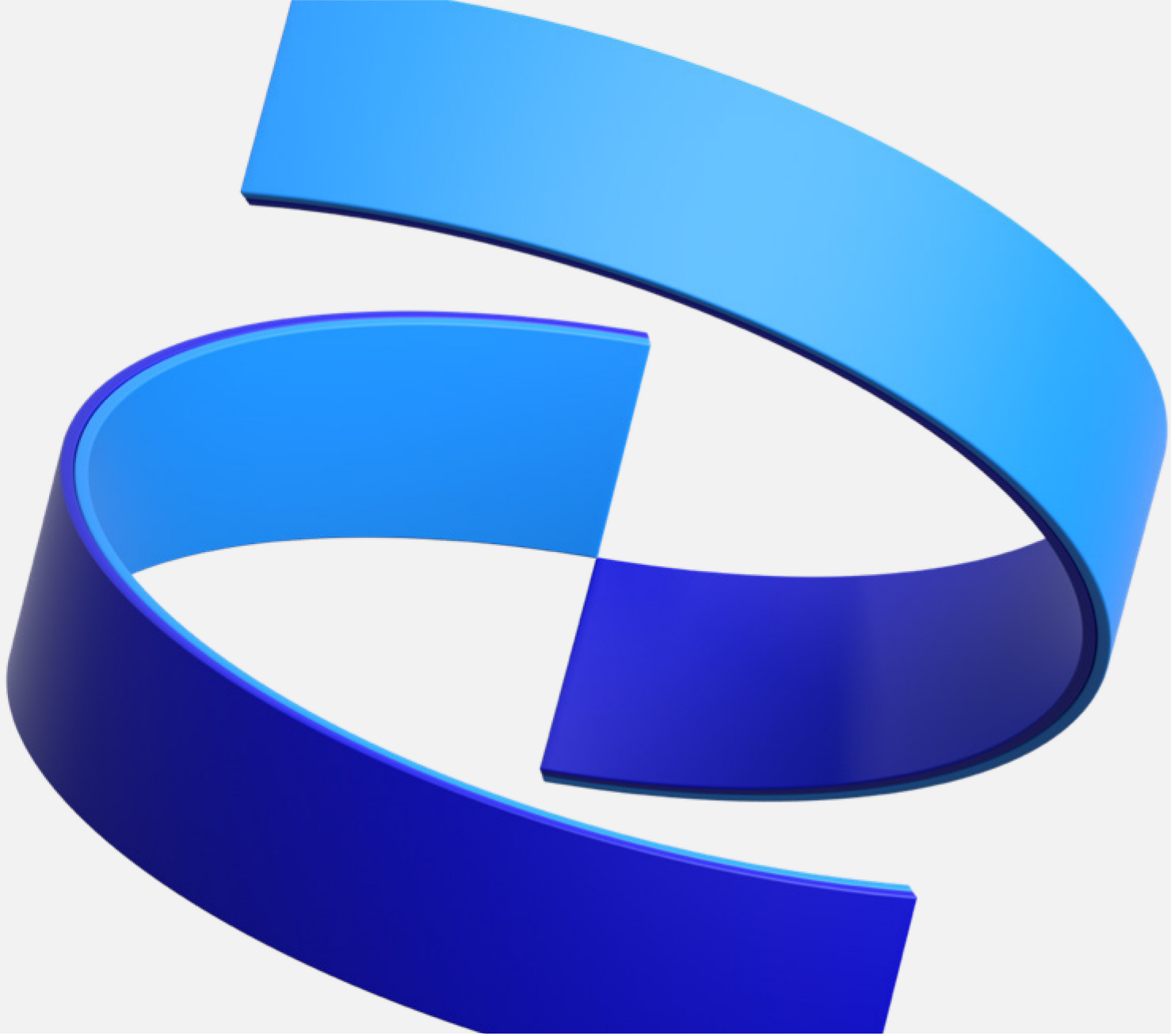
Collective Advantage: Collaborations to Drive Impact



Bruce Altevogt, PhD
Head, External Medical Engagement
Hospital Business Unit

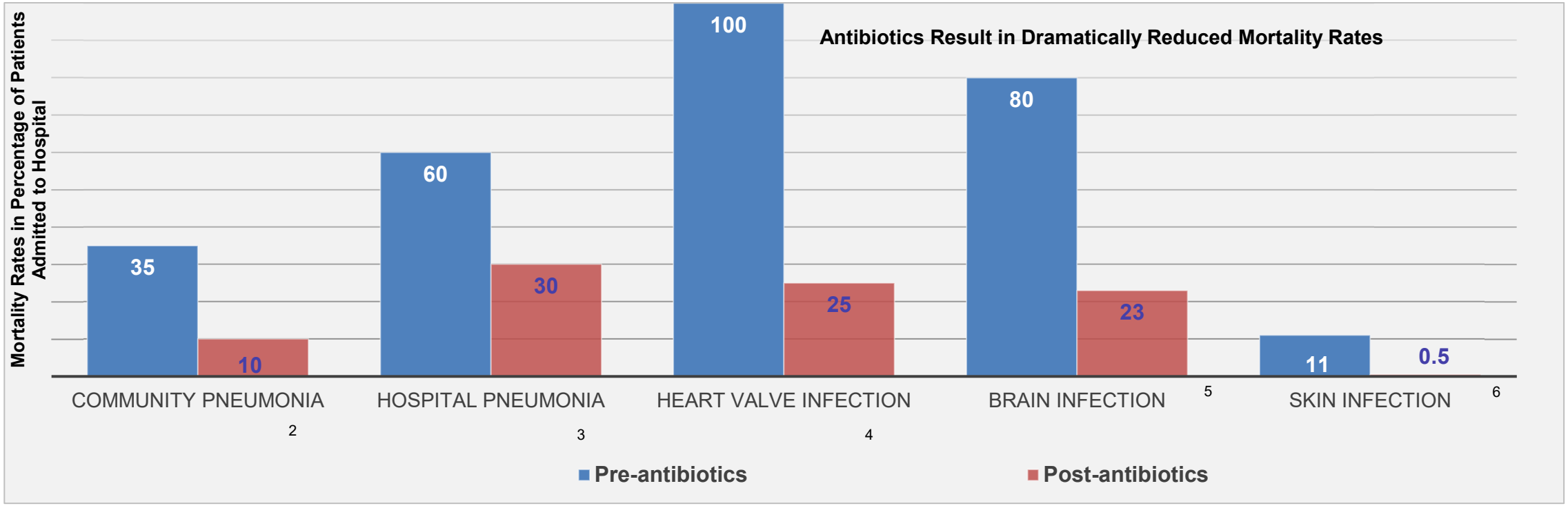
October 15, 2021

Legal Disclaimer

- This presentation contains statements that may constitute personal views and opinions of the presenter.
- This presentation is subject to further review and revision.

Antibiotics Enable the Practice of Modern Medicine

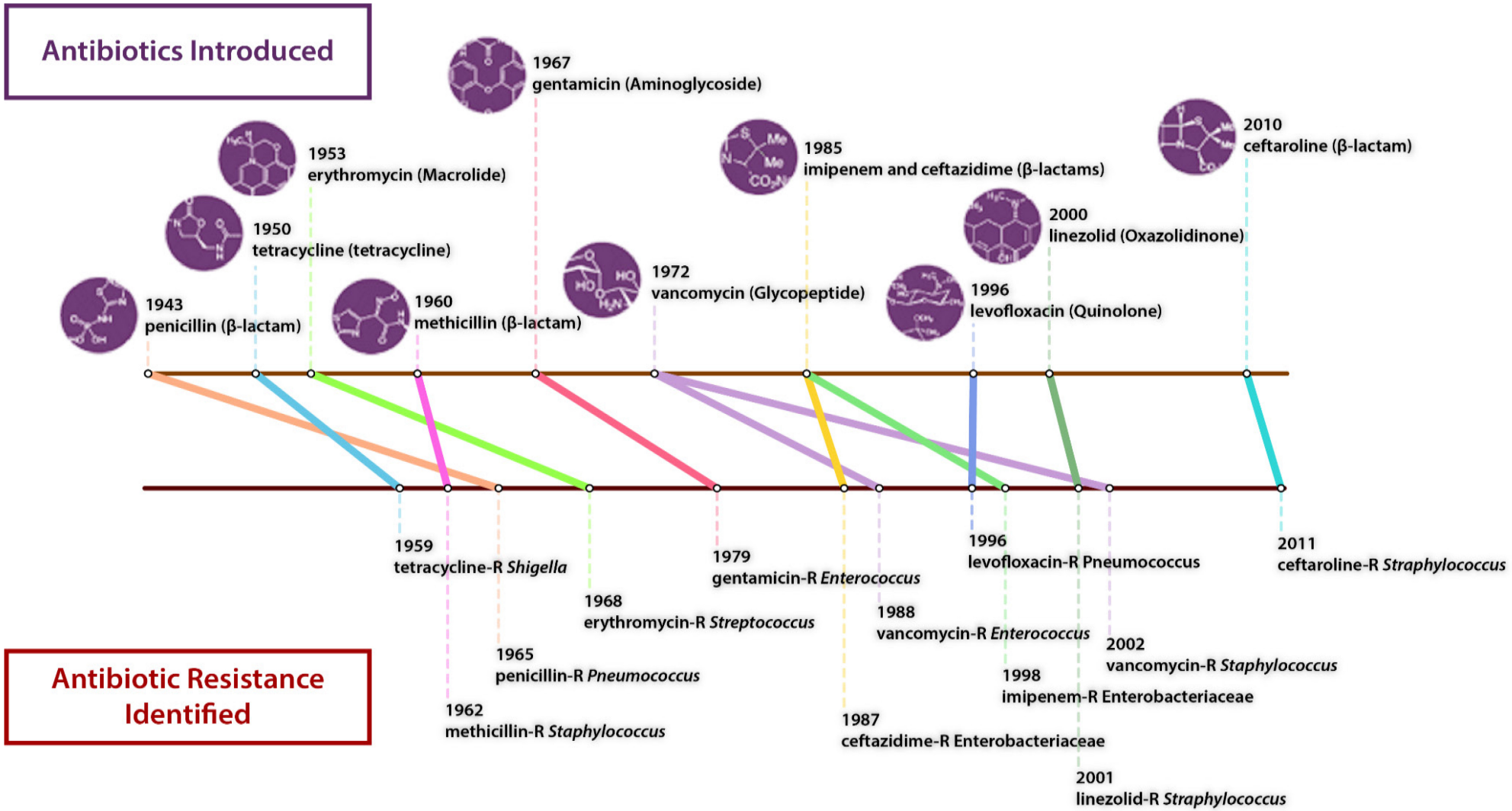
- Effective antibiotics have enabled the development of modern medicine[1]
- Antibacterial drugs are critically important across medicine, including in the care of premature infants and for use in surgery, chemotherapy, and organ transplantation[1]
- Mortality rates significantly improved with the introduction of antibiotics[2-6]



Hospital

Woodcock J. Sept 19 2014. FDA. Testimony. www.fda.gov/NewsEvents/Testimony/ucm415387.htm; 2. IDSA Position Paper. Clin Infect Dis. 2008;47: S249-65; 3. IDSA/ACCP/ATS/SCCM Position Paper. Clin Infect Dis 2010; 4. Kerr AJ. Lancet. 1935;226:383-4; 5. Lancet. 1938;231:733-4 and Waring et al. Am J Med. 1948;5:402-18; 6. Spellberg et al. Clin Infect Dis. 2009;49:383-91

Antibiotic Discovery versus Emerging Resistance



Adapted from: SwitchYard Media and Food & Environment Reporting Network. 2013. [Online]. https://thefern.org/2013/11/imagining-the-post-antibiotics-future/timeline-of-antibiotic-resistance/

Global Leaders Have Prioritized Needs: WHO priority pathogens

Priority 1: CRITICAL

- *Enterobacteriaceae**
- *Acinetobacter baumannii*
- *Pseudomonas aeruginosa*

Priority 2: HIGH

- *Enterococcus faecium*
- *Staphylococcus aureus*
- *Salmonellae*
- *Helicobacter pylori*
- *Campylobacter spp.*
- *Neisseria gonorrhoeae*

Priority 3: MEDIUM

- *Haemophilus influenzae*
- *Streptococcus pneumoniae*
- *Shigella spp.*

Mycobacteria (including Mycobacterium tuberculosis, the cause of human tuberculosis), was not subjected to review for inclusion in this prioritization exercise as it is already a globally established priority for which innovative new treatments are urgently needed.

* Enterobacteriaceae include: Klebsiella pneumonia, Escherichia coli, Enterobacter spp., Serratia spp., Proteus spp., and Providencia spp, Morganella spp

WHO, 2017. GLOBAL PRIORITY LIST OF ANTIBIOTIC-RESISTANT BACTERIA TO GUIDE RESEARCH, DISCOVERY, AND DEVELOPMENT OF NEW ANTIBIOTICS. https://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf

Current Pipeline

There are only **43 antibiotics** in clinical development.*

* Total number of antibiotics in Phases 1-3 does not add up to 43 because new drug applications have been submitted for two drugs.

Only 15 antibiotics in development have the potential to treat WHO's critical threat pathogens.

Source: The Pew Charitable Trusts. The Critical Need for New Antibiotics. March 2021. Accessed 4/24/2021. For further information, please visit: https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2016/the-critical-need-for-new-antibiotics

Pfizer's Commitment to Collective Action

Pfizer's Legacy & Commitment to Infectious Diseases

1849

Santonin - Pfizer's First Product

1944

World's largest producer of penicillin

Today

- ***One of the largest and most diverse portfolios of anti-infective therapies***
- ***Evolving commitments to leverage products, resources and expertise to address infectious disease***

Pfizer's AMR Policy Platform and Commitments

Antimicrobial Stewardship

- Greater oversight of antibiotic usage
- Enable rational and judicious prescribing
- Promote education

Antimicrobial Surveillance

- Understand resistance patterns to enable physicians and healthcare providers to chose appropriate antibiotic therapies while informing stewardship strategies

Regulatory Framework

- Adoption of greater regulatory harmonization and flexibility
- Supports pathogen-based label indications

Manufacturing

- Support measures to reduce environmental contribution from production of antibiotics

Access to Vaccines

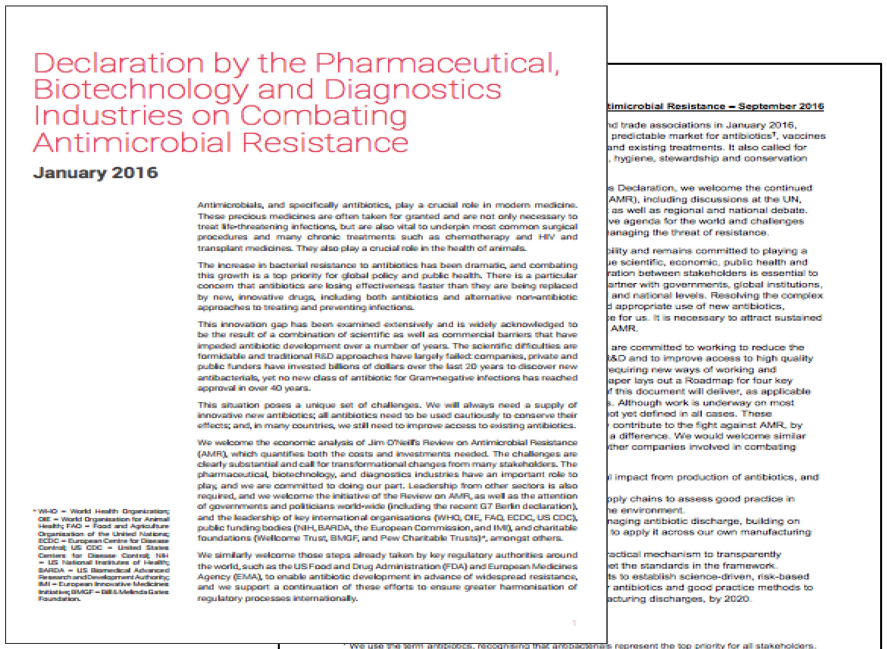
- Effective tool for preventing disease
- Conjugate vaccines particularly valuable

R&D Incentives & New Business Models

- Advocate for market-based incentives that are needed to increase R&D investments
- Strengthen and build a more sustainable marketplace

Davos Declaration and Roadmap Commitments

AMR Alliance Declaration & Industry Roadmap



Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance

January 2016

Antimicrobials, and specifically antibiotics, play a crucial role in modern medicine. These precious medicines are often taken for granted and are not only necessary to treat life-threatening infections, but are also vital to underpin most common surgical procedures and many chronic treatments such as chemotherapy and HIV and transplant medicines. They also play a crucial role in the health of animals.

The increase in bacterial resistance to antibiotics has been dramatic, and combating this growth is a top priority for global policy and public health. There is a particular concern that antibiotics are losing effectiveness faster than they are being replaced by new, innovative drugs, including both antibiotics and alternative non-antibiotic approaches to treating and preventing infections.

This innovation gap has been examined extensively and is widely acknowledged to be the result of a combination of scientific as well as commercial barriers that have impeded antibiotic development over a number of years. The scientific difficulties are formidable and traditional R&D approaches have largely failed: companies, private and public funders have invested billions of dollars over the last 20 years to discover new antibacterials, yet no new class of antibiotic for Gram-negative infections has reached approval in over 40 years.

This situation poses a unique set of challenges. We will always need a supply of innovative new antibiotics; all antibiotics need to be used cautiously to conserve their effects; and, in many countries, we still need to improve access to existing antibiotics.

We welcome the economic analysis of Jim O'Neill's Review on Antimicrobial Resistance (AMR), which quantifies both the costs and investments needed. The challenges are clearly substantial and call for transformational changes from many stakeholders. The pharmaceutical, biotechnology, and diagnostics industries have an important role to play, and we are committed to doing our part. Leadership from other sectors is also required, and we welcome the initiative of the Review on AMR, as well as the attention of governments and politicians world-wide (including the recent G7 Berlin declaration), and the leadership of key international organisations (WHO, OIE, FAO, ECDC, US CDC), public funding bodies (NIH, BARDA, the European Commission, and IMI), and charitable foundations (Wellcome Trust, BMGF, and Pew Charitable Trusts)*, amongst others.

We similarly welcome those steps already taken by key regulatory authorities around the world, such as the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), to enable antibiotic development in advance of widespread resistance, and we support a continuation of these efforts to ensure greater harmonisation of regulatory processes internationally.

* WHO = World Health Organization; OIE = World Organization for Animal Health; FAO = Food and Agriculture Organization of the United Nations; ECDC = European Centre for Disease Control; US CDC = United States Centers for Disease Control; NIH = US National Institutes of Health; BARDA = US Biomedical Advanced Research and Development Authority; IMI = European Innovative Medicines Initiative; BMGF = Bill & Melinda Gates Foundation.

timicrobial Resistance – September 2016

d trade associations in January 2016, predictable market for antibiotics†, vaccines and existing treatments. It also called for , hygiene, stewardship and conservation

s Declaration, we welcome the continued AMR), including discussions at the UN, as well as regional and national debate. ve agenda for the world and challenges anaging the threat of resistance.

bility and remains committed to playing a e scientific, economic, public health and ration between stakeholders is essential to artner with governments, global institutions, and national levels. Resolving the complex d appropriate use of new antibiotics, e for us. It is necessary to attract sustained AMR.

are committed to working to reduce the &D and to improve access to high quality equiring new ways of working and aper lays out a Roadmap for four key f this document will deliver, as applicable . Although work is underway on most ot yet defined in all cases. These contribute to the fight against AMR, by a difference. We would welcome similar her companies involved in combating

l impact from production of antibiotics, and

pply chains to assess good practice in e environment. naging antibiotic discharge, building on to apply it across our own manufacturing

actical mechanism to transparently et the standards in the framework. ts to establish science-driven, risk-based antibiotics and good practice methods to acturing discharges, by 2020.

* We use the term antibiotics, recognising that antibacterials represent the top priority for all stakeholders.
† These principles could subsequently be applied to other types of antimicrobial over time.
‡ Pharmaceutical Supply Chain Initiative https://pscinitiative.org/home

- Support measures to reduce environmental impact from production of antibiotics
- Commit to antibiotics only being used in patients who need them
- Align promotional activities with appropriate use
- Partner with stakeholders to improve access to antibiotics, diagnostics and vaccines
- Advance R&D through new collaborations and incentives

amr INDUSTRY ALLIANCE
UNITED AGAINST ANTIMICROBIAL RESISTANCE

Pfizer has been recognized as one of the leading pharmaceutical companies in the infectious diseases market by the Access to Medicine Foundation's 2020 Antimicrobial Resistance (AMR) Benchmark Report.

Antimicrobial Resistance Benchmark 2020. https://accesstomedicinefoundation.org/amr-benchmark

Indian Council of Medical Research (ICMR) Partnership

Pfizer &

ICMR INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

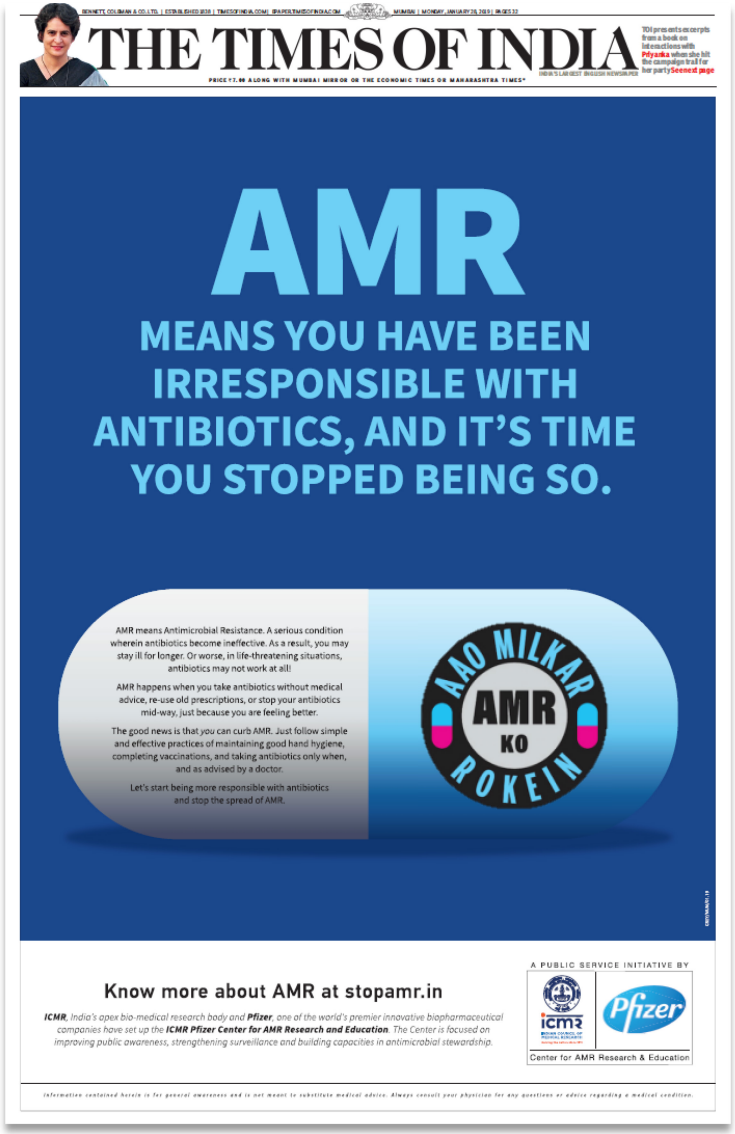
Strengthening the movement against antimicrobial resistance and for infection prevention & control in India

ICMR & Pfizer: Combating the threat of AMR in India

Enhance/ strengthen the existing surveillance programme/ system

Expand ICMR* antimicrobial stewardship (AMSP) and infection control programme (IPC)

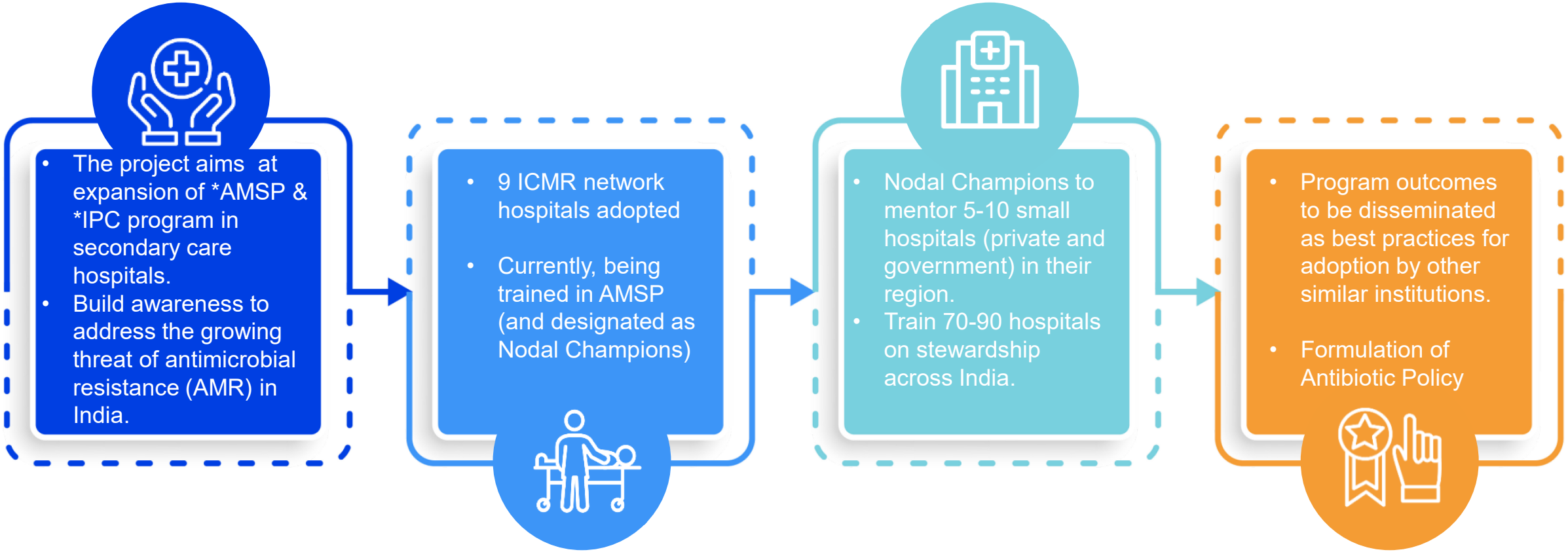
India's first-ever mass media campaign: Aao Milkar AMR ko Rokein (let's stop AMR together)



*ICMR – Indian Council of Medical Research

Pfizer Hospital

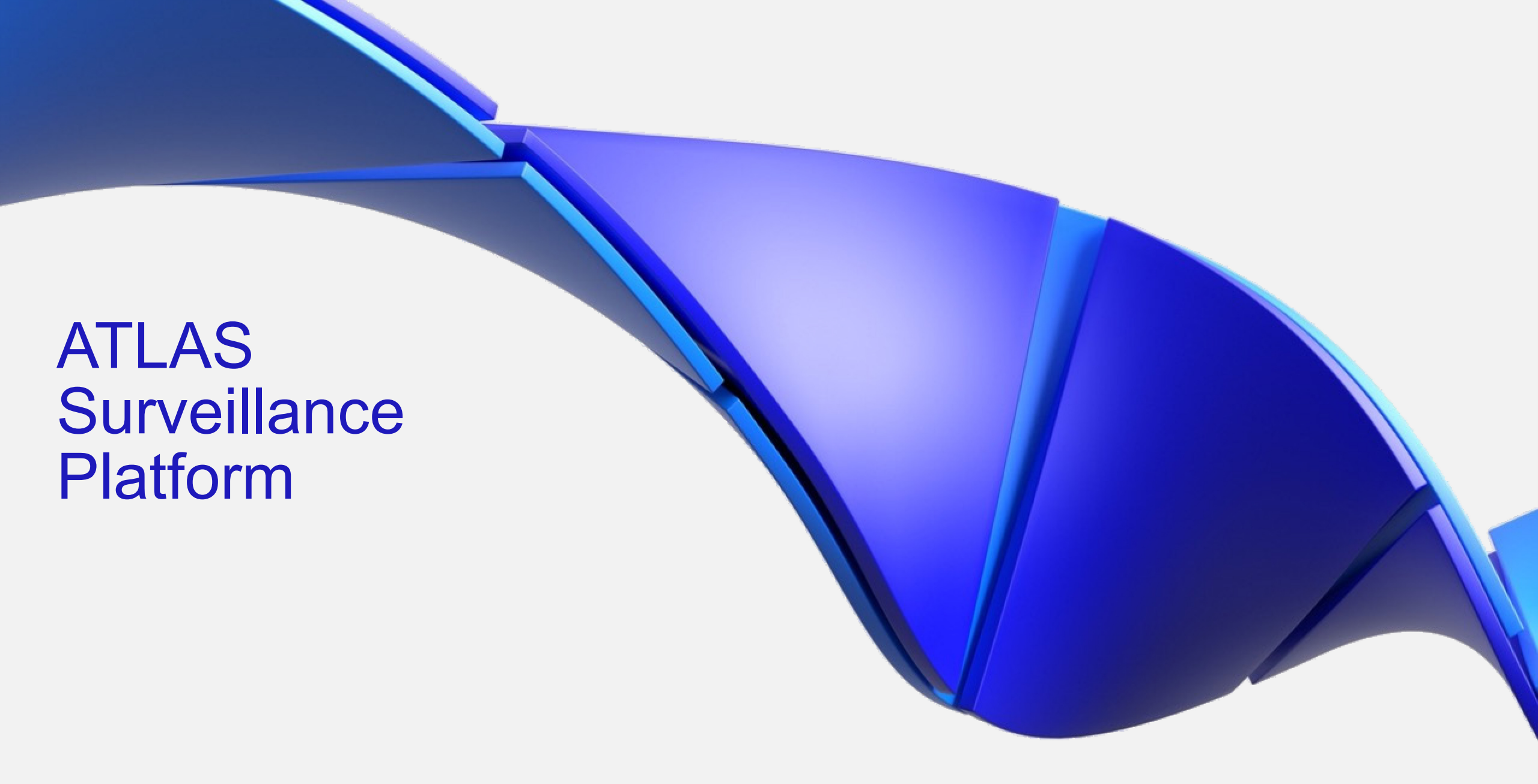
“The ICMR Pfizer – AMR Alliance Initiative” - private-public partnership on the ground in collaboration with experts



*AMSP – Antimicrobial Stewardship Program
*IPC – Infection Prevention Control

Pfizer Hospital

ATLAS Surveillance Platform



Value of AMR Surveillance

- Identify global, regional and local changes in the resistance rates of pathogens
  - Outbreaks of resistant pathogens
  - Recognize the emergence of new resistance mechanisms
- Detect trends in multidrug resistance by analyzing data longitudinally over time
- Provide reliable, global, regional or national *in vitro* susceptibility data

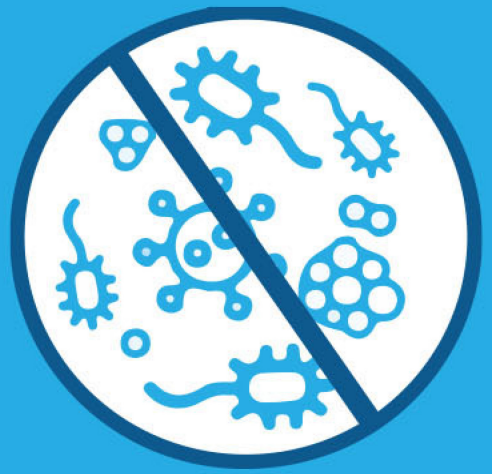
ATLAS

Antimicrobial Testing Leadership and Surveillance

ATLAS

15 YEARS

OF SURVEILLING **BACTERIA**,



9 YEARS

surveilling

fungi

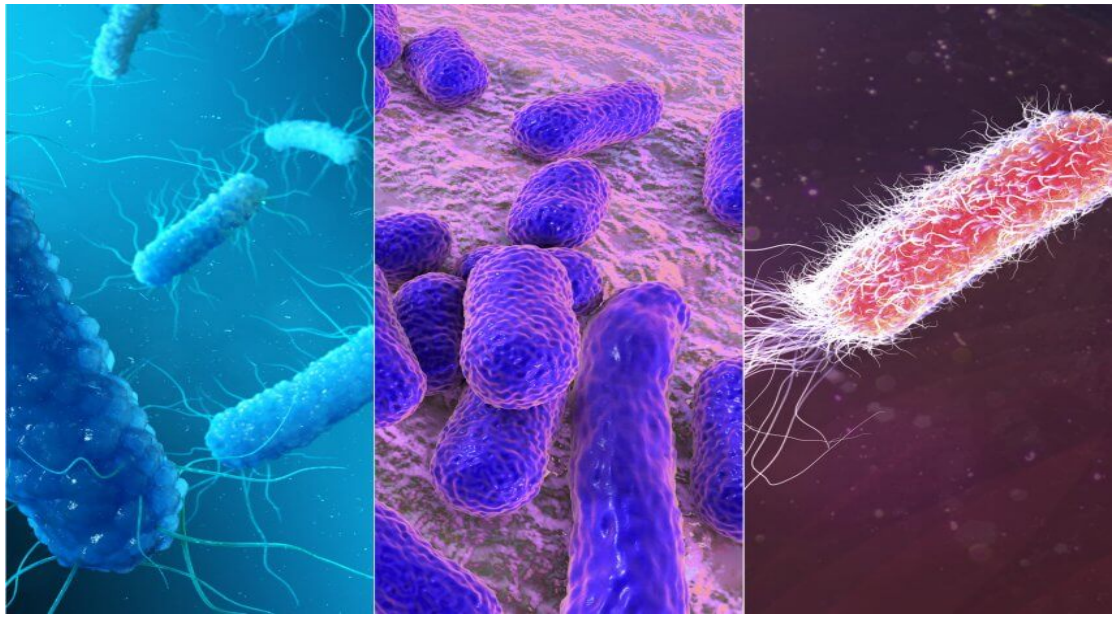
ATLAS Strain Expansion: 9 of 13 WHO Priority Pathogens

2018 18,080 total isolates

Going forward 30,880 isolates.

Impact: A more complete picture of current resistance patterns (longitudinal trending analyses)

Strengthened assessment for new and different resistance mechanisms that may arise from this additional collection



© shutterstock

The complete WHO priority pathogens list

Priority 1: CRITICAL

- *Acinetobacter baumannii*
- *Pseudomonas aeruginosa*
- *Enterobacteriaceae* (*E. coli*, *Klebsiella* spp.)

Priority 2: HIGH

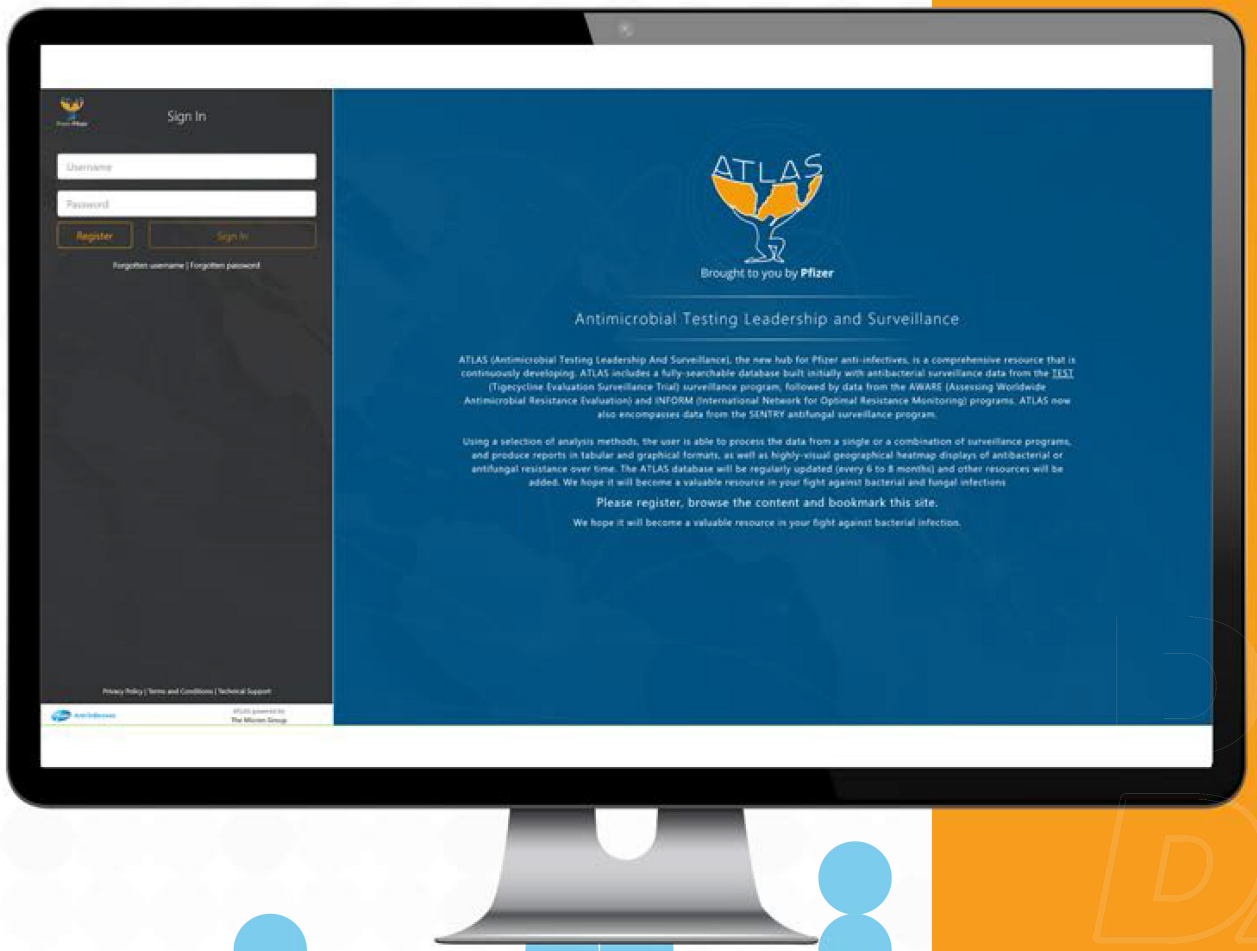
- *Enterococcus faecium*
- *Staphylococcus aureus*
- *Salmonellae*
- *Helicobacter pylori*
- *Campylobacter spp.*
- *Neisseria gonorrhoeae*

Priority 3: MEDIUM

- *Haemophilus influenzae*
- *Streptococcus pneumoniae*
- *C. difficile (US CDC urgent)*
- *Shigella spp.*

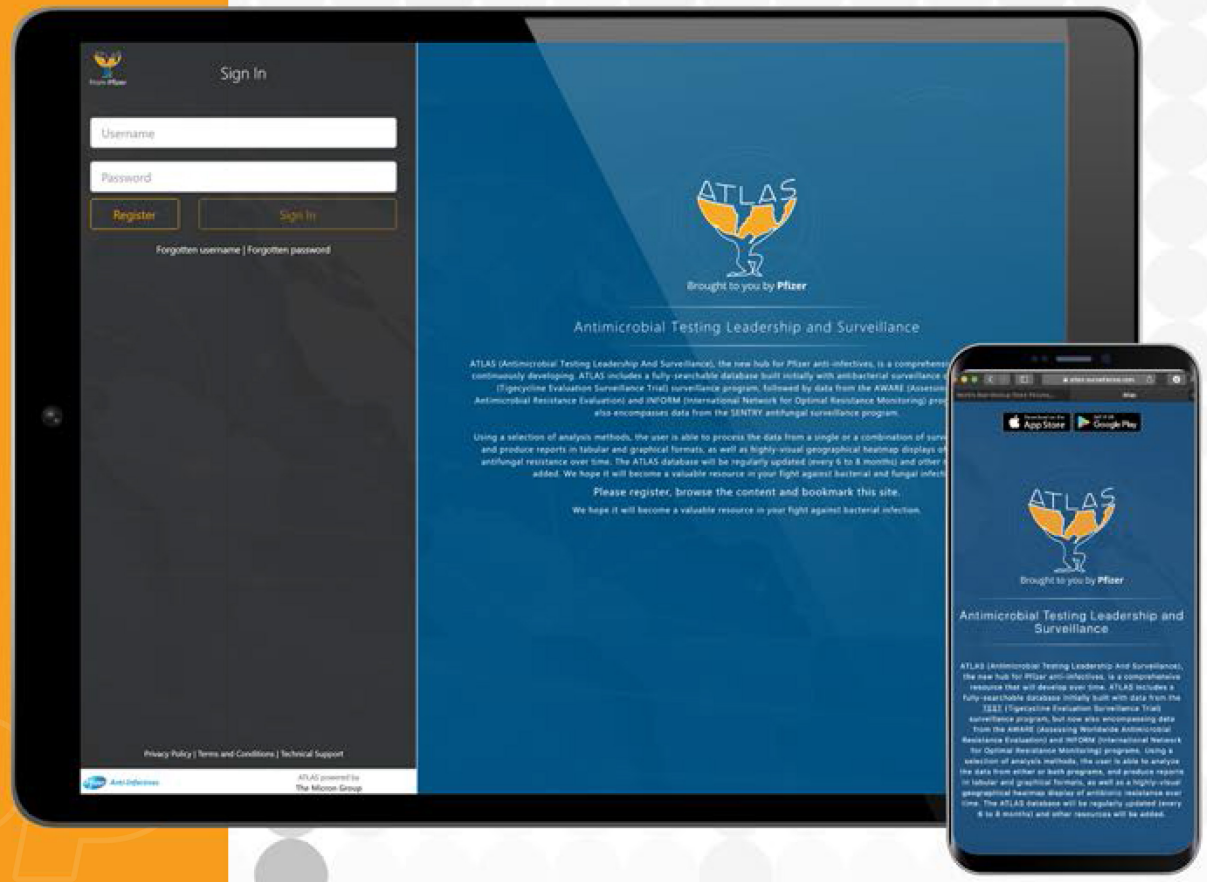
Free access to data on **various antimicrobial resistance patterns** and

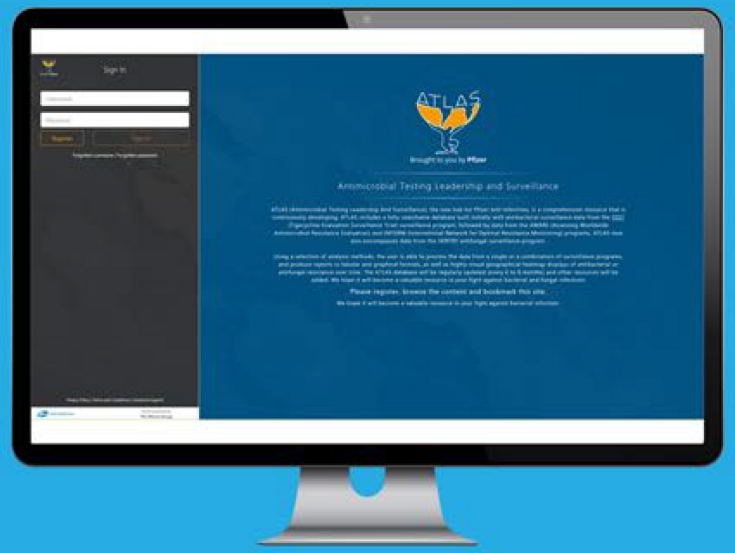
emerging **resistance patterns**



Includes a **fully-searchable** ***DATABASE*** where users,

both on WEBSITE and **mobile app,**



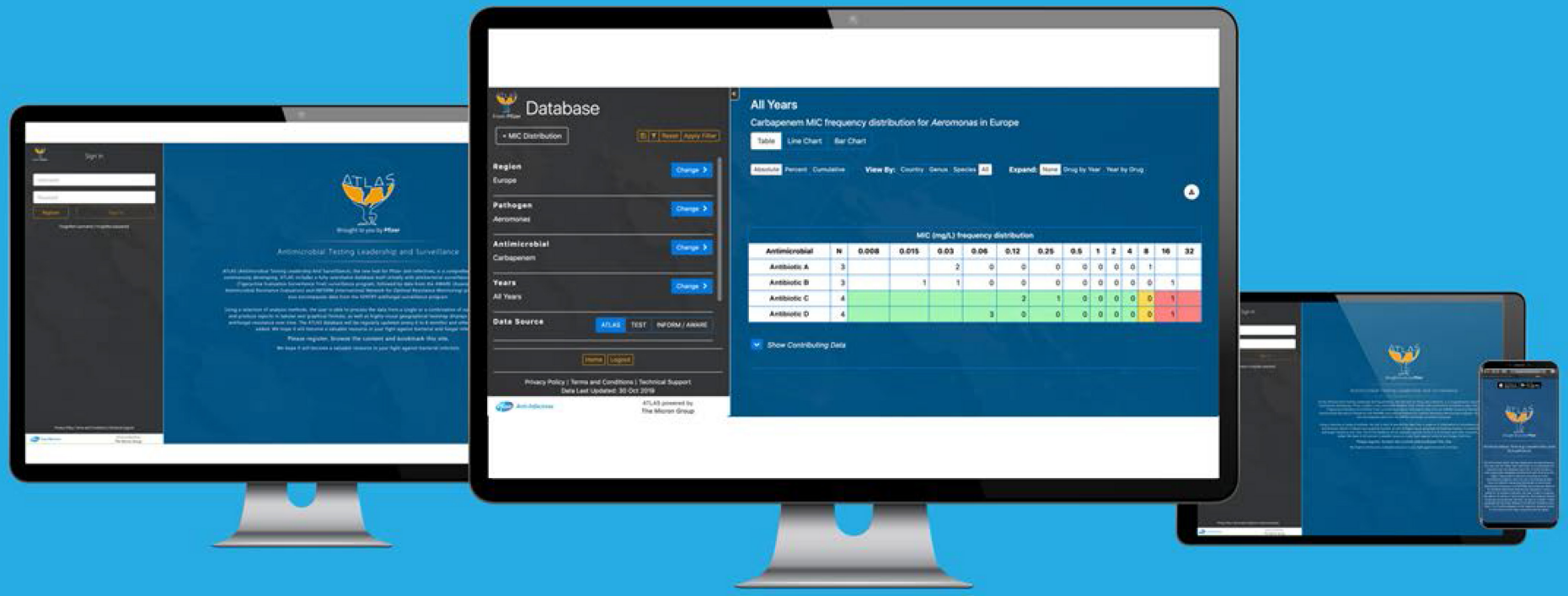


are able to

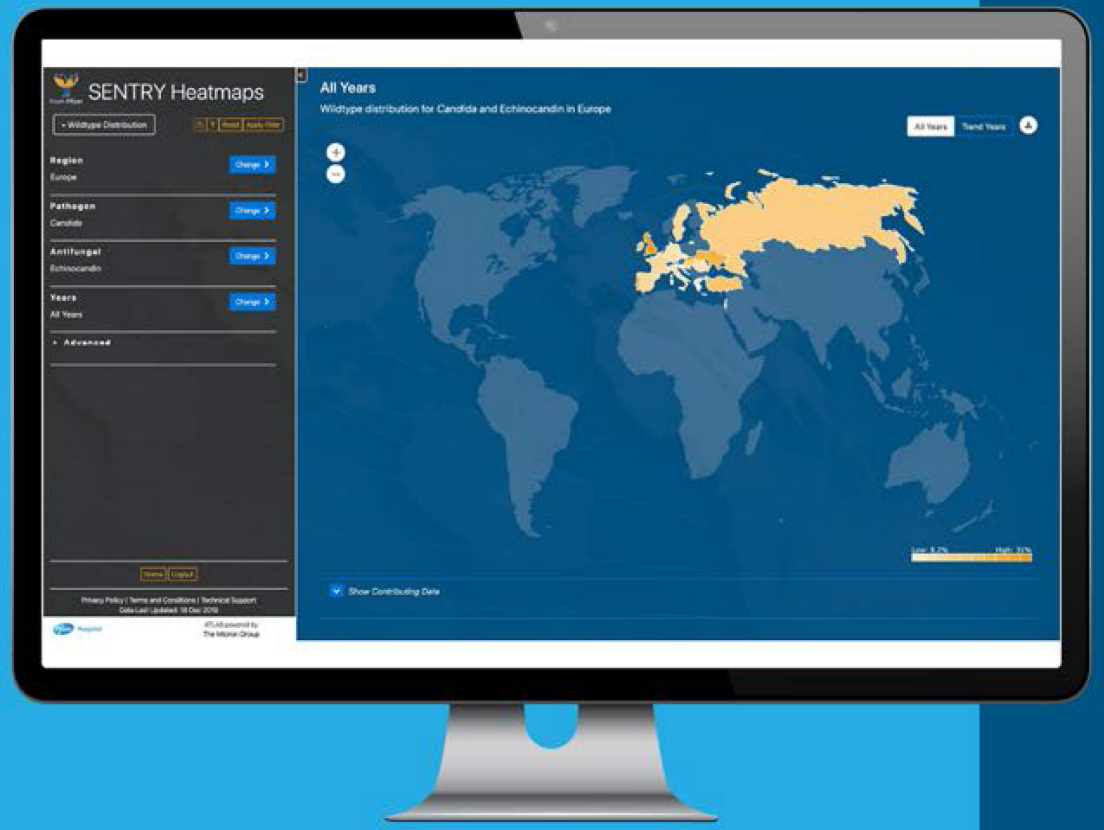
ANALYZE *the* DATA

PRODUCE

reports in tabular



and graphical formats,



and generate

GEOGRAPHICAL

heat-maps which

HIGHLIGHT

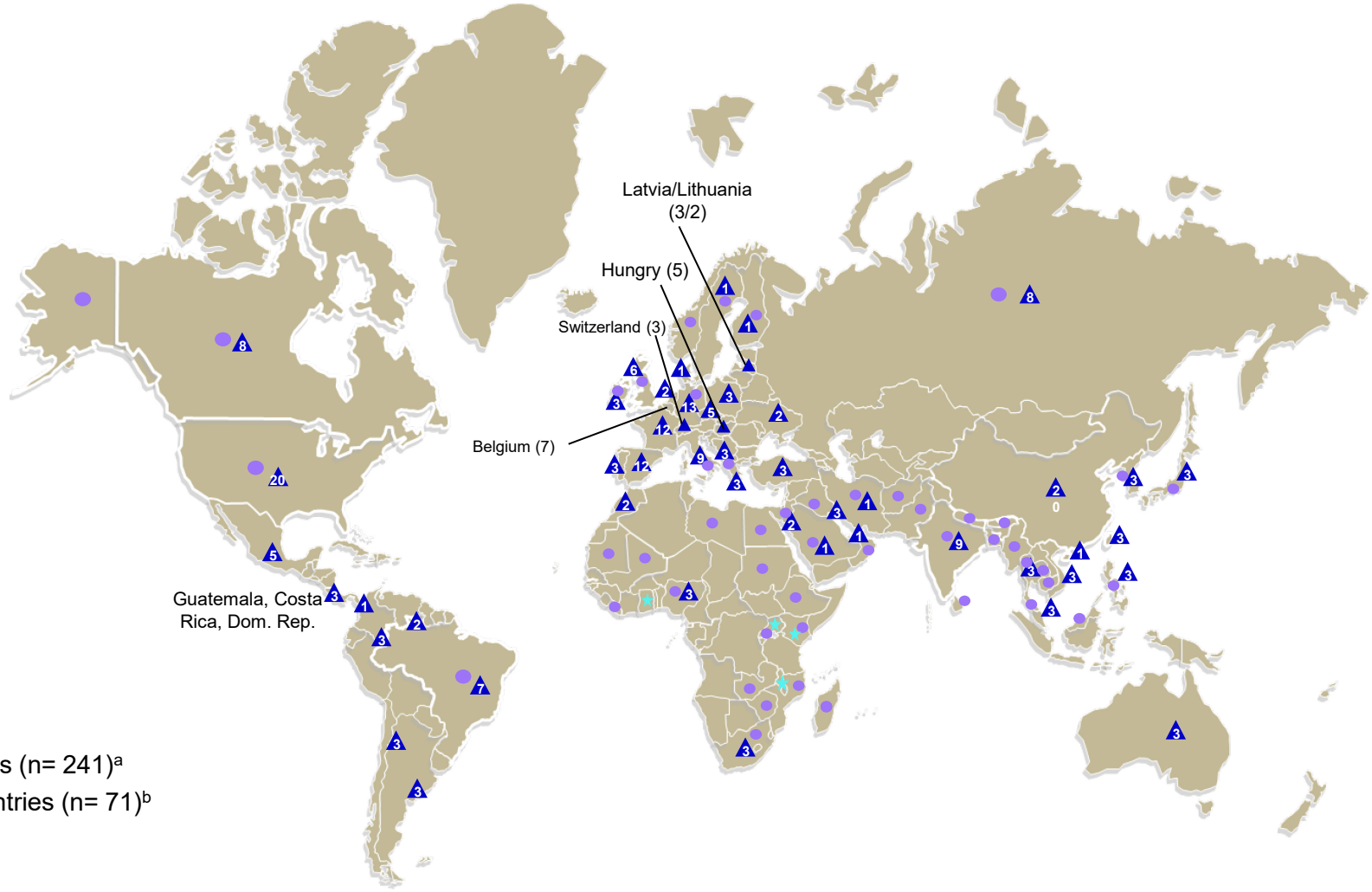
antimicrobial

RESISTANCE

OVER TIME

SPIDAAR: Surveillance Partnership to Improve Data for Action

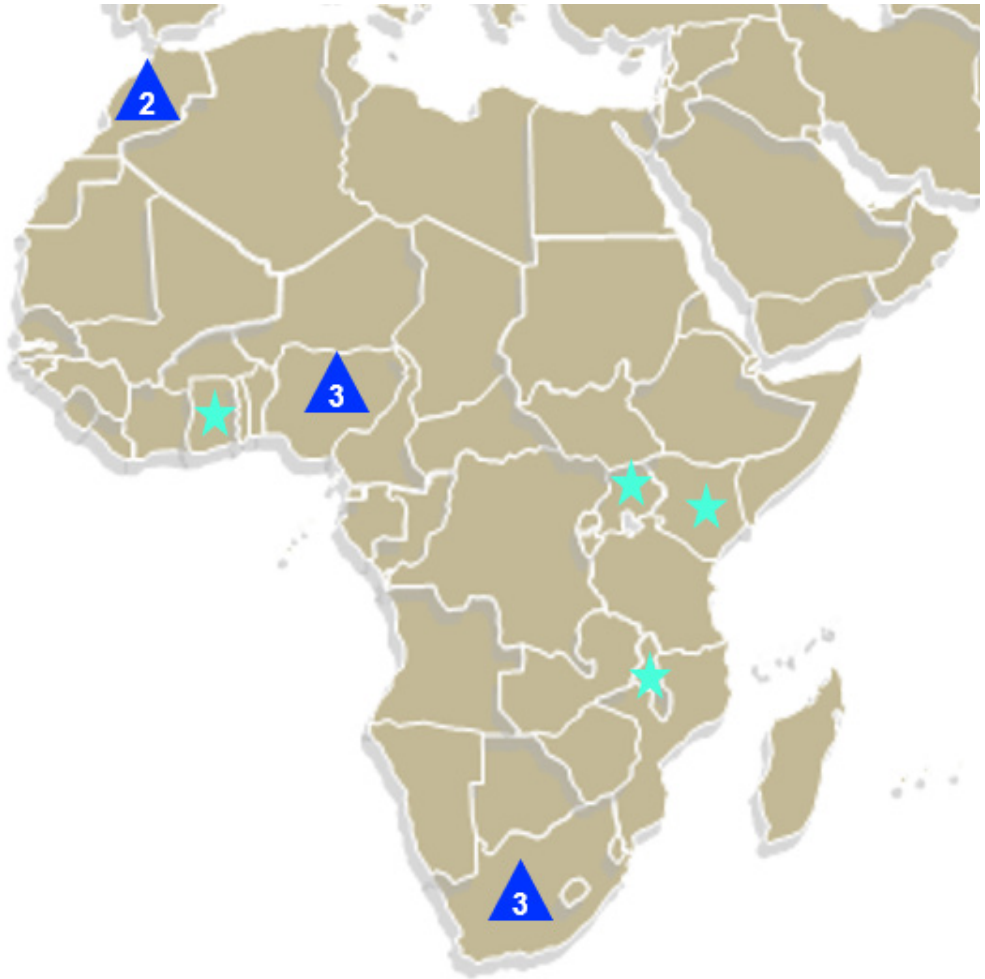
ATLAS Global Reach: 241 Collection Centers . . .



- ▲ Global Atlas Centers (n= 241)[a]
- ● Glass Enrolled countries (n= 71)[b]
- ★ Atlas Satellite Sites

[a] Projected for 2019, subject to change
[B] Country enrollment status as of December 2018

. . . But Largely Absent in Africa



▲ Global Atlas Centers (n= 241)[a]

★ Atlas Satellite Sites

[a] Projected for 2019, subject to change
[B] Country enrollment status as of December 2018

SPIDAAR: Surveillance Partnership to Improve Data for Action on Antimicrobial Resistance

Goal:

A scalable surveillance platform, supported by a robust **public-private partnership**, that expands **AMR resistance data**, **strengthens public health capacity**, and **improves patient outcomes** in low-middle-income countries

Initial focus on Sub-Saharan Africa: Ghana, Kenya, Malawi and Uganda

Two Pillars to this initiative:

1. A new **pilot Sub-Saharan regional surveillance hub** centralized around a single lab that uses Pfizer's ATLAS core methodology to assess AMR resistance from 8 regional healthcare facilities
2. A novel registry platform and first of kind industry-sponsored **AMR RWE study** to correlate data between antimicrobial resistance and clinical outcomes

> This program will provide us with real-world data on which drug resistance patterns are emerging and where.
>
> – Charles Mwansambo, Malawian Health Ministry

Together We Can Impact Change

Pfizer

wellcome

CDC*

SEDRIC

The Surveillance and Epidemiology of Drug-resistant Infections Consortium

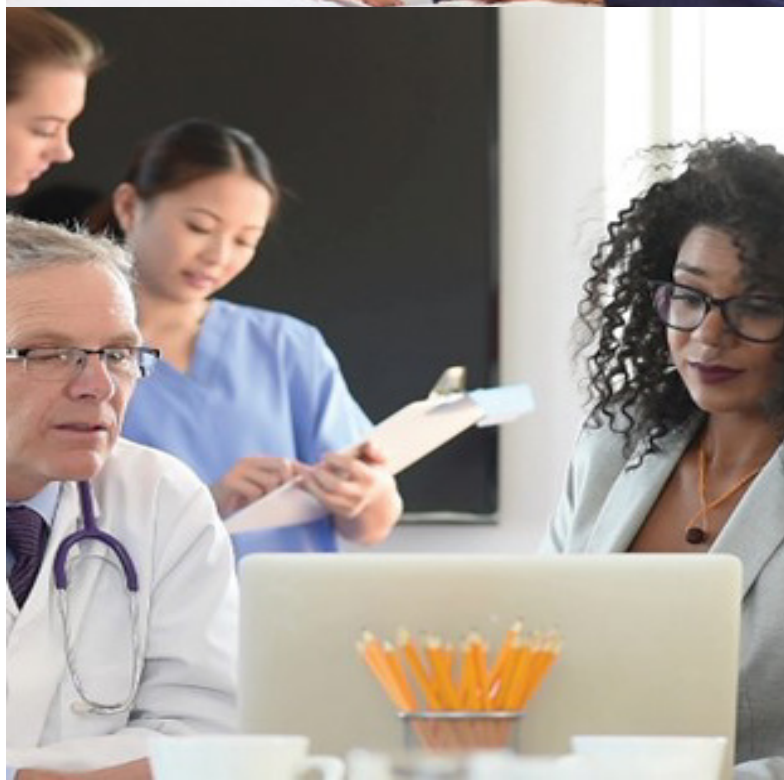
* The U.S. CDC and SEDRIC serve as expert advisors.

SPIDAAR Regional Surveillance Hub Pillar Overview

- Surveillance pillar will provide high quality data using established methodology to enrich current national-level data
- Two collection sites selected per country (8 sites total) and testing conducted in central laboratory
- Combines:
  - High-level microbiological methodology
  - Additional epidemiological and patient outcomes research
- Pilot Phase to demonstrate success of the methodologies prior to wider potential engagement with other regions

SPIDAAR RWE Study Pillar Overview

- The RWE Pilot Study Pillar is an opportunity to gather & integrate **real world data** to explore the impact of antimicrobial resistance
- The RWE Pilot Study is intended to deliver **patient demographics, clinical & economic outcomes data** to assess the influence of antimicrobial resistance upon mortality, morbidity, length of hospital stay and healthcare costs
- It is hoped that data from the RWE Pilot Study will help participating sites & countries **to inform antimicrobial stewardship efforts and to support local treatment guidelines**
- As this is a Pilot Study, a secondary aim would be to assess which real-world data elements are most meaningful to track in future studies of this type



Pfizer Hospital

WHAT WE CAN ACHIEVE TOGETHER:

- Improve AMR data and infrastructure in regions with limited surveillance capacity
- Provide systematic data that informs appropriate use of antimicrobials and helps drive policy reforms
- Improve access to data
- Develop a uniform surveillance protocol that integrates clinical, laboratory and demographic data
- Establish a framework and demonstrate the value proposition of partnership
- Create a platform that is scalable and can be augmented

WHAT WE CAN ACHIEVE TOGETHER:

Improved outcomes for patients!

We All Can Support Collective Action

Through:

- Build greater trust
- Be clear about our intentions
- See partnerships not silos
- Greater transparency
- Seek out the “yes” and avoid the “no’s”

Together We Can Impact Change

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

wellcome

Pfizer