Minutes of the 7th Meeting of CSC held on 18th February 2020.

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1. The 7th Meeting of CSC was held on 18th February 2020 at the Committee Room of DRAP, Islamabad under chairmanship of Dr. Abdur Rashid, Chairman of Clinical Studies Committee.

2. At the scheduled time of the meeting number of CSC members were not fulfilling the requirements of qouram to constitute CSC meeting as per rule 13(3) of the Bio-Study Rules 2017.

3. At scheduled time for the meeting there were four notified members & two co-opted members along with observer from Pharma Beureu, to resolve the matter & for legal opinion Chairman called Mr. Aamir Latif, Deputy Director, Legal Affairs Division.

4. Mr. Aamir Latif, Deputy Director, Legal Affairs Division, elaborated the rule position & clarified that refer to rule 13(3) of the Bio-Study Rules 2017, to constitute a qouram for the meeting there should be at least five members, further clarified that referring to rule 13(6) of the Bio-Study Rules 2017, co-opted may also counted for fulfilment of qouram to constitute a meeting.

5. During discussion regarding qouram as per the Bio-Study Rules 2017, another CSC notified member arrived and requirement for qouram fulfilled to constitute a meeting.

6. The Meeting started with the Holy Verses of Quran & introduction of meeting participants. Chairman also highlighted need of this urgent meeting, Secretary CSC briefed background of Clinical Trials in Pakistan and elaborated comparison between Pakistan & rest of the world.

7. The Additional Director (PS) / Secretary CSC presented the agenda of 7th CSC meeting to the members of CSC committee. The following attended the meeting:-

Ser.	Name	Designation
i.	Dr. Abdur Rashid	Chairman CSC / Director Pharmacy Services, DRAP
ii.	Dr. Masud ur Rehman	Secretary CSC / Additional Director, Pharmacy Services, DRAP
iii.	Dr. Nighat Murad	Research Director NBC-Nominee of Chairman PHRC
iv.	Salwa Ahsan	Chief of Pharmacy, Shifa Intl Hospital
v.	Dr. Farhana Badar	SKMCH, Lahore
vi.	Prof. Dr. Rizwana Chaudhry	HOD Gynecologist Holy Family Hospital, Rawalpindi Co-opted Member.
vii.	Prof: Dr. Mushtaq Ahmed	Professor of Cardiology, Bach Khan Medical College, Mardan, KPK Co-opted Member.
viii.	Nadeem H. Alamgir	Representative from Pharma Bureau

AGENDA ITEM - I: CONFIRMATION OF THE MINUTES OF THE 6TH CLINICAL STUDIES COMMITTEE MEETING.

1.1 Minutes of 6th CSC meeting are placed for confirmation & signature of CSC members.

1.2. The CSC confirmed the minutes of 6th Meeting of Clinical Studies Committee (CSC) held on 20th February 2019, at Committee Room of DRAP and signed the minutes.

AGENDA ITEM - II: **LICENSING & REGISTRATION OF CLINICAL TRIAL SITE & CLINICAL TRIALS AND BIO-ANALYTICAL LABORATORY UNDER THE BIO STUDY RULES, 2017.**

2.1) **APPLICATION FOR LICENCE TO ACT AS CLINICAL TRIAL SITE FOR HALO (HEPARIN ANTICOAGULATION TO IMPROVE OUTCOMES IN SEPTIC SHOCK) TRIAL, AT THE INDUS HOSPITAL, KARACHI. F. NO.15-38/2020 DD (PS)**

2.1.1. Application is from Dr. Samreen Sarfaraz, the Indus Hospital Karachi, dated 4th February 2020, wherein F.R. is received along with reply submitted via National Institute of Health, Islamabad (NIH), which was subsequently forwarded to Division of Pharmacy Services through CEO-DRAP Office.

2.1.2. After initial scrutiny & evaluation following shortcomings were communicated to the applicant vide letter number F.No.15-**38/2020 DD** (PS), dated 14th February 2020:

i) Application is not properly filled with relevant information & mentioned Clinical Trial Site is in Canada.
ii) Particulars regarding the legal status of the applicant are not provided.
iii) Details of premises including layout plan of the site is not provided.
iv) Details of the section wise equipment is not provided.
v) Names and qualifications of the above sections along with their staff are not provided.
vi) Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc, are not described.

2.1.3. Whereas verified fee deposit slips submitted by Mr. Raheel A. Bhatti, Senior Officer Operations, the Indus Hospital, on behalf of Dr. Rabia Shahab, Coordinating person from Canada for "Heparin Anticoagulation to Improve Outcomes in Septic Shock" (HALO), Clinical Trial.

2.1.4. Some documents received through email from Dr. Rabia Shahab (Coordinator from Canada for HALO clinical Trial), after taking prints of email & scanned documents are attached in the file and application re-evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, and description of application is as follow:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Fee	Prescribed fee of Rs.100000/- deposited vide Challan No.0830786. .

3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	SECP registration certificate is provided.
4	Details of premises including layout plan of the site.	Brief detail about the Indus hospital is attached. Layout not provided.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Brief detail about equipment is attached. Applied site is a tertiary care private Hospital.
6	Names and qualifications of the above sections along with their staff.	Brief detail of staff is attached. Name & Qualifications are not described.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Brief detail about the Indus hospital is attached. It's a tertiary care private Hospital.
8	Undertaking.	Attached

2.1.5. Application evaluation summary is as above.

2.1.6. Submitted for perusal, discussion and decision of CSC.

Decision of 7th CSC Meeting:-

The CSC after deliberations decided that, as the applied site is a tertiary care charitable & well established hospital, hence decided to approve the Clinical Trial Site, to conduct "Heparin Anticoagulation to Improve Outcomes in Septic Shock" (HALO) Clinical Studies.

2.2) **APPLICATION FOR LICENCE TO ACT AS CLINICAL TRIAL SITE FOR HALO (HEPARIN ANTICOAGULATION TO IMPROVE OUTCOMES IN SEPTIC SHOCK) TRIAL, AT MAYO HOSPITAL, LAHORE. F. No.15-34/2019 DD (PS)**

2.2.1. Application is from Dr. Irshad Hussain, dated 17th December 2019, wherein F.R. is only an application on form-I of the Bio-Study Rules 2017 received through TCS courier sent by Dr. Samreen Sarfaraz, The Indus Hospital, Korangi Campus, Plot C-76, Sector 31/5, Opposite Darussalam Society, Korangi Crossing, Karachi.

2.2.2. After initial scrutiny & evaluation following shortcomings were communicated to the applicant vide letter number F.No.15-34/2019 DD (PS), dated 14th February 2020:

i) Application is not properly filled with relevant information & mentioned Clinical Trial Site is in Canada.
ii) Particulars regarding the legal status of the applicant are not provided.
iii) Details of premises including layout plan of the site is not provided.
iv) Details of the section wise equipment is not provided.
v) Names and qualifications of the above sections along with their staff are not provided.
vi) Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc, are not described.

2.2.3. Whereas verified fee deposit slips submitted by Mr. Raheel A. Bhatti, Senior Officer Operations, the Indus Hospital, on behalf of Dr. Rabia Shahab, Coordinating person from Canada for "Heparin Anticoagulation to Improve Outcomes in Septic Shock" (HALO), Clinical Trial.

2.2.4. Some documents received through email from Dr. Rabia Shahab (Coordinator from Canada for HALO clinical Trial), after taking prints of email & scanned documents are attached in the file and application re-evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, and description of application is as follow:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Fee	Prescribed fee of Rs.100000/- deposited vide Challan No.0830786. .
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Not provided. Applied site is a Govt. Hospital.
4	Details of premises including layout plan of the	Brief detail about

	site.	Mayo Hospital is attached. Layout not provided.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Brief detail about equipment is attached. Applied site is a tertiary care Govt. Hospital.
6	Names and qualifications of the above sections along with their staff.	Brief detail of staff is attached. Section wise & Qualifications details are not described.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Brief detail about Mayo Hospital is attached. Applied site is a Govt. Hospital.
8	Undertaking.	Attached

2.1.5. Application evaluation summary is as above.

2.1.6. Submitted for perusal, discussion and decision of CSC.

Decision of 7th CSC Meeting:-

The CSC after deliberations decided that, as the applied site is a tertiary care government hospital, hence decided to approve the Clinical Trial Site, to conduct "Heparin Anticoagulation to Improve Outcomes in Septic Shock" (HALO) Clinical Studies.

2.3) APPLICATION FOR LICENCE TO ACT AS CLINICAL TRIAL SITE FOR HALO (HEPARIN ANTICOAGULATION TO IMPROVE OUTCOMES IN SEPTIC SHOCK) TRIAL, AT SHAHEED MOHTARMA BENAZIR BHUTTO TRAUMA CENTER & MEDICAL UNIT OF CIVIL HOSPITAL CHAND BIBI ROAD, CIVIL HOSPITAL KARACHI, FROM DOW UNIVERSITY OF HEALTH SCIENCES KARACHI. F. No.15-35/2019 DD (PS)

2.3.1. Application from Dr. Sadqa Aftab, dated 17th December 2019, wherein F.R. is only an application on form-I of the Bio-Study Rules 2017 received through TCS courier sent by Dr. Samreen Sarfaraz, The Indus Hospital, Korangi Campus, Plot C-76, Sector 31/5, Opposite Darussalam Society, Korangi Crossing, Karachi.

2.3.2. After initial scrutiny & evaluation following shortcomings were communicated to the applicant vide letter number F.No.15-35/2019 DD (PS), dated 12th February 2020:

i) Application is not properly filled with relevant information & mentioned Clinical Trial Site is in Canada.
ii) Particulars regarding the legal status of the applicant are not provided.
iii) Details of premises including layout plan of the site is not provided.
iv) Details of the section wise equipment is not provided.
v) Names and qualifications of the above sections along with their staff are not provided.
vi) Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc, are not described.

2.3.3. Whereas verified fee deposit slips submitted by Mr. Raheel A. Bhatti, Senior Officer Operations, the Indus Hospital, on behalf of Dr. Rabia Shahab, Coordinating person from Canada for "Heparin Anticoagulation to Improve Outcomes in Septic Shock" (HALO), Clinical Trial.

2.3.4. Some documents received through email from Dr. Rabia Shahab (Coordinator from Canada for HALO clinical Trial), after taking prints of email & scanned documents are attached in the file and application re-evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, and description of application is as follow:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Fee	Prescribed fee of Rs.100000/- deposited vide Challan No.0830788.
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Not provided. Applied site is a tertiary Care Govt. Hospital.
4	Details of premises including layout plan of the site.	Brief detail about Civil Hospital Karachi is attached. Layout not provided.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Brief detail about equipment is attached. Applied site is a tertiary care Govt. Hospital.

6	Names and qualifications of the above sections along with their staff.	Brief detail of staff is attached. Section wise details & Qualifications are not described.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Brief detail about Civil Hospital Karachi is attached. It's a tertiary care Govt. Hospital.
8	Undertaking.	Attached

2.3.5. Application evaluation summary is as above.

2.3.6. Submitted for perusal, discussion and decision of CSC.

2.3.7. **Decision of 7th CSC Meeting:-**

The CSC after deliberations decided that, as the applied sites are belongs to a tertiary care government hospital, hence decided to approve the Clinical Trial Site, to conduct "Heparin Anticoagulation to Improve Outcomes in Septic Shock" (HALO) Clinical Studies, at Shaheed Mohtarma Benazir Bhutto Trauma Center & Medical Unit of Civil Hospital Chand Bibi Road, Civil Hospital Karachi, under Dow University Of Health Sciences Karachi.

2.4) APPLICATION FOR REGISTRATION OF PHASE-II CLINICAL TRIAL "HEPARIN ANTICOAGULATION TO IMPROVE OUTCOMES IN SEPTIC SHOCK". F. No.03-17/2019-DD (PS)

2.4.1. Application received from Dr. Ryan Zarychanski, MD MSc, Principal Investigator, HALO International Studies, Assistant Professor, Department of Internal Medicines, University of Manitoba, Canada, submitted by Dr Samreen Sarfaraz, The Indus Hospital, Korangi Campus, Karachi dated 17th December, 2019, for registration & approval of subject clinical trial, which will be carried out at following four Clinical Trial Sites in Pakistan:

i. The Indus Hospital, Karachi.
ii. Mayo Hospital, Gawal Mandi Lahore.
iii. Shaheed Mohtarma Benazir Bhutto Trauma Center, Karachi.
iv. Dr. Ruth K.M. Pfau, Civil Hospital, Karachi.

2.4.2. It is a multicenter, multi-country, open-label, randomized clinical trial comparing therapeutic dose intravenous unfractioned heparin (UFH) to standard care venous thromboprophylaxis in patient diagnosed with septic shock. As per updated available record on U.S National Trial Registry with identification number ***NCT03378466,*** the trial will be carried out at following centers around the globe:

1-UNITED STATES, Wisconsin

Froedtert Hospital — Recruiting
Milwaukee, Wisconsin, United States, 53226
Contact: Rahul Nancha, MD rnanchal@mcw.edu
Contact: Jennifer Peterson jenpeterson@mcw.edu
Principal Investigator: Rahul Nancha, MD

2-BRAZIL

Hospital Santo Agostinho — Not yet recruiting
Altamira, Brazil
Contact: Felipe Dal Pizzol, MD fdpizzol@gmail.com
Principal Investigator: Felipe Dal Pizzol, MD

Hospital de Amor Barretos — Not yet recruiting
Barretos, Brazil
Contact: Christina Prata Amendola, MD cp.amendolauti@gmail.com
Principal Investigator: Christina Prata Amendola, MD
Sub-Investigator: Fernanda Aparecida de Magalhaes Scuoteguazza, MD
Sub-Investigator: Gustavo Larcen Ciorlia, MD
Sub-Investigator: Luis Henrique Simoes Covello, MD
Principal Investigator: Luciana Sanchez, MD

Hospital Ortopedico e Medicina Especializada ltda. – HOME — Not yet recruiting
Brasília, Brazil
Contact: Roberta Teixeira Tallirico, MD betatt@gmail.com
Principal Investigator: Roberta Teixeira Tallirico, MD

Instituto de Cardiologia do Distrito Federal — Not yet recruiting
Brasília, Brazil
Contact: Rodrigo Santos Biondi, MD
Principal Investigator: Rodrigo Santos Biondi, MD

Hospital de Amor Jales — Not yet recruiting
Jales, Brazil
Contact: Pablo Oscar Tomba, MD pablotomba@gmail.com
Principal Investigator: Pablo Oscar Tomba, MD
Sub-Investigator: Fred Charles Turner Lizidatti, MD

Fundacao do ABC — Not yet recruiting
São Paulo, Brazil
Contact: Caio Cesar Ferreira Fernandes, MD drcaiofernandes@yahoo.com.br
Principal Investigator: Caio Cesar Ferreira Fernandes, MD

Hospital AC Camargo — Not yet recruiting
São Paulo, Brazil
Contact: Antonio Paulo Nassar Junior, MD paulo.nassar@accamargo.org.br
Principal Investigator: Antonio Paulo Nassar Junior, MD

Hospital da Luz — Not yet recruiting
São Paulo, Brazil

Contact: Bruno Adler Maccagnan Pinheiro Besen, MD
Principal Investigator: Bruno Adler Maccagnan Pinheiro Besen, MD

Hospital e Maternidade Sao Vicente — Not yet recruiting

São Paulo, Brazil
Contact: Thales Anibal Leite Barros Agostinho, MD thalesanibal@yahoo.com.br
Principal Investigator: Thales Anibal Leite Barros Agostinho, MD
Sub-Investigator: Meton Soares de Alencar, MD
Sub-Investigator: Maxsuel Rolim de Costa, MD

Universidade Federal de Sao Paulo – UNIFESP — Not yet recruiting

São Paulo, Brazil
Contact: Helio Penna Guimaraes, MD heliopg@yahoo.com.br
Principal Investigator: Helio Penna Guimaraes, MD

Hospital Ana Nery — Not yet recruiting

Taguatinga, Brazil
Contact: Rodrigo Morel Vieira de Melo, MD rodrigo.morel@ufba.br
Principal Investigator: Rodrigo Morel Vieira de Melo, MD

3-CANADA

Canada, Alberta

Foothills Medical Centre — Recruiting

Calgary, Alberta, Canada, T2N 2T9
Contact: Stacy Ruddell 403-944-8748 stacy.ruddell@albertahealthservices.ca
Contact: Joshua Booth 403-943-5786 joshua.booth@albertahealthservices.ca
Principal Investigator: Brent Winston, MD
Sub-Investigator: Henry T Stelfox, MD
Sub-Investigator: Paul E Boucher, MD

Canada, British Columbia

Vancouver Island Health Authority — Recruiting

Victoria, British Columbia, Canada, V8R 1J8
Contact: Fiona Auld 250-213-7778 fiona.auld@viha.ca
Contact: Gayle Carney 250-213-7778 gayle.carney@viha.ca
Principal Investigator: Gordon Wood, MD
Sub-Investigator: Daniel Ovakim, MD

Canada, Manitoba

St Boniface General Hospital — Recruiting

Winnipeg, Manitoba, Canada, R2H 2A6
Contact: Nicole Marten 204-235-3223 nmarten@sbgh.mb.ca
Contact: Maggie Wilson 204-787-1405 maggie.wilson@umanitoba.ca
Sub-Investigator: Anand Kumar, MD
Sub-Investigator: Ryan Zarychanski, MD
Principal Investigator: Kendiss Olafson, MD

Health Sciences Centre Winnipeg — Recruiting

Winnipeg, Manitoba, Canada, R3A 1R9
Contact: Maggie Wilson 204-787-1405 maggie.wilson@umanitoba.ca
Contact: Nicole Marten 204-235-3223 nmarten@sbgh.mb.ca
Principal Investigator: Ryan Zarychanski, MD
Sub-Investigator: Anand Kumar, MD

Canada, Ontario

The Ottawa Hospital - General Campus — Recruiting
Ottawa, Ontario, Canada, K1H 8L6
Contact: Irene Watpool 613-737-8724 iwatpool@toh.on.ca
Contact: Rebecca Porteous 613-737-8823 rporteous@ohri.ca
Principal Investigator: Lauralyn McIntyre, MD

The Ottawa Hospital - Civic Campus — Recruiting
Ottawa, Ontario, Canada, K1Y 4E9
Contact: Irene Watpool 613-737-8724 iwatpool@toh.on.ca
Contact: Brigette Gomes bgomes@ohri.ca
Principal Investigator: Lauralyn McIntyre, MD

Niagara Health System - St Catharines Site — Recruiting
St. Catherines, Ontario, Canada, L2S 0A9
Contact: Jennifer LY Tsang, MD 1-905-378-4647 ext 42919
mailto:jennifer.tsang@mail.utoronto.ca
Principal Investigator: Jennifer LY Tsang, MD

St Michael's Hospital — Recruiting
Toronto, Ontario, Canada, M5B 1W8
Contact: Jan Friedrich, MD 1-416-864-6060 ext 3197 friedrichj@smh.ca
Principal Investigator: Jan Friedrich, MD
Sub-Investigator: John Marshall, MD

Canada, Quebec

Centre Hospitalier de l'Universite de Montreal (CHUM) — Recruiting
Montréal, Quebec, Canada, H2X 0A9
Contact: Francois M Carrier, MD 1-514-473-6677 fm_carrier@me.com
Contact: Dounia Boumahni, BSc 1-514-890-8000 ext 20065
dounia.boumahni.chum@ssss.gouv.qc.ca
Principal Investigator: Francois M Carrier, MD

Institut Universitaire de Cardiologie et de Pneumologie de Quebec - Universite Laval — Recruiting
Québec, Quebec, Canada, G1V 4G5
Contact: Francois Lellouche, MD 1-418-656-8711 francois.lellouche@criucpq.ulaval.ca
Contact: Patricia Lizotte, BACC 1-418-656-8711 ext 3937
Patricia.lizotte@criucpq.ulaval.ca
Principal Investigator: Francois Lellouche, MD

Canada

Hopital de l'Enfant-Jesus — Recruiting
Quebec, Canada, G1J 1Z4
Contact: Alexis Turgeon, MD 418-649-0252 ext 6064 alexis.turgeon@fmed.ulaval.ca
Principal Investigator: Alexis Turgeon, MD

4-GREECE

ATTIKON University Hospital — Recruiting
Athens, Greece
Contact: Antonios Papadopoulos, MD antpapa1@otenet.gr
Contact: Nikolitsa Salomondi, MD nickouli81@gmail.com
Principal Investigator: Antonios Papadopoulos, MD
Sub-Investigator: Nikolaos Antonakos, MD
Sub-Investigator: Maria Tsilika, MD

Sub-Investigator: Adami Maria Evangelia, MD
Sub-Investigator: Maria Kalogridi, MD
Sub-Investigator: Maria Roumpoutsou, MD
Sub-Investigator: Evdoxia Kyriazopoulou, MD
Sub-Investigator: Vasileios Lekakis, MD
Sub-Investigator: Nikolaos Melachroinopoulos, MD

Korgialeneion Benakeion Hospital — Recruiting
Athens, Greece
Contact: Chrysostomos Katsenos, MD kats_ch@otenet.gr
Principal Investigator: Chrysostomos Katsenos, MD
Sub-Investigator: Georgios Marinakis, MD
Sub-Investigator: Maria Patrani, MD
Sub-Investigator: Marios Moukas, MD
Sub-Investigator: Michail Paraschos, MD
Sub-Investigator: Argyro Amygdalou, MD
Sub-Investigator: Niki Karampela, MD

5-INDIA

AMRI Hospital Kolkata — Not yet recruiting
Kolkata, India
Contact: Subash Todi, MD drsubhashtodi@gmail.com
Principal Investigator: Subash Todi, MD

6-PAKISTAN

Dr Ruth K.M. PFAU Civil Hospital — Not yet recruiting
Karachi, Pakistan
Contact: Tanveer Alam, MD alamtanviralam@yahoo.com
Principal Investigator: Tanveer Alam, MD

Shaheed Mohtarma Benazir Bhutto Trauma Center — Not yet recruiting
Karachi, Pakistan
Contact: Sadqa Aftab, MD sadqa.aftab@smbbtc.gos.pk
Contact: Humera Ismail humera.ismail@smbbtc.gos.pk
Principal Investigator: Sadqa Aftab, MD

The Indus Hospital — Not yet recruiting
Karachi, Pakistan
Contact: Samreen Sarfaraz, MD samreen.sarfaraz@tih.org.pk
Principal Investigator: Samreen Sarfaraz, MD

Mayo Hospital Lahore — Not yet recruiting
Lahore, Pakistan
Contact: Irshad Hussain, MD profirshad@kemu.edu.pk
Principal Investigator: Irshad Hussain, MD

7-PHILIPPINES

The Asian Hospital — Not yet recruiting
Manila, Philippines
Contact: Joseph A Buensalido, MD jalbuensalido@yahoo.com
Principal Investigator: Joseph A Buensalido, MD

The Medical City Manila, Philippines Contact: Jose Emmanuel Palo, MD jempalo@themedicalcity.com Principal Investigator: Jose Emmanuel Palo, MD	Not yet recruiting
The Philippines General Hospital Manila, Philippines Contact: Marissa Alejandria, MD mmalejandria@up.edu.ph Principal Investigator: Marissa Alejandria, MD	Not yet recruiting

2.4.3. Sponsors and Collaborators:

University of Manitoba
Canadian Institutes of Health Research (CIHR)
CancerCare Manitoba

2.4.4. Investigators:

1-Principal Investigator: Ryan Zarychanski, MD MSc University of Manitoba
2- Principal Investigator: Anand Kumar, MD, University of Manitoba
3- Principal Investigator: Dean A Fergusson, PhD MHA, University of Manitoba

2.4.5. The trial comprises of following primary objective;

i. The primary outcome of efficacy is vasopressor-free days to day 30. The goal of Phase-II trial is to provide the international Data Safety Monitoring Board (DSMB) with a sensible estimate to justify continued enrollment in an adaptive (sample size) trial. Vasopressor use, reflecting cardiovascular collapse due to overwhelming systematic inflammation, is a key inclusion criterion for the trial and durable discontinuation of such drugs and meaningful clinical improvement. Vasopressor-free days has been recommended as a preferred clinical outcome in Phase-II trials in Critical illness.

2.4.6. After initial scrutiny & evaluation following shortcomings were recorded & communicated:

i) Application is not on prescribed form-II of the Bio-Study Rules 2017.
ii) Prescribed fee of Rs.200000/- is not provided.
iii) Informed consent form is not provided in local language (Urdu).
iv) In list of participating country Canada, Brazil, Greece, USA, India, Philippines, South Africa & Pakistan are mentioned in application, whereas in the US National Trial Registry record Canada is only country mentioned.
v) Quantity of drug / trial material to be imported is not described.
vi) None of the described four Clinical Trial Sites are approved from DRAP.
vii) Institutional Review Board (IRB) approval of sites with complete composition of committee is not provided.
viii) GMP certificate along with COPP & free sale certificate are not provided.

ix) Pre-clinical/clinical safety studies are not provided & claimed that as Heparin is an approved & marketed drug being studied for new indication.
x) Summary of Investigator Brochure is not provided.
xi) All described investigators are from abroad, none of Principal Investigator nominated in Pakistan.
xii) Evidence of registration in country of origin is not provided.
xiii) Sample of label of the investigational product / drug is not provided.
xiv) Undertaking on stamp paper is not provided.

2.4.7. Shortcomings were communicated to the applicant vide letter number F.No.03-17/2019 DD (PS), dated 08th January 2020.

2.4.8. Reply from Dr. Ryan Zarychanski, MD MSc, Principal Investigator, HALO International Studies, Assistant Professor, Department of Internal Medicines, University of Manitoba, Canada, received from National Institute of Health to CEO-DRAP office on 4th February 2020, and subsequently forwarded to Division of Pharmacy Services. Wherein F.R. is in reply of this division letter even number dated 8th January 2020.

2.4.9. It is informed by the applicant that the subject trial will be carried out at following clinical trial sites under supervision of nominated lead investigators:

S.No.	Trial Site	Sub-Site / Departments	Lead Investigator
01	The Indus Hospital Karachi.	--	Dr. Samreen Sarfaraz.
02	Mayo Hospital Lahore.	--	Dr. Irshad Hussain.
03	Dow University of Health Sciences Karachi	i. Shaheed Mohtarma Benazir Bhutto Institute of Trauma Center, Civil Hospital Karachi. ii. Medical Unit of Civil Hospital, Karachi	Dr. Sadqa Aftab.

2.4.10. After scrutiny & re-evaluation of submitted reply & documents through email, description of application is as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached. Not on prescribed format.
2	Fee	i. Prescribed fee of Rs.200000/- deposited vide Challan number

		0820369, dated 03.12.2019 for Clinical Trial (Photocopy attached) ii. Prescribed fee of Rs.100000/- deposited vide Challan number 0830786, dated 05.12.2019 for Clinical Trial Site (Photocopy attached) iii. Prescribed fee of Rs.100000/- deposited vide Challan number 0830787, dated 05.12.2019 for Clinical Trial Site (Photocopy attached) iv. Prescribed fee of Rs.100000/- deposited vide Challan number 0830788, dated 05.12.2019 for Clinical Trial Site (Photocopy attached) None of the above challan, original & verified copy is not provided.
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	Canada, Brazil, Greece, USA, India, Philippines, South Africa & 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.	Trial Drug will not be imported and already registered & available brands will be utilized in the study as per trial subject's needs. Details regarding availability of brands is provided as under Heparin (Na) and Heparin (Cl) is available in following trade names in Pakistan, click on any dosage to view brands of this drug. Single Ingredient Inj:5000 IU1000 IU/ml2500 IU/ml4100 IU/ml5000 IU/ml6150 IU/ml25000 IU/ml100000 IU/ml

		Multi Ingredient Gel:5000 IU/ml Heparin (Na) and Heparin (Cl) [Inj 5000 IU/ml] Brand Name Manufacturer/Mnf. Representative 1.,EPSOCLAR NOBLE PHARMA 2. HEPARIN HAJI MEDICINE CO. 3.HEPARIN FRENCH PHARMACEUTICAL GROUP 4.HEPARIN USMANCO INTERNATIONAL 5.HEPARINOL REHMAT PHARMA 6.PINE HOSPITAL SUPPLY CORPORATTION
9	Site of the trial	i. The Indus Hospital, Karachi. ii. Mayo Hospital, Gawal Mandi Lahore. iii. Dow University of Health Sciences Karachi (Two sub sites) (A. Shaheed Mohtarma Benazir Bhutto Trauma Center, Karachi. B. Dr. Ruth K.M. Pfau, Civil Hospital, Karachi.). * None of the above Clinical Trial Site is yet approved by DRAP.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Approval from Biomedical Research Ethics Board (BREB), University of Manitoba and approval from IRD-IRB of Singapore is attached. Whereas IRB / ERC approval from each Clinical Trial Site are not provided.
11	Approval of National Bio-ethics Committee (NBC)	NBC-PHRC letter Ref: No. 4-87/NBC-370/19/1393. Issued on 21st November 2019. Attached.

12	CV's of the Investigators	**i. Dr. Samreen Sarfaraz The Indus Hospital, Karachi- Site.** **ii. Dr. Sadqa Aftab, Dow University of Health Sciences Karachi.** **iii. Dr. Irshad Hussain, Lead PI for Mayo Hospital Lahore.** **iv. Dr. Ryan Zarychanski (International P.I. & Sponsor), University of Manitoba, Canada.**
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Not provided. Its claimed & informed that already registered Brands available in Pakistan will be utilized in the Trial.
14	Pre-clinical/clinical safety studies	Not provided. It is claimed that as Heparin is an approved & marketed drug being studied for new indication.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Not provided. Its claimed & informed that Heparin is not a new drug.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	Approximately 20-30 subjects per site. A total of 500 subjects globally. Total 50-80 Subjects will be enrolled in Pakistan.
19	Name of Monitors & Clinical Research Associate	i. Dr. Ryan Zarychanski (P.I.), University of Manitoba, Canada. ii. Dr. Anand Kumar (P.I.), University of Manitoba, Canada. iii. Dr. Dean Fergusson (P.I.), University of Ottawa. * All above researchers not belongs to Pakistan
20	Evidence of registration in country of origin.	Not provided. Its claimed & informed that already registered Brands available in Pakistan will be

		utilized in the Trial.
21	Copy of registration letter (if registered in Pakistan)	N/A Product used in the trial is not registered in Pakistan.
22	Sample of label of the investigational product / drug.	Not provided. It is claimed & informed that already registered Brands available in Pakistan will be utilized in the Trial and controlled by local investigators.
22	Duration of trial	36 months.
23	Undertaking on Stamp paper	Attached. But not provided on undertaking.

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2.4.11. After re-evaluation of application following shortcomings were recorded:

i) Institutional Review Board (IRB) / Ethical Review Committee (ERC) approval from all sites with complete composition of committee is not provided.
ii) GMP certificate along with COPP & free sale certificate are not provided.
iii) Evidence of registration in country of origin is not provided.
iv) Sample of label of the investigational product / drug is not provided.

2.4.12. Dr. Rabia Shahab telephonically asked to send their representative for presentation of Clinical Trial before CSC.

2.4.13. Submitted for perusal discussion and decision of CSC.

2.4.14. Dr. Faheem Tahir, PSO-PHLD, National Institute of Health (NIH), Islamabad participated the meeting and briefed the CSC regarding the subject trial.

2.4.15. **Decision of 7th CSC Meeting: -**

1. The CSC after deliberations approved the clinical studies titled, "Heparin Anticoagulation to Improve Outcomes in Septic Shock (HALO)", to be conducted at following Clinical Trial Sites under supervision of nominated national principal investigators:

A. Dr. Samreen Sarfaraz the Indus Hospital, Karachi- Site.

B. Dr. Irshad Hussain, Lead PI for Mayo Hospital Lahore.

C. Dr. Sadqa Aftab, Dow University of Health Sciences Karachi. (two sub sites)

I. Shaheed Mohtarma Benazir Bhutto Trauma Center, Karachi.

II. Dr. Ruth K.M. Pfau, Civil Hospital, Karachi.

2. Best brand of the trial drug available in the market of Pakistan will be used at all sites & informed to Division of Pharmacy Services DRAP.

3. Infusion pump should be utilized for controlled administration of investigational medicinal product (IMP) (i.e. Heparin).

4. Close monitoring system for ADR will developed and communicated to Pakistan National Pharmacovigilance Center, Division of Pharmacy Services DRAP.

2.5) APPLICATION FOR CLINICAL TRIAL SITE, AGA KHAN UNIVERSITY, MATIARI RESEARCH AND TRAINING CENTER

2.5.1. Application is from Dr. Zulfiqar A. Bhutta, founding Director, Centre of Excellence in Women and Child Health, the Aga Khan University Hospital, Stadium Road, Karachi, dated 20th January 2020, wherein application is for approval of Matiari Research & Training Center as a Clinical Trial Site for conduct of "Cluster Randomized Evaluation of the Effectiveness of Supplementation with Multiple Micronutrients and Life Skills Development Education provided from Preconception on Health and Birth outcomes among young, reproductive-age {[Pakistani Women (15-24 Years)".

2.5.2. It is submitted that application evaluated according pre-requisite as mentioned in Form-I of the Bio-Study Rules 2017, and following shortcomings observed & communicated:

i. Particulars regarding the legal status of the applicant / firm are not provided.
ii. Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc, are not provided.
iii. Undertaking on stamp paper is not provided

2.5.3. Dr. Zulfiqar A Bhutta, Founding Director, Center of Excellence in Women and Child Health, The Aga Khan University Hospital, Stadium Road, Karachi, dated 13th February 2020, through courier submitted his reply.

2.5.4. After re-evaluation of application summary of provided documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached,
2	Prescribed fee	Rs.100000/- submitted vide challan number 0741122, dated 08th January, 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 firm the name and names and addresses of its partners and in the case of company the	Charter of the Aga Khan University, provided. And described that Matiari Research &

	name and address of the company and its directors).	Training Center is AKU's own center.
4	Details of premises including layout plan of the site.	Attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached.
6	Names and qualifications of the above sections along with their staff.	CVs Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	It is informed that the applied Center had facility of emergency transportation to any sick patients (enrolled in study) to nearby rural health center or District Headquarter Hospital or even to Hyderabad Civil Hospital.
8	Undertaking on stamp paper	Attached

2.5.5. Submitted for perusal, discussion and decision of CSC.

2.5.6. **Decision of 7th CSC Meeting:-**

The CSC after deliberations decided to conduct the inspection of Matiari Research and Training Center, Matiari, Sindh, from team, comprising of the following experts. 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. Abdur Rashid (Coordinator).
ii.	Dr. Ali Jawa.
iii.	Waqas Latif.
Iv	Salwa Ahsan.
v	Dr. Najam Us Saquib.

2.6) APPROVAL FOR PROCUREMENT OF MICRONUTRIENT TABLETS FOR PROSPECTIVE, CLUSTER RANDOMIZED EVALUATION OF THE EFFECTIVENESS OF SUPPLIMENTATION WITH MULTIPLE MICRONUTRIENTS AND LIFE SKILLS DEVELOPMENT EDUCATION PROVIDED FROM PRECONCEPTION ON HEALTH AND BIRTH

OUTCOMES AMONG YOUNG, REPRODUCTIVE-AGE [PAKISTANI WOMEN (15-24 YEARS). F. No.03-14/2019-DD (PS)

2.6.1. Application is from Dr. Zulfiqar A. Bhutta, MBBS, FRCPCH, FAAP, Ph.D., The Noordin Noormahomed Sheriff Professor & Founding Director, Centre of Excellence in Women and Child Health, Aga Khan University Hospital, Karachi, dated 14th October, 2019, wherein FR is in reply of letter no. F.No. 1-2(NA)/2019-Dir (Nut)-NHSRC, wherein FR request has been made for procurement of trial drug and registration of trial.

2.6.2. Brief summary of the trial is as follows:

"The primary aims of this study is to evaluate the impact of supplementation with multiple micronutrients (MMN) from preconception and life skills education among women 15-18.9 years of age at enrolment on the prevalence of anemia in a population setting; and 2) To evaluate the impact of supplementation with MMN from preconception and life skills education among young women 15-24 years of age on the rate of low birth weight (LBW) in a population setting. Infants born to mothers enrolled in the study will be followed for 1 year. This study aims to enroll 25,400 non-pregnant young women in Matiari district. This sample size is anticipated to equate to 1456 births. Participants will be randomized by cluster to receive either MMN supplements and life skills education or the standard of care at enrolment. Clusters have been defined based on health facility catchment areas. MMN supplements will be provided twice weekly during the preconception period, once daily during the pregnancy period, and once daily until 6 months after giving birth during the postpartum period; and a package of life skills education materials will be provided bi-monthly during the preconception period. In addition to the primary outcomes, measurements will include micronutrient status, anthropometrics, birth outcomes, dietary intake and feeding practices, adherence, and indices of empowerment."

2.6.3. The trial is registered on U.S. National Trial Registry with reference number **NCT03287882**, as per available details on the registry (last update posted on 19th September, 2017), the study location is Matiari Research and Training Centre, Matiari, Sindh, Pakistan and trial is on recruiting stage, trial timelines are as follows:

- Actual Study Start Date: **June 30, 2017.**
- Estimated Primary Completion Date **April 30, 2020.**
- Estimated Study Completion Date **April 30, 2021.**

2.6.4. The study is under sponsorship of Aga Khan University, with collaboration of The Hospital for Sick Children, National Program for Family Planning and Primary Health Care and Bill and Melinda Gates Foundation, and responsible person is Dr. Zulfiqar Ahmed Bhutta (PI), Aga Khan University.

2.6.5. It is pertinent to mention here that the application is for approval of ongoing trial, which was started from 30th June, 2017 without intimation and approval from DRAP and NBC-PHRC.

2.6.6. Objectives of the study are as follows:

i) **Primary Study Objective:**

To evaluate the impact of life skill based education (LSBE) materials and supplementation with multiple micronutrients (MMN) among adolescent girls (15-19 years of age at enrolment) on the prevalence of anemia in a population setting.

To evaluate the impact of LSBE materials and supplementation with MMN among young women (15-24 year of age) on the rate of low birth weight (LBW) in a population setting.

ii) **Secondary Study Objective:**

Secondary objective are aimed to evaluate the impact of interventions on micronutrient status (iron, vitamin A, and D), participants' BMI, pregnancy outcomes, infant growth and mortality and empowerment, menstrual hygiene management, early marriages and continued education.

2.6.7. It is submitted that application evaluated according pre-requisite as mentioned in Form-II of the Bio-Study Rules 2017, and following shortcomings observed & communicated:

i) Provided Investigator's Brochure is not as per ICH-GCP Guidelines.

ii) Quantity of drug / trial material to be imported described only for remaining period of the Trial.

iii) Sample of label of the investigational product / drug is not provided.

iv) Approval from National Bio-ethics Committee (NBC) is attached Dated March, 29th 2019, whereas study started since June 30, 2017 (as per U.S National Trial Registry record), without intimation & approval from NBC-PHRC & DRAP.

v) Clinical Trial site is not yet approved or applied for approval

vi) M/s Aga Khan University Hospital Karachi is mentioned as Clinical trial site in application, whereas Matiari Research and Training Centre, Matiari, Sindh, Pakistan. Is the trial territory as per U.S. National Trial Registry record.

vii) Role of M/s Aga Khan University Hospital Karachi, as per U.S. National Trial Registry record, is as Sponsor, but in application M/s Aga Khan University Hospital Karachi mentioned as trial site. Its need to be clarified.

2.6.8. Dr. Zulfiqar A. Bhutta, MBBS, FRCPCH, FAAP, Ph.D., The Noordin Noormahomed Sheriff Professor & Founding Director, Centre of Excellence in Women and Child Health, Aga Khan University Hospital, Karachi, submitted his reply in reference to communicated shortcomings.

2.6.9. After re-evaluation of application, the description & details of the submitted documents is as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.
2	Fee	Copy Attached. Prescribed fee of Rs.200000/- submitted vide challan number 0801281, dated

		October 2019.
3	Investigator Brochure (s)	Attached. Not as per ICH-GCP Guidelines.
4	Final protocol	Attached.(Version-4)
5	Informed consent and participant information sheet (Urdu to English)	Attached
6	List of participating countries	Pakistan.
7	Phase of trial.	Phase – III (Effectiveness Trial) Proposed timeline 2016-2020
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.	1500 MMN Jars required for remaining trial. (Each jar contains 1000 tablets).
9	Site of the trial	Matiari Research and Training Centre, Matiari, Sindh, Pakistan **of** M/s Aga Khan University Hospital Karachi. **(**Not yet licensed by DRAP**).**
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. Certificate Ref: No. 4-87/NBC-377/19/1870, Dated 29th March 2019
12	CV's of the Investigators	**CVs of following investigators & concerned employees are attached:** **1-Dr. Zulfiqar A. Bhutta**, MBBS, FRCPCH, FAAP, Ph.D. Founding Director, Center of Excellence in Women & Child Health, Pediatrics & Child Health, The Aga Khan University, South Central

		Asia, East Africa & United Kingdom, Karachi, 74800 Pakistan. (P.I) **2-Dr. Sajid b. Soofi**, Associate professor, Pediatrics & Child Health & Associate Director, Center of Excellence in Women & Child Health, Pediatrics & Child Health-MC The Aga Khan University Karachi, 74800, Pakistan. (Co-P.I) **3-Dr. Jo-Anna Baxter, (**PhD candidate) Canadian Institute for Health Research, Government of Canada. **4-Mr. Yaqub Wasan** (Manager Research), Department of Pediatrics & Child Health, Aga Khan University Karachi
13	GMP certificate along with COPP & free sale certificate of the investigational product.	GMP certificate of Lomapharm GmbH, Langes Feld 5, 31860 Emmerthal, Germany & COPP for "Pregnancy & Lactation Micronutrient tablets" is attached.
14	Pre-clinical/clinical safety studies	Attached.
15	Summary of Protocol	Not provided and claimed that as drugs used in the trial is not an investigational product.
16	Summary of Investigator Brochure	Not provided.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	25400 Subjects (Approx.). As per National Trial Registry record
19	Name of Monitors & Clinical Research Associate	Attached.
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	48 Months

23	Undertaking	Attached.

2.6.10. After re-evaluation following shortcomings were observed & will communicated to the applicant:

i. Evidence of registration in country of origin is not provided.
ii. Sample of label of the investigational product / drug is not provided.
iii. Summary of Investigator Brochure is not provided.
iv. Provided investigator's brochure is not as per ICH-GCP Guidelines.
iv. Summary of protocol is not provided and claimed that as drugs used in the trial is not an investigational product.

2.6.11. Submitted for perusal, discussion and decision of CSC.

2.6.12. Mr. Yaqub Wasan (Manager Research), from Department of Pediatrics & Child Health, Aga Khan University Karachi, participated in the 7th CSC meeting & briefed CSC members regarding subject trial.

2.6.13 CSC members after getting background of the study questioned and discussed that as this study is an ongoing study, which was started in June 2017 after getting ethical approval from Aga Khan University ERC & NBC-PHRC, but Clinical Trial Site is not yet approved, so the members of CSC decided as follows:

2.6.14. **Decision of 7thCSC Meeting:** -

"The CSC after deliberations decided to defer the case till fulfilment of all prerequisites as per Form-II of the Bio-Study Rules 2017 & inspection of Matiari Research and Training Center, Matiari, Sindh & recommendations of inspection panel.

2.7) APPLICATION FOR LICENSE FOR CHUGHTAI LAB, LAHORE, TO ACT AS BIO-ANALYTICAL LABORATORY FOR CLINICAL TRIALS. F. No.15-36/2020-DD (PS).

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

2.7.2. 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/- & Rs. 250000/- submitted

		vide challan number 1927647 & 1980787 dated 15th & 28th 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 firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	SECP Registration certificate attached. Certificate No.007795. Punjab Healthcare Commission Certificate No. REG.No-R-09524 attached
4	Details of premises including layout plan of the site.	Only layout plan is attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	List of equipment along with calibration 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.

2.7.3. Submitted for perusal, discussion and decision of CSC.

2.7.4. **Decision of 7th 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), from team, comprising of the following experts. 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.

2.8) **APPLICATION FOR APPROVAL FOR THE PROJECT TITLED "TRANSNASAL CAPSULE ENDOMICROSCOPY FOR VISUALIZATION OF THE SMALL INTESTINE IN ENVIRONMENTAL ENTERIC DYSFUNCTION (EED) POPULATION IN PAKISTAN. F. No.03-18/2020-DD (PS).**

2.8.1. Application is from Dr. Sayed Asad Ali, Professor, Department of Pediatrics & Child Health, Associate Dean, Research, Medical College, Aga Khan University, Karachi, dated 3rd January 2020, wherein request has been made for approval of subject studies / trial on prescribed Form-II of the Bio-Study Rules 2017, and fee of Rs.200000/- submitted vide challan No 0801290, dated 03 January 2020.

2.8.2. The study is sponsored by **Bill and Melinda Gates Foundation,** The aim of the study is as follows:

Primary Outcome:

The primary outcome of this research is the translation and dissemination of these minimally-invasive medical devices (TNIT and a compatible image guided brush biopsy, cryobiopsy and IPD) that will enable the detailed evaluation of the small intestine of infants for the development of effective environmental enteric dysfunction (EED) interventions. This result will be achieved upon demonstration of the use of these devices in infants in setting where EED is endemic (e.g. Matiari district in Pakistan) and the capability of these technologies to differentiate the EED intestine.

Sustainability will be addressed by developing infrastructure/partnerships to fabricate and support these devices so that they can be widely deployed and utilized for EED studies.

2.8.3. Study will be conducted only in Pakistan & 30 subjects / Children of 06 to 59 months residing in Matiari district will be recruited.

2.8.4. Application scrutinized & evaluated as per prerequisites of the Bio-Study Rules 2017, details of the submitted documents is as under;

S. No.	Document	Remarks
1	Application on prescribed form	Attached
2	Fee	Rs.200000/- submitted vide challan No 0801290, dated 03 January 2020.
3	Investigator Brochure (s)	Attached but not as per ICH-GCP guidelines.
4	Final protocol	Version 1.0

5	Informed consent and participant information sheet (Urdu to English)	Attached
6	List of participating countries	Pakistan.
7	Phase of trial.	Not described.
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.	In subject study medical devices is utilized, description & quantity is as follows: 1- Fifty (50) Trans-nasal Endomicroscopy devices will be imported for the total duration of study at different time points. 2. Accessories includes: i-Compact Imaging System (02pcs) ii-Rotary Junction (02pcs)
9	Site of the trial	Aga Khan University, Matiari Research Center, Matiari.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	IRB approval from ERC of Aga Khan Hospital is attached.
11	Approval of National Bio-ethics Committee (NBC)	Attached. Certificate Ref: no. 4-87/NBC-429/19/1111, dated 17th October 2019.
12	CV's of the Investigators	i- Dr. Sayed Asad Ali (PI), Aga Khan University Hospital, Karachi. ii- Dr. Guillermo J. Tearney (PI), Professor of Harvard Medical School. iii- Dr. Kamran Sadiq (Co-PI), Aga khan University, Karachi. iv- Dr. Sheraz Ahmed, (Manager Research), Aga khan University, Karachi. iv- Dr. Fayaz Ahmed (Research Specialist), Aga khan University, Karachi. **(CVs Attached)**
13	GMP certificate along with	Not provided.

	COPP & free sale certificate of the investigational product.	It is informed & claimed that the Transdermal Endomicroscopy, Compact Imaging System, Rotary Junction and its accessory device are developed and assembled in a not for profit, academic research lab at the Massachusetts General Hospital in Boston, MA, USA. The devices are not intended to be commercialized and are intended to be research purpose only. The devices are not registered in the country of origin (USA), hence GMP, CoPP or Free Sale Certificates are not provided.
14	Pre-clinical/clinical safety studies	Irrelevant documents attached.
15	Summary of Protocol	Version 1.0
16	Summary of Investigator Brochure	Attached but not as per ICH-GCP guidelines.
17	Adverse Event Reporting Form	Attached
18	No of patients to be enrolled in each center.	Children of 06 to 59 months residing in Matiari district. Study total sample size (30 subjects): i- 15 Well-nourished. ii- 15 Malnourished.
19	Name of Monitors & Clinical Research Associate	i- Dr. Sayed Asad Ali (PI), Aga Khan University Hospital, Karachi. ii- Dr. Guillermo J. Tearney (PI), Professor of Harvard Medical School.
20	Evidence of registration in country of origin.	Not provided. It is informed & claimed that the Transdermal Endomicroscopy, Compact Imaging System, Rotary Junction and its accessory device are developed and assembled in a not for profit, academic research lab at the Massachusetts General Hospital in Boston, MA, USA. The devices are not intended to be commercialized and are intended to

		be research purpose only. The devices are not registered in the country of origin (USA)
21	Copy of registration letter (if registered in Pakistan)	N/A.
22	Sample of label of the investigational product / drug.	N/A In subject study medical devices is utilized by experts.
23	Duration of trial	Subject participation duration is 3-6 months. Total study duration is from December 2019 to May 2022. (29 Months)
24	Undertaking on stamp paper	Attached.

2.8.5. After evaluation following shortcomings were recorded:

i. Attached investigator brochure is not as per ICH-GCP guidelines.
ii. Phase of trial / study is not described.
iii. GMP certificate along with COPP & free sale certificate of the investigational product are not provided and informed & claimed that the Transdermal Endomicroscopy, Compact Imaging System, Rotary Junction and its accessory device are developed and assembled in a not for profit, academic research lab at the Massachusetts General Hospital in Boston, MA, USA. The devices are not intended to be commercialized and are intended to be research purpose only.
iv. Pre-clinical/clinical safety studies are not provided.
v. Evidence of registration in country of origin is not provided & informed that the devices are not registered in the country of origin (USA)

2.8.6. Application evaluation summary is as above, shortcomings will also be communicated to the applicant.

2.8.7. Submitted for perusal, discussion and decision of CSC.

2.8.8. Dr. Asad Ali from Department of Pediatrics & Child Health, Aga Khan University Karachi, participated in the 7th CSC meeting & briefed CSC members regarding subject trial.

2.8.9. CSC members after getting background of the study questioned and discussed different aspects of the study and as the Clinical Trial Site for the trial (i.e. Matiari Research and Training Center, Matiari, Sindh) is not yet approved, so the members of CSC decided as follows:

2.8.10. **Decision of 7thCSC Meeting: -**

"The CSC after deliberations decided to defer the case till fulfilment of all prerequisites as per Form-II of the Bio-Study Rules 2017 & inspection of Matiari Research and Training Center, Matiari, Sindh & recommendations of inspection panel.

AGENDA ITEM - III: Miscellaneous Clinical Trials/Studies Matters.

3.1) INVESTIGATION OF RHEUMATIC AF TREATMENT USING VITAMIN K ANTAGONISTS, RIVAROXABAN OR ASPIRIN STUDIES (INVICTUS TRIAL)

3.1.1. Progress report for the subject trial is submitted from Syed Khawar Abbas Kazmi, Country/National Principal Investigator for INVICTUS Study, Aga Khan University, Karachi.

3.1.2. The trial application was placed before the Drug Registration Board in its 270th meeting, held on 25th and 26th May, 2017. The Board decided the matter as under;

"Decision: Registration Board discussed the case in detail and in the light of discussion and deliberations, the Board decided the matter as under:-

i) The Board approved the one part of the subject clinical trial i.e "**A prospective, randomized, parallel group, open label clinical trial of Rivaroxaban versus standard Vitamin K Antagonist (VKA) therapy to show non-inferiority of Rivaroxaban to VKA, with testing for superiority if non-inferiority is satisfied". However the applicant will have to seek fresh approval for the other part of the trial i.e "Superiority Trial".**

ii) The Board approved the Aga Khan University, Karachi as National Coordinator site and Syed Khawar Abbas Kazmi as National Principal Investigator.

iii) The Board approved the following five proposed trial sites and relevant Principal Investigators, as mentioned against each;

S. No.	Name of Trial Site	Principal Investigator
1	Lady Reading Hospital, Peshawar	Prof. M. Hafizullah
2	Isra University Hospital, Hyderabad	Prof. Feroz Memon
3	Rawalpindi Institute of Cardiology, Rawalpindi	Maj. Gen (R). Azhar Mehmood Kayani
4	Punjab Institute of Cardiology, Lahore	Prof. Nadeem Hayat Mallick
5	Nishtar Hospital, Multan	Dr. Abu Bakar Ali Saad

iv) The Board also granted the permission to procure the proportionate trial material i.e. XARELTO (Rivaroxaban) 15mg & 20mg Tablets and WARFIN (Warfarin Sodium B.P 2.5mg) Registration No.063195, as per requirement of the study/protocol, from M/s Bayer Pharma AG, Germany and M/s Shaigan Pharmaceuticals (Pvt.) Ltd., Rawalpindi (through Aga Khan Hospital Pharmacy, Karachi), respectively".

3.1.3. According to decision of the Registration Board, the approval letter issued on 10th July 2017, for a duration of four (04) years.

3.1.4. In the progress report of subject trial, applicant informed regarding recruitment of trial subjects on each trial site as follows:

S.No.	Trial Site	Recruited Subjects
01	Lady Reading Hospital, Peshawar	74
02	Isra University Hospital, Hyderabad	16
03	Rawalpindi Institute of Cardiology, Rawalpindi	117
04	Punjab Institute of Cardiology, Lahore	113
05	Nishtar Hospital, Multan	2
Total		322

3.1.4. Principal Investigator further informed that drug import license issued on 22nd September 2017 and allowed import of 195 bottles of **Xeralto 15mg** & 1105 bottles of **Xeralto 20mg** and until expiry of the Import Licence, they have imported 132 bottles of Xeralto 15mg and 643 bottles of Xeralto 20 mg.

3.1.5. Summery for approved trial medicine is as follows:

S.no.	Name of Trial Drug	Manufacturer	Approved Quantity (As per import Licence)	Quantity Imported	Quantity Remained to be imported.
01	**XARELTO (Rivaroxaban) 15mg & 20mg Tablets**	**M/s Bayer Pharma AG, Germany.**	**195 Bottles.**	**132 Bottles.**	**63 Bottles.**
02	**WARFIN (Warfarin Sodium B.P 2.5mg**	**M/s Bayer Pharma AG, Germany.**	**1105 Bottles.**	**643 Bottles.**	**462 Bottles.**

3.1.5. As per information communicated follow-ups will continue for this year & National Coordinating Center **"Aga Khan University, Karachi"** will continue to extend support & guidance to all recruiting sites across Pakistan and required to import balance number of Investigational Medicinal Products (IMP) & will report events and issues to concerned authorities appropriately.

3.1.6. Syed Khawar Abbas Kazmi, Principal Investigator requested for extension in import license for further two years, which was expired on 21st September 2019.

3.1.7. It is submitted that the trial was approved on 10th July 2017 for a duration of four (04) years before promulgation of the Bio-Study Rules 2017.

3.1.8. Submitted for perusal discussion and decision of CSC.

3.1.9. CSC members discussed the matter and decided as follows:

3.1.10. **Decision of 7th CSC Meeting: -**

The CSC after deliberations decided to approve the request for import of remaining quantities of Investigational Medicinal Products (IMP) till expiration date of trial approval (i.e. June 2020), as per quantity approved previously.

AGENDA ITEM - IV:

4.A) DELEGATION OF POWER TO CHAIRMAN CSC FOR CONSTITUTION OF INSPECTION PANEL FOR APPLICATIONS RECEIVED ON FORM-I OF THE BIO-STUDY RULES.

4.A.1. Many applications for approval to act as CROs, Clinical Trial Sites, Bio-Analytical Laboratories & BA/BE Studies Centers are processed by the division of Pharmacy Services and placed before CSC for constitution of panel. On inspection date, if any member of panel is not available, addition of another member of relevant expertise to replace the non-available member become time consuming and bothers the ongoing inspection as scheduled.

4.A.2. The CSC may release its burden and for speedy disposal by authorizing Chairman CSC for addition of another relevant member to already constituted panel by CSC. The panel shall consist of four members who has been trained for such inspections at UHS or other institution for such relevant purpose, having relevant experience. The panel shall have composition of a clinician having experience of epidemiology, a biostatistician, a pharmacist having clinical experience of clinical pharmacy and an IT relevant person. The panel shall inspect the site at one time compositely, and not in bit and pieces. This initiative is not from driven from section but has added by the initiative of Director / Chairman CSC.

4.A.3. Submitted for perusal, discussion and decision of CSC.

4.A.4. Chairman CSC elaborated the case & its background and stated that as other Boards & Committees delegated their power to their Chairman for constitution of Panel for inspection for quick & prompt disposal of application, so the agenda is placed before CSC for consideration.

4. A.5. Refer to rule 13 (9) of the Bio-Study Rules 2017, The CSC may delegate any of its powers to Chairman of the Committee in writing with appropriate justification.

4.A.6. After discussing the matter CSC member decided as follows:

Decision of 7th CSC Meeting: -

The CSC after deliberations decided to delegate its power to Chairman CSC for constitution of inspection panel for applications applied on Form-I of the Bio-Study Rules 2017, for quick & prompt disposal of the applications.

Inspection panel will be constituted from approved pool of inspectors, as CSC approved in its 2nd meeting with rationale to knowledge based diversity.

4.B) **APPLICATION FOR LICENSE TO ACT AS CRO AND CLINICAL TRIAL MONITORING SERVICES-IQVIA SOLUTIONS PAKISTAN (PRIVATE) LIMITED. F. No.15-09/2019 DD (PS)**

4.B.1. Application from Dr. Aman Ullah Khan CEO, M/s IQUVIA Solutions Pakistan (Pvt) Ltd. Karachi, wherein the request has been made to license their company with DRAP to work as Clinical Research Organization (CRO) and Clinical Trial Monitoring Services, the application is on prescribed Form-I of the Bio-Study Rules 2017 along without fee, which may be paid/ asked after notification.

4.B.2. 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	Fee	Rs. 50000/- paid vide challan number 0825664, dated 25 February 2019 & then differential fee of Rs250,000/-, deposited vide challan number 1951501, dated 16th July 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).	Attached
4	Details of premises including layout plan of the site.	Layout of ground & first floor attached.
5	Details of the section wise equipment and machinery required for the analytical or bio- analytical and clinical studies.	Not Provided.
6	Names and qualifications of the above sections along with their staff.	Attached
7	Details of the allied facilities associated with the trial center including ambulatory	Not provided. Firm Reply:

	services, emergency handling etc.	Please note that the ambulatory services are not required in relation to Contract Research Organization license application, hence we understand that such information is not required along with the application IQVIA will manage study within the approved hospital / clinical site by DRAP under the supervision on local EC & NBC with qualified investigators as per ICH-GCP guidelines
8	Undertaking	Attached.

4.B.3. Application was discussed in the 3rd CSC meeting & the CSC decided as follows:

Decision of 3rd CSC Meeting:-

The CSC afire deliberations decided to conduct the inspection of CRO from team of Pool-A comprising of the following experts. These experts shall get training at UHS, Lahore prior to moving for inspection. In case any member is not available the committee authorized its chairman to add another suitable member of the relevance experties from the pool of experts. The applicant shall be inform for the proposed date of inspection accordingly. The CSC also directed the applicant to remove the shortcomings, which have been described in agenda:-

i.	Prof. Dr. Javed Akram
ii.	Dr. Salva Ahsan
iii.	Prof. Dr. Nadeem Afzal
iv.	Dr. Farhana Badar
v.	Dr. Abdur Rashid (Coordinator)

4.B.4. Inspection panel conducted the inspection & inspection report placed before CSC in its 4th meeting, with recommendations **"Recommended for provisional approval for improvements**", after discussion CSC in its 4th meeting decided as follows:

Decision of 4th CSC Meeting:-

The CSC after deliberations decided to defer the case for re-inspection by the same panel nominated in the 3rd CSC meeting after fulfilment of all requirements as per the Bio-Study Rules 2017 & intimation by the applicant. CSC further directed the applicant for development of separate infra-structure & H.R.

4.B.5. Due to unavailability of Dr. Salwa Ahsan & Dr. Farhana Badar in scheduled dates, Chairman CSC / Director Pharmacy Services exercising powers delegated by the CSC substituted Dr. Salwa Ahsan & Dr. Farhana Badar with Mr. Waqas Latif, UHS, Lahore & Dr. Saif Ur Rehman, Additional Director, CDL-Karachi. And letter for inspection issued on 13th November 2019.

4.B.6. Prof. Dr. Javed Akram, Dr. Saif Ur Rehman Khattak & Dr. Abdur Rashid (Coordinator) conducted inspection of the M/s IQVIA Solutions Pakistan (Pvt) Ltd, on 16th November 2019 & due to

unavailability of Mr. Waqas Latif, UHS, Lahore & Prof. Dr. Nadeem Afzal, Chairman CSC / Director Pharmacy Services nominated following members for inspetion:

i.	Prof. Dr. Nisar Hussain Shah
ii.	Dr. Najam Us Saquib

4.B.7. Nominated members conducted inspection of the M/s IQVIA Solutions Pakistan (Pvt) Ltd, on 31st December 2019.

4.B.8. **The report submitted by Dr. Najam Us Saqib (Additional Director DRAP Karachi) to the division of pharmacy Services for the Inspection of the M/s IQVIA Solutions Pakistan (Pvt) Ltd, on 16th November 2019 & 31st December 2019 concluded the following remarks:**

"All necessary / relevant documents were thoroughly reviewed by the team and found satisfactory. The team especially reviewed the subsidiary certificate issued in favor of IQVIA Solution Pakistan (Pvt) Ltd, by IQVIA Inc. NJ, and SECP Company Reg: Certificate presented by the management which are also attached with the report"

4.B.9. **Concluding status / remarks of inspection panel:**

Recommended for approval

4.B.10. The inspection was done in bit and pieces and not compositely. Further that the active composition of CRO has been changed, and is only two member from actual composition i.e. Dr. Abdur Rashid & Dr. Javed Akram had conducted the inspection.

4.B.11. Submitted for perusal discussion and decision of CSC.

Decision of 6th CSC Meeting:-

The CSC after deliberations & upon recommendation of inspection panel, decided to approve the M/s IQUVIA Solutions Pakistan (Pvt) Ltd., Karachi to act as Contract Research Organization (CRO), under the Bio Study Rules 2017.

4.C) APPLICATION FOR THE APPROVAL OF CLINICAL STUDY "ACCURACY OF BODY COMPOSITION MONITORS IN ASSESSMENT OF FLUID STATUS IN THE CHRONIC KIDNEY DISEASE [CKD] PATIENTS ON HEMODIALYSIS VERSUS CLINICAL ASSESSMENT", F.No.03-05/2019 DD (PS).

4.C.1. Application is from Javaid Nasir Qureshi, Managing Director Pakistan & Afghanistan for M/s Fresenius Medical Care Pakistan (Pvt) Ltd., wherein request has been made for approval of subject clinical assessment studies, which was being carried out at Fatima Memorial Hospital College of Medicine & Dentistry, Karachi. Under supervision of Dr. Hafiz Usman (PI) and Dr. Nauman Tarif (Co-Investigator).

4.C.2. After scrutiny following observations were recorded as per prerequisites of prescribed **Form-II** of the **Bio-Study Rules 2017.**

S. No.	Required Documents	Remarks
1.	Application on prescribed Form-II	Attached
2.	Fee	Not provided.
3.	Investigator Brochure	Not provided.
4.	Final Protocol	Not provided.
5.	Informed consent form (English & Urdu)	Not provided.
6.	List of participating countries (If applicable)	Nil
7.	Phase of trial	Not provided.
8.	Quantity of Drug(s) to be imported/procured/manufactured for the trial	01 Body Composition Machine (BCM) (Medical Device) & 600 electrodes for 150 patients.
9.	Site(s) of the trial	1. Fatima Memorial Hospital College of Medicine & Dentistry, Karachi.
10.	C.Vs of investigator(s)	CVs of both Investigators are attached.
11.	Ethical committee approval with complete composition of committee i.e. Name and designations of the members	Attached
12.	Approval from National Bio-ethics Committee (PHRC)	Not provided.
13.	GMP certificate along with Free Sale Certificate/Certificate of Pharmaceutical Product (Note: For locally manufactured product GMP Cert., COA of the Product and Registration Letter will be required)	Not provided.
14.	Pre-clinical, clinical data and safety studies.	Not provided.
15.	Summary of the protocol	Not provided.
16.	Summary of the Investigator Brochure	Not provided.
17.	Adverse Event Reporting form	Not provided.
18.	No. of Patients to be enrolled in each center	150 patients.
19.	Name of monitors/clinical research associate	Not provided & claimed that it's an already

		registered & marketed.
20.	Evidence of registration of study drug in country of origin	Not provided.
21.	Copy of registration letter (if drug is registered in Pakistan)	Not provided.
22.	Sample of label of drug	Attached
23.	Duration of trial	Not provided.
24.	Undertaking on Stamp Paper	Not provided

4.C.3. **Description of shortcomings:**

i) Investigators brochure, final protocol, and informed consent form is not provided.
ii) Clinical trial site is not approved from DRAP.
iii) Approval from National Bio-ethics Committee (PHRC), is not provided.
iv) GMP certificate along with Free Sale Certificate/Certificate of Pharmaceutical Product is not provided.
v) Pre-clinical, clinical data and safety studies is not provided.
vi) Summary of protocol and summery of investigators brochure is not provided.
vii) Adverse Event Reporting form is not attached.
viii) Evidence of registration of study drug in country of origin is not provided.
ix) Copy of registration letter (if drug is registered in Pakistan), is not provided.
x) Sample of label of drug is not attached
xi) Duration of trial is not described.
xi) Processing Fee is not provided.
xii) Undertaking on Stamp paper is not provided.

4.C.4. Application discussed in the 3rd CSC meeting and the CSC decided as follows:

Decision of 3rdCSC Meeting:-

The CSC after deliberations decided to defer the case till the approval of study site. The CSC also directed the applicant to remove the shortcomings. The applicant shall be informed to apply for approval of trial site first and then its clinical trial.

4.C.5. The firm was communicated through letter no. F.No.03-05/2019 DD (PS), dated 11th April, 2019 and 08th July, 2019, firm replied through letter no. T010719-BCM-DRAP01L, dated 09th July, 2019, due to financial reasons and approval for Clinical Trial Sites by Principal Investigator, they are termination of the project and will not conduct the said studies.

4.C.6. Application again discussed in the 4th CSC meeting and the CSC decided as follows:

Decision of 4th CSC Meeting:-

No representative of the firm / institution appeared before the CSC for presentation of the studies. The case was so deferred. Applicant directed to fulfil all requirements as per Form-II of the Bio-Study Rules 2017.

4.C.7. The firm informed through letter no. T010719-BCM-DRAP01L, dated 09th July, 2019, due to financial reasons and approval for Clinical Trial Sites by Principal Investigator, they are terminating the project and will not conduct the said studies & want to withdraw their application.

4.C.8. Submitted for perusal discussion and decision for rejection by the CSC.

4.C.9. **Decision of 7th CSC Meeting:-**

The CSC after deliberations based on mentioned shortcomings & upon request of applicant/firm, decided to approve the withdrawal application.

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5. Miscellanious Agenda Item:

5.1. After completion of agenda items Dr. Rizwana Chaudhry raised discussion regarding nomination of inspection panel and arrangments for their inspection, air tickets, accommodation and other facilities.

5.2. She asked that *Is DRAP is responsible for all expenditures for inspection?,* During discussion it is suggested that inspection members should be selected on the basis of their locality in respect to applied sites or burden of the expenditure for the inspection should be on applicant as DRAP processing fees is not enough for expenditures for whole process of application evaluation, site inspection and monitoring of approved sites & studies. She also highlighted that there should be difference in the fee structre for Primary & Secondary Sites.

5.3. Chairman CSC elaborated further that it is practically a difficult task to gather four to five members at scheduled date & time for inspection and arrange air tickets & accommodation & payment of TA/DA.

5.4 Chairman CSC proposed that a four member committee should be constituted who addresses the matter regarding fee structure, inspection expenditure, payment of TA/DA & honorarium.

5.5 Secretary CSC elaborated & briefed the CSC regarding need of multidicipilinary inspection panel & difference between inspection of Clinical Studies Site & Pharmaceutical Units , he further informed the CSC members about FDA & EMA fee structre, which is a huge amount in dollors.

5.6 Decision of 7th CSC Meeting:-

i- The CSC after deliberations decided to constitute a committee regarding fee structure, inspection expenditure, payment of TA/DA & honorarium and other matter regarding expenditure, comprising of the following experts:-

i.	Dr. Masud Ur Rehman (Coordinator).
ii.	Mr. Amanullah (Director B&A Division DRAP)
iii.	Prof. Dr. Javed Akram.

Iv	Dr. Rizwana Choudhry.
v	Dr. Najam Us Saquib.

ii- The committee discuss the matter in detail and present their proposals in the next CSC meeting.
