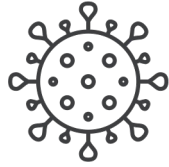


# Biopharmaceutical Industry Efforts to Fight COVID-19, Lessons Learned and Preparing for Future Pandemics

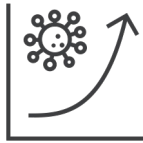
*February 2023*





## **COVID: Biopharmaceutical Industry Response**

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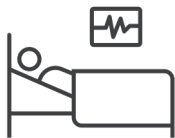
## **Preparing for the Next Pandemic**

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## **Efforts to Address Antimicrobial Resistance**

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## **Assistance Programs for Patients**

# PhRMA Members' Efforts to *Fight* Coronavirus

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We rapidly screened our vast global libraries of medicines to identify potential treatments and have thousands of clinical trials underway to test new and existing therapies

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We expanded our unique manufacturing capabilities and shared capacity to manufacture over 16 billion doses of vaccines

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We dedicated our top scientists, invested in new technologies and worked closely with regulators to speed the development of safe and effective vaccines

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We collaborated with government agencies, hospitals, doctors and others to donate supplies and medicines to help those affected around the world

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We shared the learnings from clinical trials in real time to advance the development of additional therapies

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We worked with governments and insurers to ensure that treatments and vaccines were available and affordable for patients

# PhRMA Members Conducted Hundreds of COVID-19 Clinical Trials



# Biopharmaceutical Industry Clinical Trials Resulted in Treatments and Vaccines for Patients

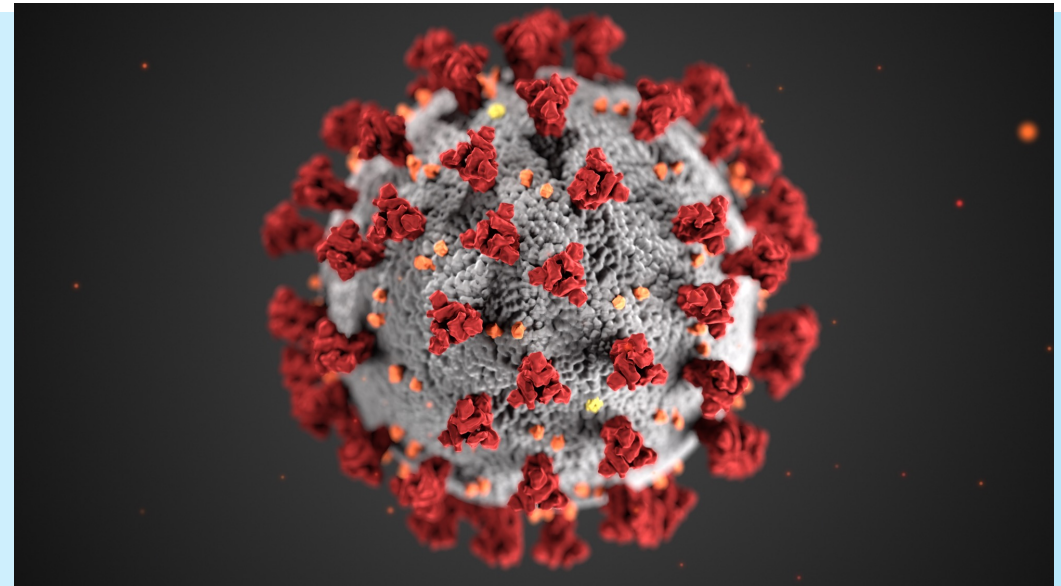
America's biopharmaceutical companies came together to achieve one shared goal of fighting COVID-19. The decades-long investments we have made in new technology, research and treatments prepared us to act swiftly.

**4**

**U.S. Approved &  
Emergency Use  
Authorized Vaccines**

**7**

**U.S. Approved and  
Emergency Use  
Authorized  
Therapeutics**



# COVID-19 Vaccinations to Date: A Global Success



## COVID-19 Vaccinations

**16.1B**

DOSES DELIVERED

Globally

**13.2B**

DOSES ADMINISTERED

Globally

**632.9M**

DOSES ADMINISTERED

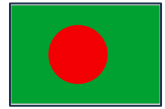
United States

# Ongoing Research on Long-COVID-19

- Estimated 1 in 5 American Adults who had COVID, have long COVID\*
- **Symptoms** (typically lasting >6 months after infection) include fatigue, cough/SOB, muscle pain, GI issues, neurological impairment, pain, diabetes
- Biopharmaceutical companies are researching **treatment options**
- **Biopharmaceutical research companies are seeking to identify biomarkers and endpoints to better address symptoms of “long-COVID-19”**
  - *A biomarker (short for biological marker) is a measure or physical sign used to evaluate how the body is functioning.*
- **46 active global clinical trials, including from industry-sponsored, are underway\*\***
- **Vaccines continue to demonstrate strong efficacy.** People who had been vaccinated against COVID-19 were roughly half as likely to develop “long COVID-19” symptoms\*\*\*

# Industry Licensing Agreements Made Possible by Intellectual Property Are Meeting Demand for COVID-19 Treatments

143 COVID-19 Treatment Licensing Agreements Span 31 Nations



Bangladesh



Belgium



Brazil



Canada



China



Dominican Republic



Egypt



Jordan



Korea



France



Germany



India



Indonesia



Ireland



Israel



Italy



Japan



Jordan



Kenya



Mexico



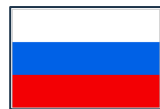
Pakistan



Paraguay



Portugal



Russia



Serbia



Singapore



South Africa



Switzerland



United Kingdom



United States

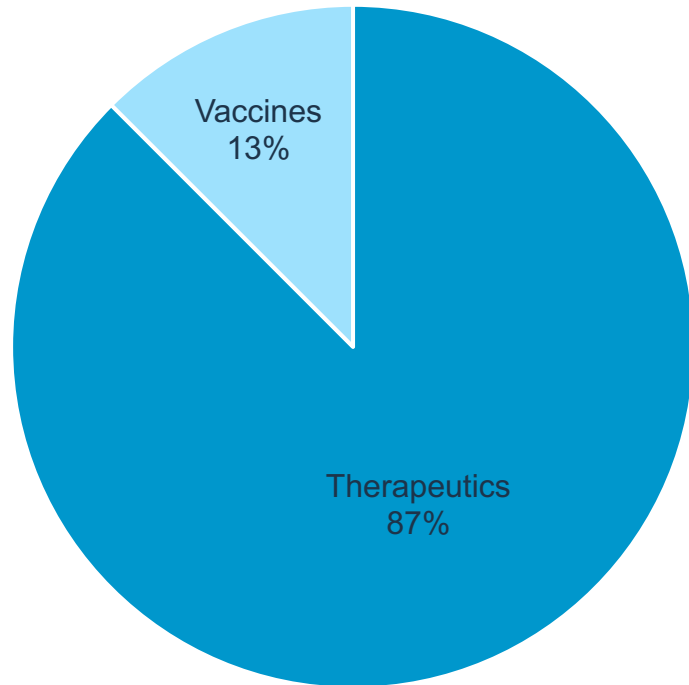


Vietnam



# Clinical Trials for COVID-19 Have Helped Boost Local Economies\*

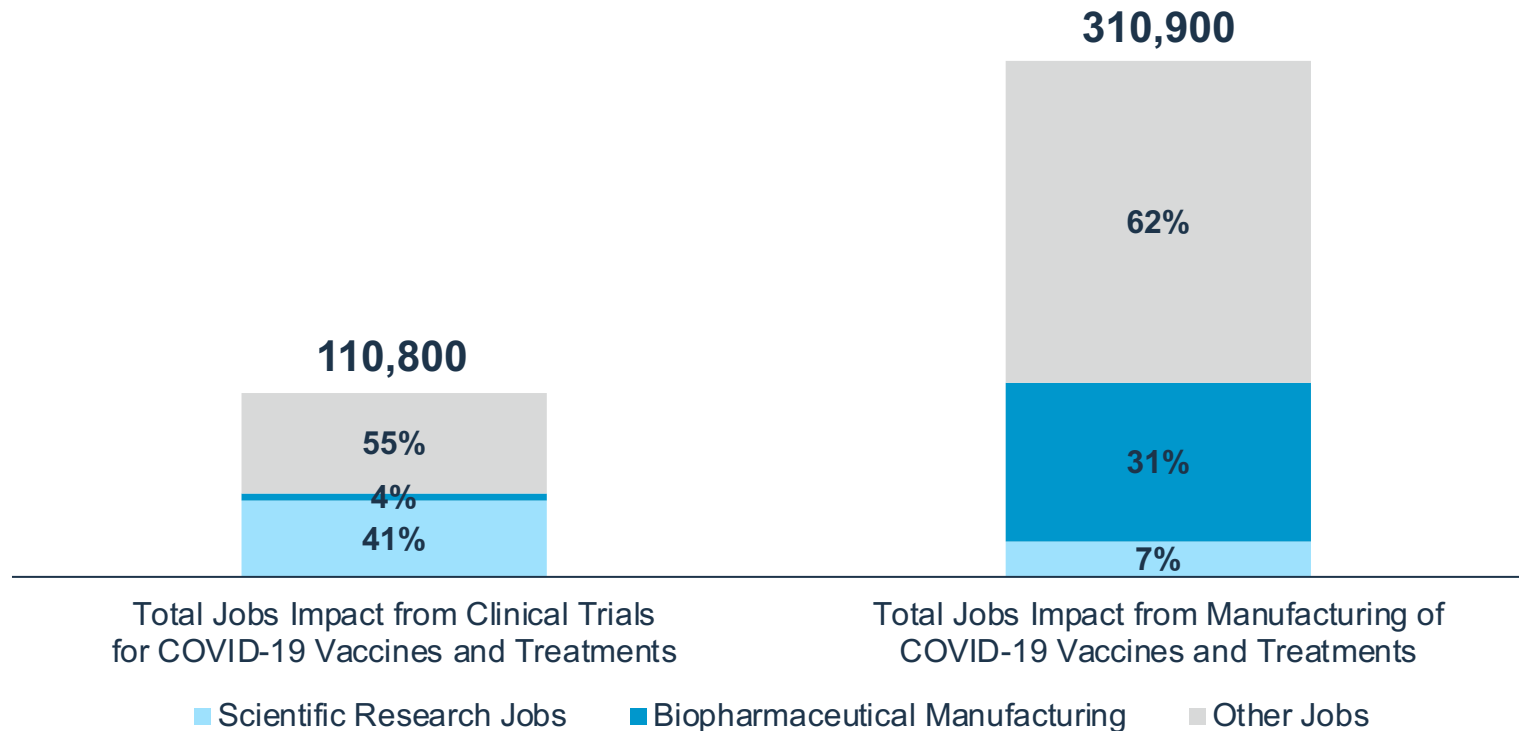
## U.S. COVID-19 Clinical Trial Costs: \$24 Billion to Date



- Over **\$24 billion** has been spent on clinical trials for COVID-19 vaccines and treatments in the United States – supporting about **100,000 U.S. jobs**
- Another **\$80 billion** will be spent in the United States over the next several years if vaccines and treatments in the pipeline continue through clinical trials to approval – supporting approximately **110,000 U.S. jobs** annually

# Thousands of U.S. Jobs Are Supported by the Development and Manufacturing of COVID-19 Vaccines and Treatments

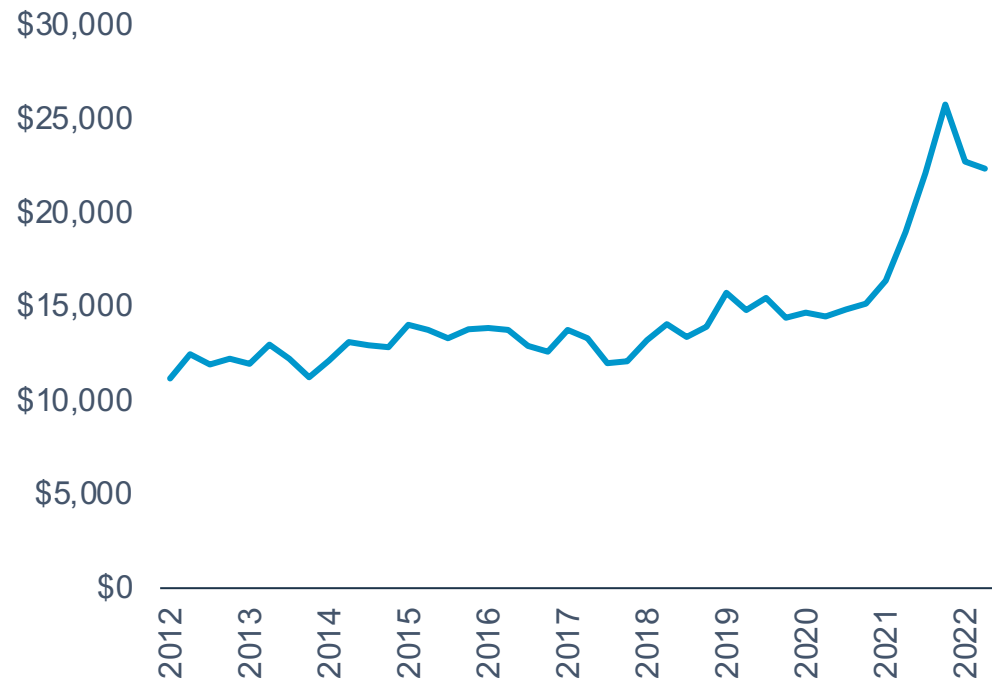
## Total Jobs Directly and Indirectly Supported by Development and Manufacturing Inside and Out of Biopharmaceutical Industry



# Exports Drive Over 55% of COVID-19 Product Manufacturing in the United States

**U.S. Exports of Biopharmaceutical Products Have Surged to Highest Levels on Record**

**U.S. Biopharmaceutical Exports  
from 2012 to Q2 2022**



- Over **300,000 U.S. jobs** are supported by the surge in U.S. biopharmaceutical manufacturing for COVID-19 vaccines and treatments
- **55%** of these jobs are supported by **U.S. exports** of biopharmaceutical products
- **U.S. exports** of biopharmaceutical products **increased over 60%** after the U.S. amended COVID-19 vaccine contracts in mid-2021

# Current Status of Fighting COVID-19 in the U.S.

**81% of Americans** have at least one COVID-19 vaccine dose with bivalent vaccines authorized by FDA to address two strains of COVID

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**Multiple options are available** for the prevention and treatment of COVID-19

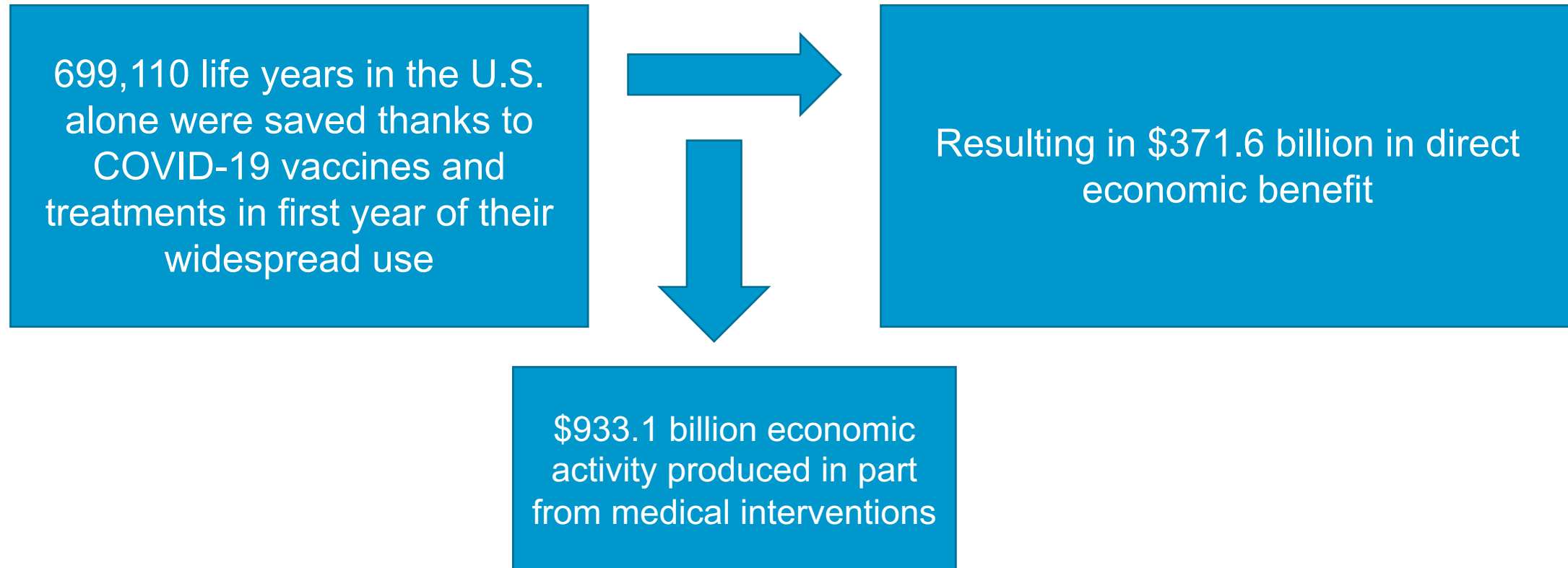
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**Public-private collaborations** across key health stakeholders at the state, national and international levels are continuing to help communities fight the pandemic

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**Ongoing research by biopharmaceutical companies** to be prepared for what comes next

# COVID-19 Vaccines and Treatments have Saved Millions of Lives and Billions of Dollars

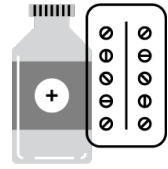


# Preparing for the Next Pandemic

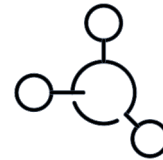
# Key Lessons Learned from COVID Response



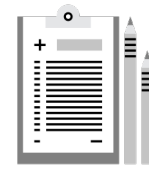
**Public and private collaboration** helped facilitate large scale manufacturing prior to approval and highlighted value of remote assessments by FDA



**Strong IP protections** enabled global partnerships and encouraged investment in research and development



**Broader acceptance of telemedicine and digital health tools** made clinical research during COVID possible



**Demonstrated potential of increased use of real-world data and evidence** in drug development

# Next Steps for Industry, U.S. Policymakers and Stakeholders

- **Modernize data & reporting infrastructure** to detect, identify & mitigate emerging infectious diseases
- **Continue adoption of regulatory flexibilities** implemented to bolster supply chains and streamline product development
- **Increase and strengthen public-private collaboration** with U.S. and its trading partners to maintain robust pandemic response capability and supply chain security
- **Foster increased R&D and advanced manufacturing** through public policies incentivizing investment
- **Strengthen cybersecurity of medical supply chain** through improved monitoring, information sharing and response
- **Provide enhanced guidance** on criteria and process for declaring and ending public health emergencies



# Efforts to Address Antimicrobial Resistance (AMR)

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*AMR is “one of the biggest threats to global health, food security, and development today.”-- WHO*

*The pandemic has increased the spread of drug-resistance infection. “We have every reason to believe the problem has gotten worse.” –Dr. Susan S. Huang, UC Irvine Medical School*

## What is antimicrobial resistance?

**Antimicrobial resistance** occurs when microorganisms such as bacteria, viruses, fungi and parasites develop the ability to survive against the drugs designed to kill them. *Inappropriate use of antimicrobial medicines may lead to resistance.*

AMR infections are directly attributable to at least **1.27 million deaths per year globally**, higher than HIV/AIDS and malaria combined.

According to the CDC, at least **3 million antibiotic-resistant infections occur in the U.S.** each year, resulting in nearly **50,000 deaths in the U.S.** each year.

# COVID-19 and Impact on AMR

AMR became a more prominent threat during the pandemic<sup>1</sup>

After years of decline, drug-resistant “superbug” infections caused a **15% increase** in hospitalizations and deaths in 2020 alone

Hospital-acquired infections became alarmingly **more resistant** from 2019 to 2020:

Carbapenem-resistant *Acinetobacter* (↑78%)

Antifungal-resistant *Candida auris* (↑60%)

Multidrug-resistant *P. aeruginosa* (↑32%)

**6** of the **18** most alarming antimicrobial resistance threats cost the U.S. **more than \$4.6 billion annually**

# Antibiotic Company Bankruptcies Underscore the Challenging Environment for Developing Medicines to Combat AMR

## Misaligned incentives plague the development of new medicines

- Developing a new antimicrobial medicine can take **10 – 20.5 years** and **\$568 - \$700 million**
- Just **1 in 15** products will ultimately be approved and reach patients
- **Stewardship programs designed to slow resistance** ensure that newer medicines are used as sparingly as possible, making it challenging for companies to recoup R&D investment
- Several high-profile **recent bankruptcies** highlight the funding challenges and lack of commercial sustainability – today only a handful of major biopharmaceutical companies and a few dozen small biotechs remain involved

# The Unique Innovation Ecosystem for AMR

Public-private partnerships and initiatives have emerged to address the market failure

## CARB-X

- Global non-profit partnership dedicated to advancing AMR research by accelerating preclinical candidates toward clinical development for priority pathogens
- Between 2016 and 2022, will fund \$480M to achieve this goal



## AMR Action Fund

- Partnership that seeks to strengthen R&D through provision of industry resources and expertise
- Aims to bring 2-4 new antibiotics to patients by 2030
- Will invest more than \$1B in smaller companies to help products get to market



# The Innovation Ecosystem Cannot Solve the Problem Alone

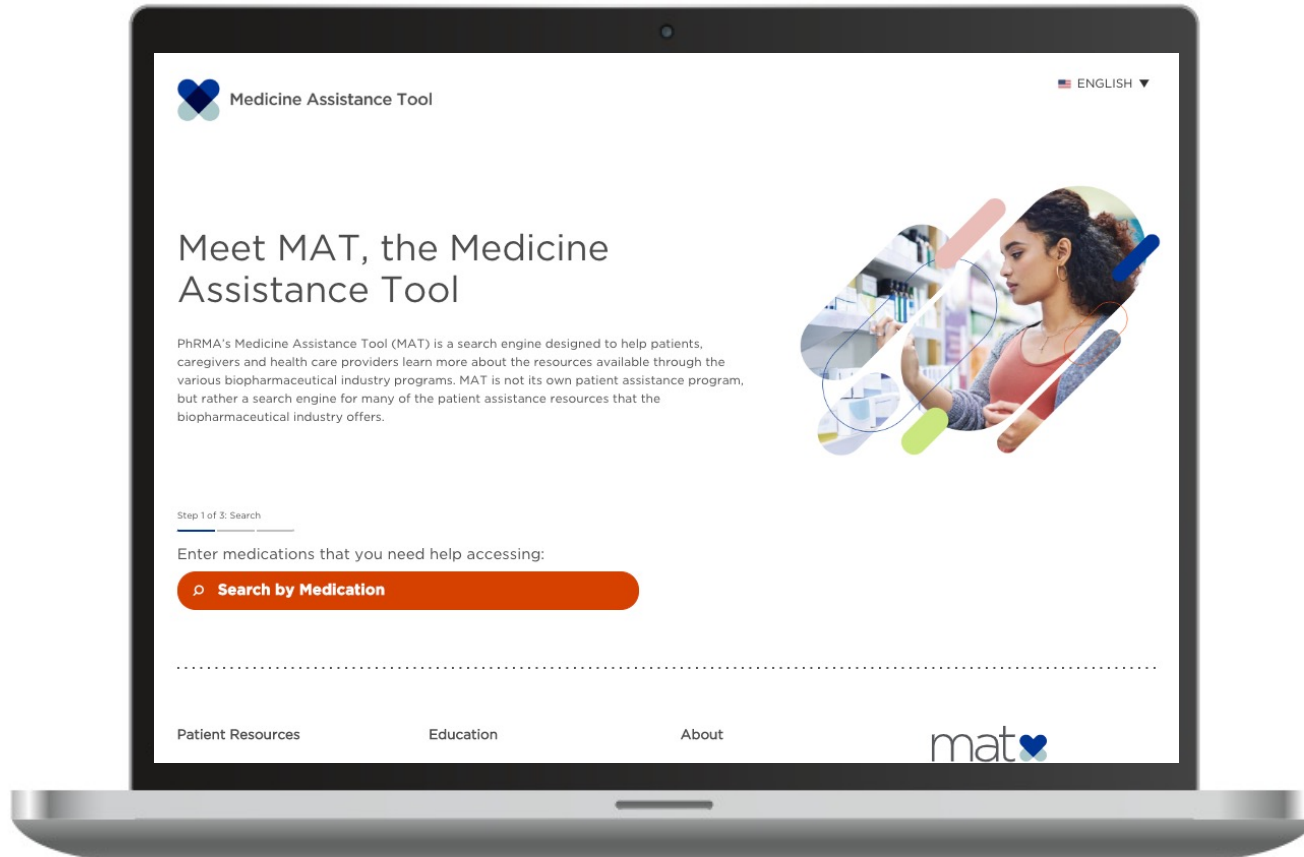
**Comprehensive policy reforms are also needed**

## **PASTEUR Act**

- Would offer “subscription” contracts to manufacturers to provide full access to antimicrobial products for patients covered under federal programs
- De-links payment from volume for government payers, with contracts offered ranging from \$750M - \$3B based on certain characteristics of the medicine
- Intent is to incentivize companies to develop highly novel antimicrobial medicines
- Includes provisions for appropriate stewardship and to ensure a reliable supply chain

# Assistance Programs for Patients

# Many of America's Biopharmaceutical Companies Are Expanding Their Assistance Programs To Help More People



950+

public and private programs

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in affording their medicines.

[www.MAT.org](http://www.MAT.org)



# Where to Go for More Information

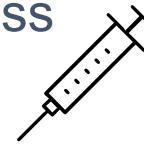


# For More Resources and Information Visit: **PhRMA.org/Coronavirus** or **PhRMA.org/AMR**

Member company efforts to combat COVID-19



Factsheets on the pipeline for new vaccine and treatments and medicines to address AMR



Updated clinical trial data and approved and authorized treatment and vaccine figures



PhRMA blog posts on COVID-19 and AMR



Infographics on how the industry is fighting COVID-19 and AMR

