

**MINUTES OF THE 15<sup>TH</sup> MEETING OF CSC, HELD ON 12<sup>TH</sup> OCTOBER 2020.**

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1. The 15<sup>th</sup> CSC Meeting was held on 12<sup>th</sup> October 2020 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). At the Committee Room, 4<sup>th</sup> Floor, Drug Regulatory Authority of Pakistan, Islamabad.

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

<b>Sr. No.</b>	<b>Name</b>	<b>Designation</b>
01	Dr. Abdur Rashid.	Chairman CSC / Director, Divison of Pharmacy Services.
02	Muhammad Arif Chaudhry.	Secretary CSC / Additional Director, Divison of Pharmacy Services.

3. Following members attended the meeting online through Zoom:

01	Prof. Nadeem Irfan Bukhari.	Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.
02	Prof. Dr. Javed Akram.	Professor of Medicine, Physician, Vice Chancellor, University of Health Sciences, Lahore.
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.

3. Mr. Muhammad Adnan Faisal Saim, Deputy Director, Pharmacy Services Division, Mr. Rana Ahsan Ul Haq Athar Assistant Director, Pharmacy Services Division & Mr. Shafqat Hussain Danish, Assistant Director, Pharmacy Services Division, assisted the Secretary CSC for evaluation & presentation of the cases.

4. Chairman, CSC welcomed all the members. He briefed the members of the meeting, regarding the meeting agenda. Chairman, CSC also thanked members for their active participation online through Zoom.

5. Meeting started with the recitation of holy verses of the Quran by Dr. Abdur Rashid, Chairman CSC/ Director, Division of Pharmacy Services.

## AGENDA ITEM - I:

### **CONFIRMATION OF THE MINUTES OF THE 14<sup>TH</sup> CLINICAL STUDIES COMMITTEE MEETING.**

1.1 Minutes of the 14<sup>th</sup> CSC meeting are placed for confirmation of CSC members.

1.2 Submitted for perusal, discussion, and the decision of CSC.

1.3 **Decision of 15<sup>th</sup> CSC meeting:**

*All the members confirmed the minutes of 14<sup>th</sup> CSC which was held on 21<sup>st</sup> September 2020.*

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## AGENDA ITEM -II:

### **APPLICATION FOR LICENSE FOR CHUGHTAI LAB, LAHORE, TO ACT AS BIO-ANALYTICAL LABORATORY FOR CLINICAL TRIALS.**

2.1. Application on Form-I of the Bio-Study Rule 2017, is from Dr. Omar Rasheed Chughtai, Chughtais Lahore Lab (Pvt) Ltd, 7-Jail Road Main Gulberg, Lahore, dated 15<sup>th</sup> January 2020, along with a fee of Rs.50,000/-, deposited vide challan number 1927647, dated 15<sup>th</sup> January 2020.

2.2. After initial evaluation as per prerequisites of Form-I of the Bio-Study Rules 2017, the details of the submitted documents are as under:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached,
2	Prescribed fee	Rs.50000/- & PKRs. 250000/- submitted vide challan number 1927647 & 1980787 dated 15 <sup>th</sup> & 28 <sup>th</sup> January, 2020 respectively.
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 a firm the names and addresses of its partners, and in the case of a company the name and address of the company and its directors).	SECP Registration certificate is attached. Certificate No.007795. Punjab Healthcare Commission Certificate No. REG.No-R-09524 attached
4	Details of premises including the layout plan of the site.	Only the layout plan is attached.
5	Details of the section-wise equipment and machinery required for the analytical or bio-	List of equipment along with the calibration

	analytical and clinical studies.	certificate is attached.
6	Names and qualifications of the above sections along with their staff.	A brief detail is provided regarding officers & staff serving in the Gynae Ward 08 & 09 of JPMC, Karachi.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Not provided. Not Applicable for Bio-Analytical Laboratory.
8	Undertaking on stamp paper	Attached.

2.3. It is submitted that the subject application was discussed in the 7<sup>th</sup> CSC meeting & CSC decided as follows:

**Decision of 7<sup>th</sup> CSC Meeting: -**

*The CSC after deliberations decided to conduct the inspection of Chughtai Lab Lahore (Pvt) Ltd, 7-Jail Road Main Gulberg Lahore (applied for Bio Analytical Lab). The team, comprising of the following experts will inspect. In case any member is not available the committee authorized its chairman to add another suitable member of the relevant expertise from the pool of experts. The applicant shall be informed for the proposed date of inspection accordingly. -*

i.	Dr. Masud Ur Rehman (Coordinator).
ii.	Prof. Dr. Javed Akram.
iii.	Dr. Farhana Badar
iv	Dr. Rizwana Choudhry.
v	Dr. Najam Us Saquib.

2.4. Due to the unavailability of Dr. Najam Us Saquib, Chairman CSC replaced him with Rana Ahsan Ul Haq Athar, Assistant Director, Division of Pharmacy Services, DRAP. And following inspection panel conducted inspection:

i.	Dr. Masud Ur Rehman (Coordinator).
ii.	Prof. Dr. Javed Akram.
iii.	Dr. Farhana Badar
iv	Dr. Rizwana Choudhry.
v	Rana Ahsan Ul Haq Ather

2.5. Inspection conducted on 24<sup>th</sup> July 2020, Dr. Rizwana Choudhry could not join the panel due to her health issue (COVID-19) and after inspection, the panel “**Recommended for Approval**”, and submitted a report with the following remarks:

**Remarks of inspection team:**

*Panel advised the management of Chughtai Lahore Lab to strengthen their Institutional Review Board, to get a certificate from Rescue 1122 for Safety and Disaster*

management plan. The management of M/s Chughtai Lab agreed with suggestions of panel. Panel further suggested that there should be more relevant person in panel and members having conflict should be avoided. Keeping in view the SOPs, Qualification of Staff, Management, Machinery/ equipment premises, layout plan, panel recommended the laboratory for approval.

**2.6 Decision of 14<sup>th</sup> CSC meeting:**

*CSC deferred the case due to shortage of time, the case will be decided in the next CSC meeting.*

2.7. Submitted for perusal and consideration of the CSC.

**2.8. Decision of 15<sup>th</sup> CSC meeting:**

*CSC after detailed deliberation & on recommendations of the inspection panel decided to approve the Chughtais Lahore Lab (Pvt) Ltd, 7-Jail Road Main Gulberg, Lahore to act as a Bio-Analytical Laboratory under the Bio-Study Rules 2017.*

**AGENDA ITEM - III:**

**REQUEST FOR APPROVAL OF CHILDREN'S HOSPITAL KARACHI AND RESEARCH INSTITUTE FOR BLOOD, GENETIC & BONE MARROW TRANSPLANT, KARACHI TO ACT AS CLINICAL TRIAL SITE.**

3.1. Application from Dr. Saqib Hussain Ansari, Children's Hospital Karachi and Research Institute for Blood, Genetic & Bone Marrow Transplant, Karachi, dated 9<sup>th</sup> June 2020. Wherein the request has been made to license their hospital with DRAP to act as Clinical Trial Site. Application is on the prescribed form along with the prescribed fee paid vide challan number 1954317, dated 4<sup>th</sup> June 2020.

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

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Fee	Attached. The fee of Rs.100000/- deposited vide challan number 1954317, dated 4 <sup>th</sup> June 2020.
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the	Details regarding the site are

	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 a company the name and address of the company and its directors).	provided but legal status like its registration letter it needs to be provided, as it is a private Hospital.  Certification from Sindh Healthcare Commission and ISO 9001:2015 attached
4	Details of premises including the 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.	Details of the section-wise equipment and machinery along with evacuation plan attached.
6	Names and qualifications of the above sections along with their staff.	Names and qualifications of Children's Hospital Karachi staff.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Attached.
8	Undertaking on stamp paper	Attached.

3.3. Dr. Saqib Hussain Ansari joined the meeting and briefed the committee regarding their application and answered all the question raised by the members.

3.4. Submitted for the constitution of inspection panel by the CSC.

3.5. **Decision of 15<sup>th</sup> CSC meeting:**

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

#### **AGENDA ITEM - IV:**

#### **APPLICATION FROM DR. GHAS-UN-NABI TAYYAB (LAHORE GENERAL HOSPITAL) FOR APPROVAL OF CLINICAL TRIAL TITLED “OPEN LABELLED RANDOMIZED PHASE-I & II CLINICAL TRIAL TO ASSESS THE SAFETY & EFFICACY OF IODINE COMPLEX (RENESSANS)”.**

4.1. Application is from Dr. Ghas-Un-Nabi Tayyab, Department of Medicine, Post Graduate Medical Institute Lahore General Hospital, Lahore, dated 21<sup>st</sup> September 2020, wherein request has been made for registration & approval of the subject clinical trial, which will be carried out at Lahore General Hospital, Post Graduate Medical Institute, Lahore. Application is submitted on prescribed Form-II with a prescribed fee of Rs.200000/- deposited vide challan number 0846170, dated 15<sup>th</sup> September 2020.

4.2. The trial is sponsored by M/s MTI Medical (Pvt) Ltd., Lahore, and the Clinical Trial agreement is attached.

4.3. Application scrutinized/evaluated according to prerequisites of Form-II of the Bio-Study Rules 2017. The details of the submitted documents are as under;

<b>S. No.</b>	<b>Document</b>	<b>Remarks</b>
1	Application on prescribed Form-II	Attached.
2	Fee	The prescribed fee of Rs.200000/- deposited vide challan number 0846170, dated 15 <sup>th</sup> September 2020
3	Investigator Brochure (s)	Attached but not as per ICH-GCP guidelines.
4	Final protocol	Attached but not as per ICH-GCP guidelines.
5	Informed consent and participant information sheet (Urdu to English)	Attached
6	List of participating countries	Pakistan only.
7	Phase of trial.	Phase-I & 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.	Iodine 10Kg Potassium Iodide 10 Kg Ascorbic Acid 5kg Locally manufacture drug Renessans® Capsules & Suspension, Manufactured by M/s MTI Medical, Lahore will be utilized.

9	Site of the trial	Lahore General Hospital, Post Graduate Medical Institute, Lahore
10	Institutional Review Board (IRB) approval of sites with the 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/COVID-34/NBC/20/297, Dated 10 <sup>th</sup> September 2020 is attached.
12	CV's of the Investigators	Attached.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	GMP Certificate of M/s MTI Medical (Pvt) Ltd, issued by DRAP is attached.
14	Pre-clinical/clinical safety studies	Not provided.
15	Summary of Protocol	Attached but not as per ICH-GCP guidelines.
16	Summary of Investigator Brochure	Not provided.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	24 Subjects in Phase I 30 Subjects in Phase II (as per application) Whereas, there are 45 subjects in Phase II (as per protocol)
19	Name of Monitors & Clinical Research Associate	Dr. Ahmed Kamal
20	Evidence of registration in the country of origin.	N/A.
21	Copy of registration letter (if registered in Pakistan)	The product is under trial, not registered yet.
22	Sample of label of the investigational product/drug.	Attached.
22	Duration of trial	3 Months for Phase-I 4 Months for Phase-II (As per protocol)
23	Undertaking on Stamp paper	Attached

4.4. Furthermore, the applicant has also submitted an application for Clinical Trial Site for Lahore General Hospital, Lahore, evaluation of the Clinical Trial Site is as follows:



<b>S. No.</b>	<b>Required Documents / Information</b>	<b>Remarks</b>
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Fee	The prescribed fee of Rs.100000/- deposited vide challan number 0846169, dated 15 <sup>th</sup> September 2020
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 a firm the name and names and addresses of its partners, and in the case of a company the name and address of the company and its directors).	Tertiary Care Hospital, under the administration of the Government of Punjab.
4	Details of premises including a layout plan of the site.	Not provided. Tertiary Care Hospital, under the administration of the Government of Punjab.
5	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not provided. Only mentioned in Application. Applied Site is a Government Hospital.
6	Names and qualifications of the above sections along with their staff.	Not provided. Only Names mentioned in the application. Applied site is a government hospital.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling, etc.	Not provided. Applied Site is a Government Hospital.
8	Undertaking on stamp paper	Attached

4.5. Dr. Ajmal joined the meeting and briefed the committee regarding their application and answered all the questions raised by the members. During the discussion Secretary Clinical Studies Committee asked about the Preclinical/Clinical Studies regarding the trial, then Dr. Aamir Jaffary (NBC-PHRC member) informed that Preclinical/Clinical Studies were also provided to NBC-

PHRC. Dr. Ajmal also informed that the Preclinical/Clinical Studies were included in Investigator's Brochure.

4.6. Submitted for consideration of the CSC.

4.7. **Decision of 15<sup>th</sup> CSC meeting:**

i. *CSC after detailed deliberation decided to approve the Lahore General Hospital, Post Graduate Medical Institute, Lahore to act as a clinical trial site. As well as CSC decided to approve the clinical trial titled "OPEN LABELLED RANDOMIZED PHASE-I & II CLINICAL TRIAL TO ASSESS THE SAFETY & EFFICACY OF IODINE COMPLEX (RENESSANS)", under the Bio-Study Rules 2017. As per recommendation of NBC-PHRC it is suggested that after completion of Phase-I safety report shall be immediately submitted to CSC before commencing the Phase-II clinical studies.*

ii. *CSC also directed the Principal Investigator to submit ADR reports to this division on monthly basis.*

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ITEM V:

**APPLICATION FROM PROF. DR JAVED AKRAM FOR LICENSING OF CLINICAL TRIAL SITE OF UNIVERSITY OF HEALTH SCIENCES, LAHORE.**

5.1. Application is from Professor Javed Akram, Vice-Chancellor of M/s University of Health Sciences Lahore, wherein a request was made for approval of the University of Health Sciences as Clinical Trial Site.

5.2. Application was evaluated according to prerequisite as mentioned in Form-I of Bio-Study Rules, 2017, and the following shortcomings were observed:

S. No	Required Documents / Information	Remarks
1.	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2.	Prescribed fee	Not 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 a firm the names and addresses of its partners, and in the case of a company the name and address of the company and its directors).	The applicant is vice-chancellor of the University of Health Sciences, Lahore
4.	Details of premises including a layout plan of the site.	Attached but not readable.

5.	Details of the section-wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Provided
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.	Provided
8.	Undertaking on stamp paper	Not provided

5.3. Dr. Ghazala Parween, representative from National Institute of Health, Islamabad, has also informed through letter number nil dated 25<sup>th</sup> August 2020, that to include University of Health Sciences, Lahore as a clinical trial site for the clinical trial titled “Phase-III, Double blind Placebo-Controlled Randomized Clinical Trial of Recombinant Novel Corona Virus Vaccine (Adenovirus Type 5 Vector)”.

5.4. Dr. Shehnoor Azhar joined the meeting and briefed the committee regarding their application and answered all the question raised by the members.

5.5. Submitted for consideration of the CSC.

5.6. **Decision of 15<sup>th</sup> CSC meeting:**

*CSC after detailed deliberation decided to approve the University of Health Sciences, Lahore to act as a clinical trial site for clinical trial titled “Phase-III, Double blind Placebo-Controlled Randomized Clinical Trial of Recombinant Novel Corona Virus Vaccine (Adenovirus Type 5 Vector)”, under the Bio-Study Rules 2017, Subject to submission of prescribed fee of Rs.100000/- under S.R.O. 1047(I)12019 & IRB approval for the trial.*

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