SUMMARY OF MINUTES OF 51ST CLINICAL STUDIES COMMITTEE MEETING HELD ON 24TH OCTOBER 2024

Division of Pharmacy Services,
Drug Regulatory Authority of Pakistan
File No: 16-51/2024-CSC (PS)

OCTOBER 24, 2024

DRUG REGULATORY AUTHORITY OF PAKISTAN
PRIME MINISTER'S NATIONAL HEALTH COMPLEX,
PARK ROAD,
ISLAMABAD.

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51st meeting of the Clinical Studies Committee was held on 24th October, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister Health Complex, Park Road, Islamabad.

The meeting was chaired by Ch. Zeeshan Nazir Bajar, Chairman, Clinical Studies Committee, DRAP. The meeting started with recitation of the Holy Verses. Secretary and all members of Clinical Studies Committee Welcome Ch. Zeeshan Nazir Bajar, Chairman, Clinical Studies Committee / Director, Pharmacy Services, Division. The Committee appreciated the efforts of Dr. Obaidullah, Ex-Chairman, Clinical Studies Committee for his services for improvement in the Division of Pharmacy Services and adaptations of international regulations.

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

Sr. No.	**Name**	**Designation**	
i.	Mr. Malik Muhammad Asad	Deputy Director, Pharmacy Services Division.	*Ex-officio Secretary*
ii.	Prof. Munawar Alam Ansari.	Professor of Pharmacology, Dean Faculty of Pharmacy, Liaquat University of Medical Sciences, Jamshoro. *(Sindh)*	Member
iii.	Prof. Dr. Mirza Tasawer Baig	Department of Pharmacy Practice, Faculty of Pharmacy, Ziauddin University, Karachi and Clinical Pharmacist at Dr. Ziauddin Hospital, Karachi, Sindh.	Member

3. Following members / observer attended the meeting online through Zoom application.

i.	Prof. Dr. Fazal Subhan	Department of Pharmacy, CECOS University of IT and Emerging Sciences, Peshawar, Khyber Pakhtunkhwa.	Member
ii.	Prof. Dr. Saeed Ahmad Khan	Professor of Medicine Bolan Medical College Quetta presently serving as head of Medicine Department Jhalawan Medical College Khuzdar, Baluchistan.	Member
iii.	Mr. Waqas Latif	Data Analyst/Biostatistician in Quality Enhancement Cell (QEC) at University of Health Sciences, Lahore, Punjab.	Member
iv.	Dr. Sadia Asim	Representative of PPMA (Observer), Director IBBPS (Institute of Biological, Biochemical & Pharmaceuticals Sciences) Dow University of Health Sciences OJHA Campus, Karachi.	(Observer)

4. Mr. Hafiz Muhammad Umair and Mr. Shafqat Hussain Danish assisted the Committee and the Secretary in presentation of the agenda and recording of minutes of the meeting.

5. Prof. Doctor Iqbal Memon, Chairman Sub-Committee on ventilators and Dr. Nabeel Anwar, HOC Research Biomedical Engineering Department, NUST, Islamabad attended the meeting through Zoom link to assist the committee on the clinical validation report of ICU ventilator "Alnnovent" manufactured by M/s Alsons group in Pakistan.

AGENDA ITEM-1:

CONFIRMATION OF THE MINUTES OF THE 50TH CLINICAL STUDIES COMMITTEE MEETING.

The 50th meeting of Clinical Studies Committee was held on 11th July, 2024. The draft minutes of the meeting were shared with CSC members through email. The CSC members submitted their consent and no comments/queries were received from the members. Accordingly, after approval of the minutes, decisions taken in the meeting have been communicated, and are placed for confirmation/signature by the CSC members.

2. Minutes of the 50th CSC meeting were placed before the Committee.

Decision:

All the Members of the CSC confirmed the Minutes of 50th CSC meeting.

AGENDA ITEM 2 Clinical Trial Site License

Case No. 2.1

APPLICATION FOR GRANT OF GENERALIZED TRIAL SITE (PHASE I, II, III & IV) TO DR. K.M. PFAU CIVIL HOSPITAL, DOW UNIVERSITY OF HEALTH SCIENCES, KARACHI. F. No.15-49/2023 CTS.

Decision:

The CSC after deliberation, discussion and keeping in view compliance of decision in 50th meeting of CSC by the applicant, decided to constitute panel of experts, by the Chairman CSC, for inspection of proposed clinical trial site.

Case No. 2.2:

APPLICATION FOR APPROVAL TO ACT AS CRO AT M/S KING EDWARD MEDICAL UNIVERSITY, LAHORE. F. No.15-69/2024-CRO

Decision:

The CSC after deliberation advised to follow up the matter with Legal Affairs Division for their valuable input. The committee authorized Chairman, CSC to decide the matter in the light of opinion of Legal Affairs Division. The matter shall accordingly be placed before the forthcoming meeting of CSC for information.

Case No. 2.3:

APPLICATION FOR RENEWAL OF LICENSE TO ACT AS CTS FOR PHASE I, II AND IV FROM AL-SHIFA TRUST EYE HOSPITAL, RAWALPINDI.F.No.15-17/2022-CTS.

Decision:

The CSC after deliberation and on recommendation of panel of experts, decided to grant the license to act as clinical trial site for Phase II (except their PK/PD parts which will be responsibility of the Sponsor), III & IV clinical trials to "M/s Al-Shifa Research Center, Al- Shifa Trust Eye Hospital, Jhelum Road Rawalpindi."

Case No. 2.4:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE III & IV FROM PREMIUM INTERNATIONAL HOSPITAL ISLAMABAD.F.No.15-72/2024-CTS.

Decision:

The CSC after deliberation and on recommendation of panel of experts, decided to defer the case for further improvements and fulfilment of shortcomings noted in its inspection report dated 04th of September, 2024.

Case No. 2.5:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM NISHTAR MEDICAL UNIVERSITY & HOSPITAL, MULTAN F. No.15-50/2023-CTS.

Decision:

The CSC after deliberation and reviewing CAPA submitted by the applicant, decided to re-inspect the site by the same panel for verification of CAPA, in the light of observations noted in inspection dated 8th April 2024. The committee further decided to delegate it power to Chairman CSC to dispose-of the matter in the light of afresh inspection report.

Case No. 2.6:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM SANDEMAN PROVINCIAL HOSPITAL, JINNAH ROAD QUETA.

Decision:

The CSC after deliberation and on recommendation of panel inspection report dated 31st July, 2024, decided to grant the license to act as trial specific clinical trial site for Phase III "IM Women" clinical trial to "M/s Sandeman Provincial Hospital (SPH) Quetta."

Case No. 2.7:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM BOLAN MEDICAL COMPLEX HOSPITAL, JINNAH ROAD QUETA.

Decision:

The CSC after deliberation and on recommendation of panel inspection report dated 31st July, 2024, decided to grant the license to act as trial specific clinical trial site for Phase III "IM Women" clinical trial to "M/s Bolan Medical Complex Hospital(BMCH) Quetta."

Case No. 2.8:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE IV OR OBSERVATIONAL STUDY PROJECTS FOR DRUGS OR MEDICAL DEVICES FROM THE CLINIC NUMBER 553 AND 554, DOCTORS PLAZA, CLIFTON, KARACHI.

Decision:

The CSC after deliberation and on recommendation of panel of experts, decided to defer the case for further improvements and fulfilment of shortcomings noted in its inspection report dated 18th October, 2024.

Case No. 2.9:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE III (ONCOLOGY) FROM DEPARTMENT OF MEDICAL ONCOLOGY, ALLIED HOSPITAL, FAISALABAD.

Decision:

The CSC after deliberation and on recommendation of panel inspection report dated 18th July, 2024, decided to grant the license to act as trial specific clinical trial site for Phase-III Clinical Trial for "BCD202 & BCD 263 studies to "M/s Allied Hospital, Faisalabad."

Case No. 2.10:

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

Decision:

The CSC after deliberation and on recommendation of panel of experts, decided to defer the case for further improvements and fulfilment of shortcomings noted in its inspection report dated 18th July, 2024.

Case No. 2.11:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FROM THE SHAIKH ZAYED FEDERAL POSTGRADUATE MEDICAL INSTITUTE, SHAIKH ZAYED HOSPITAL, LAHORE.

Decision:

The CSC after deliberation and on recommendation of panel of experts, decided to defer the case for further improvements and fulfilment of shortcomings noted in its inspection report dated 15th July, 2024.

AGENDA ITEM 3: BA/BE Studies

Case No. 3.1:

APPLICATION FOR APPROVAL OF BIOEQUIVALENCE STUDY TITLED, "A SINGLE CENTER. OPEN LABEL. BALANCED. RANDOMIZED. SINGLE-DOSE. TWO-PERIOD, TWO-SEQUENCE, TWO-WAY, CROSS-OVER ORAL BIOEQUIVALENCE STUDY COMPARING RITBAN® 10mg (RIVAROXABAN) TABLET MANUFACTURED BY SAMI PHARMACEUTICALS (PVT) LIMITED WITH XARELTO® 10mg (RIVAROXABAN) TABLET MANUFACTURED BY BAYER HEALTHCARE A.G. IN HEALTHY, ADULT MALE SUBJECTS UNDER FASTING CONDITION", RECEIVED FROM M/S CENTER FOR BIOEQUIVALENCE STUDIES AND CLINICAL RESEARCH (CBSCR), ICCBS, UNIVERSITY OF KARACHI, KARACHI. F. No.14-04/2024-BE (PS)

Decision:

The CSC after deliberation and on recommendation of expert members decided to approve the bioequivalence study titled, "A single center. open label. balanced. randomized. single-dose, two-period, two-sequence, two-way, cross-over oral bioequivalence study comparing Ritban® 10mg (Rivaroxaban) tablet manufactured by M/s Sami Pharmaceuticals (Pvt.) Limited with Xarelto® 10mg (Rivaroxaban) tablet manufactured by M/s Bayer healthcare A.G. in healthy, adult male subjects under fasting condition", at M/s Center for Bioequivalence Studies and Clinical Research (CBSCR), ICCBS, University of Karachi.

Case No. 3.2:

APPLICATION FOR APPROVAL OF BIOEQUIVALENCE STUDY TITLED, "A SINGLE CENTER. OPEN LABEL. BALANCED. RANDOMIZED. SINGLE-DOSE. TWO-PERIOD, TWO-SEQUENCE, TWO-WAY, CROSS-OVER ORAL BIOEQUIVALENCE STUDY COMPARING RITBAN® 20mg (RIVAROXABAN) TABLET MANUFACTURED BY SAMI PHARMACEUTICALS (PVT) LIMITED WITH XARELTO® 20mg (RIVAROXABAN) TABLET MANUFACTURED BY BAYER HEALTHCARE A.G. IN HEALTHY, ADULT MALE SUBJECTS UNDER FASTING CONDITION", RECEIVED FROM M/S CENTER FOR BIOEQUIVALENCE STUDIES AND CLINICAL RESEARCH (CBSCR), ICCBS, UNIVERSITY OF KARACHI, KARACHI. F. No.14-03/2024-BE (PS)

Decision:

The CSC after deliberation and on recommendation of expert members decided to approve the bioequivalence study titled, "A single center. open label. balanced. randomized. single-dose, two-period, two-sequence, two-way, cross-over oral bioequivalence study comparing Ritban® 20mg (Rivaroxaban) tablet manufactured by M/s Sami Pharmaceuticals (Pvt.) Limited with Xarelto® 20mg (Rivaroxaban) tablet manufactured by M/s Bayer healthcare A.G. in healthy, adult male subjects under fasting condition", at M/s Center for Bioequivalence Studies and Clinical Research (CBSCR), ICCBS, University of Karachi.

Case No. 3.3:

APPLICATION FOR APPROVAL OF BIOEQUIVALENCE STUDY TITLED, "AN OPEN LABEL, BALANCED. RANDOMIZED, TWO TREATMENTS, TWO SEQUENCES, TWO PERIODS, SINGLE DOSE, CROSS OVER, BIOEQUIVALENCE STUDY OF VALSATRIL™ (SACUBITRIL/VALSARTAN) 24MG/26MG TABLET OF SAMI PHARMACEUTICALS (PVT) LTD VERSUS ENTRESTO® (SACUBITRIL/VALSARTAN) 24MG/26MG TABLET OF NOVARTIS PHARMACEUTICALS UK LTD., UNDER FASTING CONDITION IN ADULT MALE SUBJECTS", RECEIVED FROM M/S CENTER FOR BIOEQUIVALENCE STUDIES AND CLINICAL RESEARCH (CBSCR), ICCBS, UNIVERSITY OF KARACHI, KARACHI. F. NO.14-06/2024-BE (PS)

Decision:

The CSC after deliberation and on recommendation of expert members decided to approve the bioequivalence study titled, "An open label, balanced. randomized, two treatments, two sequences, two periods, single dose, cross over, bioequivalence study of Valsatril™ (sacubitril/valsartan) 24mg/26mg tablet of M/s Sami Pharmaceuticals (Pvt) Ltd versus Entresto® (sacubitril/valsartan) 24mg/26mg tablet of M/s Novartis Pharmaceuticals UK Ltd., under fasting condition in adult male subjects", at M/s Center for Bioequivalence Studies and Clinical Research (CBSCR), ICCBS, University of Karachi.

Case No. 3.4:

APPLICATION FOR APPROVAL OF BIOEQUIVALENCE STUDY TITLED, "AN OPEN LABEL, BALANCED. RANDOMIZED, TWO TREATMENTS, TWO SEQUENCES, TWO PERIODS, SINGLE DOSE, CROSS OVER, BIOEQUIVALENCE STUDY OF VALSATRIL™ (SACUBITRIL/VALSARTAN) 97MG/103MG TABLET OF SAMI PHARMACEUTICALS (PVT) LTD VERSUS ENTRESTO® (SACUBITRIL/VALSARTAN) 97MG/103MG TABLET OF NOVARTIS PHARMACEUTICALS UK LTD., UNDER FASTING CONDITION IN ADULT MALE SUBJECTS", RECEIVED FROM M/S CENTER FOR BIOEQUIVALENCE STUDIES AND CLINICAL RESEARCH (CBSCR), ICCBS, UNIVERSITY OF KARACHI, KARACHI. F. NO.14-05/2024-BE (PS)

Decision:

The CSC after deliberation and on recommendation of expert members decided to approve the bioequivalence study titled, "An open label, balanced. randomized, two treatments, two sequences, two periods, single dose, cross over, bioequivalence study of Valsatril™ (sacubitril/valsartan) 97mg/103mg tablet of M/s Sami Pharmaceuticals (Pvt) Ltd versus Entresto® (sacubitril/valsartan) 97mg/103mg tablet of M/s Novartis Pharmaceuticals UK Ltd., under fasting condition in adult male subjects", at M/s Center for Bioequivalence Studies and Clinical Research (CBSCR), ICCBS, University of Karachi.

AGENDA ITEM 4: Clinical Trials

Case No. 4.1:

APPLICATION FOR APPROVAL OF CLINICAL TRIAL TITLED "PHASE III CLINICAL STUDIES TO EVALUATE THE SAFETY, TOLERABILITY, AND EFFICACY OF CHLORINE E6 (GEL FORMATION) AS A PHOTOSENSITIZING AGENT FOR THE MANAGEMENT OF DIABETIC FOOT ULCERS WITH PHOTODYNAMIC THERAPY" FROM CREEK GENERAL HOSPITALKARACHI. F. NO.03-55/2024-CT (PS)

Decision:

The CSC after deliberation:

i. *Did not acceded to request of the applicant M/s Creek General Hospital, Karachi to conduct Phase-IIb Clinical Trials, as the site does not possess lincese to act as Phase-II clinical trial site. The committee decided to advise the PI to submit application on Form-I with requisite fee for further processing the case.*
ii. *The Committee observed that there is a conflict of interest of the Chairman of DSMB, constituted by the Sponsor. The Chairman of the DSMB is full time employee of the DRAP.*

2. In view of above, the Committee decided to defer the case for rectifications of above mentioned observations.

Case No. 4.2:

APPLICATION FOR APPROVAL OF A PHASE-IV CLINICAL TRIAL TITLED "STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK (THE SHIPSS TRIAL)", FROM SHIFA CLINICAL RESEARCH CENTER SHIFA INTERNATIONAL HOSPITAL LTD. ISLAMABAD.F. No.03-58/2024-CT (PS)

Decision:

The CSC after deliberation decided to defer the case for submission of response of this Division's letters dated 28th August 2024 and 03rd October 2024.

Case No. 4.3:

APPLICATION FOR APPROVAL OF A CLINICAL TRIAL TITLED "MICRONUTRIENT SUPPLEMENTATION IN PREGNANCY AND POSTPARTUM", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-59/2024-CT (PS)

Decision:

The CSC after deliberation decided to:

i. *Defer the case for submission of shortcomings conveyed vide letter dated 18th October, 2024.*
ii. *Recommended to refer the case to DRAP Authority for manufacturing of IMPs by M/s Remington Pharmaceutical Industries, Lahore for the following q*uantities:

- **Pregnancy trial:**
  - 3000 women pregnant women will be enrolled

- They will have 2 arms:
- MMSplus (1500 women) – 345,000 sachets (including 10% buffer)
- MMS (1500 women) - 345,000 sachets (including 10% buffer)

➢ **Lactating women trial (post pregnancy):**
- 3000 women in the pregnancy trial will continue
- They will have 3 arms:
- MMSplus (1000 women) – 200,000 sachets
- MMS (1000 women) - 200,000 sachets
- Iron and folic acid (1000 women) - 200,000 sachets

AGENDA ITEM 5: Amendments in already approved Clinical Trials

Case No. 5.1

REQUEST FOR APPROVAL OF PROTOCOL AMENDMENT VERSION 4.0 AND ASSOCIATED DOCUMENTS - CT-0058 CLINICAL TRIAL TITLED: A PHASE-II, RANDOMIZED. OBSERVER-BLINDED, PLACEBO CONTROLLED TRIAL TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF HECOLIN (R) IN HEALTH PREGNANT WOMEN BETWEEN GESTATIONAL AGE 14-24 WEEKS AND NON-PREGNANT WOMEN OF 16-45 YEARS OLD.

Decision:

The CSC after deliberation decided to approve following amended documents of already approved Clinical Trial titled "A Phase-II, Randomized, Observer-Blinded, Placebo Controlled Trial to Evaluate the Safety and Immunogenicity of Hecolin (R) in Health Pregnant Women between Gestational age 14-24 Weeks and Non-Pregnant Women of 16-45 years old", registration no. (CT-0058)*":*

S.No.	*Documents*	*Version*	*Dated*
1	*VI Hecolin - P001 -Protocol Version 4*	*Version 4.0*	*25 June 2024*
2	*IVI_Hecolin_P001- Main ICF Version 5 - English*	*Version 5.0*	*19 June 2024*
3	*IVI_Hecolin_P001- Main ICF Version 5 - Urdu*	*Version 5.0*	*19 June 2024*
4	*IVI_Hecolin_P001- ICF HD – Version 4 - English*	*Version 4.0*	*19 June 2024*
5	*VI_Hecolin_P001- ICF HD – Version 4 - Urdu*	*Version 4.0*	*19 June 2024*
6	*VI_Hecolin_P001- CRF- Version 4.1 (Note: this CRF version supersedes CRF V4.0 attached with this submission)*	*Version 4.1*	*06 Aug 2024*
7	*IVI_Hecolin_P001- CRF- Version 4.0 (Note: this CRF version is superseded by CRF V4.1 attached with this submission)*	*Version 4.0*	*04 July 2024*

Case No. 5.2

APPLICATION FOR AMENDMENT IN PROTOCOL AND RELATED DOCUMENTS OF ALREADY APPROVED CLINICAL TRIAL TITLED "A DOUBLE-BLIND, RANDOMIZED CLINICAL STUDY OF THE EFFICACY AND SAFETY OF MONOTHERAPY WITH BCD-254 AND DARZALEX® IN SUBJECTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA" FROM SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY, ISLAMABAD. F. No.03-49/2023-CT (PS).

Decision:

The CSC after deliberation decided to approve following amended documents of already approved Clinical Trial titled "A Double-Blind, Randomized Clinical Study of the Efficacy and Safety of Monotherapy with BCD-264 and Darzalex ® in Subjects with Relapsed and Refractory Multiple Myeloma", registration no. (CT-0058)":

S.No.	*Documents*	*Version*	*Dated*
1	*Protocol Version 2.0*	*Version 2.0*	*05 February 2024*
2	*Informed Consent Form (English & Urdu)*	*Version 2.0*	*21 June 2024*

Case No. 5.3

APPLICATION FOR AMENDMENTS IN PROTOCOL AND RELATED DOCUMENTS OF CLINICAL TRIAL TITLED "A MULTICENTER, RANDOMIZED, CONTROLLED, OPEN-LABEL PHASE IIB STUDY TO ASSESS EFFICACY AND SAFETY OF HH-003 INJECTION IN SUBJECTS WITH CHRONIC HEPATITIS DELTA VIRUS INFECTION (HH-003-204)", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-45/2023-CT (PS)

Decision:

The CSC after deliberation decided to approve following amended documents of already approved Clinical Trial titled "A multicenter, randomized, controlled, open-label, phase IIb study to assess efficacy and safety of HH-003 injection in subjects with chronic hepatitis delta virus infection":

S.No.	*Document Name*	*Version*	*Version Date*
1	*Clinical Study Protocol*	*V4.0*	*08Mar2024*
2	*Investigator Brochure*	*V6.0*	*27Jan2024*
3	*HH003-204 PAK Main ICF (English, Urdu)*	*V4.0 PAK1.0*	*25April2024*
4	*HH003-204 PAK Pregnancy Information Collection ICF (English, Urdu)*	*V4.0 PAK1.0*	*29April2024*
5	*Data and Safety Monitoring Board (DSMB) Charter or Justification for lack of DSMB*	*V1.0*	*12Mar2024*
6	*Annotated CRF (Unique & with matrix)*	*V3.0*	*07May2024*

AGENDA ITEM 6: Trial Reports

Case No. 6.1

QUARTERLY PROGRESS REPORT OF CLINICAL TRIAL TITLED "A DOUBLE-BLIND, RANDOMIZED CLINICAL STUDY OF THE EFFICACY AND SAFETY OF MONOTHERAPY WITH BCD-254 AND DARZALEX® IN SUBJECTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA" FROM SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY, ISLAMABAD. F. No.03-49/2023-CT (PS).

Decision:

The CSC after discussion acceded to the Quarterly Progress Report of already approved Clinical Trial titled, "A Double-Blind, Randomized Clinical Study of the Efficacy and Safety of Monotherapy with BCD-264 and Darzalex® in Subjects with Relapsed and Refractory Multiple Myeloma".

Case No. 6.2

FINAL CLINICAL STUDY REPORT OF TRIAL TITLED, "A PHASE 3, MATRIX DESIGN, PARTIALLY DOUBLE-BLIND, RANDOMIZED STUDY OF THE EFFICACY AND SAFETY OF 50 MG LONAFARNIB/ 100 MG RITONAVIR BID WITH AND WITHOUT 180 MCG PEG IFN-ALFA-2A FOR 48 WEEKS COMPARED WITH PEG IFN-ALFA-2A MONOTHERAPY AND PLACEBO TREATMENT IN PATIENTS CHRONICALLY INFECTED WITH HEPATITIS DELTA VIRUS BEING MAINTAINED ON ANTI- HBV NUCLEOS(T)IDE THERAPY (D-LIVR)". F. No.03-08/2019-DD (PS)

Decision:

The CSC after deliration:

i. *acceded to the final Clinical Study Report of already approved Clinical Trial titled, "A PHASE 3, MATRIX DESIGN, PARTIALLY DOUBLE-BLIND, RANDOMIZED STUDY OF TFIE EFFICACY AND SAFETY OF 50 MG LONAFARNIB/ 100 MG RITONAVIR BID WITH AND WITHOUT I80 MCG PEG IFN-ALFA.2A FOR 48 WEEKS COMPARED WITH PEG IFN-ALFA-2A MONOTHERAPY AND PLACEBO TREATMENT IN PATIENTS CHRONICALLY INFECTED WITH HEPATITIS DELTA VIRUS BEING MAINTAINED ON ANTIHBV NUCLEOS(T)IDE THERAPY (D-LIVR)".*

ii. *Decided to conduct GCP Inspection of the trial.*

Case No. 6.3

QUARTERLY PROGRESS REPORT OF CLINICAL TRIAL TITLED "A MULTICENTER, RANDOMIZED, CONTROLLED, OPEN-LABEL PHASE IIB STUDY TO ASSESS EFFICACY AND SAFETY OF HH-003 INJECTION IN SUBJECTS WITH CHRONIC HEPATITIS DELTA VIRUS INFECTION (HH-003-204)", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-45/2023-CT (PS)

Decision:

The CSC after deliration acceded to the Quarterly Progress Report of already approved Clinical Trial titled, "A multicenter, randomized, controlled, open-label, phase IIb study to assess efficacy and safety of HH-003 injection in subjects with chronic hepatitis delta virus infection.".

Case No. 6.4

CLOSE OUT REPORT OF ViDiSAM PROJECT, TRIAL OF HIGH DOSE VITAMIN D IN THE TREATMENT OF COMPLICATED SEVERE ACUTE MALNUTRITION Ref. No: 03-53/2021.

Decision:

The CSC after deliration:

i. *acceded the Close-Out report of already approved Clinical Trial titled, "Double-Blind Randomized Placebo-Controlled Trial of High-Dose Vitamin D Supplementation in the Treatment of Complicated Severe Acute Malnutrition".*

ii. *Decided to conduct GCP Inspection of the trial.*

Case No. 6.5

PROFGRESS REPORT OF CLINICAL TRIAL TITLED "A MULTI-COUNTRY, MULTI-CENTER, OPEN - LABELLED, RANDOMIZED, CONTROLLED, EXTENDED PHASE III CLINICAL TRIAL TO EVALUATE THE IMMUNOGENICITY AND TOLERABILITY OF SABIN STRAIN INACTIVATED POLIOVIRUS VACCINE ADMINISTERED WITH OR WITHOUT ROUTINE INFANT VACCINES", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-40/2023-CT (PS).

Decision:

The CSC after deliberation acceded to the Progress Report of already approved Clinical Trial titled, "A Multi-country, Multi-center, Open-labelled, Randomized, Controlled, Extended Phase III Clinical Trial to Evaluate the Immunogenicity and Tolerability of Sabin Strain Inactivated Poliovirus Vaccine Administered with or without Routine Infant Vaccines".

Case No. 6.6

PROGRESS REPORT OF CLINICAL TRIAL TITLED "RANDOMIZED CONTROLLED TRIAL TO ASSESS THE IMMUNOGENICITY AND SAFETY OF FULL VERSUS FRACTIONAL DOSE OF PFIZER/BIONTECH, ASTRAZENECA, AND SINOVAC COVID-19 VACCINES GIVEN AS A BOOSTER DOSE AT LEAST 6 MONTHS AFTER PRIMARY VACCINATION SERIES OR PCR-CONFIRMED INFECTION WITH SARS-COV-2 IN HEALTHY ADULTS", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-08/2022-DD (PS)

Decision:

The CSC after deliberation acceded to the Progress Report *of already approved Clinical Trial titled, "Randomized controlled trial to assess the immunogenicity and safety of full versus fractional dose Pfizer/BioNTech, AstraZeneca, and Sinovac COVID-l9 vaccines given as a booster dose at least 6 months after primary vaccination series or PCR-confirmed infection with SARS -CoY-2 in healthy adults.".*

Case No. 6.7

QUARTERLY PROGRESS REPORT OF CLINICAL TRIAL TITLED "A RANDOMIZED, DOUBLE-MASKED, PARALLEL-GROUP, MULTICENTER CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AVT06 COMPARED WITH EU-EYLEA ® IN SUBJECTS WITH NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (ALVOEYE)", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-12/2022-CT.

Decision:

The CSC after deliberation acceded to the Quarterly Progress Report of already approved Clinical Trial titled, "A Randomized, Double-masked, Parallel-group, Multicenter Clinical Study to Evaluate the Efficacy and Safety of AVT06 Compared with EU-Eylea® in Subjects with Neovascular (wet) Age-related Macular Degeneration (ALVOEYE)".

Case No. 6.8

APPLICATION FOR IMPs RECONCILIATION OF CLINICAL TRIAL TITLED "FINDING TREATMENTS FOR COVID-19: A PHASE-II, MULTI-CENTRE, ADAPTIVE PLATFORM TRIAL TO ASSESS ANTIVIRAL PHARMACODYNAMICS IN EARLY SYMPTOMATIC COVID-19 (PLATCOV)", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI.F.No.03-18/2022-CT

Decision:

The CSC after deliberation acceded to the report of panel dated 21st October, 2024 regarding reconciliation and destruction of IMP of Clinical Trial titled, "Finding Treatments for COVID-19: A Phase-II, Multi-Centre, Adaptive Platform Trial to Assess Antiviral Pharmacodynamics in Early Symptomatic COVID-19 (PLATCOV)".

Case No. 6.9

CLOSEOUT REPORT FROM SHIFA INTERNATIONAL HOSPITAL FOR CLINICAL TRIAL "A RANDOMIZED, PHASE-III PLACEBO CONTROLLED TRIAL OF COLCHICINE FOR THE PREVENTION OF PERIOPERATIVE ATRIAL FIBRILLATION IN PATIENTS UNDERGOING THORACIC SURGERY (COP-AF)" CT-0013 / 03-37/2020-DD (PS)

Decision:

The CSC after deliberation acceded to the Close-Out report of already approved Clinical Trial titled, "A Randomized, Phase-III Placebo-Controlled Trial of Colchicine for the Prevention of Perioperative Atrial Fibrillation in Patients Undergoing Thoracic Surgery (COP-AF)".

AGENDA ITEM 7: Miscellaneous Case

Case No. 7.1

APPLICATION FOR GRANT OF 1-YEAR EXTENSION IN TRIAL DURATION OF STUDY TITLED: A PHASE 2 OPEN LABEL STUDY TO ASSESS THE SAFETY AND EFFICACY OF BEMNIFOSBUVIR AND RUZASVIR IN SUBJECTS WITH CHRONIC HEPATITIS C VIRUS INFECTION) REF NO: F.NO.03-17 2023-CT (PS)

Decision:

The CSC after deliberation decided to grant extension in trial duration (as granted by the NBC) for follow-up of the enrolled subjects in Clinical Trial titled, "A Phase 2 Open Label Study to Assess the Safety and Efficacy of Bemnifosbuvir and Ruzasvir in Subjects with Chronic Hepatitis C Virus Infection)".

Case No. 7.2:

APPLICATION FOR EXTENSION IN TRIAL DURATION OF ALREADY APPROVED CLINICAL TRIAL TITLED AS "AZITHROMYCIN & CEFEXIME TREATMENT OF TYPHOID IN SOUTH ASIA TRIAL (ACT-SOUTH ASIA TRIAL). F.NO.03-51/2020 DD (PS).

Decision:

The CSC after deliberation decided to grant extension in trial duration (as granted by the NBC) of Clinical Trial titled, "Azithromycin & Cefixime Treatment of Typhoid in South Asia Trial (ACT-South Asia Trial)", and grant approval for procurement/import of following IMPs:

S. No.	*IMP*	*Dosage Form*	*Strength*	*Pack Size*	*Total quantity required*
1.	*Azithromycin 250 mg*	*Tablet*	*250 mg*	*6 tablets/strip*	*100 strips*
2.	*Azithromycin 500 mg*	*Tablet*	*500 mg*	*3 tablets/strip*	*770 strips*
3.	*Cefixime 400 mg*	*Tablet*	*400 mg*	*10 tablets/strip*	*240 strips*

Further, it is decided that enrollment at following site(s) will be allowed after issuance of their renewed licenses:

i. National Institute of Child Health, Karachi. (CTS-0063).
ii. Aga Khan Hospital for Women, Garden, Karachi. (CTS-0062.

Case No. 7.3

QUERIES RECEIVED FORM INTERNATIONAL JOURNAL OF DERMATOLOGY AND VENEREOLOGY, FOR ETHICAL AND REGULATORY COMPLIANCE OF THE CLINICAL TRIAL TITLED, EFFICACY AND SAFETY OF INFLIXIMAB BIOSIMILAR IN THE TREATMENT OF MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA AN OPEN LABEL SINGLE GROUP CLINICAL TRIAL. F.No.08-10/2024

Decision:

The CSC after deliberation decided to:

i. *Grant personal hearing to Dr. Faria Asad, Professor & Head of Dermatology Department, SIMS/Services Hospital Lahore, under Rule 22(2) for violation of Rule 14 (1&2) of Bio-Study Rules, 2017.*

ii. *Refer the case to I&E Section of QA&LT Division for violation of the conditions of NOC issued under the Drugs (Import & Export) Rules 1976.*

Case No. 7.4

REVIEW REPORT ON "NATIONAL BIOSAFETY GUIDELINES FOR RESEARCH, DEVELOPMENT AND PRODUCTION OF HUMAN STEM CELLS" AND CONSTITUTION OF A WORKING GROUP FOR REVISION / AMENDMENT OR DEVELOPMENT OF STEM CELL GUIDELINES IN LINE WITH THE BIO-STUDY RULES, 2012, THE DRAP ACT, 2012, RULES MADE UNDER. F. No.08-18/2021 DD (PS)

Decision:

The CSC after deliberation decided to:

i. *Share "National Biosafety Guidelines for Research, Development and Production of Human Stem Cells" with all CSC member through email for review.*

ii. *The CSC members will review local and international guidelines on instant matter and will share their comments to the Pharmacy Services Division for consideration in the forthcoming meeting.*

Case No. 7.5

DSMB REPORT OF EXTENDED CLINICAL TRIAL REFRENCE TO THE CLINICAL VALIDATION REPORT ICU VENTILATOR "ALNNOVENT" MANUFACTURED BY THE ALSONS GROUP IN PAKISTAN. [03-68/2021-DD(PS).

Decision:

The CSC after deliberation:

i. *Advised to follow up the case with Legal Affairs Division for their valuable input.*

ii. *The committee authorized Chairman, CSC to dealt the matter in the light of opinion of Legal Affairs Division;*
and keeping in view recommendations by the Chairman Sub-Committee on Ventilators, Prof. Dr. Iqbal Memon & Dr. Nabeel Anwar, HOD Research Bio-

Medical Engineering, NUST (Co-Opted Member for the Sub-Committee) to refer the case to the Medical Devices Board for further evaluation, interpretation of technical details contained in the DSMB report submitted by the applicant.

iii. *The matter shall accordingly be placed before the forthcoming meeting of CSC for information.*

Case No. 7.6:

APPLICATION FOR APPROVAL OF IMPORT OF REFERENCE TESTING KITS FOR CLINICAL TRIAL TITLED "LAY USER EVALUATION OF THE PANBIO™ HCV SELF TEST: A PROSPECTIVE, MULTICENTER, OBSERVED UNTRAINER USER STUDY" (SDRD-I-030-P) FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI THOUGH M/S METRICS RESEARCH KARACHI (CRO). F. No.03-57/2024-CT (PS)

Decision:

The CSC after deliberation decided to:

i. *allow import of reference testing kits. Details of reference kits is as mentioned below:*

Estimated No of Samples to be tested	***Extra/backup***	***Total no. of kits to be imported***
60-80	*20*	*100*
Number of Packs and boxes	*1 Kit*	
	20 Kits/Box (05 Boxes)	
Packaging Site and Address of Kits	*Technologie park 6-B-9052 Gent, Belgium*	
Batch Number and Expiry Date of Kits	*Batch no. 291838.* *Manufacturing date: 2024.08.19 &* *Expiry Date: 2025.09.30*	

ii. *The applicant shall approach relevant field office of DRAP for issuance of import license under Import & Export Rules, 1976.*

The Meeting ended with vote of thanks to and from the Chair.

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