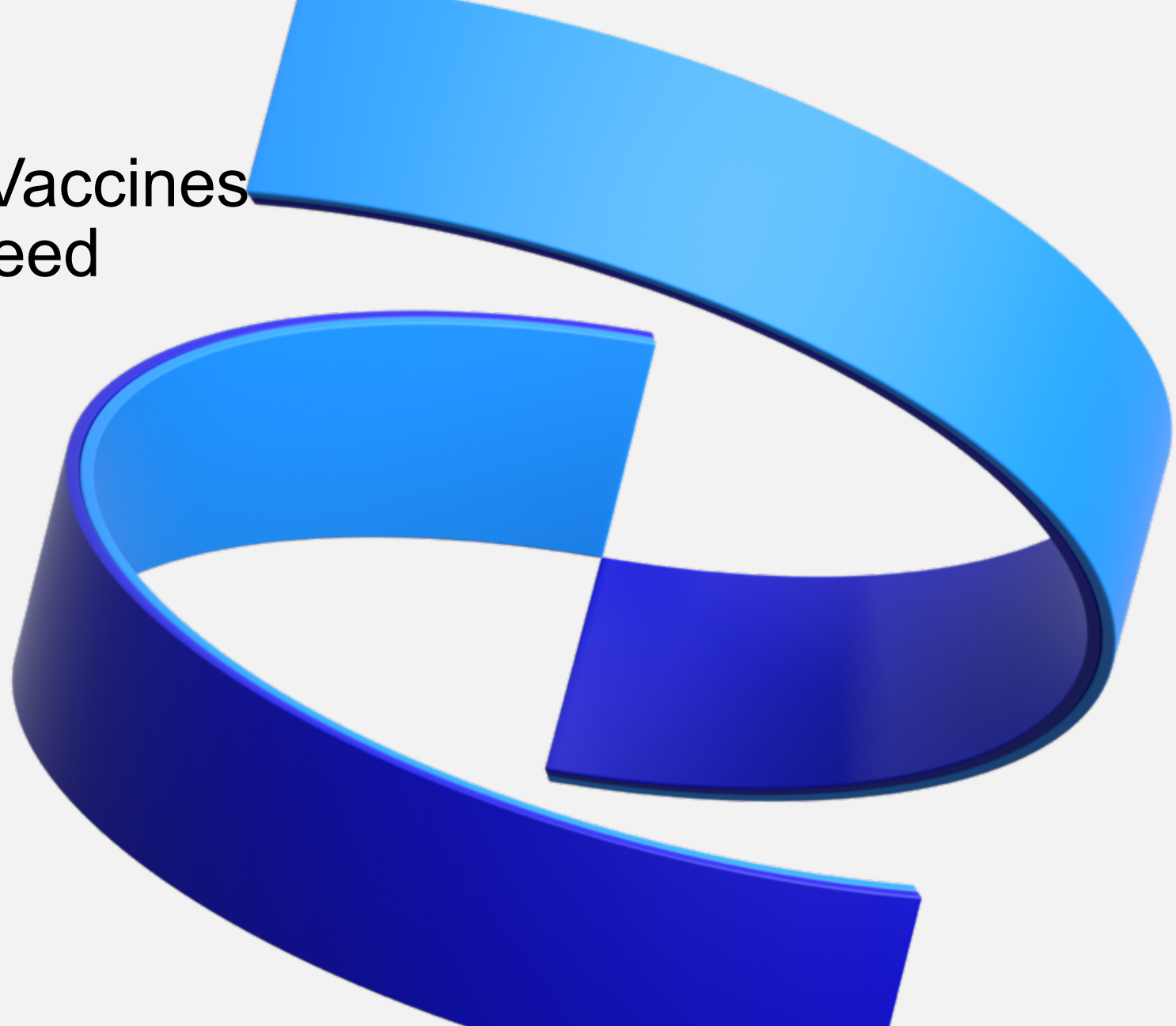




High Quality COVID-19 Vaccines Submission with Lightspeed

Helen Yang, Kiran Challagali
Statistical Programming & Analysis - Vaccines
Pfizer INC

PHUSE US Connect May 1st -4th, 2022

Over 1,000
colleagues and
vendor partners in
clinical development
working in
synchrony to drive
efficiencies

20

Vendor Collaborations

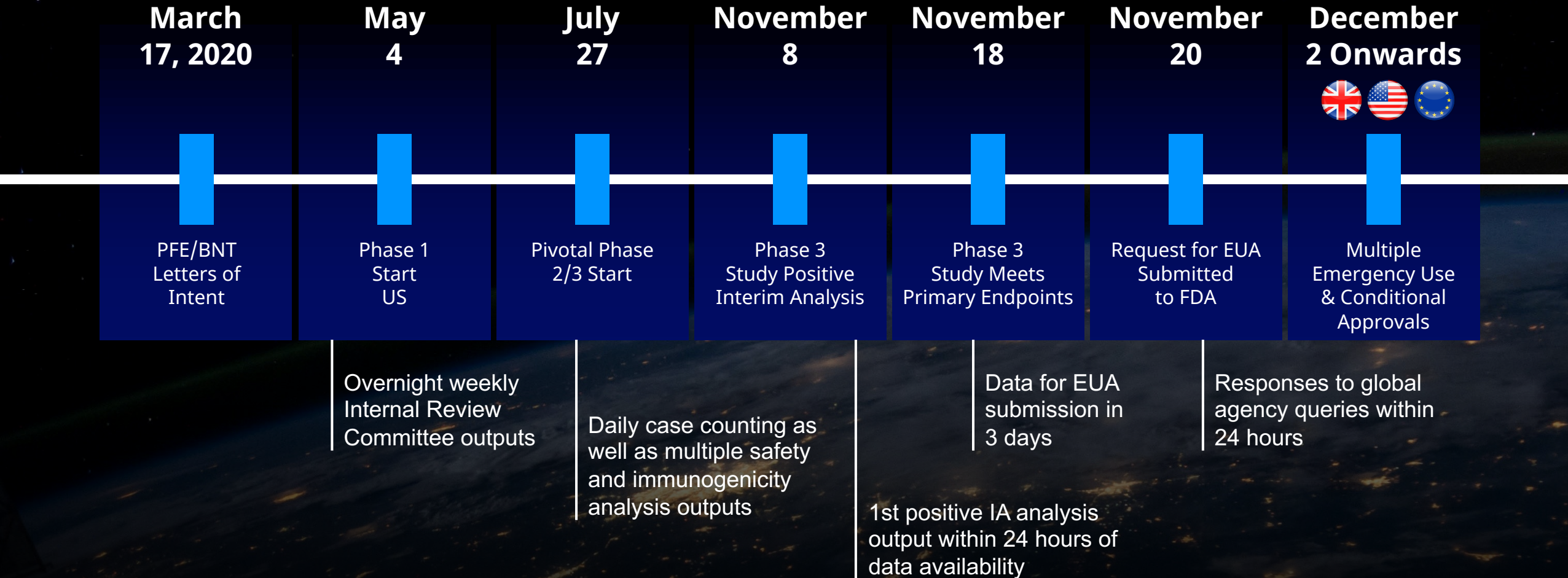
18

Pfizer functional lines

Team Structure

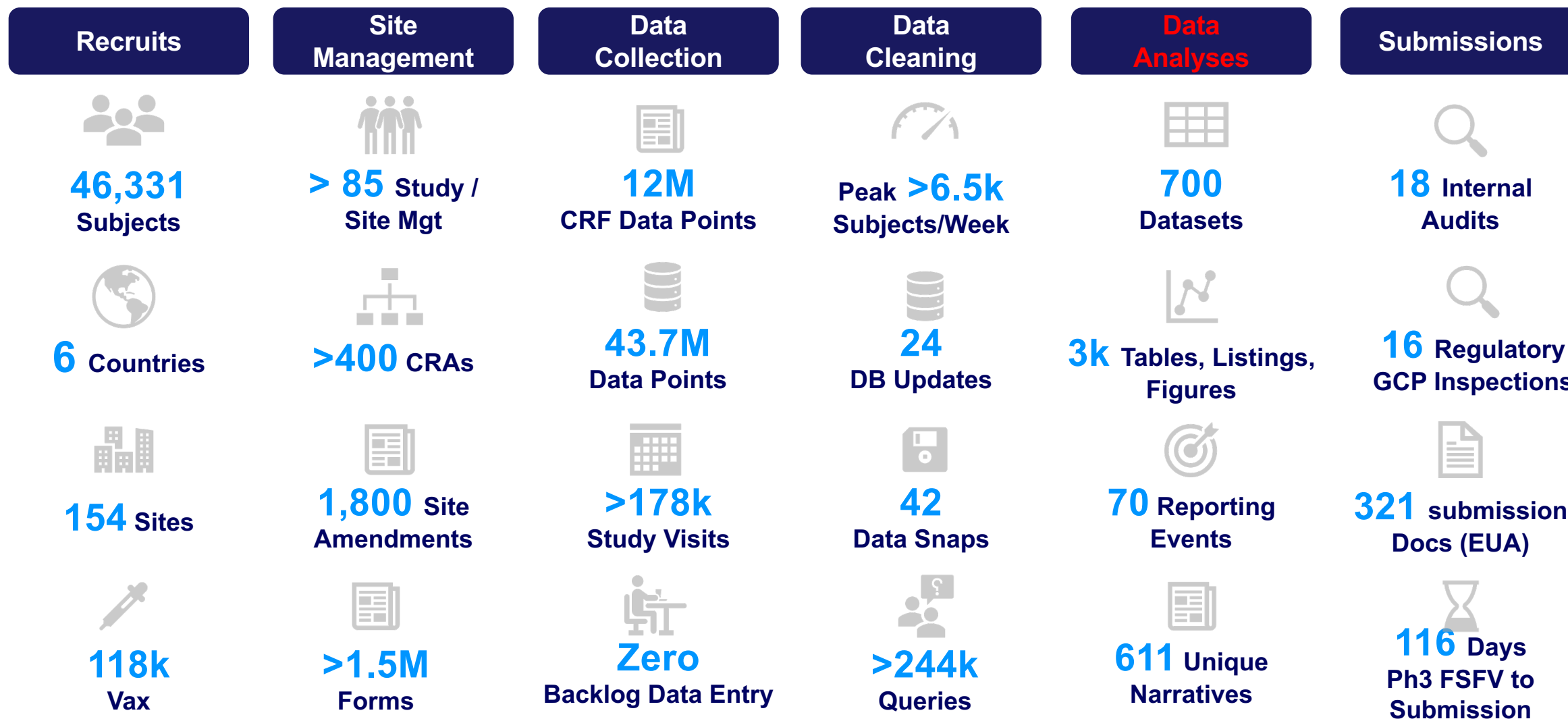


Major Milestones and Programming Support/Accomplishments



COVID By the Numbers*....

* Data gathered in Feb-2021



Real time delivery of an extremely large dataset gathered under accelerated timelines required significantly augmented resources and a hyper-care environment

Key Programming Contributions

- IND, EUA, MAA and BLA regulatory filings
- Weekly IRC and DMC
- 508 documents and VRBPAC
- Safety Narratives, RMP and Label
- Global regulatory responses
- E-sub
- Documentation for Audit

Contributors to the Accelerated EUA Submission

1

Dedicated focus programming teams

2

Programming standards

3

Limiting/controlling output

4

Leveraging technology

5

Regulatory engagement

6

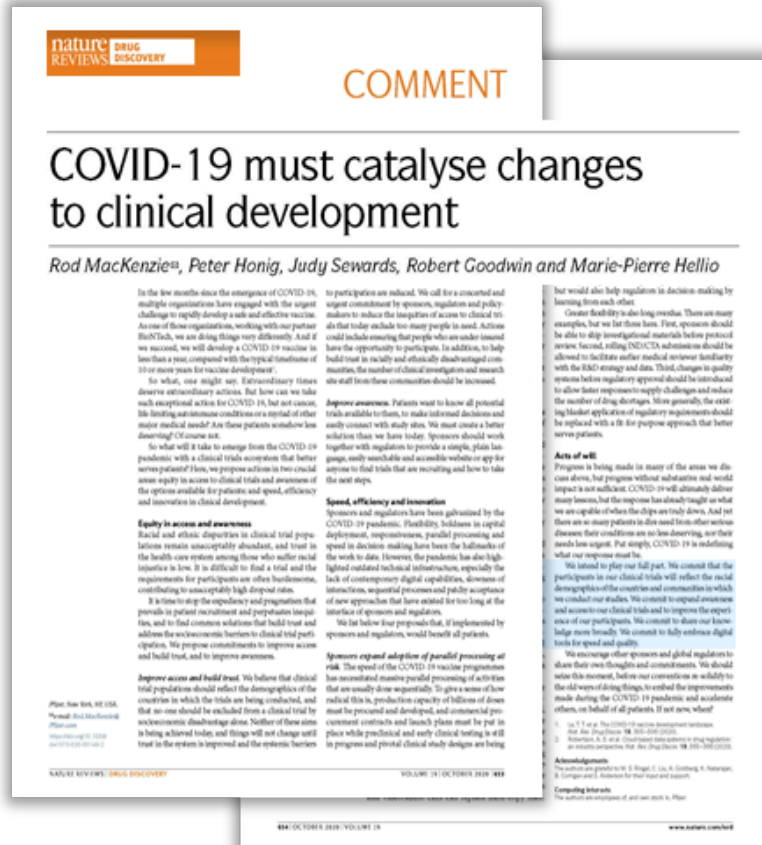
Ensuring high quality

7

Planning & cross-functional alignment



What Pfizer has done – Applying Learnings from Covid-19 Trial EUA



4 Public Commitments

1. Participants in our clinical trials will reflect the racial demographics of the countries and communities in which we conduct our studies.
2. Expand awareness and access to our clinical trials and improve the experience of our participants.
3. Share our knowledge more broadly.
4. Fully embrace digital tools for speed and quality.

¹ Sample source formatting.

² Sample source formatting.



1

**Science should be
the only limiting
factor to speed of
development**

2

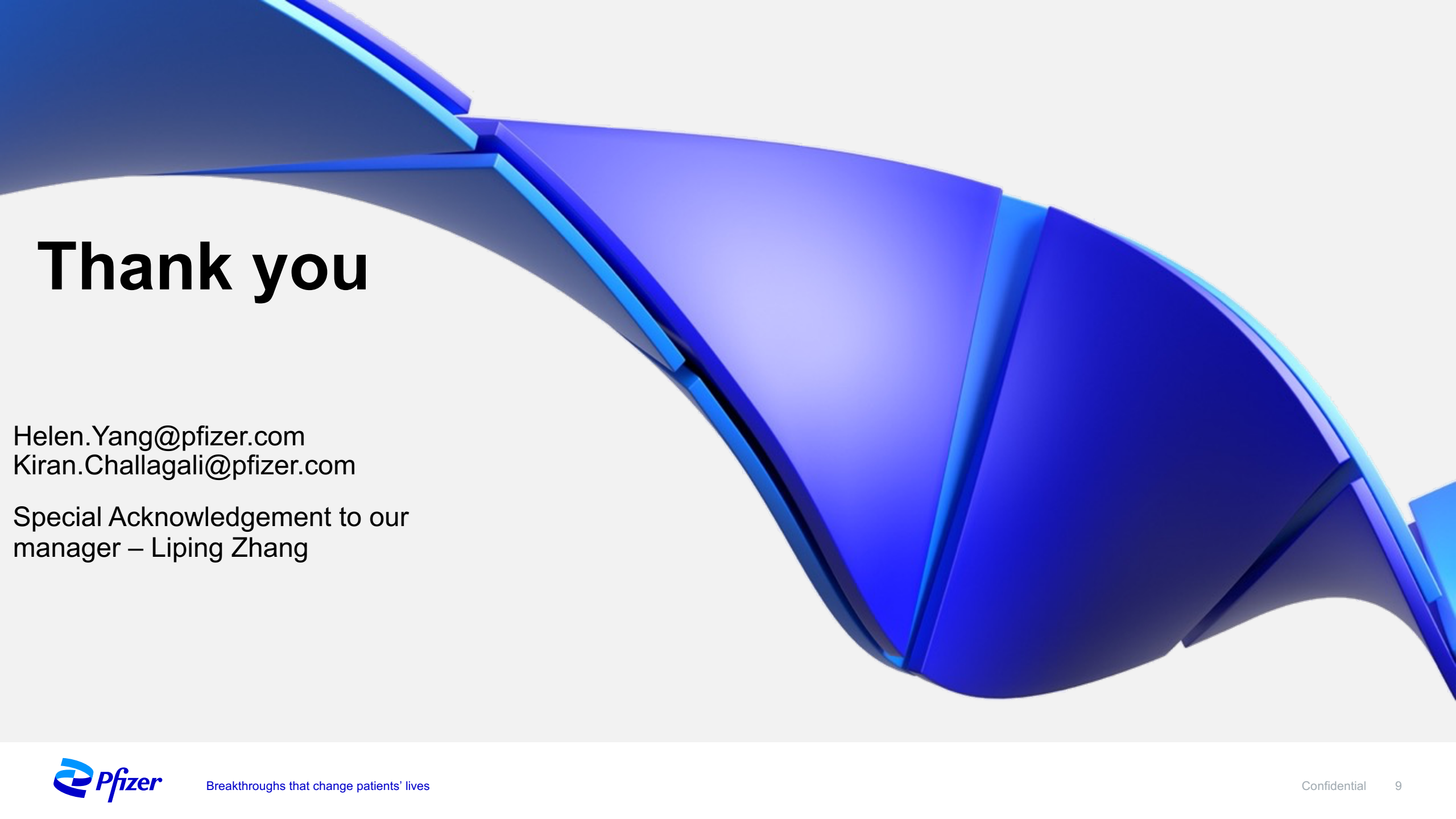
**The team is much
greater than the
sum of its parts**

3

**Process and
technology are
key enablers, but
dedicated people
got the job done**

4

**Lessons learned
must be
integrated into
how we do
business**



Thank you

Helen.Yang@pfizer.com
Kiran.Challagali@pfizer.com

Special Acknowledgement to our
manager – Liping Zhang