A vaccine to protect against the COVID-19 disease caused by the SARS-Cov-2 virus is urgently needed to protect human life, stop the epidemic and prevent its resurgence, and ultimately to allow us return to a normal life.

The platforms and networks needed, for rapid vaccines development to meet this challenge as quickly as possible, can also help us to be better prepared in case of future pandemics.

The development of a new vaccine, including global scale-up of manufacturing, normally takes more than a decade and costs around €2 billion. A significant part of the costs is due to the high number of unsuccessful candidates because of safety or efficacy issues. Therefore, multiple candidates are developed simultaneously to increase the chances of success.

A vaccine, as any medicinal product, can only be placed on the EU market after authorisation has been granted either at national or EU level. In both cases, this can only take place after the European Medicines Agency (EMA) or national regulators evaluate its quality, safety and efficacy on the basis of data from the clinical trials and after a positive benefit-risk analysis.
EMA and the European Commission are prepared to proceed with marketing authorisation within the shortest possible timelines. However, the essential factor for rapid approval of a new vaccine is the time required to generate data from clinical trials and the robustness of this data to demonstrate that the vaccine is safe and effective. Fast track approval must not compromise sound assessment of safety and efficacy of any vaccine.

Furthermore, manufacturing the billions of doses that will be required to prevent future outbreaks, and ensuring that they are affordable and accessible, is a huge challenge that will require close co-operation between the pharmaceutical industry and the public sector.

3 What R&I actions is the EU already taking

The EU continues to fund research actions and infrastructures through Horizon 2020, its programme for research and innovation. This includes dedicated emergency funding for coronavirus in March 2020 that is supporting two new projects on CoVid-19 candidate vaccines.

In addition, the InnovFin Infectious Disease Financing Facility (InnovFin IDFF) co-developed by the Commission and the European Investment Bank (EIB) and also funded under Horizon 2020, is to provide up to €80 million to CureVac AG, Germany, to scale up development and production of a vaccine against the coronavirus.

A number of co-operative platforms or mechanisms that already exist at European and international level are refocussing effort on COVID-19 candidates. They aim to make use of investments into vaccine development and manufacture in general, to spread the risk of development and to accelerate regulatory approval while guaranteeing safety and efficacy.

These infrastructures include the TRANSVAC2 consortium coordinated by the European Vaccine Initiative (EVI), providing services for both prophylactic and therapeutic vaccine development, the European Advanced Translational Infrastructure in Medicine (EATRIS), and the European Clinical Research Infrastructure Network (ECRIN).

The Coalition for Epidemic Preparedness Innovations (CEPI), an international initiative with European input from its inception, receives direct funding from the European Commission and Member States. It combines a strong focus on product development with a competitive element that intends to ensure only the most promising vaccine candidates are supported. CEPI is presently seeking large-scale funding to support the development of eight vaccine candidates with the goal of submitting three for regulatory approval in 2021.

The European Commission is also working closely with the European Medicines Agency (EMA) to accelerate the regulatory pathway for a COVID-19 vaccine.