Editorial

When we will have a Corona Vaccine

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More than 170 teams of researchers are running to develop a safe & effective vaccine to combat corona/ Covid-19. Their progress upto 11th August'20 can be outlined as (Source-WHO, last updated 11.08.20):

Pre-Clinical: Vaccines not, yet in human trials- 139
Phase-1: Vaccines in small scale safety trials- 25
Phase-2: Vaccines in elaborate safety trials- 17
Phase-3: Vaccines in efficacy trials at large scale- 7
Approved: Vaccines approved for general use - 0

Researchers throughout the world are trying for the development of an active vaccine against Covid-19 with more than 170 candidate vaccines now tracked by the World Health Organization (WHO). Vaccines normally require years of testing and another sufficient time to produce at large scale, but the scientists are trialing to develop a corona virus vaccine within 12 to 18 months. Vaccines mimic the virus or a part of the virus - they protect against, stimulating the immune system to develop antibodies. They must follow higher safety standards than other drugs because they are given to millions of healthy people.

Recently on 12.08.20 Russian health authorities have approved a corona virus vaccine which has yet to complete clinical trials. In the **pre-clinical stage** of testing researchers give the vaccine to animals to see any enhancement of immune response. In **phase-1** of Clinical testing the vaccine is given to a small group of people to determine whether it is safe & to learn more about the immune response it provokes. In **phase-2**, the vaccine is given to hundreds of people so scientists can learn more about its safety and correct dosage. In **phase-3**, the vaccine is given to thousands of people to confirm its safety including rare side effects and effectiveness. These trials involve a control group which is given a placebo.

Vaccine in clinical trials

University of Oxford/ Astra Zeneca

The vaccine is delivered via a chimpanzee virus, called the vaccines vector. The vector contains the generic code of the protein spikes found on the corona virus and triggers a strong immune response in the human body. The vaccine is in a combined phase-2 and phase-3 trials in the UK and has recently gone into phase-3 trials in South Africa and Brazil.

Moderna/ NIAID

American biotech company Moderna is developing a vaccine candidate using messenger RNA (or mRNA for short) to trick the body into producing viral proteins itself. No mRNA vaccine has ever been approved for an infectious disease and Moderna has never brought a product to market. But proponents of the vaccine say it could be easier to mass production than traditional vaccines.

Sinovac

Chinese company Sinovac is developing a vaccine based on inactivated Covid-19 particles. The vaccine has shown a promising safety profile in the early stages of testing and is now moving into phase-3 trials in Brazil.

Moving into phase-3 trial are: 1) Wuhan Institute of Biological products/ Sinopharm, 2) Beijing Institute of Biological products/ Sinopharm, 3) Bio N Tech/ Fosum pharma/ Pfizer.

Moving into phase-2 trials are: Bharat Biotech, Novavax, Cadila Healthcare Limited, Cansino Biologies Inc/ Beijing Institute of Biotechnology, Anhul Zhifei Langcom Biopharmaceuticals, Arctures/ Dalke NUS, Kentucky Bioprocessing Inc, Inovio pharmaceuticals/ International Vaccine Institute, Janssen Pharmaceutical Companies, Institute of Medical Biology/ Chinese Academy of Medical Sciences, Genexine Consortium, Osaka University/ AnGes/ Takara Bio, Vaxine Pty Ltd/ Medytox, Medicago Inc, University of Queensland/ CSL/Seqirus, Gamaleya Research Institute, Clover Biopharmaceuticals Inc/ GSK/ Dynavax, Imperial College London, Curevac, Peoples Liberation Army (PLA) Academy of Military Sciences/ Walvax Biotech, Medigen vaccine Biologics corporation/ NIAID/ Dynavax.

University of Melbourne/ Murdoch Children's Research Institute

In Australia they are conducting a phase-3 trial using a nearly 100-year-old tuberculosis vaccine. The vaccine is not thought to protect directly against Covid-19 but might boost the body's non-specific immune response.

Russia registers the world's first Covid-19 vaccine, Putin says, his daughter was given a shot on 12.08.20. He says vaccine has been approved for use. The New York Time says Russia approves

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Corona virus vaccine before completing tests. Aljazeera says not enough information to evaluate Russian coronavirus vaccine. The major powers are locked in a global race for a vaccine that President Trump, Mr. Putin and Xi Jinping are treating as a proxy war for their personal leadership and competing national systems. Health officials worry that Russia is trying to snatch a victory by cutting corners. In Russia, the minister of health, Mikhail Murashkov has said that the country will begin a mass vaccination campaign in the fall, and said on 11.08.20 that it would start with teachers and medical workers this month.

Vaccines generally go through three stages of human testing before being approved for widespread use. The first two phases test the vaccine on relatively small groups of people to see if it causes harm and stimulates the immune system. The last phase, known as phase-3, compares the vaccine to a placebo in tens of thousands of people. The Russian Scientific body that developed the vaccine, the Gamaleya Institute, has yet to conduct phase-3 trials. That final phase, however, is the only way to know with statistical certainty whether a vaccine can prevent an infection and how effective it is. And because it tests a much larger group of people, a phase-3 trial can also detect more subtle adverse effects of vaccine that earlier trials could not.

The Russian vaccine uses two strains of adenovirus that typically cause mild colds in humans. Scientists genetically modified them to cause infected cells to make protein from the spike of the new coronavirus, officials have said. The approach is similar to the one used in a vaccine developed by Oxford University and Astra Zeneca that is now undergoing phase-3 tests in Britain, Brazil and South Africa. Russia also tested the vaccine on soldiers raising concerns about consent though the ministry of Defense said that all the soldiers had volunteered. Kirill Dimitriev, the Head of a Government-controlled fund that is vested in the vaccine, denied in a conference call with journalists on 11.08.20 that Russia had cut corners on testing, or that it had stolen intellectual property to get ahead. Mr. Dimitriev said Russia relied on a formidable legacy of research into viruses and vaccines in the Soviet Union, and had focused on established technologies, like the approach already used for the Ebola vaccine. He said the Russian vaccine is "more proven, on a larger number of people, than any of the new technologies that people are trying."

On 11.08.20, **Trump Administration** announced a 1.5 billion dollar agreement with **Moderna** to manufacture and deliver 100 million doses of its coronavirus vaccine, which entered a late stage, phase-3 clinical trial last month, the first to that mark in the United States, Russia has already received orders for 1 billion doses from 20 countries and plans to manufacture the vaccine in Brazil, India, South Korea, Saudi Arabia & Cuba, according to the Gamaleya Institute. If Russian Scientists have taken an unorthodox route to the corona virus vaccine, it would not be the first time. Back in the 1950's, a team of researchers tested a promising and ultimately successful, Polio vaccine on their own children.

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases said, "It is likely that at the beginning of next year i.e. 2021 we would have tens of millions of doses available. We are investing in the development and manufacture of the top six vaccine candidates to ensure rapid delivery". The US is only obligated to pay the next tranche of funding if the vaccines are cleared by the Food and Drug Administration. The deals stand so far.

⁕The US has already invested $ 955 million in **Moderna's** vaccine development bringing its total investment upto $ 2.48 billion, the company said.

⁕The US earlier this year awarded **Johnson & Johnson** $ 456 million to develop its vaccine and to deliver 100 million doses of its vaccine.

⁕The US will have the option to order an additional 500 million doses from **Sanofi and GSK** who have predicted their vaccine will enter clinical trials in September'20 and late-stage trials by the end of the year.

⁕US agreed to purchase 100 million doses of their potential coronavirus vaccine from German based **Bio N Tech and Pfizer** in late July'20 to be supplied by the end of 2020.

⁕**Novavax** said it hopes to begin delivering 100 million doses of vaccines by the beginning of the next year (2021).

⁕In June'20 the UK based company **Astra Zeneca** said it is working to deliver 2 billion doses of its vaccine, called AZD-1222 and could begin distributing doses in the fall.

Oxford coronavirus vaccine is in phase-3 trials to conclude by November'20 published in the times of India on 14.08.20. Mass production expected by 2021. It was considered to be the first one to get launched for the public in 2020 will be most likely available to public deployment by 2021. Currently phase-3 clinical trials are being conducted in research facilities across UK, US, Brazil and South Africa. Trials are also expected to start from next week in India in partnership with Serum Institute of India. The Oxford University backed vaccine called

AZD-1222 was one of the first to head into the human trial stage as well as start late stage trials. Its also one vaccine, which has found to be "safest" yet by the WHO in the pre-development phase. Oxford researchers hopeful of seeing the end of clinical trials by November'20 and also signed an agreement with Mexico and Argentine authorities to scale up production in the first quarter of 2021. The university of Oxford has also signed pacts with global vaccine makers and vaccine federations. The WHO also asked top vaccine makers in the race to be a part of its global vaccine alliance. Pune-based serum Institute of India will also be receiving close to $ 150 million "at-risk" funding from Bill & Melinda Gates Foundation to develop a low cost, readily available doses for populations at large.

The Bangladesh Medical Research Council (BMRC) has given clearance to phase-3 trial of a Covid-19 vaccine developed by the Chinese company **Sinovac Biotech.** The vaccine will be applied to around 4,200 healthcare workers of seven Covid-19 dedicated hospitals in Dhaka during the trial period. BMRC Director Mahmood Uz Jahan said "If the trail succeeds, Bangladesh will be in a pole position to get the vaccine for free or at a cheap price". ICDDR'B is in the process of completion other formalities with Sinovac and Bangladeshi authorities. Sinovac had initiated the development of the inactivated vaccine Corona Vac against Covid-19 in January'20. The company got the approval to conduct its phase-1 & phase-2 clinical trials in China that began in April'20. Chinese state-owned pharmaceutical company Sinopharm began phase-3 clinical trials of a Covid-19 vaccine in Abu Dhabi using upto 15,000 volunteers. In a recent summit organized by European commission and Global citizen Bangladesh foreign minister announced the contribution of USD 50,000/- for supporting the development of safe and effective vaccine and to ensure equitable access to health care. Health Minister said on 12.08.20 that the decision to purchase Covid-19 vaccine will be taken in the next week after discussion with the Honourable Prime Minister.

Very recently the Head of Research & Development of **Globe Biotech Ltd.** Dr. Asif Mahmud declared in the media that they are successful in preparing a vaccine against Covid-19. It has got a successful trial upon animal and they are going to give trial on human body. They have started work for vaccine on 08.03.2020, now animal trial is going to be completed and within September'20 they will apply for human trial. If everything becomes OK Dr. Asif said they will be able to deliver it in the market after completing three phases in the month of December'20. In a press release the Institute said as per database of NCBI upto 30th June'20 5743 genome sequence reached to the authority from the whole of the world among which 76 sequences were supplied from Bangladesh. Depending on these Bioinformatics sequences Globe Biotech Ltd. have fixed their target to reach the vaccine production which will be reasonable to this geographical area. At last we want to say Dr. Asif to go ahead and take the challenge of preparing corona vaccine by December'20 for which total Bangladesh is waiting with a great hope.