MINUTES OF THE 20TH MEETING OF CSC, HELD ON 10TH MARCH 2021.

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The 20th Meeting of the CSC was held on 10th March 2021 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). At the Committee Room, 4th Floor, Drug Regulatory Authority of Pakistan, Islamabad.

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

Sr. No.	**Name**	**Designation**
01	Dr. Abdur Rashid.	Chairman CSC / Director, Division of Pharmacy Services-DRAP.
02	Abdul Sattar Sohrani.	Secretary CSC, Additional Director, Division of Pharmacy Services-DRAP.

3. Following members attended the meeting online through Zoom:

01	Prof. Brig. (R), Muzammil Hassan Najmi.	Professor of Pharmacology, Foundation University, Islamabad.
02	Prof. Nadeem Irfan Bukhari.	Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.
03	Prof. Dr. Javed Akram.	Professor of Medicine, Physician, Vice Chancellor, University of Health Sciences, Lahore.
04	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.
05	Dr. Faiza Bashir.	Chairman, Pakistan Health Research Council or his nominee, Islamabad.
06	Prof. Dr. Sheikh Riaz-Ud-Din	Director of Center for Excellence in Molecular Biology (CEMB) in Lahore. Co-opted Member.
07	Dr. Naseem Salahuddin.	Director Infectious Diseases Indus Hospital, Karachi Co-opted Member.
08	Dr. Aamir Jaffary	Sindh Institute of Urology & Transplantation (SIUT), Karachi Co-opted Member.
09	Prof. Dr. Rizwana Chaudhri	HOD Gynecologist Holy Family Hospital, Rawalpindi Co-opted Member.
10	Prof: Dr. Mushtaq Ahmed	Professor of Cardiology, Bach Khan Medical College, Mardan, KPK Co-opted Member.

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

AGENDA ITEM - I: CONFIRMATION OF THE MINUTES OF THE 19TH CLINICAL STUDIES COMMITTEE MEETING.

1.1 Confirmation of Minutes of 19th CSC meeting, held on 12th February 2021. Since the occurrences of COVID pandemic majority of the meetings are being conducted online through Zoom.

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

Submitted for consideration of CSC.

Decision:

Minutes of the 19th meeting of CSC were confirmed by the committee.

AGENDA ITEM - II: RATIFICATION OF 17TH CSC MEETING

17th CSC meeting held on 22nd December 2020 & following members of the committee attended the meeting through Zoom: -

Sr. No.	Name	Designation
01	Dr. Abdur Rashid.	**Chairman CSC** / Director, Division of Pharmacy Services.
02	Prof. Brig. (R), Muzammil Hassan Najmi.	Professor of Pharmacology, Foundation University, Islamabad. **Member CSC.**
03	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore. **Member CSC.**
04	Dr. Naseem Salahuddin.	Director, Infectious Diseases Indus Hospital, Karachi **Co-opted CSC Member.**
05	Dr. Aamir Jaffary	Sindh Institute of Urology & Transplantation (SIUT), Karachi **Co-opted Member.**
06	Dr. Mushtaq Ahmed	Professor of Cardiology, Bach Khan Medical College. Mardan **Co-opted Member.**
07	Dr. Zeba Ahmed Shuja	Nominated by Pakistan pharmaceutical Manufacturer association **Observer**

03. It is pertinent to mention here that as per rule 13(3) of the Bio-Study Rules, the quorum to constitute a meeting of the CSC shall not be less than five members. In the 17th meeting Chairman CSC, two CSC members, three co-opted members & one observers attended the meeting.

04. Minutes of 17th meeting of CSC are submitted for consideration and requested to confirm the decision taken may be executed.

Submitted for consideration of CSC.

Decision:

Clinical Studies Committee ratified & confirmed the minutes of the 17th meeting of CSC, attached as annexure-I.

AGENDA ITEM - III: NOTIFICATION OF CO-OPTED MEMBERS FOR CLINICAL STUDIES COMMITTEE.

01. The matter regarding co-opted members nomination was discussed in the 19th CSC meeting & the committee decided as follows:

Decision of 19th CSC meeting:

CSC unanimously co-opted following experts for a period of one year:

i. *Dr. Naseem Salahuddin, Director Infectious Diseases Indus Hospital, Karachi,*
ii. *Dr. Aamir Jaffary, Sindh Institute of Urology & Transplantation (SIUT), Karachi, Sindh;*
iii. *Dr. Rizwana Chaudhry, Gynecologist Holy Family Hospital, Rawalpindi, The Punjab;*
iv. *Prof: Dr. Mushtaq Ahmed, Professor of Cardiology, Bacha Khan Medical College Mardan, Khyber Pakhtunkhwa.*
v. *Dr. Ahsan Siddiqui, MBBS, DTCP, MCPS, MPH (London) as Chest Specialist, Karachi.*
vi. *Dr. Beena Ali, Regulatory Affairs & AEFI, Lahore.*

02. There was a complaint to the higher authorities that following members have conflict of interest, being working with some commercial organization in the private sector:

i. ***Dr. Ahsan Siddiqui, MBBS, DTCP, MCPS, MPH (London) as Chest Specialist, Karachi.***
ii. ***Dr. Beena Ali, Regulatory Affairs & AEFI, Lahore.***

03. Accordingly, their nomination was held in abeyance for reconsideration by the CSC.

Submitted for consideration of CSC.

04. CSC members discussed the matter specifically following points:

The matter was discussed at length. It was identified that there is shortage of researchers in various specialties of medical system. Conflict of interest generally may occur due to one of the other reasons. It is appropriate that the experts should declare its conflict & do not participate in the proceedings of relevant case. Keeping in view the above deliberations it was reiterated that CSC is empowered under rule 13(7) of the Bio-Study Rules to co-opt experts of any specialty.

The committee devised following principals:

Decision:

i. ***Experts shall declare his/her conflict of interest and would not participate in the proceedings of that case. Conflict of interest should be case specific.***
ii. ***The quorum of meeting would be constituted without his/her vote that particular case.***
iii. ***The Authority may make regulations for the guidance of CSC for co-opted experts.***
iv. ***CSC unanimously endorsed its decision made in its previous meeting about both co-opted members, mentioned herein above. Accordingly, the secretariat of CSC should issue their notification.***

AGENDA ITEM - IV:

APPLICATION FOR THE LICENSE OF CLINICAL TRIAL SITE AT INTERNATIONAL CENTER FOR CHEMICAL AND BIOLOGICAL SCIENCES (ICCBS), UNIVERSITY OF KARACHI. F. No.15-08/2019-DD (PS)

Application resubmitted by Prof. Dr. M. Raza Shah, (CNIC: 42201-4178970-1), General Manager, Center for Bioequivalence Studies and Clinical Research (CBSCR), dated 23rd February, 2021, wherein the request has been made to license their firm with DRAP to act as a Clinical Trial Site, the application is on prescribed Form-I of the Bio-Study Rules 2017 along without fee, which may be paid/ asked after notification.

2. 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.	Attached
	Prescribed fee	Fee of Rs.49970 submitted vide challan number 0813984, Rs.50000/- vide challan no. 0813987 dated 03-03-2021& Rs.30/- vide challan no. 0813988, dated 03-03-2021.
2	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).	It's a Government organization working under the University of Karachi.
3	Details of premises including layout plan of the site.	Attached.
4	Details of the section wise equipment and	Attached.

	machinery required for the analytical or bio-analytical and clinical studies.	
5	Names and qualifications of the above sections along with their staff.	Attached.
6	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Attached.

03. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection. Following members of the panel inspected the clinical trial site:

04. Inspection report forwarded by Chairman CSC. Inspection of subject Clinical Trial Site conducted by following experts on 26th February 2021:

i.	**Dr. Abdur Rashid** (Coordinator) Chairman CSC/Director, Division of Pharmacy Services-DRAP.
ii.	**Dr. Ahson Siddiqui** HOD & Consultant Infectious Diseases, The Indus Hospital, Karachi.
iii.	**Dr. Naseem Salahuddin** Director Infectious Diseases Indus Hospital, Karachi.
iv	**Dr. Najam Us Saquib** Additional Director-DRAP, Karachi.
v	**Miss Hira Bhutto** Assistant Director / F.I.D.-III Karachi.

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

Keeping in view the premises, equipment, incinerator, Solar facilities, ambulances, human resource & their expertise and trainings, documentations and record, I.T. system and handling and transportation of emergency patient to Dow Hospital(1.5 KM), presence of physician and other facilities PCMD-ICCBS, Karachi University is recommended for Clinical Trial Sites.

06. Concluding status / remarks of inspection panel:

Recommended for approval.

Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to the M/s Center for Bioequivalence Studies and Clinical Research (CBSCR), International Center for Chemical and Biological Sciences (ICCBS), University of Karachi, Karachi as Clinical Trial Site, as per inspection panel recommendations.

AGENDA ITEM - V:

APPLICATION FOR LICENSE TO ACT AS CRO AT INSTITUTE OF BIOLOGICAL BIOCHEMICAL & PHARMACEUTICAL SCIENCES (IBBPS), AT DOW UNIVERSITY OF HEALTH SCIENCES, KARACHI. F. No.15-16/2019-DD (PS)

Application submitted by Dr. Sadia Asim, Director, Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS), At Dow University of Health Sciences, Karachi, dated 26th April, 2019, wherein the request has been made to license their firm with DRAP to act as a CRO, on prescribed Form-I of the Bio-Study Rules, with fee OF Rs.300000/- submitted Vide challan no. 1932881, dated 25th April 2019.

02. It is submitted that application evaluated according prerequisites as mentioned in Form-I of the Bio-Study Rules:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules.	Attached.
2	Prescribed fee	Fee of Rs.300000/- submitted vide challan number 1932881, dated 25th April 2019.
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).	It's a Semi Government organization working under the Dow University of Health Sciences, Ojha Campus, Karachi.
4	Details of premises including layout plan of the site.	Only layout plan 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	Attached

03. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection. Following members of the panel inspected the clinical trial site:

i.	**Dr. Abdur Rashid** (Coordinator) Chairman CSC/Director, Division of Pharmacy Services-DRAP.
ii.	**Dr. Ahson Siddiqui** HOD & Consultant Infectious Diseases, The Indus Hospital, Karachi.
iii.	**Dr. Naseem Salahuddin** Director Infectious Diseases Indus Hospital, Karachi.
iv	**Dr. Najam Us Saquib** Additional Director-DRAP, Karachi.
v	**Miss Hira Bhutto** Assistant Director / F.I.D.-III Karachi.

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

Keeping in view the premises, Facilities, human resources their trainings, IT system, documentation and records, emergency & safety measures and others, the panel recommends the Contract Research Organization of Institute of Biologicals, Biochemical & Pharmaceuticals Sciences of Dow University, Karachi, Ojha Campus

05. Concluding status / remarks of inspection panel:

Recommended for approval.

Submitted for consideration of CSC.

Decision of 20th CSC meeting:

CSC unanimously granted approval to issue licence to the M/s Institute of Biologicals, Biochemical & Pharmaceuticals Sciences of Dow University, Karachi, Ojha Campus, Karachi as Contract Research Organization as per inspection panel recommendations.

AGENDA ITEM - VI:

APPLICATION OF GRANT OF NEW LICENCE FOR INDUS HOSPITAL & HEALTH NETWORK, THE INDUS HOSPITAL, KARACHI , TO ACT AS CLINICAL TRIAL SITE. F. NO.15-21/2021-DD (PS)

Application submitted by Prof. Dr. Naila Baig Ansari (CNIC 42201-6183356-4), Chair-Research, Indus Hospital Research Center, Indus Hospital & Health Network, The Indus Hospital, Karachi, dated 12th January, 2021, wherein the request has been made for approval of Clinical Trial Unit at M/s Indus Hospital & Health Network (formerly The Indus Hospital) to act as a Clinical Trial Site, the application is on prescribed Form-I of the Bio-Study Rules 2017 with prescribed fee submitted vide challan number2062062, dated 11th February 2021.

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.	Attached

2	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
3	Details of premises including layout plan of the site.	Only Layout is attached no details provided.
4	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached
5	Names and qualifications of the above sections along with their staff.	Attached
6	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Applied site is a tertiary care private hospital & is already approved CTS for other clinical trials.
7	Affidavit on Stamp paper	Attached
8	Prescribed fee	Prescribed fee of Rs.100000/- submitted vide challan number 2062062, dated 11th February 2021.

03. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection. Following members of the panel inspected the clinical trial site:

i.	**Dr. Abdur Rashid** (Coordinator) Chairman CSC/Director, Division of Pharmacy Services-DRAP.
ii.	**Dr. Ahson Qavi Siddiqui** HOD & Consultant Infectious Diseases, The Indus Hospital, Karachi.
iii	**Dr. Najam Us Saquib** Additional Director-DRAP, Karachi.

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

Keeping in view the Clinical Research Center, clinical human resources their experience, trainings, health facilities provided, records and documentations, previous experience of clinical trials, panel recommends Indus Hospital Karachi as Clinical Trial Site.

05. Concluding status / remarks of inspection panel:

Recommended for approval.

06. It is proposed that subject application along with inspection panel report may place before CSC in its forthcoming meeting.

Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to act as Clinical Assessment Unit, Examination Unit of M/s Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad for Phase-III Clinical Trials as per inspection panel recommendations.

AGENDA ITEM - VII:

APPLICATION FOR APPROVAL OF CLINICAL TRIAL TITLED "A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE-II CLINICAL TRIAL TO EVALUATE THE EFFICACY & SAFETY OF CBP-307 IN SUBJECTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS (UC)"F.NO.03-59/2021 DD (PS).

Application submitted by Dr. Saeed Hamid (CNIC 42000-0516220-5), Director, Clinical Trial Unit, Professor & Consultant Gastroenterologist, Aga Khan University Hospital, Karachi, dated 18th February 2021, on prescribed Form-II along with a fee of Rs.200000/- deposited vide challan no.0831708 dated 18th February 2021. Wherein request has been made for registration & approval of subject clinical trial, which will be carried out at Aga Khan University Hospital Main Campus, Stadium Road, Karachi.

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

i. **Sponsor:** Suzhou Connect Biopharmaceuticals, Ltd., China.

ii. **Contact information:** F3, R&D East Building, Science and Technology Venture Park, No.6, Beijing West Road, Taicang City, Jiangsu Province, China 215400, China, Tel.: 0512 -53577866, Cellphone: 18962401588.

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

To compare clinical efficacy by evaluating the clinical response to CBP- 307 (P.O. for 12 consecutive weeks) versus placebo in subjects with moderate to severe Ulcerative Colitis.

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

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.
2	Prescribed processing fee	Rs.200000/- deposited vide challan no.0831708, dated 18th February 2021.
3	Investigator Brochure (s)	Attached. Edition 5.0, dated 17th January 2020.
4	Final protocol	Attached. Protocol no. CBP-307CN002

5	Informed consent and participant information sheet (Urdu to English)	Attached
6	List of participating countries	Australia, China, India Russia, Ukraine, USA & Pakistan
7	Phase of trial.	Phase – II
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Details of Placebo & IMP attached. Approximately 203 cartons (5771 bottles) required for the trial.
9	Site of the trial	Aga Khan University Hospital, Karachi.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Attached.
11	Approval of National Bio-ethics Committee (NBC)	Certificate Ref: No.4-87/NBC-591/21/1306, dated 17th February 2021.
12	CV's of the Investigators	CVs of following (P.Is) are attached: i. Dr. Saeed Hamid, Director, Clinical Trial Unit, Aga Khan University Hospital, Karachi. ii. Sayed Faisal Mahmood, AKUH, Karachi.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Statement regarding GMP compliance for M/s China Gateway Pharmaceutical Development Co. Ltd., China, is attached, as GMP certificate not issued to Drug Research Institutes by Chinese Regulatory Authority.
14	Pre-clinical/clinical safety studies	Attached.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Attached.

17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	For Pakistan: 07 subjects.
19	Name of Monitors & Clinical Research Associate	M/s IQVIA Solutions Pakistan (Pvt) Ltd., Karachi CV of following CRA is attached: Bharti Kachela.
20	Evidence of registration in country of origin.	N/A
21	Copy of registration letter (if registered in Pakistan)	N/A
22	Sample of label of the investigational product / drug.	Attached.
22	Duration of trial	13 months.
23	Undertaking on Stamp paper	Attached.

04. For technical evaluation, technical documents (i.e. Study Protocol & investigator's brochure) forwarded to experts through email on 13th January 2021, for review & evaluation under sub-rule 4 of rule 7 of the Bio-Study Rules.

05. The facility is not licensed to conduct pharmacokinetic / BA/BE investigational studies required in the Phase-II clinical trial of investigational product.

Submitted for consideration of CSC.

06. Dr. Saeed Hamid (PI) joined the meeting through Zoom & presented his study before CSC. CSC members asked many questions regarding the trail.

Decision:

The CSC after detailed deliberation decided to grant approval for registration of the clinical trial titled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase-II Clinical Trial to Evaluate the Efficacy & Safety of CBP-307 in Subjects with Moderate to Severe Ulcerative Colitis (UC)". The applicant shall ensure the compliance to the GCP/GLP as prescribed in the Bio-Study Rules. QMS shall also be ensured for data integrity.

AGENDA ITEM - VIII:

APPLICATION FOR APPROVAL OF PHASE-II/III CLINICAL TRIAL STUDY TITLED "TO EVALUATE EFFICACY & SAFETY OF C-IVIG THERAPY IN SEVERE COVID-19 PATIENTS." F. No.03-58/2021-DD (PS)

Application submitted by Dr. Shaukat Ali (CNIC 42201-3085587-5), Principal C-IVIG Project, Dow University of Health Sciences, Karachi, , dated 03rd February 2021. Wherein application has been made on prescribed form-II without a prescribed fee, for approval of subject clinical trial, which will be carried out at following clinical trial sites:

i. Dow University of Health Sciences (Ojha Campus), Karachi.
ii. Sindh Infectious Disease Hospital & Research Center, Karachi.
iii. PAF Hospital, Faisal Base, Karachi.

02. Outcomes/ objective of studies are as follow:

i. **Primary Outcomes**:
The aim of this trial is to investigate the safety and clinical efficacy of passive immunization therapy through Hyperimmune anti-COVlD-19 Intravenous Immunoglobulin (C-IVIG: 5% liquid formulation), on severe COVID-19 patients.

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

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.
2	Prescribed fee	Rs.200000/- deposited vide challan no.0788982, dated 02nd March 2021. *Photo copy of deposit slip forwarded through Whats app, original copy of challan needs to be provided & verified from Budget & Accounts Division.
3	Investigator Brochure (s)	Attached. But not as per ICH-Guidelines
4	Final protocol	Attached. But not as per ICH-Guidelines
5	Informed consent and participant information sheet (Urdu to English)	Informed consent forms for both recipient & donor are attached.
6	List of participating countries	Pakistan only
7	Phase of trial.	Phase-II/III
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Claimed as not applicable, as the investigational product "ANTI-COVID-19 IVIG" will be manufactured in research facility of D.U.H.S using convalescent plasma obtained from Pakistani population.

9	Site of the trial	i. Dow University of Health Sciences (Ojha Campus), Karachi. ii. Sindh Infectious Disease Hospital & Research Center, Karachi. iii. PAF Hospital, Faisal Base, Karachi.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	IRB/ERC approval from Dow University of Health, Karachi is attached. But not on DUHS letter head & without any sign.
11	Approval of National Bio-ethics Committee (NBC)	Certificate Ref: No.4-87/COVID-60/NBC/21/1265, dated 08th February 2021.
12	CV's of the Investigators	Attached.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Claimed as not applicable, as the investigational product "ANTI-COVID-19 IVIG" will be manufactured in research facility of D.U.H.S using convalescent plasma obtained from Pakistani population.
14	Pre-clinical/clinical safety studies	Not provided.
15	Summary of Protocol	Not provided.
16	Summary of Investigator Brochure	Not provided.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	Total 310 Subjects
19	Name of Monitors & Clinical Research Associate	Dr. Shaukat Ali (PI) Dr. Shobha Luxmi (Co-PI) Abdul Samad Khan (Co-PI) Dr. Muneeba Ahsan Sayyed (Co-PI)
20	Evidence of registration in country of origin.	Claimed as not applicable, as the investigational product "ANTI-COVID-19 IVIG" will be manufactured in research facility of D.U.H.S using convalescent plasma obtained from Pakistani population.
21	Copy of registration letter (if registered in Pakistan)	Claimed as not applicable, as the investigational product "ANTI-COVID-19 IVIG" will be manufactured in research facility of D.U.H.S using convalescent plasma obtained from Pakistani population.

22	Sample of label of the investigational product / drug.	Attached.
22	Duration of trial	One Year
23	Undertaking on stamp paper	Not provided.

04. After initial scrutiny following shortcomings observed:

i) Rs.200000/- deposited vide challan no.0788982, dated 02nd March 2021.
***Photo copy of deposit slip forwarded through Whats app, original copy of challan needs to be provided & verified from Budget & Accounts Division.**
ii) Provided Investigator Brochure & Study protocol are not as per ICH-GCP Guidelines.
iii) Institutional Review Board (IRB) approval of sites with complete composition of committee need to be provided from all sites.
iv) Undertaking on stamp paper need to be provided.

05. Shortcomings were communicated to the applicant vide letter even number dated 08th March 2021, yet response is awaited.

06. For technical evaluation, technical documents (i.e. Study Protocol & investigator's brochure) forwarded to experts through email on 08th March 2021, for review & evaluation under sub-rule 4 of rule 7 of the Bio-Study Rules.

Submitted for consideration of CSC.

07. Dr. Shaukat Ali (PI) joined the meeting through Zoom & presented his study before CSC. CSC members asked many questions regarding the trial. Specifically, Dr. Farhana Badar said that the proposal provided says it is a superiority trial but the margin of superiority is not defined. However, the investigators informed her that it is a non-inferiority trial. In response to this, Dr. Farhana said that the margin of non-inferiority along with the outcome of interest should be defined and sent back to the Committee for review.

Decision:

CSC after deliberation decided to approve the trial titled "Phase-II/III Clinical Trial to Evaluate Efficacy & Safety of C-IVIG Therapy in Severe COVID-19 Patients", as per decision of the majority of the CSC members, subject to submission of following prerequisites:

i. Investigator Brochure & Study protocol as per ICH-GCP Guidelines.
ii. Institutional Review Board (IRB) approval of sites with complete composition of committee need to be provided from all sites.

AGENDA ITEM - IX:

REQUEST FOR REGISTRATION OF CLINICAL STUDY TITLED "ANTI-CORONAVIRUS THERAPIES TO PREVENT PROGRESSION OF COVID-19. F. No.03-57/2021-DD (PS).

Application submitted by Dr. Khawar Kazmi, Visiting Faculty Department of Medicine, Professor & Consultant Cardiologist, Aga Khan University Hospital, Karachi, dated 02nd February 2021, on prescribed Form-II along with a fee of Rs.200000/- deposited vide challan no.0831707, dated 01st February 2021. Wherein request has been made for registration & approval of subject clinical trial, which will be carried out at following clinical trial sites:

S.No.	Clinical Trial Site	Site P.I.	Expected enrollment
01	Aga Khan University Hospital, Karachi. (National Coordinating & Participating Site)	National Coordinator: Dr. Khawar Kazmi. Site P.I. Dr. Zainab Samad.	Inpatient: 50 Outpatient: 150
02	Tabba Heart Institute, Karachi.	Dr. Bashir Hanif, Medical Director & Head of Cardiology.	Inpatient: 50 Outpatient: 100
03	Jinnah Post Graduate Medical Center / Jinnah Sindh Medical University, Karachi.	Dr. Zeeshan Ali, Associate Professor of Medicine.	Inpatient: 50

02. The study is also enlisted at U.S. National Trial Registry under identification number: NCT04324463. The summary regarding sponsor, responsible party & trial is as under:

i. **Sponsor:** Hamilton Health Sciences through its Population Health Research Institute, Canada.

ii. **Collaborators:**
   a. Bayer

iii. Information provided by (Responsible Party):
   Population Health Research Institute, Canada.

iv. **Name of Investigational product , including all available names ; trade , generic or INN name etc.**
   a. Anti - inflammatory : colchicine vs. control . (both inpatient and outpatient)
   b. Antithrombotic : acetylsalicylic acid (ASA) vs. control (outpatient only.
   c. Antithrombotic : combination of ASA and rivaroxaban vs. control . (Inpatient only)
   d. Interferon-Beta, subcutaneous injection

v. **Purpose of trial defining the indication along with the anticipated cost of the project and sources of fund**:
   a. The aim of the study is to evaluate anti - inflammatory and anti-thrombotic therapy to determine whether they prevent clinical progression of COVID-19 in outpatients and inpatients . Disease progression and mortality appear to be related to an intense inflammatory response and secondary thrombosis in the pulmonary , cardiac and cerebral vasculature . We will likely need combinations of several widely available and affordable interventions that target different pathways (e.g. inflammation,

thrombosis) to substantially reduce the risk of COVID - 19 disease progression . We need to test these treatments as soon as possible after diagnosis.

b. Source of funding : Hamilton Health Sciences through its Population Health Research Institute (PHRI), Canada.

03. The trial comprises of following primary objectives;

i. Outpatient trial - Colchicine vs. control and Aspirin vs. control [Time Frame: 45 days post randomization] composite of hospitalization or death.
ii. Inpatient trial - Interferon-β vs. control and Colchicine vs. control [Time Frame: 45 days post randomization] invasive mechanical ventilation or death.
iii. Inpatient trial - Aspirin and rivaroxaban vs. control [Time Frame: 45 days post randomization] invasive mechanical ventilation or death

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

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.
2	Prescribed processing fee	Rs.200000/- deposited vide challan no.0831707, dated 01st February 2021.
3	Investigator Brochure (s)	Attached, version 28.0 Package Leaflets of Drugs
4	Final protocol	Attached. Version 15.0
5	Informed consent and participant information sheet (Urdu to English)	Attached
6	List of participating countries	Argentina, Brazil, Canada, Chile, Columbia, Ecuador, Egypt, India, Philippines, Russia, Saudi Arabia, United Arab Emirates, United States of America & Pakistan
7	Phase of trial.	It is claimed that the study is combination of Phase – II & III design
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	i. Aspirin 75mg Tablets (7280 Tablets) ii. Colchicine 0.5 mg Tablets (10740 Tablets) iii. Xarelto (Rivaroxaban) 2.5 mg Tablets (5488 Tablets). iv. Interferon-ß (No Details Provided).
9	Site of the trial	1. Aga Khan University Hospital, Karachi 2. Tabba Heart Institute, Karachi. 3. Jinnah Postgraduate Medical Center, Karachi. *All clinical trial sites are not approved from DRAP for subject Clinical Trial.

10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Attached.
11	Approval of National Bio-ethics Committee (NBC)	Attached. Ref:No.4-87/COVID-56/NBC/20/1148, dated 13th January 2021.
12	CV's of the Investigators	CVs of following (P.Is & Co-PIs) are attached: iii. Dr. Sayed Khawar Abbas Kazmi, AKUH, Karachi. iv. Dr. Zainab Samad, AKUH, Karachi. v. Dr. Bashir Hanif, Tabba Heart Institute, Karachi. vi. Dr. Zeeshan Ali, JPMC, Karachi.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	1. GMP certificates of followings are attached: a. M/s Tiofarma B.V., Benjamin Franklinstraat, Netherlands. b. M/s Bayer AG, Leverkusen, Germany. c. M/s Almac Clinical Services Limited, Northern Ireland, UK. 2. COPP are attached for following IMPs: a. Xarelto (Rivaroxaban) 2.5 mg Tablets. Mfg. by Bayer AG, Leverkusen, Germany * COPP for following IMPs are not provided: a. Colchicine 0.5mg Tablets. b. Aspirin 75mg Tablets. c. Interferon-ß SQ Injections.
14	Pre-clinical/clinical safety studies	EMA assessment report for Xarelto (Rivaroxaban) is attached.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Attached.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	Attached.
19	Name of Monitors & Clinical Research Associate	Monitoring plan is attached.
20	Evidence of registration in country of origin.	COPP is attached only for Xarelto (Rivaroxaban) 2.5 mg Tablets. Mfg. by Bayer AG, Leverkusen, Germany.

		No relevant documents provided for following IMPs: a. Colchicine 0.5mg Tablets. b. Aspirin 75mg Tablets. c. Interferon-ß SQ Injections.
21	Copy of registration letter (if registered in Pakistan)	Copy of registration letter for Xarelto (Rivaroxaban) 2.5 mg Tablets. Mfg. by Bayer AG, Leverkusen, Germany is attached.
22	Sample of label of the investigational product / drug.	Attached for following IMPs: a. Colchicine 0.5mg Tablets. b. Rivaroxaban 2.5mg Tablets. c. Aspirin (ASA) 75mg Tablets. d. Interferon-ß SQ Injections.
22	Duration of trial	12 Months
23	Undertaking on Stamp paper	Attached.

05 After initial scrutiny following shortcomings observed:

i. **Evidence of registration in country of origin (CoPP/Free sale certificate) is not provided for following products:**
   a. **Colchicine 0.5mg Tablets.**
   b. **Aspirin 75mg Tablets.**
   c. **Interferon-ß**

ii. **No details for quantity of drug / trial material to be imported is provided for interferon-ß SQ Injections.**

06. In the view of above, it is proposed that the above-mentioned shortcomings may communicate to the applicant, DFA attached.

07. Technical documents (i.e. Study Protocol & investigator's brochure etc.) were forwarded to all CSC experts for review & evaluation under sub-rule 4 of rule 7 of the Bio-Study Rules 2017, on 1st February 2021.

08. Application was discussed in the 19th CSC meeting & CSC decided as follows:

Decision of 19th CSC meeting:

The CSC after detailed deliberation deferred till fulfilment of all prerequisites & clinical trial site(s) approval.

Submitted for consideration of CSC.

09. Dr. Khawar Kazmi (PI) joined the meeting through Zoom & presented his study before CSC. CSC members asked many questions regarding the trail.

Decision:

The CSC after detailed deliberation deferred for completion of application.

AGENDA ITEM - X:

AMENDMENTS IN ALREADY APPROVED CLINICAL TRIAL TITLED "AN INTERNATIONAL, MULTI-CENTER, CONTROLLED, RANDOMIZED CLINICAL TRIAL TO EVALUATE RIFAMPICIN 1200MG AND 1800MG DAILY IN THE REDUCTION OF TREATMENT DURATION FOR PULMONARY TUBERCULOSIS FROM 06 MONTHS TO 04 MONTHS" RIFASHOT.

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

02. Summary of amendments is as follows:

Version No.	Date	Summary of minor changes
8.0	30/09/2019	• Inclusion of baseline culture negative but GeneXpert positive patient to trial. • Removal of Bolivia as site and addition of Indus Hospital (Pakistan). • Updated details of new Trial Manager/Clinical Trial Coordinator. • Note on follow-up period for patients recruited towards end of enrolment period. • Addition of new site in Pakistan, addition of PI's and lab in Guinea. • Other minor clarifications: addition of amendment summary, contraceptive method, toxicity management section, addition of laboratory. Patients will change dose in event of a weight change.
9.0	10/06/2020	• Minor amendments to the wording of 'Primary Outcome' statement in line with the SAP definition; and Follow up statement in Section 6.1. • Removal of Mexico and Indus Hospital, Pakistan as trial sites. • Addition of Dr Imran Ahmed as Co-Investigator at AKU, Karachi. Pakistan.

03. Following supporting documents are attached along with amendment application:

S.No.	Description

01	Prescribed fee of Rs25000/- submitted vide challan number 0831709, dated 22nd February 2021.(Not verified from Division of Budget & Accounts)
02	Ethical approval from NBC-PHRC for amended protocol version 8.0, dated 25th June 2020 & version 9.0, dated 21st September 2020.
03	Aga Khan University Hospital & Shaukat Khanum Memorial Cancer Hospital & Research Center-Ethical Review Committee approval.
04	Summary of amendments.
05	Subject recruitment status at Aga Khan University Hospital & Shaukat Khanum Memorial Cancer Hospital & Research Center.
06	Amended protocol version 8.0 & 9.0.

04. After scrutiny of amendment application following shortcomings observed:

i. **Amended protocol version 7.0 along with ethical approval from NBC-PHRC & ERC of the Site(s) need to be provided.**
ii. **Prescribed fee of Rs25000/- for each amendment (i.e. version 7.0 & 9.0) need to be submitted.**

05. Shortcomings were communicated to the applicant vide letter even number dated 08th March 2021, yet response is awaited.

Submitted for consideration of CSC.

Decision:

The CSC after detailed deliberation deferred till fulfilment of all prerequisites and codal formalities as prescribed under the rules.

AGENDA ITEM - XI:

APPLICATION FOR CHANGE OF THE PRINCIPAL INVESTIGATOR FROM DRK PHARMA SOLUTION.

DRK Pharma Solutions has submitted application for change of principal investigator of clinical trial titled " A phase III randomized, double blind, parallel controlled clinical trial in 18 years of age and above to determine the safety and efficacy of ZF2001, a recombinant novel corona virus vaccine (CHO cell) for prevention of Covid-19". Applicant has submitted that due to some personal reasons Dr. Waheed-Uz-Zaman Tariq has requested to relieve him from this responsibility and same has been accepted by sponsor. Prof. Dr. Javed Akram Principal Investigator at the University of Health Sciences site has been nominated and he has accepted to work as lead investigator as well. Applicant has attached letters from DRK Pharma solution, letter from Prof. Waheed Uz zaman Tariq, Chughtai Lab. and letter by Prof. Javed Akram, U.H.S. Lahore.

2. Following queries need to be addressed before decision of the case.
   i. The applicant is the principal investigator. It is to be clarified weather new application is required on prescribed Form by the new Principal/Lead Investigator or change of principal investigator could be made after approval from CSC.
   ii. As the principal Investigator is to be regulated under Bio-Study Rules 2017, the member of CSC could be principal Investigator being member of CSC or is there any conflict of interest.

Submitted for the consideration of CSC.

Decision:

Before the consideration of the case Dr. Javed Akram left the meeting to avoid conflict of interest as per decision of CSC in case/agenda item-III. All the CSC members unanimously decided that the member who have the study application will not sit in the meeting during discussion of his case. The CSC after detailed discussion approve the Dr. Javed Akram as Principal/ Lead Investigator.

AGENDA ITEM - XII:

APPLICATION FOR CHANGE OF CENTRAL LABORATORY IN CLINICAL TRIAL TITLED "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".

1. FR (page 807/corr.) is request from Mr. Azam Jeffery, Director commercial and Operations, DRK Pharma Solutions in which he has stated that they have changed the Laboratory Islamabad Diagnostic Center (IDC) Lahore as Central Laboratory to perform the RT-PCR test in this Clinical trial. Previously Chughtai lab was their central laboratory. Applicant has provided the agreement between Anhui Zhifei Longcom Biopharmaceutical Co., ltd and Mr. Atif Saeed, legal representative of Islamabad Diagnostic Center, plot No. 4, beside Shadman police station, jail road, Shadman II, Lahore and a certificate from Punjab Healthcare Commission for collection of samples for COVID-19 PCR testing at Islamabad Diagnostic Center, Jail road, Lahore.
2. Following queries need to be addressed before decision of the case.
   i. Fee of Rs. 25,000/- required under SRO 1047(I)/2019 dated 12th September 2019 under miscellaneous heading.
   ii. Contract is between Anhui Zhifei Longcom Biopharmaceutical Co., ltd and Mr. Atif Saeed, legal representative of Islamabad Diagnostic Center, plot No. 4, beside Shadman police station, jail road, Shadman II, Lahore. As per Punjab Healthcare

Commission has granted permission the Islamabad Diagnostic Center, Lahore to proceed with the collection of collection of samples for COVID-19 PCR testing at IDC, Lahore. This permission was granted keeping in view the emergency situation due to covid-19 pandemic and is subject to review by the commission from time to time. This needs to be clarifies about testing at Islamabad diagnostic Center, Lahore.

iii. Certificate of registration is required for IDC, Lahore from Punjab Healthcare Commission for Laboratory services.

Submitted for the consideration of CSC.

Decision:

The CSC decided that this committee has No Objection for testing of RT-PCR from Islamabad Diagnostic Center, Lahore instead of Chughtai lab, Lahore. Registration of clinical laboratories is purview of Healthcare Regulatory Authority or Healthcare Commission as the case may be. However, it is the responsibility of applicant & sponsor to ensure the integrity of testing & clinical data generated during the trial as per GCP & GLP guidelines from certified labs as per relevant laws.

AGENDA ITEM - XIII:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FROM ABDUL WAHEED TRUST HOSPITALS/ INSTITUTIONS AS CLINICAL TRIAL SITE.

1. The case of Abdul Waheed Trust to act as Clinical trial Site was placed in 19th CSC meeting held on 12.02.2021, and CSC decided as following;

The CSC after detailed deliberation decided to authorize the Chairman CSC for the constitution of inspection panel for the inspection of M/s Abdul Waheed Trust, Avicenna Medical college & Hospital, Lahore. The case will be again placed before the CSC for further deliberations and decisions after submission of inspection report. Meanwhile applicant is directed to fulfill all prerequisite as per the Bio-Study Rules.

2. Accordingly, The Chairman CSC constituted the following panel
   a. Prof. Dr. Javed Akram, VC, University of Health Sciences, Lahore.
   b. Dr. Farhana Badar, SKMCH&RC, Lahore.
   c. Prof. Dr. Nadeem Irfan Bukhari, UCP, University of the Punjab Lahore.
   d. Dr. Abdur Rashid, Director Pharmacy Services Division, DRAP, Islamabad.
   e. Mist. Majida Mujahid, FID, DRAP, Lahore.
   f. Rana Ahsan-ul-Haq Athar, AD (PS), DRAP, Islamabad.

3. The panel planned to conduct inspection of Clinical Trial Site situated at Avicenna Dental College, Abdul Waheed Trust on 18.02.2021. Prof. Dr. Javed Akram was not available due to his busy schedule. Following panel inspected the clinical trial site;

a. Dr. Abdur Rashid, Chairman CSC
b. Prof. Dr. Nadeem Irfan Bukhari, UCP, PU, Lahore.
c. Dr. Uzma Malik, Associate Professor.
d. Dr. Farhana Badar, SKCH&RC, Lahore.
e. Mist. Majida Mujahid. FID, DRAP, Lahore.
f. Rana Ahsan-ul-Haq Athar, AD, DRAP, Islamabad.

4. Panel unanimously recommended the clinical trial site for approval with following comments;

g. "Keeping in view the human resource, technical trainings related to Covid trial, premises allocated for the trial, equipment, medical facilities, emergency handling, hospital and allied facilities, technical know how about trial, waste management and other related facilities, panel recommends Avicenna Dental College, Abdul Waheed Trust as clinical trial site"

5. The Chairman CSC informed that recommendations for Avicenna Dental College, Abdul Waheed Trust as clinical trial site may be considered for **Phase III and Phase IV Trials.**

6. Submitted for consideration of CSC.

Decision:

CSC decided to grant licence to the Avicenna Dental College of Abdul Waheed Trust Lahore as Clinical Trial Site for Phase III & IV Clinical trials as recommended by panel in their report.

AGENDA ITEM - XIV:

APPLICATION FOR LICENSE TO ACT AS CENTER, CLINICAL TRIAL SITE BY CENTRAL PARK TEACHING HOSPITAL LAHORE.

1. The case of Central Park Teaching Hospital, Lahore was placed in 19th CSC meeting held on 12.02.2021 and was decided as followings;

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

2. The Chairman, CSC, constituted the following panel;
   a. Prof. Dr. Javed Akram, VC, University of Health Sciences, Lahore.
   b. Dr. Farhana Badar, SKMCH&RC, Lahore.

c. Prof. Dr. Nadeem Irfan Bukhari, UCP, University of the Punjab Lahore.
d. Dr. Abdur Rashid, Director Pharmacy Services Division, DRAP, Islamabad.
e. Mr. Sheikh Abdul Rasheed, FID, DRAP, Lahore.

3. Due to non-availability of Prof. Nadeem Irfan Bukhari and Dr. Farhana Badar, Following panel conducted the inspection on 19.02.2021;

a. Prof. Dr. Javed Akram, UHS, Lahore.
b. Waqas Latif Biostatistician, UHS, Lahore
c. Prof. Muhammad Siddique, CMH, Lahore Medical College, Lahore.
d. Abdur Rashid FID, DRAP, Lahore
e. Dr. Abdur Rashid, Division of Pharmacy services, DRAP, Islamabad.

4. Panel unanimously recommended the Central Park Teaching Hospital, Lahore for approval with following comments.

"Keeping in view the separate facility of premises, medical equipment, human resource, trainings, documentation and record, archive room, IT facilities, waste management, emergency handling, panel recommends the clinical trial site of Central Park Medical College/ teaching Hospital Lahore"

5. Inspection report may be considered for clinical trial site of Central Park Medical College/ teaching Hospital Lahore for **Phase III & IV.**

Submitted for the consideration of CSC.

Decision:

CSC decided to grant licence to the Central Park Medical College/ Teaching Hospital, Ferozpur Road, Lahore as Clinical Trial Site for Phase III & IV Clinical trials as recommended by panel in their report.

AGENDA ITEM - XV:

APPLICATION FOR LICENSE TO ACT AS CENTER, CLINICAL TRIAL SITE BY AZIZ FATIMA HOSPITAL FAISALABAD.

1. The case of Aziz Fatima Hospital Faisalabad was placed in 19th CSC meeting held on 12.02.2021 and was decided as followings;

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

2. The following panel was constituted by the Chairman, CSC.

i. Dr. Syed Haroon Khalid, GC, University, Faisalabad.
ii. Muhammad Imran Younas, Deputy Director, Faisalabad.
iii. Dr. Ali Jawa, UHS, Lahore.

iv. Abdur Rashid, Chairman CSC

3. The panel conducted the inspection of Clinical Trial Site situated at Aziz Fatima Hospital situated at Gulsitan Colony, Raja Road, Faisalabad on 17.02.2021 and Panel unanimously recommended the clinical trial site for approval with following remarks;

"Keeping in view the premises, provided facilities, human resources, trainings, emergency facilities, and patient handling, pharmacy facilities recommends the clinical trial site of Aziz Fatima Hospital, Gulsitan Colony, Raja Road, Faisalabad"

4. Inspection report may be considered for clinical trial site of Aziz Fatima Hospital Faisalabad for **Phase III**.

Submitted for consideration CSC.

Decision:

CSC decided to grant licence to the Aziz Fatima Hospital, Gulsitan Colony, Raja Road, Faisalabad as Clinical Trial Site for Phase III Clinical trials as recommended by panel in their report.

AGENDA ITEM - XVI:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE BY CHUGTAI LAB 07 JAIL ROAD LAHORE.

1. The case of Chughtai Lab., Lahore was placed in 19th CSC meeting held on 12.02.2021 and was decided as followings;

The CSC after detailed deliberation decided to authorize the Chairman CSC for the constitution of inspection panel for the inspection of M/s Chughtai Lab, Lahore. Prof. Dr. Javed Akram & Dr. Farhana Badar will be the part of inspection panel, as they have already inspected the premises for Bioanalytical Laboratory. The case will be again placed before the CSC for further deliberations and decisions after submission of inspection report. Meanwhile applicant is directed to fulfill all prerequisite as per the Bio-Study Rules.

2. The Chairman, CSC, constituted the following panel;

a. Prof. Dr. Javed Akram, VC, University of Health Sciences, Lahore.
b. Dr. Farhana Badar, SKMCH&RC, Lahore.
c. Prof. Dr. Nadeem Irfan Bukhari, UCP, University of the Punjab Lahore.
d. Dr. Abdur Rashid, Director Pharmacy Services Division, DRAP, Islamabad.
e. Mr. Sheikh Abdul Rasheed, FID, DRAP, Lahore.

3. The panel planned to conduct inspection of Clinical Trial Site situated at Chughtai Lab. Lahore on 18.02.2021. Prof. Dr. Javed Akram was not available due to his busy schedule. Following panel inspected the clinical trial site;

i. Prof. Dr. Nadeem Irfan Bukhari, UCP, PU, Lahore

ii. Dr. Farhana Badar, SKCH&RC, Lahore.
iii. Dr. Uzma Malik, Associate Professor.
iv. Abdur Rashid, FID, DRAP, Lahore.
v. Dr. Abdur Rashid, Chairman CSC

4. Panel unanimously recommended the clinical trial site for approval with following comments;

"Keeping in view the testing facilities, human resource training, handling, transportation and collecting blood samples, waste management, record and documentation, emergency handling in Ammar Hospital, panel recommends Chughtai laboratory, Main Gulberg Road, jail Road, Lahore as clinical Trial site."

5. CSC may consider the following queries before deliberation on the case;

i. How much away is the Ammar Hospital from the Chughtai Lab. Applied for the clinical trial site?
ii. Whether panel visited the Ammar Hospital to verify the facility?
iii. Whether MOU is part of the application submitted by the applicant?
iv. Is there justification that clinical trial may be licensed without emergency management facility?

Submitted for consideration CSC.

Decision of 20th CSC meeting:

CSC after detailed deliberation decided to grant licence to the Chughtai laboratory, Main Gulberg, 07 jail Road, Lahore as clinical Trial site for Phase III Clinical trials as recommended by panel in their report.

AGENDA ITEM - XVII:

REQUEST FOR APPROVAL & REGISTRATION OF "A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED, NON-INFERIORITY PHASE-II CLINICAL TRIAL ON THE EFFICACY & SAFETY OF HOUTOU JIANWEILING TABLET IN THE TREATMENT OF CHRONIC NON-ATROPIC GASTRITIS.

1. Application is from Dr. Muhammad Raza Shah, General Manager, CBSCR, Dr. Panjwani Center for Molecular Medicine & Drug Research, International Center for Chemical & Biological Sciences, University of Karachi, dated 9th March 2020, wherein request has been made for registration & approval of subject Clinical Trial, which will be carried out at DOW University of Health Sciences, Karachi & the Indus Hospital, Karachi. It is a Randomized, Double Blind, Placebo Controlled, **Phase-II** Clinical Trial, Application is on prescribed Form-II, along with a fee of Rs.200000/- deposited vide challan no.0813994.

2. The study sponsored by Hunan Xinhui Pharmacy Co. Ltd, 18 Weilouke Road Wangcheng Economic Development Zone, Changsha City, Hunan Province, China. Study will be carried out under the supervision of Prof. Dr. Muhammad Raza Shah, by investigating CRO "Center for Bioequivalence & Clinical Research, International Center for Chemical & Biological Sciences, University of Karachi

3. The primary objective of the trial is to evaluate the efficacy and safety of "Houtou Jianweilling Tablets" through the non-inferiority Clinical Trial of Houtou Jianweilling Tablets with Omeprazole Enteric-Coated Tablet in patients with chronic non-atrophic gastritis.

4. The application was placed before CSC in its 11th meeting held on 20th May 2020, the CSC decided as follows:

The CSC after detailed deliberation and decided to defer the case till ethical approval from NBC-PHRC & IRB/ERC.

5. It is submitted that provided document for ethical approval are from Interactive Research Development (IRD-IRB), which is an international organization involved in clinical research as sponsor/collaborator, so its status to act as an IRB/ERC is not clear.

6. Further the applicant informed & asked repeatedly for submission of IRB/ERC approval letter from the clinical trial site (i.e. The Indus Hospital, Karachi but applicant failed to provide the said approval letter.

Submitted for consideration CSC.

Decision of 20th CSC meeting:

CSC decided to grant registration for Phase-II Clinical Trial subject to the following:

- ***i. IRB approval of the Indus Hospital Karachi.***
- ***ii. Formulation of the product to be tested in the clinical trial regarding all ingredients.***