The Biopharmaceutical Industry's Efforts to Develop Vaccines for Coronavirus

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December 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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Our Commitment to Developing Safe and Effective Vaccines

PRESS RELEASE

America's Biopharmaceutical Companies Working Around the Clock to Beat Coronavirus

Companies are Coming Together to Achieve Shared Goal of Eradicating the Virus

PhRMA | March 20, 2020 | SHARE THIS

Washington, D.C. (March 20, 2020) — Today, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) underscored the industry's commitment to finding solutions to prevent, diagnose and treat those with COVID-19, a disease caused by a novel strain of coronavirus. The decades-long investments biopharmaceutical companies have made in new technologies, research and treatments have prepared the industry to act swiftly to respond to the public health crisis.

PRESS RELEASE

PhRMA Statement on Biopharmaceutical Companies' Pledge on COVID-19 Vaccines

PhRMA | September 8, 2020 | SHARE THIS

PRESS RELEASE

PhRMA Statement on U.S. Food and Drug Administration COVID-19 Emergency Use Authorization Vaccine Guidelines

PhRMA | October 6, 2020 | SHARE THIS

PRESS RELEASE

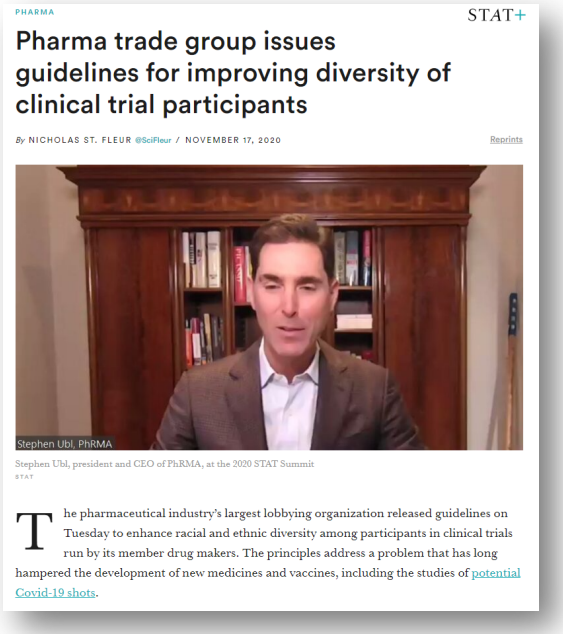
Pharmaceutical Supply and Payment Chain Coalition Announces Guiding Principles for Safe, Efficacious Access to COVID-19 Vaccine

PhRMA | October 22, 2020 | SHARE THIS

Ensuring Diversity in Clinical Trials

- First Principles on Clinical Trial Diversity (released November 2020)

- **4 Primary Areas of Focus:**
  - Educate the medical community and patients on the role of clinical trials
  - Promote information about diversity and inclusion in clinical trial participation, build trust while acknowledging wrong doings
  - Reduce barriers to clinical trial access (i.e. enrollment/ retention, trial design and eligibility criteria)
  - Use data to enhance information on diverse populations beyond product approval



PHARMA

STAT+

Pharma trade group issues guidelines for improving diversity of clinical trial participants

By NICHOLAS ST. FLEUR @SciFleur / NOVEMBER 17, 2020 Reprints

Stephen Ubl, president and CEO of PhRMA, at the 2020 STAT Summit
STAT

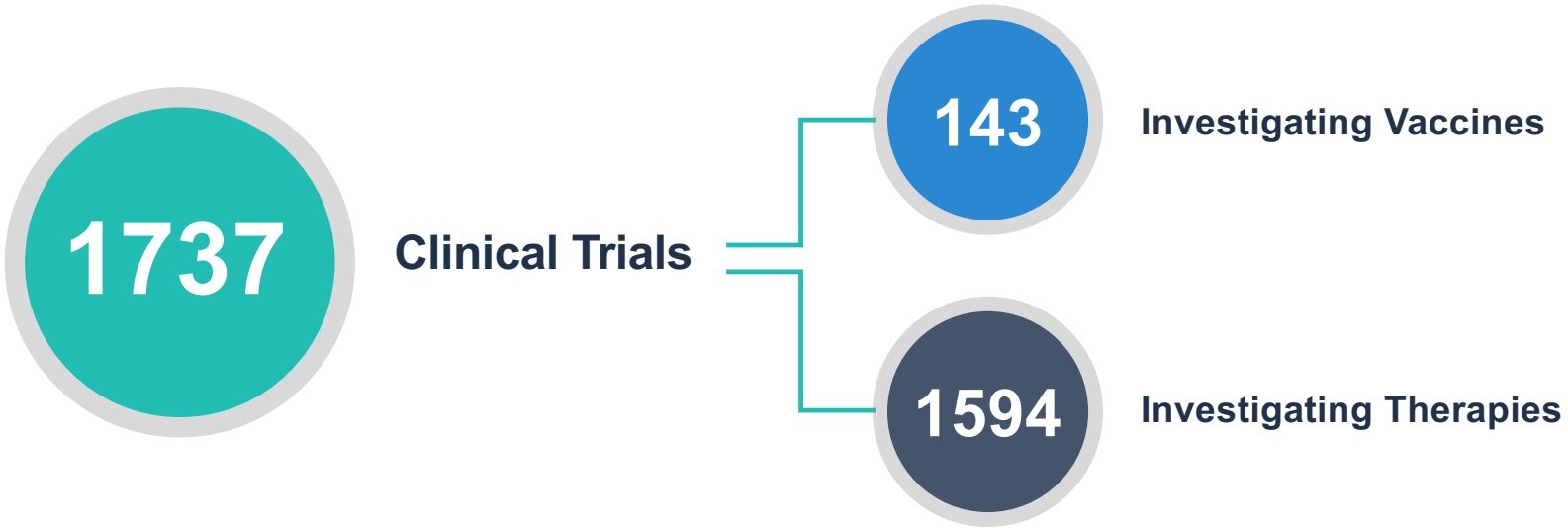
The pharmaceutical industry's largest lobbying organization released guidelines on Tuesday to enhance racial and ethnic diversity among participants in clinical trials run by its member drug makers. The principles address a problem that has long hampered the development of new medicines and vaccines, including the studies of potential Covid-19 shots.

https://www.phrma.org/Press-Release/PhRMA-Announces-First-Ever-Industry-Wide-Principles-on-Clinical-Trial-Diversity

Developing Vaccines

Developing Treatments and Vaccines to Fight COVID-19

There are **1737 clinical trials under way across the globe** for vaccinations and treatments.

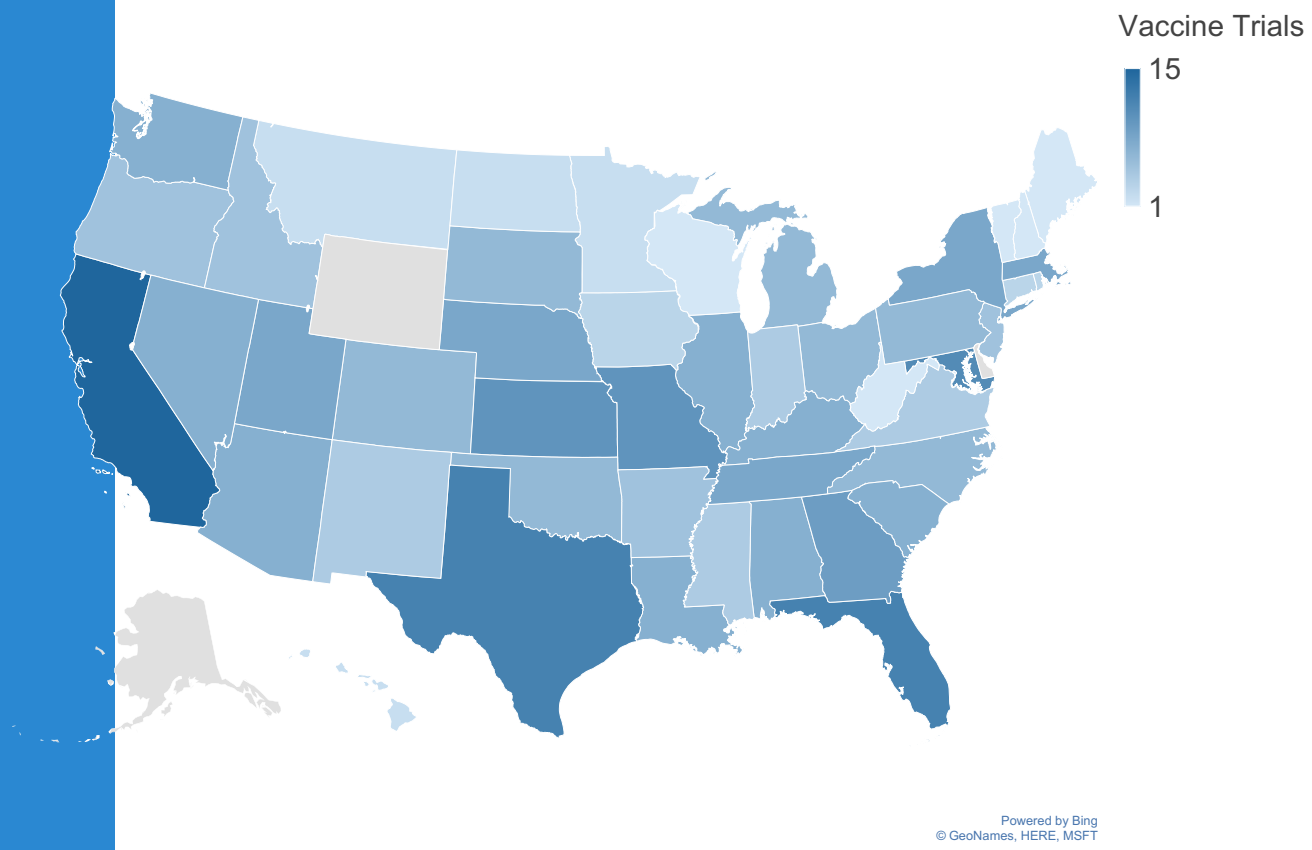


Data as of 12/03/2020

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

U.S. Clinical Trials of Vaccines

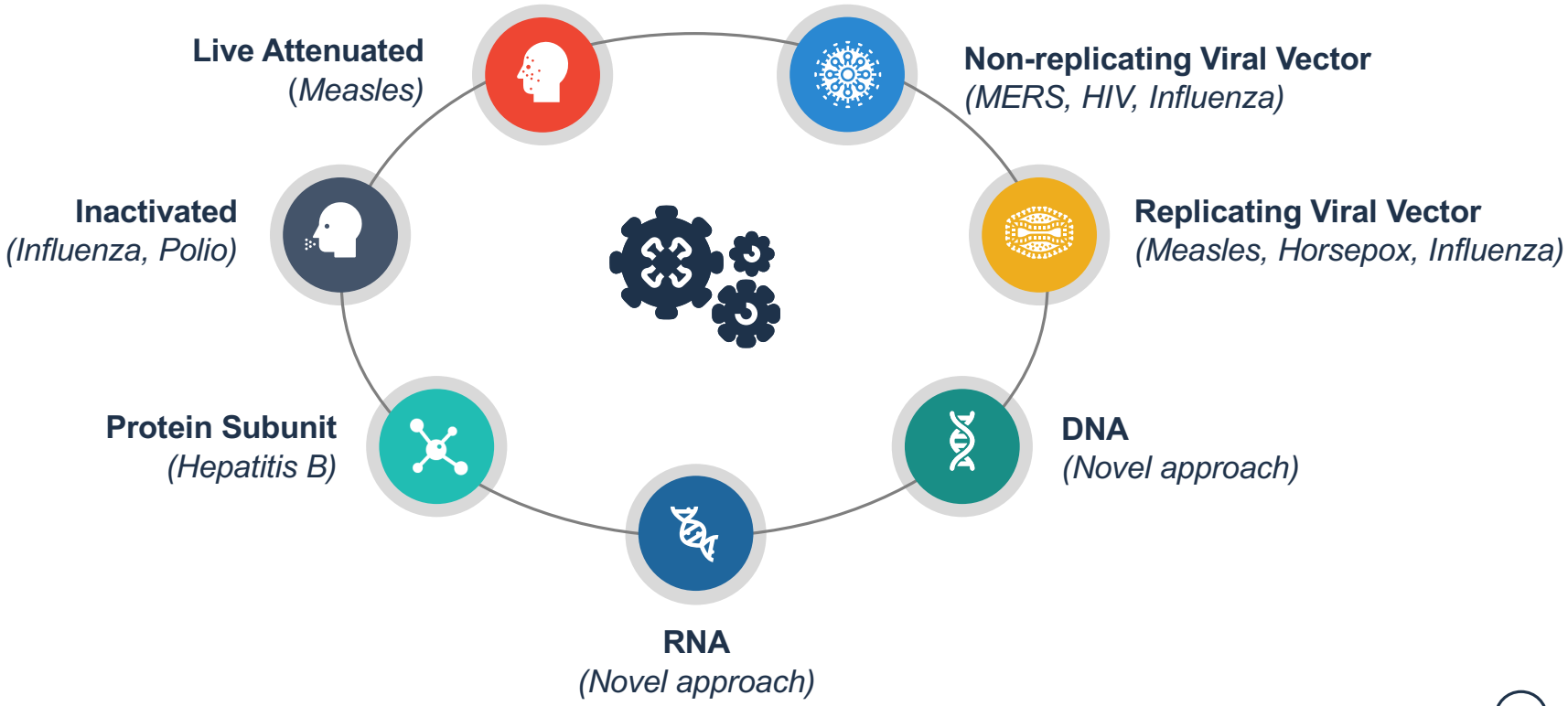
29 clinical trials testing vaccine candidates are occurring across 47 states and Washington, D.C.



Data as of 12/3/2020

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

Using Many Approaches to Develop Vaccines

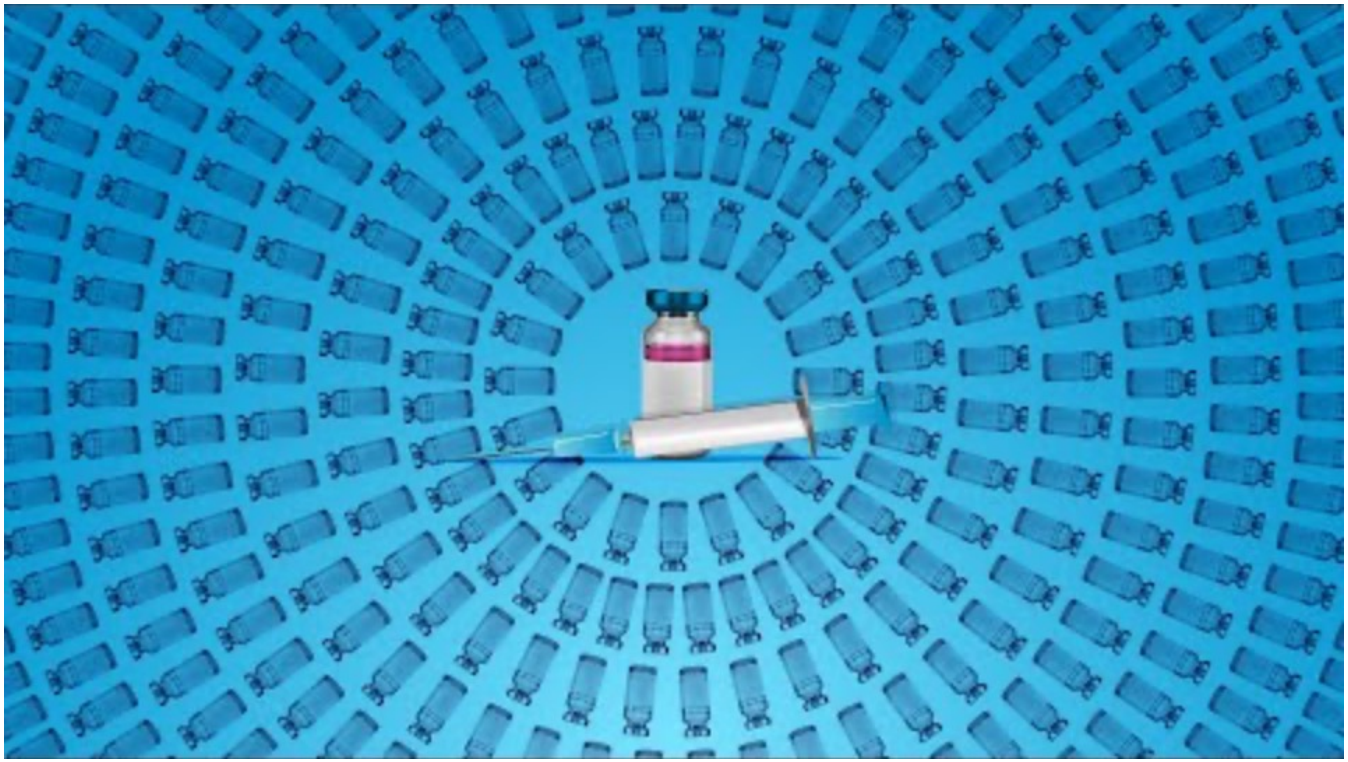


Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

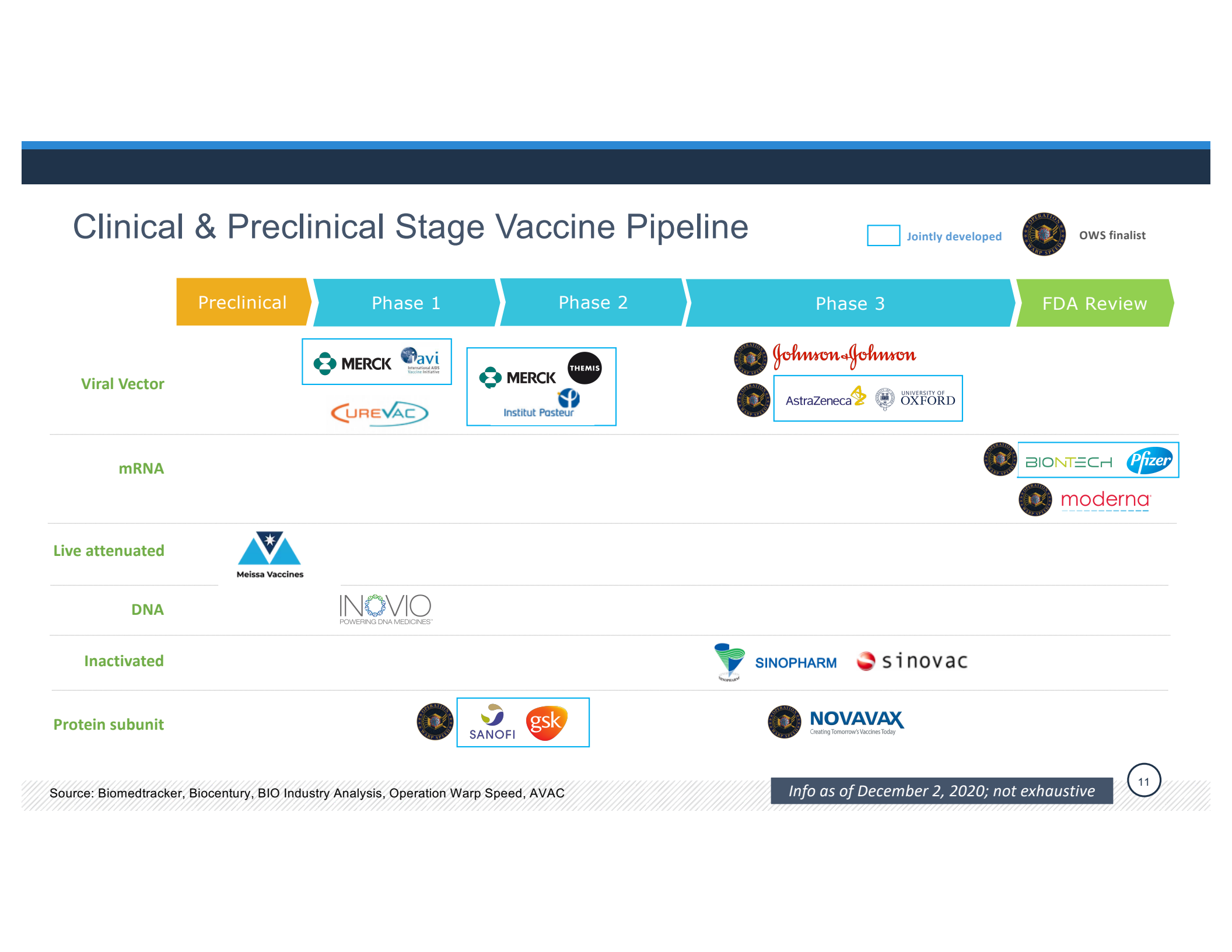
Addressing public misconceptions about mRNA vaccines

- Traditionally, vaccines work by exposing the body to a weakened (or dead) form of the virus.
  - mRNA uses the body's genetic machinery to create antigens that will trigger an immune response.
- mRNA does not use the live virus; it teaches the body to respond and fight.
- MRNA does not affect, interact or change DNA in your body.
- mRNA never enters the nucleus of the cells where our DNA material is kept.
- mRNA vaccines require less amounts of vaccine for manufacturing purposes.
- No mRNA vaccine approved to date, yet it's held to same rigorous standard as other vaccines.

mRNA Deeper Dive



Clinical & Preclinical Stage Vaccine Pipeline



Source: Biomedtracker, Biocentury, BIO Industry Analysis, Operation Warp Speed, AVAC

Info as of December 2, 2020; not exhaustive

Tools to Safely Accelerate Vaccine Development During a Pandemic

Traditional Development: *8-10 years*

Pandemic Development: *12-18 months*

Process is accelerated by:

1. Scientists sequence virus in record time and immediately create vaccine candidates using existing technologies
   - Conduct clinical trial phases simultaneously
2. Companies and government invest in large-scale manufacturing at-risk while still in Phase 3 clinical trials to ensure they are ready immediately upon FDA EUA or licensure
3. Government and private sector plan for infrastructure and distribution before the vaccines are approved or authorized
4. ACIP considers and votes on prioritization of allocation before vaccines authorized or licensed

Vaccine Development and Approval Milestones

FDA : EMERGENCY USE AUTHORIZATION AND/OR APPROVAL

Phase 3 Trials
Randomized, double-blind, placebo-controlled trials with greater than 30K volunteers, including diverse populations.

Data Safety Monitoring Board
Independent board evaluates data from ongoing Phase 3 trial, advises manufacturer, among other things, whether the pre-specified success criteria is met.

Emergency Use Authorization (EUA)
Granted by the FDA upon a determination, among other things, that based on the totality of scientific evidence available the vaccine may be effective and the known and potential benefits outweigh the known and potential risks. FDA plans to make its determination following a meeting of the **Vaccines and Related Biological Products Advisory Committee (VRPBAC).**

Biologics Licensure Application (BLA)
Includes additional safety and efficacy data along with further
product, manufacturing and clinical studies Information.

CDC ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) : PRIORITIZATION AND ALLOCATION DECISIONS

National Academies of Science, Engineering, and Medicine
Informs ACIP on which populations should receive priority for vaccines.

ACIP
Recommends plan for prioritization of populations to receive COVID-19 vaccines to CDC Director.

State/Local Jurisdictions
Create and implement allocation and distribution plans, taking ACIP guidance into account.

Delivery
Distributed to states based on data for prioritized groups, begins 24 hours after EUA granted.

Source: Adapted from Operation Warp Speed https://media.defense.gov/2020/Nov/05/2002529886/-1/-1/1/OPERATION-WARP-SPEED-VACCINE-DELIVERY-MILESTONES.PDF

Next steps after a vaccine is authorized by FDA

1) CDC's ACIP (Advisory Committee on Immunization Practices): recommends standards for coverage, payment, clinical recommendations, prioritized population recommendations

2) Dept of Defense (purchases vaccines that will be free, distribution by National Guard to satellite locations)

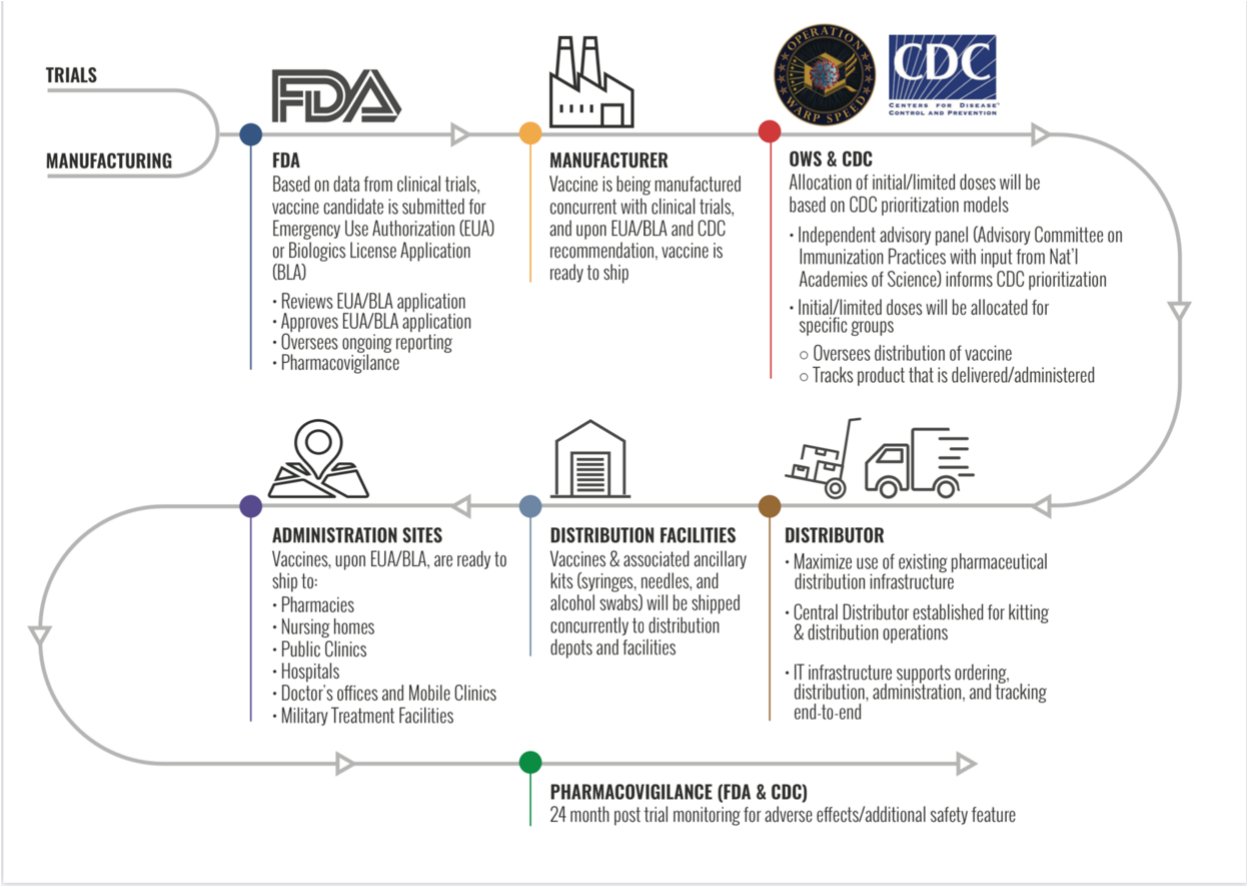
3) Vaccine administration by healthcare providers at Points of Dispensing (POD) locations

3) Post Trial Safety Monitoring continues (manufacturers & monitoring systems):

- **Vaccine Adverse Event Reporting System (VAERS):** monitors side effects with VSD, PRISM, CISA
- **Vaccine Safety Datalink (VSD):** monitoring of adverse events through e-health records

4) Manufacturers: focus on R&D, clinical trials, manufacturing efforts to meet global demand (in addition to ongoing safety monitoring)

Vaccines Distribution – Initial Process



Source: Operation Warp Speed

State Challenges Pertaining to Logistics

1) New systems and processes
2) Phased rollout to high priority populations (states ultimately decide; federal ACIP guide)
3) Provider enrollment and onboarding to administer/record vaccines
4) Ultracold storage requirements (unique requirements that impacts distribution/adherence)
5) Multiple vaccines and doses (requires different doses; not interchangeable, need right time)
6) Mass vaccination sites (Hospitals, pharmacies, CHCs, FQHCs, RHCs, mobile sites, schools, worksites, etc.)

Source: NGA COVID Resources for States: December 2020

Our Work on Vaccine Confidence

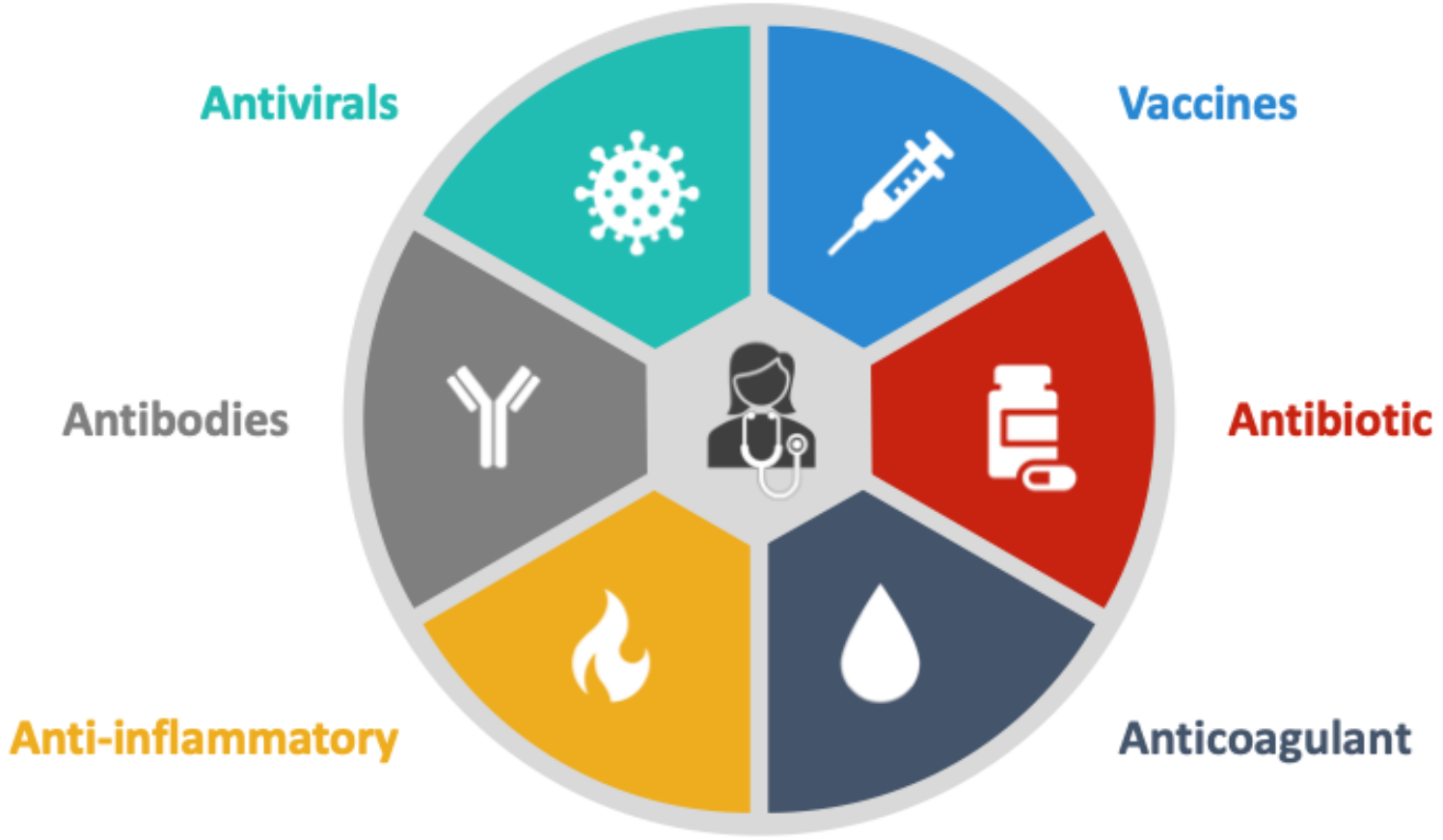
FIRST OPINION

What the biopharma industry is doing to build confidence in Covid-19 vaccines

By STEPHEN J. UBL / NOVEMBER 25, 2020 Reprints

- Meeting the highest standards
- Providing transparency
- Advancing diversity
- Looking to the future

COVID-19 Treatments and Vaccines



Where to Go for More Information

For More Resources and Information, Visit
PhRMA.org/Coronavirus & PhRMA.org/Vaccines

- **Ongoingly updated member company efforts to combat COVID-19**
- **Weekly updated tracker on the pipeline for new vaccine and treatments**
- **Fact sheets, graphics and blogs on importance of transparency and safety**
- **Deep dives into process of developing COVID-19 vaccines**
- **Reports on vaccines and infectious disease medicines in development**