Draft Environment Impact Assessment Notification 2020

- Recently, the Delhi High Court extended till August 11 the deadline for public feedback on the draft Environment Impact Assessment (EIA) Notification 2020. This was after the government had changed the deadline from August 10 to June 30.

Background

- A signatory to the **Stockholm Declaration (1972) on Environment**, India enacted laws to control water (1974) and air (1981) pollution soon after. But it was only after the Bhopal gas leak disaster in 1984 that the country legislated an umbrella Act for environmental protection in 1986.
- **Under the Environment (Protection) Act, 1986, India notified its first EIA norms in 1994**, setting in place a legal framework for regulating activities that access, utilise, and affect (pollute) natural resources. Every development project has been required to go through the EIA process for obtaining prior environmental clearance ever since.
- An EIA notification is issued under Section 3 of the Environment Protection Act, 1986, to impose restrictions on setting up new projects or expansion or modernisation of existing projects. The section stipulates that such measures must benefit the environment.
- The 1994 EIA notification was replaced with a modified draft in 2006. Earlier this year, the government redrafted it again to incorporate the amendments and relevant court orders issued since 2006, and to make the **EIA "process more transparent and expedient."**
- The basis in global environmental law for the EIA is the "**precautionary principle".** Environmental harm is often irreparable — one cannot reverse an oil spill. It is cheaper to avoid damage to the environment than to remedy it. We are legally bound to the precautionary principle under international treaties and obligations, as well as by Supreme Court judgments.
- The EIA process scrutinises the potential environmental impact and negative externalities of a proposed project before ground is broken and determines whether it can be carried out in the form proposed, or whether it is to be abandoned or modified. The assessment is carried out by an Expert Appraisal Committee (EAC), which consists of scientists and project management experts. The EAC frames the scope of the EIA study and a preliminary report is prepared.
- That report is published, and a public consultation process takes place, where objections can be heard including from project-affected people. The EAC can then make a final appraisal of the project and forward that to the regulatory authority, which is the Ministry of Environment and Forests (MoEF). The regulatory authority is ordinarily obliged to accept the decision of the EAC.

Issues (with EIA process)

- The reports on projects' potential (damaging) impact on the environment — the bedrock of the EIA process — are frequently shoddy and consultant agencies that prepare those reports for a fee are rarely held accountable.
- Lack of administrative capacity to ensure compliance often renders long lists of clearance conditions meaningless.
- Then there are **periodic amendments** exempting one category of industries or the other from scrutiny.
- On the other hand, developers complain that the EIA regime dampened the spirit of liberalisation, leading to red tape and rent-seeking.

The 2020 draft

- **Strategic sectors**- While projects concerning **national defence and security** are naturally considered strategic, the government gets to decide on the "strategic" tag for other projects. The 2020 draft says **no information** on "***such projects shall be placed in the public domain***". This opens a window for summary clearance for any project deemed strategic without having to explain why.
- Additionally, the new draft **exempts** a long list of projects from **public consultation**. For example, linear projects such as roads and pipelines in border areas will not require any public hearing. The '**border area'** is defined as "area falling within 100 kilometres aerial distance from the Line of Actual Control with bordering countries of India." That would cover much of the Northeast, the repository of the country's richest biodiversity.
- All **inland waterways** projects and **expansion/widening of national highways** will be exempt from **prior clearance**. These include roads that cut through forests and dredging of major rivers.
- The **2020 draft also exempts most building construction projects of built-up area up to 1,50,000 sq** m. This is a reiteration of the Environment Ministry's December 2016 notification that was set aside by the National Green Tribunal in December 2017. The government subsequently moved the Supreme Court but did not get any relief.
- The other two changes in the new draft are the provisions for **post-facto project clearance and abandoning the public trust doctrine.**

  Projects operating in violation of the Environment Act will now be able to apply for clearance. It is a reiteration of a March 2017 notification for projects operating without clearance.

  All a violator will need are **two plans** for **remediation and resource augmentation** corresponding to 1.5-2 times the ecological damage assessed and economic benefit derived due to violation.

  Where an EIA clearance was never sought or granted, and the construction of the project took place regardless, the project proponent can enter an assessment procedure, with some minor fines for the violations, and find its sins blessed.

In an order on April 1, 2020, the **Supreme Court held ex post facto environmental clearances contrary to law.** It said that Environment law cannot countenance the notion of an ex post facto clearance. This would be **contrary** to both the **precautionary principle as well as the need for sustainable development.**

The 2020 draft also spells out how the government will take cognisance of such violations. It has to be reported either by a government authority or the developers themselves. There is **no scope** for any public complaint about violations. Instead, the reliance is on the violators to disclose, Suo-motu, that they broke the law.

- The draft notification also **shortens the time** for the **public** to furnish responses on the project. For project-affected people, who are frequently forest dwellers or otherwise do not have access to information and technology, this will make it harder to put forth representations.
- **Monitoring** requirements have been slackened. The draft EIA notification **halves the frequency of reporting requirements from every six months to once a year** and extends the validity period for approvals in critical sectors such as mining.
- The **scope** of the EIA requirement has shrunk as industries that previously fell under the **categories that required a full assessment have been downgraded.** The construction industry will be one such beneficiary, where only the largest projects will be scrutinised fully.

  While defence and national security installations were always understandably exempt, a vague new category of projects "involving other strategic considerations" will also now be free from public consultation requirements. Would a power plant fall into that category?

  Weakening the EIA process is essentially anti-democratic. For affected communities, where seismic shifts in the local environment can threaten livelihoods, flood a valley or destroy a forest, public consultation is a referendum on existential threats. To curtail it is to silence voices that are scarcely heard otherwise.

(Where the Minister for Environment and Forests and the Minister for Heavy Industries and Public Enterprises are the same person, the conflict of interest is perfect and complete. Two charges that are oppositional are vested with the same person.)

(Oil India Limited's oil wells in the Tinsukia district, Assam, only a few kilometres away from protected forests, went up in flames this month. Recent processes for expansion and modification apparently took place without fresh environmental clearance. A deadly gas leak at LG Polymers' Visakhapatnam plant in May killed 12 people and harmed hundreds. What came to light after the disaster was that the plant had been operating without a valid environmental clearance for decades.)

Understanding EIA

- Environment Impact Assessment or EIA can be defined as the study to predict the effect of a proposed activity/project on the environment. A decision-making tool, EIA compares various alternatives for a project and seeks to identify the one which represents the best combination of economic and environmental costs and benefits.
- EIA systematically examines both beneficial and adverse consequences of the project and ensures that these effects are taken into account during project design. It helps to identify possible environmental effects of the proposed project, proposes measures to mitigate adverse effects and predicts whether there will be significant adverse environmental effects, even after the mitigation is implemented.
- By considering the environmental effects of the project and their mitigation early in the project planning cycle, environmental assessment has many benefits, such as protection of environment, optimum utilisation of resources and saving of time and cost of the project. Properly conducted EIA also lessens conflicts by promoting community participation, informing decision makers, and helping lay the base for environmentally sound projects. Benefits of integrating EIA have been observed in all stages of a project, from exploration and planning, through construction, operations, decommissioning, and beyond site closure.

- The Indian experience with Environmental Impact Assessment started in 1976-77 when the Planning Commission asked the Department of Science and Technology to examine the river-valley projects from an environmental angle. This was subsequently extended to cover those projects, which required the approval of the Public Investment Board. Till 1994, environmental clearance from the Central Government was an administrative decision and lacked legislative support.

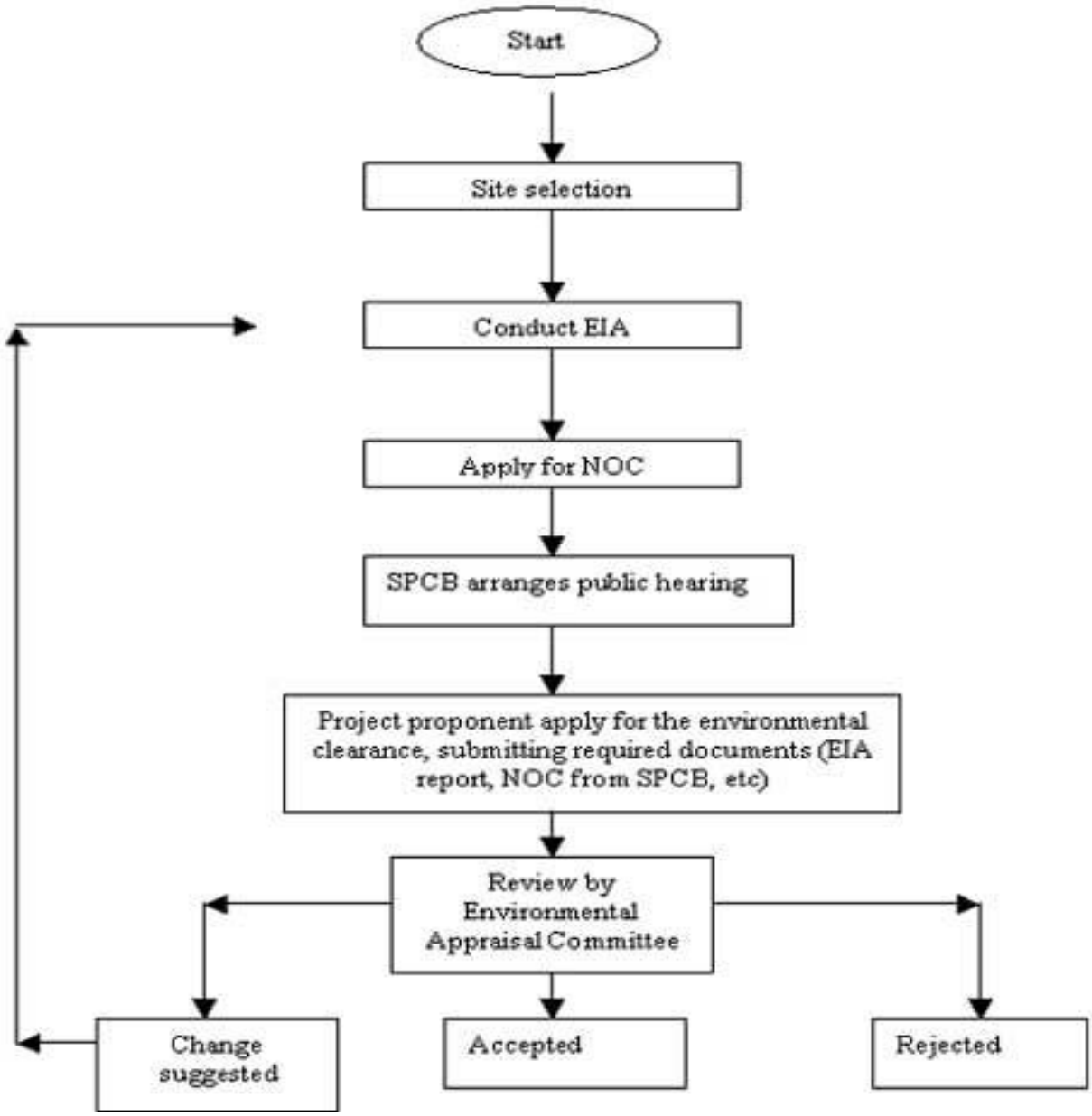
- On 27 January 1994, the Union Ministry of Environment and Forests (MEF), Government of India, under the Environmental (Protection) Act 1986, promulgated an EIA notification making Environmental Clearance (EC) mandatory for expansion or modernisation of any activity or for setting up new projects listed in Schedule 1 of the notification.

- The stages of an EIA process will depend upon the requirements of the country or donor. However, most EIA processes have a common structure and the application of the main stages is a basic standard of good practice.

  The environment impact assessment consists of eight steps with each step equally important in determining the overall performance of the project. Typically, the EIA process begins with screening to ensure time and resources are directed at the proposals that matter environmentally and ends with some form of follow up on the

implementation of the decisions and actions taken as a result of an EIA report. The eight steps of the EIA process are presented in brief below:

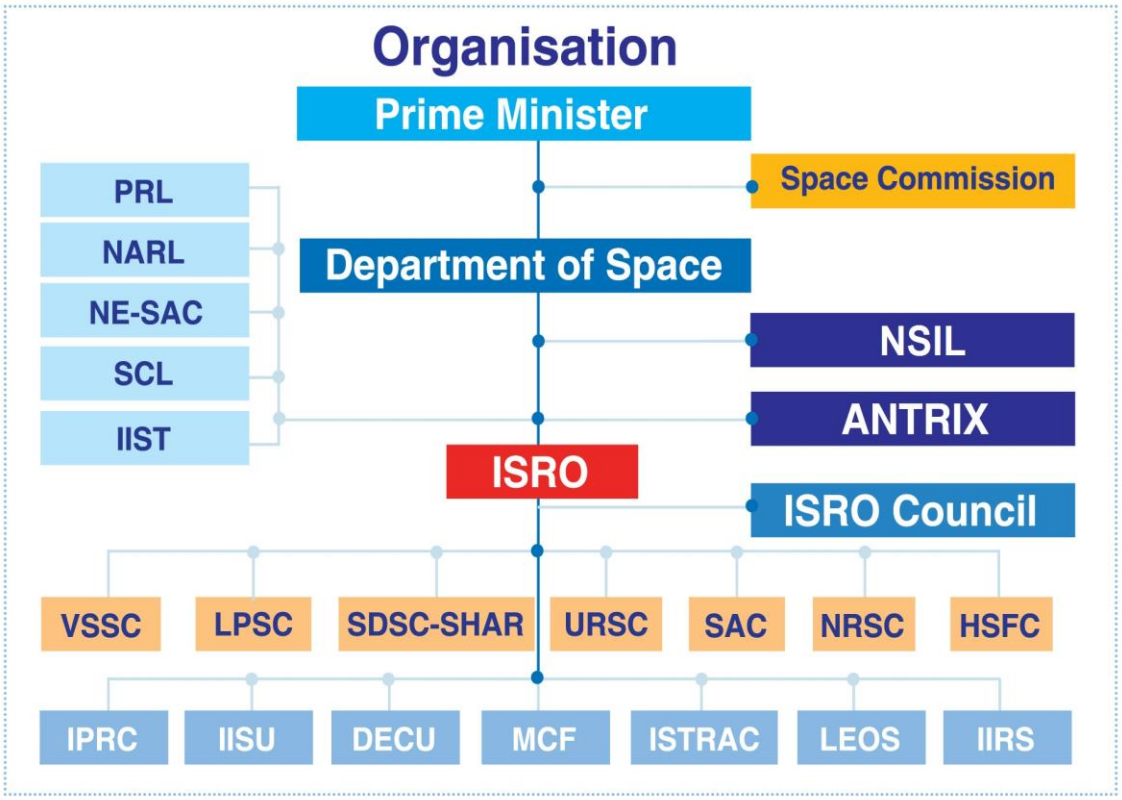
1) **Screening**: First stage of EIA, which determines whether the proposed project, requires an EIA and if it does, then the level of assessment required.
2) **Scoping**: This stage identifies the key **issues and impacts** that should be further investigated. This stage also defines the boundary and time limit of the study.
3) **Impact analysis**: This stage of EIA identifies and **predicts** the likely **environmental and social impact** of the proposed project and evaluates the significance.
4) **Mitigation**: This step in EIA recommends the actions to reduce and avoid the potential adverse environmental consequences of development activities.
5) **Reporting**: This stage presents the **result of EIA in a form of a report** to the decision-making body and other interested parties.
6) **Review of EIA:** It examines the adequacy and effectiveness of the EIA report and provides the information necessary for decision-making.
7) **Decision-making**: It decides whether the project is **rejected, approved or needs further change.**
8) **Post monitoring**: This stage comes into play once the project is commissioned. It checks to ensure that the impacts of the project do not exceed the legal standards and implementation of the mitigation measures are in the manner as described in the EIA report.



- There are various forms of impact assessment such as Health Impact Assessment (HIA) and Social Impact Assessment (SIA) that are used to assess the health and social consequences of development so that they are taken into consideration along with the environmental assessment. One of the forms of impact assessment is strategic environment assessment, which is briefly discussed below: Strategic Environment Assessment (SEA) refers to systematic analysis of the environmental effects of development policies, plans, programmes and other proposed strategic actions. This process extends the aims and principles of EIA upstream in the decision-making process, beyond the project level and when major alternatives are still open. SEA represents a proactive approach to integrating environmental considerations into the higher levels of decision-making.

IN-SPACe

- Government has announced a new organisation, IN-SPACe, part of reforms to increase private participation in the space sector.
- The new **Indian National Space Promotion and Authorisation Centre (IN-SPACe),** which is expected to be functional within six months, will assess **the needs and demands of private players, including educational and research institutions, and, explore ways to accommodate these requirements in consultation with ISRO.** Existing ISRO infrastructure, both ground- and space-based, scientific and technical resources, and even data are planned to be made accessible to interested parties to enable them to carry out their space-related activities.



PRL: Physical Research Laboratory **NARL:** National Atmospheric Research Laboratory **NE-SAC:** North Eastern Space Applications Centre **SCL:** Semi-Conductor laboratory **IIST:** Indian Institute of Space Science and Technology **ISRO:** Indian Space Research Organisation **Antrix:** Antrix Corporation Limited **VSSC:** Vikram Sarabhai Space Centre **LPSC:** Liquid Propulsion Systems Centre **SDSC:** Satish Dhawan Space Centre **URSC:** U R Rao Satellite Centre **SAC:** Space Applications Cenrtre **NRSC:** National Remote Sensing Centre **HSFC:** Human Space Flight Centre **IPRC:** ISRO Propulsion Complex **IISU:** ISRO Inertial Systems Unit **DECU:** Development and Educational Communication Unit **MCF:** Master Control Facility **ISTRAC:** ISRO Telemetry, Tracking and Command Network **LEOS:** Laboratory for Electro-Optics Systems **IIRS:** Indian Institute of Remote Sensing **NSIL:** NewSpace India Limited

- IN-SPACe is supposed to be a **facilitator, and also a regulator**. It will act as an interface between ISRO and private parties, and assess how best to utilise India's space resources and increase space-based activities.
- IN-SPACe is the **second** space organisation created by the government in the last two years. In the 2019 Budget, the government had announced the setting up of a **New**

Space India Limited (NSIL), a **public sector company** that would serve as a marketing arm of ISRO. Its main purpose is to market the technologies developed by ISRO and bring it more clients that need space-based services.

- Govt also said the government said it was redefining the role of NSIL so that it would have a **demand-driven approach rather than the current supply-driven** strategy. Essentially, what that means is that instead of just marketing what ISRO has to offer, NSIL would listen to the needs of the clients and ask ISRO to fulfil those. This change in NSIL's role is also part of the reforms that have been initiated in the space sector.
- Highlighting that the roughly $350 billion global space market is comprised of around 2% in launch vehicles, 5% satellites, 45% in space applications and 48% in ground equipment, India has a 3% share.

Why private participants

- It is not that there is no private industry involvement in India's space sector. In fact, a large part of manufacturing and fabrication of rockets and satellites now happens in the private sector. There is an increasing participation of research institutions as well. ***Right now, India's contribution in the $360 billion space economy is just 3%.***
  Indian industry, however, is unable to compete, because till now its role has been mainly that of **suppliers** of components and sub-systems. Indian industries do not have the resources or the technology to undertake independent space projects of the kind that US companies such as **SpaceX** have been doing, or provide space-based services.
- Additionally, the **demand** for space-based applications and services is growing even within India, and ISRO is unable to cater to this. The need for **satellite data, imageries and space technology** now cuts across sectors, from weather to agriculture to transport to urban development, and more. ISRO would have to be expanded 10 times the current level to meet all the demand that is arising.
- At the same time, there were several Indian companies waiting for make use of these opportunities. There are a few companies that were in the process of developing their own launch vehicles, the rockets like ISRO's PSLV that carry the satellites and other payloads into space, and ISRO would like to help them do that. Right now, all launches from India happen on ISRO rockets, the different versions of PSLV and GSLV.
- ISRO would provide all its facilities to private players whose projects had been approved by IN-SPACe. Private companies, if they wanted, could even build their own launchpad within the Sriharikota launch station, and ISRO would provide the necessary land for that.
- Promote building of routine satellites, rockets and commercial launch services through Indian industry and startups.

How ISRO gains

- There are two main reasons why enhanced private involvement in the space sector seems important. One is **commercial**, and the other **strategic**.

There is need for greater dissemination of space technologies, better utilisation of space resources, and increased requirement of space-based services. And ISRO seems unable to satisfy this need on its own.

- The private industry will also free up ISRO to concentrate on **science, research and development, interplanetary exploration and strategic launches**. Right now, too much of ISRO's resources is consumed by routine activities that delay its more strategic objectives. There is no reason why ISRO alone should be launching weather or communication satellites. The world over, an increasing number of private players are taking over this activity for commercial benefits. ISRO, like NASA, is essentially a scientific organisation whose main objective is exploration of space and carrying out scientific missions. There are a number of ambitious space missions lined up in the coming years, including a mission to observe the Sun, a mission to the Moon, a human spaceflight, and then, possibly, a human landing on the Moon.

Will IN-SPACe affect the functioning of Isro?

- The setting up of nodal agency IN-SPACe won't affect Isro's functioning as the proposed nodal agency will be a **fourth vertical** under the department of space. Currently, **Isro** is **one** vertical under which there are so many centres, then the **second** vertical is of **autonomous bodies** and the **third** one is the public sector entity **New Space India Ltd (NSIL).** IN-SPACe will be a totally autonomous body, which won't be influenced by Isro and it won't influence Isro's work. It will have its chairman, directorate and cadre.
- The Space Commission is the apex body controlling space activities in India; it will remain so and above the new entity. Like ISRO, IN-SPACe will also report to it as and when required.

Will IN-SPACe's decisions be binding on Isro?

- When a private company makes a demand before IN-SPACe for either using testing facilities or systems of Isro, the nodal agency will talk to the respective Isro centres for providing the facility to the company. Once IN-SPACe has made a decision on an application in consultation with Isro, then that decision will be binding on Isro and other stakeholders. So, only the mission-specific IN-SPACe's decision will be binding.

Where will it be located?

- Mainly for ease of operation, the headquarters of IN-SPACe will be located in Bengaluru [where the DoS has also been based for nearly 50 years.] As time progresses, things may evolve. However, its separate branches or directorates will be spread across the country depending on requirement. The technical directorate, for example, may be in Thiruvananthapuram.

Randomised control trials

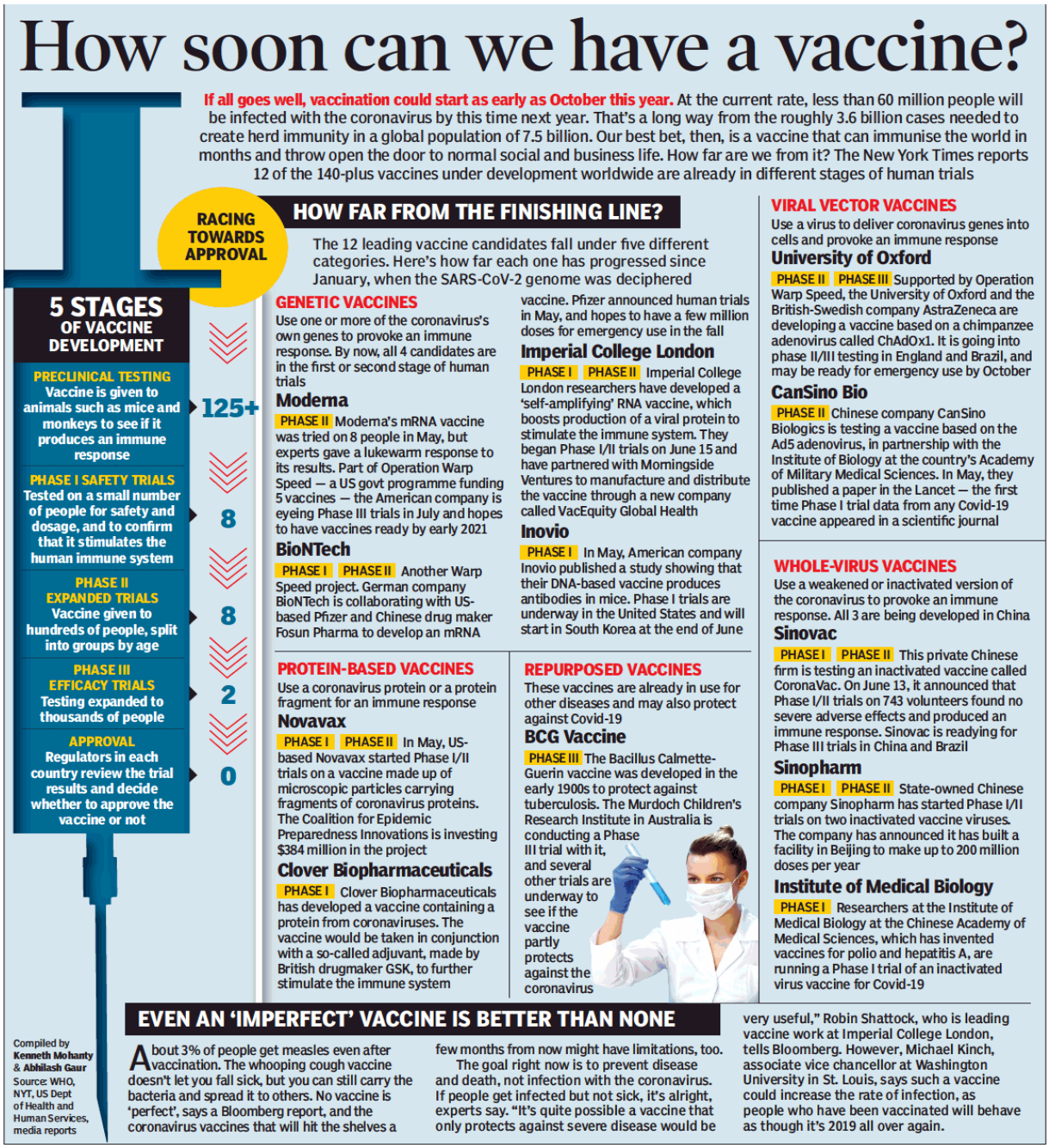
- The government, through the Ministry of AYUSH (ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) responding a short while later, told the company **to stop advertising the drug as a cure for COVID-19**, pointing out that it would attract provisions of **Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.**

What is the place of RCTs place in clinical trials?

- As per definition, a randomised controlled trial, or RCT, is a study in which people are allocated at random, entirely by chance, to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be standard practice/treatment options, a placebo (a drug without an active substance, or a 'sugar pill'), or no intervention at all. The idea is to measure and compare the outcomes against the control after the participants receive the treatment.
- RCTs are based on multiple factors, including type of interventions being evaluated, and number of participants. In single-blind trials, the participants, or the investigators do not know who is assigned what; in double-blind trials, both participants and investigators do not know; and triple and quadruple-blind trials, where three or four of the relevant groups are not aware of the treatment assignment.
- RCTs are widely taken as the gold standard for establishing causal conclusions.The **Solidarity (WHO) and RECOVERY** (or **Randomised Evaluation of COVid-19 thERapY UK**) trials are examples of large-scale RCTs done with multiple partners at many locations,

Clinical trials

- The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July **2007**.
- Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication.



How soon can we have a vaccine?

If all goes well, vaccination could start as early as October this year. At the current rate, less than 60 million people will be infected with the coronavirus by this time next year. That's a long way from the roughly 3.6 billion cases needed to create herd immunity in a global population of 7.5 billion. Our best bet, then, is a vaccine that can immunise the world in months and throw open the door to normal social and business life. How far are we from it? The New York Times reports 12 of the 140-plus vaccines under development worldwide are already in different stages of human trials

RACING TOWARDS APPROVAL

5 STAGES OF VACCINE DEVELOPMENT

PRECLINICAL TESTING — Vaccine is given to animals such as mice and monkeys to see if it produces an immune response — 125+

PHASE I SAFETY TRIALS — Tested on a small number of people for safety and dosage, and to confirm that it stimulates the human immune system — 8

PHASE II EXPANDED TRIALS — Vaccine given to hundreds of people, split into groups by age — 8

PHASE III EFFICACY TRIALS — Testing expanded to thousands of people — 2

APPROVAL — Regulators in each country review the trial results and decide whether to approve the vaccine or not — 0

HOW FAR FROM THE FINISHING LINE?

The 12 leading vaccine candidates fall under five different categories. Here's how far each one has progressed since January, when the SARS-CoV-2 genome was deciphered

GENETIC VACCINES

Use one or more of the coronavirus's own genes to provoke an immune response. By now, all 4 candidates are in the first or second stage of human trials

Moderna

PHASE II Moderna's mRNA vaccine was tried on 8 people in May, but experts gave a lukewarm response to its results. Part of Operation Warp Speed — a US govt programme funding 5 vaccines — the American company is eyeing Phase III trials in July and hopes to have vaccines ready by early 2021

BioNTech

PHASE I PHASE II Another Warp Speed project. German company BioNTech is collaborating with US-based Pfizer and Chinese drug maker Fosun Pharma to develop an mRNA vaccine. Pfizer announced human trials in May, and hopes to have a few million doses for emergency use in the fall

Imperial College London

PHASE I PHASE II Imperial College London researchers have developed a 'self-amplifying' RNA vaccine, which boosts production of a viral protein to stimulate the immune system. They began Phase I/II trials on June 15 and have partnered with Morningside Ventures to manufacture and distribute the vaccine through a new company called VacEquity Global Health

Inovio

PHASE I In May, American company Inovio published a study showing that their DNA-based vaccine produces antibodies in mice. Phase I trials are underway in the United States and will start in South Korea at the end of June

PROTEIN-BASED VACCINES

Use a coronavirus protein or a protein fragment for an immune response

Novavax

PHASE I PHASE II In May, US-based Novavax started Phase I/II trials on a vaccine made up of microscopic particles carrying fragments of coronavirus proteins. The Coalition for Epidemic Preparedness Innovations is investing $384 million in the project

Clover Biopharmaceuticals

PHASE I Clover Biopharmaceuticals has developed a vaccine containing a protein from coronaviruses. The vaccine would be taken in conjunction with a so-called adjuvant, made by British drugmaker GSK, to further stimulate the immune system

REPURPOSED VACCINES

These vaccines are already in use for other diseases and may also protect against Covid-19

BCG Vaccine

PHASE III The Bacillus Calmette-Guerin vaccine was developed in the early 1900s to protect against tuberculosis. The Murdoch Children's Research Institute in Australia is conducting a Phase III trial with it, and several other trials are underway to see if the vaccine partly protects against the coronavirus

VIRAL VECTOR VACCINES

Use a virus to deliver coronavirus genes into cells and provoke an immune response

University of Oxford

PHASE II PHASE III Supported by Operation Warp Speed, the University of Oxford and the British-Swedish company AstraZeneca are developing a vaccine based on a chimpanzee adenovirus called ChAdOx1. It is going into phase II/III testing in England and Brazil, and may be ready for emergency use by October

CanSino Bio

PHASE II Chinese company CanSino Biologics is testing a vaccine based on the Ad5 adenovirus, in partnership with the Institute of Biology at the country's Academy of Military Medical Sciences. In May, they published a paper in the Lancet — the first time Phase I trial data from any Covid-19 vaccine appeared in a scientific journal

WHOLE-VIRUS VACCINES

Use a weakened or inactivated version of the coronavirus to provoke an immune response. All 3 are being developed in China

Sinovac

PHASE I PHASE II This private Chinese firm is testing an inactivated vaccine called CoronaVac. On June 13, it announced that Phase I/II trials on 743 volunteers found no severe adverse effects and produced an immune response. Sinovac is readying for Phase III trials in China and Brazil

Sinopharm

PHASE I PHASE II State-owned Chinese company Sinopharm has started Phase I/II trials on two inactivated vaccine viruses. The company has announced it has built a facility in Beijing to make up to 200 million doses per year

Institute of Medical Biology

PHASE I Researchers at the Institute of Medical Biology at the Chinese Academy of Medical Sciences, which has invented vaccines for polio and hepatitis A, are running a Phase I trial of an inactivated virus vaccine for Covid-19

EVEN AN 'IMPERFECT' VACCINE IS BETTER THAN NONE

About 3% of people get measles even after vaccination. The whooping cough vaccine doesn't let you fall sick, but you can still carry the bacteria and spread it to others. No vaccine is 'perfect', says a Bloomberg report, and the coronavirus vaccines that will hit the shelves a few months from now might have limitations, too.

The goal right now is to prevent disease and death, not infection with the coronavirus. If people get infected but not sick, it's alright, experts say. "It's quite possible a vaccine that only protects against severe disease would be very useful," Robin Shattock, who is leading vaccine work at Imperial College London, tells Bloomberg. However, Michael Kinch, associate vice chancellor at Washington University in St. Louis, says such a vaccine could increase the rate of infection, as people who have been vaccinated will behave as though it's 2019 all over again.

Compiled by **Kenneth Mohanty** & **Abhilash Gaur**
Source: WHO, NYT, US Dept of Health and Human Services, media reports

- Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH is expected to register the trial in the CTRI before enrollment of the first participant.
- Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc before the enrollment of the first patient. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI.

- **In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured.** After a trial is registered, trialists are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display.

Stage I: R&D

This typically takes two to four years. For Covid-19, this stage has been progressing fast for two reasons. First, a large number of candidates are based on the virus's genetic code instead of its protein, and Chinese researchers globally shared the genetic sequence in January itself. The second reason is technology. For instance, Moderna is using m-RNA technology, which involves injecting genetic instructions to human cells for creating proteins to fight the virus. However, it is still unproven technology.

Stage II: Pre-clinical

This is when scientists test the vaccine on cell cultures and animals. They first inactivate the virus, pull out parts of the genetic sequence, and test if it triggers an immune response. More critically, they check if vaccine candidate continues to harm the cell. If there is no immune response and if the candidate harms the animals, the researchers return to stage 1. This stage can take two to three years.

For Covid-19, this stage is being shortened by performing various sub-stages simultaneously. However, most vaccine candidates are still in the pre-clinical stage.

Stage III: Clinical trials

On the basis of data submitted from the pre-clinical phase, regulators allow testing in humans. Very few candidates enter this stage. This phase consists of three phases and usually takes more than 90 months.

PHASE I: The vaccine is given to a small group of people — this takes about three months — and scientists measure antibodies in their blood.

PHASE II: If found safe, it moves to the next phase (6-8 months). The vaccine is given to several hundred people. Three aspects are assessed: reactogenicity (ability to produce common, adverse reactions), immunogenicity (ability to provoke an immune response) and safety. There is also a control to compare how the vaccine works in different variables.

This stage has been shortened in Covid-19 vaccine development. Moderna took just 63 days to reach clinical trials. The Oxford Vaccine Group researchers, which began phase I trials of Astra Zeneca's vaccine in April, has now entered phase III.

PHASE III: Thousands of people are enrolled. This takes 6-8 months. This assesses how the vaccine works in larger populations.

Stage IV: Regulatory review

The manufacturer submits the data to receive a licence. In the US, approval typically comes after 10 months. However, this is fast-tracked during emergencies. The regulators allow a rolling review: the vaccine candidate submits sections of the application for review as and when they are completed.

Stage V: Manufacturing

This requires immense resources — funds running into millions of dollars, infrastructure, raw material, and scientific expertise. Pharma giants like Pfizer, Johnson & Johnson, Merck and Astra Zeneca, all trying to develop a vaccine, will have a clear advantage to scale up manufacturing if their product is found successful.

Stage VI: Quality control

The safety of the vaccine is monitored by both the regulator and the manufacturer.