MINUTES OF THE 33RD CLINICAL STUDIES COMMITTEE (CSC), HELD ON 11TH NOVEMBER 2021.

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The 33rd Meeting of the Clinical Study Committee (CSC) was held on 11th November 2021 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). at the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, 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	Ahmad Din Ansari.	Secretary CSC/ Additional Director, Division of Pharmacy Services-DRAP.

3. Following members attended the meeting online through Zoom:

01	Prof. Dr. Javed Akram.	Professor of Medicine, Physician, Vice Chancellor, University of Health Sciences, Lahore.
02	Prof. Nadeem Irfan Bukhari.	Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.
03	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.
04	Dr. Faiza Bashir.	Chairman, Pakistan Health Research Council or his nominee, Islamabad.
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 Mr. Ahmad Din Ansari. Chairman, CSC welcomed all the members & appreciated their active online participation through Zoom. Further he informed that, he is retiring from the post on 18th November 2021 & it is probably his last meeting. Chairman CSC recognized & appreciated the services & contribution of all CSC members & Co-Opted members & that he enjoyed working with all of them and jointly we have worked a lot. He specially appreciated efforts of Dr. Javed Akram for his contribution & training in initial stages, afterwards two 5 membered group started inspection after training started from licence number one & at present approx. 80 health care facilitates are inspected & licenced and that at the moment there is no pendency on part of Division of Pharmacy Services.

5. Alhamdulilah, this Committee approved 1st Vaccine trial in Pakistan, Chairman apprised the Committee that, he couldn't encompass the efforts of the Committee in words and will always remember the working environment & efforts of the Committee as the Committee not only strengthen the regulatory system but also served the nation.

6. Prof. Dr. Javed Akram apprised the Committee that, he on behalf of all CSC colleagues appreciate the untiring contribution from Dr. Abdur Rashid Sb & it should be recorded on minutes that Dr. Abdur Rashid was the founding Chairman of the CSC & at starting level it was a huge responsibility & a very difficult task to start Clinical Research in Pakistan with a very limited resources & technical expertise but Dr Rashid worked day & night & set an example for others & he not only learned himself but also taught others & moved forward together in a very pleasant

environment. Dr. Javed again appreciated efforts of Dr Abdur Rashid on behalf of all Committee members & wished that Dr. Abdur Rashid should be part of this Committee as he is very learned asset and any how he should be a part of this Committee after his retirement. And possibility should be seeking through legal provisions. Further he added that all CSC members wants to arrange a farewell party for him that will be honour for us if Dr. Abdur Rashid Sb accept it, the farewell party may be arranged either in Lahore or Islamabad.

7. Dr. Mushtaq Ahmad added that, he wants to add his sentiments and said that, it goes to the credit of the Chairman that he laid down the foundation of the CSC and started this work from a scratch. And that he worked tirelessly to lay down an extensive infrastructure for this research forum. And that we as members facilitated his efforts . It was our understanding that once the groundwork is laid down, fine tuning can be done at some later stage, we salute him & wish best of luck for future.

8. Ahmad Din Ansari, Secretary CSC also apprised the working of the Committee and contribution of Dr. Abdur Rashid Sb as Clinical Trials started in his leadership, about 80 Clinical Trial Sites inspected & about 40 Clinical Trials approved due to his untired efforts & clinical research in Pakistan is on track & we will try to continue the journey in the same pace. Whenever we will require guidance from Dr. Abdur Rashid we will seek his expertise & that he should play his part in Clinical Research in Pakistan. Secretary CSC thanked to Prof Dr. Javed Akram, Prof Dr. Mushtaq Ahmad & all CSC members for recognition & admission of services rendered by Dr. Abdur Rashid Sb. As CSC members suggested that a party from the Authority will be arranged in honour of the Dr. Abdur Rashid Sb. Division of Pharmacy Services is also working on arrangement of farewell party & it is also feasible that we may invite CSC members in that farewell party. Dr. Javed Akram informed that CSC members also wants to arrange another party for Dr. Abdur Rashid Sb in which Division of Pharmacy Services & all Directors from DRAP may also be invited & party may be arranged in Islamabad Club

9. Afterwards, Secretary CSC presented the agenda items one by one as mentioned below, before CSC for consideration & decisions.

AGENDA ITEM I:

CONFIRMATION OF THE MINUTES OF THE 32nd CLINICAL STUDIES COMMITTEE MEETING.

1. Confirmation of Minutes of 32nd CSC meeting held on 12th October 2021. Since, the occurrence of Covid-19 pandemic majority of the meeting are being conducted online through zoom.

2. The minutes of the 32nd CSC meeting were shared with all CSC members through email on 13th October 2021. None of the comments/queries received from the members. Accordingly, decision of the meeting communicated. Minutes are placed again for confirmation to satisfy legal provision.

Submitted for confirmation of CSC.

Decision:

All the Members of the CSC unanimously confirmed the Minutes of 32nd CSC meeting held on 12th October 2021.

AGENDA ITEM II:

APPLICATION FOR APPROVAL OF M/S CENTER FOR BIOEQUVALENCE STUDIES & CLINICAL RESEARCH (CBSCR)-ICCBS, UNIVERSITY OF KARACHI, KARACHI TO ACT AS BIOANALYTICAL LABORATORY. F. No.15-43/2021 DD (PS)

Application is from Prof. Dr. Raza Shah (CNIC:42201-4178970-1), General Manager, CBSCR-ICCBS, Karachi. Wherein the request has been made to license the subject site with DRAP to act as Bioanalytical Laboratory, the application is on prescribed Form-I of the Bio-Study Rules along with a prescribed fee of Rs.300000/- submitted vide challan No.8645320838, dated 05th October, 2021.

02. Details of attached documents as per Form-I of the Bio-Study Rules is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed Fee	Rs.300000/- submitted vide challan No.8645320838, dated 05th October, 2021.
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	The organization is a part of public university & notification is attached.

	company the name and address of the company and its directors).	
4	Details of premises including layout plan of the site.	Only layout 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.	Not applicable as the site is applied for Bioanalytical Laboratory.
8	Undertaking on stamp paper.	Attached.

03. As powers conferred by the CSC, the Chairman CSC constituted following panel of experts for inspection & panel letter was issued on 13th October 2021:

i. **Dr. Abdur Rashid (Coordinator)**, Chairman CSC / Director, Division of Pharmacy Services-DRAP.
ii. **Dr. Iqbal Afridi**, Physician/ Ex. Dean CPCS, Karachi.
iii. **Dr. Ahson Siddiqui**, CEO, Healthcare Commission of Sindh/ Physician.
iv. **Dr. Aamir Jaffrey**, Sindh Institute of Urology & Transplant, Karachi, Sindh.
v. **Dr. Saif Ur Rehman Khattak**, Additional Director, In charge CDL- Karachi.

04. Due to unavailability of some nominated panel member, following panel of expert inspected the site:

i. **Dr. Abdur Rashid (Coordinator),** Chairman CSC / Director, Division of Pharmacy Services-DRAP.
ii. **Dr. Iqbal Afridi**, Physician/ Ex. Dean CPCS, Karachi.
iii. **Dr. Saif Ur Rehman Khattak,** Additional Director, In charge CDL- Karachi.
iv. **Hafiz Dr. Rab Nawaz,** Assessor PNAC PCSIR, Karachi.

05. Experts panel inspected the subject site on 15th October 2021 & submitted inspection report with following remarks:

Keeping in view the infrastructure, highly sophisticated equipment/machinery, qualified and highly experienced human resource, experience, trainings, testing SOPs, calibration, validation, documentation, record, archive room, storage facilities, accredited by PNAC, 17025, Incinerator, solvent recycling plant, panel recommends the Bio-analytical Laboratory of Center for Clinical Research (CBSCR) ICCBS, University of Karachi.

- **Recommended for approval**

06. Submitted for consideration of CSC:

07. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection by panel of experts as already mentioned above.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Center for Bioequivalence Studies & Clinical Research (CBSCR)-ICCBS, University of Karachi, Karachi to act as Bio-analytical Laboratory, Under the Bio-Study Rules.

AGENDA ITEM III:

APPLICATION FOR APPROVAL OF M/S CREEK GENERAL HOSPITAL, KARACHI TO ACT AS CLINICAL TRIAL SITE FOR PHASE-I, II, III & IV CLINICAL TRIALS. F. No.15-45/2021 DD (PS)

Application is from Dr. Danish Muhammad Khan (CNIC:42201-2225978-9), M/s Creek General Hospital, Nasir Jump, Sector 48 H, Korangi Creek, 74200, Karachi. Wherein the request has been made to license the subject hospital with DRAP to act as Clinical Trial Site for Phase-I, II, III & IV clinical trials, the application is on prescribed Form-I of the Bio-Study Rules along with a fee of Rs.100000/- submitted vide challan No. 025131203671, dated 06th October, 2021.

02. It is submitted that application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules, summary of submitted documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed Fee	Rs.100000/- submitted vide challan No. 025131203671, dated 06th October, 2021. * **Original challan (DRAP Copy) need to be provided.**
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 and its directors).	SECP Certificate Ref No.0067150 is attached.
4	Details of premises including layout plan of the site.	Only layout attached.

5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached list of equipment is not fulfilling Phase-I/II clinical trials requirements.
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

03. As powers conferred by the CSC, the Chairman CSC constituted following panel for inspection & inspection panel letter was issued on 13th October 2021.:

i. **Dr. Abdur Rashid** (Coordinator), Chairman CSC / Director, Division of Pharmacy Services-DRAP.
ii. **Prof. Dr. Raza Shah**, GM, CBSCR-ICCBS, Karachi.
iii. **Dr. Ahson Siddiqui**, CEO, Healthcare Commission of Sindh/ Physician.
iv. **Naseem Salahuddin**, Director Infectious Diseases, The Indus Hospital & Health Network, Karachi.
v. **Dr. Saif Ur Rehman Khattak**, Additional Director, In charge CDL- Karachi.

04. Due to unavailability of some nominated panel member, following panel of expert inspected the site on 14th October 2021:

v. **Dr. Abdur Rashid (Coordinator),** Chairman CSC / Director, Division of Pharmacy Services-DRAP.
vi. **Prof. Dr. Muhammad Raza Shah,** GM, CBSCR-ICCBS, University of Karachi.
vii. **Dr. Naseem Salahuddin,** Director Infectious Diseases, The Indus Hospital & Health Network, Karachi.
viii. **Dr. Saif Ur Rehman Khattak,** Additional Director, In charge CDL- Karachi.

05. Experts panel of inspectors submitted inspection report with following remarks:

Keeping in view the human resources, technical background, IT facilities, documentation and archive room, Emergency facilities and handling management, infrastructure, Clinical trial unit and other allied facilities the panel recommends the "Clinical Trial Unit", Creek General Hospital, Korangi Town Hospital for Phase-III & IV Clinical trials.

Panel also discussed some points regarding address & Phases of study applied for. The applicant rectified the points forthwith and shown as objective the points forth and shown as objective evidence to the panel.

- **Recommended for approval**

06. Inspection report may be placed before CSC in its forthcoming meeting after fulfilment of all prerequisites.

07. Submitted for consideration of CSC:

08. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection as already mentioned above. Secretary also informed that, applicant applied for Phase-I, II & III Clinical Trials but as per evaluation applicant have no requisite equipment required for Phase-I & II Clinical Trials. Moreover, inspection panel after inspection recommended the site for Phase-III & IV Clinical Trials only. Original fee challan is the only shortcoming which need to be submitted, applicant provided photocopy of the challan but original challan need to be provided. So, as they provide original challan then after their licence will be issued. Chairman CSC added that, fee structure of the DRAP is now online. As before online system Karachi University submitted a challan of Rs.300000/- without bank charges, so the bank deducted their charges of Rs.30 so the challan haven't verified and due to shortcoming communication DRAP & Applicant spent a thousand Rupees in courier services. So, the DRAP take up the problem & an online system is developed that until the bank charges not given a challan can't be submitted. So, the Chairman suggested that as challans are now generated on line so may be verified online and if challan & fee submitted can be verified online, it is more than sufficient for verification of fee. Chairman also informed the CSC that he directed to desk officer to verify all challan online and record the date & time of verification. And if applicants provided photocopy of challan verified online so there is no need to wait for original copy & application shouldn't be delayed for original copy of the challan. Applicant may be informed telephonically & asked to submit original challan, meanwhile application may be processed & approval letter may be issued because applicant spent a lot of money on establishment of organization & there are foreign commitments. If a copy of challan can be verified online so there is no need to delay application. Chairman suggested to approve the application & he also said that the matter of original challan submission & online verification will also be discussed by hem in the Authority's meeting

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Creek General Hospital, Nasir Jump, Sector 48 H, Korangi Creek, 74200, Karachi to act as Clinical Trial Site for Phase III & IV Clinical Trials only.

AGENDA ITEM IV:

APPLICATION FOR APPROVAL OF M/S PAK-INTERNATIONAL HOSPITAL, KARACHI TO ACT AS CLINICAL TRIAL SITE FOR PHASE-I, II & III CLINICAL TRIALS. F. No.15-31/2021 DD (PS)

Application is from Mr. Muhammad Hamza Afridi (CNIC:42301-0947156-1), forwarded by Mr. Rashid Khan Jadoon, GM (Operations), M/s Pak International Hospital (Pvt.) Limited, Plot No. 39-C 22nd East Street DHA Phase-I, Karachi. Wherein the request has been made to license the subject hospital with DRAP to act as Clinical Trial Site for Phase-I, II & III clinical trials, the application is on prescribed Form-I of the Bio-Study Rules along with a fee of Rs.100000/- submitted vide challan No. 1906671, dated 29th March, 2021.

02. Details of submitted documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed Fee	Rs.100000/- submitted vide challan No. 1906671, dated 29th March, 2021.
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 and its directors).	Certificate Ref No. KYC No.1001 OF 2019-20 is attached, issued by Registrar of Firms, Karachi on 17th January 2020
4	Details of premises including layout plan of the site.	Only layout attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached list of equipment is not fulfilling Phase-I/II clinical trials requirements.
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.	Copy of affidavit on stamp paper is attached.

03. As powers conferred by CSC, the Chairman CSC/Director Pharmacy Services, constituted following panel for inspection:

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. Saif Ur Rehman Khattak** Additional Director, In charge CDL- Karachi.

04. Due to unavailability of some panel members, following panel of expert inspected the site:

i. **Dr. Abdur Rashid (Coordinator),** Chairman CSC / Director, Division of Pharmacy Services-DRAP.
ii. **Prof. Dr. Muhammad Raza Shah,** GM, CBSCR-ICCBS, University of Karachi.
iii. **Prof. Dr. Aamir Jaffary**, Sindh Institute of Urology & Transplantation (SIUT), Karachi.
iv. **Dr. Saif Ur Rehman Khattak,** Additional Director, In charge CDL- Karachi.

05. Experts panel inspected the subject site on 14th October 2021 & submitted inspection report with following remarks:

Keeping in view the infrastructure, human resources, experience and trainings, documents, archive facility, IT system, Pharmacy, Pharmacovigilance experience and indoor and outdoor, emergency handling facilities etc., Panel recommends Clinical Trial Site of Pak International Hospital 39-C, 22nd Street, DHA, Phase-I Karachi for Phase-III & Phase-IV.

- **Recommended for approval**

06. Inspection report may be placed before CSC in its forthcoming meeting after fulfilment of all prerequisites.

07. Submitted for consideration of CSC:

08. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection as already mentioned above. Secretary also informed that, applicant applied for Phase-I, II & III Clinical Trials but as per evaluation applicant have no requisite equipment required for Phase-I & II Clinical Trials. Moreover, inspection panel after inspection recommended the site for Phase-III & IV Clinical Trials only.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Pak International Hospital (Pvt.) Limited, Plot No. 39-C 22nd East Street DHA Phase-I, Karachi to act as Clinical Trial Site for Phase III & IV Clinical Trials only.

AGENDA ITEM V:

EXTENSION IN TRIAL DURATION & AMENDMENTS IN ALREADY APPROVED CLINICAL TRIAL TITLED "CHLOROQUINE/ HYDROXYCHLOROQUINE PREVENTION OF CORONAVIRUS DISEASE (COVID-19) IN THE HEALTHCARE SETTING; A RANDOMIZED, PLACEBO-CONTROLLED PROPHYLAXIS STUDY (COPCOV)". F. No.03-43/2020-DD (PS)

Application is from Dr. Muhammad Asim Beg, Professor & Consultant Parasitologist, Aga Khan University, dated 11th June 2021, along with a fee of Rs.25000/- deposited vide Challan No.48751437 dated 09th June 2021. Wherein request has been made for amendments in already approved protocol of clinical trial titled "Chloroquine/ Hydroxychloroquine Prevention of Coronavirus Disease (COVID-l9) in the Healthcare Setting; a Randomized, Placebo-controlled prophylaxis study (COPCOV)".

02. Applicant provided following documents:

i. Application along with prescribed fee.
ii. AKUH-IRB approval for amendment of protocol version from 5.0 to 6.0.
iii. NBC- amendment approval letter reference No.4-87/NBC-COVID-28-Amend/21/, dated 24th May 2021.
iv. Amended protocol version 6.0 along with its summary.
v. Amended Investigator's Brochure version 6.0.
vi. Revised Subjects Screening Form.
vii. Revised Patient Information Sheet.
viii. Revised Informed Consent Form (English & Urdu)
ix. Prescribed fee of Rs.25000/- for trial extension application submitted vide challan number 67145995038, dated 17th October 2021

03. Subject clinical trial (Protocol version 5.0) was approved on 28th August 2020 for a period of 05 months, which was expired on 27th January 2021.

04. Technical documents (Amended protocol version 6.0 track change copy & other) were shared with expert CSC members through email on 30th September 2021 for review & comments.

05. **Submitted for perusal, discussion and decision of CSC.**

06. Dr. Anum Dr. Momin Qazi & Dilshad Begum joined the meeting through Zoom as representative of PI from Aga Khan University Hospital, Karachi & briefed the Committee regarding amendments & need for extension and answered the questions raised by the CSC members.

07. Prof. Brig. (R), Muzammil Hassan Najmi, Dr. Abdur Rashid, Dr Naseem Salahuddin, Dr. Aamir Jaffary & other CSC members raised questions about the study & informed that in first wave of COVID-19 after many clinical studies it is published that, Chloroquine/ Hydroxychloroquine are not effective against COVID-19 as these molecules have no antiviral effects. It was also observed that there is no such data provided by the PI by which it can be evaluated that there is a need of extension in the trial duration.

Decision:

The CSC after deliberation / detailed discussion decided to defer the application for amendment & extension as no data has been furnished as evidence to substantiate the efficacy of Chloroquine/ Hydroxychloroquine for Prevention/prophylaxis of Coronavirus Disease (COVID-19).

Further it is decided that the applicant Dr. Muhammad Asim Beg who is also the PI of the study shall submit trial data for evaluation of IMPs efficacy & he will personally participate & brief the CSC in its next meeting regarding the reasons for amendment & extension of the trial as the studies have become obsolete worldwide.

08. Applicant shared some articles regarding Chloroquine/ Hydroxychloroquine studies through email on 21st October 2021 and upon direction of Chairman CSC, these articles were shared with CSC members on 25th October 2021. It is submitted that, most of literature is not supporting the claim of PI for extension in trial duration of the subject Clinical Study. (Attached as **Annex-I**)

09. Submitted for consideration of CSC:

10. Secretary CSC presented the case before CSC & apprised the Committee regarding case background as the case was also presented before CSC in its 32nd meeting & deferred. Applicant was informed regarding decision of the CSC. Afterwards applicant submitted some article regarding Chloroquine/Hydroxychloroquine Clinical Trials through email, however after evaluation desk officer informed that, most of literature is not supporting the claim of PI for extension in trial duration of the subject Clinical Study. Secretary CSC asked the desk officers to brief the CSC regarding evaluation of literature provided by the PI. Desk officer apprised the CSC regarding articles shared by Dr. Asim Baig (PI) that, in the provided articles, evidence of efficacy of Chloroquine/Hydroxychloroquine in treatment or prophylaxis is not found. Secretary CSC asked the CSC members to add their comments. Dr. Mushtaq Ahmad apprised the Committee that, as so many drugs tested against COVID-19 in the pandemic so there is no harm to test these drugs, even if does not benefits it would no harm if also continued to be tested.

11. Dr. Asim Baig PI of the trial joined the meeting through Zoom & briefed the Committee for need of extension in the trial & answered the question raised by the CSC members. Dr. Faiza Bashir was in favor of extension for completion of the trial as NBC has already approved the extension in duration of the trial.

Decision:

The CSC after detailed discussion & deliberation granted the approval of amendments and extension in the clinical trial titled, "CHLOROQUINE/ HYDROXYCHLOROQUINE PREVENTION OF CORONAVIRUS DISEASE (COVID-19) IN THE HEALTHCARE SETTING; A RANDOMIZED, PLACEBO-CONTROLLED PROPHYLAXIS STUDY (COPCOV)" for completion of the trial as allowed by NBC.

AGENDA ITEM VI:

APPLICATION FOR APPROVAL OF APPLICATION TO ACT AS CRO AT M/S TIGERMED CONSULTING PAKISTAN LIMITED, LAHORE F. No.15-42/2021 DD (PS).

Application is from Muhammad Tanseer Ali, CNIC:35401-6440356-9, Country Head & COM of M/s Tigermed Consulting Pakistan Limited, Lahore., Pakistan. Wherein the request has been made to license their firm with DRAP to act as Clinical Research Organization (CRO), the application is on prescribed Form-I of the Bio-Study Rules along with a fee of Rs.300000/- submitted vide challan No. 2222575165, dated 06th August 2021.

02. It is submitted that application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules, summary of submitted documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed fee challan	Attached
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	SECP Registration Certificate No. 0175374,

	addresses of its partners and in the case of company the name and address of the company and its directors).	
4	Details of premises including layout plan of the site.	Only layout attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not applicable as applied for CRO.
6	Names and qualifications of the above sections along with their staff.	Details regarding minimum division/departments required to work as CRO is need to be submitted, as approved by the CSC.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not applicable as applied for CRO.
8	Undertaking on affidavit	Attached

03. After initial scrutiny following shortcomings observed:

i. Appointment letter of Muhammad Tanseer Ali as Country Head & COM issued by company
ii. Clarification of organogram as it is not reflecting the position of CEO and Director as per SECP document.
iii. Details regarding minimum division/departments required to work as CRO is need to be submitted, as approved by the CSC.

04. Firm has submitted the deficiencies and Chairman, Clinical Studies Committee (CSC) has constituted the following Panel of Inspectors for inspection of Site of M/s Tigermed Consulting Pakistan Limited to act as Contract Research Organization (CRO).

i. Prof Dr Nadeem Irfan Bukhari, Member CSC/Pharmacist, Dean, College of Pharmacy, Punjab University, Lahore.
ii. Dr Farhana Badar, Bio-Statistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.
iii. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)

05. In response the panel of experts inspected the premises on dated **26-10-2021,** Rana Ahsan ul Haq Athar, Assistant Director, Pharmacy Services also joined the panel and recommendation is as under:

"Tigermed Consulting Pakistan is a part of Chinese CRO, China headquarter give a presentation to the panel of inspectors keeping in view the presence of Pharmacists, their training, documentation, computers and its back up, archive room, the panel

recommended Tigermed Consulting Pakistan, Jail road, Lahore as Contract Research Organization"

06. Submitted for consideration of CSC:

07. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection & recommendations of panel.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Tigermed Consulting Pakistan Limited, Lahore., Pakistan to act as Contract Research Organization (CRO).

AGENDA ITEM-VII:

APPLICATION FOR APPROVAL TO ACT AS CRO M/S COVANCE PHARMA SOLUTIONS, LAHORE F. No.15-47/2021 DD (PS).

Application is from Dr Uzair Nagra, CNIC:35200-6409218-7, CEO of M/S Covance Pharma Solutions Pakistan, H#6-B, Kamran Block, Allama Iqbal Town, Lahore, Pakistan. Wherein they have requested for license of their firm with DRAP to act as Clinical Research Organization (CRO).

02. The firm has applied on Prescribed form and fee as required under Bio-Study Rules is submitted vide challan amounting Rs.300030 Number 68893719626 dated 21-10-2021.

03. The application evaluated according to pre-requisites as mentioned in Form-I of the Bio-Study Rules notified vide SRO 697(I)/2018, summary of submitted documents is as follows: -

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed fee challan	challan amounting Rs.300030 Number 68893719626 dated 21-10-2021
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 and its directors).	Registration of Firm Registration Certificate No. 1587.
4	Details of premises including layout plan of the site.	layout attached.

5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not applicable as applied for CRO.
6	Names and qualifications of the above sections along with their staff.	Provided
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not applicable as applied for CRO.
8	Undertaking on affidavit	Attached

04. The firm has submitted all the pre-requisite as per Form-I, Chairman, Clinical Studies Committee (CSC) has constituted the following Panel of Inspectors for inspection of site to act as Contract Research Organization (CRO).

i. Dr Uzma Malik, Clinician/Medicine Expert.
ii. Prof Dr Nadeem Irfan Bukhari, Member CSC/Pharmacist, Dean, College of Pharmacy, Punjab University, Lahore.
iii. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)
iv. Rana Ahsan Ul Haq Athar, Assistant Director, DRAP, Islamabad.

05. In response the panel of experts inspected the premises on dated 25-10-2021 and recommendation is as under:

"Keeping in view the infrastructure, space, human resource, record, documentation, archive room, IT, QA& LT and other facilities Covance Pharma Solutions, Pakistan, 6-B, Kamran Block, Allama Iqbal Town, Lahore, panel unanimously recommends for Contract Research Organization CRO"

06. Submitted for consideration of CSC:

07. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection by panel of experts & panel recommendation as already mentioned above.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Covance Pharma Solutions Pakistan, H#6-B, Kamran Block, Allama Iqbal Town, Lahore, Pakistan to act as Contract Research Organization (CRO).

AGENDA ITEM VIII:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FROM SURAYYA AZEEM WAQAF TEACHING HOSPITAL LAHORE F. No.15-41/2021 DD (PS).

Application is from Dr Muhammad Asif Naveed Consultant Hematologist, CNIC 35202-271257-7 of M/s Surayya Azeem (Waqf) Teaching Hospital, Alkhidmat Health Foundation,5 Bahawalpur Road, Chuburgi, Mozang Chungi, Lahore wherein he has applied to act as Clinical trial Site for phase III & IV clinical trials. The application is on Form-I of the Bio-Study Rules with fee of Rs.100,000/-.

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

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed processing fee	Fee challan of Rs.100,000/- attached submitted vide slip No. 820876880 dated 17-08-2021.
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 and its directors).	Form-C of M/s Central Hospital Gujranwala is attached instead of applied site. PHC certificate attached. Memorandum of Association attached but readable copy required.
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.

03. After evaluation, it has been observed

i. Form-C of M/s Central Hospital Gujranwala is attached instead of applied site.
ii. Readable copy of Memorandum of Association is required.

04. In response Dr M Asif Naveed Consultant Hematologist, PI, M/s Surayya Azeem (Waqf) Teaching Hospital, Alkhidmat Health Foundation,5 Bahawalpur Road, Chuburgi, Mozang Chungi, Lahore has submitted the deficiencies communicated:-

i. Certificate of Registration, Directorate of Social Welfare, Government of Punjab & its renewal certificate (69-70).
ii. Provision of space for clinical trial agreement between Alkhidmat Health Foundation and Surayya Azeem (Waqf) Teaching Hospital, Lahore.
iii. Readable copy of Memorandum of Association of Alkhidmat Health Foundation.

05. In light of above Chairman, Clinical Studies Committee (CSC) has constituted the following Panel of Inspectors for Clinical Trial Site of M/s Surayya Azeem (Waqf) Teaching Hospital, 5 Bahawalpur Road, Chuburgi, Mozang Chungi, Lahore.

i. Prof Dr Javed Akram, Member CSC/Clinician, UHS, Lahore.
ii. Prof. Dr Nadeem Irfan, Bukhari, Dean College of Pharmacy, University of Lahore, Lahore.
iii. Farhana Badar, Bio-Statistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.
iv. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)
v. Mst Majida Mujahid, Additional Director, Lahore,

06. Due to non-availability of Prof Dr Javed Akram and Mst Majida Mujahid following panel inspected the site on dated **26-10-2021:** -

i. Prof. Dr Nadeem Irfan, Bukhari, Dean College of Pharmacy, University of Lahore, Lahore.
ii. Farhana Badar, Bio-Statistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.
iii. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)
iv. Rana Ahsan Ul Haq Athar, Assistant Director, DRAP, Islamabad.

07. The recommendation of the panel is as under: -

"*Keeping in view the premises, separate facility for clinical trial, emergency handling and facilities, human resource and their trial related training, pathology lab, x-ray, separate facility for pharmacy, panel recommends, Surayya Azeem (Waqf) Teaching Hospital, 5 Bahawalpur Road, Chuburgi, Mozang Chungi, Lahore, as clinical trial site for Phase-III and IV."*

08. Submitted for consideration of CSC:

09. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection report along with recommendations already mentioned above. Secretary also informed that, applicant applied for Phase-III & IV Clinical Trials.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Surayya Azeem (Waqf) Teaching Hospital, Alkhidmat Health Foundation,5 Bahawalpur Road, Chuburgi, Mozang Chungi, Lahore to act as Clinical Trial Site for Phase III & IV Clinical Trials only.

AGENDA ITEM IX:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FROM CENTRAL HOSPITAL, GUJRANWALA.F. No.15-40/2021 DD (PS).

Application is from Dr. Salman Athar Qureshi, Consultant Anesthetist & Intensivist (Principal Investigator), CNIC 36502-4689020-3 of M/s Central Hospital, Kangniwala, Main G.T. Road, Gujranwala, wherein he has applied to act as Clinical trial Site for phase III clinical trials. The application is on Form-I of the Bio-Study Rules with fee of Rs.100,000/-.

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

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed processing fee	Fee challan of Rs.100,000/- attached submitted vide slip No. 30661200410 dated 03-08-2021.
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 and its directors).	Attached.
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.

03. After evaluation, it has been observed that applicant has attached all necessary documents as per Form-I of the Bio-Study Rules. Further, the fitness of the site to carry out phase III trial may be verified by the panel by inspection.

04. Chairman, Clinical Studies Committee (CSC) has constituted the following panel for inspection of Clinical Trial Site situated at M/s Central Hospital, Kangniwala, Main G.T. Road, Gujranwala.

a. Dr. Farhana Badar, SKCH&RC, Lahore.
b. Dr Uzma Malik, Associate Professor, Meo Hospital, Lahore.
c. Dr. Abdur Rashid, Director Pharmacy Services Division, DRAP, Islamabad.
d. Dr Nadeem Irfan Bukhari, Dean College of Pharmacy, University of Punjab, Lahore.
e. Dr Sami Mumtaz, Principal Gujranwala Medical Centre, Gujranwala.(Co-opted Member/Inspector)

05. Due to unavailability of Dr Uzma Malik and Dr Sami Mumtaz following panel of experts inspected the premises on dated 26-10-2021:

i. Dr. Farhana Badar, SKCH&RC, Lahore.
ii. Dr. Abdur Rashid, Director Pharmacy Services Division, DRAP, Islamabad.
iii. Dr Nadeem Irfan Bukhari, Dean College of Pharmacy, University of Punjab, Lahore.
iv. Rana Ahsan ul Haq Athar, Assistant Director, DRAP, Islamabad.

06. The recommendation of the panel is as under:
"Keeping in view the availability of learned physicians, other human resource, training, infrastructure, equipment, x-ray, pathological facilities, emergency handling and ambulance facility, documentation, archive room, the panel recommends Central Hospital, Kangniwala, Main G.T. Road, Gujranwala as a clinical trial site for Phase-III & Phase-IV."

07. Submitted for consideration of CSC:

08. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection report along with recommendations, as already mentioned above. Secretary also informed that, inspection panel recommended the site for Phase-III & IV Clinical Trials only.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Central Hospital, Kangniwala, Main G.T. Road, Gujranwala, to act as Clinical Trial Site for Phase III & IV Clinical Trials only.

AGENDA ITEM X:

APPLICATION FOR APPROVAL OF APPLICATION TO ACT AS CRO M/S GLOBAL CONTRACT RESEARCH (PVT LTD), ISLAMABAD F. No.15-44/2021 DD (PS).

Application is from Dr Mobashir Ahmed Bhatti, CNIC:35202-8650523-5, CEO of M/S Global Contract Research (Pvt Ltd), 14-N, Wi-Tribe building, F-8 Markaz, Islamabad, Pakistan. Wherein the request has been made to license their firm with DRAP to act as Clinical Research Organization (CRO).

02. Application is on prescribed form and prescribed as required under Bio-Study Rules has been submitted.

03. The application evaluated according to pre-requisites as mentioned in Form-I of the Bio-Study Rules notified vide SRO 697(I)/2018, summary of submitted documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed fee challan	Photocopy provided
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 and its directors).	SECP Registration Certificate No. 0183936.
4	Details of premises including layout plan of the site.	Only layout attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not applicable as applied for CRO.
6	Names and qualifications of the above sections along with their staff.	Details regarding minimum division/departments required to work as CRO is need to be submitted, as approved by the CSC.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not applicable as applied for CRO.
8	Undertaking on affidavit	Attached

04. The chairman CSC has constituted following panel of experts for inspection of M/s Global Contract Organization to act as CRO:-

i. Dr. Abdur Rashid, Chairman CSC-DRAP (Chairman)
ii. Dr Faiza Bashir, Member CSC, PHRC, Islamabad.
iii. Muhammad Ansar, Assistant Director, Pharmacy Services, Islamabad.

05. The constituted panel inspected the site on dated 01-11-2021 and recommendation is as under:

"*Keeping in view the infrastructure, human resource, their experience, clinical operations, QA, QC, IT record room/archive room, coordination system etc Global Contract Research (Pvt Ltd), 14-N, first floor, Wi-Tribe building, F-8/4, Markaz, Islamabad, unanimously recommends Contract Research Organization."*

06. Submitted for consideration of CSC:

08. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection report along with recommendations, as already mentioned above. Secretary also informed that, in this application details regarding minimum divisions required to work as CRO as approved by the CSC in its 2nd meeting is required. Applicant should furnish the details & technical persons engaged & perform different functions as laid down in the ICH guidelines & also approved by the CSC. Chairman CSC asked Dr. Faiza Bashir to add her comments, as she was also part of inspection panel for the CRO. Dr. Abdur Rashid apprised the Committee that, Dr. Faiza Bashir & Mohammad Ansar was in the panel members & they physically verified the organogram of the CRO and it is strange that, the things which are physically verified how can be evaluated in the office/files. So, comments from Secretary CSC & recommendations of inspection panel are before CSC for decision. Dr. Faiza Bashir asked the Ahmad Din Ansari, Secretary CSC to kindly again elaborate the shortcomings, then Secretary CSC informed her & the CSC members that details regarding minimum division to work as aa CRO need to be provided as applicant not supplied in application. These minimum divisions were approved by the CSC in its 2nd meeting. Dr. Faiza Bashir informed that, during the inspection the panel verified all the documents and also all documents & Job Description documents provided with panel report so kindly recheck it. Secretary CSC submitted that all SOPs are checked which are unsigned & JDs are also stereotype documents which are downloaded from internet & attached and are not clarifying the role & responsibilities & files were also rechecked. And details regarding minimum division also mentioned in evaluation sheet it is necessary to work as CRO. Dr. Faiza Bashir emphasize that, all documents were in place and it is not possible that these documents were not submitted to the DRAP & if the documents are not signed so the documents may be signed by the applicant. Chairman again presented the recommendations of the panel & also informed that Human Resource head was from Navy equivalent to Maj. General rank of the Army & an American Return was its CEO & Documentation section was headed by a Harvard Graduate & Dr. Suhail was their full-time employee which is a PIMS retired professor, Dr. Faiza Bashir added that they have also a fully department of IT & the panel personally met with Admin & Finance Division. Chairman CSC continued that, Clinical Operations, Quality Assurance, Quality Control, IT, Record/Archive Room, Coordination System with Dubai & America. Further Chairman CSC apprised the Committee and pointed out that organogram is not readable so he verified the Job Descriptions he thanks to Dr. Farhana Badar as she taught him to verify JDs during inspection. So they verified all job descriptions & SOPs. So due to nitty gritty in application should not be hurdles in its processing. As panel recommended the site & as per practice CSC on the basis of panel recommendation so Chairman suggested to approve the site.

Dr. Faiza Bashir submitted that, before to proceed further, if there are DRAP's in-house observation for an application after panel inspection recommendation so these observations should be communicated to applicant & should be waited for applicant response, after submission of reply/justification by applicant then if response is no justified then it should be placed for discussion

before CSC. So, the guidance/way forward may be discussed in the Committee not deficiencies. Secretary CSC informed that, it was for information of CSC so the all facts should be before CSC.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Global Contract Research (Pvt Ltd), 14-N, Wi-Tribe building, F-8 Markaz, Islamabad, to act as Contract Research Organization (CRO).

AGENDA ITEM XI:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE-III PHASE-IV FROM M/S NORTHWEST GENERAL HOSPITAL & RESEARCH CENTRE (APROJECT OF ALLIANCE HEALTHCARE (PVT) LTD), SECTOR A-3, PHASE-V, HAYATABAD, PESHAWAR F. No.15-49/2021 DD (PS).

The application is from Prof Dr Tariq Khan Chairman, CNIC 17301-4944887-5 of M/s Northwest General Hospital & Research Centre (A project of Alliance Healthcare (Pvt) Ltd), Sector A-3, Phase-V, Hayatabad, Peshawar, wherein he has applied to act as Clinical trial Site for phase III & IV clinical trials. The application is on Form-I of the Bio-Study Rules with fee of Rs.100,000/- .

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

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached
2	Prescribed processing fee	Fee challan of Rs.100,000/- attached submitted vide slip No. 852596369 dated 27-102021.
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 and its directors).	Attached. Relationship between AHL and Northwest Hospital.
4	Details of premises including layout plan of the site.	Attached. Healthcare Commission Certificate
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.

03. After evaluation, it has been observed that applicant has attached all necessary documents as per Form-I of the Bio-Study Rules. Further, the fitness of the site to carry out phase III & IV trial may be verified by the panel by inspection.

04. The Chairman, Clinical Studies Committee (CSC) has constituted the following Panel of Inspectors for Clinical Trial Site of M/s Northwest General Hospital & Research Centre (A project of Alliance Healthcare (Pvt) Ltd), Sector A-3, Phase-V, Hayatabad, Peshawar.

a. Dr. Abdur Rashid, Director Pharmacy Services Division, DRAP, Islamabad.
b. Dr Mushtaq Ahmed/Clinician from Peshawar.
c. Mr. Muhammad Ansar, Assistant Director (PS), DRAP, Islamabad.
d. Mr. Attiq Ul Bari, FID, DRAP, Peshawar.

05. Due to non-availability of Dr Mushtaq Ahmed, Dr Fayaz Ur Rehman, Clinician from Khyber Teaching Hospital, Peshawar joined the inspection team and inspected the site on dated **02-11-2021** and recommendation is as under: -

> "*Keeping in view the infrastructure, human resource, professional experience, IT system, SOPs, Documentations, Archive room, waste management facilities, x-rays, pathological lab, other clinical facilities, emergency handling, panel recommends, clinical trial site of Northwest general hospital and Research Centre, clinical trial unit, Phase-5, Hayatabad Peshawar for Phase-III and Phase-IV.*"

06. Submitted for consideration of CSC:

07. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection report along with recommendations, as already mentioned above. Secretary also informed that, inspection panel recommended the site for Phase-III & IV Clinical Trials only. Chairman CSC informed the CSC that, in Peshawar, Rehman Medical Institute is also an approved Clinical Trial Site which is a good site but this is also a much better site. Pathological Lab & X-Ray Lab were thoroughly inspected. All the equipments was from leading companies of the world & their reporting system was online even reports were shared through Whats App. And that panel was happy with standards & private sector is growing day by day, so now in KPK there are two Clinical Trial Sites Rehman Medical Institute & North West General hospital where patients can be available for Clinical Trial, it is for information & appraisal of Committee.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Northwest General Hospital

& Research Centre (A project of Alliance Healthcare (Pvt) Ltd), Sector A-3, Phase-V, Hayatabad, Peshawar, to act as Clinical Trial Site for Phase III & IV Clinical Trials only.

AGENDA ITEM XII:

APPLICATION FOR LICENSE TO ACT AS BA/BE STUDIES LAB, AT M/S UNIVERSITY OF LAHORE F. No.15-46/2021 DD (PS).

Application is from Mr. Awais Raoof, Chairman Board of Governors(BOG), M/s University of Lahore, 1 KM Defense Road (Off Raiwind road), Lahore, wherein the request has been made to license their premises with DRAP to work as BA/BE studies lab M/s University of Lahore, 1 KM Defense Road (Off Raiwind road), Lahore, the application is on prescribed Form-I of the Bio-Study Rules along with fee.

02. It is submitted that application evaluated according pre- requisites as mentioned in Form-I of the Bio-Study Rules, and status of application is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Unsigned Attached
2	Fee	Rs.300000/- deposited vide challan no.85704080, dated 6th October 2021.
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 and its directors).	Not Attached
4	Details of premises including layout plan of the site.	Only layout Attached, details not provided.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	List attached, but equipment required for BA/BE Studies Center as approved by CSC are not in the list.
6	Names and qualifications of the above sections along with their staff.	Not Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not attached.
8	Undertaking on stamp paper	Not provided.

03. After evaluation following shortcoming observed:

i. Application on prescribed Form-I of The Bio-Study Rules required to be signed.

ii. 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 and its directors) require to be submitted.

iii. Only layout plans provided, details and bifurcation of the premises should be provided

iv. Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies as approved by CSC to carry out necessary tests require to be submitted furthermore the applicant has provided the list of equipment that are present in different departments of University i.e. Department of Pharmacy, Molecular & CRISPR Lab, Hi-Tech Lab, Institute of Molecular Biology and biotechnology Hi-Tech Lab Nanobiology and plant tissue culture which requires clarification (as License can be granted to premises which has facilities for BA/BE at one place/premises).

v. Names and qualifications of the above sections along with their staff.

vi. Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.

vii. Undertaking on stamp paper

04. Shortcomings are communicated to applicant for fulfilment of prerequisite vide letter dated 22nd October, 2021.

05. Chairman, Clinical Studies Committee (CSC) has constituted the following Panel of Inspectors for Clinical Trial Site of M/s University of Lahore.

iv. Prof Dr Nadeem Irfan Bukhari, Member CSC/Pharmacist, Dean, College of Pharmacy, Punjab University, Lahore.

v. Farhana Badar, Biostatistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.

vi. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)

vii. Dr Uzma Malik, Clinical Medicine Expert.

viii. Rana Ahsan Ul Haq Athar, Assistant Director, DRAP, Islamabad.

06. Due to non-availability of Rana Ahsan Ul Haq Athar, Assistant Director following panel inspected the site:

i. Prof Dr Nadeem Irfan Bukhari, Member CSC/Pharmacist, Dean, College of Pharmacy, Punjab University, Lahore.
ii. Farhana Badar, Biostatistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.
iii. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)
iv. Dr Uzma Malik, Clinical Medicine Expert.

07. The shortcomings were communicated to the applicant vide this office letter F.No.15-46/2021 DD (PS) dated 22nd October, 2021 and reply is still awaited, the recommendation of the panel is as under: -

"Keeping in view the infrastructure, human resource, training and experience, equipment/machinery, SOPs, documentation, archive room, IT data management, waste management, spacious building, panel unanimously recommended BA/BE centre for University of Lahore."

08 Submitted for consideration of CSC.

09. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection report along with recommendations, as already mentioned above. Further, Secretary CSC informed the Committee regarding shortcomings in detail one by one, shortcomings are already mentioned in para 3 of the agenda item. Shortcomings already communicated to the applicant on 22nd October 2021 but response is yet awaited. Moreover, facility haven't equipment's required for a BA/BE Studies Center. Applicant informed that, they have signed an MOU with M/s PDTRS, Lahore, there is no provision in rules for MOU for a BA/BE Studies Center. As per rules an independent facility should be there to act as BA/BE Studies Center. Secretary CSC also presented the inspection panel recommendation. Further Secretary CSC apprised the Committee that whole university can't be approved as a BA/BE Studies Center & a BA/BE Center should have all equipment's required for BA/BE Studies under one roof. Dr. Javed Akram suggested that, the case should be deferred as BA/BE Studies Center are the most prestigious centers and they set standards for drug testing & are very very sophisticated facilities where volunteer participate in the studies. He added that, previously he said to the Chairman that, there should be only one Committee for whole Pakistan who can inspect the BA/BE Studies Centers because there is 0% tolerance for the BA/BE Studies Centers. So, the Dr. Javed Akram Suggested, to defer the case & applicant should be informed regarding shortcomings need to be fulfilled. Further a whole university can't be a BA/BE studies Center, it should be a separate facility. We are also establishing a centre at Kala Shah Kaku which will be operated under UHS Lahore but UHS, Lahore itself can't be a BA/BE Studies Center. There should also an attached hospital & ICUs in case of any ADRs during the studies. So today we should decide for a Committee who should inspect the BA/BE Studies Center & for approval of BA/BE Studies Center there should no hurry. If a Committee is nominated it should be trained, UHS, Lahore can be trained them, that how to inspect a BA/BE Studies Center & what are the mandatory requirements internationally & locally for a BA/BE Studies Center. Chairman added that the same offer was previously offered by Dr. Javed Akram, but due to COVID it was not possible to arrange the training. So as per Dr. Javed Akram suggestion the case is deferred at the moment, after nomination of Committee and its training from UHS Lahore. Chairman CSC further added that, the University has highest standards like foreign countries and when panel of inspector visits a site obviously check the legal requirements as per rules. Accordingly, in the university campus there was a separate facility of hospital, other departments & the BA/BE Studies Center & the panel visited a separate entity named BA/BE Study

Center and there was all equipment's like HPLC, GC, FTIR & others required for BA/BE Studies Center except one. They haven't LCMS/GCMS which is of worth Rs.50000000/- further GCMS/LCMS is not required in many BA/BE Studies & as per his opinion there is also a provision in rules that a bioanalytical laboratory can sign an agreement/MOU with BA/BE Studies Center that if any test facility is not available at the BA/BE Studies Center then it can be carried out at Bioanalytical Laboratory. PDTRC of Sundar estate is also a government facility and PDTRC of Sundar estate is also a government facility and they have signed an MOU with PDTRC whenever GCMS/LCMS test required then can be carried out there. As it is a very expensive equipment and if we make it mandatory then BA/BE Studies Center can't work in Pakistan. But as worthy senior member said we nominate a four membered team & after training at UHS Lahore then the BA/BE Studies Center, will be inspected, at the moment the case is deferred.

Decision:

The CSC after deliberation / detailed discussion decided to defer the case for further deliberations clarification & till fulfilment of all prerequisites of the application.

Prof Dr Javed Akram Suggested that a Committee may be constituted and he is ready to provide platform for training on BA/BE centers inspection. After training the same trained Committee will inspect all the BA/BE study centers for all fresh applications.

AGENDA ITEM XIII:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, AT M/S UNIVERSITY OF LAHORE F. No.15-45/2021 DD (PS).

Application is from Mr. Awais Raoof, Chairman Board of Governors(BOG), M/s University of Lahore, 1 KM Defense Road (Off Raiwind road), Lahore, wherein the application is in reference to approval of M/s University of Lahore as Clinical Trial Site.

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

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Unsigned application mentioning the request for approval of BE/BA studies however as per fee submitted and covering letter it pertains to Approval of Clinical trial site of University of Lahore without mentioning the specific department used for such purpose.
2	Fee	Rs.100030 submitted vide challan No. 960255074977 dated 06-10-2021.

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 and its directors).	Not provided.
4	Details of premises including layout plan of the site.	Layout provided without specifying the area of University to act as CTS.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Provided but requires clarification.
6	Names and qualifications of the above sections along with their staff.	Not provided.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not provided.
8	Undertaking on stamp paper	Not provided.

03. After evaluation following shortcoming observed:

i. Application on prescribed Form-I of The Bio-Study Rules required to be signed.

ii. 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 and its directors) require to be submitted.

iii. Only layout plans provided, details and bifurcation of the premises along with exact site of university to act as CTS should be provided

iv. Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies as approved by CSC to carry out necessary tests require to be submitted furthermore the applicant has provided the list of equipment that are present in different departments of University i.e. Department of Pharmacy, Molecular & CRISPR Lab, Hi-Tech Lab, Institute of Molecular Biology and biotechnology Hi-Tech Lab Nanobiology and plant tissue culture which requires clarification (as License can be granted to premises which has facilities for BA/BE at one place/premises).

v. Names and qualifications of the above sections along with their staff.

vi. Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.

vii. Undertaking on stamp paper

04. The shortcomings are forwarded to applicant for fulfilment of prerequisite vide letter dated 25-10-2021.

05. The Chairman, Clinical Studies Committee (CSC) has constituted the following Panel of Inspectors for Clinical Trial Site of M/s University of Lahore.

i. Prof Dr Nadeem Irfan Bukhari, Member CSC/Pharmacist, Dean, College of Pharmacy, Punjab University, Lahore.
ii. Farhana Badar, Biostatistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.
iii. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)
iv. Dr Uzma Malik, Clinical Medicine Expert.
v. Rana Ahsan Ul Haq Athar, Assistant Director, DRAP, Islamabad.

06. Due to non-availability of Rana Ahsan Ul Haq Athar, Assistant Director following panel inspected the site:

i. Prof Dr Nadeem Irfan Bukhari, Member CSC/Pharmacist, Dean, College of Pharmacy, Punjab University, Lahore.
ii. Farhana Badar, Biostatistician, Shaukat Khanum Memorial Cancer and Research Hospital, Lahore.
iii. Dr. Abdur Rashid, Chairman CSC/ Director, Pharmacy Services Division, DRAP, Islamabad. (Coordinator)
iv. Dr Uzma Malik, Clinical Medicine Expert.

07. The shortcomings were communicated to the applicant vide this office letter F.No.15-45/2021 DD (PS) dated 22nd October, 2021 and reply is still awaited, the above panel inspected the site on dated 25-10-2021and the recommendation of the panel is as under: -

"Keeping in view the Hospital infrastructure, Professional human resource, experience and training, spacious building, equipment, machinery, emergency facilities and its handling, IT system, SOP, record and documentation, waste management and organizational will, the panel unanimously recommended Clinical Trial Unit of University of Lahore, Hospital for clinical trial of Phase-III & Phase IV."

Submitted for consideration of CSC.

09. Secretary CSC presented the case before CSC & appraised the Committee regarding case background & its inspection report along with recommendations, as already mentioned above. Further Secretary elaborated shortcomings of the application observed during evaluation, which were already shared with applicant on 22nd October 2021 & response is yet awaited. Any how the panel has inspected the site on 25th October 2021 & recommended it to act as clinical trial site for Phase-III & IV Clinical Trials only. In the light of panel inspection, the case is placed before CSC for further consideration. Secretary CSC suggested that, deficient documents need to be provided before issuance of licence. The case may be approved subject to submission of shortcomings for

satisfaction of Chairman CSC, so the application shall be complete & in line with rules. Moreover, a whole university or Hospital cannot be approved as Clinical Trial Site, there should be a specific ward or Clinical Trial Unit identified by the applicant that may be considered and approved accordingly. Chairman appraised the Committee it is present in the record & on inspection he also took its photos its Clinical Trial Unit is a separate facility, Dr. Farhana Badar was also in panel & she requested to add her comments. Dr. Farhana Badar added that, the panel submitted its recommendations. Chairman Said that CTU was a separate facility from hospital & there were two doctors & observation rooms and the panel submitted report informing that CTU was a separate facility & what is written in the report the panel is sure on it. Applicant should submit an application for CTU in University of Lahore Teaching Hospital, University of Lahore, but applicant everywhere mentioned only University of Lahore. Secretary CSC appraised the Committee that applicant hasn't identified the premises in layout, Dr. Farhana Badar also in opinion that applicant should identify the premises of CTU in the layout.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to Clinical Trial Unit of M/s University of Lahore Teaching Hospital, University of Lahore, 1 KM Defense Road (Off Raiwind road), Lahore, to act as Clinical Trial Site for Phase III & IV Clinical Trials only.

AGENDA ITEM XIV:

APPLICATION FOR APPROVAL OF M/S CLINTRA, KARACHI TO ACT AS CRO.F. No.15-50/2021 DD (PS)

Application from Mr. Farhan Khan S/o Haji Abdul Rauf Khan (CNIC:42101-1704677-7), CEO of M/s Clintra (Contract Research Organization) situated at G-7, Channel Building, Block No.06, P.E.C.H.S, Shahrah-e Faisal Karachi.

02. It is submitted that application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules, summary of submitted documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached * Application is not signed & stamped in original.
2	Fee	Fee of Rs.300000/- submitted vide challan number 92085894455, dated 02nd November 2021. * Verified on line
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	No evident documents are provided for firm registration.

	company the name and address of the company and its directors).	
4	Details of premises including layout plan of the site.	Only layout attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not applicable as applied for CRO.
6	Names and qualifications of the above sections along with their staff.	List of some technical staff is attached. * Attached list of technical staff is not fulfilling the requirements for a CRO
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not applicable as applied for CRO.
8	Undertaking on stamp paper	Attached. * Affidavit is not signed & stamped in original.

03. After evaluation of the application following shortcomings observed:

i. Application & affidavit are not signed & stamped in original.
ii. Particulars regarding the legal status of the applicant/firm are not provided.
iii. Attached list of technical staff is not fulfilling the requirements for a CRO. (i.e. Medical Function, Regulatory Submission Team, Clinical Operations, Data Management, Biostatistics, Medical Writing, Quality Assurance, IT Team, Admin & Finance, Human Resources, Training & Development,

04. Application was received in the Division on 03rd November 2021 & as visit of Chairman CSC was scheduled in Karachi for inspection. So, as powers conferred by the CSC, Chairman CSC constituted following panel for inspection of the subject CRO:

i. Dr. Abdur Rashid, Chairman CSC/Director, Division of Pharmacy Services, Karachi.
ii. Dr. Ahson Siddiqui, CEO, Sindh Health Care Commission, Karachi.
iii. Dr. Aamir Jaffrey, Co-Opted Member CSC/SIUT, Karachi.
iv. Dr. Najam Us Saquib, In-charge DRAP-Karachi.

05. The Chairman CSC due to unavailability of some nominated panel member, following panel of expert inspected the site on 04th November 2021:

i. **Dr. Abdur Rashid (Coordinator),** Chairman CSC / Director, Division of Pharmacy Services-DRAP.
ii. **Dr. Iqbal Afridi,** Dean College of Physician & Surgeon of Pakistan, Karachi.
iii. **Dr. Najam Us Saquib**, In-charge DRAP-Karachi.

06. Experts panel of inspectors submitted inspection report with following remarks:

Keeping in view the infrastructure, Clinical Operations, technical human resources, experience & training, SOPs, documentation, archive room, IT and other facilities the panel

recommends Clintra Contract Research Organization G-7, Channel, Shahrah-e-Faisal Karachi as Contract Research Organization (CRO)

- **Recommended for approval**

07. Submitted for consideration of CSC:

08. Secretary CSC presented the case before CSC & apprised the Committee regarding case background & its inspection report along with recommendations, as already mentioned above. Secretary also informed that, application was received on 3rd November 2021 & the Chairman CSC constituted the inspection panel on the same day & inspection conducted on 4th November 2021. When the application evaluated some shortcomings observed as the application form & affidavit are not signed & stamped in original & it is colour print out. Other shortcomings were also briefed by the Secretary CSC which are already mentioned in para 3 of the agenda item. As applicant not provided details regarding minimum divisions required to work as CRO, which are approved by the CSC in its 2nd meeting. Secretary CSC further elaborated that CROs sometimes also referred as Clinical Research Organization is basically a company / organization that, helps to conduct research of Sponsor Company. Research can be preclinical studies, development to post market research. CROs as per ICH guidelines may be defined as "A person or organization commercial, academic, contracted by the Sponsor to perform one or more trial specific duties or functions". A CRO can work with a number of organization & conducting a Clinical Trial is complex process so CRO required a diversified large team with different expertise & skills. The main functions required for a CRO, as per ICH guidelines are Medical Function, Regulatory Submission Team, Clinical Operations, Data Management, Biostatistics, Medical Writing, Quality Assurance, IT Team, Admin & Finance, Human Resources, Training & Development. But the applicant not provided organogram & as per documents the employees have not the relevant experience, but as per the panel recommendations the case is placed before CSC for deliberation as per the facts & documents on record. Chairman informed that, stamp paper is original & it is my last meeting, I was the president Pharmacy Council & DRAP Act is prepared by me & being Chairman CSC I have shared my view with Secretary CSC & other junior colleagues that all the application even complete or incomplete I want to visit it & our pendency should be zero. There are only two application in process, one is from NUMS, the applicant, I want to visit the facility but the applicant informed that, they are not ready for inspection another application is of ventilator & applicant haven't got permission from their medical directorate both organizations is under Army. All other applications across from Pakistan have been processed & even on the same day of application receipt being Chairman CSC, nominated the panel & visited the facility so there should no pendency on behalf of Division of Pharmacy Services. In the panel Dr. Najam Us Saquib & Dr Iqbal Afridi was there & when we visited the 1st CRO that is DRK then we were thought that what it can do, now DRK is bringing million-dollar business & it is now Pakistan's multinational CRO. Clintra CRO is bigger organization than DRK. Clinical Trials is a new field in Pakistan, so we never asked anyone for experience in Clinical Trials. We only look for experienced full time officers & related facilities & panel was satisfied upon inspection. Stamp paper is original but signatures are may be printed as he may be away but it should not the basis for rejection. Chairman CSC again presented panel recommendation before CSC & asked for any comments otherwise the CRO considered as approved.

Decision:

The CSC in pursuance to the recommendations of the inspection panel & in the light of discussion/deliberations unanimously decided to grant licence to M/s Clintra (Contract Research Organization) situated at G-7, Channel Building, Block No.06, P.E.C.H.S, Shahrah-e Faisal Karachi, to act as Contract Research Organization (CRO).

AGENDA ITEM XV:

MEETING OF SUB-COMMITTEE ON NEED OF COPP & GMP CERTIFICATE FOR BA/BE STUDIES APPLICATIONS

CSC discussed the matter in the 32nd meeting & decided as under:

"The Chairman CSC constituted a sub-committee comprising of following members as per deliberation / detailed discussion by CSC on the matter:

i. *Dr. Abdur Rashid, Chairman CSC, Director Pharmacy Services Division.*
ii. *Prof. Brig. (R), Muzammil Hassan Najmi, Member CSC & Professor of Pharmacology, Foundation University, Islamabad.*
iii. *Prof. Nadeem Irfan Bukhari, Member CSC & Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.*
iv. *Dr. Farhana Badar, Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.*

The sub-committee shall evaluate the matter as provided under the Bio-Study Rules & in accordance with international standards/guidelines & practices & submit its report on the issue, which shall be placed before the CSC in its next meeting".

02. The sub-committee conducted its first meeting on Friday, 05th November 2021 at 03:00 PM through Zoom. Chairman CSC started the meeting with recitation of holy versus of the Quran, after which Chairman briefed the members of the sub-committee regarding the matter.

03. The sub-committee meeting attended by all members except Prof. Brig. (R), Muzammil Hassan Najmi due to his prior engagements. Prof. Dr. Raza Shah also joins the meeting through Zoom & briefed the Committee regarding the matter.

04. The sub-committee after detailed deliberation decided the matter as under:

Decision & recommendations:

*The CSC needs to adapt "Annex 8 Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products". (**Annex-II**.)*

Further, GMP and CoPP should only be a prerequisite for registered product only whereas only GMP certificate should be asked for unregistered products.

05. Recommendation of sub-committee are placed before CSC for considerations & perusal.

06. Secretary CSC presented the case before CSC & apprised the Committee regarding case background as the matter was discussed previously in 32nd CSC Meeting when two cases of BA/BE Studies of CBSCR-ICCBS submitted by Prof. Dr. Raza Shah, Secretary apprised the Committee that applicant informed that they are facing problems due to CoPP & GMP Certificate requirement for standard product but there is a legal requirement for submission of CoPP & GMP Certificate. The Chairman CSC constituted following four membered Committee to deliberate the matter & submit its recommendations:

"The Chairman CSC constituted a sub-committee comprising of following members as per deliberation / detailed discussion by CSC on the matter:

i. Dr. Abdur Rashid, Chairman CSC, Director Pharmacy Services Division.
ii. Prof. Brig. (R), Muzammil Hassan Najmi, Member CSC & Professor of Pharmacology, Foundation University, Islamabad.
iii. Prof. Nadeem Irfan Bukhari, Member CSC & Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.
iv. Dr. Farhana Badar, Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.

The sub-committee shall evaluate the matter as provided under the Bio-Study Rules & in accordance with international standards/guidelines & practices & submit its report on the issue, which shall be placed before the CSC in its next meeting".

07. Secretary also apprised the Committee regarding sub-committee proceedings as already mentioned in para 02-04/N of the agenda item. Recommendations are placed before CSC for further deliberation. Secretary CSC further informed that, CoPP & GMP requirement is as per the Bio-Study Rules to ascertain the quality of the standard product by which reference products will be compared. Secretary CSC asked other members of the sub-committee to emphasize the matter. Dr. Farhana Badar also informed regarding recommendation submitted by the sub-committee. Secretary informed the CSC that even if CSC adopt the Annex 8 of the WHO there are many points and it will again be deliberated how applicant fulfil the requirements for standard/reference products & even after adaptation it may be not allowed to purchase standard drug from open market & bring it in personal baggage. Applicant provided the purchase receipt from Dubai & air ticket, this is not the way to procure the reference drug from which a local product will be compared. Internationally this is not the practice, even in Jordon which is a renowned BA/BE Center which is also recognized & its reports are also accepted all over the world and if our BA/BE Studies Center will not follow the international practices their result will not be recognized for exports of local products. Chairman CSC briefed the Committee that as per rules if a BA/BE Center want to conduct study it will compare the product with innovator or the products available in markets of stringent regulatory authority but practically it is not possible, Chairman emphasized that there were no BA/BE Studies Centers in Pakistan recently some BA/BE Studies Centers started working in Pakistan. As many of procedures or requirements are not possible in practical. CSC approved some BA/BE Studies but their approval is not issued yet, he asked that why the decisions of the Committee not conveyed yet & if there is any problem so the matter should be brought before CSC with a brief regarding rules & difficulties found in practical. Because in the foreign countries medicines are not available without prescription. And then being Chairman CSC I take up the matter

& constituted the sub-committee & the decision will not only for the pending application but for all future applications also. Chairman again briefed the Committee regarding sub-committee discussion & decision & suggested Secretary CSC to again deliberate the six points of the WHO Annex-8. Chairman CSC informed that as per WHO recommendations the sub-committee adapted the annex-8 for comparative products & as per WHO standard we seek the documents for previously discussed BA/BE Studies & for future applications. And after fulfilment of the requirements as per WHO Annex-8 registration letter of previously discussed application should be issued. Further Chairman said that products in a Phase-I study its GMP certificate may be asked but its CoPP may be omitted. Secretary CSC informed the Committee that, there are two drugs one is moxifloxacin & another is Dexilant, applicant himself informed that the drugs will be procured from Japan & Germany respectively, and are registered drugs so the CoPP & GMP were asked, whereas CoPP for a Phase-I product is never asked from applicant as it is not possible. And decisions of the CSC taken in the32nd meeting were communicated to applicant also. Further the case is placed before CSC.

Decision:

The CSC after discussion & deliberations, accepted the following recommendations of sub-committee:

*CSC adapted "WHO, Annex 8 Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products". (**Annex-II**.)*

1. The innovator product for which quality, safety and efficacy has been established if this product has been granted a national marketing authorization (nationally authorized innovator);
2. National market leader product for which a national marketing authorization has been granted;
3. The WHO-recommended comparator product included in the International list of comparator products (1) or, if different and if it exists for the active pharmaceutical ingredient in question, the one suggested within the context of the Prequalification Team;
4. An innovator product approved by a stringent regulatory authority, i.e. a country associated to The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
5. A product that has been granted approval in an ICH-associated country;
6. In the case that no innovator or comparator product can be identified according to the above, the choice of the comparator should be made carefully and should be comprehensively justified.

Further, GMP and CoPP should be a prerequisite for registered product only whereas only GMP certificate should be asked for unregistered products.

The applicant will be asked to submit the source of reference drugs as per six source points already mentioned above along with requisite document(s) and mode of its procurement for the study.

The decision will be communicated to the applicant(s) and the application(s) will be processed accordingly.

AGENDA ITEM XVI:

IMPORT OF MEDICAL DEVICES "A GLOBAL, MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE III CLINICAL STUDY TO EVALUATE THE EFFICACY, SAFETY, AND IMMUNOGENICITY OF SEQUENTIAL IMMUNIZATION OF RECOMBINANT SARS-COV-2 FUSION PROTEIN VACCINE (V-01) AGAINST COVID-19 IN HEALTHY ADULTS AGED 18 YEARS AND OLDER AFTER THE VACCINATION OF 2 DOSES OF INACTIVATED VACCINES" F. NO.03-74/2021 DD (PS)

The case is from DRK Pharma Solutions wherein A Global, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of Sequential Immunization of Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01) Against COVID-19 in Healthy Adults Aged 18 Years and Older after the Vaccination of 2 Doses of Inactivated Vaccines was approved in the 32nd meeting of CSC, however the following devices used in the said trial were not presented in the meeting, now these are placed before the CSC for consideration.

S.No.	Medical Device	Manufactured by	Quantity per subject for 6 visits	Total Quantity (Packages)	Total Quantity (No. of Pieces)	Description
1	SST collection tubes	BD	12	48 Packages (100 tubes/package)	4,800	Blood sample collection
2	Cryogenic vials 1.5ml	Guangzhou Jet Bio	30	120 Packages (100 tubes/package)	12,000	Serum storage
3	Disposable pipette	Zhejiang Gong Dong	6	24 Packages (100 tubes/package)	2,400	Blood sample collection
4	Labels	Custom made	42	16,800 pcs	16,800	Sample labelling
5	Cryogenic box, 9*9	Wange	/	200 Boxes	200	Sample storage
6	Biohazard Bags	Qingdao Bomei	/	200 Bags	200	Sample storage
7	Freezer Maker	Thermo Fisher	/	7 pcs per site	7	Sample labelling
8	Swab	Citotest	3	/	1200	Virus Sample Collection
9	VTM-N	Citotest	2	/	800	Virus Sample Collection

10	Labels	Custom Made	2	800 pcs	800	Sample Labelling

02. Submitted for consideration of CSC.

03. Secretary CSC presented the case before CSC & appraised the Committee regarding case background.

Decision:

The CSC after discussion & deliberations acceded to request of the applicant for the import of above said quantities of medical devices subject to confirmation from study protocol. It was also decided that the applicant will approach to the MDMC Division/QA&LT Division for approval of import & clearance of the said medical devices under provision of relevant rules, under intimation to the Division of Pharmacy Services.

AGENDA ITEM XVII:

A PHASE III RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED CLINICAL TRIAL IN 18 YEARS OF AGE AND ABOVE TO DETERMINE THE SAFETY AND EFFICACY OF ZF2001, A RECOMBINANT NOVEL CORONA VACCINE (CHO CELL) FOR PREVENTION OF COVID-19.

The case is from DRK Pharma Solutions wherein they have requested for the import of 480 RT-PCR Kits from China as per detailed below to be used in already approved trial. They have submitted that RT-PCR test kits are mandatory for every subject to be tested. Further throughout the clinical trial any subject having symptoms like COVID-19 is also tested with the RT-PCR kits to confirm if the subject is having COVID-19 infection. So far in this clinical trial more than 20,000 subjects were screened, 11500 are given vaccination after confirming that they are COVID-19 negative.

2. The instant case was considered in 26th meeting of CSC and CSC recommended the import of SARs CoV-2 IgM/IgG antibody detection kits and also decided to ask the applicant to approach the MDMC Division/QA&LT Division for approval of import & clearance of the said kits under provision of relevant rules: -

Medical Device / Components or Raw material	**Manufactured by**	**Total Boxes**	**Test kit per Box**	**Total Quantity**
SARs CoV-2 nucleic acid detection kit (RT-PCR)	Shanghai Fosun Long March Medical Science Co., Ltd.	10	48	480

Submitted for consideration of CSC.

03. Secretary CSC presented the case before CSC & apprised the Committee regarding case background.

Decision:

The CSC after discussion & deliberations acceded to request of the applicant for the import of above said quantities of medical devices subject to confirmation from study protocol. It was also decided that the applicant will approach to the MDMC Division/QA&LT Division for approval of import & clearance of the said medical devices under provision of relevant rules, under intimation to the Division of Pharmacy Services.

AGENDA ITEM XVIII:

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 is from Mr. Irfan Ullah Irfan, Country Pharmacy Manager, M/s Médecins Sans Frontières-OCA (Holland) Pakistan Mission, building 3A, Street 65, Muslim Market, Sector F-10/3, Islamabad, dated 05th November 2021. Wherein the application, Investigational Medicinal Product's (IMPs) quantities along with justification is mentioned & request has been made for issuance of IMPs quantity letter for the subject clinical trial.

2. It is submitted that, registration letter of subject Clinical Trial was issued on 14th June 2021. (Minutes attached **Annex-III**)

3. Details of Investigational Medicinal Products is as follows:

i. Miltefosine/Hexadecyl phosphocholine (Impavido) 10mg Capsules. 5936 Capsules.
ii. Miltefosine/ Hexadecyl phosphocholine (Impavido) 50mg Capsules. 30576 Capsules
iii. ThermoMed 1.8 (Thermotherapy apparatus). 05 Devices with accessories.
iv. Glucantime (Meglumine antimoniate) intralesional injections 900 Ampoules.

4. Justification details also attached as **Annex-IV**
5. Submitted for consideration of CSC.

6. Secretary CSC presented the case before CSC & apprised the Committee regarding case background. Secretary CSC asked the relevant desk officer to brief the Committee regarding the case. Relevant Assistant Director apprised the Committee the case was already discussed & approved by the CSC. Applicant does not provide the justification regarding Glucantime injection so the letter for IMPs import was not issued previously. As applicant now provided justification letter so the case again presented before CSC for its appraisal. Dr Faiza Bashir commented that as there is no hitch and required documents are submitted so may be approved.

Decision:

The CSC after discussion & detailed deliberations acceded to the request of the applicant for issuance of letter for following IMPs for already approved Clinical Trial:

i. Miltefosine/Hexadecyl phosphocholine (Impavido) 10mg Capsules. **5936 Capsules**.
ii. Miltefosine/ Hexadecyl phosphocholine (Impavido) 50mg Capsules. **30576 Capsules**
iii. ThermoMed 1.8 (Thermotherapy apparatus). **05 Devices** with accessories.
iv. Glucantime (Meglumine antimoniate) intralesional injections **900 Ampoules**.

AGENDA ITEM XIX:

1ST MEETING OF SUB-COMMITTEE FOR PREPARATION OF TORS & PROFORMA FOR EVALUATION & INSPECTION OF ALTERNATIVE MEDICINE (HERBAL/UNANI, AYURVEDIC, CHINESE OR OTHER TRADITIONAL SYSTEM OF TREATMENT) CLINICAL TRIAL APPLICATIONS.

It is informed that, while concluding the matter of preparation of TORs & proforma for evaluation & inspection of ventilator trial applications, at the end of his welcome remarks in the 32nd Meeting of CSC held on 12th October 2021 the Chairman CSC also discussed the matter regarding subject cited above.

2. The Chairman CSC after discussion and deliberation on the subject matter was pleased to constitute following sub-committee for preparation of TORs & proforma for evaluation & inspection of alternative medicine's (Herbal/Unani, Ayurvedic, Chinese or other traditional system of treatment) Clinical Trial applications.

Decision:

i. **Dr. Abdur Rashid,** Director, Division of Pharmacy Services-DRAP (Chairman)
ii. **Prof. Nadeem Irfan Bukhari**, Member CSC & Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore. (Member)
iii. **Dr. Anwar Ahmed Gillani**, Vice Chancellor /Chairman Pakistan Council for Science & Technology, Islamabad. (Member)
iv. **Dr Saiqa Ishtiaq,** Associate Professor, Pharmacognosy**,** University of Punjab, Lahore(Member).
v. **Prof. Dr. Raza Shah,** General Manager, CBSCR-ICCBS, University of Karachi, Karachi. (Member)
vi. **Three Hakeems,** to be nominated/co-opted by Chairman CSC.

a. Hakeem Abdul Bari, Karachi
b. Hakeem Sheraz Muhammad Siddique, Karachi.
c. Dr. Abdur Rehman, Faisalabad.

3. Nominated members of sub-committee shall prepare TORs & proforma for evaluation & inspection of alternative medicine's (Herbal/Unani, Ayurvedic, Chinese or other traditional system of treatment) Clinical Trial applications, which will be placed before CSC in its forthcoming meetings for further consideration.

4. The sub-committee after detailed deliberation prepared a document named "*Guidelines for Clinical Trials of Herbal Medicines*", attached as **Annex-V**

5. Submitted for consideration of CSC.

6. Chairman CSC briefed the members regarding the case background, that CSC may be appreciated that we don't know about the ventilators as we haven't expertise regarding ventilators but we with the help of biomedical engineers of NUST, pharmacist, DRAP team & other experts, we have developed Clinical Validation Protocol prepared within one month & CSC appreciated for

its approval & is available online on DRAP website. Now we have also developed guidelines for herbal medicines for Clinical Research, there were 03 Hakeems in the Committee nominated by myself which were Ph.D. & master in eastern medicines. The sub-committee prepared a draft which was discussed and a final draft was shared to all CSC members through Whats App group. In the final draft unani medicines are not included as there are many complications in unani drugs. So in the final draft only pure herbal & Chinese medicines are included. So, as we prepared guidelines for ventilators we prepared guidelines for herbal/Chinese medicines clinical research so our herbal medicine manufacturer proves their product claims. In these guidelines Phase-I is exempted as the products being in use from a long time. Chairman requested the CSC as the CSC approved the guidelines for ventilators, CSC should also approve these guidelines for the herbal products so the claims of herbal products may be assessed. These guidelines are derived from WHO, Malaysia & US FDA guidelines as they have worked in this field, further guidelines prepared in view of our regulatory & manufacturing structure so if any member have not any observation so the guidelines may be approved. Dr. Mushtaq Ahmad the Committee haven't expertise for the herbal medicines or its trials if the CSC also look the trials of herbal medicines so there should be herbal medicine specialist as member in the CSC, Dr. Farhana Badar agreed with the concerns raised by Dr. Mushtaq Ahmad. Secretary CSC apprised the Committee that the Bio-Study Rules are for research on therapeutic goods & therapeutic goods includes drugs, biologicals, medical devices alternative medicines & or other related products as may be notified by the Authority and as herbal medicine is included in the definition of therapeutic goods so the all application should be in accordance with the Bio-Study Rules and will be processed accordingly. Purpose of these guidelines may be that those aspects not covered in the Bio-Study Rules may be addressed. Dr. Mushtaq Ahmad added that at the moment no expert is in the CSC so there should be an expert in the Committee, Dr. Farhana Badar also agree with the comments. Dr, Faiza Bashir added that universally it is a practice that as the matter came before the Committee & the Committee becomes more comprehensive & inclusive so the CSC should also co-opt 2 to 3 experts for the matter. Secretary suggested that the matter may be deferred till nomination of relevant co-opted members. Dr. Faiza Bashir suggested that do not defer the matter as deferring the case is not a solution, nominate 3 members today & after their consent co-opt them & refer the matter to them. Chairman CSC added that the matter was discussed in the 32nd CSC meeting and the Committee decided to constitute a sub-committee in which three Hakeems were co-opted by myself, as empowered by the CSC their CVs also in record. So, the sub-committee co-opted experts from eastern medicine, expert from Hamdard & Qarshi university, scientists from Islamia University Bahawalpur & Karachi university. Dr Saiqa was also in the Committee meeting from Punjab University. After detailed deliberation the guidelines prepared & placed before CSC & these Guidelines are in compliance with Bio-Study Rules & the DRAP Act 2012. As Dr Mushtaq Ahmad & Dr. Faiza Bashir said member should co-opted for the matter as the members already co-opted. Dr. Mushtaq again emphasize that herbal specialist should also in the CSC, Dr Faiza Bashir explains the point that the herbal experts was part of the guidelines preparation & will also be the part of reviewing process. The guidelines prepared by the experts now these guidelines are for review of CSC. Chairman CSC clarified that as per rules CSC notified by the Fed. Govt. CSC co-opted member on recommendation of supreme court & ministry but even of Supreme court order new notification of the CSC is not possible. So co-opting member at the moment is not possible. Dr. Faiza Bashir added that straight away deferring the case should not be practice of CSC either it is yes or no or improvement within a time frame & cases should be defer with a time frame. Dr. Faiza Bashir added further that the documents are not reviewed by her so the

document again circulated to all members & may be approved by circulation. Chairman CSC suggested that the guidelines will shared again with all CSC members & the members will submit their comments up to Monday 15th October 2021. Secretary CSC apprised the Committee that after review & approval of the CSC these guidelines must be placed before the Authority and after approval from the Authority then can be adapted. During the meeting most of the member requested to forward the document for review, after review they will submit their comments & accordingly the fate of document will be decided afterwards as per CSC members comments.

Decision:

It was decided to share the soft copy of guidelines to all CSC members for perusal, review and input at their end and in the light of same the guidelines will be finalized afterwards.