



The role of the HPRA: Authorisation and safety monitoring of Covid vaccines in Ireland

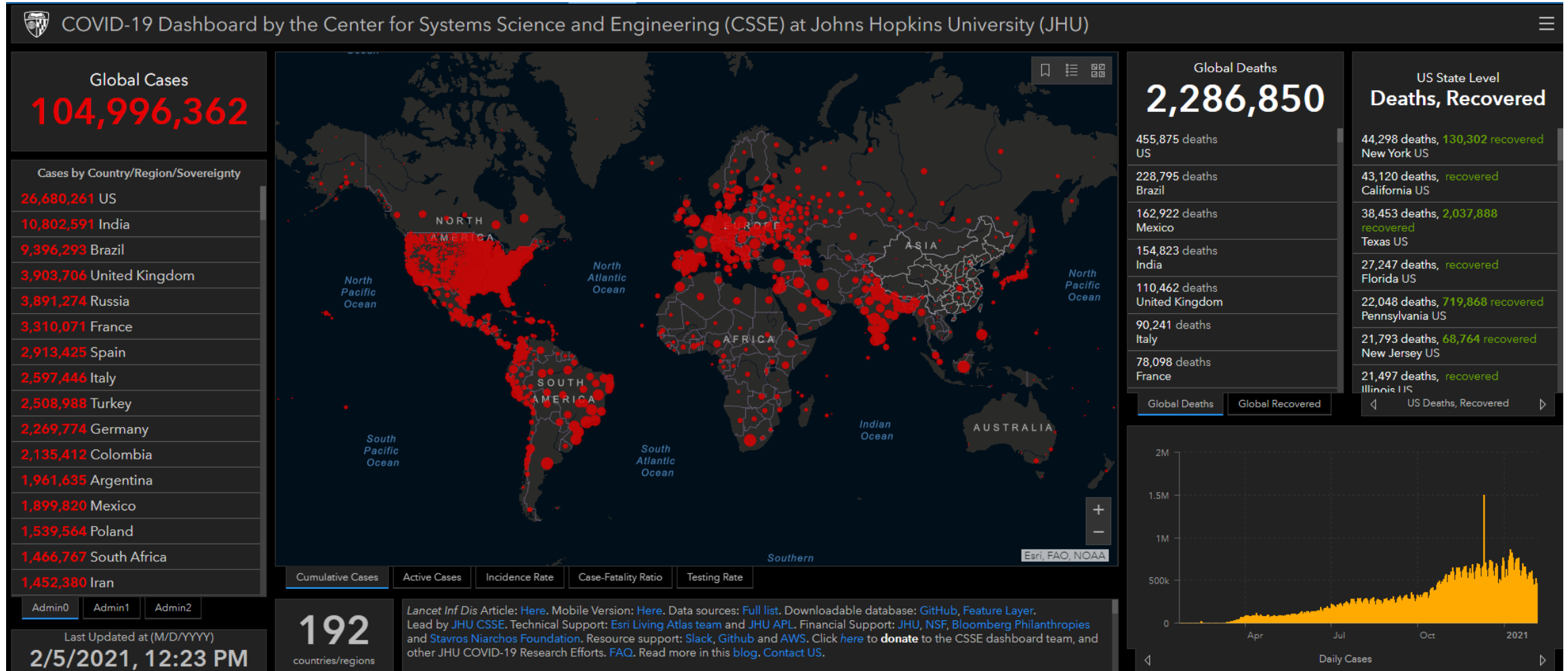
Dr Lorraine Nolan

10th February 202



Background

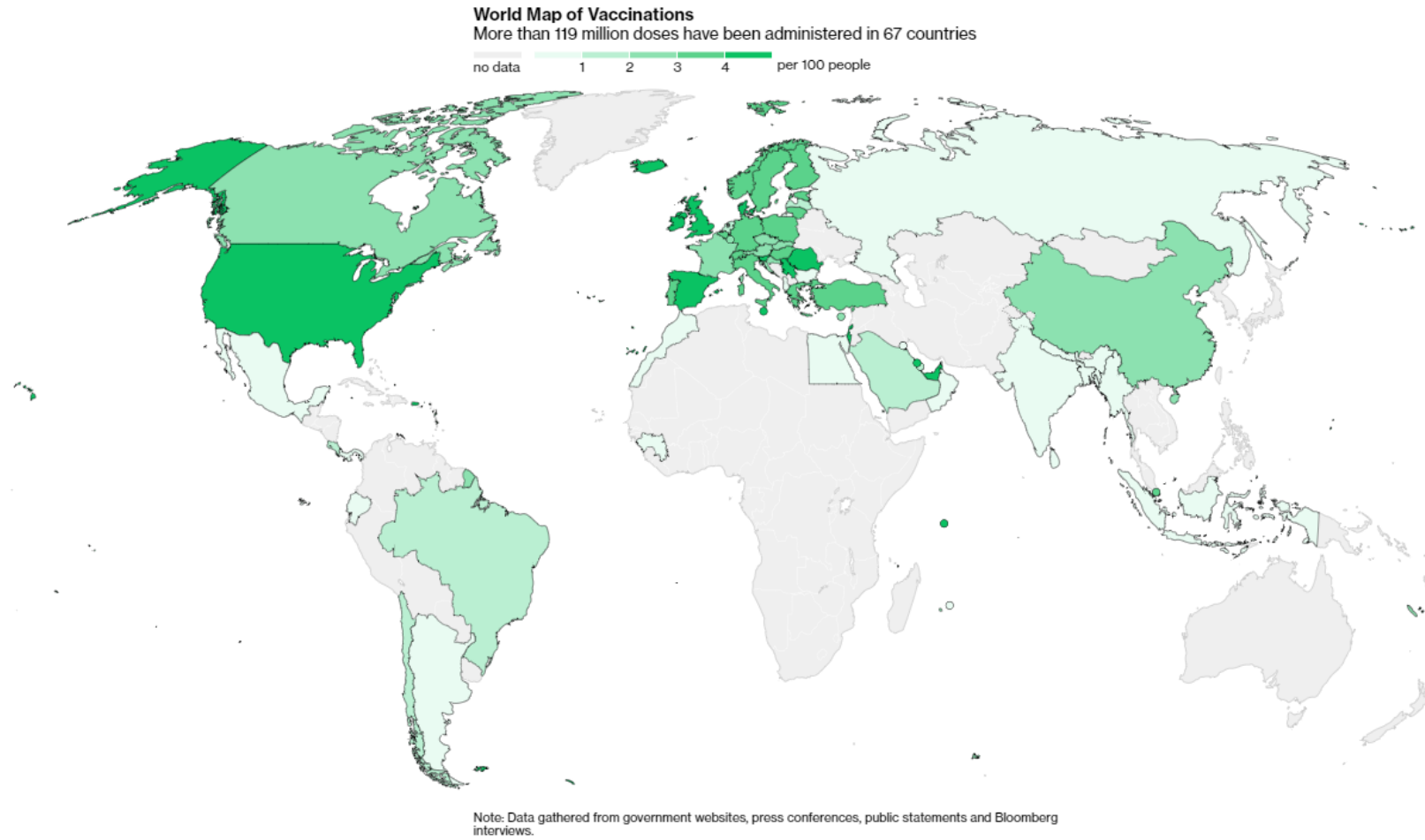
Unprecedented Global Crisis





Background

Unprecedented Global Response



Over **119 million people vaccinated** globally to date.



Scientific Progress

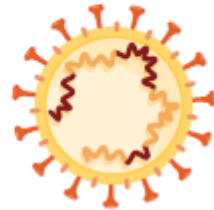
Vaccine Technologies

Traditional Virus Vaccines

Inactivated vaccines contain SARS-CoV-2 that is grown in cell culture and then chemically inactivated



Live attenuated vaccines are made of genetically weakened versions of SARS-CoV-2 that is grown in cell culture



Protein and Protein Nanoparticles

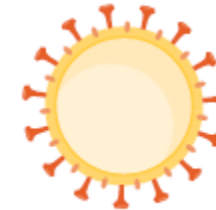
Recombinant spike-protein-based vaccines



Recombinant RBD-based vaccines

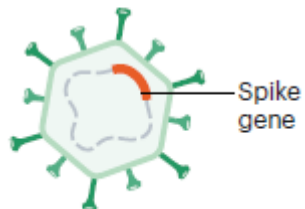


VLPs carry no genome but display the spike protein on their surface



Viral Vector Vaccines

Replication-incompetent vector vaccines cannot propagate in the cells of the vaccinated individual but express the spike protein within them



Replication-competent vector vaccines can propagate to some extent in the cells of the vaccinated individual and express the spike protein within them



Inactivated virus vector vaccines carry copies of the spike protein on their surface but have been chemically inactivated

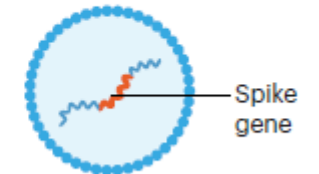


Nucleic Acid Based Vaccines

DNA vaccines consist of plasmid DNA encoding the spike gene under a mammalian promoter



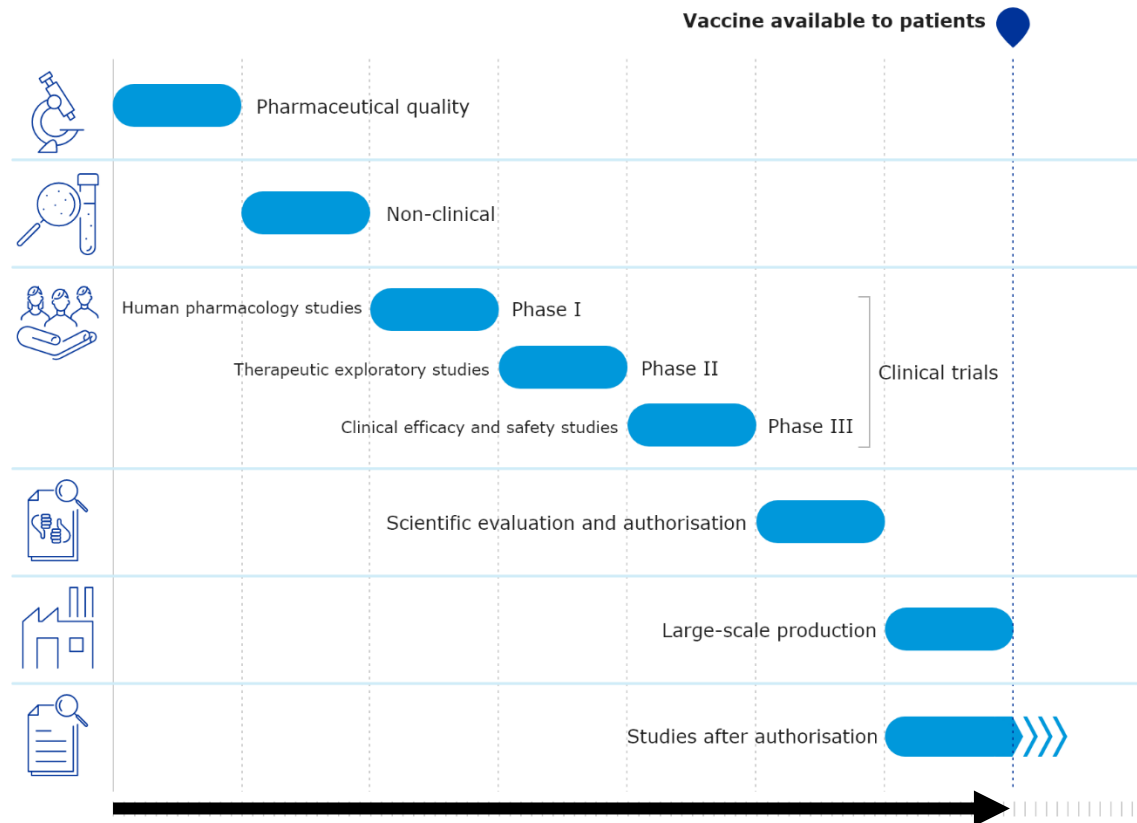
RNA vaccines consist of RNA encoding the spike protein and are typically packaged in LNPs



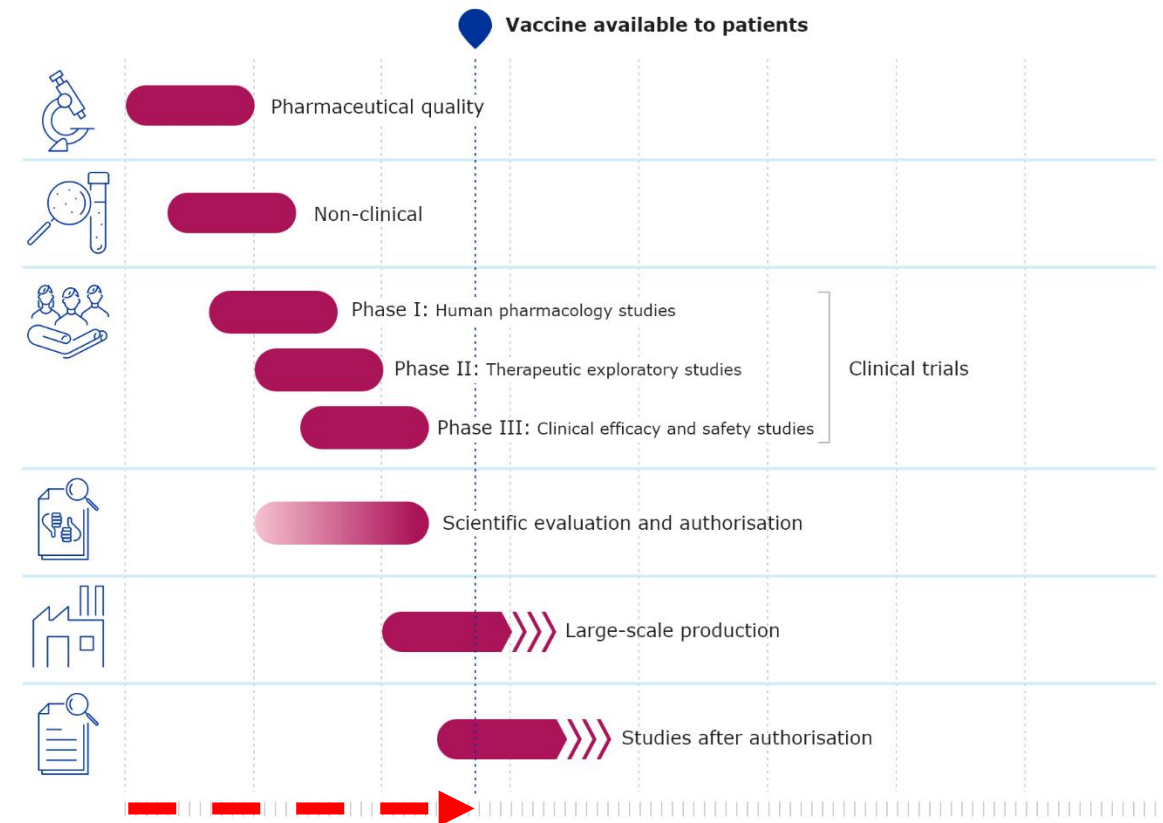


Regulatory Agility

Standard v Accelerated Process



Standard Process



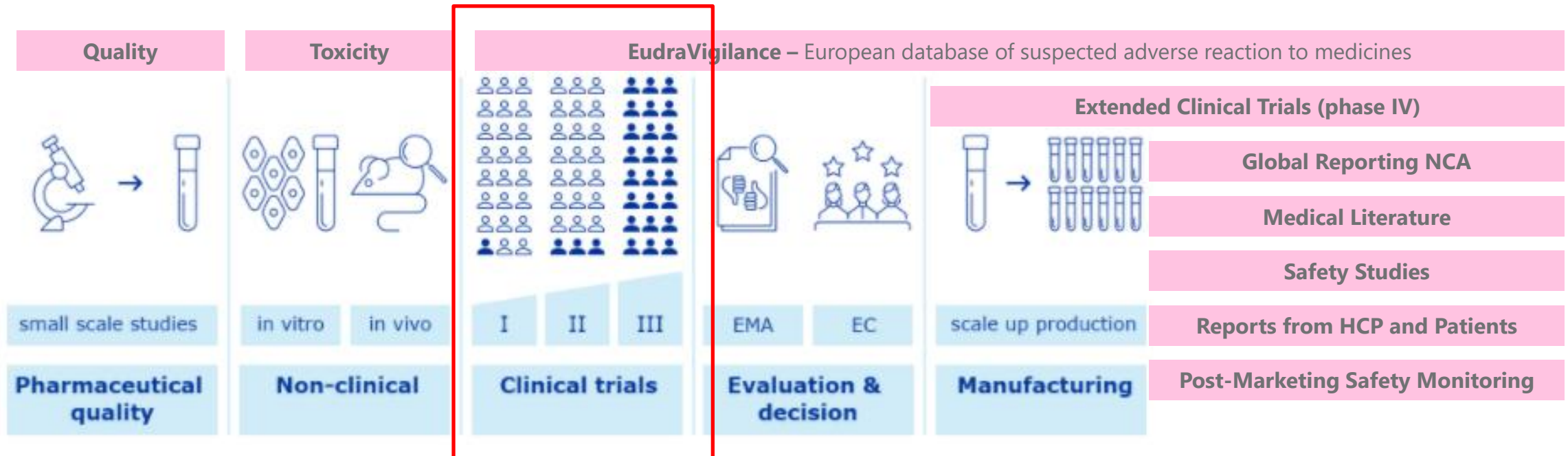
COVID-19 Vaccines



Safety Monitoring

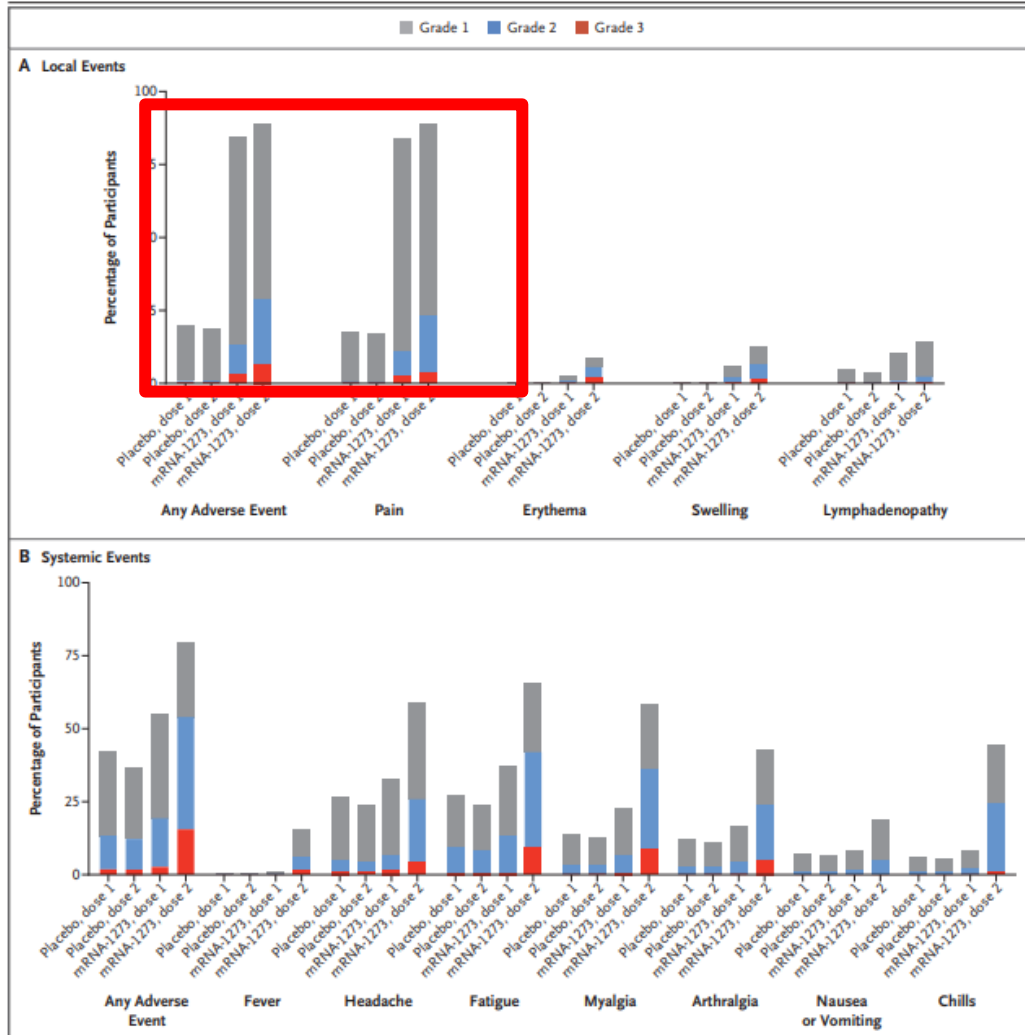
Vaccine Lifecycle Overview

- Vaccine Development Stage
- Vaccine Safety Monitoring



Pre-Authorisation Safety Monitoring

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine



Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine



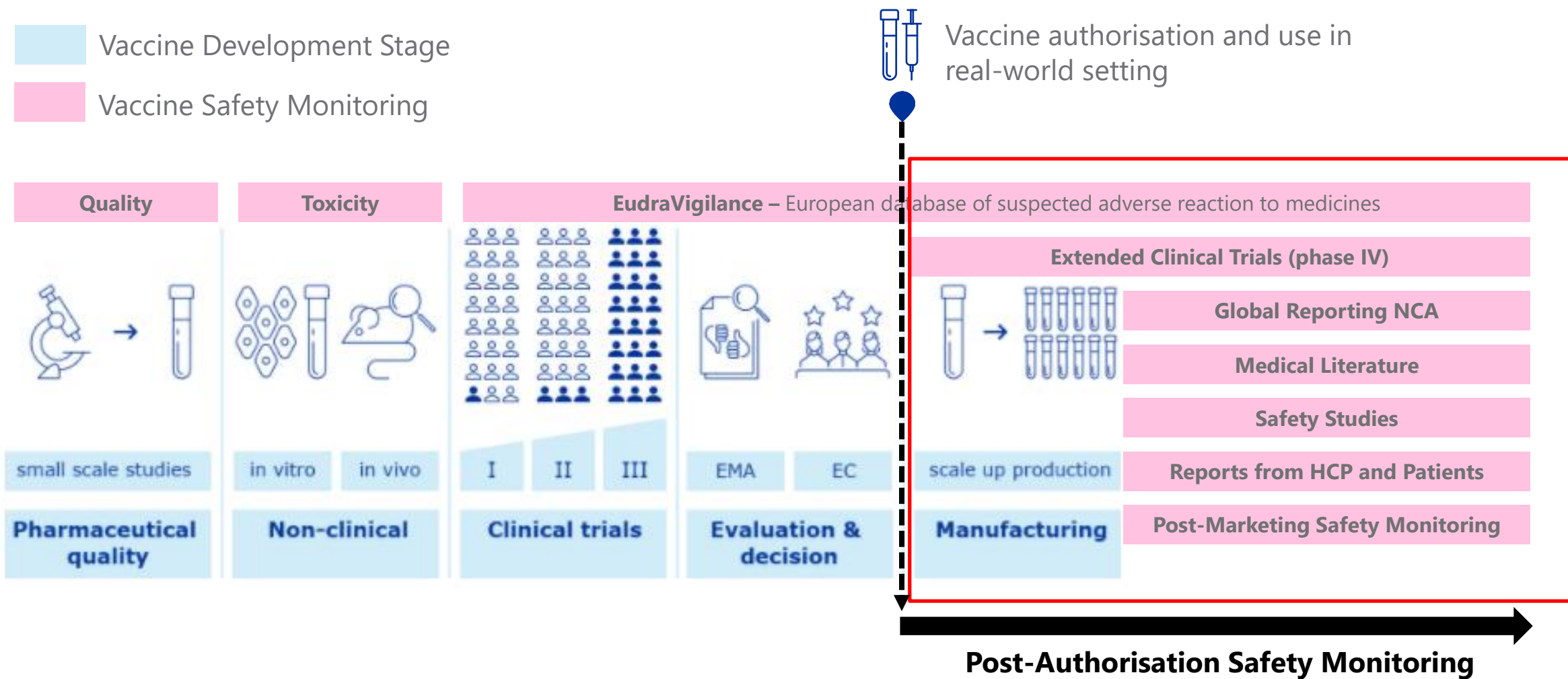


Safety Monitoring

Post-Authorisation

Vaccine Development Stage

Vaccine Safety Monitoring



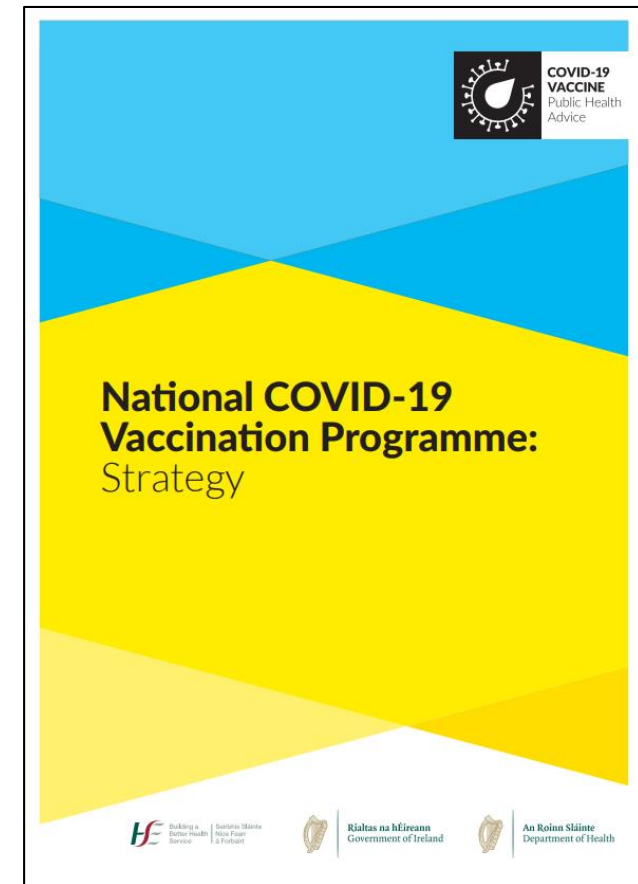


Safety Monitoring

Specific Role of HPRA

HPRA Safety Monitoring Actives:

- Overseeing enhanced passive reporting from health-care professionals and members of the public, as well as the HSE, of suspected adverse reactions, with onward reporting of anonymised individual case safety reports to the EMAs Eudravigilance database, for inclusion in further analysis to detect and evaluate any potential signals.
- Aligning with EMA plans to communicate regular and periodic public updates on safety experience.
- Involvement in EU-wide safety reviews, including of periodic data provided by the marketing authorisation holders, as well as any emerging data from other sources, such as independent studies.
- Escalation of emerging safety issues, if any, as appropriate.



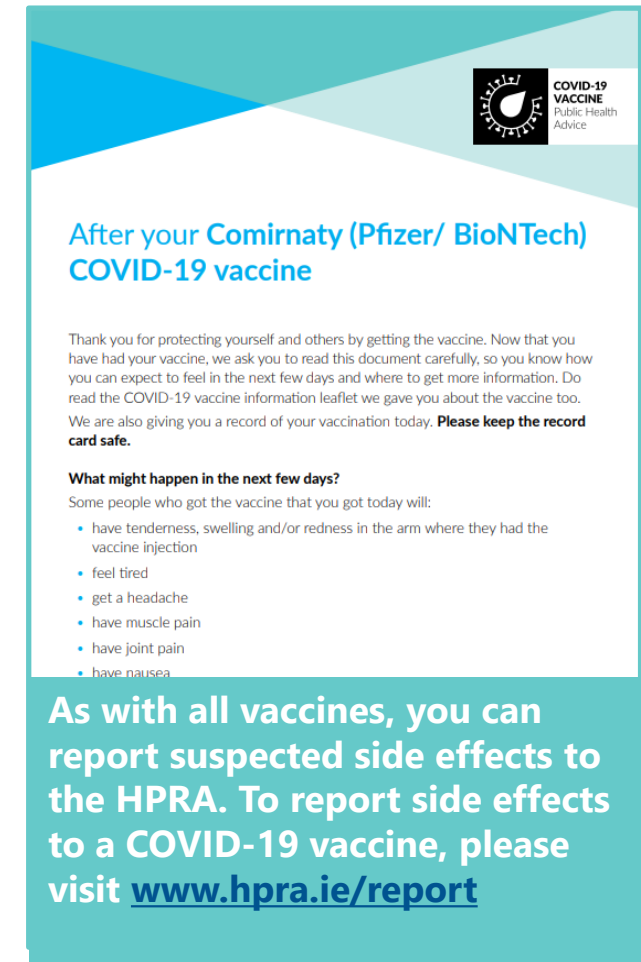



Safety Monitoring

Specific Role of HPRA

HPRA Safety Monitoring Actives:

- The HPRA is **proactively calling** for reports of suspected side effects following vaccination from members of the public and healthcare professionals to:
 - **Further inform** what we already know about the safety profile;
 - **Act as an early warning system** for the identification of previously unrecognised or rare side effects (signal detection).
- Safety monitoring at an **Irish, European and global level.**
- The **largest and broadest safety monitoring programme of any medicine ever** with regulators across the globe sharing new and emerging data.



 COVID-19 VACCINE Public Health Advice

After your Comirnaty (Pfizer/ BioNTech) COVID-19 vaccine

Thank you for protecting yourself and others by getting the vaccine. Now that you have had your vaccine, we ask you to read this document carefully, so you know how you can expect to feel in the next few days and where to get more information. Do read the COVID-19 vaccine information leaflet we gave you about the vaccine too. We are also giving you a record of your vaccination today. **Please keep the record card safe.**

What might happen in the next few days?
Some people who got the vaccine that you got today will:

- have tenderness, swelling and/or redness in the arm where they had the vaccine injection
- feel tired
- get a headache
- have muscle pain
- have joint pain
- have nausea

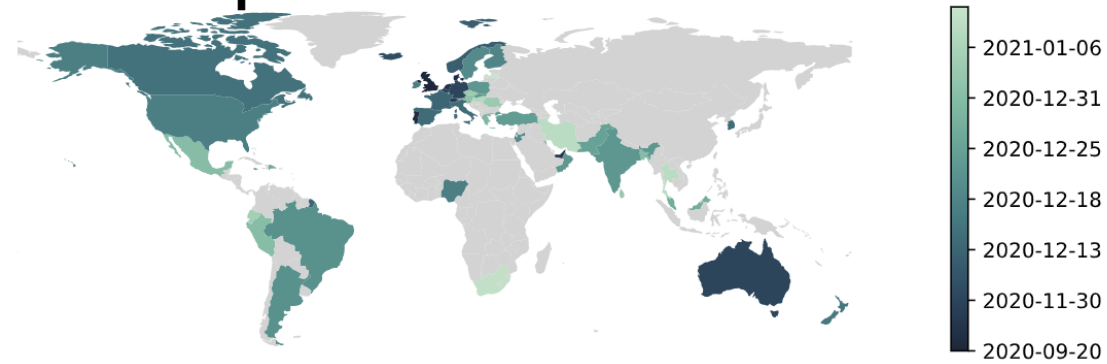
As with all vaccines, you can report suspected side effects to the HPRA. To report side effects to a COVID-19 vaccine, please visit www.hpra.ie/report



Future Considerations

Variants and Vaccine Efficacy

**Map of B.1.1.7 (“UK”) sequence counts
Reported 73 Countries to date**



**Map of B.1.351 (“South African”) sequence counts
Reported 25 Countries to date**



Data from Centre for
Genomic Pathogen
Surveillance



Future Considerations

Variants and Vaccine Efficacy – Evidence for Escape Mutants

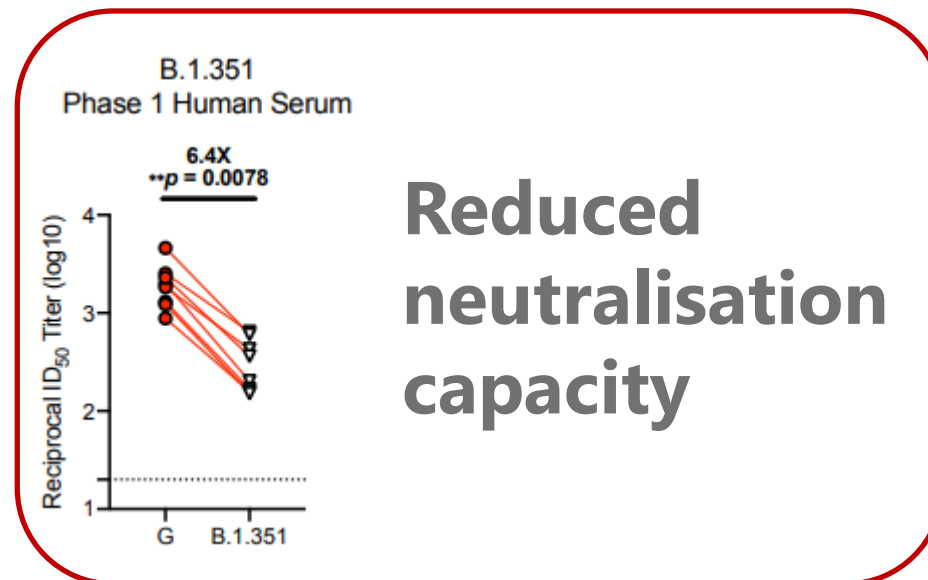
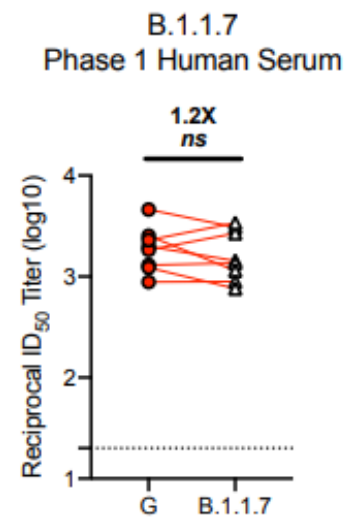


THE PREPRINT SERVER FOR BIOLOGY

mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants

Kai Wu, Anne P. Werner, Juan I. Moliva, Matthew Koch, Angela Choi, Guillaume B. E. Stewart-Jones, Hamilton Bennett, Seyhan Boyoglu-Barnum, Wei Shi, Barney S. Graham, Andrea Carfi, Kizzmekia S. Corbett, Robert A. Seder, Darin K. Edwards

doi: <https://doi.org/10.1101/2021.01.25.427948>



**Reduced
neutralisation
capacity**



Future Considerations

Variants and Vaccine Efficacy – Evidence for Escape Mutants

NOVAVAX

Creating Tomorrow's Vaccines Today

Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial

January 28, 2021



*"In the South Africa Phase 2b clinical trial, **60% efficacy (95% CI: 19.9 – 80.1)** for the prevention of mild, moderate and severe COVID-19 disease was observed in the 94% of the study population that was HIV-negative [...] the primary efficacy endpoint in the **overall trial population**, including HIV-positive and HIV-negative subjects (**efficacy of 49.4%; 95% CI: 6.1 – 72.8**)"*

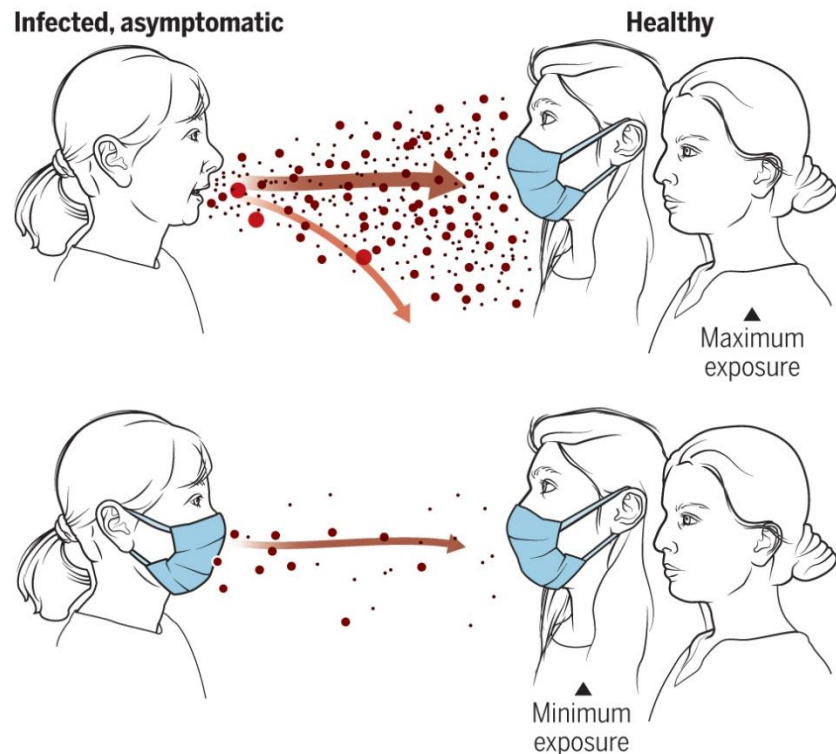
*"Janssen's COVID-19 vaccine candidate was **66% effective overall in preventing moderate to severe COVID-19**, 28 days after vaccination [...] The level of protection against moderate to severe COVID-19 infection was 72% in the United States, 66% in Latin America and **57% in South Africa...**"*



Future Considerations

Transmission

Impact of PH Measures and Vaccines on Transmission

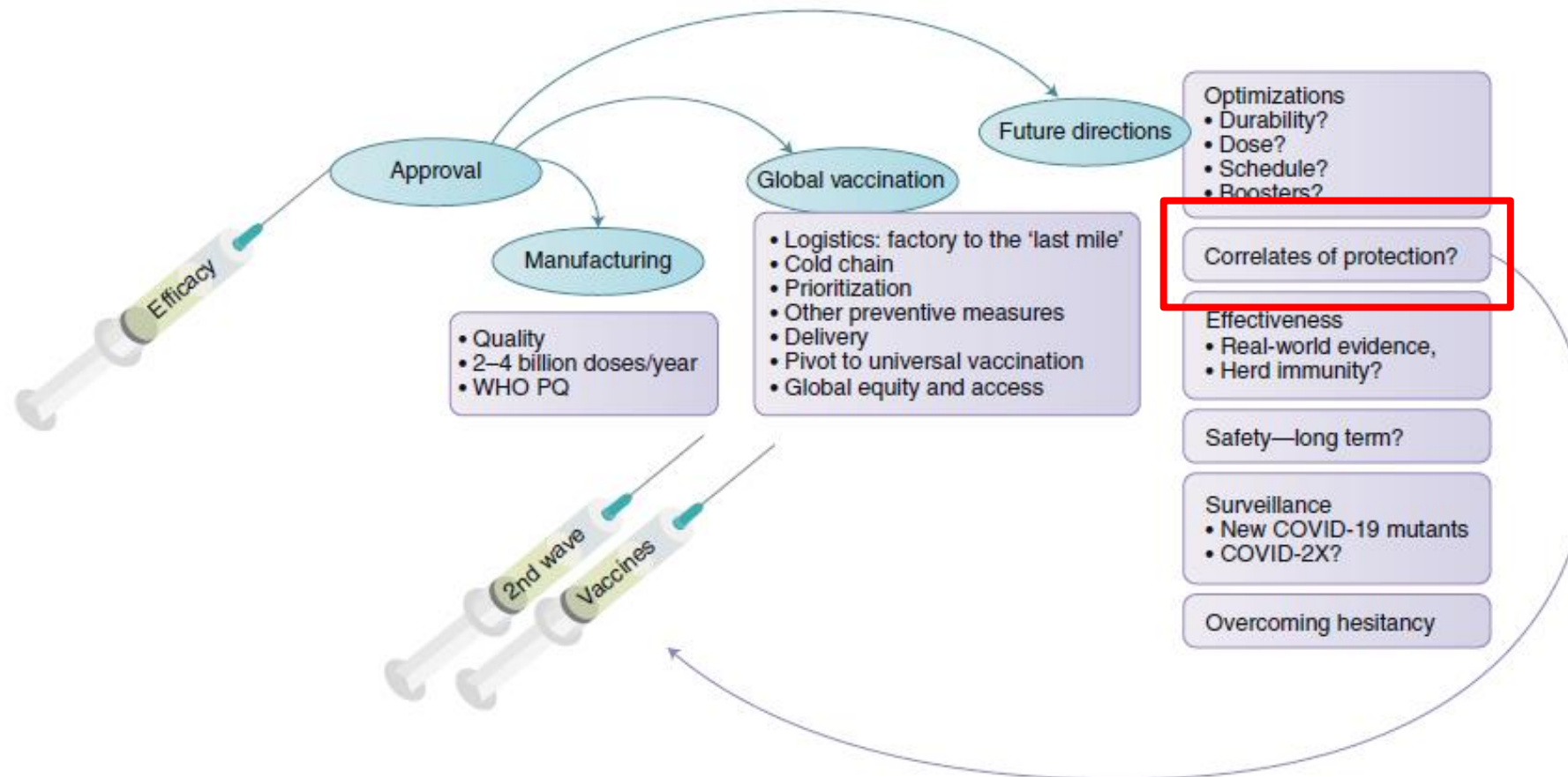


- Protection from disease versus protection from infection
- Evidence of asymptomatic infections in the vaccinated cohorts
- Impact of vaccines on shedding of virus by asymptomatic individuals
- Further data required
- Continue to adhere to public health guidelines



Future Considerations

Vaccines





Conclusion

Hopeful but Cautious

