



Vaccine Alliance

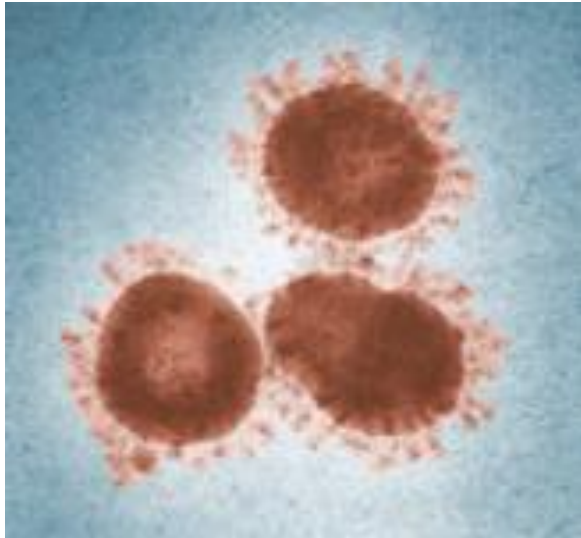
Dr Lorraine Nolan

16th December 2020



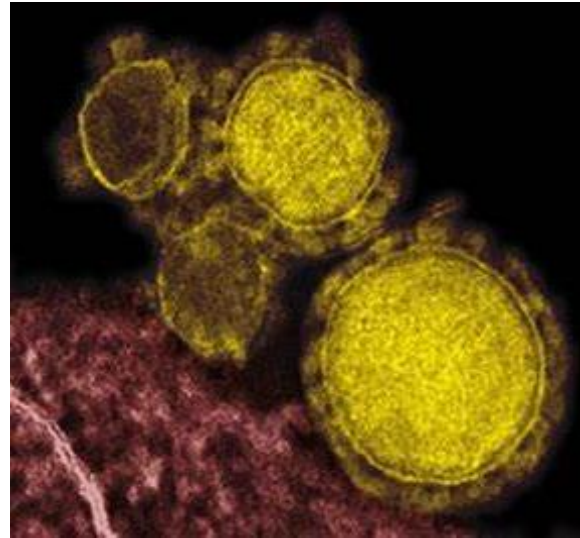
Background

Coronaviruses and SARS-CoV-2



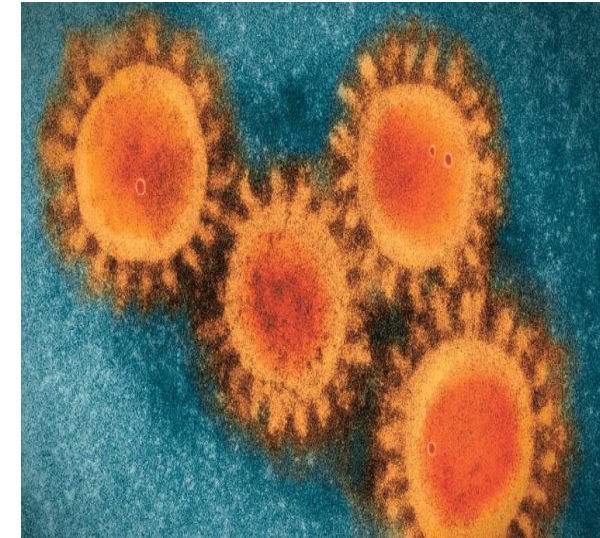
2002-2003

Severe Acute Respiratory
Syndrome
(SARS)



2012-Present

Middle East Respiratory
Syndrome
(MERS)



2019-Present

Severe Acute Respiratory
Syndrome
(SARS-CoV-2)



Background

Unprecedented Global Crisis

COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

Global Cases

73,070,972

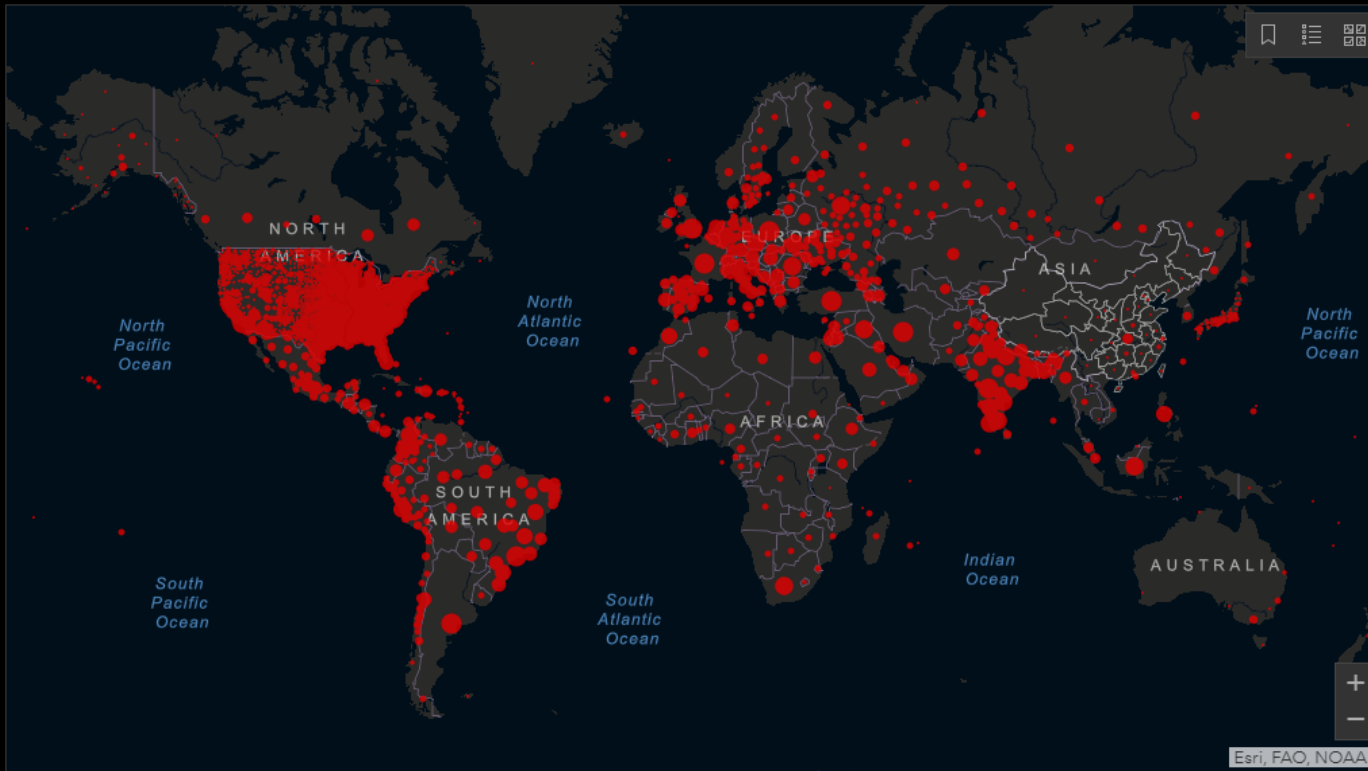
Cases by Country/Region/Sovereignty

- 16,545,465 US
- 9,906,165 India
- 6,927,145 Brazil
- 2,682,866 Russia
- 2,433,975 France
- 1,874,889 United Kingdom
- 1,870,576 Italy
- 1,866,345 Turkey
- 1,751,884 Spain
- 1,503,222 Argentina
- 1,434,516 Colombia
- 1,370,914 Germany
- 1,255,974 Mexico
- 1,147,446 Poland
- 1,123,474 Iran

Admin0 Admin1 Admin2

Last Updated at (M/D/YYYY)

12/15/2020, 4:26 PM



Cumulative Cases Active Cases Incidence Rate Case-Fatality Ratio Testing Rate

191

countries/regions

Lancet Inf Dis Article: [Here](#). Mobile Version: [Here](#). Data sources: [Full list](#). Downloadable database: [GitHub](#), [Feature Layer](#).
 Lead by JHU CSSE. Technical Support: [Esri Living Atlas team](#) and [JHU APL](#). Financial Support: [JHU](#), [NSF](#), [Bloomberg Philanthropies](#) and [Stavros Niarchos Foundation](#). Resource support: [Slack](#), [Github](#) and [AWS](#). Click [here](#) to **donate** to the CSSE dashboard team, and other JHU COVID-19 Research Efforts. [FAQ](#). Read more in this [blog](#). [Contact US](#).

Global Deaths

1,626,712

- 301,264 deaths US
- 181,835 deaths Brazil
- 143,709 deaths India
- 114,298 deaths Mexico
- 65,857 deaths Italy
- 64,500 deaths United Kingdom
- 58,392 deaths

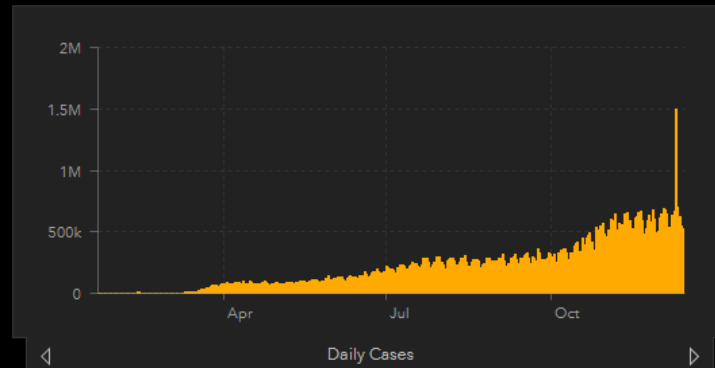
Global Deaths Global Recovered

US State Level

Deaths, Recovered

- 35,427 deaths, **91,366 recovered** New York US
- 24,444 deaths, **1,185,628 recovered** Texas US
- 21,151 deaths, **recovered** California US
- 20,003 deaths, **recovered** Florida US
- 17,775 deaths, **48,951 recovered** New Jersey US
- 15,454 deaths, **recovered** Illinois US

US Deaths, Recovered





Scientific Progress

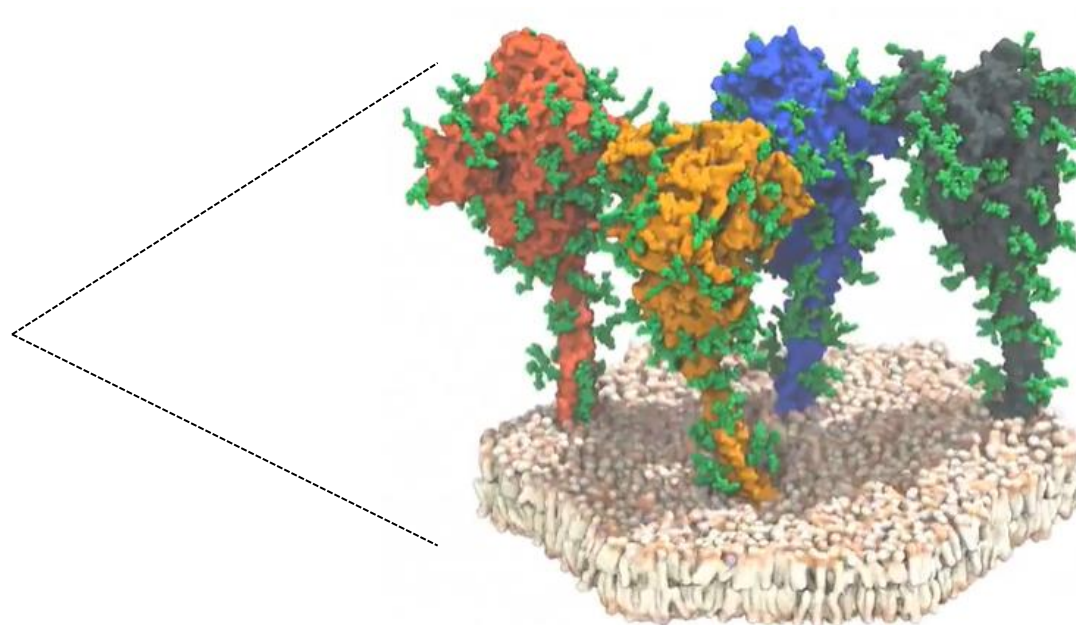
Technologies, Information Sharing and Investment

Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome

GenBank: MN908947.3

[FASTA](#) [Graphics](#)

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A simulation of four spike proteins, each bending on three hinges.
Sören von Bülow, Mateusz Sikora and Gerhard Hummer, Max Planck
Institute of Biophysics



Scientific Progress

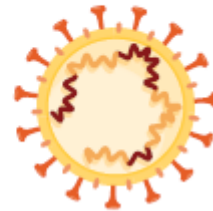
Vaccine Technologies

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

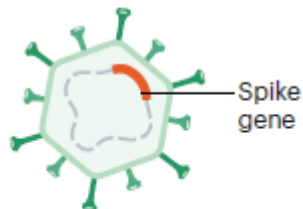


VLPs carry no genome but display the spike protein on their surface



Viral Vector Vaccines

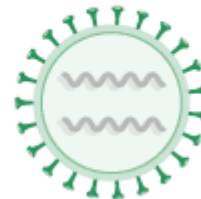
Replication-incompetent vector vaccines cannot propagate in the cells of the vaccinated individual but express the spike protein within them



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

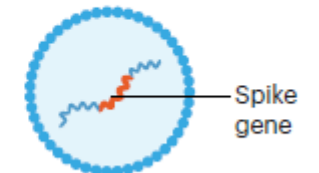


Nucleic Acid Based Vaccines

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





Previous Experience

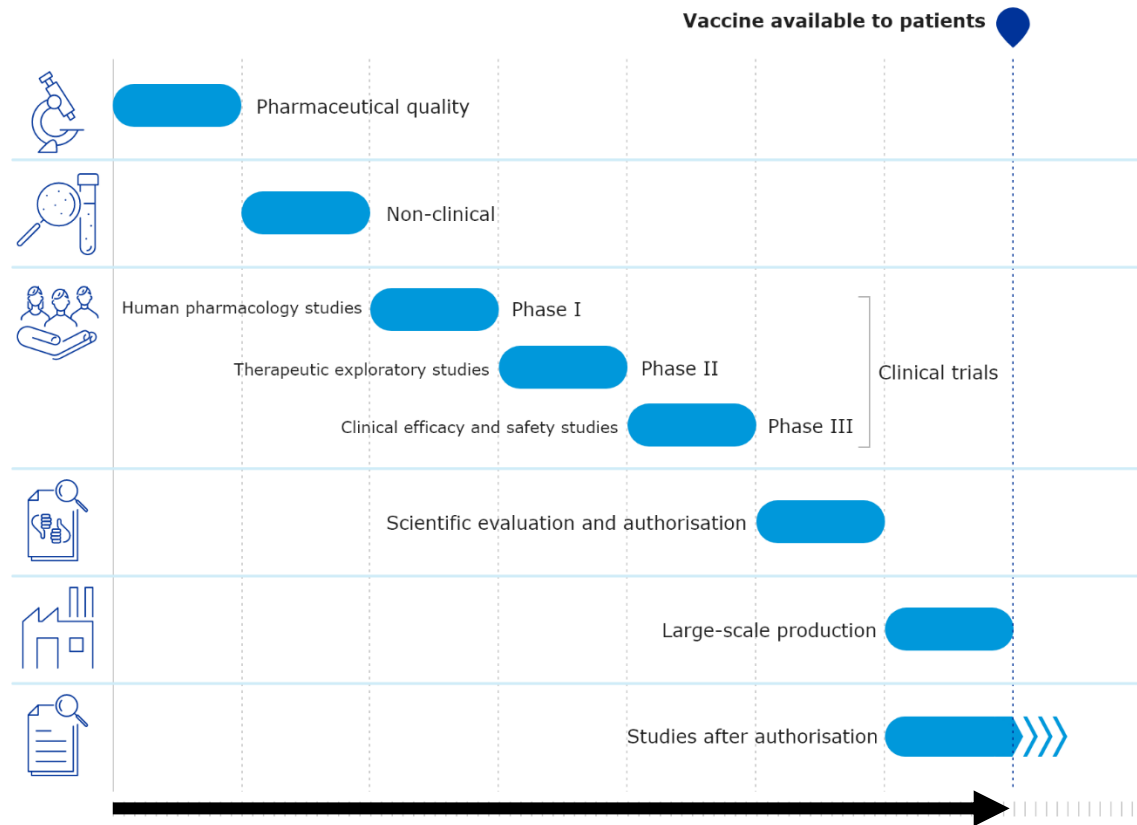
Ebola and Zika



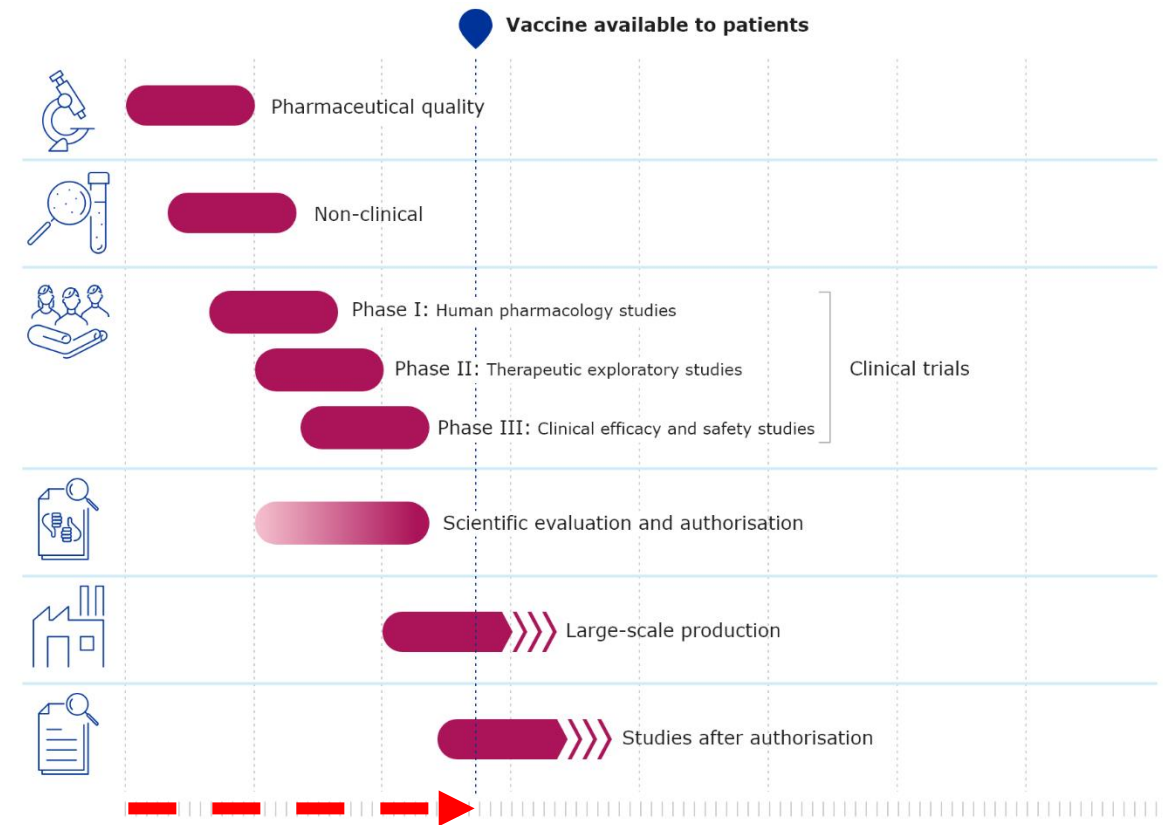


Regulatory Agility

Standard v Accelerated Process



Standard Process



COVID-19 Vaccines



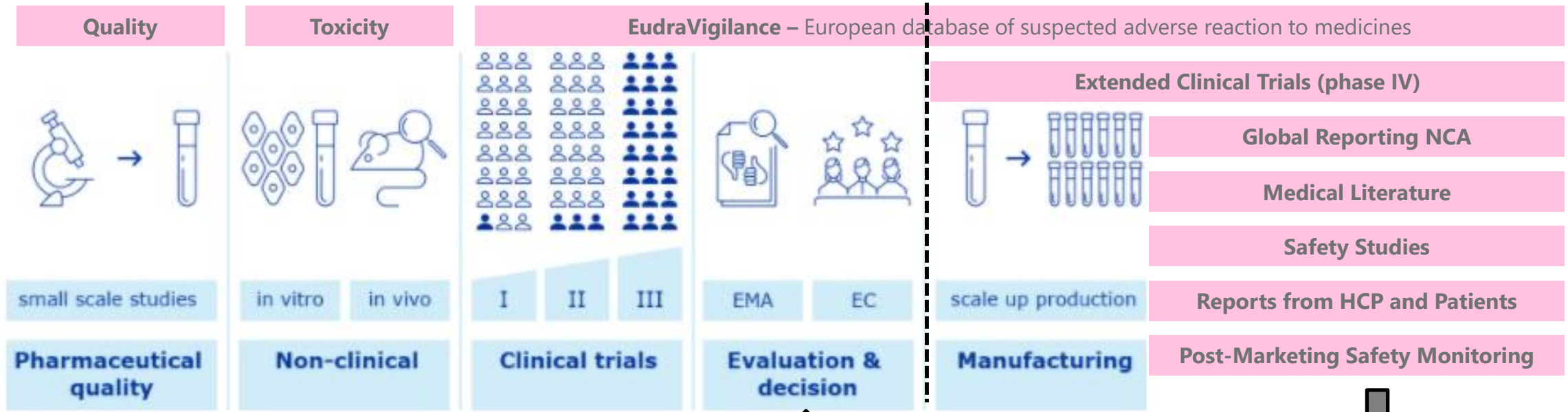
Safety Monitoring

Vaccine Lifecycle

Vaccine Development Stage

Vaccine Safety Monitoring

Official Authorisation



Post-marketing safety monitoring continually assessed

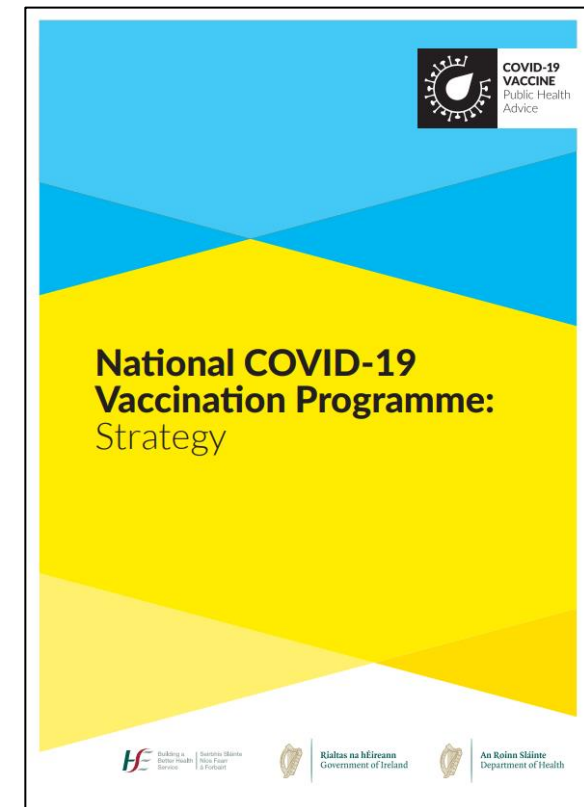


Safety Monitoring

Post Approval

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.
- Onward provision of anonymised vaccine coverage data, to enable scientific analysis of observed rates of adverse events of special interest.
- 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.





Rolling Reviews and Conditional Marketing Authorisations

Leading Vaccine Candidates



Start Rolling Review
CMA Review Start
CHMP Opinion

Oct 6
Dec 1
Dec 21



Start Rolling Review
CMA Review Start
CHMP Opinion*

Nov 16
Dec 1
Jan 12

* Timeline may be subject to change due to later start of rolling review/less early interaction w/EMA



Start Rolling Review
Estimated CHMP Opinion

Oct 1
Q1 2021



Estimated Start Rolling Review
Estimated CHMP Opinion

Dec 1
Q2 2021