you save – register **NOW** at **www.terrapinn.com/antimicrobial**

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- CSO
- VP of Business Development
- Scientist
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