

The value of surveillance data in defining the medical need for new antimicrobials

Guest speakers: Ian Morrissey, Rebecca Li & Patricia Bradford

Moderator: Fernanda Lessa

Host: Victor Kouassi

23 July 2024



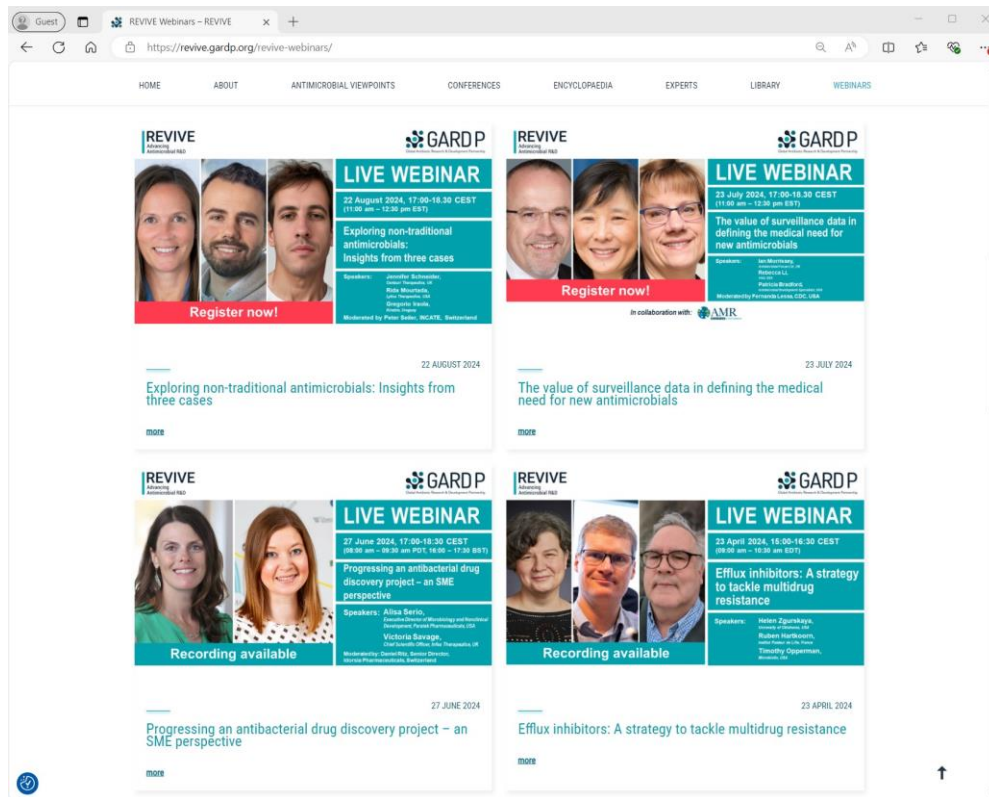
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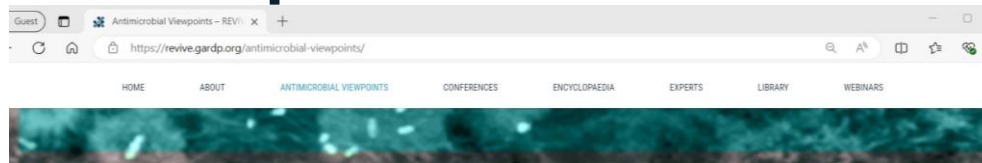


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Webinar Title	Date & Time (CEST)	Recording Status
Exploring non-traditional antimicrobials: Insights from three cases	22 August 2024, 17:00-18:30 (11:00 am - 12:30 pm BST)	Register now!
The value of surveillance data in defining the medical need for new antimicrobials	23 July 2024, 17:00-18:30 (11:00 am - 12:30 pm BST)	Register now!
Progressing an antibacterial drug discovery project – an SME perspective	27 June 2024, 17:00-18:30 (10:00 am - 10:30 am PST; 14:00 - 17:30 AEST)	Recording available
Efflux inhibitors: A strategy to tackle multidrug resistance	23 April 2024, 16:00-18:30 (09:00 am - 10:30 am BST)	Recording available

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Antimicrobial Viewpoints



4 JULY 2024

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17 MAY 2024

Targeting bacterial virulence to tackle the antimicrobial resistance crisis – by Ronan R. McCarthy

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18 APRIL 2024

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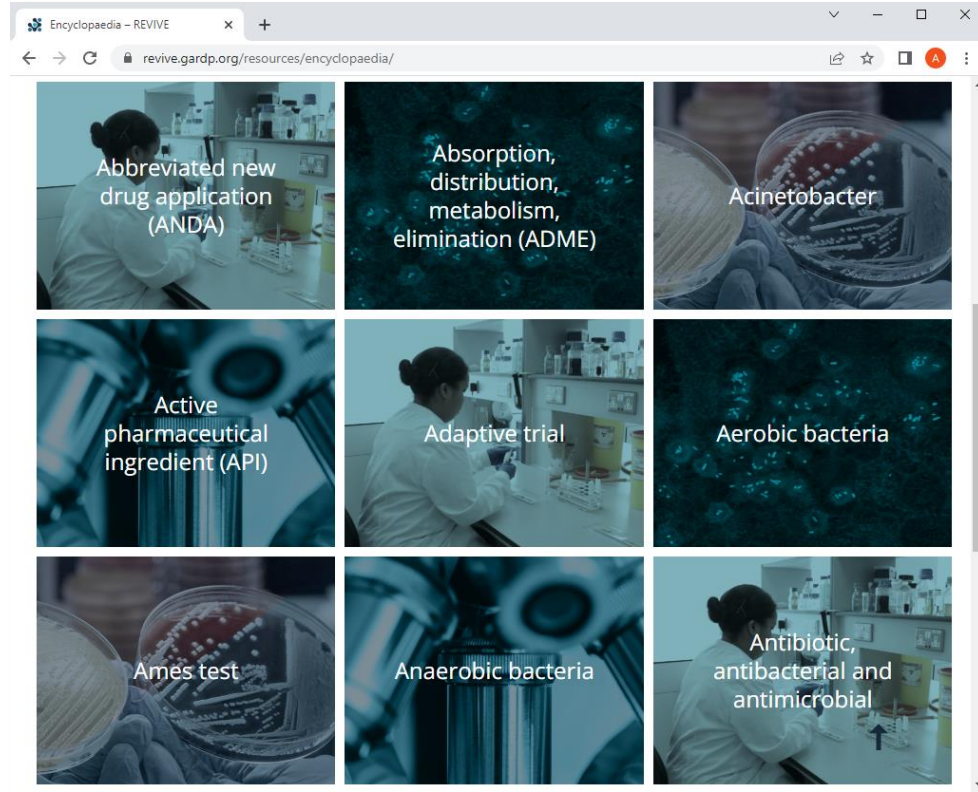
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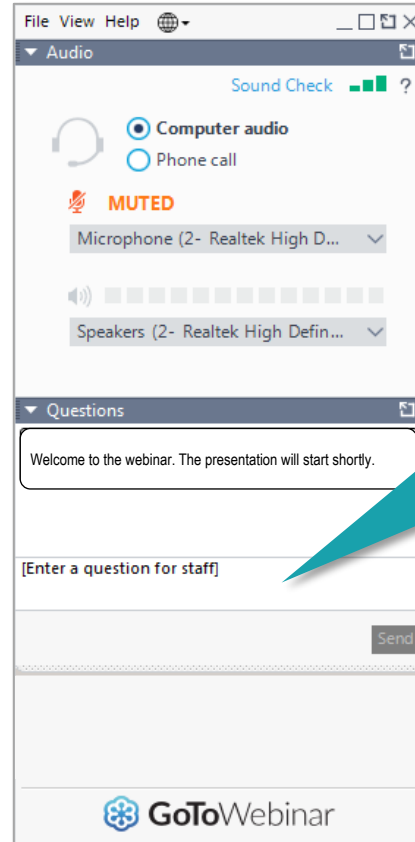
Antimicrobial Encyclopaedia



revive.gardp.org/resources/encyclopaedia

How to submit your questions

If your question is addressed to a specific speaker, please include their name when submitting the question.



The presentation will be followed by an interactive Q&A session.

Please submit your questions via the 'questions' window. We will review all questions and respond to as many as possible after the presentation.

This webinar was developed in collaboration with Vivli.



<https://vivli.org/amr-data-register/>



Today's speakers

The value of surveillance data in defining the medical need for new antimicrobials



Ian Morrissey
Consultant
Antimicrobial Focus Ltd. (UK)



Rebecca Li
Chief Executive Officer
Vivli (USA)



Patricia Bradford
Consultant
Antimicrobial Development Specialists LLC (USA)



Moderator:
Fernanda Lessa
Chief of International Infection Control,
Centers for Disease Control and Prevention (USA)

Ian Morrissey



Ian Morrissey is the founder of Antimicrobial Focus Ltd. Before this, he was Chief Scientific & Development Officer at IHMA Europe Sàrl, Switzerland, which supports all phases of antimicrobial drug development through dedicated laboratories and expert scientific personnel.

Ian received his PhD from the University of London, UK in 1990. He went on to an Executive MBA from Imperial College London, UK in 2001. He is a voting member of the Clinical Laboratory Standards Institute (CLSI) veterinary antimicrobial susceptibility standards subcommittee. Ian is also involved in the BSAC Standing Committee on Antibacterial Drug Discovery and Development and is a Fellow of the Royal Society of Medicine.



Susceptibility Surveillance Studies & New Antimicrobial Development

Ian Morrissey

Antimicrobial Focus Ltd.

23rd July 2024

Meaning

surveillance

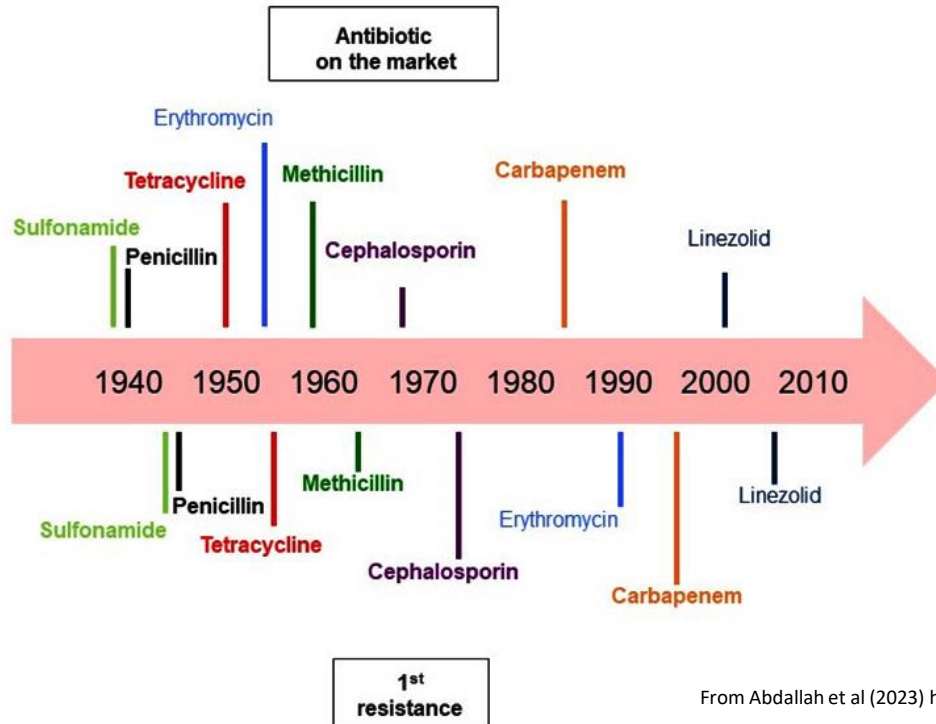
/ sɜːˈveɪləns /

noun

- 1 close observation or supervision maintained over a person, group, etc, esp one in custody or under suspicion

"Collins English Dictionary — Complete & Unabridged" 2012 Digital Edition © William Collins Sons & Co. Ltd. 1979, 1986 © HarperCollins Publishers 1998, 2000, 2003, 2005, 2006, 2007, 2009, 2012

Why AMR surveillance?



From Abdallah et al (2023) <https://dx.doi.org/10.13005/bpj/2656>

Factors driving resistance

- Inappropriate antimicrobial use
- Inadequate antimicrobial dosing
- Poor hygiene & infection control
- Travel
- Biology
 - Evolution
 - Prevalence of existing resistant organisms
 - Link between resistance and virulence

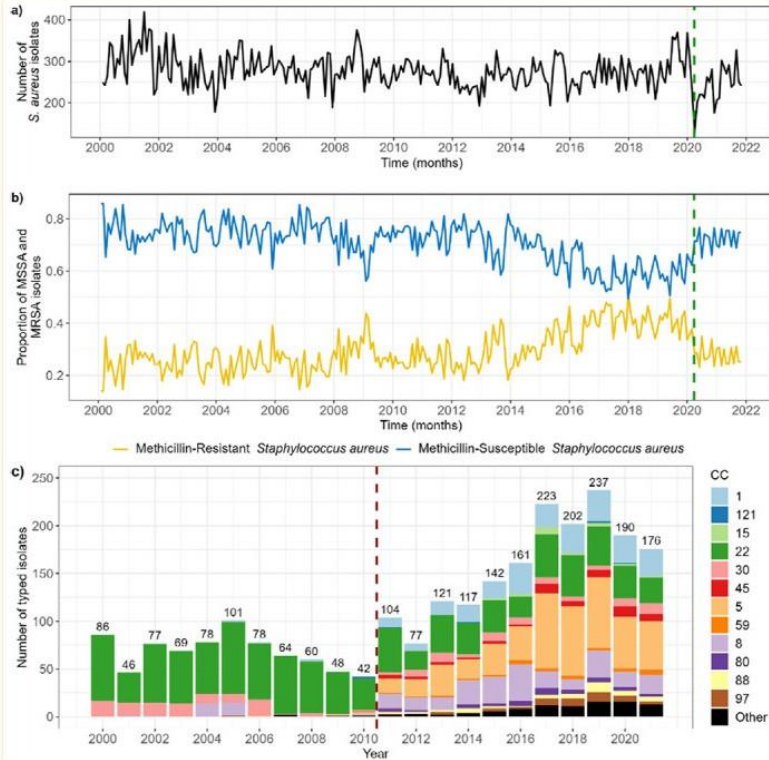
Variables associated with resistance:

- Geography
- Pathogen
- Infection site

Types of resistance surveillance data

- Hospital data
 - Local antibiograms
 - Mandatory reporting to health authorities
- Government agency data
 - WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS)
 - Central Asian and European Surveillance of Antimicrobial Resistance (CAESAR) network
 - European Antimicrobial Resistance Surveillance Network (EARS-Net)
- Global resistance surveillance data
 - On-line resources
 - Vivli Centre for Global Research data [request pharma company datasets]
 - JMI SENTRY database
 - Pfizer ATLAS database [IHMA]
 - Sponsor own surveillance

Hospital antibiograms



Example MRSA/MSSA data for Great Ormond St. Hospital London

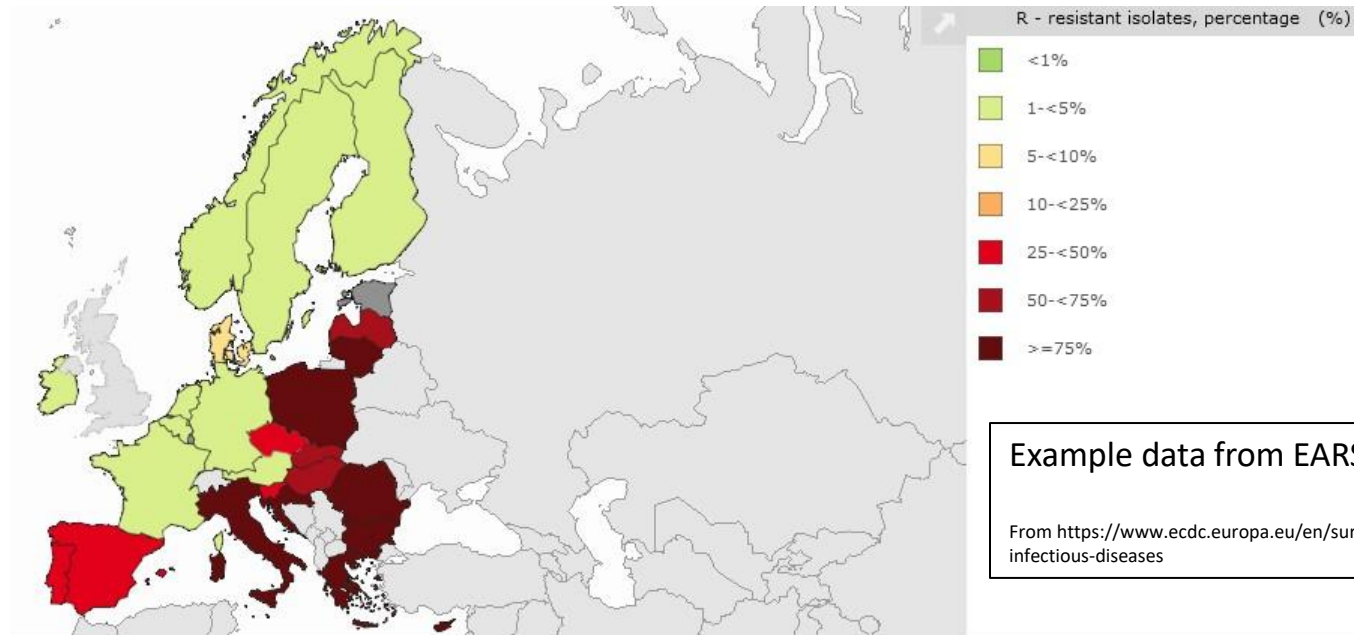
From Leclerc et al (2023) DOI: 10.1099/jmm.0.001724

Government Agencies



Surveillance Atlas of Infectious Diseases

← → Antimicrobial resistance ▾ Acinetobacter spp. ▾ Carbapenems ▾ R - resistant isolates, percentage ▾ 2022 ▾ →



Example data from EARS-Net

From <https://www.ecdc.europa.eu/en/surveillance-atlas-infectious-diseases>

JMI SENTRY database



423,099 isolates selected

[View Analysis](#)

Customize the criteria by selecting options on the fields to the right. After you have finalized your criteria, you can view the analysis by clicking the button above.

Organism Filters

Group	Include <input type="checkbox"/>	Genus	Include <input type="checkbox"/>	Organism	Include <input type="checkbox"/>
<input type="text"/>		<input type="text"/>		<input type="text"/>	

Geographic Filters

Year	Geographic Region	Countries
<input type="text"/>	<input type="text"/>	<input type="text"/>

Category & Demographic Filters

Infection Type	Infection Source
<input type="text"/>	<input type="text"/>
Objectives	Resistance Subsets
<input type="text"/>	<input type="text"/>
Nosocomial	ICU/non-ICU
<input type="text"/>	<input type="text"/>
Gender	VAP/non-VAP
<input type="text"/>	<input type="text"/>



JMI SENTRY database

Min Age	Max Age	Medical Service
<input type="text" value="0"/>	<input type="text" value="125"/>	<input type="text"/>
Core Sites	CF/NCFB Patient	
<input type="text"/>	<input type="text"/>	

MIC & Resistance Profiles

Drug	Profiles
<input type="text"/>	<input type="text"/>
Authorities	
<input type="text"/>	
<input type="button" value="Add Profile"/>	

Molecular Profiles

Enzyme Spectrum	Gene Group	Gene
<input type="text"/>	<input type="text"/>	<input type="text"/>

JMI SENTRY database

Drugs to Include

Toggle all

Aminoglycosides

Toggle all

Amikacin	<input checked="" type="checkbox"/>
Gentamicin	<input checked="" type="checkbox"/>
Tobramycin	<input checked="" type="checkbox"/>

β -lactamase inhibitor combinations

Toggle all

Amoxicillin-clavulanic acid (2:1 ratio)	<input checked="" type="checkbox"/>
Ampicillin-sulbactam	<input checked="" type="checkbox"/>
Ceftazidime-avibactam	<input checked="" type="checkbox"/>
Cefoperazone-sulbactam	<input checked="" type="checkbox"/>
Ceftolozane-tazobactam	<input checked="" type="checkbox"/>
Meropenem-vaborbactam	<input checked="" type="checkbox"/>
Piperacillin-tazobactam	<input checked="" type="checkbox"/>

Carbapenems

Toggle all

Doripenem	<input checked="" type="checkbox"/>
Ertapenem	<input checked="" type="checkbox"/>
Imipenem	<input checked="" type="checkbox"/>
Meropenem	<input checked="" type="checkbox"/>

Cephems

Toggle all

Cefepime	<input checked="" type="checkbox"/>
Cefiderocol	<input checked="" type="checkbox"/>
Cefoperazone	<input checked="" type="checkbox"/>
Cefoxitin	<input checked="" type="checkbox"/>
Ceftaroline	<input checked="" type="checkbox"/>
Ceftazidime	<input checked="" type="checkbox"/>
Ceftriaxone	<input checked="" type="checkbox"/>

Folate Pathway Antagonists

Toggle all

Trimethoprim-sulfamethoxazole	<input checked="" type="checkbox"/>
-------------------------------	-------------------------------------

Glycopeptides

Toggle all

Teicoplanin	<input checked="" type="checkbox"/>
Vancomycin	<input checked="" type="checkbox"/>

JMI SENTRY

Activity of antimicrobial agents tested against 467 *Acinetobacter baumannii* and *Acinetobacter baumannii-calcoaceticus species complex* isolates in the SENTRY program collected from medical centers in USA during 2022

Organisms include *Acinetobacter baumannii* (3) and *A. baumannii-calcoaceticus species complex* (464).

Overview Tables Charts Split Results Export

Antimicrobial agent	No. of isolates	mg/L			CLSI ^a			EUCAST ^a			US FDA ^a		
		MIC ₅₀	MIC ₉₀	MIC range	%S	%I	%R	%S	%I	%R	%S	%I	%R
Piperacillin-tazobactam	460	2	>128	≤0.06 to >128	62.6	6.1	31.3				62.6 ^b	6.1	31.3
Imipenem	467	0.25	>8	≤0.12 to >8	74.3	0.2	25.5	74.3	0.2	25.5	74.3 ^b	0.2	25.5
Meropenem	467	0.5	>32	0.03 to >32	73.7	0.4	25.9	73.7 ^c 73.7 ^d		26.3 25.5	73.7 ^b	0.4	25.9
Trimethoprim-sulfamethoxazole	467	0.25	>4	≤0.12 to >4	76.0		24.0	76.0	0.9	23.1			
Ciprofloxacin	394	0.25	>4	0.06 to >4	71.8	2.3	25.9						

^a Criteria as published by CLSI (2023), EUCAST (2023), and US FDA (2023).

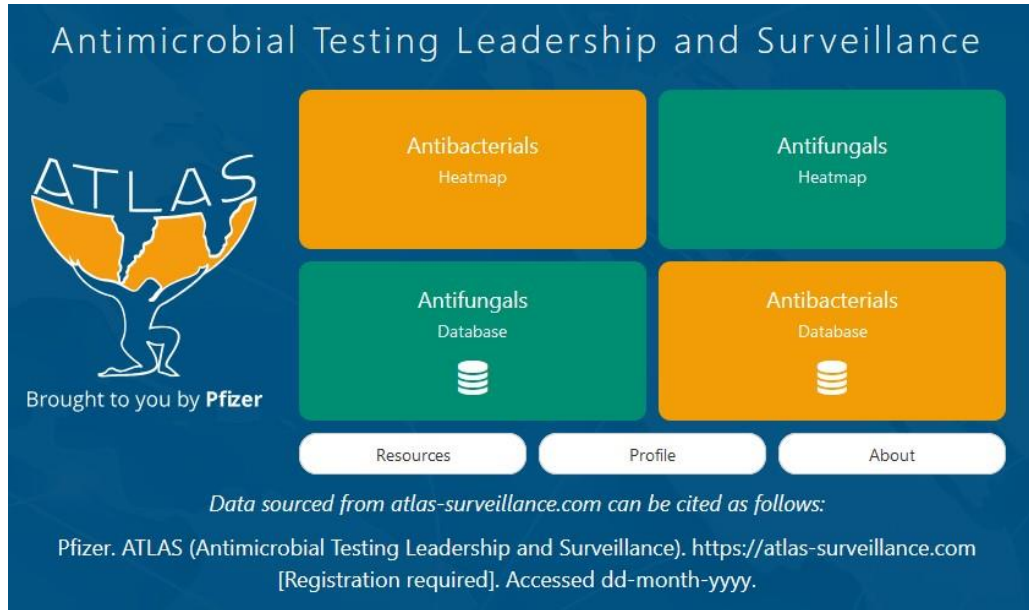
^b CLSI M100 standard is recognized.

^c Using meningitis breakpoints.

^d Using non-meningitis breakpoints.

<https://sentry-mvp.jmilabs.com/projects/2/filters/new>

Pfizer ATLAS database



Antimicrobial Testing Leadership and Surveillance

ATLAS
Brought to you by Pfizer

Antibacterials
Heatmap

Antifungals
Heatmap

Antifungals
Database

Antibacterials
Database

Resources Profile About

Data sourced from atlas-surveillance.com can be cited as follows:
Pfizer. ATLAS (Antimicrobial Testing Leadership and Surveillance). <https://atlas-surveillance.com>
[Registration required]. Accessed dd-month-yyyy.

<https://atlas-surveillance.com/#/login>

Pfizer ATLAS database

The screenshot displays the Pfizer ATLAS Database interface. At the top left is the ATLAS logo with the text "From Pfizer". The main heading is "Database". Below this is a filter dropdown menu currently set to "Susceptibility". To the right of the dropdown are buttons for "Reset" and "Apply Filter".

The interface features several filter categories, each with a "Change" button and a right-pointing arrow:

- Region:** North America, United States
- Pathogen:** *Acinetobacter baumannii*
- Antibacterial:** Carbapenem, Folate inhibitor, Quinolone
- Years:** 2022
- Phenotype:** All Phenotypes
- Genotype Classification:** All Genotypes

At the bottom, there are two sections:

- Data Source:** Includes buttons for "ATLAS", "TEST", and "INFORM / AWARE".
- Breakpoints:** Includes buttons for "EUCAST" and "CLSI".

<https://atlas-surveillance.com/#/login>

Pfizer ATLAS database

Percentage Susceptibility (N = 221)

Report Date: 19th July 2024 09:51:11

Antibacterial	Code	N	Susc.	Int.	Res.	Susceptible at \leq (mg/L)	Resistant at \geq (mg/L)
Ciprofloxacin	CIP	221	47.06	6.33	46.61	1	4
Imipenem	IPM	221	52.04	4.07	43.89	2	8
Levofloxacin	LEV	221	50.23	4.07	45.7	2	8
Meropenem	MEM	221	51.13	1.36	47.51	2	8
Trimethoprim sulfa	TRMSUL	221	62.9	0	37.1	2	4

The clinical significance of in vitro activity is unknown.

CLSI 2024 (M100-ED34) approved breakpoints have been used in this analysis.

Antimicrobials contributing data were:

Levofloxacin | Ciprofloxacin | Imipenem | Meropenem | Trimethoprim sulfa

Organisms contributing data were:

Acinetobacter baumannii

Countries contributing data were:

Canada | United States

Isolate sources contributing data were:

Blood | Bronchus | Bronchoalveolar lavage | Endotracheal aspirate | Sputum | Respiratory: Other

Ward sources contributing data were:

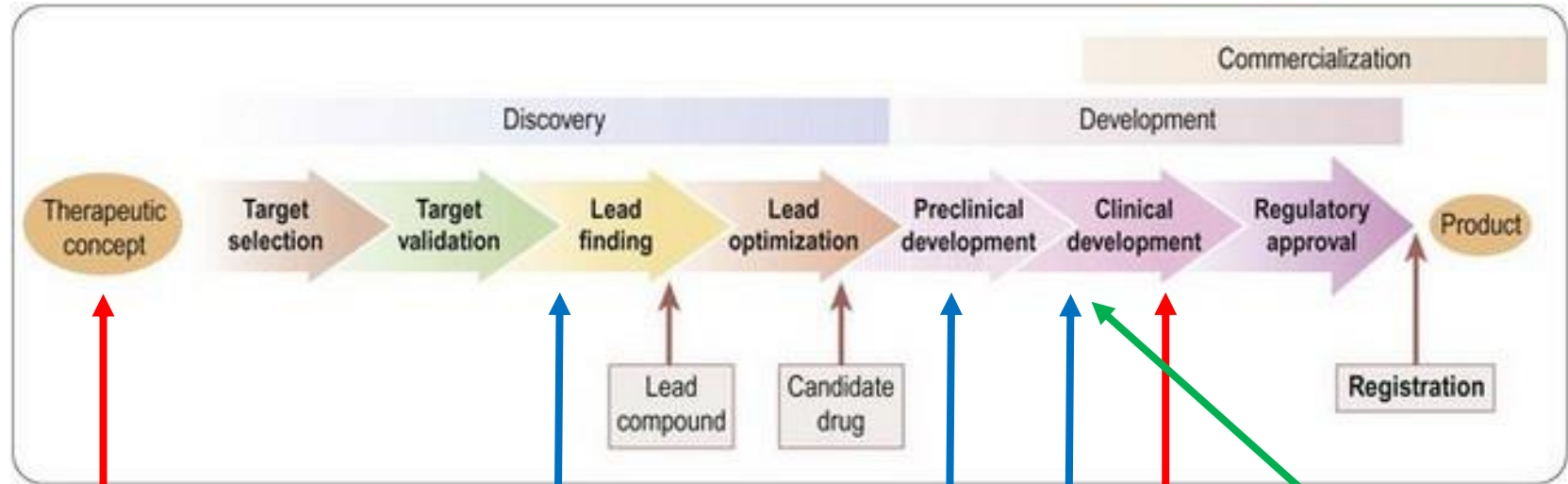
Emergency Room | Medicine General | Medicine ICU | Pediatric General | Pediatric ICU | Surgery (

Years contributing data were:

2022

<https://atlas-surveillance.com/#/login>

Surveillance and Antimicrobial development



'Government
'surveillance

Pharmaceutical surveillance

- Use well characterised isolates
- Bespoke panels

'Government
'surveillance

Own surveillance

- Validates clinical data
- Breakpoint setting

Summary

Resistance surveillance plays an important role in:

1. Local hospital epidemiology
 - for empirical therapy/infection control et,
2. Global epidemiology
 - Informs government policy
 - Highlights unmet medical needs
3. Surveillance data:
 - Highlights unmet medical needs
 - Supports lead compound selection
 - Validates new antimicrobials during development
 - MICs drive PK/PD targets
 - Are vital for breakpoint setting

Rebecca Li



Rebecca Li is the Executive Director of Vivli. She is also on the faculty at the Center for Bioethics at the Harvard Medical School. Before this, she was the Executive Director of the MRCT Center of Brigham and Women's Hospital at Harvard for over 5 years and remains a Senior Advisor at the Center.

Rebecca received her PhD in Chemical and Biomolecular Engineering from Johns Hopkins University, USA and completed a fellowship in the Division of Medical Ethics at Harvard Medical School, also in USA. She has over 25 years of experience spanning the entire process of drug development with experience in biotech, pharma, and CRO environments.





AMR

REGISTER A Vivli Initiative

Introduction to Vivli and the AMR Register

July 2024

Vivli is the leading non-profit organization which runs a global platform for clinical trial data sharing

Vivli



- 7,000+ clinical trials
- 4.1 million participants
- 129 countries



Selected by Wellcome Trust to manage this effort for an industry surveillance








Vivli AMR Register



- Share AMR surveillance data in a single platform
- Bridge the silos between academic, private and public information.

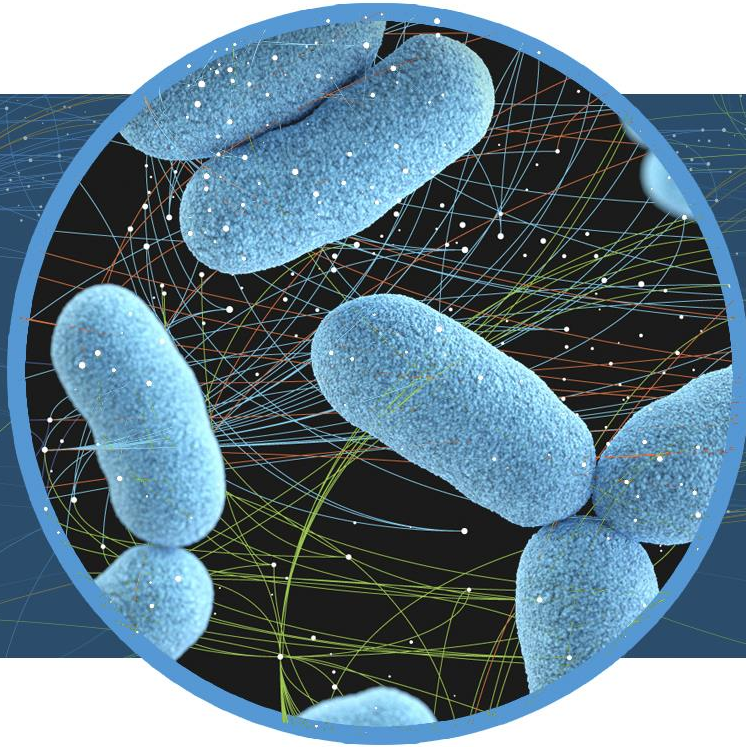


Vivli Current Externally Funded Projects

PROJECT	Impact	Project Funder
Platform Scale-up	Ability to enhance the Vivli platform to enable larger scale data handling (imaging, genomics)	
COVID Therapeutics Accelerator	Consortium of funders (Gates, Wellcome, others) to speed COVID Therapeutics, Vivli's objectives are to make COVID data more discoverable.	
AMR Register – (Anti-microbial resistance)	Platform to share industry AMR surveillance data	
ADDI/Gates Ventures	Project funded to enable federated access to Alzheimer's data, images across platforms for broader sharing	 Alzheimer's Disease Data Initiative
T1 Diabetes Program	Project funded to enable access to T1D Exercise data collected under Helmsley's T1-DEXI's large observational studies	
Bill & Melinda Gates Foundation data sharing	Grant to work with BMGF grantees to share trial data (primarily focused on COVID)	
NIH – Generalist repository	Vivli was named an NIH generalist repository, in advance of NIH's data sharing policy coming into effect.	

Introducing the AMR Register

Innovative, fully
searchable
platform for high
quality industry
surveillance data



- Detect trends in multi-drug resistance over time
- Inform national and international policy and antibiotic stewardship
- Allow modeling of future resistance trends

<https://amr.vivli.org>



AMR Register and Pharma Commitments

- In 2020 the members of the AMR Industry Alliance recommitted to surveillance data sharing echoing the Davos Declaration and the Industry Roadmap on Combatting AMR. There is an opportunity to bring in more pharma, generic and diagnostic companies.
- Access To Medicine AMR Benchmark scorecard includes antimicrobial surveillance with maximum points awarded for companies that collect and share raw surveillance data on an open platform
- 2021 G7 Communique includes AMR

UN Call to Action on Antimicrobial Resistance 2021:

“we commit to...strengthen effective and integrated AMR surveillance systems, addressing AMR in infection prevention and control, stewardship, monitoring, regulatory frameworks, enforcement; promote integrated target setting and share best practice, scientific knowledge and technical assistance between countries and regions, upon their request.”



AMR Register – Key Objectives

- To enable industry to **fulfill their commitments to surveillance data sharing** in the Davos Declaration and the Industry Roadmap on Combatting AMR.
- To provide **researchers with a single platform** where they are able to openly access high-quality industry surveillance datasets.
- Access to the surveillance datasets will help researchers, governments and healthcare professionals **understand the spread and impact of drug-resistant infections on human health**.
- To enable industry to achieve maximum points for antimicrobial surveillance on the **Access To Medicine AMR Benchmark scorecard** by collecting and sharing raw data on an open platform, recognized by **governments, NGOs and WHO**.
- To provide a dedicated space for industry to share surveillance datasets and convene with like-minded stakeholders.



AMR Register Scientific Advisory Board



Janet Midega
Wellcome Trust



Henry Kajumbula
Makerere University
College of Health Sciences



Trudie Lang
Oxford University,
Global Health Network



Marc Mendelson
University of
Cape Town,
Chair, AMR Register
Scientific Advisory Board



Arjun Srinivasan
Centers for Disease
Control and Prevention
(CDC)



Andy Stergachis
University of
Washington, affiliated
to IHME

- Advise Vivli during the development of the platform from a scientific perspective
- Assist with outreach to promote the platform to key stakeholder groups
- Advise on the value proposition
- Advise on outreach to researchers

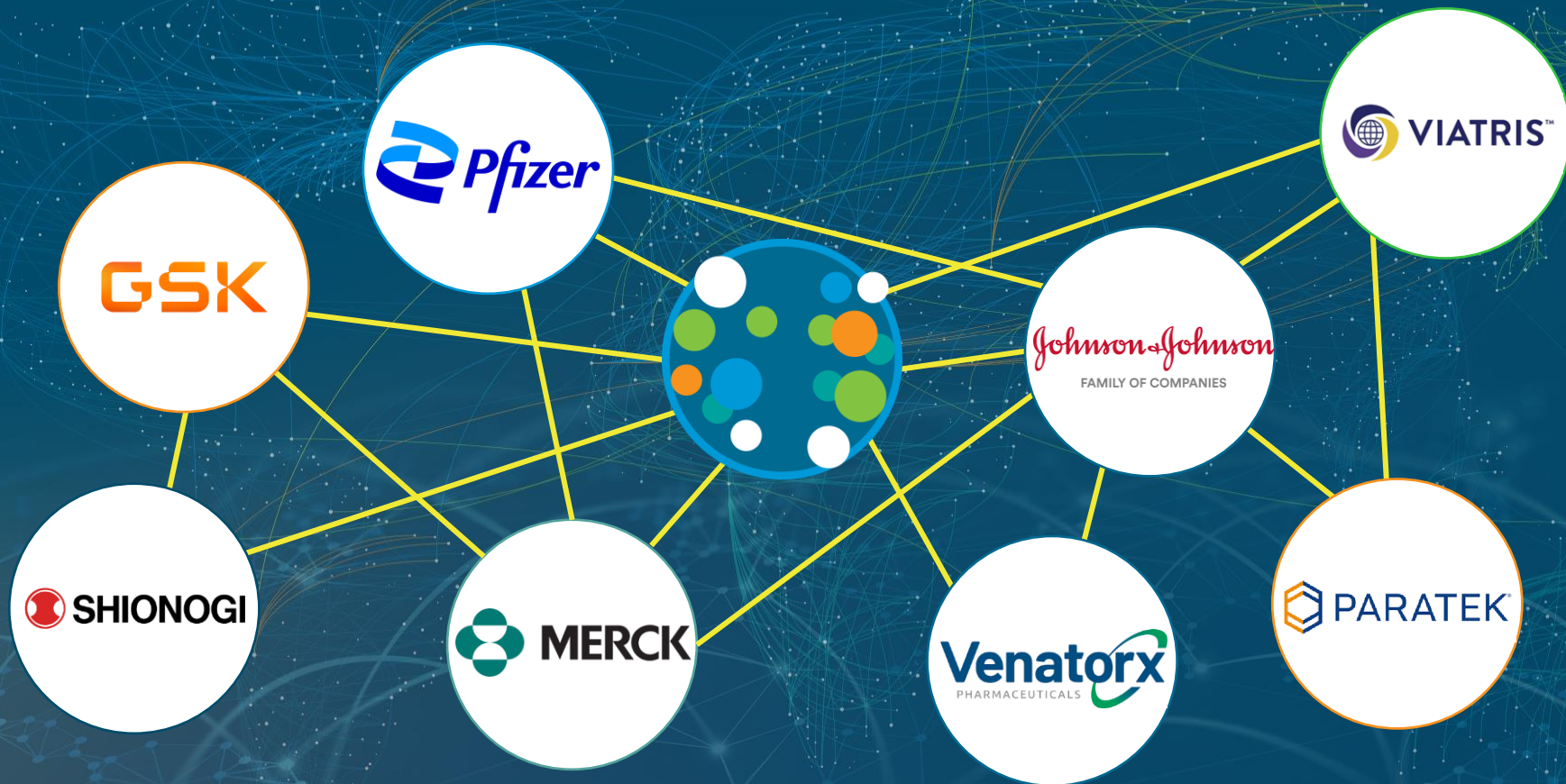


AMR Register Data

- **What are Antimicrobial susceptibility surveillance programs?**
 - Conducted by industry mandated to comply with regulatory agency (FDA, EMA) requirements for commercial approval of new antimicrobial agents
 - Post-approval surveillance must be conducted over a period of years as an important tool to monitor the development of resistance to a new agent
- Industry datasets include minimum inhibitory concentration (MIC) data and are typically generated by a central laboratory using reference methods that adhere to CSLI and EUCAST guidelines
- In addition to the new antimicrobial, numerous comparators are tested, resulting in a robust picture of the state of AMR
- Datasets generally include MIC data drug-bug pairs for the sponsor's new antimicrobial and several comparators, specimen source, basic demography such as gender, age, country, year collected
- Raw data is provided in Excel format and is downloadable



AMR Register Founding Steering Committee



Datasets available in the Register include:

>1,000,000*
isolates

10
datasets

collected
2004-2023

from 89**
countries

testing 80
antimicrobials

on 550
organisms

*Including some genotype and pediatric data

Including 20 LMICs (7 in **Sub-Saharan Africa):

Cambodia, **Cameroon**, Egypt, **Ghana**, Honduras, India, **Ivory Coast**, Jordan, **Kenya**, Lebanon, **Malawi**, Morocco, Nicaragua, **Nigeria**, Pakistan, Philippines, Tunisia, **Uganda**, Ukraine, Viet Nam (LMICs as classified by the World Bank in 2024)

AMR Register Surveillance Programs

<https://amr.vivli.org/members/research-programs/>

← → ↻ 🔍 ☆ 🌐 📄 🏠 🌍 ⋮



REGISTER A Vivli Initiative

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Our Members
Become a Member
Why we support the AMR Register
Surveillance Programs

A global AMR surveillance platform for data sharing

Dedicated to helping industry share antimicrobial resistance surveillance data with researchers in the fight against AMR. Updated datasets now available!

[REQUEST DATASETS](#)

NOW OPEN!

2024 Vivli AMR Surveillance Data Challenge, funded by GARDP, Paratek, Pfizer and Vivli



Surveillance Programs

- Our Members
- Become a Member
- Why we support the AMR Register
- [Surveillance Programs](#)

To view details of the available surveillance programs go to:

<https://amr.vivli.org/members/research-programs/>

Datasets from the following AMR surveillance programs are available to request via the Vivli AMR Register.

Pharmaceutical industry AMR surveillance programs are conducted to fulfill regulatory requirements for antimicrobials in development and also as post approval commitments to monitor susceptibility and resistance for marketed antimicrobials.

Programs are usually global in scope and conducted via experienced vendors within three years of expected filing and continued post approval to monitor changes in resistance patterns and trends at a global, regional and local level and to provide healthcare practitioners with susceptibility data to support the appropriate use of antimicrobials.

GSK – SOAR 201818



GSK – SOAR 201910



Johnson & Johnson – Bedaquiline Drug Resistance Assessment in MDR-TB (DREAM)



Merck – SMART Surveillance



Paratek – KEYSTONE



Pfizer – ATLAS



Shionogi – SIDERO-WT



Venatorx – GEARS



ATLAS (Antimicrobial Testing Leadership and Surveillance) Program

Conducted by Pfizer

Active: 2004 Onwards

Countries: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, Egypt, El Salvador, Estonia, Finland, France, Germany, Ghana, Greece, Guatemala, Honduras, Hong Kong, Hungary, India, Indonesia, Ireland, Israel, Italy, Ivory Coast, Jamaica, Japan, Jordan, Kenya, Kuwait, Latvia, Lebanon, Lithuania, Malawi, Malaysia, Mauritius, Mexico, Morocco, Namibia, Netherlands, New Zealand, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, Serbia, Singapore, Slovak Republic, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, United States, Venezuela, Vietnam

Primary objective

The ATLAS programme monitors changes in antibiotic susceptibility, bacterial resistance trends and emergence of new resistance mechanism for both marketed and in development antibiotics. In addition, provides genotypic information when tested. The SENTRY platform data allow for monitoring of antifungal susceptibility and resistance trending of key antifungals.

Protocol Summary	The ATLAS program is one overall study (formerly TEST, INFORM and AWARE) fulfilling regulatory requirements and supporting appropriate use measures for both marketed antibiotics (Tygacil, Zyvox, Zosyn/Tazocin, Zavicefta, Zinforo, Merrem and others) by monitoring changes in antibiotic susceptibility, bacterial resistance trends and emergence of new resistance mechanisms. CLSI breakpoints are utilized but the option exists to analyse the data by using EUCAST breakpoints. All bacterial isolate identifications and susceptibility profiles are performed by standardized broth microdilution methods by a central lab. The antifungal data from the SENTRY platform are generated by standardized antifungal susceptibility methods performed at a central laboratory.
Isolates collection method:	Actively collected from local labs and sent to central laboratory for identification and susceptibility testing.
Types of surveillance:	Isolates are collected specifically for surveillance.
Methodology and breakpoints:	CLSI breakpoints are utilized but the option exists to analyse the data by using EUCAST breakpoints.
Number of Isolates	917,049 antibiotic isolates, 21,631 antifungal isolates

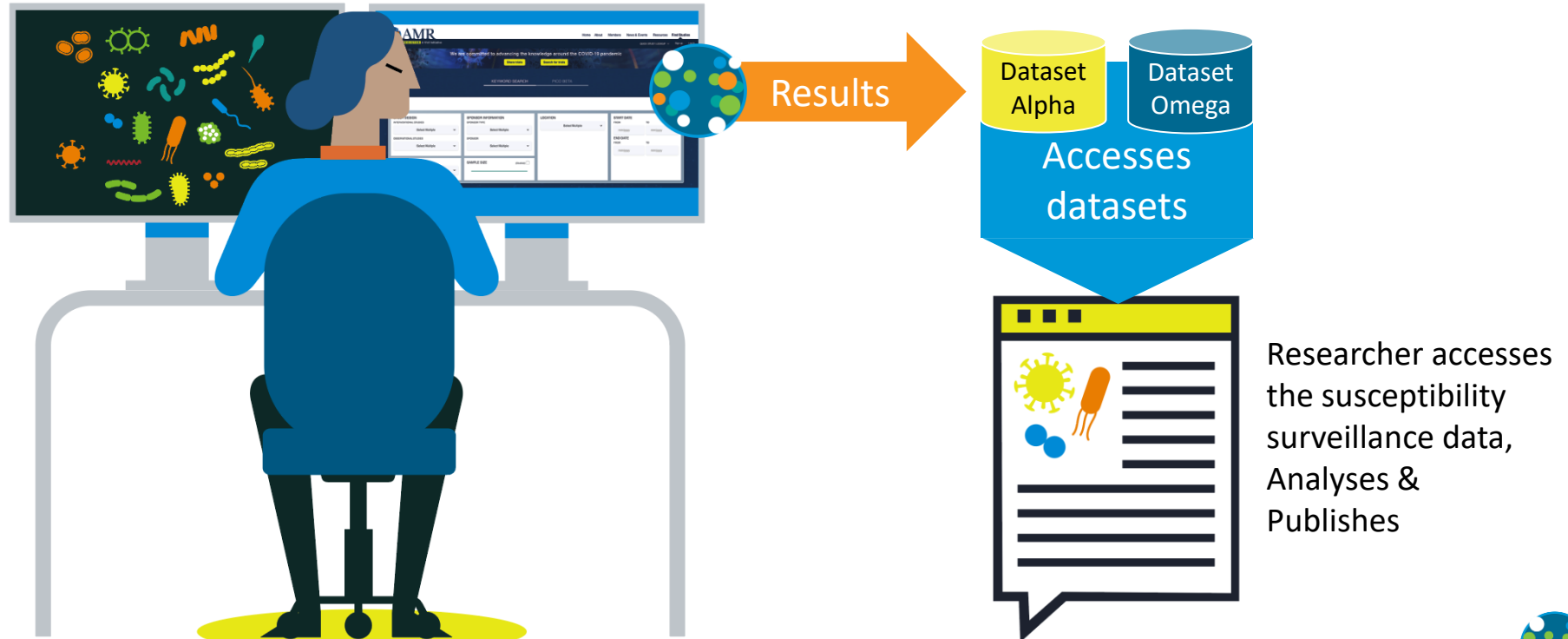
Contains pediatric data?	Yes
Contains genotype data?	Yes
Date Last Updated	June 2024
Expected frequency of updates to the dataset	Annually
List of publications to be linked	Can be found at www.atlas-surveillance.com on the resources tab. Published poster with some details on the protocol: www.ihma.com/app/uploads/Pfizer_P107_ATLAS-Overview_IDWeek-2020_FINAL.pdf
Any additional information	The ATLAS database is updated every 9 to 12 months with emerging data from across 83 countries. Data for compounds in development are not made available via the public website but are available via publications and medical requests for information. Year in and year out integrated, with search by individual year possible as well. Database system built by Micron Research, UK.



AMR Register - How it works

<https://searchamr.vivli.org>

Researcher conducts a Search for Datasets



KEYWORD SEARCH

BROWSE

What are you looking for today?



<p>Antimicrobials</p> <p>Select Multiple ▾</p>	<p>Data Contributor</p> <p>Select Multiple ▾</p>	<p>Country</p> <p>Select Multiple ▾</p>	<p>Years Data Collected</p> <p>From: Select One ▾ To: Select One ▾</p>
<p>Organisms</p> <p>Select Multiple ▾</p>	<p>Resistance Grouping</p> <p>Select Multiple ▾</p>	<p>Region</p> <p>Select Multiple ▾</p> <ul style="list-style-type: none"> Europe Africa/Middle East Asia North America Latin America and the Caribbean Oceania 	<p>Sources of Samples</p> <p>Select Multiple ▾</p> <p><input type="checkbox"/> Includes Genotype Information</p> <p><input type="checkbox"/> Includes Pediatrics Information</p>
<p>Time of Sample</p> <p>Select Multiple ▾</p>			

Datasets

Request History

Request

Chat

Lead Researcher's Name

Lead Researcher's Affiliation

Lead Researcher's Location

- Select an Option -

Recipient agrees to include the following acknowledgment in any publication or presentation of the Analysis results. "This publication or presentation is based on research using data from Pfizer, obtained through <https://amr.vivili.org>"

Terms of Use:

Vivili, Inc., ("Vivili") an independent non-profit entity, operates the Vivili AMR Website and the AMR Register (the "Platform") for the purpose of allowing users the ability to search and request certain data that has been provided for such use by third-party contributors ("Data Contributors"). This data (the "Data") is available to a user ("you" or "your") upon request for public health, scientific, educational and research purposes. Access to this data may be further subject to approval by the individual Data Contributors, based upon their own data sharing policies if stipulated on their member's page. The data may be accessed either via download or in a format as determined by the Data Contributor. The terms set forth below (the "Terms of Use"),

Please provide a background and summary of the proposed research that is suitable for a general audience. Describe how your proposed research will:

- Help improve patient outcomes
- Strengthen stewardship
- Inform public health practice
- Strengthen health systems

Research Summary

Lead Researcher's Email Address

Lead Researcher's ORCID ID [?](#)

Purpose(s) of Analysis [?](#)

Purpose(s) of Analysis is required.

- AMR trends for a country/region
- AMR trends for a pathogen
- AMR trends for a specific resistance mechanism including phenotype to genotype comparisons
- AMR trends for infection type or indication
- AMR trends over different years
- PK/PD
- Inform Antimicrobial Stewardship
- Other (elaborate below)



Partner Perspectives



“Making relevant data openly accessible can accelerate research and the development of strategies to combat AMR. GSK is in the forefront of developing prevention and treatment options to focus on pathogens that have a high probability of developing AMR. We are pleased to join hands with Vivli to make our multi-country Surveillance of Antimicrobial Resistance (SOAR) surveillance data accessible to researchers, public health agencies, and other stakeholders with the overall aim to combat AMR.”

ANAND MANOHARAN

**SCIENTIFIC AND ANTIBIOTIC SUSCEPTIBILITY PROGRAM LEAD,
INFECTIOUS DISEASES MEDICAL & SCIENTIFIC AFFAIRS, GSK**



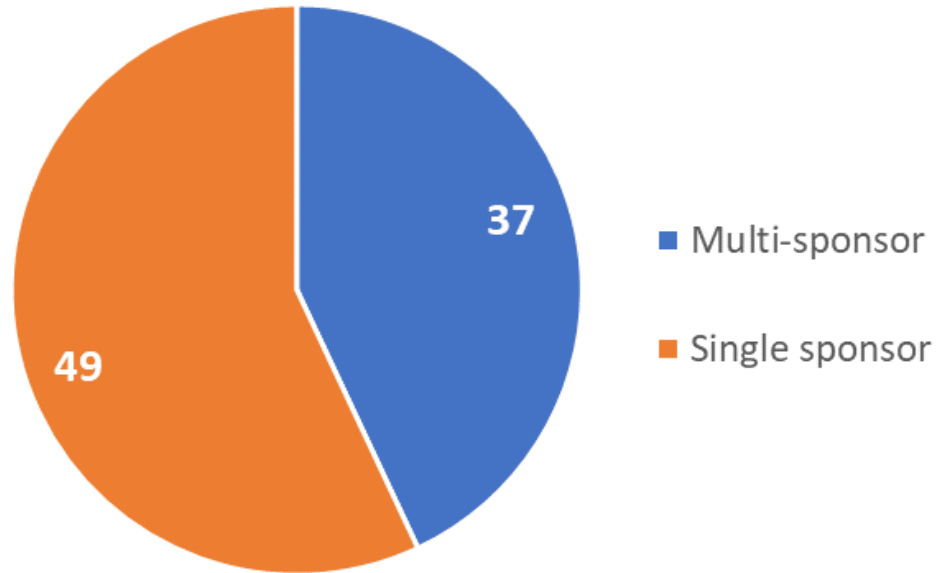
“As a private, clinical-stage pharmaceutical company focused on improving health outcomes for patients with drug-resistant bacterial infections, Venatorx Pharmaceuticals is greatly encouraged that 33 research teams have already used its global surveillance data in their projects, and commends the Vivli AMR Register team for advancing antimicrobial resistance (AMR) research globally.”

GREG MOECK

VICE PRESIDENT, MICROBIOLOGY AT VENATORX PHARMACEUTICALS, INC.

1-Year Review

94 requests submitted
86 requests fulfilled

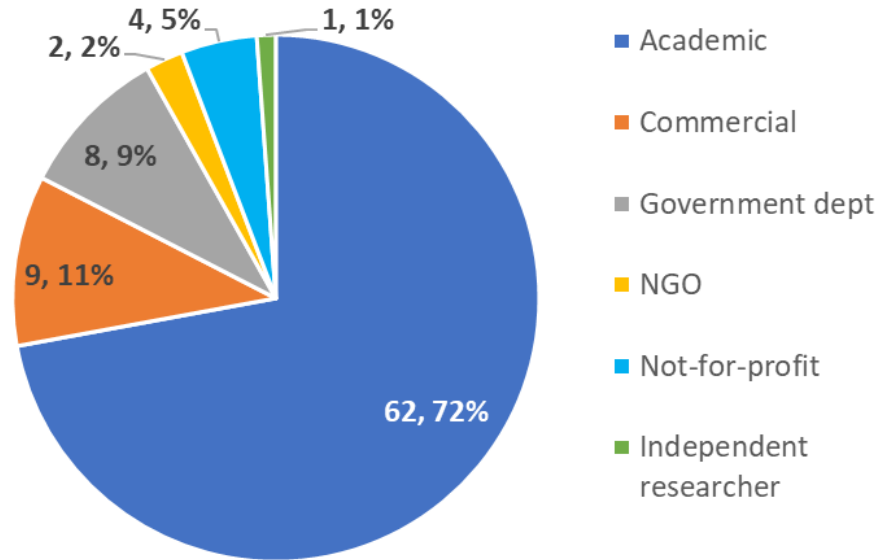


1-Year Review

Researchers from 29 countries requested data

Including 15 LMICs

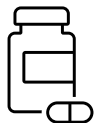
(Bangladesh, Egypt, Ethiopia, Ghana, India, Kenya, Lesotho, Nepal, Nigeria, Pakistan, Sri Lanka, Tanzania, Uganda, Vietnam, Zimbabwe)



1 publication to date, more in the pipeline from the data challenge



1-Year Review



Outcome*	# requests
Drug resistance trends and profiling	35
Strengthen stewardship	21
Inform local public health policies	19
Inform prescribing practices	19
Tool - model for predicting resistance trends	18
Support drug or diagnostic development	4
Strengthen understanding of global AMR trends	4
Methods in AMR surveillance	3
Tool - Inform prescribing practices	3
Identify surveillance gaps	2
Identifying mechanisms of resistance by geography	2
OneHealth objectives	2
Tool - Aid for diagnosis	2
WHO priority pathogens	2
Audit	1
Estimate economic burden of AMR	1
Personalised medicine	1
Tool - Strengthen stewardship	1

Types of Requests received

*Some requests have more than one outcome



View all fulfilled requests here:

<https://amr.vivli.org/requests-fulfilled/>

Search:

Data Request ID	Researcher's Name	Researcher's Affiliation	Data Request Title	Data Contributors
8010-8014	Moska Hellamand	Access To Medicine Foundation, Netherlands	Assessment of datasets shared on the AMR Register	GSK, Johnson & Johnson, Paratek, Pfizer, Shionogi, Venatorx
8055	Jose Lopez Revilla	Instituto Nacional de salud del Niño San Borja, Peru	The impact of resistance on sepsis mortality in pediatrics	Pfizer
8173	Catrin Moore	St George's, University of London, UK	ADILA (AMR data for local action)	GSK, Johnson & Johnson, Paratek, Pfizer, Shionogi, Venatorx
8235	Megan Coffee	Mailman School of Public Health, USA	Nigeria AMR	Pfizer, Shionogi, Venatorx
8430	Victoria Savage	Infex Therapeutics, UK	Establishing the prevalence of metallo-B-lactamases and carbapenem-resistance in Gram negative pathogens	Merck, Pfizer
8432	Ghanshyam Lad	Independent researcher, India	The trend of antibiotic resistance of tetracycline in adults in recent years	Pfizer
8447, 8594, 8595, 8596	Benn Sartorius	University of Oxford, UK	The Global Research on Antimicrobial Resistance (GRAM) Project	Paratek, Pfizer, Shionogi, Venatorx
8544	Gwen Knight	London School of Hygiene and Tropical Medicine, UK	Medical Research Council - Career Development Award (MRC CDA) fellowship project	GSK, Johnson & Johnson, Paratek, Shionogi, Venatorx
8554	Ying Huang	The Chinese University of Hong Kong, China	To explore pathogens and antibiotic susceptibility in hospital	Pfizer
8612/8613	Camille Andre	Harvard Medical School, USA	Epidemiology and antimicrobial resistance of bacteria causing eye infections	Paratek, Pfizer
8745	Ingrid Jacobson	University of Minnesota Twin Cities - Center for Infectious Disease Research and Prevention (CIDRAP), USA	Master's Thesis Project on Antifungal Resistance	Pfizer

Showing 1 to 11 of 11 entries



Patricia Bradford



Patricia A. Bradford owns Antimicrobial Development Specialists LLC, a consulting company that focuses on the late-stage development of antibiotics. She has previously been responsible for microbiology support at AstraZeneca, where she contributed to the successful development and approval of ceftazidime-avibactam. Patricia has also previously worked in antibiotic research for Novartis and Wyeth Pharmaceuticals.

Patricia completed her PhD in Medical Microbiology at Creighton University (USA). She has served as an editor for Antimicrobial Agents Chemotherapy, is a fellow of the American Academy of Microbiology and has over 115 publications in peer-reviewed scientific journals.





AMR

REGISTER A Vivli Initiative

2023 Vivli AMR Open Data Re-use Data Challenge

Funded by Wellcome



AMR Data Challenge

The AMR Data Challenge launched in April 2023 with three aims:

1

ENGAGE

researchers and the scientific community globally to access and utilize the Vivli AMR Register and participate in the longer-term sustainability of the platform

2

GENERATE

new insights or applications in AMR through access and re-use of AMR surveillance data

3

PROMOTE

the AMR Register to encourage more industry partners to share surveillance data through the platform when they see the data having a real impact

Participating Data Contributors



The Challenge was well-received, resulting in:

56

ENTRIES

from

28

COUNTRIES

11

FINALISTS

5

**AWARD
WINNING
TEAMS**

AMR Data Challenge Winners



FRED MUTISYA



**RACHAEL
KANGUHA**

“AntiMicro.ai: an artificial intelligence web app that helps predict antibacterial/antifungal susceptibility and builds custom machine learning models”

Team led by Fredrick Mutisya of Ministry of Health, Narok County, Kenya, with Rachael Kanguha, Chuka County Referral Hospital, Kenya

“Our team feels incredibly privileged to have participated in such a meaningful data challenge. Winning the grand prize not only fills us with a profound sense of fulfilment but also ignites a stronger motivation within us to continue seeking solutions for global issues, especially in combating antimicrobial resistance,” he said. “We are deeply grateful to Vivli for providing a platform that facilitates data accessibility. This is particularly significant for scientists like us hailing from the Global South, where opportunities like these are often scarce.”

FRED MUTISYA – GRAND PRIZE WINNER

MINISTRY OF HEALTH, NAROK COUNTY, KENYA

ANTIMICRO.AI WEB APP

The screenshot shows a web browser window displaying the Antimicro.ai web application. The browser's address bar shows the URL `antimicroai.streamlitApp`. The application interface includes a navigation menu with the following items: Home, AI Antibacterial Predictor, AI Antibacterial Predictor (Genotypic data), AI Antifungal Predictor, Build your own AI model, and About AntiMicro.ai. The main content area features a dark blue header with the Antimicro.ai logo and a white text box that reads: "Welcome to Antimicro.ai, your ultimate companion in predicting antimicrobial resistance." Below this, a light blue text box provides a detailed description of the platform's capabilities, mentioning its use of advanced AI algorithms and machine learning techniques, and its development based on Pfizer data from the Vivli data challenge. A large graphic of a brain composed of circuitry is centered on the page, with a pink arrow pointing from the right towards it. At the bottom right of the application, there is a dark blue button labeled "Manage app".

AntiMicro.AI Timeline



Dr. Rachael Kanguha
Paediatrician & Health policy expert



Dr. Fredrick Mutisya
Medical Doctor, FETP resident and AI developer



Nov 2023

Infrastructure

Used Prize money to purchase a \$4000 Deep learning enabled computer that can double up as a host server if needed



Dec 2023

Mentorship & advocacy

Mentorship of vulnerable youth (one per quarter for sustainability).
Prize money used for purchase of laptop and internet connection for Mr. DK



Feb 2024

Product development

Incorporating client factors, antibiogram

Incorporating Open Source Large Language models into the tool to link the results to online, peer literature strengthening the model capabilities



**April/
May 2024**

Networks & Partnerships

2 researchers have used AntiMicro.ai in their own data sets.
Uganda & Canada

Explored grants with the Kenya Medical Association
Challenge- AMR is not an established program in LMIC



Future

Future

User acceptability studies
Linkage to prognostic markers



Impact Award winners

“Stronger together? Potential and limitations of combining industry datasets to fill in global AMR surveillance gaps.”

Team from the Institut Pasteur, France, led by Quentin Leclerc with Aleksandra Kovacevic, Eve Rahbe and Lulla Opatowski



“Global Geographic Patterns and Trends of WHO Priority Pathogens and AWaRe Antibiotic Resistances among Children: amrinkids.com”

Team led by Yanhong Jessica Hu with Penelope Bryant, both of Murdoch Children’s Research Institute, Australia, Joseph Harwell (The Warren Alpert Medical School of Brown University, USA), Hong Qiu (The Chinese University of Hong Kong)



Innovation Award winners

“Data Challenge – Are antibiotic breakpoints globally consistent, does it matter if not?”

Team led by Robert Beardmore with Emily Wood, both of University of Exeter, UK, Pablo Catalan (Universidad Carlos III, Spain), Jon Iredell (Westmead Hospital/University of Sydney, Australia)



“Novel approach to antibiogram analysis: looking at the composite resistance phenotype”

Team led by Shraddha Karve with Rintu Kutum, Vasundhara Karthikeyan, Ragul N, all of Ashoka University, India, and Devojit Sarma (ICMR, NIREH, India)



Data Challenge - Publications

- Wellcome Open Research has published a collection of articles from the Data Challenge finalists with an editorial from Vivli and the judges is now live

<https://wellcomeopenresearch.org/collections/vivli/about>

The screenshot shows the 'Vivli AMR Open Data Reuse Data Challenge' page on the Wellcome Open Research website. The page features a teal header with the text 'Wellcome Open Research / Collections' and a 'SIGN IN' link. Below the header is a dark banner with the 'AMR REGISTER | A Vivli Initiative' logo and the title 'Vivli AMR Open Data Reuse Data Challenge'. Navigation links for 'ABOUT' and 'BROWSE' are visible, along with 'TRACK' and 'SUBMIT TO THIS COLLECTION' buttons. The main content area includes a section titled 'About this Collection' with a paragraph describing the challenge's use of antimicrobial resistance (AMR) surveillance data. Below this is a 'Collection Advisors' section listing Rebecca Li and Patricia Bradford.

Wellcome Open Research / Collections SIGN IN

AMR REGISTER | A Vivli Initiative Vivli AMR Open Data Reuse Data Challenge

ABOUT BROWSE TRACK SUBMIT TO THIS COLLECTION

About this Collection

The Vivli AMR Open Data Reuse Data Challenge utilised antimicrobial resistance (AMR) surveillance data, collected by the pharmaceutical industry and made available within the [AMR Register](#). Launched as a catalyst for the inventive reutilization of the wealth of surveillance data available, the resulting solutions were diverse, impactful and innovative, proposing groundbreaking advancements and tools for use in AMR surveillance. This Collection brings together articles written by a selection of finalist and award-winning teams who participated in the challenge. More details about the data challenge can be found [here](#).

Collection Advisors

Rebecca Li
Vivli Inc., USA

Patricia Bradford
Antimicrobial Development Specialists, LLC, USA

Rebecca Li
Rebecca Li, PhD, is the CEO of Vivli and on faculty at the Center for Bioethics at the Harvard Medical School. She acts as the lead for the Vivli AMR Register. Previous to her current role she was the Executive Director of the MRCT Center of Brigham and Women's Hospital and Harvard for over 5 years and remains a Senior Advisor at the Center. She has over 30 years of experience spanning the entire drug development process with experience in Biotech, Pharma and CRO environments with a focus in clinical trials. She completed a [Fellowship](#) in 2013 in the Division of Medical Ethics at Harvard Medical School. She earned her PhD in



Vivli AMR Open Data Reuse Data Challenge

10 finalists and awardees
Published in the
Wellcome Open
Collection

RESEARCH ARTICLE

AWAITING PEER REVIEW

A predictive algorithm for the analysis of AMR trends and healthcare decision support

[version 1; peer review: awaiting peer review]

AUTHORS Tochukwu Agboeze, Oluwasegun Daramola, Ayobami Akomolafe, Roqeeb Adedeji, Julius Markwei

FUNDER Wellcome

PEER REVIEWERS Invited

PUBLISHED 16 May 2024

RESEARCH ARTICLE

AWAITING PEER REVIEW

AntiMicro.ai: An Artificial Intelligence powered web application for predicting antibacterial/antifungal susceptibility and constructing personalized machine learning models

[version 1; peer review: awaiting peer review]

AUTHORS Fredrick Mutisya, Rachael Kanguha

FUNDER Wellcome

PEER REVIEWERS Invited

PUBLISHED 16 May 2024

RESEARCH ARTICLE

✓

Investigating the feasibility and potential of combining industry AMR monitoring systems: a comparison with WHO GLASS

[version 1; peer review: 1 approved]

AUTHORS Eve Rahbé, Aleksandra Kovacevic, Lulla Opatowski, Quentin J. Leclerc

FUNDER Wellcome

PEER REVIEWER Arun S. Kharat

PUBLISHED 10 May 2024

RESEARCH ARTICLE

✓





AMR

REGISTER A Vivli Initiative

2024 Vivli AMR Surveillance Data Challenge

Funded by



AMR Data Challenge

The AMR Data Challenge, launched June 17, with the same aims as the 2023 challenge:

1

ENGAGE

researchers and the scientific community globally to access and utilize the Vivli AMR Register and participate in the longer-term sustainability of the platform

2

GENERATE

new insights or applications in AMR through access and re-use of AMR surveillance data

3

PROMOTE

the AMR Register to encourage more industry partners to share surveillance data through the platform when they see the data having a real impact

Meet the Judges



Diane Anastasiou

Paratek Pharmaceuticals,
Inc.



Patricia Bradford

Antimicrobial Development
Specialists, LLC



Ana Gales

Universidade Federal de São
Paulo



Direk Limmathurotsakul

Mahidol-Oxford Tropical
Medicine Research Unit



Anand Manoharan

GSK



Marc Mendelson

University of Cape Town



Seamus O'Brien

Global Antibiotic Research and
Development Partnership (GARDP)



Katherine Perez

Pfizer



Arjun Srinivasan

Centers for Disease Control
and Prevention (CDC)

2024 VIVLI AMR SURVEILLANCE DATA CHALLENGE

2024 Judging and Awards

- **Judging Criteria**

Entries will be scored overall for methodology and study design, and also on:

- I. **Innovation** – how creative is this idea, technique or solution?
- II. **Impact** – how would you rate the impact of this solution or tool on the field if successfully implemented?

- **Awardee Prizes**

- **Grand Prize Award** - \$10,000 and \$5,000 for travel to present their abstract (if it is accepted) at ESCMID Global or ASM Microbe in 2025
- 4 awards of \$5,000 and \$2,500 for travel to present their abstract (if it is accepted) at ESCMID Global or ASM Microbe in 2025 - 2 awards each for innovation and impact
- AMR Student Innovation award - \$5,000 for travel to present their abstract (if it is accepted) at ESCMID Global or ASM Microbe in 2025

- **Encouraging open-source data sharing**

- All finalists to post their solutions in open-source forums



2024 VIVLI AMR SURVEILLANCE DATA CHALLENGE

Key activities

DEADLINE EXTENDED!

PHASE 1: SUBMIT EXPRESSION OF INTEREST

Today → ~~July 28~~
August 11

- Teams submit a 300-word Expression of Interest (EOI)
- Once approved, teams are given access to the data



PHASE 2: ANALYZE DATASETS

Within 30 Days of approved EOI

- Teams have 30 days to access the data and analyze the datasets



PHASE 3: SUBMIT SOLUTIONS

Within 30 Days of approved EOI

- Teams submit written solutions after 30 days of data access to qualify for the "finalist round"

PHASE 4: LIVE JUDGING OF FINALISTS

October

- Finalists present their solutions to the judging panel in a live video conference



PHASE 5: AWARDEES CHOSEN

Early November

- Awardees are chosen by the judging panel
- Awardees may submit their abstracts for conference



PHASE 6: LOOKING AHEAD

2025

- All finalists invited to publish in Wellcome Open Research
- Abstracts accepted-> Travel to conferences





A global AMR surveillance data sharing platform

Dedicated to helping industry share antimicrobial resistance data with researchers in the fight against AMR. Updated datasets now available!

REQUEST DATASETS

- Data Challenge Overview
- How to Participate
- How To Videos
- FAQs
- Terms of Participation
- 2023 Finalist and Award-Winning Solutions

For more information on how to enter the data challenge, go to <https://amr.vivli.org/> and follow the links in the drop-down menu

NOW OPEN!

2024 Vivli AMR Surveillance Data Challenge, funded by GARDP, Paratek, Pfizer and Vivli

The aim of the 2024 Vivli AMR Surveillance Data Challenge is to promote utilization of the Vivli AMR Register to more researchers and drive advances in the AMR field. We believe that important questions in surveillance would be

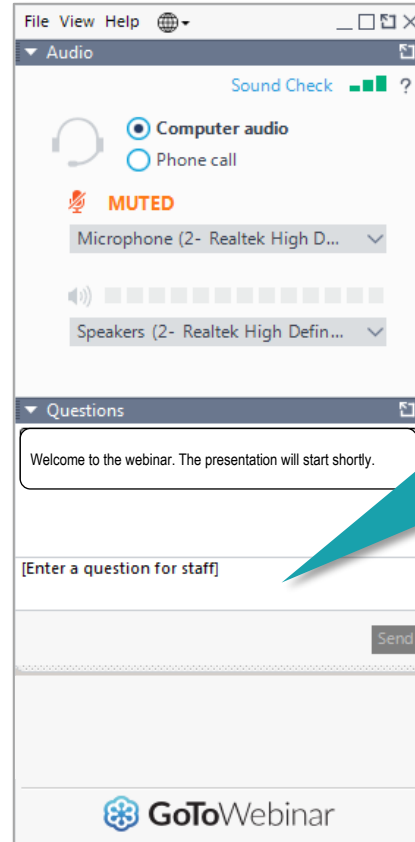
Closing thoughts

- The AMR Register is an important free resource of industry surveillance data at searchamr.vivli.org that is continually updated
- We welcome interested researchers to join a data challenge currently open at amr.vivli.org
- Resources are available on-line and our team is available to answer further questions



How to submit your questions

If your question is addressed to a specific speaker, please include their name when submitting the question.



The presentation will be followed by an interactive Q&A session.

Please submit your questions via the 'questions' window. We will review all questions and respond to as many as possible after the presentation.

Today's speakers

The value of surveillance data in defining the medical need for new antimicrobials



Ian Morrissey
Consultant
Antimicrobial Focus Ltd. (UK)



Rebecca Li
Chief Executive Officer
Vivli (USA)

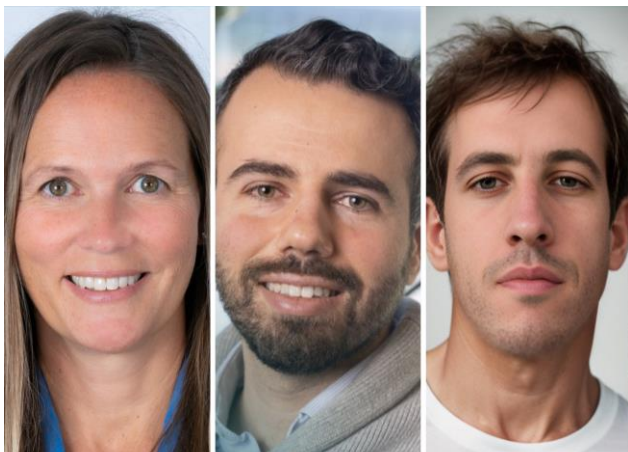


Patricia Bradford
Consultant
Antimicrobial Development Specialists LLC (USA)



Moderator:
Fernanda Lessa
Chief of International Infection Control,
Centers for Disease Control and Prevention (USA)

Upcoming webinars

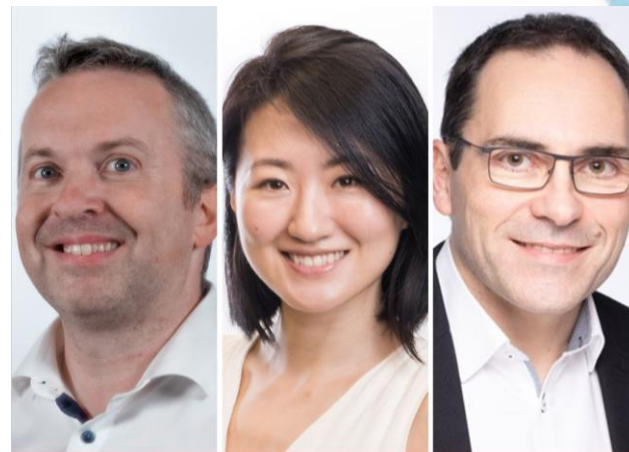


Register now!

**Exploring non-traditional antimicrobials:
Insights from three cases**

With Jennifer Schneider, Rida Mourtada & Gregorio Iraola

22 August 2024, 17:00-18:30 CEST



Register now!

An introduction to antibiotic research and development

With Alan Hennessy, Mo Yin & Herbert Wetli

19 September 2024, 10:00-11:30 CEST

revive.gardp.org/webinars



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Thank you for joining us

