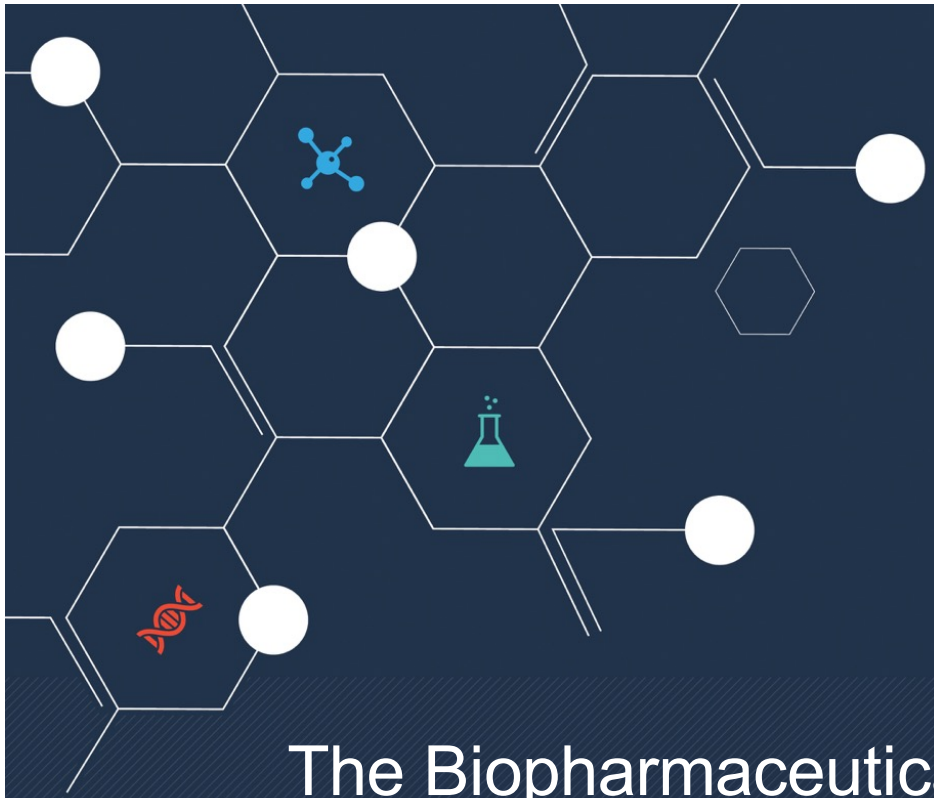

The Biopharmaceutical Industry's Efforts to Beat Coronavirus

PhRMA
RESEARCH • PROGRESS • HOPE

October 2020

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

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

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

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

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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.

Developing Treatments and Vaccines to Fight COVID-19

There are **1634 clinical trials under way across the globe** for vaccinations and treatments.

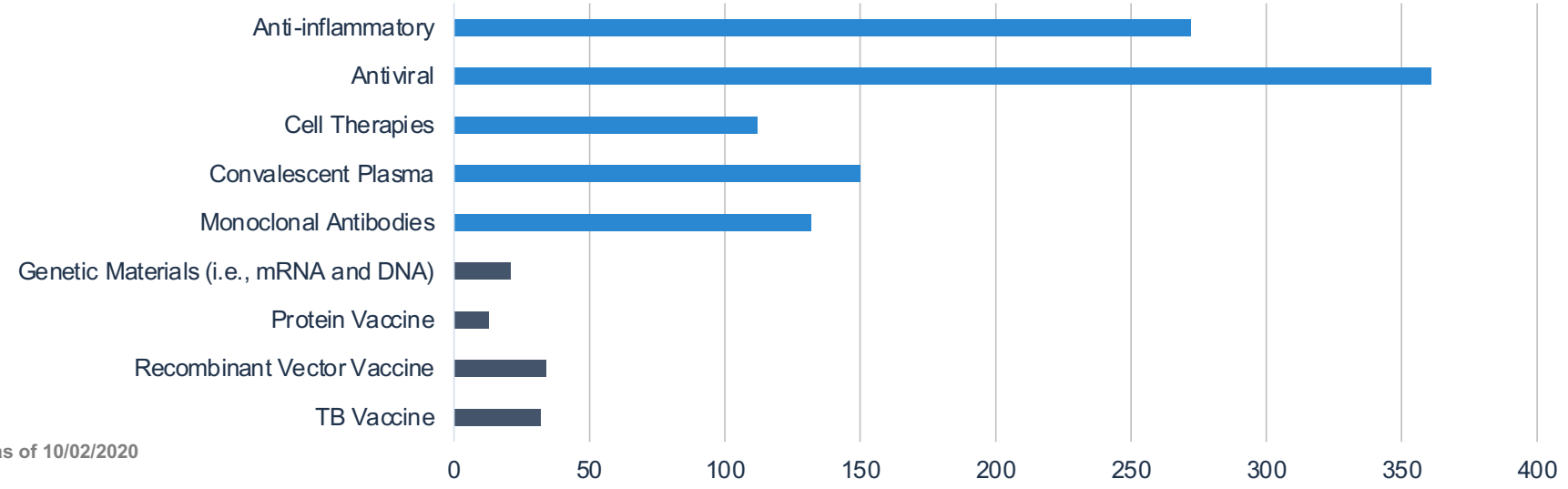
Data as of 10/02/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Building a Diverse Research and Development Pipeline

These hundreds of clinical trials represent **multiple approaches for COVID-19 vaccines and therapies.**

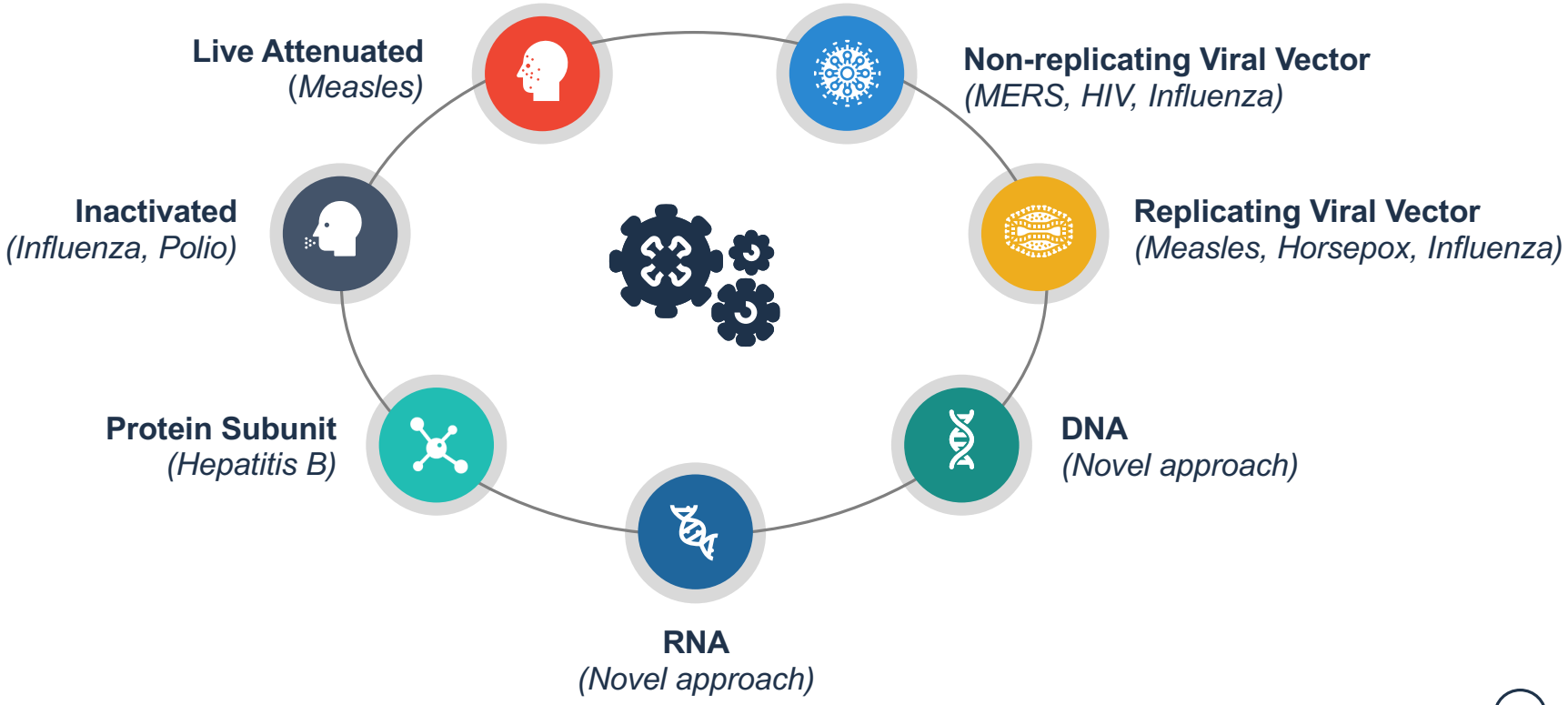
Number of Trials Testing Types of Therapies and Vaccines for COVID-19



Data as of 10/02/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

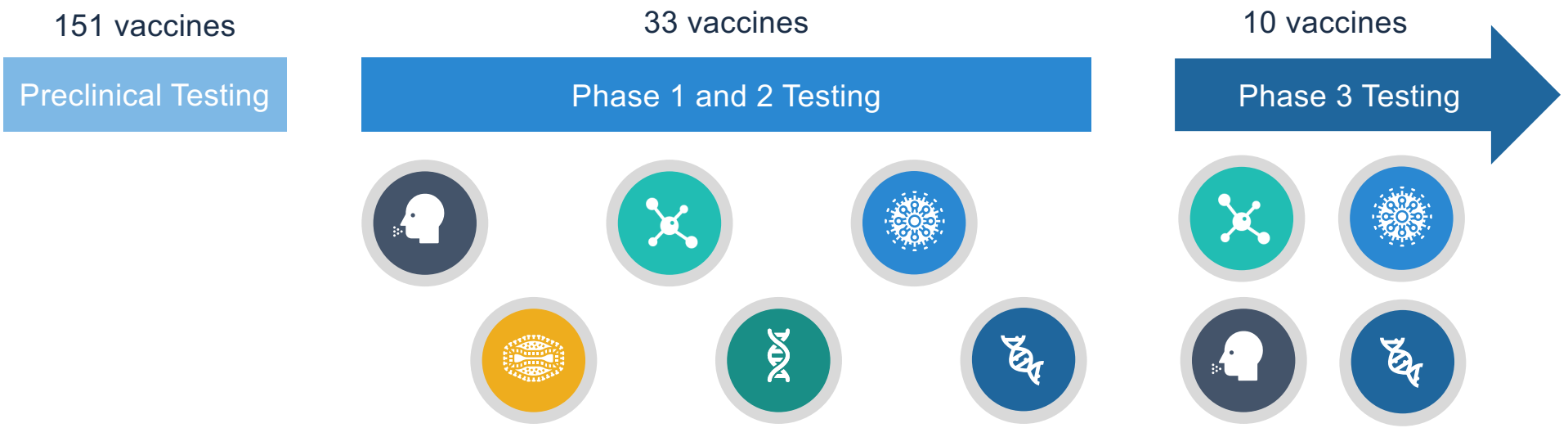
Using Many Approaches to Develop Vaccines



Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Developing and Testing Vaccines to Prevent COVID-19

COVID-19 vaccines currently under investigation include **over 190 unique "shots on goal"**

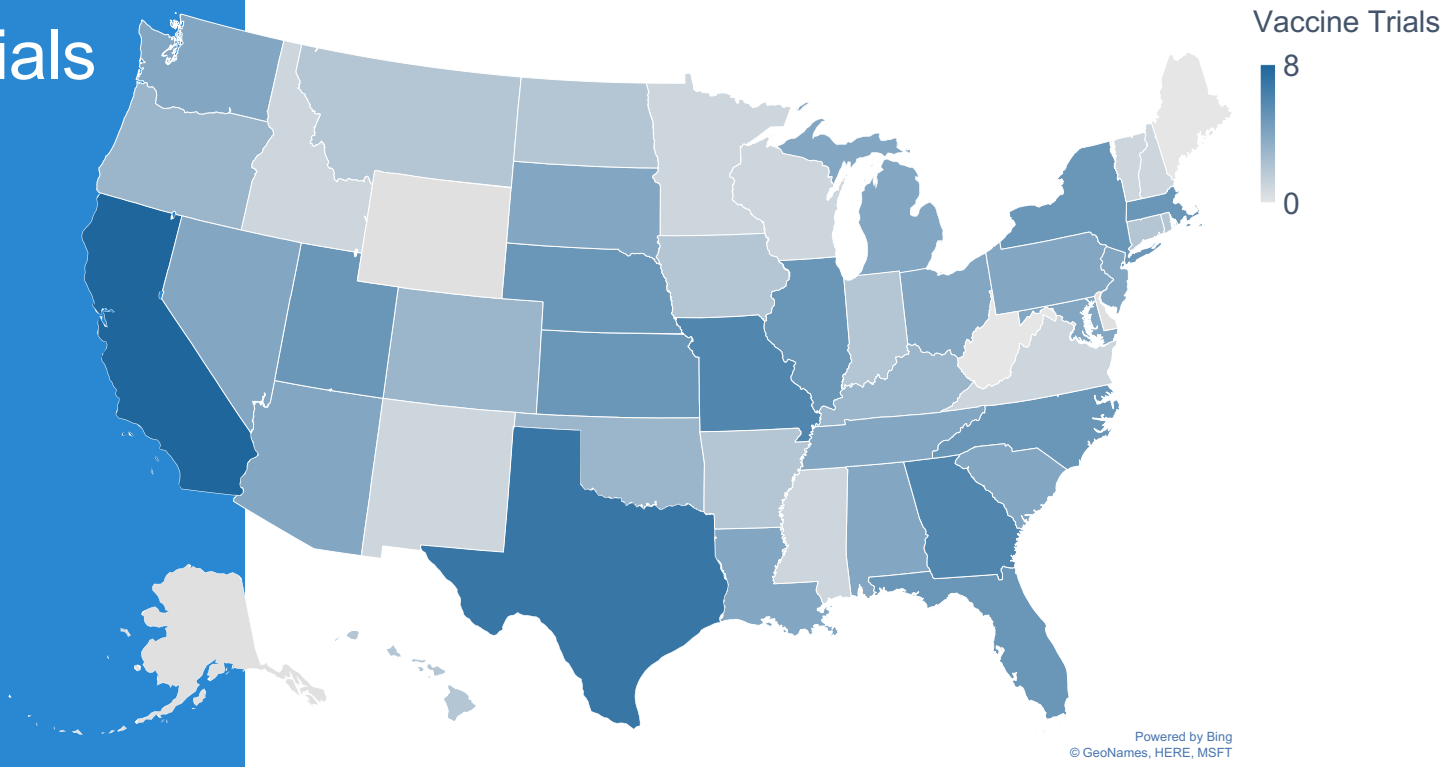


Data as of 10/02/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

U.S. Clinical Trials of Vaccines

15 clinical trials testing vaccine candidates are occurring across 46 states



Data as of 8/28/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

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

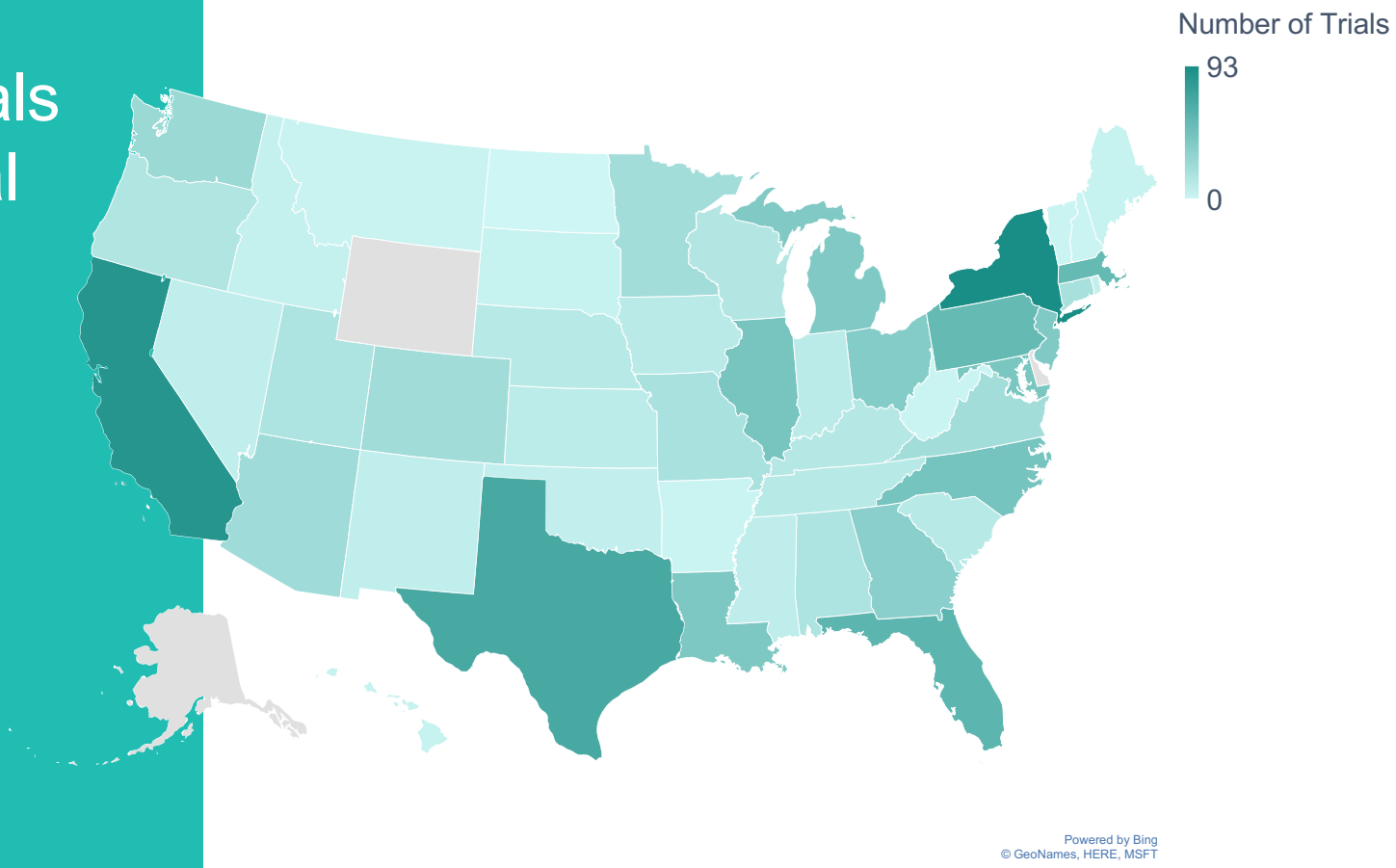
Failure Rate

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

U.S. Clinical Trials of Investigational Therapies

There are 349 clinical trials investigating therapeutics in 46 states and Washington, D.C.

117 of the 349 clinical trials are being conducted in more than one state



Data as of 8/28/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Hundreds of these Clinical Trials are Testing 133 Unique Investigational Therapies from PhRMA Members

Data as of 8/28/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

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

Manufacturers' Supply Chain Responsibilities

Report to FDA sourcing of API including information on all intermediate and final drug substance manufacturing and testing sites.

Register with FDA and list each drug manufactured at their U.S. and foreign drug manufacturing establishments for commercial distribution and submit updated drug listing information to FDA twice yearly.

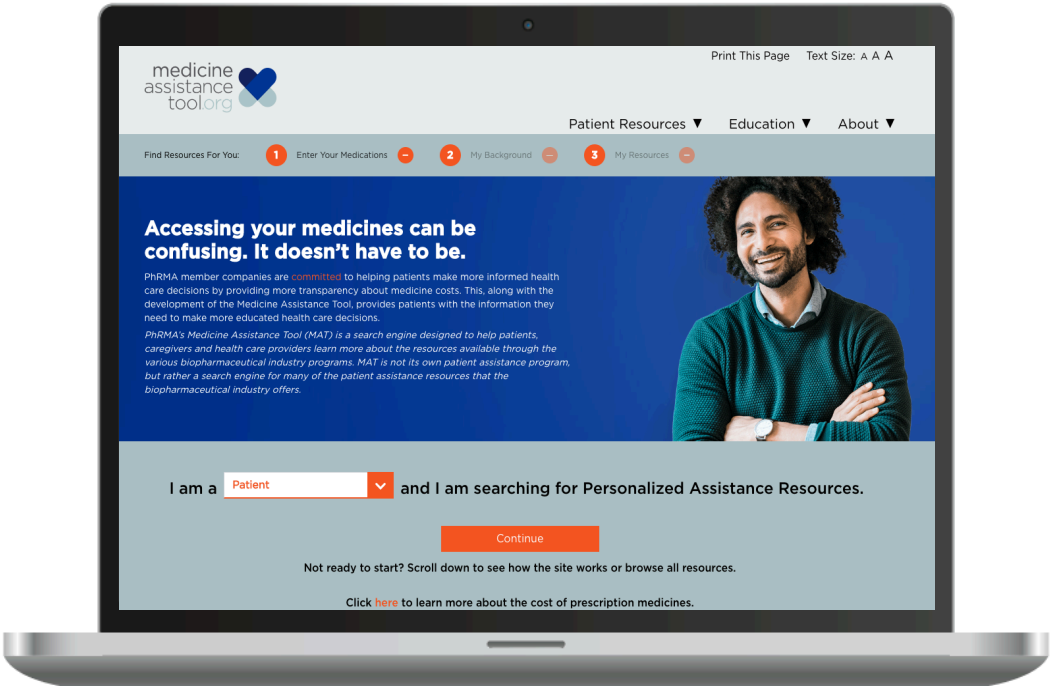
Comply with FDA's Current Good Manufacturing Practice (CGMP) requirements for all components of a finished drug product, including APIs.

Ensure API – made in the U.S. or abroad – **meets certain quality standards** before they are used in finished drug products sold to American patients.

Perform certain tests to **ensure that finished drugs meet requirements for its intended use.**

Establish robust supplier qualification programs to vet potential vendors before engaging in transactions with them, and, as a matter of course, enter into quality agreements with their API suppliers to audit their suppliers to ensure they meet CGMP requirements.

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

Each member company has individually and independently determined the content of any cost information provided on their websites.

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.

For More Resources and Information, Visit
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