MINUTES OF THE 30TH CSC MEETING HELD ON 12TH AUGUST 2021.

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The 30th Meeting of the CSC was held on 12th August 2021 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC) in Committee Room-I, 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	Ahmad Din Ansari.	Secretary CSC / Additional Director, Division of Pharmacy Services-DRAP.

3. Following members attended the meeting online through Zoom:

01	Dr. Faiza Bashir.	Chairman, Pakistan Health Research Council or his nominee, Islamabad.
02	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.
03	Dr. Naseem Salahuddin.	Director Infectious Diseases Indus Hospital, Karachi Co-opted Member.
04	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 Ahmad Din Ansari, Secretary CSC. The Chairman CSC welcomed all the members and asked the Secretary CSC to present agenda. The Secretary CSC informed the background of the meeting and presented the agenda. Mr. Muhammad Adnan Faisal Saim, Deputy Director (Pharmacy Services Division), Mr. Muhammad Ansar, Assistant Director and Mr. Ahsan AD were also present in the meeting.

AGENDA ITEM I:

CONFIRMATION OF THE MINUTES OF THE 29TH CLINICAL STUDIES COMMITTEE MEETING.

1. Confirmation of Minutes of 29th CSC meeting held on 5th August 2021. Since, the occurrence of Covid-19 pandemic majority of the meeting are being conducted online through zoom.

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

Submitted for consideration of CSC.

Decision: *All the Members of the CSC unanimously confirmed the Minutes of 29th CSC meeting held on 05th August 2021.*

AGENDA ITEM II:

TEMPORARY REGISTRATION OF ASPIRIN, TICAGRELOR AND PLACEBO FOR MULTI-CENTRE RANDOMIZED CONTROLLED TRIAL F. No. 03-16/2019-DD (PS).

The case vide letter No. EC-I/COVEERING/ PIC/19/34832 dated 19.11.2019 was received from Prof. Dr. Saqib Shafi Sheikh, Chief Executive, PIC, Lahore, Principal Investigator, Punjab Institute of Cardiology, Lahore dated 18.11.2019 addressed to the Director, Pharmacy Services, DRAP, Islamabad. Wherein he stated that three centers from Pakistan have been selected for a very innovative Multi-Centre randomized trial that might change the international guideline. This would be a great honor for Pakistan.

2. Since the trial is ready to start in other countries and high-volume centers in Pakistan can take a lead in trial subject to early participation. It is therefore requested to grant subject temporary registration of drug on fairly urgent basis so that leading role of Pakistan center is not jeopardized due to inordinate delay. Centers approved other than Punjab Institute of Cardiology (PIC) Lahore, for this trial are: Rawalpindi Institute of Cardiology (RIC) Rawalpindi and National Institute of Cardiovascular diseases (NICVD), Karachi.

3. This is a multicenter, randomized controlled research project titled "Comparison of 1-month versus Dual Antiplatelet Therapy after implantation of Drug-Eluting Stents Guided by either Intravascular Ultrasound or Angiography in Patients with Acute Coronary Syndrome" as per submitted documents (page 21/Corr) by applicant, it is informed that the trial record is available on U.S National Trial Registry with identification number ***NCT03971500.*** Followings are details of contact and location as per the U. S. National Trial Registry.

Contacts

Shao-Liang Chen, MD, PhD	+86-25-52208048	chmengx@126.com
Jing Kan, MPH	+86-25-52271398	kanjingok@126.com

Locations

China, Jiangsu

Nanjing First Hospital — **Recruiting**

Nanjing, Jiangsu, China, 210006

Contact: Shaoliang Chen, MD +86 13605157029 chmengx@126.com
Contact: Jing Kan, MPH +86 15305140515 kanjingok@126.com

Sponsors and Collaborators

Nanjing First Hospital, Nanjing Medical University

Investigators

Study Chair: Shao-Liang Chen, MD, PhD Nanjing First Hospital, Nanjing Medical University

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

S. No.	Document	Remarks
1	Application on prescribed Form-II	Application is not on prescribed Form
2	Fee	Not Attached
3	Investigator Brochure (s)	Not Provided
4	Final protocol	Attached
5	Informed consent and participant information sheet (Urdu to English)	Not Attached
6	List of participating countries	Para 6/N as per US National Trial Registry.
7	Phase of trial.	Not Motioned
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.	Not mentioned
9	Site of the trial	Punjab Institute of Cardiology (PIC) Lahore. Rawalpindi Institute of Cardiology (RIC) Rawalpindi. National Institute of Cardiovascular diseases (NICVD), Karachi. **None of these trial site is approved by CSC**
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Attached but complete composition of committee i.e. names and designation of members are to be provided
11	Approval of National Bio-ethics Committee (NBC)	Not provided.
12	CV's of the Investigators	Not provided.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	GMP certificate provided but COPP & Free Sale Certificate not attached
14	Pre-clinical/clinical safety studies	Not provided.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Not Attached.

17	Adverse Event Reporting Form	Need to be elaborated
18	No of patients to be enrolled in each center.	Not Mentioned
19	Name of Monitors & Clinical Research Associate	Prof Dr. Saqib Shafi Sheikh (Principal Investigator Pakistan) Dr. Muhammad Anjum (Co-Ordinator & Co-Investigator)
20	Evidence of registration in country of origin.	Not provided.
21	Copy of registration letter (if registered in Pakistan)	N/A
22	Sample of label of the investigational product / drug.	Not provided.
22	Duration of trial	Not Clear from provided documents
23	Undertaking on Stamp paper	Not provided.

08. In the view of above shortcomings, the applicant may be advised to submit application on prescribed Form along with prescribed fee documents as per checklist for clinical trial.

09. The shortcomings were communicated vide this office letter dated 3rd December 2021 and reminder dated 12th March 2020.

10. Dr. Asim Javaid, representative from Rawalpindi Institute of Cardiology, Rawalpindi visited DRAP on 09th March 2021and meeting regarding application status held in the office of Additional Director (PS). Application along with shortcomings were briefed to representative. A brief of the case was also forwarded to CEO-DRAP office for the Secretary M/o NHSR&C.

11. An application was received from Maj Gen (R) Dr. Azhar Mehmood Kayani, Executive Director, Rawalpindi Institute of cardiology, Rawalpindi in the name of CEO, DRAP, Islamabad in continuation to previously submitted application by Prof. Dr. Saqib Shafi Sheikh, Chief Executive, PIC, Lahore, Principal Investigator, Punjab Institute of Cardiology, Lahore dated 18.11.2019.

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

S. No.	Document	Remarks
1	Application on prescribed Form-II	Application is on Form II **but without seal of the firm/ company**
2	Fee	Copy of fee challan attached **but original challan (DRAP Copy) required endorsed by Budget and Accounts Division.**
3	Investigator Brochure (s)	Attached
4	Final protocol	Attached
5	Informed consent and participant information sheet (Urdu to English)	Attached
6	List of participating countries	Para 6/N as per US National Trial Registry. China, Indonesia, Thailand, Italy, Malaysia
7	Phase of trial.	Phase III

8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Tablet/ capsule Ticagrelor 90mg =36,000 Tablet/ capsule Aspirin 75mg =9,000 Tablet/ capsule Placebo =9,000 Boston Scientific IVUS Catheters =750
9	Site of the trial	Punjab Institute of Cardiology (PIC) Lahore. Rawalpindi Institute of Cardiology (RIC) Rawalpindi. National Institute of Cardiovascular diseases (NICVD), Karachi. CPE Institute of Cardiology, Multan **None of these trial site is approved by CSC**
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
12	CV's of the Investigators	Attached
13	GMP certificate along with COPP & free sale certificate of the investigational product.	GMP certificate, COPP attached for Aspirin and Ticagrelor
14	Pre-clinical/clinical safety studies	In Clinical study protocol
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.	Not Mentioned
19	Name of Monitors & Clinical Research Associate	Attached.
20	Evidence of registration in country of origin.	COPP attached for Aspirin and Ticagrelor
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	4 years

23	Undertaking on Stamp paper	Not provided.

13. Previously application was submitted by Prof. Dr. Saqib Shafi Sheikh, Chief Executive, PIC and now has been submitted by Maj Gen (R) Dr. Azhar Mehmood Kayani, Executive Director, Rawalpindi Institute of cardiology, Rawalpindi. Further applicant has requested CEO, DRAP to grant for the site Centers fee to help him to avoid unnecessary audit objection.

14. Applicant may be asked to submit undertaking on stamp paper along with name, signature and seal of the firm/ company. He may also be advised to submit fee for trial Centers along with necessary documents required for the approval of trial sites.

15. The applicant has submitted the prescribed Fee along with undertaking on stamp paper.

16. Rawalpindi Institute of Cardiology, Rawalpindi has been approved as CTS in 29th CSC meeting held on 05.08.2021.

SUBMITTED FOR CONSIDERATION OF CSC

Decision:

The CSC after detailed deliberation and discussion decided to approve the Clinical Trial/ Study titled "Comparison of 1-month versus 12-month Dual Antiplatelet Therapy after implantation of Drug-Eluting Stents Guided by either Intravascular Ultrasound or Angiography in Patients with Acute Coronary Syndrome: The Prospective, Multicenter, Randomized, Placebo-controlled IVUS-ACS and ULTIMATE-DAPT trials" at following site;

1. *M/s Rawalpindi Institute of Cardiology, Rawal Road, Rawalpindi.*

The other three proposed sites will be considered to carry out this trial after inspection by the panel of experts and approval by CSC as CTS accordingly.

AGENDA ITEM II

APPROVAL OF ViDiSAM PROJECT i.e. TRIAL OF HIGH DOSE VITAMIN D IN THE TREATMENT OF COMPLICATED SEVERE ACUTE MALNUTRITION. F. No.03-53/2020 DD (PS)

The case is an application from Dr. Javeria Saleem cNIC No. 352102-9632593-0 from M/s University of the Punjab wherein the applicant has applied for approval or registration of clinical trial titled; Trial of high dose vitamin d in the treatment of complicated severe acute Malnutrition (ViDiSAM). The application is on Form-II of the Bio-Study Rules 2017.

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

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.

2	Prescribed processing fee	Fee of Rs.200,000/- submitted vide Challan No. 2013290 dated 28.12.2020.
3	Investigator Brochure (s)	Only label and promotional material attached instead of Investigator brochure.
4	Final protocol	Attached.
5	Informed consent and participant information sheet (Urdu to English)	Attached.
6	List of participating countries	Pakistan.
7	Phase of trial.	Phase 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.	500 Ampoules (250 participants x 2 visits) with 10% Extra. Locally Manufactured.
9	Site of the trial	Sir Ganga Ram Hospital, Lahore The Children's Hospital & The Institute of Child Health (CH & ICH) Lahore. Tehsil Headquarters (THQ), Hospital, Kahna Nau, Lahore.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	IRB approval of Tehsil Headquarters (THQ), Hospital, Kahna Nau, Lahore along with complete composition of committee not attached.
11	Approval of National Bio-ethics Committee (NBC)	Attached. Ref:No.4-87/NBC-516/20/477, Dated 12th October 2020.
12	CV's of the Investigators	Attached
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Only GMP certificate attached.
14	Pre-clinical/clinical safety studies	Attached.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Not Attached.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	250 subjects.
19	Name of Monitors & Clinical Research Associate	DRK Pharma Solution, Lahore.
20	Evidence of registration in country of origin.	Attached
21	Copy of registration letter (if registered in Pakistan)	Attached

22	Sample of label of the investigational product / drug.	Attached.
22	Duration of trial	Three years
23	Undertaking on stamp paper.	Not Attached.

3. After evaluation following shortcomings were recorded:

i) Data of Phase I Trial may provided.
ii) IRB approval from DHQ, Kahna Nau, Lahore is required along with composition of committee i.e. names and designation of members.
iii) Separate application for each clinical trial site is required on Form 1 of Bio-Study Rules 2017.
iv) License to manufacture for experimental purposes is required under Chapter II Rule 3(v) & 21 of LRA Rules 1976 is required.
v) Investigator Brochure and summary of Investigator Brochure is required.
vi) Detailed CV of principal investigator for each trial site is required.
vii) Soft Copy of Final Protocol, Investigator Brochure, Pre-clinical data & Safety studies and Phase I trial data required for onward submission to Expert under Rule 7(4) of Bio-Study rules 2017, is required.
viii) Undertaking of Stamp paper is required.

4. Shortcomings were communicated vide this office letter no. 03-53/2021 DD (PS) dated 19th January 2021.

5. The reply of the applicant in response to this office letter dated 19th January 2021 ia as following;

Documents Requested	Reply of the Firm
Data of Phase-I Trial may be provided	applicant has attached the article "A phase I/II dose escalation trial of vitamin D3 and calcium in multiple sclerosis" High-dose vitamin D3 in the treatment of severe acute malnutrition: a multicenter double-blind randomized controlled trial.
IRB approval from DHQ, Kahna Nau, Lahore is required along with composition of committee i.e. names and designation of members.	Not Attached
Separate application for each clinical trial site is required on Form-I of Bio-Study Rules 2017.	Not received from Kahana Nau, DHQ, Lahore.

License to manufacture for experimental purpose is required under chapter II Rule 3(v) & 21 of Schedule G of LRA Rules 1976 is required.	Not Attached.
Investigator Brochure and summary of Investigator Brochure is required.	attached
Detailed CV of principal Investigator for each trial site is required.	Following CVs attached. Dr. Rameeza Kaleem, Assistant Professor, FJMU/ Sir Ganga Ram Hospital. Dr. Attia Bari, Associate Professor, The Children Hospital & The Institute of Child Health Lahore
Undertaking on stamp paper is required.	Attached.
Copy of ID Card and business Address of applicant is required.	Correct CNIC No.32102-9632593-0 and address is Department of Public Health, University of the Punjab, Quaid-e-Azam campus
Soft Copy Final protocol, Investigator Brochure, Pre-Clinical Data & Safety Studies and Phase-I trial data required for onward submission to Expert under Rule 7 (4) of Bio-Study Rules 2017.	Not Provided.

6. Applicant has provided above mentioned documents but following required yet.
   i. IRB approval from DHQ, Kahna Nau, Lahore is required along with composition of committee i.e. names and designation of members.
   ii. Separate application for each clinical trial site is required on Form-I of Bio-Study Rules 2017 from DHQ, Kahna Nau, Lahore.
   iii. License to manufacture for experimental purpose is required under chapter II Rule 3(v) & 21 of Schedule G of LRA Rules 1976 is required.
7. Shortcomings were communicated vide this office letter dated 2nd April 2021.
8. The reply from Dr Javeria Saleem, Principal investigator in response to this office letter dated 2nd April 2021 is as following;

9. A separate application has been made from CTS Kahana Nau on Form-I. Previously IRB approval was issued by IRD Global Limited, Singapore and now same has been edited and logo of IRD has been erased. Further, IRB approval has been issued to Public Health/ University of Punjab instead of THQ Kahna Nau. License to manufacture placebo for experimental purpose under chapter II Rule 3(v) & 21 of Schedule G of LRA Rules 1976 has not been provided.

10. It was proposed that applicant may be asked again to provide IRB approval from DHQ Kahna Nau to carry out the trial at DHQ Kahna Nau and license to manufacture placebo or the case may be placed before CSC along with shortcomings.

11. Following queries were asked from applicant vide this office letter dated 27th July 2021.

i) IRB approval from THQ, Kahna Nau, Lahore is required along with composition of committee i.e. names and designation of members.

ii) License to manufacture for experimental purposes is required under Chapter II Rule 3(v) & 21 of LRA Rules 1976 is required.

iii) Clarification is required for phase of trial as documents provided previously indicate that this trial is of Phase II while current documents submitted reveals that phase II trial has already been conducted by PI and paper has been published in American Journal of clinical Nutrition on 8th June 2010.

iv) The product, intended to be used as investigational product, is already registered in Pakistan and freely available in market, then why PI wants to conduct the trial of the same product? How the case for already registered product can be considered for Phase II trial.

12. A letter from PI and CRO was received respectively wherein they have addressed the queries of this office. PI has enclosed the IRB approval issued by IRB of Indus Hospital & Health Network under ICH guidelines for GCP E6, USFDA 21 CRF parts 50 and 56, US Department of health and Human Services (45 CFR part 46) etc. They have also enclosed the copy of Form 3 where in manufacturer i.e. M/s GT pharma has applied for grant of Drug Manufacturing Locense for experimental purposes. PI has explained that previous trial was on uncomplicated severe acute malnutrition children, community based conducted by lady health workers. Test conduct in that biochemical test were albumin, calcium and vitamin D, body composition was not measured and development assessment by DDST. The current applied trial is in complicated sever acute malnutrition children, hospital based to be conducted by pediatrician, blood tests to be conducted are calcium, albumin, CRP, 25 (OH)D, total alkaline, ferritin, Hepcidin, Urine examination include calcium, creatinine, osmolarity and stool examination include inflammatory market and microbiome. They have further stated that product intended to be used as investigational product is already registered in Pakistan and freely available but the safety of the product in the age group of 6-59 months with complicated severe acute malnutrition in the hospitalized children is not reported in the

Pakistan population. The indication and dose being used in this age group and study is not available from previous study. Applicant has also attached PHCC registration certificate, DRAP license for Chugtai lab, MOU of Chugtai lab and Punjab university, SOP for albumin, calcium, CBC testing, SOP for handling and testing of samples, contract of PU with QMUL, material transfer agreement with QMUL.

13. It was proposed that application may be forwarded to Expert under rule 7 (4) of Bio-Study Rules 2017 or may be forwarded to CSC members and case may be placed in forthcoming CSC meeting.

14. Following proposed clinical trial sites applied for this trial have been approved by CSC in its 29th CSC meeting held on 05th August 2021.

i. Tehsil Headquarter (THQ), Kahna Nau, Lahore to carry out Phase III & IV clinical trials.

ii. Fatima Jinnah Hospital/ Sir Ganga Ram Hospital, Lahore to carry out Phase III & IV clinical trials.

SUBMITTED FOR CONSIDERATION OF CSC

Decision:

The CSC after detailed deliberation and discussion decided to approve the Clinical Trial/ Study titled "Trial of High Dose Vitamin D in The Treatment of Complicated Severe Acute Malnutrition (ViDiSAM)." Phase II at following sites subject to submission of license/ permission to manufacture Vitamin D and its placebo with the name of ViDiSAM from concerned DRAP's Directorate/Board.

1. *M/s Tehsil Headquarter (THQ), Kahna Nau, Lahore*
2. *Department of Social & Preventive Pediatrics situated at M/s Fatima Jinnah Hospital/ Sir Ganga Ram Hospital, Lahore.*

The CSC further deliberated and discussed in details that both sites mentioned above are allowed to carry out this specific study i.e. ViDiSAM clinical trial for Phase II as it was informed by the applicant that these sites will only collect samples while testing will be done/ performed at M/s Chugtai Lab. (DRAP approved Bio-analytical Lab), Lahore, University of East Anglia, Bioanalytical Facility, Norwich Research Park, Norwich, NR4 7UQ, UK and Blizard Institute, Barts and The London School of Medicine and Dentistry Queen Mary University of London.

ADDITIONAL AGENDA

AGENDA ITEM I: -

Subject: **APPLICATION FOR APPROVAL OF M/S SOUTH CITY HOSPITAL, KARACHI TO ACT AS CLINICAL TRIAL SITE. F. NO 15-33/2021-DD (PS).**

Case is from Dr. Sadia Virk Rizvi (CNIC-42302-5833928-2), CEO, South City Hospital, Karachi, dated 17th May 2021, the site is situated at St-1, Block-3, Shahra-e-Firdousi, Clifton, Karachi. Wherein the request has been made to license the subject site to act as Clinical Trial Site for Phase I, II, III & IV Clinical Trials. Application is on prescribed form-I along with a prescribed fee of Rs.100000/- paid vide challan number 5500258312, dated 19th May 2021.

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

S. No.	Required Documents / Information	Page No.	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	07-08	Attached.
2	Prescribed processing fee	02-03	Fee of Rs.100000/- paid vide challan number 5500258312, dated 19th May 2021.
3	Particulars regarding the legal status of the applicant i.e. in the case of proprietorship the names of proprietors and their addresses, in the case of a firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	11-19	Provisional licence number SHCC/DLA/PL/0002/2019, dated 11/03/2019 is attached, issued by the Healthcare Commission Sindh. Regular licence to be issued by the Healthcare Commission Sindh, needs to be provided. SECP registration certificate need to be provided.
4	Details of premises including layout plan of the site.	21-30	Attached.
5	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	33-58	Attached list of equipment is not fulfilling the requirements of Phase-I & II clinical trials in which Pharmacokinetic studies are required.
6	Names and qualifications of the above sections along with their staff.	91-96	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	---	Not provided.
8	Undertaking on stamp paper	08	Attached.

3. Following shortcomings observed after initial scrutiny:

a. Regular licence issued by the Healthcare Commission Sindh, needs to be provided.

b. SECP registration certificate need to be provided.

c. Attached list of equipment is not fulfilling the requirements of Phase-I & II clinical trials in which Pharmacokinetic studies are required.

d. Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc., need to be provided.

4. The following panel was constituted by chairman CSC to conduct the inspection of M/S South City Hospital, Karachi:

i. Prof. Dr. Aamir Jaffary, SIUT, Karachi;
ii. Dr. Ahson Siddiqi Karachi;
iii. Dr. Abdur Rashid, DRAP, Islamabad;
iv. Prof. Muhammad Raza Shah, HEJ, Karachi;
v. Dr. Saif Ur Rehman, CDL, DRAP, Islamabad

5. However, the inspection was conducted by Prof. Dr. M. Iqbal Afridi, Prof Dr. M. Raza Shah, Dr. Abdur Rashid, Dr.Saif Ur Rehman Khattack and Dr. Naseem Salahudin**.** Remarks of the Inspection Team are followings;

"Keeping in view the infrastructure, spacious space and environment, equipment, emergency and ambulatory services including ambulance, SOPs, documentation, archive room, human resource and training, the panel recommends the South City Hospital as clinical trial site for Phase III and IV."

6. SUBMITTED FOR CONSIDERATION OF CSC.

Decision:

The CSC after due deliberation and discussion, in the light of panel inspection report and the recommendation of panel of experts/inspectors, unanimously decided to approve the Clinical Trial Site situated at M/s South City Hospital, Karachi as clinical trial site for Phase III and IV clinical trials."

AGENDA ITEM II

REQUEST FOR APPROVAL OF CHILDREN'S HOSPITAL KARACHI AND RESEARCH INSTITUTE FOR BLOOD, GENETIC & BONE MARROW TRANSPLANT, KARACHI TO ACT AS CLINICAL TRIAL SITE. F. No.15-47/2020 DD (PS)

Case is from Dr. Saqib Hussain Ansari, Children's Hospital Karachi and Research Institute for Blood, Genetic & Bone Marrow Transplant, Karachi and was presented in 15th CSC meeting, which decided as under:

"CSC after detailed deliberation decided to authorize the Chairman, CSC for constitution of an inspection panel for inspection of facilities at applied clinical trial site. The case will be again brought after before the CSC after deliberation and decision after inspection"

2. The Chairman, CSC constituted the following panel for re-inspection of M/s Children Hospital Karachi:

i. Dr. Abdur Rashid, DRAP, Islamabad;
ii. Prof. Dr. Ammir Jaffary, SIUT, Karachi;
iii. Dr. Ahson Siddiqui, Karachi;
iv. Dr. Najam Us Saqib; DRAP, Karachi
v. Prof. Dr. Nisar Hussain Shah, BZU, Multan.

3. However, the inspection was conducted by Prof. Dr. M. Iqbal Afridi, Prof Dr. M. Raza Shah, Dr. Abdur Rashid, Dr. Najem Us Saqib, and Dr. Naseem Salahudin. The remarks are as under:

"This was the second visit of Children Hospital Karachi. Keeping in view the experienced and trained human Clinical Personnel, Children Bone Transplant facilities, approved site of HOTA, SOPs, documentation, archive facilities, IT facilities, hired biostatician and other emergency and ambulatory services panel recommend Children Hospital, Karachi., St 2/2, Block 5, Gul-Shan-E Iqbal Karachi recommends Clinical Trial Site for Phase-III and IV."

3. SUBMITTED FOR CONSIDERATION AND DELIBERATION OF CSC.

Decision:

The CSC after due deliberation and discussion, in the light of panel inspection report and the recommendation of panel of experts/inspectors, unanimously decided to approve the Clinical Trial Site situated at M/s Children's Hospital Karachi and Research Institute for Blood, Genetic & Bone Marrow Transplant, Karachi., St 2/2, Block 5, Gul-Shan-E Iqbal Karachi as clinical trial site for Phase III and IV clinical trials."

AGENDA ITEM III

APPLICATION FOR THE GRANT OF GENERALIZED TRIAL SITE LICNSE TO DOW UNIVERSITY OF HEALTH SCIENCES, OJHA CAMPUS, KARACHI. F. No: 15-36/2021-DD (PS)

Case is from Prof. Badar Faiyaz Zuberi, CNIC No.42301-0868312-5, Dow University of Health Sciences, KDA Scheme 33, Gulzar-e-Hijri, SUPARCO Road, Ojha Campus, Karachi, dated 20th May 2021, wherein the request has been made for the grant of generalized Clinical Trial Site license to Dow University of Health Sciences, Ojha Campus, Karachi. The application is on prescribed Form-I of the Bio-Study Rules 2017, along with prescribed fee of Rs.100000/- deposited vide challan number 96509260264 dated 18th May 2021.

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	Page No.	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	05	Attached Not signed by applicant.
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).	08	Attached. It's a chartered university under the Dow University of Health Sciences Act 2004. Applied site is tertiary care Government Hospital.
3	Details of premises including layout plan of the site.	10-24	Attached.
4	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	26-55	Attached
5	Names and qualifications of the above sections along with their staff.	57-63	Attached
6	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	65-66	Attached
7	Affidavit on Stamp paper	68	Attached
8	Prescribed Fee	02	Rs.100000/- deposited vide challan number 96509260264 dated 18th May 2021.

3. After initial scrutiny following shortcomings observed

i. Application form was not signed by the applicant.

ii. Phases of trial were not elaborated so that the application/inspection may be conducted accordingly.

4. Accordingly, the applicant submitted the signed Form-I and informed that site is for conduct of Phase-I, II, III, and IV. The subject applied site was approved for specific trial titled "Immunoglobulin Therapy for Passive Immunization of Critically Ill COVID-19 Patients", and licence to act as Clinical Trial Site (CTS) issued (CTS-0040). The organization (Dow University of Health Sciences, Ojha Campus, Karachi) is already licensed for BA/BE Studies Center. As the applied site is for conduct of Phase-I, II, III & IV Clinical Trials, the site was again inspected.

5. The Chairman, CSC constituted the following panel for inspection of Generalized Trial Site of Dow University of Health Sciences, Ojha Campus, Karachi:

i. Prof. Dr. Aamir Jaffary, SIUT, Karachi;
ii. Dr. Ahson Siddiqi Karachi;
iii. Dr. Abdur Rashid, DRAP, Islamabad;
iv. Dr. Najmul Saqib, Additional Director, Karachi, DRAP; and
v. Prof. Dr. Nisar Hussain Shah, Faculty of Pharmacy, B.Z. U, Multan.

6. However, the inspection was conducted by Prof. Dr. M. Iqbal Afridi, Dr. Abdur Rashid, Dr. Naseem Salah Udin and Dr. Najam Us Saqib (no signature). The fee for generalized trials are submitted only for two *i.e. Dow University of Health Sciences* sites *Gulzar-e- Hijri/ Suparco Road, KDA scheme-3 Karachi, and Dow Medical Hospital Sindh,* The Remarks of Panel are as under:

" Keeping in view the whole infrastructure of Dow University of Health Sciences (Clinical Trial Unit), Trained professional Human resources, equipment, instruments, approved BA/BE studies, CRO, Clinical trial site for IVIG, SOPS for animal/ preclinical studies, Research Facilities for animal studies, biologicals, clinical research facilities in different departments, surgical operation theatres, OPD and indoor facilities, emergency and ambulatory services, waste management and other allied facilities, the Panel Unanimously recommends for Clinical Trial Site for zero (animal/ preclinical studies) Phase I, II, III, and IV at Gulzar-e- Hijri/ Suparco Road, KDA scheme-3 Karachi, including Dow Medical Hospital Sindh, Infectious Disease Hospital and Dental Hospital. They will use facilities jointly for research purpose."

7. Detailed Inspection Report signed by Dr. Abdur Rashid is under as under:

i. Dow University Karachi has very good facility for zero phase (animal studies / pre-clinical study) located at Ojha Campus near Dow University Hospital. Section wise equipment list is attached with the report. There is basic biological manufacturing facility central animal house research and development department allied facilities equipped with latest equipment instruments and machinery are available to conduct all phase zero studies. 23 technical human resources having expertise in Toxicology, molecular pathology immunology, microbiology, veterinarians, chemistry, animal nutrition and feed sciences, stem cells and regenerative medicines and other relevant expertise are available for zero

phase studies. There is facility of advance research laboratory (Pre-clinical), Toxicity testing laboratory system, quality control system, QC equipment, basic biological manufacturing system (plasma processing) central animal house, QA along-with all SOP's are available.

ii. Dow University of Health Sciences have also facilities for phase-I and II. They have also ready approved Bioavailability / Bioequivalence Centre, contract research organization (CRO) and clinical trial site for COVID (IVIG) by Drug Regulatory Authority of Pakistan and license number are uploaded at DRAP website. They have the facility for pharmacokinetic and pharmacodynamics studies clinical trial unit can conduct Phase-I and Phase-II facilities for normal subjects and diseased subjects using BA/BE centre, CRO, COVID approved site, using Dow University Hospital, Sindh Infectious Disease Hospital, Dental Hospital, ICU, liver transplant facilities, Emergency and ambulatory services facilities in all departments, animal studies, research laboratories and other allied Testing facilities.

iii. Dow University of Health Sciences Clinical Trial Unit have also facilities for conduct of Phase-III and IV. As already mentioned they have approved license for BA/BE, CRO, Clinical Trial Site (IVIG) at Ojha Campus (Main Campus) and at Clinical Trial Site for COVID at Sindh Infectious Disease hospital (Nipa Churangi) and other facilities of Dow University Health Sciences, Dow University Hospital, Dow Dental Hospital Main Campus called Ohja Campus and Sindh Infectious Disease Hospital (NIPA). The Clinical Trial Unit can conduct Phase-I and Phase IV trial.

iv. So, keeping in view the facilities at Dow University of Health Sciences, Clinical Trial Unit, Ojha Campus, Suparco Road, Offman University Road, Gulzar-e- Hijri, Scheme 33, Karachi, along with allied hospitals are recommended for Phase I, II, III and IV clinical trials/ study.

8. **SUBMITTED FOR CONSIDERATION AND DELIBERATION OF CSC.**

Decision:

The Secretary CSC pointed out the shortness of quorum and the case was deferred accordingly as advised the Chair.

Meeting ended with thanks to and from the Chair.

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