



# **COVID-19 Immunization: Overview of Pakistan**

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[www.dra.gov.pk](http://www.dra.gov.pk)



# Introduction.

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- ✓ **Drug Regulatory Authority of Pakistan** is the Apex Authority for regulation of medicines, that was established under the DRAP Act, 2012.
- ✓ DRAP has thirteen Divisions. following two have role regarding the COVID-19 vaccines:
  - **Pharmacy Services Division:** Approval of clinical trials of COVID-19 vaccines and subsequent surveillance of AEFIs.
  - **Biological Drugs Division** responsible for evaluation, assessment and registration of COVID-19 vaccines.
- ✓ **Pakistan National Pharmacovigilance Centre** is working under the Division of Pharmacy Services, that collect ADRs from patients, healthcare professionals, provincial centres, and now also from EPI.
- ✓ Federal EPI is immunization programme, responsible for collection & assessment of AEFIs.



# Approved Clinical Trials COVID-19 Vaccines

S. No.	Name of study	PI	Phase	Subjects	Sites
01	Phase-III, Double Blind, Placebo-Controlled, Randomized, Clinical Trial of Recombinant Novel Corona Virus Vaccine (Adenovirus Type 5 Vector)".  <b>CanSino Biologicals and Beijing Institute of Biotechnology, China.</b>	Major General Prof. Dr. Aamer Ikram, M/s National Institute of Health, Islamabad.	III	18000	1. Aga Khan University Hospital, Karachi. 2. The Indus Hospital, Karachi. 3. Shaukat Khanum Memorial Cancer & Research Hospital, Lahore. 4. Shifa International Hospital, Islamabad.



# Approved Clinical Trials COVID-19 Vaccines

	Name of study	PI	Phase	Subjects	Sites
02	Randomized, Double Blinded, Parallel, Placebo-Controlled Phase-I Clinical Trial to Evaluate the Safety & Immunogenicity of Inactivated <b>Sars-Cov 2 Vaccine</b> in Healthy Population Aged 18 & Above".  Beijing Institute of Biological Products Co ( <b>SinoPharm</b> )	Prof. Dr. Iqbal Choudhary, Director, International Center for Chemical & Biological Sciences (ICCBS), University of Karachi.	I	112	The Indus Hospital



# Approved Clinical Trials COVID-19 Vaccines

S.N	Name of study	PI	Sites
03	<p>A Phase III Randomized, Double Blind, Placebo Controlled Clinical Trial In 18 years of age and above to determine the safety and efficacy of ZF2001, a recombinant Novel Corona Vaccine (CHO CELL) for prevention of COVID-19.</p> <p>Anhui Zhifei Biopharmaceutical co ltd, China.</p>	<p>Prof. Waheed Uz Zaman Tariq</p> <p>PI finally approved in 20th meeting: Prof Dr Javed Akram</p>	<p>Agha Khan Hospital Karachi</p> <p>2. INDUS Hospital Karachi</p> <p>3. UHS, Lahore</p> <p>4. Chughtais Lab Lahore.</p> <p>5. Central Park Teaching Hospital, Lahore.</p> <p>6. Avicenna Hospital, Lahore.</p> <p>7. Aziz Fatima Hospital Faisalabad</p>



# Registered Vaccines of COVID-19 in Pakistan.

Brand Name	Strength	Registration Holder/MAH	Country of MAH
<b>SARS-CoV-2 Vaccine (Vero Cell), Inactivated</b>	Each Pre-filled Syringe (0.5ml) contains: Inactivated SARS-CoV-2 antigen.6.5U	<b>Registration Holder :</b> National Institute of Health (NIH), Chak Shehzad Islamabad,  <b>Marketing Authorization Holder (MAH):</b> M/s Beijing Institute of Biological Products Co., Ltd., No.6 & 9, Boxing 2"d Road, Economic- Technological Development Area, Beijing, 100176, China.	CHINA
<b>CoviShield ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)</b>	Each dose of 0.5ml contains: Replication-deficient chimpanzee adeno virus particles encoding SARS-CoV - 2 spike (S) glycoprotein*....6.5U *Produced in genetically human embryonic kidney (HEK) 293 cells	<b>Registration Holder :</b> M/s Sindh Medical Store, Sector 13B/B-10, Block 6, PECHS, Karachi  <b>Marketing Authorization Holder (MAH):</b> M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road Hadapsar Pune, Maharashtra, India - 41 1 028.	INDIA



# Registered Vaccines of COVID-19 in Pakistan.

Brand Name	Strength	Registration Holder/MAH	Country of MAH
<b>Gam-COVID-Vac Solution for Intramuscular Injection</b>	<p>Component I: Each dose of 0.5ml contains: Serotype 26 recombinant adenovirus particles containing SARS-CoV-2 protein S gene .....(1.0 ± 0.5) x 10<sup>11</sup> particles</p> <p>Component II: Each dose of 0.5ml contains: Serotype 5 recombinant adenovirus particles containing SARS-CoV-2 protein S gene .....(1.0 ± 0.5) x 10<sup>11</sup> particles</p>	<p><b>Registration Holder:</b> M/s AGP Limited, B-23-C, S.I.T.E., Karachi.</p> <p><b>Marketing Authorization Holder (MAH):</b> <b>Medgamal Branch, FSBI N.F. Gamaleya</b> "National Research Center for Epidemiology and Microbiology" of the Ministry of Health of the Russian Federation, 18 Gamalei Street, Moscow 123098, Russia.</p>	RUSSIA



# Registered Vaccines of COVID-19 in Pakistan.

Brand Name	Strength	Registration Holder/MAH	Country of MAH
<b>Convidecia Vaccine in Prefilled Syringe</b>	Each 0.5ml dose contains: Recombinant replication-deficient human type-5 adenovirus expressing the novel coronavirus S protein.....5 x 10 <sup>10</sup> VP	Registration Holder: M/s AJM Pharma (Pvt) Ltd 1 <sup>st</sup> floor, Shafi Court Civil Lines, Merewether Road, Karachi.  Marketing Authorization Holder (MAH): <b>M/s CanSino Biologics Inc.</b> , Floor 3 and 4, 185 South Ave., TEDA West District, Tianjin, China.	CHINA
<b>Convidecia Vaccine in Vial</b>	Each 0.5ml dose contains: Recombinant replication-deficient human type-5 adenovirus expressing the novel coronavirus S protein.....5 x 10 <sup>10</sup> VP	Registration Holder: M/s AJM Pharma (Pvt) Ltd 1 <sup>st</sup> floor, Shafi Court Civil Lines, Merewether Road, Karachi.  Marketing Authorization Holder (MAH): <b>M/s CanSino Biologics Inc.</b> , Floor 3 and 4, 185 South Ave., TEDA West District, Tianjin, China.	CHINA





# Strategy for reporting COVID-19 AEFIs

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- ✓ In Pakistan, Federal EPI already has a well-established system for collection & assessment of AEFIs of other vaccines.
- ✓ Therefore, COVID-19 vaccination is also being carried in 582 adult vaccination counters across the country through EPI.
- ✓ Vaccinating staffs at these vaccination counters will administered the COVID-19 vaccine in person and wait for 30 mins for any AEFI to occur.
- ✓ This data is entered directly in National Immunization Management System (NIMS). The dashboard is available on website and updated on daily basis.



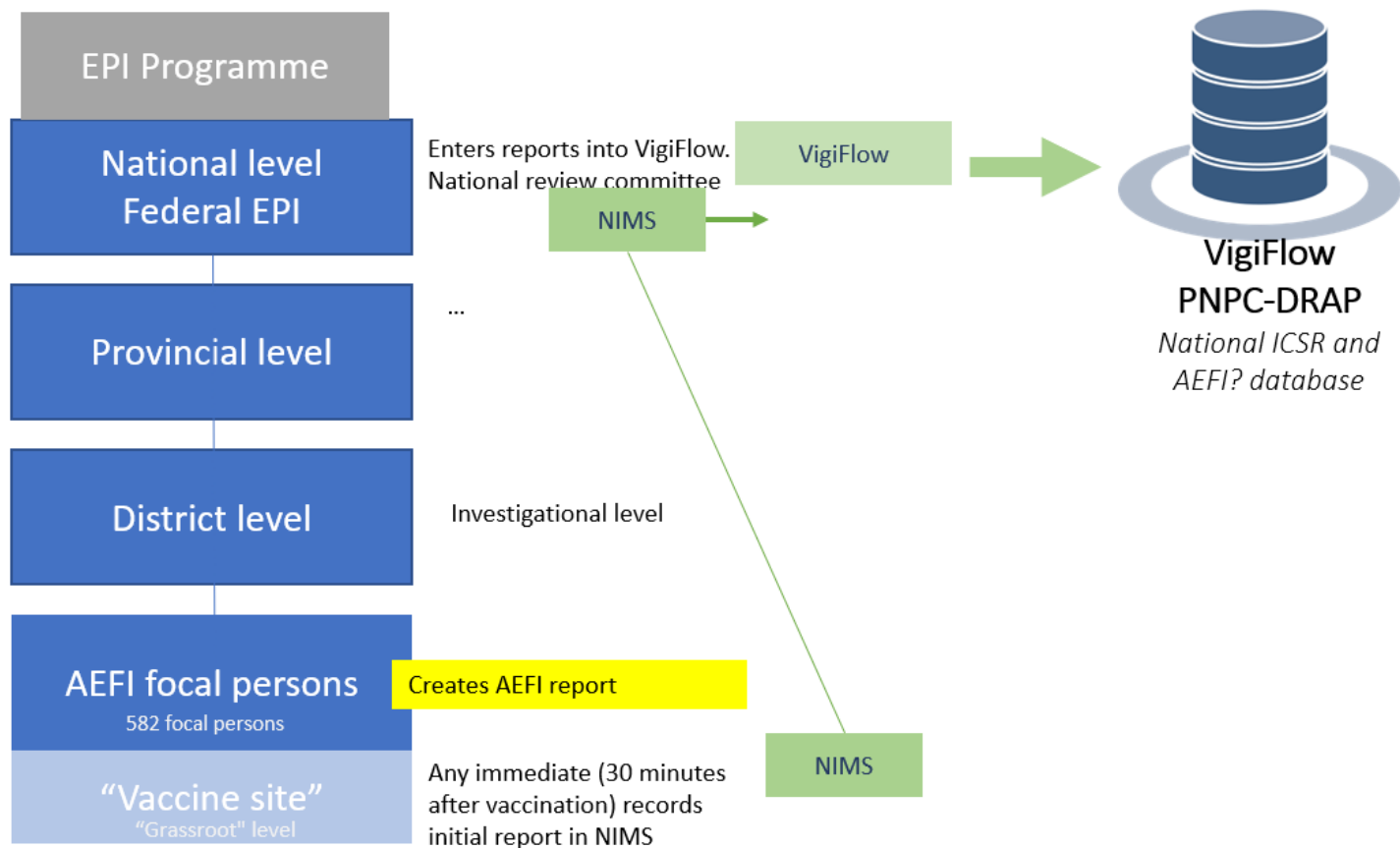
# Strategy for reporting COVID-19 AEFIs

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- ✓ Focal Persons of AEFIs at these adult vaccination counters report the AEFI data on daily basis to DHO office.
- ✓ The AEFI data at DHO office is compiled on weekly basis and entered in EPI-MIS and transferred to Federal EPI.
- ✓ There is a AEFI review committee at the level of Federal EPI for assessment of AEFI.
- ✓ The data compiled at Federal EPI will be entered in VigiFlow database and transferred to Pakistan National Pharmacovigilance Centre, DRAP



# Reporting paths Covid-19 AEFI reports





## Registered Vaccines of COVID-19 in Pakistan.

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- ✓ The vaccination drive was initiated on 2<sup>nd</sup> February, 2021 when 0.5million doses of SinoPharm vaccines donated by China arrived in Pakistan.
- ✓ In the first phase only healthcare professionals were vaccinated.
- ✓ In the 2<sup>nd</sup> Phase from 10<sup>th</sup> of March, 2021 onwards, vaccination in people elder then 60 years of age has been initiated.
- ✓ So far, 274859 Healthcare Professionals and 3291 citizens have been vaccinated as of 11-03-2021.
- ✓ 956 AEFIs have been reported to Federal Expended Programme on Immunization. Out of which 2 are Major and 954 are minors.



# THANK YOU