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Phase II/III Clinical Trials of Covishield

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Why in News

Recently, the **Drugs Controller General of India** (DCGI) has given approval to the **Serum Institute of India (SII)**, Pune to conduct **Phase II/III clinical trials of Covishield** in India.

SII is the world's largest maker of vaccines and it has a **tie-up with AstraZeneca**, the **Swedish-British pharma giant**, to manufacture the **Covid-19** vaccine for **low- and middle-income countries**.

Key Points

- **Covishield:**
 - It is the name given to an **Oxford-AstraZeneca Covid-19 vaccine candidate** which is technically referred to as **AZD1222** or **ChAdOx 1 nCoV-19**.
 - It is **already being tested in the UK, South Africa and Brazil**, where participants are being administered two doses nearly a month apart.
 - It had **triggered an immune response** in humans against the **novel coronavirus** in early trials and is considered to be one of the global frontrunners for the Covid-19 vaccine.
- **Background:**
 - The **Subject Expert Committee (SEC)** for **Covid-19 related therapies** of the **Central Drugs Standard Control Organisation (CDSCO)** felt that the **SII needed to take a 'pan India' approach** while considering trial sites.
 - It recommended that **authorisation** to market Covishield **should be granted after considering clinical data generated from both the India and international trials**.

- **Trials:**

- SII can now start its larger phase II/III trials, ahead of other vaccine candidates like **Bharat Biotech's Covaxin** and **Zydus Cadila's ZyCov-D** which are still in **phase I/II trials**.

However, the **exact timings of trial beginning are not clear** yet. It would take at least a week to get the ethics committee's approval before starting the trials. If everything goes well, the vaccine could be out by the end of 2020.

- The trials for Covishield will have **around 1,600 participants at 18-odd sites across the country** including those identified by the **National Biopharma Mission and Grand Challenges India Programme**.

- **Current Trend in India:**

India continues to improve the **Case Fatality Rate** (CFR-number of deaths per positive case) and maintain its global position of having **one of the lowest Covid-19 fatalities rates**.

The **current CFR is 2.11%**.

Grand Challenges India Programm

- It is a **partnership framework** for the **Department of Biotechnology (DBT)** in India, its **Biotechnology Industry Research Assistance Council (BIRAC)** and the Bill and Melinda Gates Foundation.

BIRAC is a Public Sector Enterprise, set up by the DBT.

- **Aim:** To launch **joint initiatives aimed at catalyzing innovative health and development research** within India.

National Biopharma Mission

- It is an **industry-academia collaborative mission** for **accelerating biopharmaceutical development** in the country.
- It was **launched in 2017** at a total cost of **Rs. 1500 crore** and is **50% co-funded** by **World Bank** loan.
- It is being **implemented by the BIRAC**.

Source: IE