Online RTI Request Form Details

RTI Request Details :-

RTI Request Registration number	CDSCO/R/E/21/00527
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	
application attached	
Concerned CPIO	Sushanta Sarkar
Supporting document ***(only pdf upto 1 MB)***	

Print Close

new RTI on CDSCO

The published literature related to AZD1222 (Covishield - University of Oxford/AstraZeneca vaccine, also known as ChAdOx1 nCoV-19) clinical trials, ' Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK' involved only healthy participants. The link to this study is here - https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1
The study is sponsored by the manufacturer themselves (at least in part).

The study compares relative risk reduction and not absolute risk reduction. If we look at this result from the study “Overall vaccine efficacy across both groups was 70·4% (95·8% CI 54·8–80·6; 30 [0·5%] of 5807 vs 101 [1·7%] of 5829).”. This is just a relative risk reduction which has no meaning.

The absolute risk reduction is just 1.2% (101/5829 minus 30/5807).

Please provide proper scientific basis for approving this vaccine for the public at large when the clinical trials:

1. Were sponsored in part by the manufacturer themselves,
2. Were conducted only on healthy individuals, and
3. Had a negligible benefit (of 1.2%) for reduction in the occurrence of symptoms

Please provide specific proof and basis (not general statements) for approving this vaccine for people with pre-existing health conditions, pregnant, and lactating women.

Please provide details of clinical trials involving Covishield done using Indian citizens.

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

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

Home Submit Request Submit First Appeal View Status View History new Login User Manual Contact Us FAQ

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	CDSCO/R/E/21/00527
Name	[redacted]
Received Date	30/10/2021
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	07/12/2021
Reply :- The vaccine was approved based on the provisions under the New Drugs and Clinical Trial Rules, 2019. M/s Serum Institute of India Pvt., Ltd. Pune had submitted safety immunogenicity & efficacy data of phase II/III clinical trials of AstraZeneca vaccine carried out in UK & Brazil & South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial in the country. The Subject Expert Committee (SEC) of CDSCO reviewed the proposal of restricted emergency use along with above details in its meetings dated 09.12.2020, 30.12.2020 and 01.01.2021, wherein, a fter detailed deliberation, the committee recommended for grant of permission for restricted emergency use of the vaccine subject to various regulatory provisions including with various conditions/restrictions. After adequate examination, CDSCO decided to accept the recommendations of the Expert Committee and accordingly, the permission was granted to M/s Serum Institute to manufacture ChAdOx1 nCOV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD) for restricted use in emergency situation in the country. Further the remarks and recommendations of Subject Expert Committee along with details of permission is publically available on cdsco website www.cdsco.gov.in. The brief of interim clinical trial results containing safety, immunogenicity and efficacy results and side-effects, contraindications, precautions and instruction of use including (pre-existing health conditions, pregnant and lactating Women) of Covishield COVID-19 vaccine is available in Summary of Product Characteristics (SmPC) and factsheet which are publically available on CDSCO website i.e. www.cdsco.gov.in. Further Sought information is exempted under Sec (8) (d) and (e) of RTI Act 2005, As third party consent is required for sharing information, Further your RTI has been transferred to Immunization division, MoHFWunder section 6(3) of the RTI ACT 2005 for providing available information, if any.	
Your RTI application has been forwarded to multiple Public Authory(s)	Click here to view details
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

Print RTI Application Print Status Go Back

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

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

Home Submit Request Submit First Appeal View Status View History new Login User Manual Contact Us FAQ

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	MOHFW/R/X/21/00512
Name	[redacted]
Received Date	07/12/2021
Public Authority	Department of Health & Family Welfare
Status	REQUEST TRANSFERRED TO OTHER PUBLIC AUTHORITY
Date of action	08/12/2021
Details of Public Autority :- Indian Council of Medical Research. vide registration number :- INCMR/R/T/21/01388 respectively. Note:- Further details will be available on viewing the status of the above-mentioned new request registration number. View Status of INCMR/R/T/21/01388	
Nodal Officer Details :-	
Telephone Number	011-23061831
Email Id	r[dot]attri54[at]nic[dot]in

Print RTI Application Print Status Go Back

सत्यमेव जयते

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

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

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	INCMR/R/T/21/01388
Name	[redacted]
Received Date	08/12/2021
Public Authority	Indian Council of Medical Research
Status	REQUEST DISPOSED OF
Date of action	13/12/2021
Reply :- 1. Trials are usually sponsored by manufacturer but approved is given only after data has been reviewed by independent subject matter expert committee. 2. Vaccine trials are conducted on healthy individuals as vaccines are usually expected to stop people from getting infected. 3. After second wave of COVID-19 in India in April-May, 2021 the National technical advisory group on immunization recommended COVID vaccine for people with pre- existing health condition, pregnant and lactating women. https://pubmed.ncbi.nlm.nih.gov/34870133/	
CPIO Details :-	Dr Nivedita Gupta Phone: 011-26588980 ngupta@icmr.org.in
First Appellate Authority Details :-	Dr Samiran Panda1 Phone: 011-26588272 samiranpanda.hq@icmr.gov.in
Nodal Officer Details :-	
Telephone Number	011-26588980
Email Id	maheshchand[dot]hq[at]icmr[dot]gov[dot]in

Print RTI Application Print Status Go Back