# From zero to billions: The story of COVID-19 vaccines

Development of innovative vaccines is complex and risky as it spans from clinical development to manufacturing and control processes. Typically, developing a new vaccine takes at least a decade.

When the SARS-CoV-2 coronavirus was first identified, most optimistic assumptions forecasted vaccine availability by summer of 2021.

The fact that the first COVID-19 vaccines were approved by different regulatory authorities worldwide and made ready for large-scale immunisation programs in December 2020 is an extraordinary achievement in the history of modern vaccination.

The next challenge ahead is to ensure that vaccines are available in sufficient quantities to cover the global population. According to WHO, at least 60 to 70% of the population needs to have immunity to break the chain of COVID-19 transmission<sup>(1)</sup>.

#### **Unprecedented 1-year achievements** MARCH 2020: DECEMBER 2020: OCTOBER 2020 MARCH 2021: COVID-19 pandemic the European Medicines Agency starts a first First COVID-19 vaccine Four COVID-19 vaccines declared by the WHO rolling review of data on COVID-19 vaccine approved in EU approved in EU Clinical development of Covid-19 vaccines Manufacturing of Covid-19 vaccines at risk at global scale (continuous process) Regulatory rolling review of data and Conditional Marketing **Authorisation Application submission (CMA)**



### R&D of COVID-19 vaccines: Investment, knowledge and network

Vaccine development is typically taking 10 to 15 years from research and development to large-scale availability. Whilst companies have followed the highest regulatory standards to demonstrate the safety and efficacy of candidate vaccines, several key factors contributed to reducing drastically the development timelines of COVID-19 vaccines.



Previous knowledge on coronaviruses following the SARS epidemic in 2002 and MERS in 2012



Rapid availability of the virus genetic sequence



The use of new vaccine technologies (mRNA and viral vectors) and their significant progress in research, spanning 20 years



High prevalence of the disease allowing to accumulate rapidly the number of cases needed to demonstrate vaccine efficacy



Unprecedented level of collaboration on R&D between small, medium and large companies and with academics



## Factors for successful manufacturing upscale

In contrast to the step-by-step approach typically taken for developing vaccines in order to reduce financial risks, massive efforts were **undertaken to scale up COVID-19**vaccine manufacturing from the very early stage of clinical development, before any indication that a candidate vaccine could be promising. Some key factors contributed to scale up vaccine manufacturing:



Unprecedented level of collaboration on manufacturing between pharmaceutical companies and with contract manufacturing organisations



Early investment in ramping up manufacturing in parallel to clinical development



Public-private partnerships and down payments as part of advance purchase agreements supported investment in manufacturing capacities



Increasing at risk production of equipment, raw materials, reagent, disposables and packaging components



Acceptance of multi-dose presentations and adapted regulatory requirements for packaging



### Thorough vaccines manufacturing processes

Vaccines manufacturing is a highly complex process that requires **specific know-how and equipment**. Typically, the manufacturing process is developed, optimized and finetuned over several years. Due to the high medical need for COVID-19 vaccines, **manufacturers focused their efforts on ramping up the manufacturing capacity**. This is why manufacturing processes of all COVID-19 vaccines are not fully optimized at the time of regulatory approval, compared to past commercially-approved vaccines.



Raw materials reception



Active ingredient manufacturing



Formulation



Filling and packaging



I ot release



Shipment

To produce a new vaccine, all production steps require adaptation of equipment, recruitment and training of qualified personnel, transfer and validation of methods, quality control tests, and certification of compliance with Good Manufacturing Practices<sup>(2)</sup> by authorities.

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<sup>(2)</sup> https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice

Today, vaccine manufacturers are pursuing every avenue to accelerate production and continue to explore possibilities for further collaborations to scale up manufacturing.







