

DRAFT MINUTES OF THE 23RD CSC MEETING TO BE HELD ON 03RD APRIL 2021.

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05/04/2021

The 23rd Meeting of the CSC was held on 03.04.2021 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). At the Committee Room, 4th Floor, Drug Regulatory Authority of Pakistan, Islamabad.

2. The meeting was attended by the following members: -

Sr. No.	Name	Designation
01	Dr. Abdur Rashid.	Chairman CSC / Director, Division of Pharmacy Services-DRAP.

3. Following members attended the meeting online through Zoom:

01	Dr. Faiza Bashir.	Chairman, Pakistan Health Research Council or his nominee, Islamabad.
02	Prof. Nadeem Irfan Bukhari.	Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.
03	Prof. Dr. Javed Akram.	Professor of Medicine, Physician, Vice Chancellor, University of Health Sciences, Lahore.
04	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.
05	Prof. Brig R Muzammil Hassan Najmi,	Professor of Pharmacology, Foundation University, Islamabad.
06	Dr. Naseem Salahuddin	Director Infectious Diseases, The Indus Hospital, Karachi (Co-opted Member)
07	Dr. Aamir Jaffery	Sindh Institute of Urology and Transplantation, Karachi (Co-opted Member)
08	Prof. Dr. Mushtaq Ahmed	Prof. of Cardiology, Bacha Khan Medical University, Mardan
09	Abdul Sattar Sohrani.	Secretary CSC, Additional Director, Division of Pharmacy Services-DRAP.

4. Meeting started with the recitation of holy verses of the Quran by Dr. Abdur Rashid, Chairman, CSC welcomed all the members & appreciated their active virtual participation through Zoom.

AGENDA ITEM - I: CONFIRMATION OF THE MINUTES OF THE 22ND CLINICAL STUDIES COMMITTEE MEETING.

1.1 Minutes of 22th CSC meeting held on 23rd March 2021 are placed for confirmation signature of CSC members.

1.2. Submitted for perusal, discussion and decision of CSC.


05/04/2021

Decision of CSC:- All the Members of the CSC unanimously approved the Minutes of 22th CSC meeting held on 23rd March 2021

Item II:

APPLICATION TO INCLUDE TWO ADDITIONAL CLINICAL TRIAL SITES IN THE CLINICAL TRIAL TITLED "A PHASE III RANDOMIZED, DOUBLE-BLIND, PARALLEL-CONTROLLED CLINICAL TRIAL IN 18 YEARS OF AGE AND ABOVE TO DETERMINE THE SAFETY AND EFFICACY OF ZE2001, A RECOMBINANT NOVEL CORONAVIRUS VACCINE (CHO CELL) FOR PREVENTION OF COVID-19"

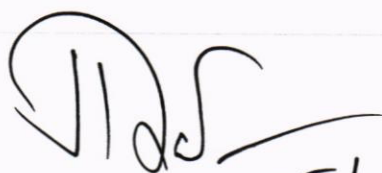
1. Prof. Dr. Javed Akram, the Principal Investigator of Clinical Study/ Trial "A PHASE III RANDOMIZED, DOUBLE-BLIND, PARALLEL-CONTROLLED CLINICAL TRIAL IN 18 YEARS OF AGE AND ABOVE TO DETERMINE THE SAFETY AND EFFICACY OF ZE2001, A RECOMBINANT NOVEL CORONAVIRUS VACCINE (CHO CELL) FOR PREVENTION OF COVID-19" has requested to include following two new clinical trial sites in Islamabad, in above mentioned Trial.
 2. Al-Shifa Trust Eye Hospital, Rawalpindi.
 3. Shaheed Zulfiqar Ali Bhutto medical university, Islamabad.
2. As per this office office record Al-Shifa Trust Research Center, Al-Shifa Trust Eye Hospital, Jhelum road, Rawalpindi, and MCH Unit-II, Pakistan Institute of Medical Sciences (PIMS), MCH Center are approved Clinical trial Sites.
3. Submitted for the perusal of CSC

Decision of CSC:- All the Members of the CSC unanimously approved both clinical trial sites of Al-Shifa Trust Research Center, Al-Shifa Trust Eye Hospital, Jhelum road, Rawalpindi, and MCH Unit-II, Pakistan Institute of Medical Sciences (PIMS), MCH Center for Clinical Study/ Trial "A PHASE III RANDOMIZED, DOUBLE-BLIND, PARALLEL-CONTROLLED CLINICAL TRIAL IN 18 YEARS OF AGE AND ABOVE TO DETERMINE THE SAFETY AND EFFICACY OF ZE2001, A RECOMBINANT NOVEL CORONAVIRUS VACCINE (CHO CELL) FOR PREVENTION OF COVID-19" with condition to submission of IRB approval.

AGENDA ITEM - III:

CLINICAL TRIAL OF INDIGENIOUS VENTILATORS (PAKVENT-I VENTILATOR).

Case of the applicant was placed in 22nd CSC meeting and was decided as following.


05/04/2021