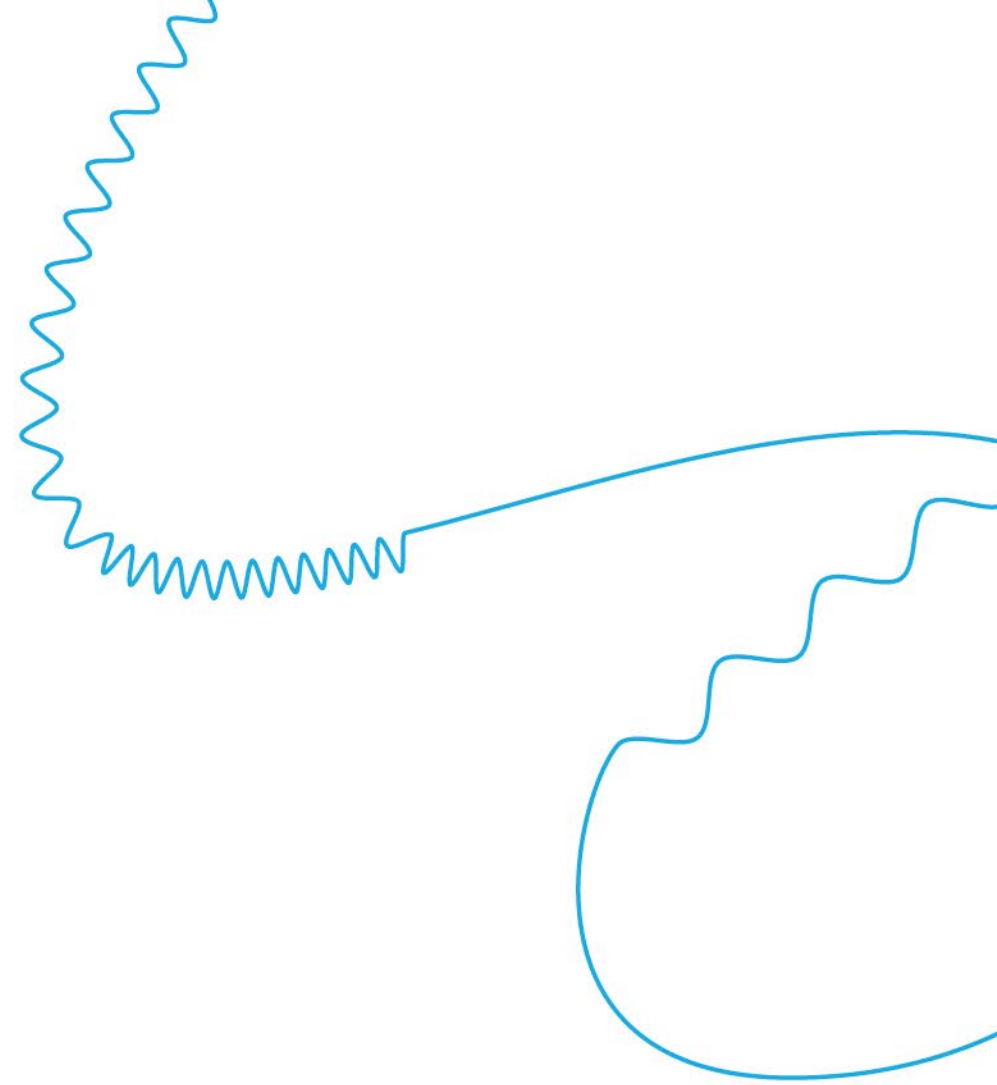




Moderna Clinical Trial Diversity

BIO Presentation

Brittany Gerald, Sr. Manager, Clinical Trial Diversity
and Inclusion
31 Jan 2023



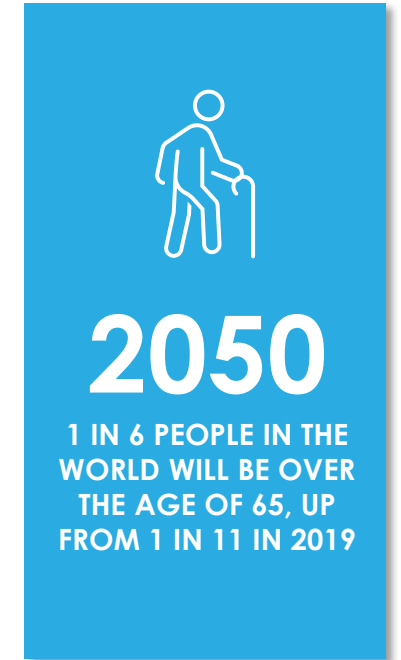
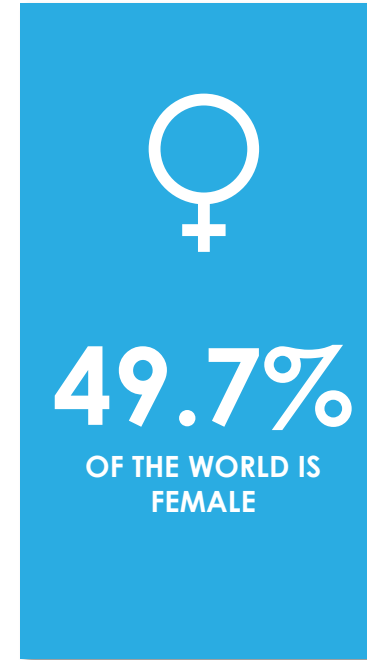
moderna®

I What constitutes diversity in Moderna clinical trials

Race, ethnicity, age, and sex can all **impact how different people respond to the same medicine or vaccine**

At Moderna, **a clinical trial can be qualified as “diverse” in healthy volunteer trials** when:

- 40% of the sample population within the US are People Of Color
- 50% female assigned at birth
- Balance across age cohorts

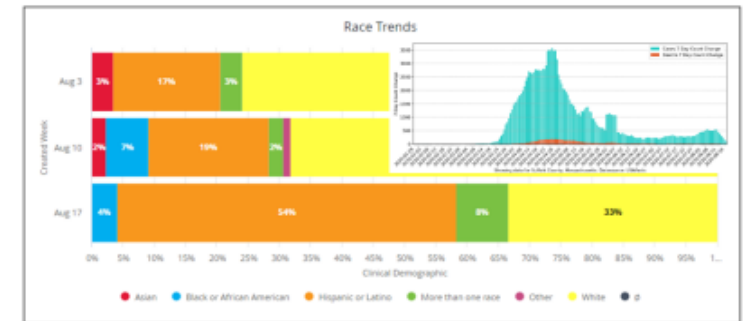


US Census Bureau,
<https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1144.pdf>

Moderna's approach to reach underrepresented groups

Drive strategy and manage initiatives to build trust and ensure medically underrepresented groups can be better engaged in our clinical trials

- Embed the importance of diversity in clinical trials into our company's culture
- Establish demographic objectives and diversity plans for each trial (**Phase 1-3**)
- Select multi-regional clinical trial sites with inclusion in mind
- Increase ways to access trials
- Collaborate with trusted voices
- Develop outreach and education tailored to specific populations
- Leverage dashboard and metrics to understand historical performance within specific indications, inform site selection and enrollment strategy, and measure future performance



Ensured that we enrolled diverse and at-risk populations for our Phase 3 COVID-19 vaccine trial (COVE Study)

Slowed enrollment in the COVE study to ensure diverse representation

Included more than 11,000 participants from communities of color, representing 37% of the study population



COVE study: Racial ethnic demographics



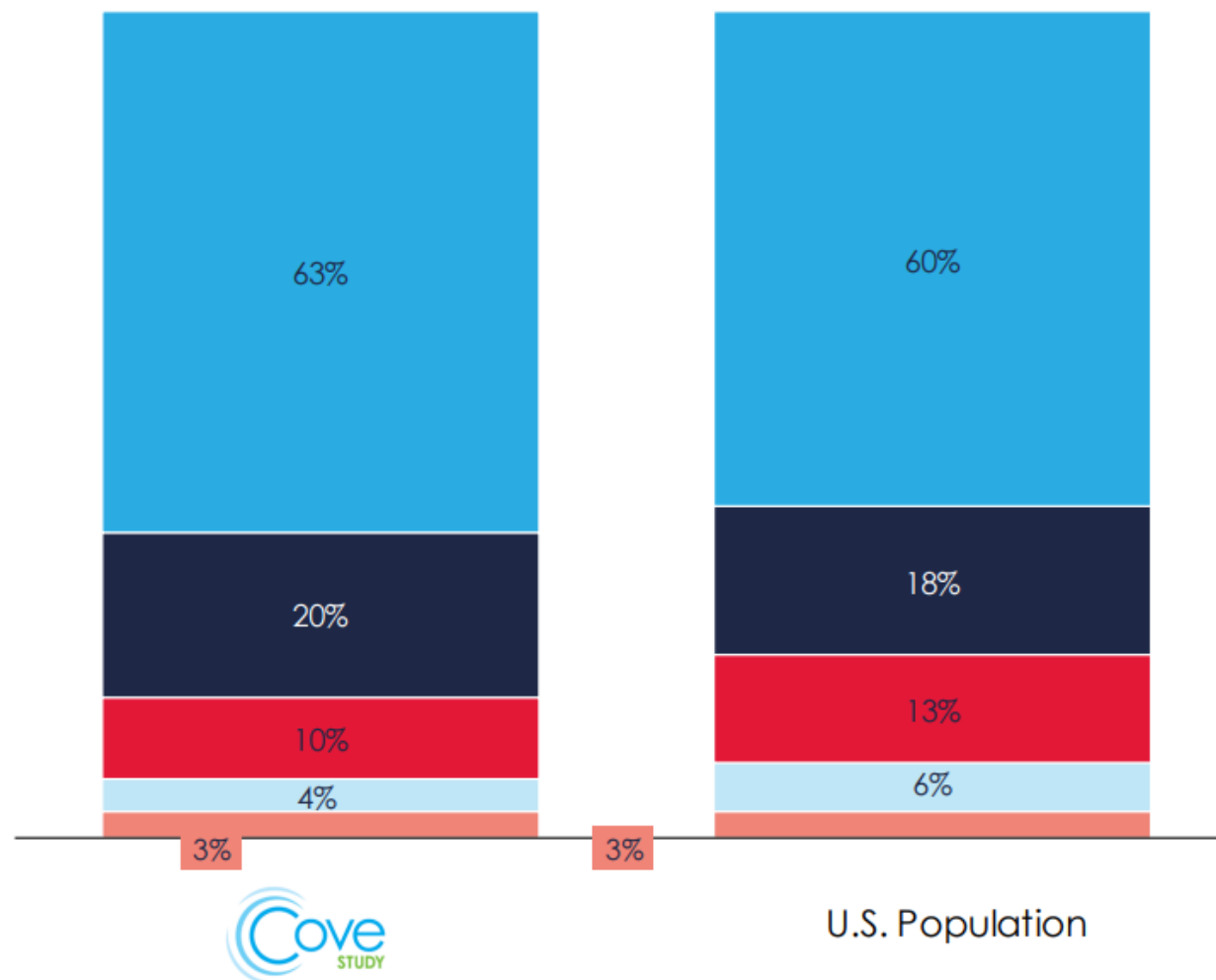
- White
- Hispanic/Latinx
- Black/AA
- Asian
- All others

COVE Study Participants	Count
White, non-Hispanic	19,060
Hispanic or Latinx	6,247
Black or African American	3,114*
Asian	1,365
Others	871^
Total	30,406+

* Includes 251 participants who identify as both Black and Hispanic/Latinx

^Including 148 American Indian or Alaska Native

+ Final Enrollment 30,423 (Oct 22, 2020)



Leveraging our digital infrastructure to support trial diversity

Real-time D&I comparison to census

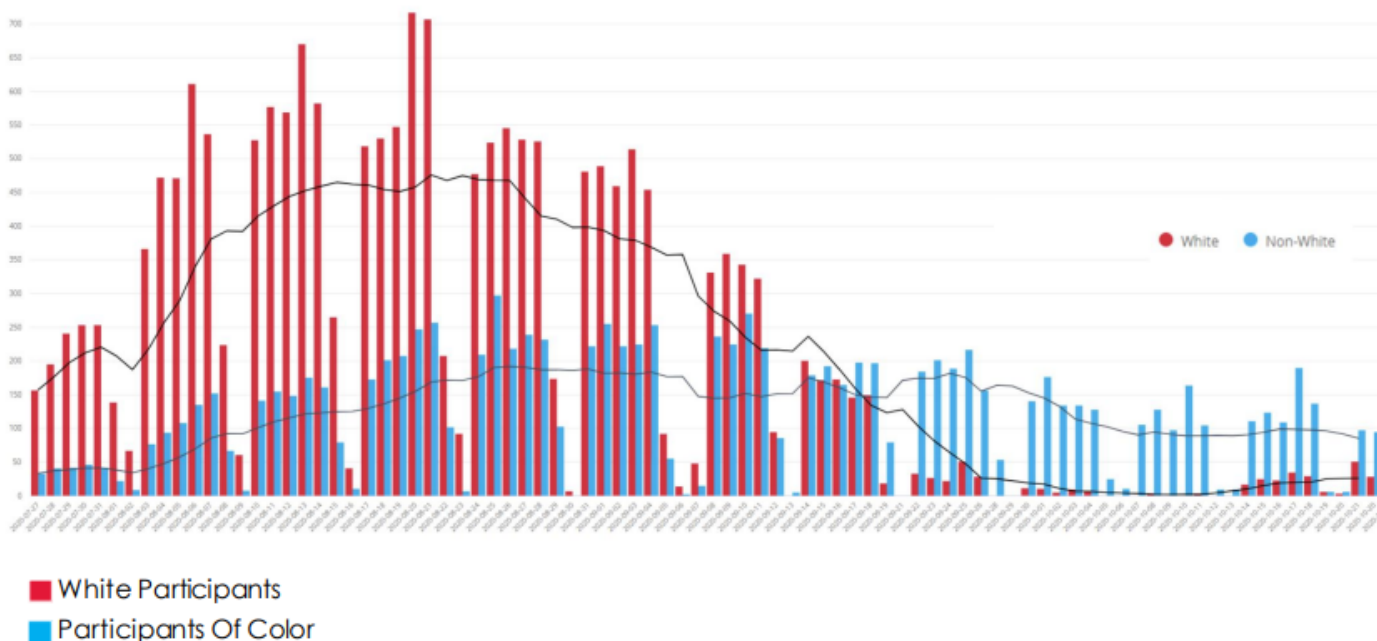
- Empowered COVE clinical team decision making and made an impact for populations most at risk

Shared insights across multiple teams

- Shared insights from central location with Moderna teams, clinical research organizations (CROs), government partners, company website & more

Evolution of diversity throughout enrollment

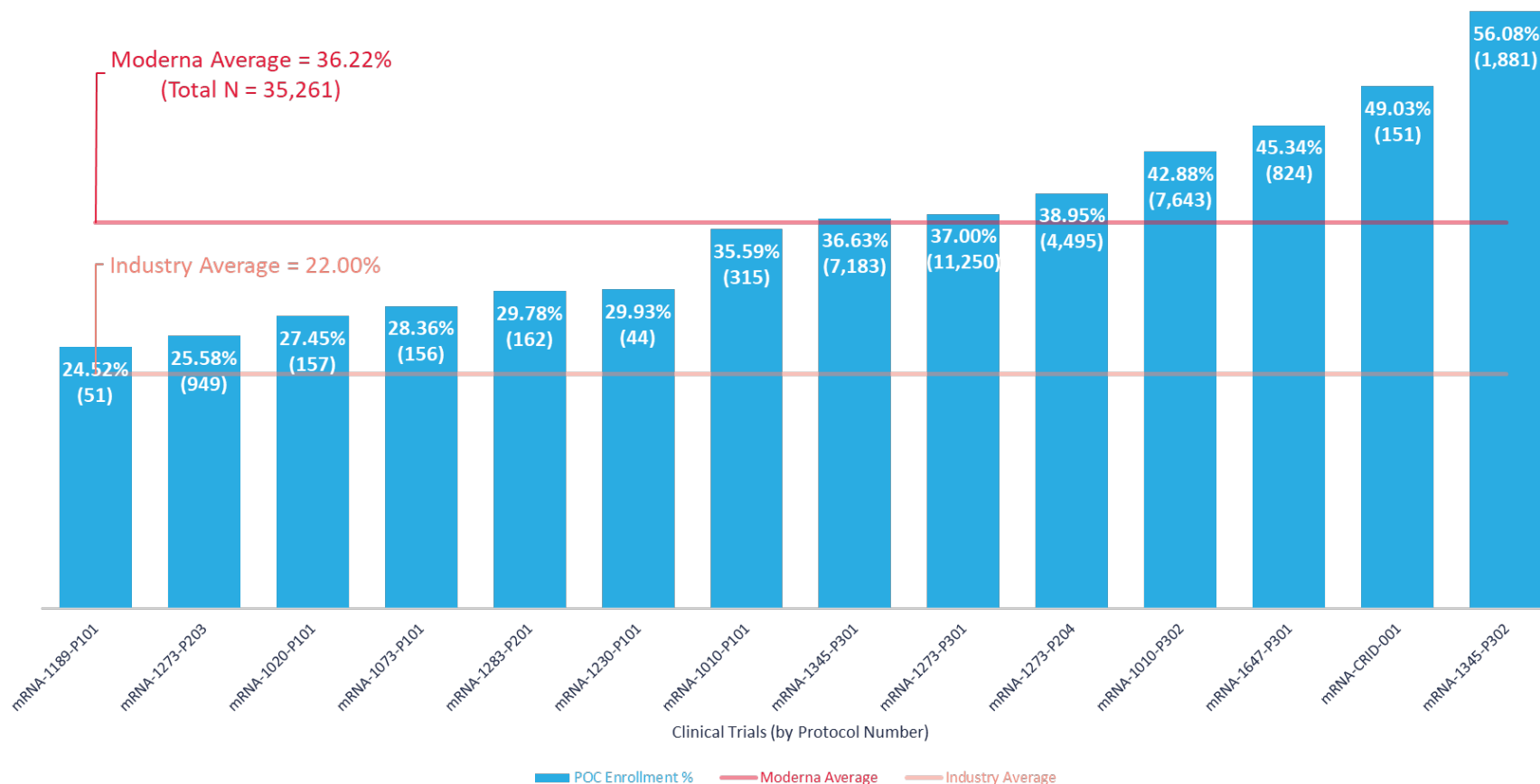
Interim data snapshot - October 21, 2020 - subject to change



Striving to be a leader in the industry

Moderna continues to lead the industry; proving that concerted efforts to provide equitable healthcare access to all populations are both possible and essential.

U.S. Participants of Color Across 14 Phase 1-3 Vaccine Trials
% (n)



Leveraging COVE Trial Methodology in other TAs

Weave trial diversity into your operational model



Use **data sources** to determine the patient populations your potential PIs have seen in previous years to anticipate future visits.



Focus on being **deliberate** in site selection.

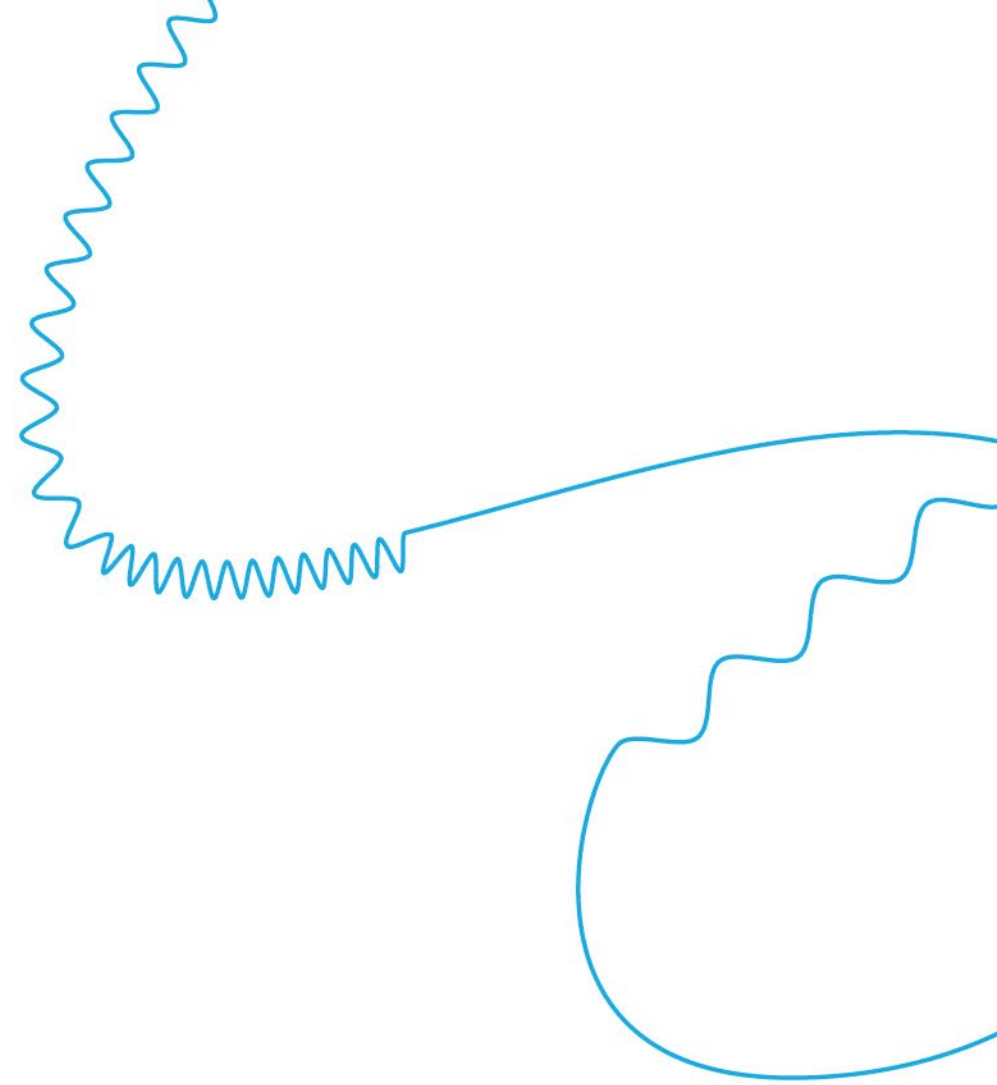


Track and analyze progress towards trial- and site-level goals

I Our Question to the FDA

- **What's happening on agency side to have qualified individuals to assess our diversity plans and methodology?**

Thank you



moderna®