MINUTES OF THE 25TH MEETING OF CSC, HELD ON 28TH APRIL2021.

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The 25th Meeting of the CSC was held on 28thApril 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.
02	Abdul Sattar Sohrani.	Secretary CSC, Additional Director, Division of Pharmacy Services-DRAP.

3. Following members attended the meeting online through Zoom:

01	Prof. Brig. (R), Muzammil Hassan Najmi.	Professor of Pharmacology, Foundation University, Islamabad.
02	Prof. Dr. Javed Akram.	Professor of Medicine, Physician, Vice Chancellor, University of Health Sciences, Lahore.
03	Dr. Naseem Salahuddin.	Director Infectious Diseases Indus Hospital, Karachi Co-opted Member.
04	Dr. Aamir Jaffary	Sindh Institute of Urology & Transplantation (SIUT), Karachi Co-opted Member.
05	Prof: Dr. Mushtaq Ahmed	Professor of Cardiology, Bach Khan Medical College, Mardan, KPK Co-opted Member.

4. Meeting started with the recitation of holy verses of the Quran by Abdul Sattar Sohrani. Abdul Rashid. Chairman, CSC welcomed all the members & appreciated their active online participation through Zoom.

AGENDA ITEM - I: **CONFIRMATION OF THE MINUTES OF THE 24TH CLINICAL STUDIES COMMITTEE MEETING.**

1. Confirmation of Minutes of 24th CSC meeting, held on 07thApril 2021. Since the occurrences of COVID pandemic majority of the meetings are being conducted online through Zoom.

2. The members are requested to confirm the minutes electronically. Confirmatory email will be made part of the minutes to satisfy legal provision.

Submitted for consideration of CSC.

Decision:

All the Members of the CSC unanimously confirmed the Minutes of 24thCSC meeting held on 07thApril 2021.

AGENDA ITEM - II:

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

1. Case of the applicant was placed 19th CSC meeting then 21st CSC meeting. In 22nd CSC meeting, the case of Clinical Trial of Indigenous Ventilators (Pak vent-I) was decided as following.

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.***

2. Reply of the applicant was placed before CSC in its 23rd meeting held on 03 April 2021 and CSC decided as following.

Decision of 23rdCSC Meeting: - *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 singed by the principal investigator to the NBC. After approval from NBC the same should be submitted to the DRAP for consideration of CSC.*

3. The Maj. Gen. Rao Shan Ali has submitted his reply as principal investigator and scanned reply of the applicant is received, the revised protocol dually approved by NBC and three pages of consent form in English & Urdu are submitted, details are attached as **Annex-I.**

Decision of CSC:-

CSC unanimously approved to conduct Clinical Validation of Pakvent-I manufactured by Project Management Organization at CMH Rawalpindi as per submitted protocol.

Agenda Item III:

CLINICAL TRIAL OF INDIGENIOUS VENTILATORS (I-LIVE VENTILATOR)

1. The Case was placed in 19th CSC meeting 12th February 2021 and was decided as followings.

The case was presented in 19th CSC meeting and committee decided as following;

Decision of 19th CSC meeting:

The CSC after detailed deliberation decided to constituted a sub-committee which will be comprised of following experts:

i. *Biomedical engineers*
ii. *Anesthetist*
iii. *Pulmonologist*
iv. *Dr. Faiza Basheer*
v. *Prof. Dr. Javed Akram*
vi. *Dr. Abdur Rasheed*
vii. *Any other expert co-opted by the sub-committee.*

2. The Sub-committee will develop TORs & proforma for evaluation & inspection of ventilator trial applications.

3. CSC constituted following panel for inspection of ventilators trial application of Lahore region:

i. *Prof. Dr. Javed Akram, V.C. UHS, Lahore. (Chairman)*
ii. *Dr. Farhana Badar*
iii. *Dr. Faheem Butt, Pulmonologist (from Shaukat Khanum Cancer Hospital & Research Center.*
iv. *Biomedical engineers (from Sheikh Zayed Hospital, Lahore.)*
v. *Prof. Dr. Sajjad Kazmi, Sheikh Zayed Hospital, Lahore.*

4. CSC constituted following panel for inspection of ventilators trial application of Islamabad region:

i. *Dr. Abdur Rashid, Chairman CSC-DRAP (Chairman)*
ii. *Maj. Gen. (Retd) Aslam*
iii. *Brig. (Retd) Muzammil Hassan Najmi*
iv. *Prof. Dr. Iqbal Memon, HOD Anesthesia, PIMS, Islamabad.*
v. *Dr. Afrasayab, Biomedical Engineer, NUST, Islamabad.*
vi. *Muhammad Mubashir Aslam, G.M. Plant, Innovative Health Technology, NUST, Islamabad.*

5. Inspection panel may co-opt any relevant experts for the inspection. Further it is also decided that application for ventilators included in this meeting, inspection will be carried out without proforma.

6. Proforma will be developed by sub-committee later on.

7. Accordingly, the following letter was sent to the applicant.

This is with reference to your application dated 14.01.2021 on subject cited above, you are informed that case was placed before Clinical Studies Committee (CSC) under Bio-Study Rules 2017.The CSC decided for the inspection of Clinical Trial Site, where the Clinical Validation of Ventilator is to be conducted, to verify facilities, equipment, supportive Intensive Care Unit (ICU) and other parameters necessary to conduct Clinical Validation.

Applicant to reply this office letter of even number dated 25.01.2021 i.e. "After evaluation, it was found that you have not attached requisite documents given in Form-II along with your application. You are

therefore advised to provide the requisite documents as per Checklist for Clinical Trial or Study Application provided in the Bio-study Rules, 2017 within seven (07) days positively."

8. Case was again placed in 21st meeting held on 22nd March 2021 and was decided as following.

CSC after detailed deliration decided to deferred the case.

9. Now the applicant has submitted their reply and scanned application of the I-Live Vent is attached as **Annex-II** for through consideration and perusal of the CSC.

Decision of CSC:-

Keeping in view the death rates in current pandemic, presentation by manufacturer and principal investigator, the CSC unanimously approved to conduct Clinical validation of I-live Ventilator based on present protocol i.e. PEC-CVP-EM-PMVS 001:2020. CSC further requested to Dr. Javed Akram, VC UHS for Clinical guidelines and guidance to Dr. Hina Nabi Ahmed (Principal Investigator).

Agenda Item IV:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FROM RAWALPINDI MEDICAL UNIVERSITY (RMU) RAWALPINDI.

The Case is an application from Prof. Dr Umar, Vice Chancellor, Rawalpindi Medical University, Rawalpindi, CNIC number 37405-6364143-5 wherein applicant has requested for grant of license to act as a Clinical Trial Site. The application is on Form-I of the Bio-Study Rules 2017 with fee of Rs.100,000/-.

2. It is submitted that application evaluated according pre- requisites as mentioned in Form-I of the Bio-Study Rules 2017, and as following are observations:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Prescribed processing fee	Fee challan of Rs.100,000/- attached submitted vide slip No. 1987991.
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company	Department of Infectious diseases / Department of medicine, Rawalpindi Medical university Rawalpindi. Its Tertiary Care Teaching Hospital working specializes Health care department, Government of the Punjab. under

	and its directors).	
4	Details of premises including layout plan of the site.	Layout Plan Attached
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	List of testing equipment Attached.
6	Names and qualifications of the above sections along with their staff.	Attached
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	List attached
8	Undertaking on stamp paper	Attached.

3. After evaluation it was found that Rawalpindi Medical university Rawalpindi has applied for Department of Infectious diseases / Department of medicine, situated in Holy family Hospital for Clinical trial site. Requisite administrative documents are attached with application.

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4. It was proposed that panel may be constituted for inspection and Chairman CSC constituted the following panel.

i. Dr. Abdur Rashid, Chairman CSC.
ii. Brig.(R) M.H. Najmi, Foundation University.
iii. Sheikh Ansar Ahmed, Ex Drug Controller, DRAP.
iv. Prof. Dr. Rizwana Chaudhary, Co-opted member CSC.
v. Abdul Mateen, Assistant Director, DRAP, Islamabad.

5. Panel inspected the site on 12.04.2021 and submitted their report where panel has recommended for approval with following remarks.

"Keeping in view the premises of Infectious Disease Department/ Department of Medicine, health facilities, emergency handling, training and human resource, incinerator, documentation, panel recommends Clinical Trial Site of Infectious disease Department/ Department of Medicine, Rawalpindi Medical University, Rawalpindi."

6. The case is submitted for the consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to Infectious disease department/department of medicine of the M/s Rawalpindi Medical University, Rawalpindi as Clinical Trial Site.

Agenda Item V:

OSELTEMIVIR PHOSPHATE COMBINED WITH ASPIRIN IN PATIENTS INFECTED WITH COVID-19 VIRUS WITH EVIDENCE FOR EARLY ACUTE RESPIRATORY FAILURE.

The Case is an application from Prof. Dr. Muhammad Umar. Vice Chancellor Rawalpindi Medical university, Rawalpindi wherein the application has requested for approval of subject Clinical Trial i.e. **Oseltamivir Phosphate combined with Aspirin in patients infected with Covid-19 virus with evidence for early acute respiratory failure.**.. The application is on Form-II of the Bio-Study Rules 2017 with fee of Rs. 200,000/-.

2. It is submitted that application evaluated according pre- requisites as mentioned in Form-II of the Bio-Study Rules 2017, and following are observations.

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached
2	Prescribed processing fee	Attached. Fee of Rs.200,000/- has been submitted vide challan No. 1987992
3	Investigator Brochure (s)	------
4	Final protocol	Attached,
5	Informed consent and participant information sheet (Urdu to English)	Attached.
6	List of participating countries	Pakistan.
7	Phase of trial.	Phase-1
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Oseltamivir Phosphate Injection 200mg 100 vials. Aspirin 500mg 50 tablets
9	Site of the trial	Department of Infectious Disease/ Department of Medicine, Holy family Hospital, affiliated with Rawalpindi Medical university.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Approval letter is attached, without complete composition of committee i.e. names and designation of members.
11	Approval of National Bio-ethics Committee (NBC)	Attached. Ref:No.4-87/COVID-

		38/NBC/20/504, Dated 19rdOctober 2020.
12	CV's of the Investigators	Attached.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Certificate of analysis attached but Whereas GMP Certificate is not provided.
14	Pre-clinical/clinical safety studies	Not Attached
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Not Attached
17	Adverse Event Reporting Form	Not Attached
18	No of patients to be enrolled in each center.	Total 10 Patients
19	Name of Monitors & Clinical Research Associate	Dr. Muhammad Mujeeb Khan, Associate Professor of Infectious Diseases, RMU, Rawalpindi CV attached
20	Evidence of registration in country of origin.	Not attached
21	Copy of registration letter (if registered in Pakistan)	N/A
22	Sample of label of the investigational product / drug.	Not provided.
22	Duration of trial	Three months.
23	Undertaking on stamp paper.	provided.

3. After evaluation following shortcomings were recorded:

   i) Approval letter is attached, without complete composition of committee i.e. names and designation of members.
   ii) Pre-clinical/clinical safety studies not attached.
   iii) Investigator Brochure and Summary of Investigator Brochure not attached.
   iv) Adverse Event Reporting Form. Not attached.
   v) Evidence of registration in country of origin not attached.
   vi) Sample of label of the investigational product / drug not attached.
   vii) Final Protocol and its summary to be provided as per ICH Guidelines.

4. The shortcomings were communicated to the applicant and the reply of the applicant is as followed.

5. The reply of the applicant is as followings.

Shortcomings/ observations	Reply of the applicant
Approval letter is attached, without complete composition of committee i.e. names and designation of members.	Composition of the committee provided. Prof. Muhammad Umar is the chairperson of the committee who is also the investigator of the study.
Pre-clinical/clinical safety studies not attached.	Registered as capsule.
Investigator Brochure and Summary of Investigator Brochure not attached.	Attached.
Adverse Event Reporting Form. Not attached.	Provided.
Evidence of registration in country of origin not attached.	Not provided
Sample of label of the investigational product / drug not attached.	Not provided
Final Protocol and its summary to be provided as per ICH Guidelines	Provided.

6. Following are the shortcomings were observed.

   i. Prof. Muhammad Umar is the chairperson of the Institutional Review committee who is also the investigator of the study.

   ii. GMP certificate along with COPP & free sale certificate of the investigational product.

   iii. Sample of label of the investigational product / drug not attached.

   iv. Evidence of registration in country of origin not attached.

7. These shortcomings were discussed with the applicant and he requested to place the case in the CSC meeting and they will defend the case in the meeting.

8. The case is submitted for consideration of CSC.

Decision:

The CSC after detailed deliberation decided to defer the case due to following quires:

a. Applicant should review the study in present state of knowledge about Oseltamivir use for COVID-19 management.

b. Is study conducted in the originator country or its results are available.

AGENDA ITEM - VI:

REQUEST FOR APPROVAL OF M/S MOHTARMA SHAHEED BHUTTO GENERAL HOSPITAL, MARIABAD, QUETTA TO ACT AS CLINICAL TRIAL SITE FOR PHASE-IV CLINICAL TRIAL TITLED "RANDOMIZED, OPEN LABEL, MULTICENTER, NON-INFERIORITY CLINICAL TRIAL FOR NEW TREATMENT MODALITIES FOR CUTANEOUS LEISHMANIASIS CAUSED BY LEISHMANIA TROPICA", F. No.15-23/2021-DD (PS).

Application submitted by Dr. Shakil Ashraf (CNIC-54400-1791522-3), M/s Mohtarma Shaheed Bhutto General Hospital, Mariabad, Quetta, dated 26thFebruary 2021, the site is situated at Musa College Road, Gulistan Town, Quetta. Wherein the request has been made to license the subject site with DRAP to act as Clinical Trial Site for subject Phase-IV clinical trial. Application is on prescribed form-I along with a prescribed fee of Rs.100000/- paid vide challan number 2085236, dated 25th February 2021.

2. After initial scrutiny summary of the application & attached documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Prescribed processing fee	Rs.100000/- paid vide challan number 2085236, dated 25thFebruary 2021.
3	Particulars regarding the legal status of the applicant i.e. in the case of proprietorship the names of proprietors and their addresses, in the case of a firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	MOU between Médecins Sans Frontières & Govt. of Baluchistan for M/s Mohtarma Shaheed Bhutto General Hospital, Mariabad, Quetta is attached. Validation letter from Medical Superintendent of Mohtarma Shaheed Bhutto General Hospital, Mariabad, Quetta is attached. Applied site is a provincial government medical facility
4	Details of premises including layout plan of the site.	Attached.
5	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Attached.5
8	Undertaking on stamp paper	Attached.

3. As powers conferred by CSC to Chairman CSC/Director Pharmacy Services for constitution of panel for inspection, Chairman CSC reconstituted the following panel for inspection of subject Clinical Trial Site as follows:

i.	**Prof. Dr. Nisar Hussain Shah** Chairman Department of Pharmacy, Bahauddin Zakariya University, Multan.
ii.	**Dr. Abdur Rashid (Coordinator)** Chairman CSC/Director, Division of Pharmacy Services-DRAP.
iii.	**Dr. Abdul Qadir Umrani** Bolan Medical College/Complex Hospital, Brewery Road, Quetta.
iv.	**Prof. Sayed Umar Jan** Dean Faculty of Pharmacy, University of Baluchistan, Quetta.

4. Panel of following experts conducted the inspection on 26th March 2021:

i.	*Prof. Dr. Sayed Nisar Hussain Shah*
ii.	*Dr. Abdur Rashid, Chairman CSC-DRAP (Coordinator)*
iii.	*Prof. Dr. Sayed Umer Jan*
iv.	*Dr. Abdul Qadir Umrani.*

5. After inspection, panel submitted report with following remarks:

Keeping in view the public sector facility, separate facility for leishmaniasis cases, pathological laboratory, human resources, documentation records, IT facilities, previous experience of doctors/nurses/staff and emergency handling facilities of Shaheed Mohtarma Benazir Bhutto General Hospital, Marri Abad, Gulistan Road Quetta, Baluchistan, recommends as Clinical Trial Site only for leishmaniasis case/patients.

Note:

i. Pharmacist must be appointed before start of the Clinical Trial.

ii. Remuneration must be given to the supporting doctors & other staff.

6. Concluding status / remarks of inspection panel:

Recommended for approval.

Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to the M/s Mohtarma Shaheed Bhutto General Hospital, Mariabad, Quetta as Clinical Trial Site for a Phase-IV clinical trial titled Randomized, Open Label, Multicenter, Non-Inferiority Clinical Trial for New Treatment Modalities for Cutaneous Leishmaniasis Caused by Leishmania Tropica.

AGENDA ITEM - VII:

REQUEST FOR APPROVAL OF M/S MEDECINS SANS FRONTIERES, KUCHLAK PRIMARY HEALTH CENTER, QUETTA TO ACT AS CLINICAL TRIAL SITE FOR PHASE-IV CLINICAL TRIAL TITLED "RANDOMIZED, OPEN LABEL, MULTICENTER, NON-INFERIORITY

CLINICAL TRIAL FOR NEW TREATMENT MODALITIES FOR CUTANEOUS LEISHMANIASIS CAUSED BY LEISHMANIA TROPICA", F. No.15-22/2021-DD (PS).

Application submitted Dr. Qadria Sardar (CNIC-54400-7632445-8), MSF medical Focal Point Assistant/s Médecins Sans Frontières, Kuchlak Primary Health Center, Quetta, dated 26thFebruary 2021, the site is situated at MSF medical Focal Point Assistant, Highway N-25, Kuchlak, Quetta. Wherein the request has been made to license the subject site with DRAP to act as Clinical Trial Site for subject Phase-IV clinical trial. Application is on prescribed form-I along with a prescribed fee of Rs.100000/- paid vide challan number 2085234, dated 25th February 2021.

2. After initial scrutiny summary of the application & attached documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Prescribed processing fee	Rs.100000/- paid vide challan number 2085234, dated 25thFebruary 2021.
3	Particulars regarding the legal status of the applicant i.e. in the case of proprietorship the names of proprietors and their addresses, in the case of a firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	MOU between Médecins Sans Frontières & Govt. of Baluchistan for M/s Kuchlak MCH, Quetta is attached. Validation letter from DHO, Quetta M/s Kuchlak MCH, Quetta is attached. Applied site is a provincial government medical facility
4	Details of premises including layout plan of the site.	Attached.
5	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Attached.
8	Undertaking on stamp paper	Attached.

3. As powers conferred by CSC to Chairman CSC/Director Pharmacy Services for constitution of panel for inspection, Chairman CSC reconstituted the following panel for inspection of subject Clinical Trial Site as follows:

i.	**Prof. Dr. Nisar Hussain Shah** Chairman Department of Pharmacy, Bahauddin Zakariya University, Multan.
ii.	**Dr. Abdur Rashid (Coordinator)** Chairman CSC/Director, Division of Pharmacy Services-DRAP.
iii.	**Dr. Abdul Qadir Umrani** Bolan Medical College/Complex Hospital, Brewery Road, Quetta.
iv.	**Prof. Sayed Umar Jan** Dean Faculty of Pharmacy, University of Baluchistan, Quetta.

4. Panel of following experts conducted the inspection on 26th March 2021:

i.	*Prof. Dr. Sayed Nisar Hussain Shah*
ii.	*Dr. Abdur Rashid, Chairman CSC-DRAP (Coordinator)*
iii.	*Prof. Dr. Sayed Umer Jan*
iv.	*Dr. Abdul Qadir Umrani.*

5. After inspection, panel submitted report with following remarks:

Keeping in view the facilities, doctors, nurses, emergency handling (3 monitors), ambulance experience of the staff, generator, solar system, IT facilities, documents, records, technical know-how panel recommends Clinical Trial Site only for leishmaniasis trials of MSF Kuchlak Health Center, Main Chamman-Quetta Highway Road, Near Police Station, Kuchlak Quetta.

6. Concluding status / remarks of inspection panel:

Recommended for approval.

Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to the M/s Médecins Sans Frontières, Kuchlak Primary Health Center, Quetta as Clinical Trial Site for a Phase-IV clinical trial titled Randomized, Open Label, Multicenter, Non-Inferiority Clinical Trial for New Treatment Modalities for Cutaneous Leishmaniasis Caused by Leishmania Tropica.

AGENDA ITEM - VIII:

REQUEST FOR APPROVAL OF PHASE-IV CLINICAL TRIAL TITLED "RANDOMIZED, OPEN LABEL, MULTICENTER, NON-INFERIORITY CLINICAL TRIAL FOR NEW TREATMENT MODALITIES FOR CUTANEOUS LEISHMANIASIS CAUSED BY LEISHMANIA TROPICA", F. No.03-60/2021-DD (PS).

Application submitted by Dr. Qadria Sardar (CNIC-54400-7632445-8), MSF medical Focal Point Assistant, M/s Médecins Sans Frontières, Kuchlak Primary Health Center, Quetta, dated 26th February 2021. Wherein the request has been made for registration of the subject clinical trial. Application is on prescribed form-II along with a prescribed fee of Rs.200000/- paid vide challan number 2085232, dated 25thFebruary 2021.

2. The details regarding trial, sponsor & responsible party is as under:

i. **Sponsor:** M/s Médecins Sans Frontières.

ii. **Name of Investigational products**:

a. Miltefosine (Impavido®), Manufactured by M/s Haupt Pharma Amareg GmbH, Germany.(Licence & product holder M/s Paesel & Lorei GmbH & Co., Germany)

b. ThermoMed® 1.8 (220V+accessories) (Thermotherapy apparatus, localized current field radio-frequency generating device), RF Ablation System, Manufactured by M/s Thermosurgery Technology Inc. USA.

c. Meglumine antimoniate intralesional injections.

iii. Primary Objective of the study:

To evaluate whether monotherapy Miltefosine (Impavido®), thermotherapy and the combination Miltefosine (Impavido®)- thermotherapy are effective, safe and tolerable alternative treatment options to treat cutaneous leishmaniasis and non -inferior to the standard of care treatment with meglumine antimoniate injections and therefore can be used first-line treatment for patients with cutaneous leishmaniasis caused by Leishmania tropica. There is a need to investigate a treatment, which can be used as alternative for the antimony treatment. Therefore, in this prospective trial, MSF aims to evaluate the effectiveness and safety of

a. thermotherapy (50°C for 30 seconds, one session).

b. Miltefosine/Hexadecyl phosphocholine(Impavido®) (2.5 mg/kg/day, 28 days)

c. Combi-therapy with thermotherapy (50°C for 30 seconds, one session) and Miltefosine (Impavido®) (2.5 mg/kg/day, 21 days)

These treatment modalities will be compared with Glucantime® (Meglumine antimoniate) intralesional injections, 8 sessions, which is the standard of care.

3. The details of the submitted documents are as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.
2	Prescribed processing fee	Rs.200000/- deposited vide challan no. 2085232, dated 25th February 2021.
3	Investigator Brochure (s)	Attached. Version 4.0
4	Final protocol	Attached. Version 5.0
5	Informed consent and participant information	Attached

	sheet (Urdu to English)	
6	List of participating countries	Pakistan only.
7	Phase of trial.	Phase – IV
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	1. Miltefosine/Hexadecyl phosphocholine (Impavido®) 10mg Capsules. 5936 Capsules. 2. Miltefosine/ Hexadecyl phosphocholine (Impavido®) 50mg Capsules. 30576 Capsules 3.ThermoMed®1.8 (Thermotherapy apparatus). 05 Devices with accessories. 3. Glucantime® (Meglumine antimoniate) intralesional injections *Quantities of IMPs utilized in the trial are not with justification.
9	Site of the trial	1. Mohtarma Shaheed Benazir Bhutto General Hospital (MSBBGH), Quetta. 2. MSF Kuchlak Health Center/MCH Kuchlak, Quetta. 3. Government Naseer Ullah Khan Babar Memorial Hospital, Peshawar.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	IRB/IRC Approval from Mohtarma Shaheed Benazir Bhutto General Hospital (MSBBGH), Quetta is attached. Ethical approval from ERB of MSF is also attached. IRB approval from following is not attached: 1. Government Naseer Ullah Khan Babar Memorial Hospital, Peshawar.
11	Approval of National Bio-ethics Committee (NBC)	Attached. 1. Ref:No.4-87/NBC-378-19/2228,dated 19th June 2019. 2. Ref:No.4-87/NBC-378-Y2-Extension/20/328,dated 16thSeptember 2021.

12	CV's of the Investigators	CVs of following (P.Is) are attached: i. Suzette Sabine Kamink, Epidemiologist/Medical Researcher Cutaneous Leishmaniasis, M/s Médecins Sans Frontières. ii. Koert Ritmeijer, Advisor/Coordinator Neglected Tropical Diseases (NTD), Public Health Department, MSF Operational Center Amsterdam.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Relevant GMP, CoPP & Medical Device enlistment/premarket certificate attached
14	Pre-clinical/clinical safety studies	Not attached & claimed as the IMPs are already marketed products.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Attached.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	832 subjects.
19	Name of Monitors & Clinical Research Associate	Not provided.
20	Evidence of registration in country of origin.	COPP for following IMPs is attached: 1. Impavido® (Miltefosine) 10mg & 50mg Capsules, Manufactured by M/s Paesel & Lorei GmbH & Co., Germany.
21	Copy of registration letter (if registered in Pakistan)	N/A.
22	Sample of label of the investigational product / drug.	Attached.
22	Duration of trial	Two years or until 832 subjects are recruited for the trial.
23	Undertaking on Stamp paper	Attached.

4. For technical evaluation, technical documents (i.e. Study Protocol & investigator's brochure) forwarded to experts through email on 22nd April 2021, for review & evaluation under sub-rule 4 of rule 7 of the Bio-Study Rules 2017. None of the expert member raised any queries.

5. Submitted for consideration of CSC.

Decision:

The CSC after detailed deliberation decided to grant approval for registration of the clinical trial titled "Phase-IV, Randomized, Open Label, Multicenter, Non-Inferiority Clinical Trial for New Treatment Modalities for Cutaneous Leishmaniasis Caused by Leishmania Tropica".

AGENDA ITEM - IX:

REQUEST FOR APPROVAL OF M/S TABBA HEART INSTITUTE, KARACHI TO ACT AS CLINICAL TRIAL SITE TO CONDUCT CLINICAL STUDY TITLED "ANTI-CORONAVIRUS THERAPIES TO PREVENT PROGRESSION OF COVID-19, F. No.15-10/2021-DD (PS).

Application submitted by Dr. Bashir Hanif (CNIC-42101-1855677-5),Executive Director, Medical Director of M/s Tabbaa Heart Institute, Karachi, dated 02nd February 2021, the site is situated at ST-01, Block-2, Federal "B" area, Karachi. Wherein the request has been made to license the subject site with DRAP to act as Clinical Trial Site. Application is on prescribed form-I along with a prescribed fee of Rs.100000/- paid vide challan number 2060446, dated 25th January 2021.

2. After initial scrutiny summary of the application & attached documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Prescribed processing fee	Rs.100000/- paid vide challan number 2060446, dated 25th January 2021.
3	Particulars regarding the legal status of the applicant i.e. in the case of proprietorship the names of proprietors and their addresses, in the case of a firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Expired registration certificate is attached. The legal status of the firm/company needs to be provided.
4	Details of premises including layout plan of the site.	Layout plan of the premises is needed to be provided.
5	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	List of some equipment is attached but section-wise details of

		equipment need to be provided.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Attached.
8	Undertaking on stamp paper	Not provided.

3. It is submitted that subject application placed before CSC in its 19th meeting held on 12th February 2021& the CSC decided as follows:

Decision of 19th CSC meeting:

The CSC after detailed deliberation decided to authorize the Chairman CSC for the constitution of inspection panel for the inspection of M/s Tabba Heart Institute, Karachi. The case will be again placed before the CSC for further deliberations and decisions after submission of inspection report. Meanwhile applicant is directed to fulfill all prerequisite as per the Bio-Study Rules.

5. As powers conferred by CSC to Chairman CSC/Director Pharmacy Services for constitution of panel for inspection, Chairman CSC reconstituted the following panel for inspection of subject Clinical Trial Site as follows:

i.	**Dr. Abdur Rashid (Coordinator)** Chairman CSC/Director, Division of Pharmacy Services-DRAP.
ii.	**Prof. Dr. Aamir Jaffary** Sindh Institute of Urology & Transplantation (SIUT), Karachi.
iii.	**Dr. Naseem Salahuddin** Director Infectious Diseases Indus Hospital, Karachi.
iv.	**Dr. Najam Us Saquib** Additional Director, In charge DRAP- Karachi.
v.	**Muneeza Khan** Deputy Director QMS, DRAP-Karachi.

6. Due to unavailability of some nominated panel members following experts conducted the inspection on 29th March 2021:

i.	*Dr. Abdur Rashid, Chairman CSC-DRAP (Coordinator)*
ii.	*Dr. Aamir Jaffrey, SIUT, Sindh*
iii	*Dr. Hira Bhutto, Area FID, DRAP-Karachi.*

7. After inspection, panel submitted report with following remarks:

Keeping in view the infrastructure, human resource and their experience & training, IT, equipment, pharmacy & clinical pharmacy, approved from health care commission, waste management, X-ray, pathology laboratory, panel recommends Tabba Heart Institute, ST-01, Block-2, Federal "B" Area Karachi for Cardiology & related studies & COVID patients having separate facilities for phase-III & IV studies.

8. Concluding status / remarks of inspection panel:

Recommended for approval.

9. Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to the M/s Tabba Heart Institute, Karachi for as Clinical Trial Site for clinical trial titled ANTI-CORONAVIRUS THERAPIES TO PREVENT PROGRESSION OF COVID-19.

AGENDA ITEM - X:

REQUEST FOR APPROVAL OF M/S JINNAH POSTGRADUATE MEDICAL CENTER, KARACHI TO ACT AS CLINICAL TRIAL SITE TO CONDUCT CLINICAL STUDY TITLED "ANTI-CORONAVIRUS THERAPIES TO PREVENT PROGRESSION OF COVID-19.

Application submitted by Dr. Zeeshan Ali (CNIC-41302-2164032-9), Associate Professor, Medicine Ward-07, Jinnah Post Graduate Medical Center, Karachi, dated 01st February 2021.Wherein the request has been made to license the **COVID Isolation Unit Ward-23**, Jinnah Post Graduate Medical Center, Karachi to act as Clinical Trial Site. Application is on prescribed form-I along with a prescribed fee of Rs.100000/- paid vide challan number 2060448, dated 25th January 2021.

2. After initial scrutiny summary of the application & attached documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Prescribed processing fee	Rs.100000/- paid vide challan number 2060448, dated 25th January 2021.
3	Particulars regarding the legal status of the applicant i.e. in the case of proprietorship the names of proprietors and their addresses, in the case of a firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	The applied site is a public sector tertiary care hospital.
4	Details of premises including layout plan of the site.	Attached.
5	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	The list of equipment in ward-23 is attached.
6	Names and qualifications of the above sections along with their staff.	Attached.

7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Attached.
8	Undertaking on stamp paper	Attached.

3. It is submitted that subject application placed before CSC in its 19th meeting held on 12th February 2021 & the CSC decided as follows:

Decision:

The CSC after detailed deliberation decided to authorize the Chairman CSC for the constitution of inspection panel for the inspection of M/s Jinnah Postgraduate Medical Center, Karachi. The case will be again placed before the CSC for further deliberations and decisions after submission of inspection report. Meanwhile applicant is directed to fulfill all prerequisite as per the Bio-Study Rules.

4. As powers conferred by CSC to Chairman CSC/Director Pharmacy Services for constitution of panel for inspection, Chairman CSC reconstituted the following panel for inspection of subject Clinical Trial Site as follows:

i.	**Dr. Abdur Rashid (Coordinator)** Chairman CSC/Director, Division of Pharmacy Services-DRAP.
ii.	**Prof. Dr. Aamir Jaffary** Sindh Institute of Urology & Transplantation (SIUT), Karachi.
iii.	**Dr. Naseem Salahuddin** Director Infectious Diseases Indus Hospital, Karachi.
iv.	**Dr. Najam Us Saquib** Additional Director, In charge DRAP- Karachi.
v.	**Muneeza Khan** Deputy Director QMS Or **Hira Bhutto** Assistant Director/FID DRAP-Karachi.

5. Due to unavailability of some panel members following experts conducted the inspection on 29th March 2021:

i.	*Dr. Abdur Rashid, Chairman CSC-DRAP (Coordinator)*
ii.	*Dr. Aamir Jaffrey, SIUT, Sindh*
iii	*Dr. Hira Bhutto, Area FID, DRAP-Karachi.*

6. After inspection, panel submitted report with following remarks:

Keeping in view the history of Jinnah Postgraduate Medical Institute Karachi, being the public tertiary care hospital, its professional human resources, trainings, equipment, premises, I.T. System, Incinerator facility, no. of indoor and outdoor patients, panel recommends as clinical trial site.

Note: *Prof. Dr. Aamir Jaffrey, Co-Opted member CSC and Dr. Abdur Rashid Coordinator DRAP reached at 9:30A.M at the site, Hira Bhutto, FID Karachi was not available at the site. Both the*

inspectors started inspection and observed different facilities in the hospital. When we contacted on mobile to Hira Bhutto, she mentioned that she came at 10:00 AM, but panel of inspectors moved to another premises/building.

Hira Bhutto was informed that remain in front of Gynecology Department. When we reached the said premises, Mst. Hira Bhutto told that she has left the hospital and in a way to DRAP-Karachi office.

It is submitted to the CSC that she is a junior officer working at higher post i.e. Federal Inspector of Drug. She do not know about Clinical Trial neither she was trained during Lahore training. Mr. Asim Rauf, CEO-DRAP has nominated Hira Bhutto and is not the proposal of Director of Pharmacy Services Division. It is requested such junior officers' may not be included further in panel.

7. Concluding status / remarks of inspection panel:

Recommended for approval.

8. Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to the M/s Jinnah Post Graduate Medical Center, Karachi for COVID Isolation Unit Ward-23 as Clinical Trial Site for clinical trial titled ANTI-CORONAVIRUS THERAPIES TO PREVENT PROGRESSION OF COVID-19.

AGENDA ITEM - XI:

PROTOCOL AMENDMENT VERSION 7.0, 8.0 & 9.0. IN ALREADY APPROVED TRIAL TITLED, "AN INTERNATIONAL MULTICENTER CONTROLLED CLINICAL TRIAL TO EVALUATE 1200MG AND 1800MG RIFAMPICIN DAILY IN THE REDUCTION OF TREATMENT DURATION FOR PULMONARY TUBERCULOSIS FROM 6 MONTHS TO 4 MONTHS (RIFASHORT)"

1. Dr. Bushra Jamil, P.I. RIFASHORT Trial, Department of Medicine, The Aga Khan University, Karachi, submitted a request for amendments in already approved protocol (Version 6.0) of clinical trial titled, *"An international multicenter controlled clinical trial to evaluate 1200mg and 1800mg rifampicin daily in the reduction of treatment duration for pulmonary tuberculosis from 6 months to 4 months (RIFASHORT)"*.

2. Summary of amendments is as follows:

Version No.	Date	Summary of minor changes
7.0	19/07/17	• Addition of new site in Pakistan, addition of PI'sand lab in Guinea. Other minor clarifications: addition of amendment summary, contraceptive method, toxicity management section, addition of laboratory. Patients will change dose in event of a weight change.

8.0	30/09/2019	• Inclusion of baseline culture negative but GeneXpert positive patient to trial. • Removal of Bolivia as site and addition of Indus Hospital (Pakistan). • Updated details of new Trial Manager/Clinical Trial Coordinator. • Note on follow-up period for patients recruited towards end of enrolment period.
9.0	10/06/2020	• Minor amendments to the wording of 'Primary Outcome' statement in line with the SAP definition; and Follow up statement in Section 6.1. • Removal of Mexico and Indus Hospital, Pakistan astrial sites. • Addition of Dr Imran Ahmed as Co-Investigator atAKU, Karachi. Pakistan.

3. Technical documents (i.e. Amended protocols (version 7.0, 8.0 & 9.0) forwarded to experts for review & evaluation under sub-rule 4 of rule 7 of the Bio-Study Rules 2017, on 27th April 2021.

4. Submitted for consideration of CSC.

Decision:

The CSC after detailed deliberation decided to approve the amendments (version 7.0, 8.0 & 9.0) in already approved protocol titled "An International Multicenter Controlled Clinical Trial to Evaluate 1200mg and 1800mg Rifampicin Daily in the Reduction of Treatment Duration for pulmonary Tuberculosis from 6 months to 4 Months (RIFASHORT)".

Agenda Item XII:

REQUEST FOR USE OF DRUGS BETWEEN TWO APPROVED TRIALS END-TB AND ENDTB-Q DUE TO SUPPLY CHANGE DISRUPTION.

1. Application submitted by Dr. Naseem Salahuddin, P.I. End-TB & End-TB Q Clinical Trial, wherein applicant submitted following request:

   a. *Due to the COVID-19 pandemic, supply chain activities have been affected worldwide. This has led to delays in order processing and clearance of medicines. However, such delays in procurement and import of medicines can hinder and halt dispensation and distribution of lifesaving medications, cither for routine use or for ongoing research.*
   b. *In this vein, for the endTB clinical trials i.e., endTB and endTB-Q - approved by National Bioethics Committee (NBC) and DRAP - the lead time for drug delivery from MSF logistique (supplier of trial medicines) to Pakistan has been increased from four to six months since the start of the pandemic. The endTB trial team are working to mitigate any possibility of drug stock out. However, we foresee risks in*

potential stock out for a few trial medicines at the start of June 2021. 3. It is important to note that anti-TB medicines used in both endTB and endTB-Q clinical trials are the same. The only difference related to drugs between the trials is the combination of regimen used in each trial. Therefore, in order to avoid potential stock out and treatment interruption due to unavailability of medicines, we should be able to use the medicines available in endTB stock for endTB-Q patients and vice versa since the source, composition and strength is the same.

c. *In light of the above, we would like to request DRAP to allow the use of medicines between the two trials in case of stock out or such emergency situations, hence not compromising on the safety of the trial participants.*

2. Submitted for consideration of CSC.

Decision:

The CSC after detailed deliberation decided to defer the case, latest study protocol of both trials (i.e. endTB & endTB-Q) will be shared with CSC members for further detailed deliberation & review.

Agenda Item XIII:

APPLICATION FOR APPROVAL OF CLINICAL TRIAL TITLED "A GLOBAL, MULTICENTER, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, PHASE-III CLINICAL STUDY TO EVALUATE THE PROTECTIVE EFFICACY, SAFETY & IMMUNOGENOCITY OF SARS-CoV-2 MESSENGER RIBONUCLEIC ACID (mRNA) VACCINE IN POPULATION AGED 18 YEARS & OLDER "F.NO.03-66/2021 DD (PS).

Application submitted by Dr. Faisal Mahmood (CNIC 42301-1116154-5), Associate professor & Section Head Medicine, Global Principal Investigator & National Coordinator, SARS-Cov-2 mRNA Vaccine Trial, Aga Khan University Hospital, Karachi, dated 23rd April 2021, on prescribed Form-II along with a fee of Rs.200000/- deposited vide challan no.2057192 dated 23rd April 2021. Wherein request has been made for registration & approval of subject clinical trial, which will be carried out at Aga Khan University Hospital Main Campus, Stadium Road, Karachi.

02. The details regarding trial, sponsor & responsible party is as under:

iv. **Sponsor:**

a. Yuxi Walvax Biotechnology Co., Ltd. China.
b. Walvax Biotechnology Co., Ltd. China.
c. Suzhou Abogen Biosciences Co., Ltd. China.

v. **Primary Objective of the study:**

The purpose of the trial is to evaluate the protective efficacy of the SARS-CoV-2 MRNA vaccine in the prevention of COVID-19 (refer to Appendix 1) starting from 14 days (2D14) after the two- dose immunization schedule (28 days interval) in subjects aged 18 years and older. It is also to evaluate the safety and reactogenicity of the SARS-CoV-2 mRNA vaccine after the two-dose immunization schedule (28 days interval) in subjects aged 18 years and older.

03. The details of the submitted documents are as under;

S. No.	Document	Remarks
1	Application on prescribed	Attached.

	Form-II	
2	Prescribed processing fee	Rs.200000/- deposited vide challan no.2057192, dated 23rd April 2021.
3	Investigator Brochure (s)	Attached. Edition 5.0, dated 22nd April 2021.
4	Final protocol	Attached. Protocol Number: ARCoV-005 Version. 1.0
5	Informed consent and participant information sheet (Urdu to English)	Attached only in English.
6	List of participating countries	Turkey, Mexico, Columbia, Argentina & Pakistan.
7	Phase of trial.	Phase – III
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	4000 drug product sample corresponding to 9600 doses will be imported (1:1 for experimental vaccine & placebo, with 20% backup). Approximately 203 cartons (5771 bottles) required for the trial.
9	Site of the trial	Aga Khan University Hospital, Karachi.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Not provided.
11	Approval of National Bio-ethics Committee (NBC)	Not provided.
12	CV's of the Investigators	CVs of Dr. Faisal Mahmood is attached.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	GMP certificate for M/s Yuxi Walvax Biotechnology Co., Ltd. China. Is attached. CoPP is not provided, not issued as drug is under testing.
14	Pre-clinical/clinical safety studies	Attached.
15	Summary of Protocol	Attached.
16	Summary of Investigator	Attached.

	Brochure	
17	Adverse Event Reporting Form	Attached but not as per CIOMS form.
18	No of patients to be enrolled in each center.	4000 subjects from Pakistan in one trial center at Aga Khan University Hospital, Karachi.
19	Name of Monitors & Clinical Research Associate	N/A.
20	Evidence of registration in country of origin.	N/A as the product is under testing.
21	Copy of registration letter (if registered in Pakistan)	N/A.
22	Sample of label of the investigational product / drug.	Attached.
22	Duration of trial	20 months.
23	Undertaking on Stamp paper	Attached.

04. After initial scrutiny following shortcomings observed:

i. Institutional Review Board (IRB) approval from AKUH is not provided.
ii. Ethical approval from National Bio-ethics Committee (NBC) is not provided.
iii. Informed consent is not provided in local languages(i.e. Urdu Sindhi etc.)
iv. Adverse Event Reporting Form as per CIOMS should be provided.

05. For technical evaluation, technical documents (i.e. Study Protocol & investigator's brochure) forwarded to experts through email on 23rdApril 2021, for review & evaluation under sub-rule 4 of rule 7 of the Bio-Study Rules 2017. None of the expert member raised any queries.

06. Submitted for consideration of CSC.

Decision:

CSC after detailed deliberation decided to defer the study till fulfillment & submission of following documents:

i. Institutional Review Board (IRB) approval from AKUH or any other site is needs to be provided.
ii. Ethical approval from National Bio-ethics Committee (NBC) is not provided.
iii. Informed consent is not provided in local languages(i.e. Urdu Sindhi etc.)
iv. Adverse Event Reporting Form as per CIOMS should be provided.

2. CSC also discussed that, as the vaccine is mRNA based so how it will be stable at (2-8°C) and asked to submit stability studies of trial vaccine.