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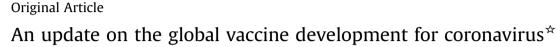
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Diabetes & Metabolic Syndrome: Clinical Research & Reviews

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Dear Editor,

Coronavirus (COVID-19) has created a global crisis and perhaps caused one of the biggest socio-economic tragedies. The world scientific community is struggling hard to develop a solution at the earliest. With the cumulative efforts, the development and implementation of various technological solutions aimed at combating the COVID-19 outbreak are taking shape across the globe. The scientific community is working towards collaborative and fast-paced solutions in terms of therapeutics and vaccines to control the spread of this virus. Globally by September 2020, hundreds of drug companies, biotechnology firms, university research groups, and health organisations were developing more than 500 potential therapies for COVID-19, and they are in various stages of preclinical or clinical research [1-4].

The positive side of early progress towards developing the vaccine for COVID-19 is the evolution of human civilisation with various diseases and previous analysis on SARS-CoV-2, which indicates that SARS-CoV-2 uses the same receptor as SARS-CoV and is approximately 79% genetically similar to SARS-CoV. Various technological platforms for vaccine development are available such as protein subunit vaccines, genetic vaccines, virus vectored vaccines, and monoclonal antibodies for passive immunisation, etc. are under evaluations for COVID-19, with each having their pros and cons [5–7].

For any disease, drug development typically requires several

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https://doi.org/10.1016/j.dsx.2020.10.023 1871-4021/© 2020 Diabetes India. Published by Elsevier Ltd. All rights reserved. years to assure the safety & efficacy and approval of regulatory agencies, such as the EMA and the FDA, related to expedite clinically testing procedures. Fig. 1 shows the detailed stage route of any drug development.

As mentioned in Fig. 1, the clinical development stage is crucial for any vaccine development, and it is divided into three different phases. I) Phase 1 trial: The trial vaccine is given to the healthy volunteers, and its safety and dosing are determined. II) Phase 2: The trial establishes an initial reading of efficacy and further explores safety in small numbers of people having the target disease. III) Phase 3: The trial vaccine is given to a large cohort to determine safety and efficacy. One study which has covered clinical research in the 1980–90s, found that only 21.5% of drug candidates that started phase I trials were approved eventually for the manufacturing stage, and during 2006–15, the success rate of obtaining approval from Phase I to successful Phase III trials was under 10% on average, and 16% specifically for vaccines development [8–10]. That is why a successful n-Cov-19 vaccine will require a cautious validation of its efficacy and adverse reactivity to the targeted population.

The World Health Organization (WHO) has implemented an Access to COVID-19 tools accelerator for coordinating global vaccine development program in collaboration with GAVI and the Coalition for Epidemic Preparedness Innovations. As of September 2020, there were 321 companies developing vaccines. However, no company has completed clinical trials to prove its safety and efficacy. In the mid of September 2020, some 42 vaccine candidates were in the clinical development stage in which 33 in Phase III trials and 9 in Phase II-III trials [11].

Russia has become the first country to approve a COVID-19 vaccine. 'Sputnik V" – formerly known as the 'Gam-COVID-Vac' vaccine, was developed by the Gamaleya Research Institute and Russian Defense Ministry to use the viral vector vaccine method on



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^{*} Google scholar link: https://scholar.google.co.in/citations?user=rfyiwvsAAAAJ &hl=en.

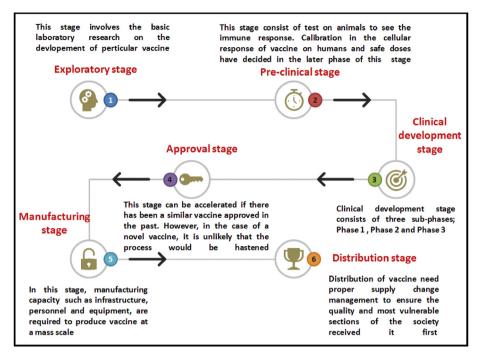


Fig. 1. The route of vaccine development.

Table 1

Lead developers for COVID-19 vaccine development & trial processes.

Vaccine candidate	Technology used	Lead developers	Clinical trial status	Tentative duration References of the trial
mRNA-1273	Lipid nanoparticle dispersion containing mRNA	Moderna	Phase III	July 2020–October [13] 2022
AZD1222	Modified chimp adenovirus vector	The University of Oxford; AstraZeneca; IQVIA; Serum Institute of India	Phase III	May 2020–August [14,15] 2021
Ad5-nCoV	Recombinant adenovirus type 5 vector	CanSino Biologics; Beijing Institute of Biotechnology of the Academy of Military Medical Sciences	Phase III	March 2020 [16] -December 2021
CoronaVac	Inactivated vaccine	Sinovac	Phase III	July 2020–October [17] 2021
JNJ-78436735 (formerly known as Ad26.COV2-S)	Non-replicating viral vector	Johnson & Johnson	Phase III	September 2020 — [18] Early 2021
BNT162	mRNA	BioNTech, Fosun Pharma, Pfizer	Phase III	April 2020–May [19] 2021
Yet to decide the name of the vaccine	Inactivated vaccine	Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	Phase III	July 2020–July [20] 2021

August 11, 2020 [12]. However, the world scientific community has raised doubts about its clinical trials to prove its safety and efficacy. Table 1 shows major COVID-19 vaccine candidates currently in Phase 3 trials. Indeed the list is not comprehensive but a short description of significant work towards vaccine development.

The current global pandemic has crippled the world in terms of development, quality infrastructure, economy, human health, and life. We have provided an up to date overview of the world scientific efforts dedicated to safe and effective vaccine development and possible solution for COVID-19. We believe that the vaccine should be effective and safe for human beings, and hence it should only be permitted for use after duly confirming its efficacy and safety in the clinical trials on a large number of subjects. It should not be rushed into for human use, for political reasons.

Declaration of competing interest

There is no conflicts of interest.

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