

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"

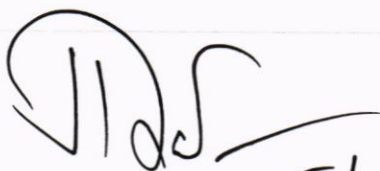
1. Prof. Dr. Javed Akram, the Principal Investigator of Clinical Study/ Trial "A PHASE III RANDOMIZED, DOUBLE-BLIND, PARALLEL-CONTROLLED CLINICAL TRIAL IN 18 YEARS OF AGE AND ABOVE TO DETERMINE THE SAFETY AND EFFICACY OF ZE2001, A RECOMBINANT NOVEL CORONAVIRUS VACCINE (CHO CELL) FOR PREVENTION OF COVID-19" 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

Decision OF 22nd CSC Meeting:

CSC after detailed deliberation & discussion decided as follows:

- i. *The specifications/features approved by the Pakistan Engineering Council (PEC) contain that the ventilator has built in compressor. Whereas the presentation by the manufacturing team was about the ventilators without compressor. At this stage use of ambient air may not be a good idea in view of contaminated environment so use of built in medical grade compressor/centralized compressed air be considered. As discussed & agreed by the Project Management Organization team that the compressor will be added in the ventilators as approved by the PEC or the existing version of ventilator to be tested may be provided and endorsed by the PEC.*
 - ii. *Since the PI plans to adopt a new methodology in the Clinical Validation Study, the PI has to come up with a new inclusion and exclusion criteria, informed consent process, data collection plan, sample size, and all other related aspects. It was also decided that the Consent Form in English as well as in Urdu & should be used for the purpose of obtaining the consent from the subject or his/her next of kin.*
 - iii. *The clinical end points for termination of the use of test ventilator should be clearly identified and included in the protocol. The Principal Investigator, Co PI and other members of the team should be identified and should sign the protocol. The method for collection of data and its statistical analysis should be part of the protocol.*
 - iv. *According to the new proposed plan, the test ventilator will be trialed initially on elective surgical subjects who will be administered intravenous anesthesia. Its stated limitation according to the protocol submitted is that this ventilator is not meant to work for more than one day & ICU subjects may require ventilation for several days, it may eventually develop into such use after clinical validation in the elective operative subjects (ASA Category 1).*
 - v. *Total number of adult subjects should be mentioned in the amended protocol. Patient safety may not be compromised during the testing of ventilators & trial of the ventilators will be under active supervision of investigation & manufacturing teams to avoid any mishap.*
 - vi. *Principal Investigator will modify/amend the protocol as presented & discussed in the meeting. This amended protocol will be approved by IRB of Combined Military Hospital, Rawalpindi & subsequently by NBC-PHRC.*
 - vii. *The approved amended protocol will be submitted to Division of Pharmacy Services along with prescribed fee for approval of amended protocol, which will be placed before the CSC for its consideration.*
12. Reply of the applicant is following and submitted for perusal of CSC along with above paras.

 25/04/2021

RESTRICTED


PA-102438 Maj Gen
Rao Ali Shan Khan
Advisor in Anaesthesiology
HoD Anaes/Pain Med/S.ICU
Combined Military Hospital
Rawalpindi
Tel - Mil - 34519
Gen / 64 / 2021
4 Apr 2021

To: Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division - Islamabad

Subj: CLINICAL TRIAL OF INDIGENOUS VENTILATORS (PAKVENT-I VENTILATOR)

Government of Pakistan Drug Regulatory Authority of Pakistan Pharmacy Services Division letter no F. No 16-21/2021 DD (PS) dated 24th March 2021 reference.

1. As it was discussed at NCOC that compressor is not need of hour, because most of the ventilators are turbine based, however compressors can be added in subsequent models.
2. The study will include inclusion and exclusion criteria, informed consent both in English and Urdu, data collection plan, sample size and all other related aspects. Attached as Anx "A". Statistication will be present. Same protocol will be followed.
3. Clinical end point for termination of the use of test vent will be according to set clinical parameters given by ATC.
4. The test ventilator will be initially used on elective surgical patients using TIVA and subsequently in ICU ventilator will be tested continuously for 96 hours to a certain limit.
5. Total no of subject are 50, a stand by vent is always present in case of emergency. PI and manufacturer will be present during study to avoid any emergency situation.
6. Trial of vent is always under direct supervision of a Medical Doctor and PMO Engineer.


Maj Gen
(Rao Ali Shan Khan)

RESTRICTED

RESTRICTED

PA-102438 Maj Gen
Rao Ali Shan Khan
Advisor in Anaesthesiology
HoD Anaes/Pain Med/S.ICU
Combined Military Hospital
Rawalpindi
Tel - Mil - 34519
Gen / 60 / 2021

29th Mar 2021

To: Med-DMS 2

Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division - Islamabad

Subj: CLINICAL TRIAL OF INDIGENOUS VENTILATORS (PAKVENT-I VENTILATOR)

Government of Pakistan Drug Regulatory Authority of Pakistan Pharmacy Services Division letter no F. No 16-21/2021 DD (PS) dated 24th March 2021 ref.

1. Introduction:

a. A prototype version of Pak Vent (Version 1.0) was made by PEC & PITC. It was then tested for engineering aspects and data was shared with DRAP for approval of this version of ventilator for human application. The Clinical Studies Committee visited Combined Military Hospital, Rawalpindi for subject purpose and approved it as a site for clinical testing vide Government of Pakistan Drug Regulatory Authority of Pakistan Pharmacy services Division letter no F. No 16-21/2021 DD (PS) dated 24th March, 2021. The Clinical Studies Committee has decided to perform trials and is of the view that a protocol to be constructed, so that this study could be performed in a systematic and schematic method.

2. Objective:

a. The objective of this study is to authorize the use of Pak Vent Version 1.0 for safe human use.

3. Material and methodology:

a. After obtaining Ethical Review Board permission from institution this study will be conducted in Operation theatre (OT) for Phase I trials and in Intensive Care (ICU) for Phase II & III trials in Department of Anesthesia Combined Military Hospital, Rawalpindi. Consent will be given by patient himself in OT settings and

by next of kin in ICU setting for use of this prototype ventilator. Keeping this in view, a consent form for the use of this prototype ventilator on patients in designed (attached Annexure A) in easy languages both in English and Urdu. This form will be read aloud and displayed to patients & next of kin before start of procedure. Only those consenting for its use will be considered. Data will be collected on a Performa (attached Annexure B) and will be kept confidential throughout the study duration.

b. As it is an experimental pilot study sample size of 50 is considered. Data of first 20 samples will be collected in OT for phase I trials. Phase I trials will include those patients who have no comorbid and those requiring surgery of less than or equal to one hour duration. Anesthesia during this phase will be given by TIVA (total intra venous anesthesia). Standard modes i.e., Pressure and Volume Control of Pak Vent 1.0 will be tested in this phase.

c. SOFA Score (attached annexure C) will be calculated to assess the severity of illness of patients. Data of next 20 samples will be collected in ICU on moderately ill patients for Phase II trials. Sedation and paralysis during this phase will be maintained by infusion midazolam as per body weight and infusion atracurium as per body weight as and when required.

d. Data of remaining 10 samples will be collected on critically ill patients in ICU for phase III trials. Total duration of these trials will be 96 hours both in OT & ICU settings. After completion of these trials a 4 days endurance run of ventilator will also be performed on a critically ill patient. The Non-invasive mode of this ventilator will also be tested after completion of phase III trials.

e. Data will be collected by only designated personals by principal investigator and record will be kept in a bolted safe. Statistician will be taken on board for analyzing data and provision of results. During testing of Pak Vent version 1 a stand by internationally manufactured ventilator will also be kept spare in order to provide safe ventilation to any unforeseen event.

f. The inclusion criteria will constitute as follows:

- (1) Age 18 and above
- (2) Both Genders i.e., Male & Female
- (3) Hemodynamically stable patients with no pre-morbid in Operation theatre
- (4) Moderate and critically ill patients in ICU

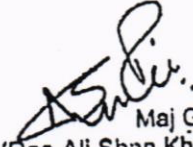
g. The exclusion criteria will constitute as follows:

- (1) Age < 18
- (2) Decline of informed consent
- (3) Psychiatric condition or medication
- (4) Pre-Cardiac Arrest State Patients.
- (5) The exclusion criteria aim to minimize bias.

4. Data analysis procedure:

a. The data, recorded on Performa will be transferred to SPSS 26.0 (version for windows) for statistical analysis. Descriptive statistics will be used for qualitative and quantitative variables. A qualitative variable like gender, ASA class will be measured by frequency or percentage. Quantitative variables like age, weight, ABGs will be recorded as mean and standard deviation. P value \leq 0.05 will be taken as significant.

5. Forwarded for necessary action and information.


Maj Gen
(Rao Ali Shan Khan)

RESTRICTED

CONSENT FORM

1. I have been told and explained in easy Urdu/_____ my mother language, the one which I can easily understand and speak, these following points:

a. During my operation in General Anesthesia, I am willing to be placed on ventilator / I have been told that my patient due to his moribund condition needs ventilatory support.

b. The ventilator used will be Pak Vent version no 1 that has been designed in Pakistan under supervision of expert personnel. They have tested it and have declared it functional for human use.

c. I have also been told about all the information about this ventilator and its advantages and disadvantages.

2. Keeping above in view, I consent to place myself/ my patient on Pak Vent Version 1.

Signature: _____

Relation with patient: _____

Time & Date: _____

Signature of Doctor: _____

اجازت نامہ

مجھے آسان اردو یاد آئی..... جو میری مادری زبان ہے۔ مندرجہ ذیل نقاط کو بتایا گیا ہے۔ میں ان نقاط کو بخوبی پڑھا اور سمجھ سکتا ہوں۔

1- مکمل بیہوشی کیساتھ جراحی کے دوران میں اپنے آپ کو پاک ویٹ ڈروئین ون پر مصنوعی سانس لینے کی اجازت دیتا یا دیتی ہوں۔ انہیں اپنے مریض کی انتہائی سنگین علالت کے بارے میں بتایا گیا ہے نیز میرے مریض کو مصنوعی سانس کی ضرورت ہے۔

2- مصنوعی سانس کی مشین جو میرے مریض پر استعمال ہوگی وہ پاک ویٹنٹ درزین ون ہے۔ یہ مشین تجربہ کار ماہرین کے زیر نگرانی تیار کی گئی ہے۔ لیبارٹری میں اسکی صلاحیت کا اندازہ لگا کر اسے انسانی استعمال کے لیے کارآمد قرار دیا گیا ہے۔

3۔ مجھے اس مشین کے فوائد و نقصانات کے بارے میں بھی مکمل آگاہی مہیا کی گئی ہے۔

ان نقاط کے مد نظر رکھتے ہوئے میں اپنے آپ کو یا اپنے مریض کو اس مشین کے ساتھ معمولی سانس لینے کی اجازت دیتا یا دیتی ہوں۔

..... رستخیز

.....مریض کے ساتھ رشتہ

..... تاریخ و وقت

.....

1. DOCUMENTATION OF PATIENT INFORMATION AND BASELINE DATA

PATIENT INFORMATION:	VALUES
Patient Hospital Number	
Age	
Gender	
Weight (actual / ideal)	
Diagnosis on Admission	
APPACHI Score (trial day)	
Sofa Score (trial day)	
PaO ₂ / FiO ₂ ratio (trial day)	
Heart Rate (range in preceding 3hrs)	
MAP (range in preceding in 3hrs)	
Right ventricular systolic function(TAPSE, 2D RV FAC) on trial day	
Left ventricular systolic function(ejection fraction) on trial day	
Chest x-ray findings (ETT position,lung collapse, new infiltrates,pneumothorax)	

2. PATIENT'S CLINICAL ASSESSMENT USING STANDARD AND TEST VENTILATOR

PATIENT'S ASSESSMENTS				
Variables	Standard ICU ventilator Time (0min)	Test Ventilator or (30min)	Test Ventilator or (60min)	Test Ventilator (90min)
Sedation / delirium (RASS / CAMICU)				
Heart rate (range in 30min trial)				
MAP (range in 30min trial)				
Central Venous Pressure (CVP)				
Breath sounds (air entry, added sounds)				
Chest Expansion				
Pallor / skin color				
Secretion (volume, consistency)				
ETT tube position				
Patient - ventilator synchrony (waves form analysis)				

3. VENTILATOR PARAMETERS USING STANDARD AND TEST VENTILATOR

Variables	Standard ICU ventilator Time (0min)	Test Ventilator (30min)	Test Ventilator (60min)	Test Ventilator (90min)
Mode				
FiO2 (set/analyzed)				
Set ventilator rate(RR)/Total Rate				
Minute ventilation \dot{V}_E				
Mean airway pressure				
Plateau pressure				
Applied PEEP				
Auto PEEP				
Trigger				
I:E ratio				
Set Vt (volume cycle)				
Measured Vt (volume cycle)				
Set PIP (pressure cycle)				
Set inspiratory flow rate				
Ins. Rise setting				
Inspiratory flow cycle				
Flow wave form				
Static Compliance (Cs)				
Airway Resistance(Raw)				
ETT cuff pressure				
Automatic tube comp.set (yes/no)				
End-tidal CO2 monitoring				
Apnea Parameters Set(yes/no)				
Press. Limit (high/low)				
Low VT				
VE (high/low)				
High Rate				

4. ARTERIAL BLOOD GAS ANALYSIS USING STANDARD AND TEST VENTILATOR

ARTERIAL BLOOD GAS ANALYSIS				
Variables	Standard ICU ventilator Time (0min)	Test Ventilator (30min)	Test Ventilator (60min)	Test Ventilator (90min)
Ph				
PaCO ₂ mm/Hg				
PaO ₂ mm/Hg				
SO ₂ mm/Hg				
HCO ₃ /				

5. SPONTANEOUS BREATHING TRIAL (SBT)

Variables	Standard ICU ventilator Time (0min)	Test Ventilator (30min)	Test Ventilator (60min)	Test Ventilator (90min)
Spontaneous rate				
Spontaneous VT				
RSBI [f/Vt (breaths /min/L)]				
Negative inspiratory force (NIF)				
Time of SBT				

SOFA SCORE

Sequential Organ failure assessment score is useful in predicting the clinical outcomes of critically ill patients. Regardless of the initial score mortality rate is 50% if score is increased. The score has six components as following:

1. Respiratory system	
PaO ₂ /FiO ₂ (mmHg (kPa))	SOFA score
≥ 400 (53.3)	0
< 400 (53.3)	+1
< 300 (40)	+2
< 200 (26.7) and mechanically ventilated	+3
< 100 (13.3) and mechanically ventilated	+4
2. Nervous system	
Glasgow coma scale	SOFA score
15	0
13-14	+1
10-12	+2
6-9	+3
< 6	+4
3. Cardiovascular system	
Mean arterial pressure OR administration of vasopressors required	SOFA score
MAP ≥ 70 mmHg	0
MAP < 70 mmHg	+1
dopamine ≤ 5 µg/kg/min or dobutamine (any dose)	+2
dopamine > 5 µg/kg/min OR epinephrine ≤ 0.1 µg/kg/min OR norepinephrine ≤ 0.1 µg/kg/min	+3
dopamine > 15 µg/kg/min OR epinephrine > 0.1 µg/kg/min OR norepinephrine > 0.1 µg/kg/min	+4
4. Liver	
Bilirubin (mg/dl) [µmol/L]	SOFA score
< 1.2 [< 20]	0
1.2-1.9 [20-32]	+1
2.0-5.9 [33-101]	+2
6.0-11.9 [102-204]	+3
> 12.0 [> 204]	+4
5. Coagulation	
Platelets × 10 ³ /µl	SOFA score
≥ 150	0
< 150	+1
< 100	+2
< 50	+3
< 20	+4
6. Kidneys	
Creatinine (mg/dl) [µmol/L] (or urine output)	SOFA score
< 1.2 [< 110]	0
1.2-1.9 [110-170]	+1
2.0-3.4 [171-299]	+2
3.5-4.9 [300-440] (or < 500 ml/d)	+3
> 5.0 [> 440] (or < 200 ml/d)	+4

No: 125/11/2020

ETHICAL COMMITTEE/ INSTITUTIONAL REVIEW BOARD (IRB)
COMBINED MILITARY HOSPITAL RAWALPINDI

Subj: "CLINICAL VALIDATION OF PAK VENT-1 DEVELOPED BY NESCOM AT
COMBINED MILITARY HOSPITAL RAWALPINDI"

Approval of IRB is accorded to carry out "CLINICAL VALIDATION TRIALS ON HUMAN SUBJECT OF PAK VENT-1 DEVELOPED BY NESCOM AT COMBINED MILITARY HOSPITAL RAWALPINDI" undersupervision of Major General Rao Ali Shan Khan, Advisor in Anaesthesiology, Anaes Department of this hospital.

President:

Dated: 4/12/2020

Members:



Bilal Umair
Maj Gen Bilal Umair, Advisor/ HoD Thoracic Surg

Brig Asher Ahmed Mashood
FCPS (Derm), MBBS (HPE), DIT (UK);
Associate Prof & Head of Skin Dept
Brig Asher Ahmed Mashood, HoD Skin

Lt Col Abdul Rasheed, CI Med Spec

Lt Col Tabassum Muzaffar
MBBS, MCPS, FCPS
Senior Lecturer & Professor
Classified Specialist
Gynaecologist
CMH, Rawalpindi

Discussion: After long discussion of CSC and representative of the applicant i.e. Col. Ahmed Burki and Brig (R) Tariq Javed following comments were given by following members:-

Dr. Abdur Rashid said that keeping in the view the current emergency situation, and knowledge for ventilators we should handle the case positively without wasting any time in the national interest.

Dr. Javed Akram said that let we do the NBC approve the protocol. We shall not be rubberstamp and we should follow the procedure applicant should send the NBC, the protocol and consent form and after the meeting of NBC we should convene the meeting of CSC.


Brig (R) Dr. Muzammil Hassan Najmi said that the all these cases are of National interest but we should follow the required procedures. He said that he don't have experience on ventilators but form the submitted documents it seems that work is not as per science. Protocol should be as per science and then follow the procedures. He further said that an intensivist should be part of CSC for discussion of this case.

Dr. Aamir Jaffery said that due process is also important for national interest. Bypassing the NBC is not as per rule applicant should follow the legal process otherwise it will be make us as rubberstamp.

Dr. Faiza Bashir said that I agree to the members of CSC. She further said that submitted protocols in this meeting differs from the already submitted protocols it should go to the NBC and it should be communicated to the applicant that both protocols are different.

Dr. Naseem Salahuddin said that the committee should not work under pressure. We should not waste the time whether we should follow the legal procedures.

Dr. Farhana Badar said that some Biomedical Engineers should be the part of this committee during discussion of this study. She recommended the engineers Hassan Mohi-uddin who have worked in SKMCH&RC.


05/04/2021

Decision of CSC:- All the Members of the CSC unanimously decided that as protocol is changed, hence NBC approval is required. The applicant should submit the changed protocol and elaborated consent form in Urdu and English duly signed by the principal investigator to the NBC. After approval from NBC the same should be submitted to the DRAP for consideration of CSC.

The meeting ended with the exchange of greetings.


25/04/2021



Abdur Rashid <rashidrap@gmail.com>

Draft Minutes of 23rd CSC meeting

5 messages

AHSAN-UL-HAQ ATHER <ahsanather@hotmail.com>

Sat, Apr 3, 2021 at 3:14 PM

To: "Dr. Abdur Rashid" <rashidrap@gmail.com>, abdul sattar <sattarsohrani123@gmail.com>, "drfaizabashir@yahoo.com" <drfaizabashir@yahoo.com>, "Dr. Farhana Badar" <farhana@skm.org.pk>, "jakramaimc@gmail.com" <jakramaimc@gmail.com>, "vc@uhs.edu.pk" <vc@uhs.edu.pk>, "nadeem_irfan@hotmail.com" <nadeem_irfan@hotmail.com>, Muzammil Najmi <najmimh@hotmail.com>, "aamirjafarey@gmail.com" <aamirjafarey@gmail.com>, Mushtaq Ahmed <mushtaq030091@gmail.com>, "naseem.salahuddin@tih.org.pk" <naseem.salahuddin@tih.org.pk>

i am directed to forward the draft minutes of 23rd CSC meeting to all members for approval. please reply/comments before 9:00 AM dated 05.04.2021 otherwise minutes will be considered as approved.

Regards

rana Ahsan ul Aaq Athar

Draft Meeting 23 csc.pdf
756K

Dr. Farhana Badar <farhana@skm.org.pk>

Sat, Apr 3, 2021 at 5:41 PM

To: AHSAN-UL-HAQ ATHER <ahsanather@hotmail.com>, "Dr. Abdur Rashid" <rashidrap@gmail.com>, abdul sattar <sattarsohrani123@gmail.com>, "drfaizabashir@yahoo.com" <drfaizabashir@yahoo.com>, "jakramaimc@gmail.com" <jakramaimc@gmail.com>, "vc@uhs.edu.pk" <vc@uhs.edu.pk>, "nadeem_irfan@hotmail.com" <nadeem_irfan@hotmail.com>, Muzammil Najmi <najmimh@hotmail.com>, "aamirjafarey@gmail.com" <aamirjafarey@gmail.com>, Mushtaq Ahmed <mushtaq030091@gmail.com>, "naseem.salahuddin@tih.org.pk" <naseem.salahuddin@tih.org.pk>

Please correct it to:

Dr. Farhana Badar said that the study submitted earlier was a validation study and the current study is a phase 1-3 study, which the researchers say has already been conducted. If the researchers have already conducted the study, its approval is an administrative issue, beyond the scope of the Clinical Studies Committee. Dr. Farhana further added that Dr. Hassan Mohy Ud Din, who is an engineer and a researcher as well, should be part of the Committee during anymore discussion of the study. She said that Dr. Hassan has worked for a few months for SKM in the past, and at present, is working for LUMS, Lahore. Dr. Rashid asked Dr. Farhana for Dr. Hassan's CV.

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From: AHSAN-UL-HAQ ATHER <ahsanather@hotmail.com>

Sent: Saturday, April 3, 2021 3:14:36 PM

To: Dr. Abdur Rashid <rashidrap@gmail.com>; abdul sattar <sattarsohrani123@gmail.com>; drfaizabashir@yahoo.com <drfaizabashir@yahoo.com>; Dr. Farhana Badar <farhana@skm.org.pk>; jakramaimc@gmail.com <jakramaimc@gmail.com>; vc@uhs.edu.pk <vc@uhs.edu.pk>; nadeem_irfan@hotmail.com <nadeem_irfan@hotmail.com>; Muzammil Najmi <najmimh@hotmail.com>; aamirjafarey@gmail.com <aamirjafarey@gmail.com>; Mushtaq Ahmed <mushtaq030091@gmail.com>; naseem.salahuddin@tih.org.pk <naseem.salahuddin@tih.org.pk>

Subject: Draft Minutes of 23rd CSC meeting

[Quoted text hidden]

Aamir Jafarey <aamirjafarey@gmail.com>

Sat, Apr 3, 2021 at 6:02 PM

To: AHSAN-UL-HAQ ATHER <ahsanather@hotmail.com>

Cc: "Dr. Abdur Rashid" <rashidrap@gmail.com>, abdul sattar <sattarsohrani123@gmail.com>, Faiza Bashir <drfaizabashir@yahoo.com>, "Dr. Farhana Badar" <farhana@skm.org.pk>, "Prof Dr. Javed Akram AIMC Principal" <jakramaimc@gmail.com>, Vice Chancellor <vc@uhs.edu.pk>, nadeem_irfan@hotmail.com, Muzammil Najmi <najmimh@hotmail.com>, Mushtaq Ahmed <mushtaq030091@gmail.com>, Naseem Salahuddin <naseem.salahuddin@tih.org.pk>

This is just for the information of the CSC, the NBC has as of 6 pm received no revised protocol for the ventilator project. We will therefore not be reviewing anything tonight.

Aamir Jafarey

[Quoted text hidden]

Javed Akram <jakramaimc@gmail.com>

Sat, Apr 3, 2021 at 6:14 PM

To: Aamir Jafarey <aamirjafarey@gmail.com>

Cc: AHSAN-UL-HAQ ATHER <ahsanather@hotmail.com>, "Dr. Abdul Rashid" <rashidrap@gmail.com>, "Dr. Farhana Badar" <farhana@skm.org.pk>, Faiza Bashir <drfaizabashir@yahoo.com>, Mushtaq Ahmed <mushtaq030091@gmail.com>, Muzammil Najmi <najmimh@hotmail.com>, Naseem Salahuddin <naseem.salahuddin@tih.org.pk>, Vice Chancellor <vc@uhs.edu.pk>, Abdul Sattar <sattarsohrani123@gmail.com>, nadeem_irfan@hotmail.com

Thank you so much Dr Abdul Rasheed & Rana Ahsan sahib for the efficient work as the minutes are well drafted.

I am so glad that we all remain a unified team while it is so unfortunate that the people who were in such a hurry are not complying so Amir very rightly

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Professor Javed Akram

MRCP(UK), FRCP (London), FRCP (Glasgow),

FRCP (Edinburgh), FACC (USA), FACP (USA), FASIM (USA)

Vice Chancellor

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jakramaimc@gmail.com

Abdur Rashid <rashidrap@gmail.com>

Mon, Apr 5, 2021 at 10:15 AM

To: Shafqat Hussain Danish <dr.s.h.danish@gmail.com>

----- Forwarded message -----

From: **AHSAN-UL-HAQ ATHER** <ahsanather@hotmail.com>

Date: Sat, Apr 3, 2021 at 3:14 PM

Subject: Draft Minutes of 23rd CSC meeting

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[Quoted text hidden]



Draft Meeting 23 csc.pdf

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