



The Biopharmaceutical Industry's Efforts to Beat Coronavirus

NCOIL Presentation

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PhRMA
RESEARCH • PROGRESS • HOPE

Our Commitment to *Beat* Coronavirus

We are **rapidly screening our vast global libraries of medicines** to identify potential treatments and have numerous clinical trials underway to test new and existing therapies

We are **expanding our unique manufacturing capabilities and sharing available capacity** to ramp up production once a successful medicine or vaccine is developed

We are **dedicating our top scientists and using our investments in new technologies** to speed the development of safe and effective vaccines

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

We are **sharing the learnings from clinical trials in real time** with governments and other companies to advance the development of additional therapies

We are **working with governments and insurers** to ensure that when new treatments and vaccines are approved they will be available and affordable for patients

Factors Contributing to the Industry's Response

Armed with experience garnered from previous outbreaks and a vast storehouse of knowledge about infectious diseases like influenza, malaria and HIV, researchers are working to develop and deliver diagnostics, treatments and vaccines to save lives and restore the rhythms of daily life for billions of people.

DIAGNOSTICS

It's essential to know who has been infected.

- ▶ Companies are accelerating the development of diagnostic testing capabilities to scale-up screening and working in partnership with governments and diagnostic companies on existing screening programs to supplement testing.

EXISTING MEDICINES

Medicines approved for other diseases may have some benefit for patients with COVID-19.

- ▶ Researchers are testing antivirals, antibiotics and other medicines.
- ▶ These medicines have the potential to reduce the burden of COVID-19 on hospitals by reducing the length and severity of disease.

NEW TREATMENTS

Various drugs are in development, with some entering human trials.

- ▶ Researchers are working on new antiviral medications to interfere with ways the virus infects cells and reproduces.
- ▶ Antibody-based drugs may be able to mobilize the immune system against the virus.

VACCINES

A vaccine would provide a preventive approach to beating COVID-19.

- ▶ Although vaccines can take longer to develop than other treatments, once enough people in a community are vaccinated, individuals are protected and the community risk of transmission is reduced. A variety of biopharmaceutical companies are taking different approaches to find a vaccine. More "shots on goal" will significantly increase the chances of success.

MANUFACTURING

We are committed to manufacturing these medicines and making them available to those who need them.

- ▶ We're ramping up output of existing medicines with demonstrated benefit and investing in infrastructure to accelerate production of new treatments.
- ▶ Biopharmaceutical companies are planning and building manufacturing capacity without assurance medicine and vaccine candidates will ultimately be successful, to ensure that if one is, distribution can occur rapidly.
- ▶ America's biopharmaceutical companies are ensuring that solutions can be made available quickly to everyone who needs them.



Developing Treatments and Vaccines to Fight COVID-19

There are **1597 clinical trials** under way across the globe for vaccinations and treatments.

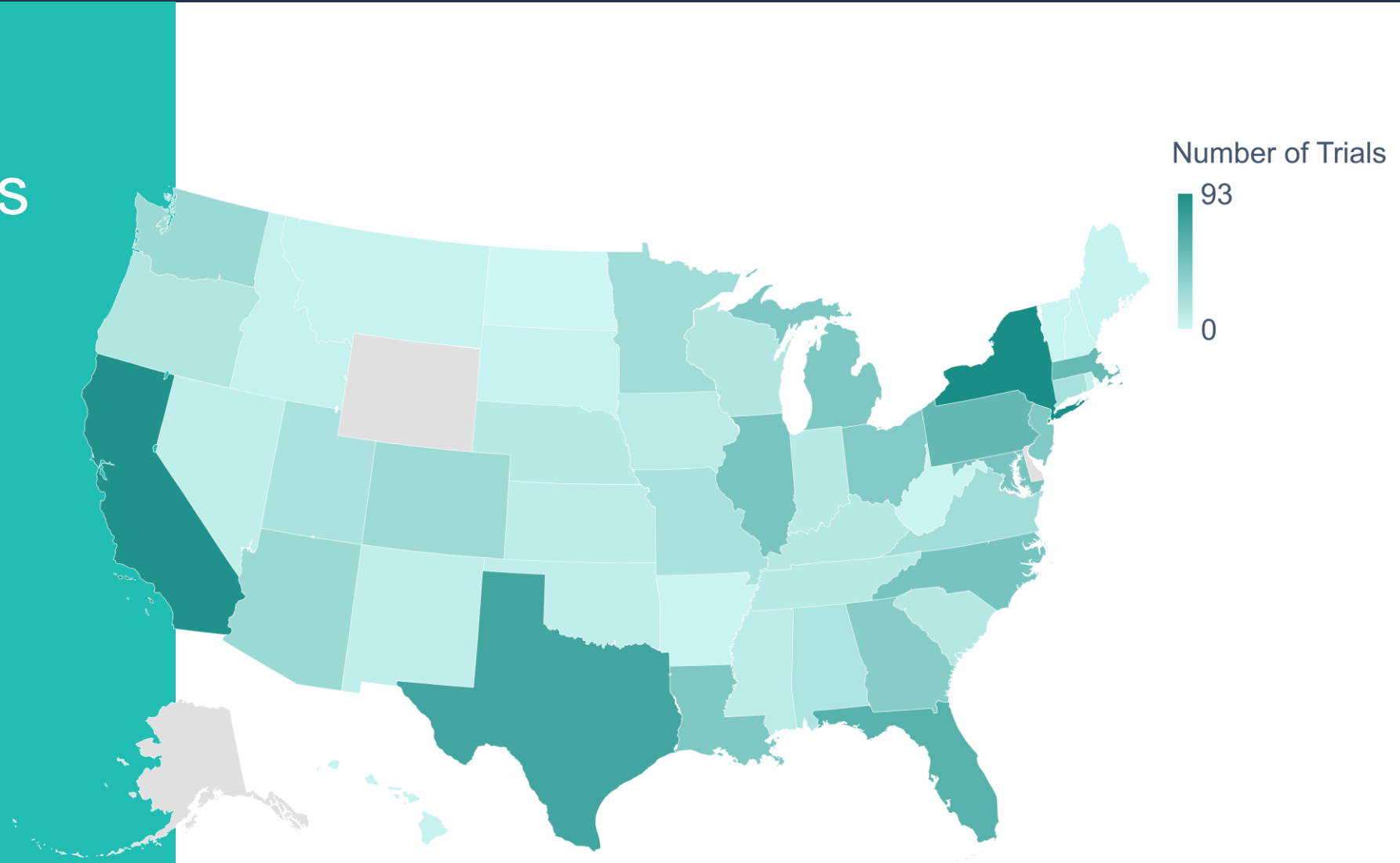


Data as of 9/11/2020

U.S. Clinical Trials of Investigational Therapies

There are 352 clinical trials investigating therapeutics in 46 states and Washington, D.C.

119 of the 352 clinical trials are being conducted in more than one state



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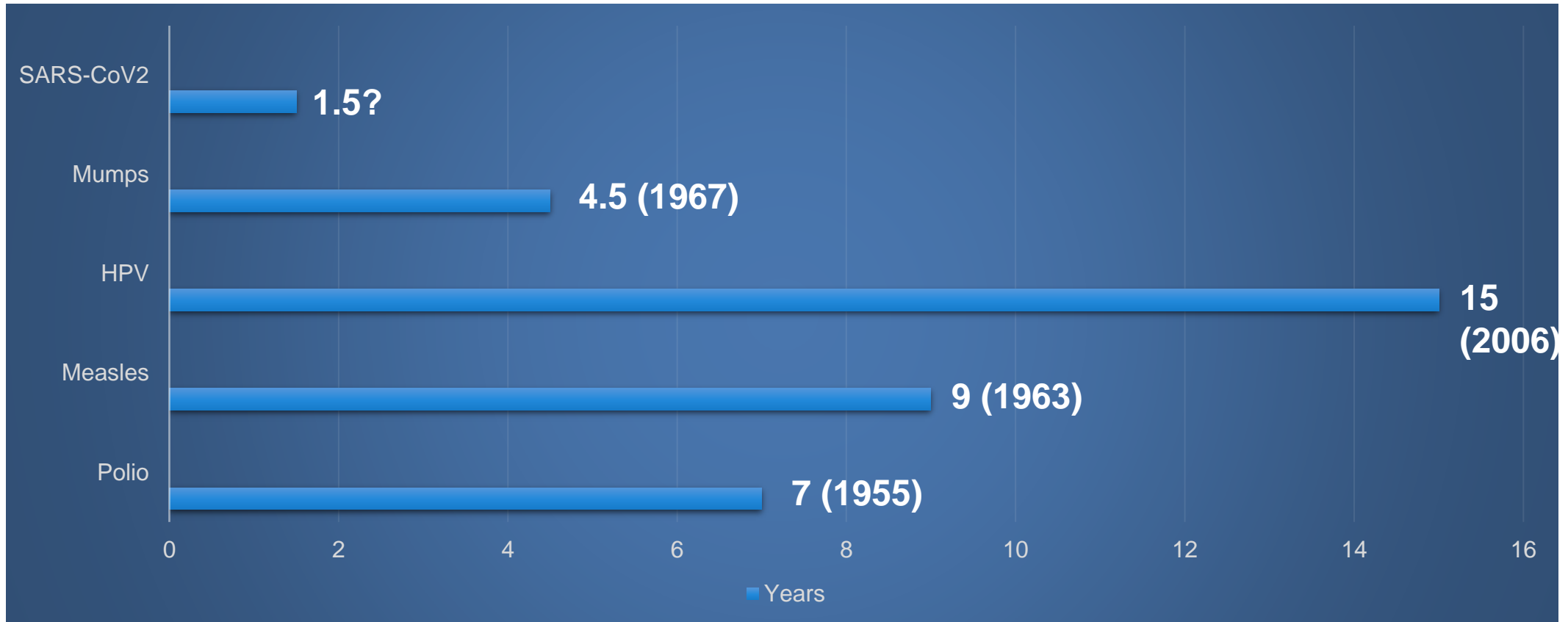
Data as of 9/04/2020

Hundreds of these Clinical Trials are Testing 135 Unique Investigational Therapies from PhRMA Members



Data as of 9/04/2020

Historical Vaccine Development timelines



It Will Take a Minimum of 18 to 24 Months for Potential FDA Approval of a COVID-19 Vaccine

Faster Timeline

- **This is significantly less time than it has taken for previous vaccine development programs**
 - In 2003, it took 20 months from sequencing SARS to the first human study of a vaccine
 - Today, it has been less than 4 months from sequencing SARS-CoV-2 to the first human study of a vaccine

Differing Approaches

- **Some approaches offer speed**
 - Knowing the virus's genetic sequence, companies can synthesize and scale up production of a RNA vaccine in a matter of weeks
- **Some approaches can boost the impact of a potential vaccine**
 - Adjuvants can boost the immune response and minimize the amount of vaccine needed

Failure Rate

- **There is a high failure rate**
 - Only 5-10% are likely to succeed
 - We need lots of shots on goal

Clinical & Preclinical Stage Vaccine Pipeline

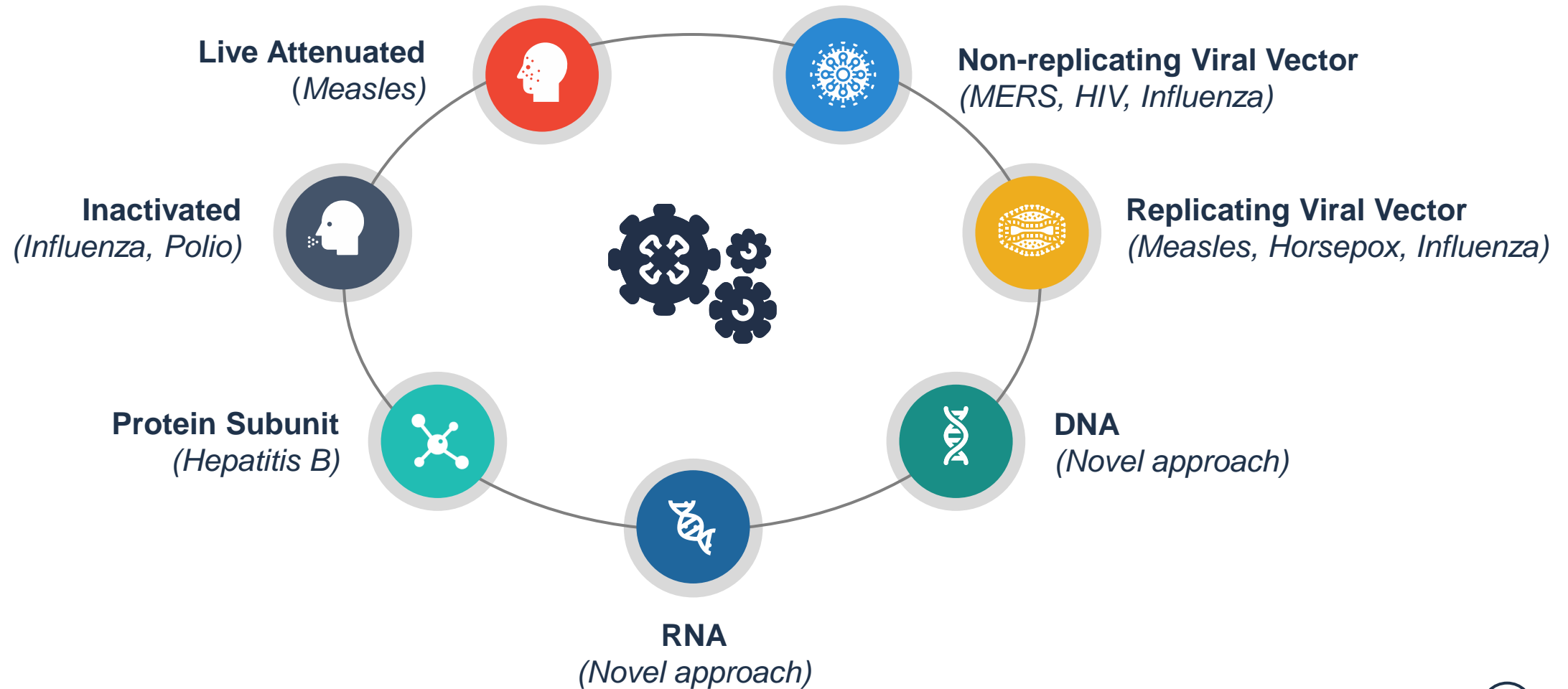
Supported by BARDA / DoD
Jointly developed



Source: Biomedtracker, Biocentury, BIO Industry Analysis
 1. PrEP Biopharm vaccine dsRNA, all others mRNA
 Oxford, AstraZeneca: ChAdOx1. Symvivo: bacTRL-Spike. Baylor College: BCG tuberculosis vaccine.
 Sinopharm with two vaccines in phase 1 trials (one beginning Apr 12 the other Apr 27)



Using Many Approaches to Develop Vaccines



CDC & National Academy of Medicine Advisory Committee will Provide Pivotal Recommendations for Use & Allocation of COVID Vaccines

- After FDA approval, vaccines typically go through the CDC Advisory Committee on Immunization Practices (ACIP) process
 - Advises CDC Director on the specific clinical use of each vaccine licensed in the United States
 - 15 voting members and ~40 non-voting reps from federal government agencies, medical societies
 - Recommendations followed by healthcare providers, creating a national standard of care for vaccines
 - Lead to reimbursement coverage decisions across payors
- COVID vaccines will be reviewed for use/allocation by a special NAM panel of experts
 - Includes medical, research, public health, ethics and other experts from academia, NIH, CDC, patient groups, etc.
 - Advises Operation Warp Speed, CDC
 - Draft report expected late September/ early October
- DOD/CDC will handle distribution



The Safety of Vaccines Is Monitored Through Multiple Systems

After being added to the U.S. Recommended Immunization Schedule, health experts continue to monitor the vaccine's safety and effectiveness.

How a vaccine's safety continues to be monitored



FDA and CDC closely monitor vaccine safety after the public begins using the vaccine.

The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

Vaccine Adverse Event Reporting System (VAERS)

VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.

Vaccine Safety Datalink (VSD) and Post-Licensure Rapid Immunization Safety Monitoring (PRISM)



Two networks of healthcare organizations across the U.S.

- VSD can analyze healthcare information from over 24 million people.

- PRISM can analyze healthcare information from over 190 million people.



Scientists use these systems to actively monitor vaccine safety.

Clinical Immunization Safety Assessment Project (CISA)

CISA is a collaboration between CDC and 7 medical research centers.

- Vaccine safety experts assist U.S. healthcare providers with complex vaccine safety questions about their patients.

- CISA conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).

FOR MORE INFORMATION, VISIT [HTTPS://WWW.CDC.GOV/VACCINESAFETY](https://www.cdc.gov/vaccinesafety)

The United States currently has the safest vaccine supply in its history. These vaccines keep children, families and communities protected from serious diseases.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



Ensuring Continuity in the Medicine Supply Chain

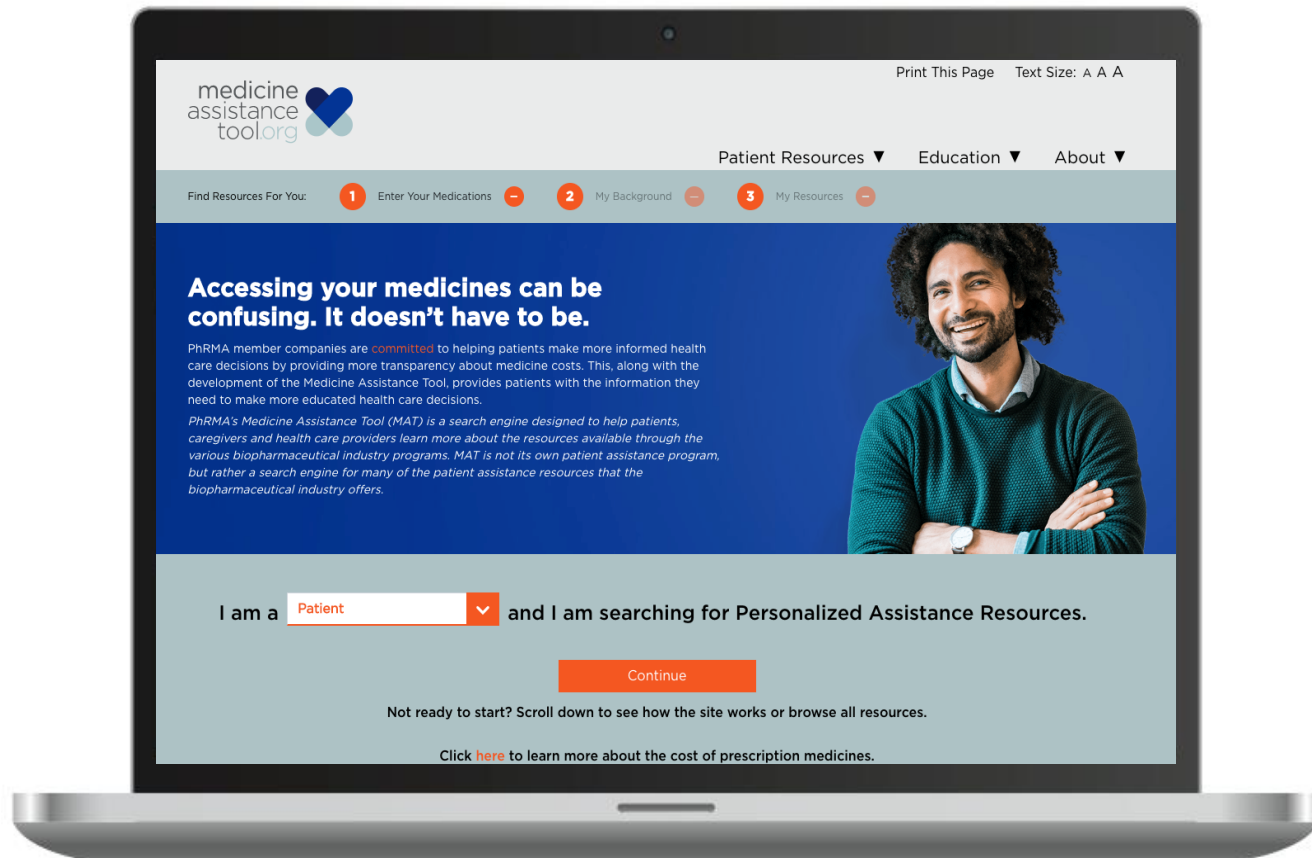
Biopharmaceutical Companies

- **Companies report substantial data on certain types of potential shortages to FDA** and they work closely with the agency to prevent and mitigate shortages
- **Companies have robust inventory management systems** that typically include:
 - Data on anticipated demand reflecting historical demand and supply data
 - Risk management plans that address additional or alternate manufacturing sites, inventory reserves, and/or a range of global external suppliers
 - Logistics planning to ensure continuity in shipping of supplies

U.S. Food and Drug Administration

- **FDA is working with individual companies to facilitate ramping up manufacturing** to address surges in demand and expediting approvals of changes in the drug supply chain
- **FDA is working closely with companies to expedite development and availability of COVID-19 treatments and vaccines**, including helping companies to leverage scientific and clinical trial data from the United States and other countries

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

MAT Can Help Patients Learn More About Their Medicine Costs

PhRMA member companies are committed to helping patients make more informed health care decisions by providing more transparency about medicine costs. Through MAT.org, we share links to member company websites that include:



**List Price of
a Medicine**



**Average Estimated
or Typical Patient
Out-of-pocket Costs**



**Other Context About
Potential Cost of the
Medicine**

PhRMA and Healthcare Ready

PhRMA has joined forces with **Healthcare Ready** to facilitate the financial support and in-kind donations of personal protective equipment, medicines, and critical medical supplies.

Examples of requests Healthcare Ready can support include:

- Personal protective equipment
- Medical supplies
- Assistance in helping a constituent fill their prescription

These requests can be made by contacting alerts [@healthcareready.org](mailto:alerts@healthcareready.org).



From CBS This Morning

Healthcare Ready Programs for Constituents

Healthcare Ready Resources

RX OPEN: Provides access to open and closed pharmacies in a disaster-stricken area.

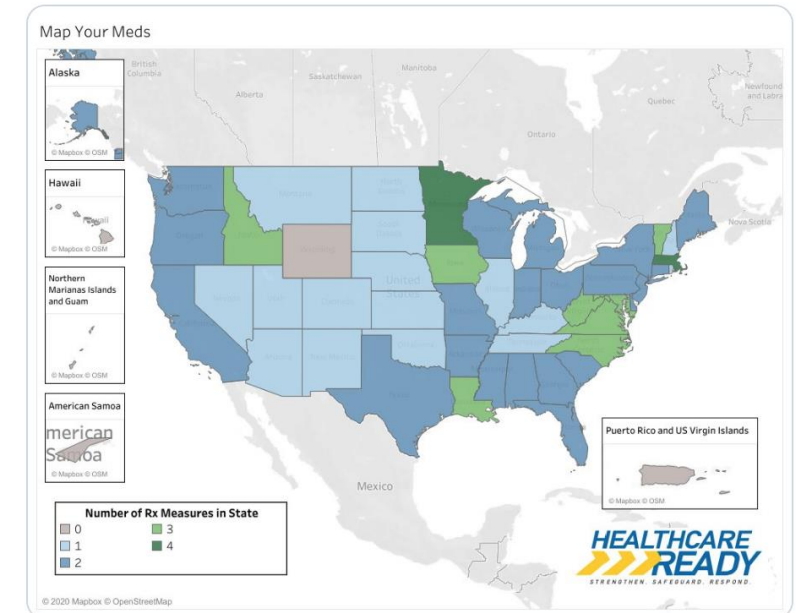
RX ON THE RUN: Personalized wallet card to document prescriptions and other important medical information.

COVID-19 Resource Hub: Resources for individuals and patients including state-level insurance emergency orders on prescription refills and telehealth coverage policies for COVID-19, and relevant pandemic business continuity resources.



#MapYourMeds: New interactive state-by-state guide to getting Rx refills during an emergency: bit.ly/HcR-MYM

#MYM #COVID-19



For More Resources and Information, Visit [PhRMA.org/Coronavirus](https://www.phrma.org/coronavirus)



An up-to-date list of member company efforts to combat COVID-19



A factsheet on the pipeline for new vaccine and treatments



An open letter from PhRMA's CEO and PhRMA's Chairman of the Board



The latest Catalyst blog posts on COVID-19



An infographic on how the industry is fighting COVID-19