The advent of COVID-19 pandemic compelled the scientific fraternity world over to concentrate their resources and faculties urgently towards managing the pandemic. From identifying the coronavirus to devising the diagnostics and therapeutics strategy and finally scientific research to develop a safe and immunogenic vaccine, global scientific communities have rallied behind a plan to accelerate and develop COVID-19 vaccine and India has been at the forefront of this effort.

Currently, three vaccine candidates undergoing human trials in India have shown promising results. ICMR backed Bharat Biotech Limited’s indigenous vaccine candidate “COVAXIN” has entered the third phase of clinical trials. Astra Zeneca/Oxford University’s “COVISHIELD” vaccine, jointly developed by Serum Institute of India and ICMR as second sponsor partner, is at advanced stage of the development. ZyCoV-D developed by Zydus Cadila will soon progress to phase-III clinical trials. The view is that unless and until a vaccine is scientifically proven for its safety, it should not be employed in public health measures. Our Honorable Prime Minister Narendra Modi has also reiterated that India would go by scientific advice in deciding which vaccine will be made available to masses and when.

Whenever any large-scale public exercise is considered in the context of India, fears of failure on account of a large population take flight. However, India has consistently allayed all such fears and has demonstrated enormous capabilities in conducting large scale public health schemes like Universal Immunisation Programme (UIP). The challenge of inoculation for the coronavirus vaccine is more complex than previously conducted UIP because it needs to be administered to a larger population base. However, existing infrastructure, recent revamp and technological and transportation advancements has placed India in a strategic position with respect to carrying out large scale vaccination of the population.

Till the time the first shot of the vaccine is administered, we should remain averse to any laxity. ICMR continues to aggressively augment and diversify testing capacities by exploring innovative and indigenous methods. We need to continue with effective implementation of the 5T approach “Test, Track, Trace, Treat and use of Technology” to contain the spread of Coronavirus.
ICMR’s innovative use of indigenous testing method recognized internationally

- Diagnostic platform ‘Truelab’ featured in renowned medical research journal ‘The Lancet’.
- ‘Truelab’ platform has been recommended by World Health Organization for testing of tuberculosis.
- 3500 ‘Truelab’ workstations operational at 1168 sites in 558 districts.

Innovative use of indigenous and affordable COVID-19 diagnostic methods in India has been recognized internationally. Indian Council of Medical Research (ICMR) approved COVID-19 diagnostic platform ‘TrueLab’ has been featured in world’s oldest and renowned medical research journal ‘The Lancet’. A research paper published in November, 2020 mentions that India has successfully used indigenous diagnostic platform ‘TrueLab’ workstations for detection of Coronavirus. The paper can be accessed here: https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(20)30164-6/fulltext

‘Truelab’, an innovative laboratory-in-a-suitcase technology has been used for diagnostic of Tuberculosis in India since 2018 and also for Nipah virus disease & leptospirosis. The ‘Truelab’ workstation includes sample preparation, an RNA extraction system, an RT-PCR machine, and disposable kit components. The workstation is a chip-based, real-time quantitative PCR system that is portable, battery-operated, and fully automated, and weighs around 3 kg. The testing kit was modified to make it compatible with testing of the COVID-19.

Portability and design of ‘Truelab’ make it ideal to work at remote locations and have facilitated deployment of testing facilities in India’s underserved areas. It is more mobile and flexible than the conventional RT-PCR which requires RNA extraction and analysis to be done in two different rooms backed with cold storage and trained experts handling laboratory designed equipment.

ICMR has always encouraged innovative diagnostic approaches that could be cheaper and technologically less demanding than the existing ones to diagnose COVID-19 cases. Indigenous and affordable diagnostics methods have helped in effective containment of epidemic situation in diverse country like India. Currently, total of 3500 ‘Truelab’ workstations are operational at 1168 sites in 558 districts of India.
ICMR backed indigenous vaccine ‘COVAXIN’ commences Phase - III clinical trials

- Phase-III trials will include 25800 participants across 25 sites in India.
- ICMR and Bharat Biotech Ltd to conduct largest ever human trials for vaccine in India.
- ICMR committed to ensuring highest ethical standards during trials.

Indian Council of Medical Research (ICMR) in collaboration with Bharat Biotech Ltd has embarked on the largest phase–III human trials for indigenous vaccine ‘COVAXIN’ to be conducted in India. Phase-III trial will be conducted on 25800 participants aged 18 years and above from across 25 sites in the 10 states. During trials under this phase, two intramuscular injections will be administered to volunteers approximately 28 days apart. The results from phase-III trial are very crucial and will determine the efficacy of the vaccine.

Typically, phase-III studies have the primary objective to demonstrate or confirmation of therapeutic benefits. Studies in phase-III are designed to confirm the preliminary evidence accumulated in phase- II that a vaccine is safe and effective for use in the intended indication and recipient population. Earlier, phase-I/II trials of ‘COVAXIN’ were successfully conducted to evaluate the safety, reactogenicity, tolerability, and immunogenicity of healthy volunteers, who received doses of vaccine formulations. The trial had a total sample size of 1125 healthy volunteers, with 375 volunteers in the phase-I and 750 volunteers in phase-II study.

‘COVAXIN’ has been categorized as an inactivated vaccine derived from a strain of SARS-CoV-2 virus, isolated at the ICMR-National Institute of Virology (NIV), Pune. It means that the virus pathogen is ‘deactivated’ to disable it from causing infection. However, some parts of the virus can be identified by the immune system, leading to an immune reaction.

Hepatitis A, influenza, and polio vaccines used in India are some examples of inactivated vaccines.
Enrollment for PHASE – II/III clinical trials of ‘COVISHIELD’ vaccine completed: ICMR

- 1600 participants identified for trials to be conducted at 14 centers.
- ICMR is providing support and funding to SII in conducting clinical trials.
- Efficacy trials of the vaccine also being done in the UK, Brazil, South Africa and USA.

The strategic alliance between Indian Council of Medical Research (ICMR) and Serum Institute of India (SII) for clinical trials of Oxford University/Astra Zeneca ‘COVISHIELD’ vaccine has advanced into final phases in India. As on 31st October 2020, ICMR has successfully completed enrollment of 1600 participants for phase-III clinical trials in India. At present, Phase-II/III clinical trial of ‘COVISHIELD’ is being conducted at 14 different centers across the country.

‘COVISHIELD’ has been developed at the SII’s Pune laboratory with a master seed from Oxford University/AstraZeneca. The vaccine made in the UK is currently being tested in large efficacy trials in the UK, Brazil, South Africa and USA. The promising results of the trials so far give confidence that ‘COVISHIELD’ could be a realistic solution to the deadly pandemic. ‘COVISHIELD’ is by far the most advanced vaccine in human testing in India. Based on the phase-II/III trial results, SII with the help of ICMR will pursue the early availability of this product for India.

Prof (Dr.) Balram Bhargava, Director General, Indian Council of Medical Research (ICMR), commented, “At present, India plays a prominent role in vaccine development and manufacturing globally. Buoyed by the latest technology and well-equipped facilities, SII has continually proven its research and manufacturing prowess. The partnership is our contribution to lending our expertise and support to bolster our fight against the global pandemic.”

The partnership between ICMR and SII is a stellar example of private-public institutes collaborating to mitigate the dire consequences of the pandemic outbreak. ICMR has funded the clinical trial site fees while SII has funded other expenses for ‘COVISHIELD’. SII has already manufactured 40 million doses of the vaccine, under the at-risk manufacturing and stockpiling license from DCGI.

ICMR has successfully completed enrollment of 1600 participants for phase-III clinical trials in India. At present, Phase-II/III clinical trial of ‘COVISHIELD’ is being conducted at 14 different centers.
Indian Council of Medical Research (ICMR) has yet again adopted an innovative approach towards providing affordable COVID-19 testing facilities. ICMR in collaboration with Spice Healthcare has launched a mobile RT-PCR testing laboratory for the New Delhi-NCR area. Mobile laboratory was inaugurated by Union Home Minister Shri Amit Shah in presence of Union Health Minister Dr. Harsh Vardhan and Director General of ICMR Prof (Dr.) Balram Bhargava on 23rd November 2020 at ICMR Headquarter in New Delhi.

Mobile RT-PCR testing laboratory is a state of art facility capable of conducting 3000 tests per day. RT-PCR tests done through the mobile laboratory will provide a report within six hours. Mobile laboratory is accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and approved by the ICMR.

COVID-19 mobile laboratory will facilitate testing at the source and enable localised containment of the coronavirus. Lab will especially be effective in COVID-19 hotspots as it can be deployed quickly, and clusters of people can be tested at once. 10 such mobile laboratories will be deployed under phase-I.

ICMR has effectively responded to the evolving epidemic through focused and collaborative efforts of the Centre, State/UTs government. It has successfully implemented the strategy of 5T approach “Test, Track, Trace, Treat and use of Technology” efficiently. Exponential increase in testing has led to early identification, prompt isolation & effective treatment of COVID-19 cases along with effective contact tracing. These COVID-19 mobile labs will help in exponentially increasing RT-PCR testing capacity in the New Delhi area and help in containing further spread of Coronavirus.
ICMR issues advisory to restrict indiscriminate use of plasma therapy

- Effectiveness of CPT is dependent on concentration of specific antibodies in convalescent plasma.
- Recipients may receive therapy 3-7 days from onset of symptoms, but not later than 10 days.
- World’s largest trials have concluded that CPT is not effective in treatment of COVID-19 cases.

Indian Council of Medical Research (ICMR) has cautioned that indiscriminate use of convalescent plasma therapy (CPT) in treatment of COVID-19 patients should be avoided.

ICMR has released an advisory which states that benefits of CPT in improving clinical outcomes, reducing severity of disease, duration of hospitalization and mortality in COVID-19 patients are dependent on the concentration of specific antibodies in convalescent plasma that could neutralize the effects of SARS-CoV-2.

ICMR advisory stipulates certain criteria that need to be met in order for plasma therapy to be effective. A potential donor can donate plasma after 14 days of recovery from COVID-19 and the donor can be a male or female in the age group of 18-65 years. Further, the therapy should be administered between 3 to 7 days from onset of symptoms, but not later than 10 days.

However, ICMR has stated that it recently conducted an open label phase-II multicentre randomised controlled trial in India across 39 public/private hospitals on use of convalescent plasma in the management of COVID-19 disease. It was concluded that CPT did not lead to reduction in progression to severe COVID-19 or all-cause mortality in the group that received CPT as compared to the group that did not receive the therapy.

PLACID trial was the world’s largest pragmatic trial on CPT conducted in 464 moderately ill laboratory confirmed COVID-19 affected adults in real world setting wherein no benefit of use of CPT could be established. Similar studies conducted in China and the Netherlands have also documented no significant benefit in improving the clinical outcomes of hospitalised COVID-19 patients.

Convalescent plasma therapy (CPT) did not lead to reduction in progression to severe COVID-19 or all-cause mortality in the group that received CPT as compared to the group that did not receive the therapy.

Convalescent Plasma Therapy has been tried in the past for treatment of viral infections like H1N1, Ebola and SARS-CoV-13 etc. But, its effectiveness as a treatment tool for COVID-19 has not been scientifically proven.
Indian Council of Medical Research observed the 71st constitution day on 26th November 2020. To commemorate the day Prof (Dr.) Balram Bhargava, Director General of ICMR along with scientific, technical and administrative staffs of ICMR recited the preamble. The representatives from ICMR’s institutes across the country joined through video conference.

It was acknowledged that India has been able to steadily build on the strong foundation laid by our founding fathers to emerge as a world leader today. The spirit of scientific rigour instilled into the Indian ethos has ensured that Indians are among the top scientists in agencies across the world. A solemn oath was taken to uphold the values of our constitution.

The Constitution of India was legally adopted by the Constituent Assembly of India on November 26, 1949. Constitution Day or Samvidhan Diwas was first announced by the Ministry of Social Justice and Empowerment in 2015 and is celebrated every year.
ICMR approves dry swab RT-PCR method for COVID-19 detection

The Indian Council of Medical Research has issued an advisory for use of a dry swab-direct RT-PCR testing method for the COVID-19. The diagnostic method involves collecting and transporting the nasal swab in a dry state which makes the transportation and handling of the samples easy and less prone to spillage. In dry swab-direct RT-PCR testing, the step of RNA isolation from the sample is omitted thereby reducing handling time.

ICMR conducted two validations of the dry swab method in August and November 2020 respectively. The earlier one with the original version and the latter one with modifications based on the results of the first validation. Results indicate that the sensitivity of the dry swab variant method is 79% and specificity is 99% when compared with standard RT-PCR test.

Considering its lesser cost and quick turn-around, the dry swab variant method has been advised to be used as a screening tool only in settings where automated RNA extraction is not available.

Indian Council of Medical Research completes 109 years

109 years back, Sir Harcourt Butler, Member, Department E. H & L of the Viceroy’s Executive Council & Sir Pardey Lukis, Director General, Indian Medical Service laid the foundation of Indian Research Fund Association (IRFA) today known as Indian Council of Medical Research (ICMR).

First meeting of the Governing Body of the IRFA was held at the Plague Laboratory, Parel, Bombay (Now Mumbai) on 15th November, 1911. Since then ICMR has blossomed into a premier institution for Health Research in the country. During these years ICMR has many milestones to its credit in finding solutions for diseases of public health importance.

ICMR’s continued developments in the field of research in alignment with National health priorities has placed it at foremost position in tackling Coronavirus pandemic in the year 2020. A robust research infrastructure, strategic alliances across sectors, public trust and proactive administration has strengthened ICMR’s resolve in the fight against Coronavirus.
Shri Amit Shah, Union Home Minister visited ICMR-HQ
ICMR is available on Facebook, Twitter and Instagram. For latest update about COVID-19 and other medical research breakthrough, you can follow ICMR’s Official handles.
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