

1 July, 2023

New Drugs and Clinical Trial Rules

Context: India's recent amendment to the New Drugs and Clinical Trial Rules (2023) permits researchers to use non-animal and human-relevant methods for testing new drugs.

- The Drugs and Clinical Trials Rules, 2019 in India will undergo an amendment.
- The amendment will incorporate alternative methods for testing new drugs.
- The alternative methods include 3D organoids, 3D bioprinters, organs-on-chip, and advanced computational methods.

Limitations of Animal Testing

- Limited predictability for human response
 - Animals may respond differently to drugs compared to humans due to biological and genetic differences.
 - Example: Thalidomide caused birth defects in humans but did not show the same effects in animal tests.
- Ethical concerns and animal welfare
 - Animal testing raises ethical concerns regarding the suffering and harm caused to animals.
 - Examples: Force-feeding, injections, and euthanasia procedures.
- High failure rate in translating to human efficacy
 - Many drugs that pass animal testing fail during human clinical trials.
 - Example: Over 90% of drugs tested on animals fail to become safe and effective treatments for humans.
- Inadequate representation of human diversity
 - Animals used in testing may not accurately represent the diversity of human populations.
 - Factors like age, sex, genetic variations, and underlying health conditions may not be adequately represented.
- Regulatory and legal considerations
 - The use of animals in testing is subject to regulatory requirements and ethical considerations.
 - This can lead to delays, increased costs, and challenges in obtaining approvals.
 - Example: The European Union has banned animal testing for cosmetics.

International Trends to Animal Testing

International developments regarding alternative methods in drug testing:

- **European Union:** In 2021, the European Union passed a resolution to transition towards non-animal technologies in research, regulatory testing, and education.
- **United States:** In December 2022, the U.S. passed the FDA Modernization Act 2.0, allowing researchers to use alternative systems for testing the safety and efficacy of new drugs.
- **South Korea:** In 2022, South Korea introduced a Bill promoting the development and use of alternatives to animal testing methods.
- **Canada:** In June 2023, Canada amended its Environmental Protection Act to replace, reduce, or refine the use of vertebrate animals in toxicity testing.

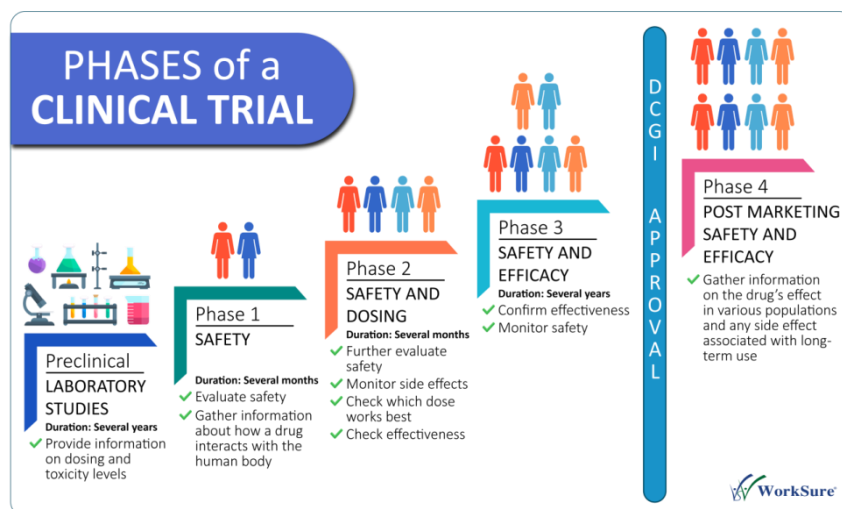
Face to Face Centres

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Solicitor General of India

Context: Tushar Mehta has been reappointed as the Solicitor-General of India by the Appointments Committee of the Union Cabinet.

About the Solicitor General

Key points about the Solicitor-General of India:

- **Position:** The Solicitor-General of India is the second highest law officer in the country.
- **Subordination:** The Solicitor-General works under the Attorney General of India, who is the highest law officer.
- **Advisory Role:** The Solicitor-General advises the government on legal matters.
- **Appointment:** The Solicitor-General is appointed for a three-year term by the Appointment Committee of the Cabinet, chaired by the Prime Minister.
- **Constitutional vs. Statutory:** The office and duties of the Attorney General are created by the Constitution (Article 76), while the Solicitor General and Additional Solicitor Generals' positions are governed by the Law Officers (Conditions of Service) Rules, 1987.
- **Parliamentary Participation:** The Attorney General has the right to participate in parliamentary proceedings but cannot vote, while the Solicitor General and Additional Solicitor Generals do not have the same rights regarding participation in Parliament.

Functions and Duties: Responsibilities of the Indian Solicitor General as per the Law Officers (Conditions of Service) Rules, 1987:

- Perform legal tasks and provide advice on matters delegated or assigned by the Government of India.
- Represent the Indian Government in cases brought before the Supreme Court by the President under Article 143 of the Constitution.
- Act as a representative for the Government of India in cases involving the Government as a party, appearing before the Supreme Court or High Courts.
- Fulfill any additional responsibilities assigned to a law officer by the Constitution or other existing laws.

Restrictions on the Indian Solicitor General's activities:

- Cannot hold briefs for parties other than the specified government entities.
- Cannot advise or appear against the Government of India or Public Sector Undertakings.

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- Cannot defend an accused person in a criminal prosecution without government permission.
- Cannot accept appointment to any office in a company or corporation without government permission.
- Cannot provide advice directly to government departments or organizations without going through the Ministry of Law and Justice, Department of Legal Affairs.

National Research Foundation (NRF)

Context: The National Research Foundation (NRF) Bill 2023, aimed at providing strategic direction to scientific research in India, has been approved by the Union Cabinet.

Highlights of the National Research Foundation (NRF) Bill:

- **Establishment:** The bill will establish the National Research Foundation (NRF) in India.
- **Repeal of SERB:** The Science and Engineering Research Board (SERB) will be subsumed into the NRF as a result of the bill.
- **Previous Status of SERB:** SERB is a statutory body established in 2009 under the Department of Science and Technology (DST) by the SERB Act, 2008.
- **Objectives of SERB:** SERB was created to promote basic research in science and engineering and provide financial assistance to scientists, academic institutions, research and development (R&D) laboratories, and science and technology (S&T) start-ups.

About NRF

National Research Foundation (NRF) - Key Points:

- **Establishment:**
 - NRF will be established as an apex body.
 - Total estimated cost: ₹50,000 crores from 2023-28.
 - Government contribution: ₹10,000 crores.
 - Private sector investment: Expected to be ~₹36,000 crores.
- **Recommendation:**
 - NRF aligns with the National Education Policy (NEP) 2020.
- **Administrative Department:**
 - NRF will be under the Department of Science and Technology (DST), Ministry of Science and Technology.
- **Governance:**
 - NRF will have a Governing Board.
 - President of the Board: The Prime Minister (ex-officio).
 - Vice-Presidents: Union Minister of Science and Technology and Union Minister of Education (ex-officio).
 - Board members: Eminent researchers and professionals from various disciplines.
 - Executive Council: Chaired by the Principal Scientific Adviser to the Government of India.
- **Purpose:**
 - NRF aims to seed, grow, and promote research and development (R&D) in India.
 - Foster a culture of research and innovation in universities, colleges, research institutions, and R&D laboratories.
- **Approach:**
 - Prioritize research funding and ensure equitable distribution across scientific research.
 - Increase private sector participation and funding in R&D.
 - Forge collaborations among industry, academia, government departments, and research institutions.
 - Create an interface mechanism for participation and contribution.

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➤ **Policy Framework and Regulatory Processes:**

- NRF will create a policy framework and regulatory processes to encourage collaboration and increased industry spending on R&D.

➤ **Significance/Need:**

- India's current spending on R&D is low (0.7% of GDP) compared to other countries.
- NRF will help democratize science funding and address major societal challenges.
- The Bill was necessary to facilitate contributions from private research organizations to the NRF.

NEWS IN BETWEEN THE LINES

Psilocybin



Context:

Recently, Australia has become one of the first countries to allow the use of MDMA (ecstasy) and magic mushrooms (psilocybin) for medical treatment.

Key highlights:

- Canada and the United States permit the medical use of these drugs in clinical trials or with special permits, Australia has reclassified them for medical use after trials found them to be relatively safe in a medically-controlled environment.
- The decision allows the use of psilocybin, found in magic mushrooms, for treatment-resistant depression, and MDMA (ecstasy) for post-traumatic stress disorder (PTSD).

Psilocybin:

- Psilocybin is a naturally occurring psychedelic compound found in certain species of mushrooms, commonly known as "magic mushrooms" or "shrooms."
- It belongs to a class of drugs called hallucinogens or psychedelics.

Treatment:

In recent years, there has been growing interest in using psilocybin for therapeutic purposes, particularly in the treatment of mental health conditions such as depression and anxiety.

Mahila Samman Saving Certificate



Context:

Recently, the Indian government has permitted all Public Sector Banks and eligible Private Sector Banks to implement and operationalize the Mahila Samman Savings Certificate, 2023.

What is Mahila Samman Saving Certificate?

- The Mahila Samman Saving Certificate is a financial scheme introduced by the Indian government.
- This scheme was introduced by the Department of Post and has been in operation since April 1st of the current year.

Objective:

- Its objective is to promote financial inclusion and empower women in India by providing them with a safe and flexible savings option.
- The scheme aims to encourage women to save and build a financial cushion for themselves, enabling them to achieve their financial goals and secure their future.

Availability:

The Mahila Samman Savings Certificate, 2023 can be subscribed to in Post Offices and eligible Scheduled Banks. Women can open an account under this scheme on or before March 31st, 2025.

Deposit Limits:

The minimum deposit amount is one thousand rupees, and any sum in multiples of 100 can be deposited. The maximum limit for deposits in this scheme is two lakh rupees.

Interest Rate:

Deposits made under this scheme will earn an interest rate of 7.5 percent per annum, compounded quarterly. This translates to an effective interest rate of approximately 7.7 percent.

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Hul Diwas



Context:

Recently, the Prime Minister of India (Narendra Modi) paid tribute to the exceptional valor and bravery displayed by tribal freedom fighters Sidho-Kanhu, Chand-Bhairav and Phulo-Jhano on the occasion of Hul Diwas.

What is Hul Diwas?

- Hul Diwas, also known as Santhal Hool or Santhal Rebellion Day, is an important observance in India that commemorates the Hul Rebellion or Santhal Rebellion of 1855-1856. It is celebrated on June 30th every year.
- The day specifically honors the sacrifices and resistance shown by tribal leaders such as Sidho-Kanhu, Chand-Bhairav, and Phulo-Jhano.

Sidho and Kanhu Murmu:

- Sidho Murmu and Kanhu Murmu were brothers and leaders of the Santhal tribe during the rebellion. They were instrumental in organizing and leading the resistance against British oppression.
- Under their leadership, the Santhal rebels fought fiercely, employing guerrilla warfare tactics and strategies to confront the British forces.

Chand and Bhairav Murmu:

- Chand Murmu and Bhairav Murmu were also brothers and key figures in the Santhal Rebellion.
- They actively participated in the armed struggle against the British authorities.

Phulo and Jhano Murmu:

- Phulo Murmu and Jhano Murmu were another pair of sisters who played significant roles in the Santhal Rebellion.
- They contributed to the organization and coordination of the rebellion, rallying the Santhal people and coordinating their actions against the British oppressors..

The Subansiri Lower Hydroelectric Project



Context:

Recently, the construction of the dam for the Subansiri Lower Hydroelectric Project has achieved completion till the top level of Elevation Level (EL) 210 M.

The Subansiri Lower Hydroelectric Project:

- The Subansiri Lower Hydroelectric Project is a 2,000 Mega Watt hydroelectric project located in the states of Arunachal Pradesh and Assam in India.
- The project is being executed by NHPC Limited, a government-owned company in the power sector.
- The construction work for the project started in January 2005 but faced delays due to agitations and protests by local stakeholders.
- However, construction resumed in October 2019 after receiving clearance from the National Green Tribunal.
- The project has made significant progress in dam concreting, with 14 blocks reaching the top level of 210 meters. This milestone was reached on June 29, 2023.

Subansiri River:

- Subansiri River, also known as the "Gold River," is the largest tributary of the upper Brahmaputra River.
- It originates from the Tibetan Himalayas and flows into India through the Miri Hills in Arunachal Pradesh.

Controversy:

- The Subansiri Lower Hydroelectric Project (SLHEP) has faced controversy and delays due to local agitation and concerns regarding dam safety and administrative issues.

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Places in News Arkadag

Context:

Turkmenistan, a country in Central Asia, has recently unveiled a new \$5 billion "smart" city called Arkadag which is designed to accommodate 70,000 residents.

Arkadag:

- The city is named Arkadag, which means "Protector" and is the title used by former President Gurbanguly Berdimukhamedov.

Geographical Location:

- Arkadag, the newly inaugurated "smart city" in Turkmenistan, is located approximately 30 kilometers (18 miles) south of the country's capital city, Ashgabat.
- Ashgabat itself is situated in the southern part of Turkmenistan, near the border with Iran.
- Turkmenistan is a Central Asian country bordered by Kazakhstan to the north, Uzbekistan to the northeast, Afghanistan to the southeast, Iran to the southwest and the Caspian Sea to the northwest.



Karakum Desert:

- The majority of Turkmenistan's territory is covered by the Karakum Desert, one of the largest sand deserts in the world.

Silk Road:

- Historically, Turkmenistan was an important region along the ancient Silk Road trade route that connected Asia with Europe.
- The country has archaeological ruins including those at Nisa and Merv which were major stops along the Silk Road.

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