

moderna®



Moderna's Focus on Diversity & Inclusion in Clinical Research



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Diseases don't discriminate.

Neither should clinical research.



Moderna's Commitment to Diversity & Inclusion – Clinical Studies

Moderna is committed to **increasing diversity** in our clinical trials by identifying the **barriers that currently impede inclusion**, and implementing approaches to more efficiently **identify, engage, recruit, and retain** study participants from **minority communities and vulnerable populations**.

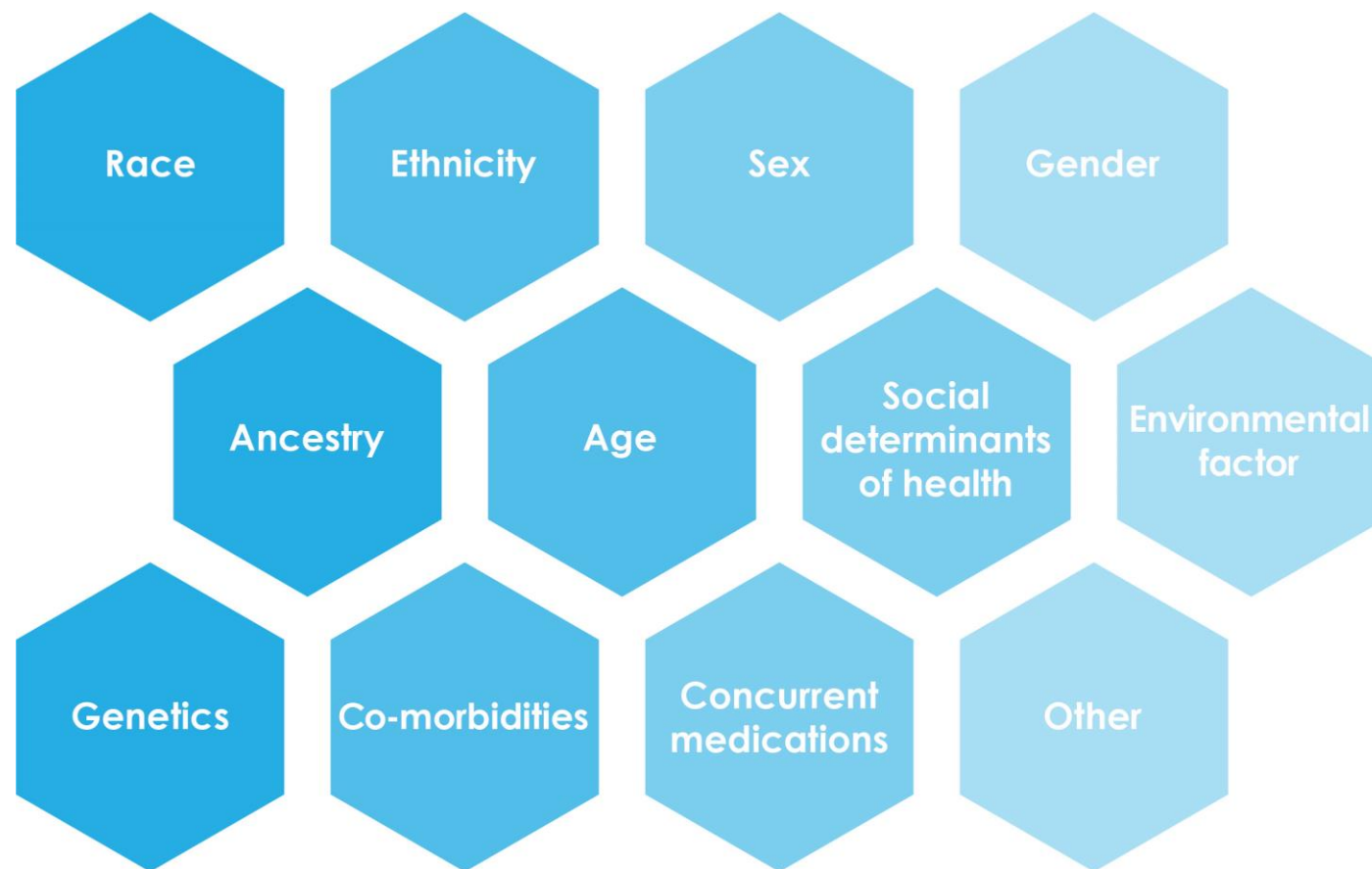


Purpose of Diversity & Inclusion in Clinical Research

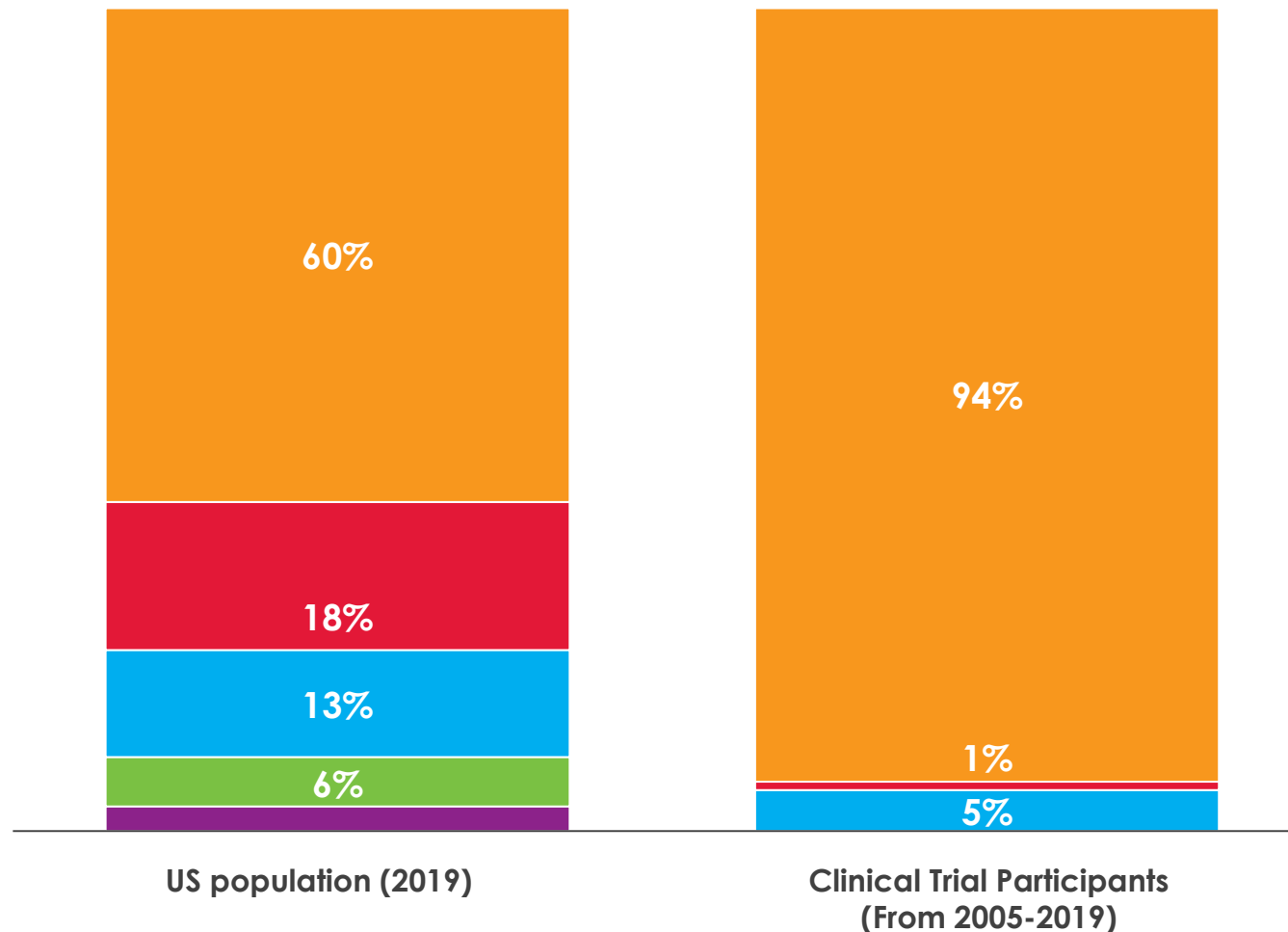
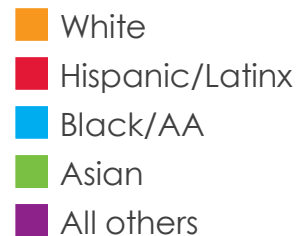
- The primary goal of diversity in clinical research is to understand the influence of age, sex, race, ethnicity, and non-demographic factors in treatment response and patient outcomes
- Through the inclusion of different races, ethnicities, genders, and age groups, the findings from the research study:
 - Are more generalizable to the entire population/ those affected by the disease
 - Identify groups where treatment may not be effective.
 - Provide more patients access to highest standard of care

Purpose of Diversity & Inclusion in Clinical Research

- **Diversity exists across many dimensions**
- **Diversity is context-specific**
- **The importance of each factor may vary depending upon the disease/ condition and the population at risk**



Diversity In Clinical Research – Where We Were Pre-COVID*



*Pre-COVID" defined as prior to January 2020

Source: US Census Bureau <https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1144.pdf>, FDA: <https://www.fda.gov/media/135337/download>

Barriers to Diversity in Clinical Trials

Mistrust

Limited Awareness of Trials

Lack of Invitation to Participate

Lack of Information

Logistical Obstacles – Time & Resource Constraints

Complexity of Protocol – Study Burden

Ethnic & Cultural Beliefs

Language/Literacy

Eligibility criteria / comorbid conditions

Moderna's Approach to Reach Underrepresented Communities

Education: Ourselves & Stakeholders

Listen

We created an Advisory Committee of experts and we listened to them

Start the Conversation

We talked to our clinical sites about the importance of diversity in clinical trials

Educate

In partnership with the NIH we conducted implicit bias training & provided expertise to support the sites

Transparency: Intent & Information

Be Transparent

We were explicit about intent;
published data on progress;
published protocol on our website

Create Tools

Tailored our Patient Information sheets and translated materials for different populations

Use Data

We provided each site with their race trends and epi weekly, and monitored enrollment daily

Help: Partner with Experts

Partner

Seek experts and those with specific experience

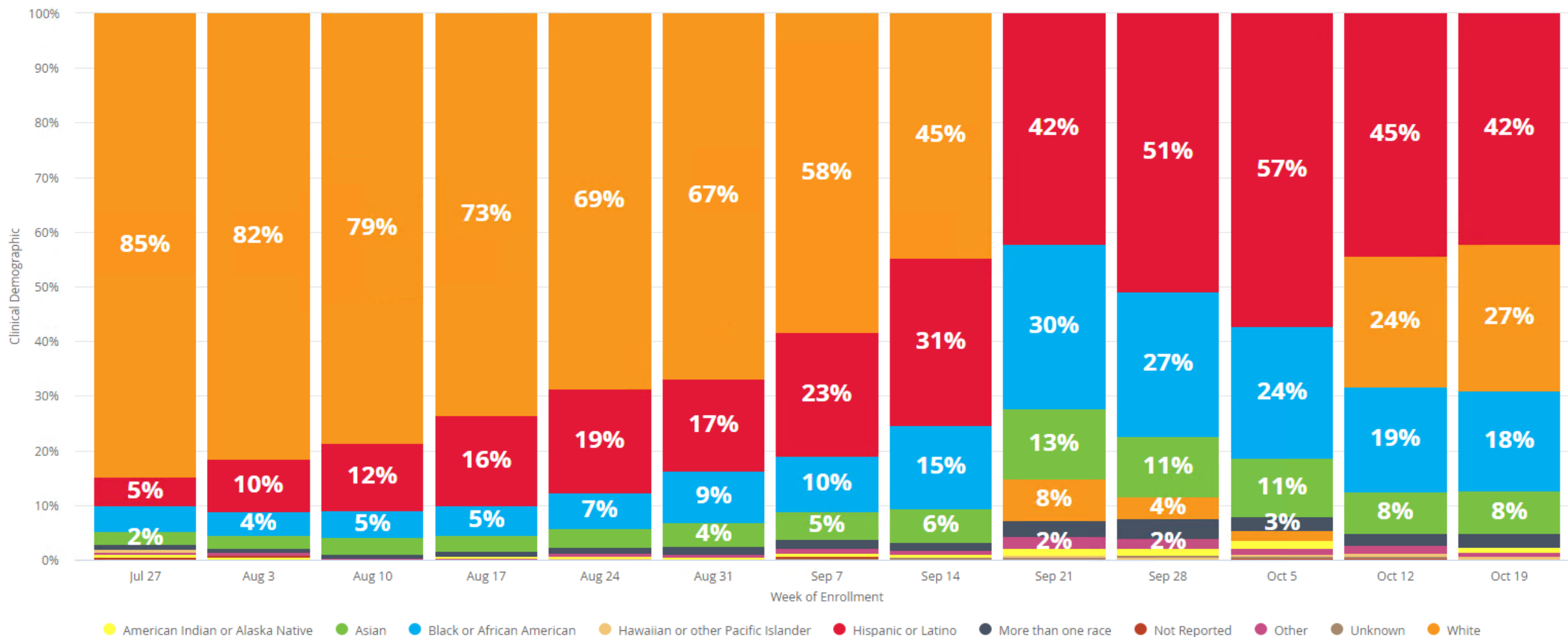
Innovate

Be creative; new solutions are needed

Motivate

Find ways to communicate with sites and listen to them

Evolution of Enrollment by Subgroup



Source: Moderna Informatics Dashboard

COVE Study – Racial Ethnic Demographics



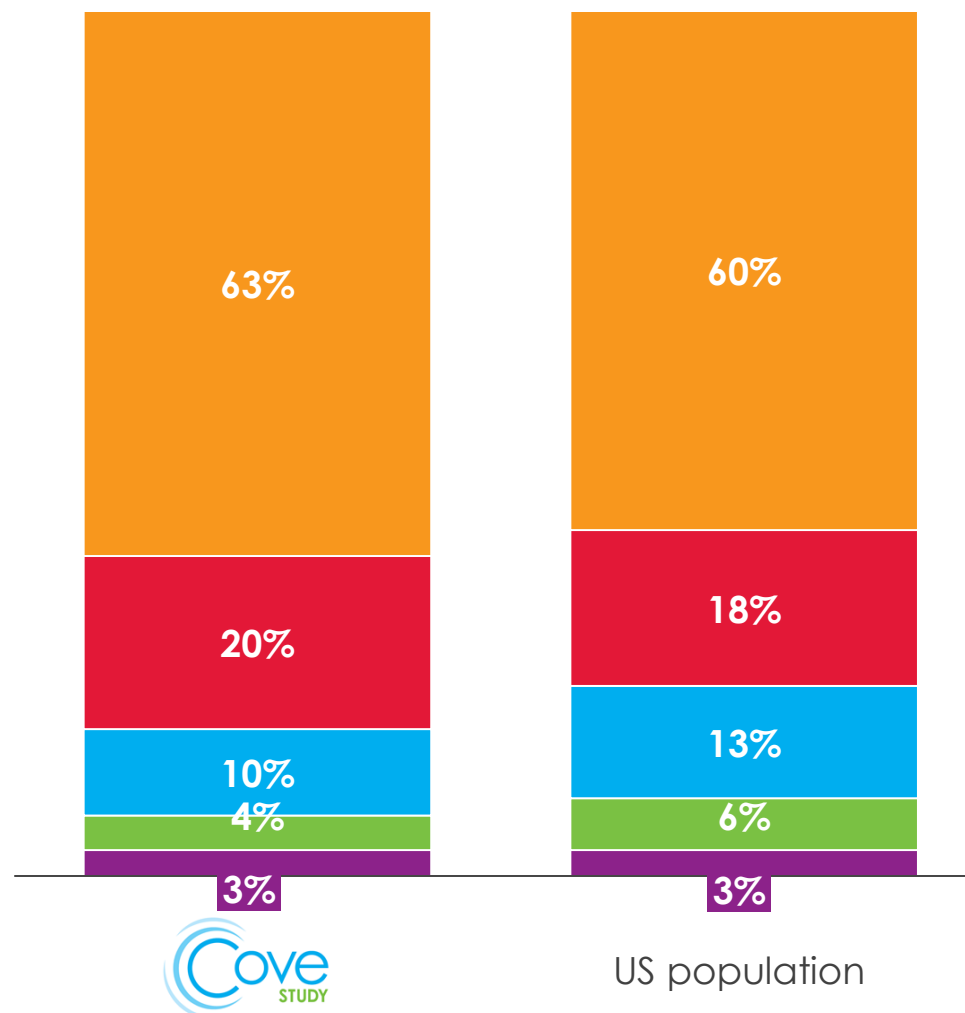
- White
- Hispanic/Latinx
- Black/AA
- Asian
- All others

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)

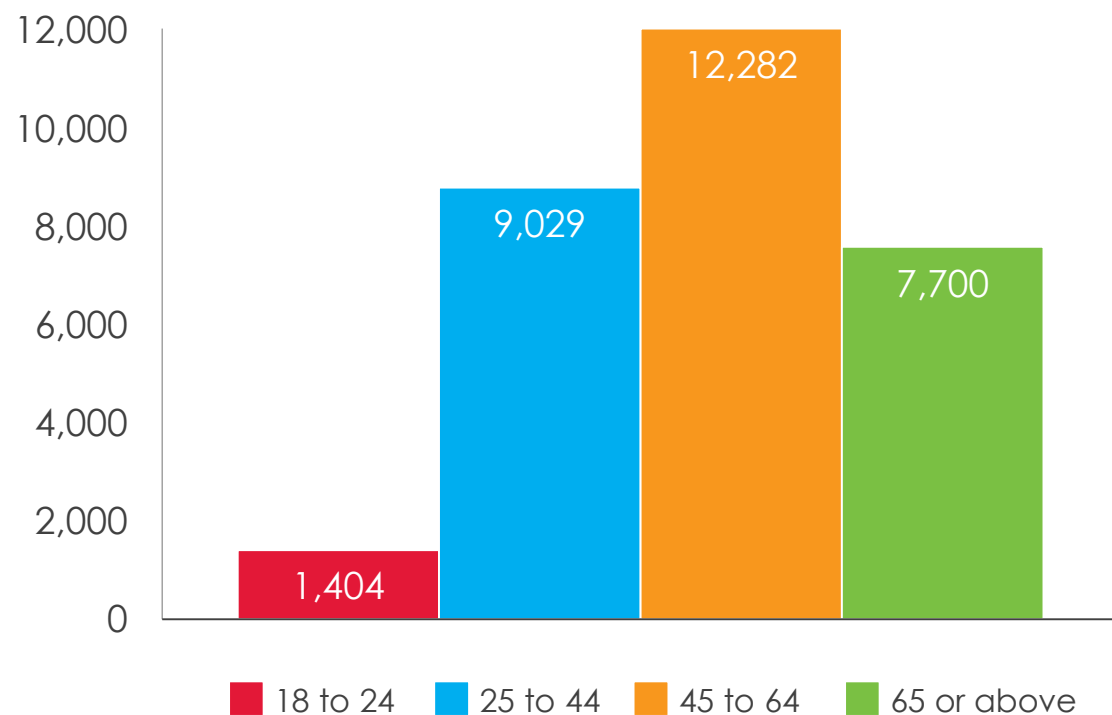


Distribution of age and gender

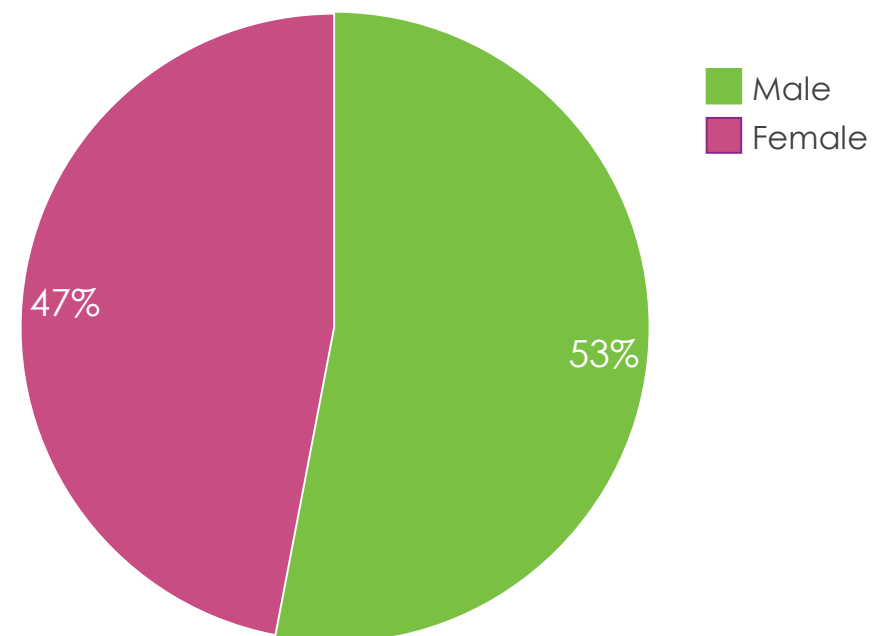


Most participants fall into the mid to older age range, with a near split among male/female

COVE Study age breakdown



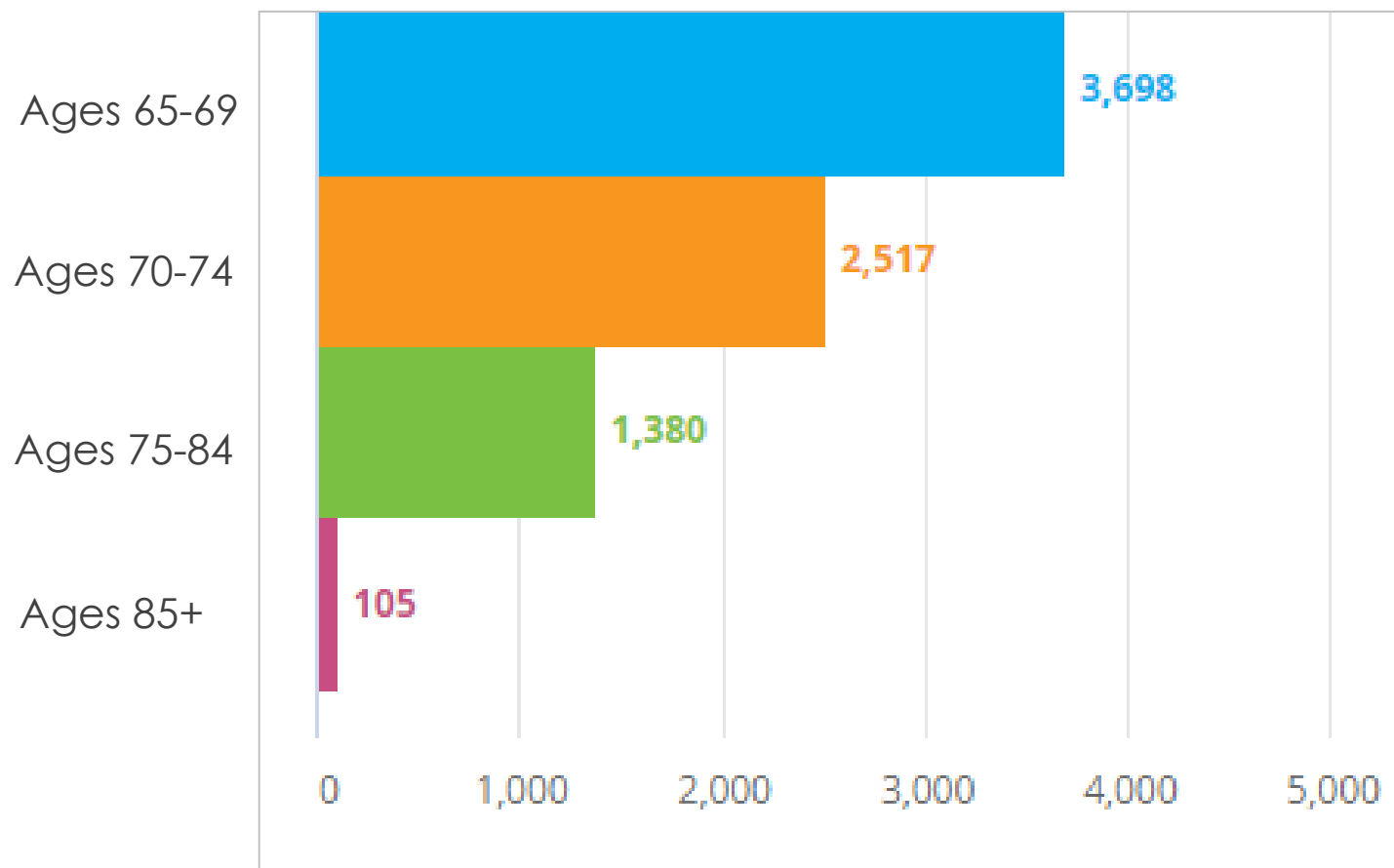
COVE Study gender distribution



Older Adults Demographics



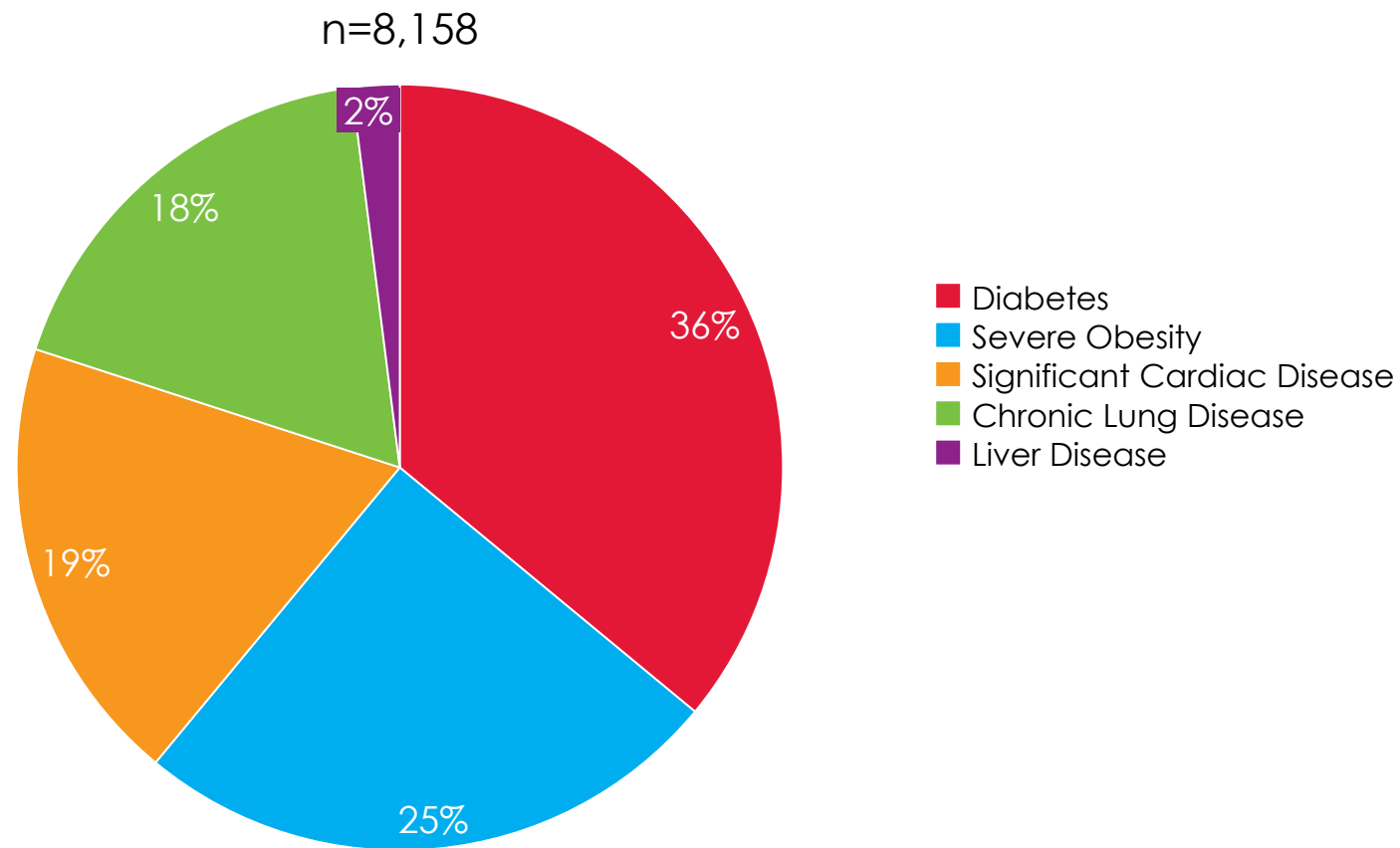
Older Adults comprised 25% of the total COVE Study enrollment



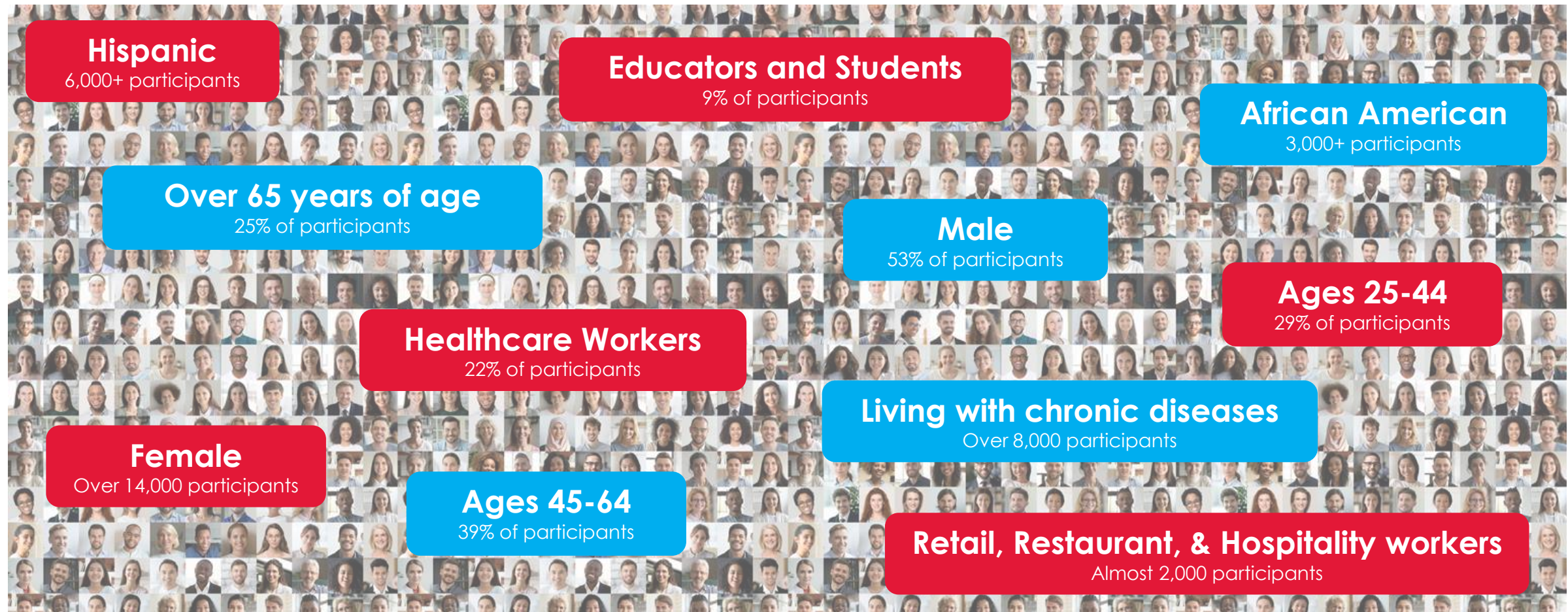
Medical Co-Morbidities in COVE Study



Approximately 27% of participants were high risk due to a co-morbidity



The population in the COVE Study is representative of the US population at-risk for COVID-19 infection



Questions?



**ONLY PEOPLE CAN
HELP SAVE PEOPLE**

Thank you to all clinical trial volunteers.
The medicines and vaccines that help
protect everyone need everyone involved.

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