



## Online RTI Request Form Details

### RTI Request Details :-

RTI Request Registration number	CDSO/R/E/21/00573
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION


### Personal Details of RTI Applicant:-

Name	[REDACTED]
Gender	[REDACTED]
Address	[REDACTED]
Pincode	[REDACTED]
Country	India
State	[REDACTED]
Status	Details not provided
Educational Status	Details not provided
Phone Number	Details not provided
Mobile Number	Details not provided
Email-ID	[REDACTED]

### Request Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No

(Description of Information sought (upto 500 characters))

Description of Information Sought	
attached	
Concerned CPIO	Sushanta Sarkar
Supporting document <i>(only pdf upto 1 MB)</i>	

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Please provide detailed information on the trials of covid19 vaccines conducted in children below the age of 18 in India.

1. Please include information on the number of Informed Consent Forms (ICFs) collected during these trials for each of the covid19 vaccines (either from children or their guardians).

2. Please provide information on the number of non-healthy Indian children who participated in these trials. Non-healthy indicates children with chronic conditions such as eczema, asthma, ADD, ADHD, autism, and so on resulting from previous vaccinations or other causes.

3. Please provide information on Absolute Risk Reduction (ARR) observed in these clinical trials and not Relative Risk Reduction (RRR).

4. Please provide information on whether these covid19 vaccines trials were sponsored by the manufacturers themselves and/or by any Foundation (such as the Bill and Melinda Gates foundation or the Rockefeller foundation or other) and/or any government agency/institution.

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Thank you


 Select Language: English

Public Authorities Available

# RTI Online

 Version 2.0  
 An Initiative of Department of Personnel & Training, Government of India

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## Online RTI Status Form

Note: Fields marked with \* are Mandatory.

Enter Registration Number	CDSCO/R/E/21/00573
Name	██████████
Received Date	28/11/2021
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	27/12/2021
Reply :- Please find attached RTI reply.	
View Document	
CPIO Details :-	Sushanta Sarkar Phone: 011-23216367 rti[dot]cell[at]cdsco[dot]nic[dot]in
First Appellate Authority Details :-	A[dot] K[dot] Pradhan Phone: 011-23216367 rti[dot]cell[at]cdsco[dot]nic[dot]in
Nodal Officer Details :-	
Telephone Number	011-23236973
Email Id	jayantwz[at]gmail[dot]com

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**Z-28020/1500/2021-DC**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**Office of DCG (I)**  
**(RTI CELL)**

**FDA Bhawan, Kotla Road,  
New Delhi**

**Point No.01 to 04:**

CDSCO has granted the permissions to conduct following clinical trials in children & adolescents (age –group):

1. Phase II/III clinical trial of Nanoparticle Vaccine (Liquid) (COVOVAX) manufactured by M/s Serum Institute of India Pvt. Ltd. in 2 to 17 years age group.
2. Phase II/III clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine manufactured by M/s Bharat Biotech in 2 to 18 years age group.
3. Phase II/III clinical trial of RBD of SARS-CoV-2 gene manufactured by M/s Biological E Limited in  $\geq 5$  to  $< 18$  years age group.

Further, all the above clinical trials are being conducted in healthy participants.

The details of number of subjects, age group, inclusion and exclusion criteria, clinical trial objectives and endpoints, sponsors are also available publically and may be seen through CTRI website i.e. [www.ctri.gov.in](http://www.ctri.gov.in).

As of now, these clinical trials are ongoing for evaluation of safety of the vaccines and complete safety data may be available after conclusion of clinical trial results as per approved clinical trial protocol.

Further, this office has given global trial permission in Form CT-17 on 13/10/2021 to M/s Johnson and Johnson Private Limited, L.B.S. Marg, Mulund West, Maharashtra (India) – 400080 with protocol title- “A Randomized, Double-blind, Placebo-controlled, Phase 2/3 Adaptive Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Different Dose Levels of Ad26.COVS Administered as a One-or Two-dose Regimen in Healthy Adolescents From 12 to 17 Years Inclusive” - HORIZON 2, Protocol Number: VAC31518COV3006, Amendment 1, dated 13-July-2021.

Further, the above clinical trial is being conducted in healthy adolescents from age 12 to 17 Years.

The details of number of subjects, age group, inclusion and exclusion criteria, clinical trial objectives and endpoints, sponsor are available at CTRI website i.e. [www.ctri.gov.in](http://www.ctri.gov.in).

**RTI Cell,  
CDSCO (HQ), New Delhi**