MINUTES OF THE 50TH CLINICAL STUDIES COMMITTEE MEETING HELD ON 11TH JULY 2024
(SUMMARY)

Division of Pharmacy Services, Drug Regulatory Authority of Pakistan
File No: 16-50/2024-CSC (PS)

JULY 11, 2024
DRUG REGULATORY AUTHORITY OF PAKISTAN
Prime Minister's National Health Complex, Park Road,
Islamabad.

	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)**	
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25.	**ITEM XXIV:** 1ST MEETING OF SUB-COMMITTEE ON SAES HELD ON 10TH JULY 2024, F.NO.16-48-1/2024-CSC (PS)	**100**

The 50th meeting of the Clinical Studies Committee was held on 11th July, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister Health Complex, Park Road Chak Shahzad, Islamabad. The meeting was started with recitation of the Holy Verses of Quran.

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

Sr. No.	Name	Designation	
i.	Dr. Obaidullah	Director Pharmacy Services Division.	*Ex-officio Chairman*
ii.	Mr. Ahsan Ul Haq Athar	Deputy Director, Pharmacy Services Division.	*Ex-officio Secretary*
iii.	Prof. Dr. Fazal Subhan	Department of Pharmacy, CECOS University of IT and Emerging Sciences, Peshawar, Khyber Pakhtunkhwa.	Member
iv.	Prof. Munawar Alam Ansari.	Professor of Pharmacology, Dean Faculty of Pharmacy, Liaquat University of Medical Sciences, Jamshoro. *(Sindh)*	Member
v.	Dr. Faiza Bashir	Nominee of Chairman, Pakistan Health Research Council, Islamabad.	Member
vi.	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 attended the meeting online through Zoom application.

i.	Prof. Dr. Saeed Ahmad Khan	Professor of Medicine Bolan Medical College Quetta presently serving as head of Medicine Department Jhalawan Medical College Khuzdar, Balochistan.	Member
ii.	Mr. Waqas Latif	Data Analyst/Biostatistician in Quality Enhancement Cell (QEC) at University of Health Sciences, Lahore, Punjab.	Member
iii.	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. Malik Muhammad Asad, Dr. Nouman Yousuf and Mr. Shafqat Hussain Danish assisted the Committee and the Secretary in presentation of the agenda and recording minutes of the meeting.

AGENDA ITEM I:

CONFIRMATION OF THE MINUTES OF THE 49th CLINICAL STUDIES COMMITTEE MEETING.

The minutes of the 49th CSC meeting, held on 16th May, 2024. Minutes 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 to all applicants and are placed for confirmation by members.

2. Minutes of the 49th CSC meeting were placed before the Committee.

Decision:

All the Members of the CSC confirmed the Minutes of 49th CSC meetings.

AGENDA ITEM II:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM DR. RUTH KM PFAU CIVIL HOSPITAL KARACHI, KARACHI F. No.15-59/2023-CTS.

Decision:

The CSC after detailed deliberation and discussion, acceded the request for cancellation of licence number CTS-0015 issued for Women-II Clinical Trial (Phase-III) and decided to grant new licence to Department of Obstetrics and Gynecology, Dr. Ruth KM Pfau Civil Hospital Karachi, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only as per CSC decision taken in its 49th meeting held on 16th May 2024.

AGENDA ITEM III:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM KOOHI GOTH WOMEN'S HOSPITAL, KARACHI F. No.15-56/2023-CTS.

Decision:

The CSC after detailed deliberation, discussion, acceded the request for cancellation of licence number CTS-0028 issued for Women-II Clinical Trial (Phase-III) and decided to grant new licence to Department of Gynecology & Obstetrics, Koohi Goth Women's Hospital, Koohi Goth, Deh Landhi, Bin Qasim Town, Karachi, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only as per CSC decision taken in its 49th meeting held on 16th May 2024.

AGENDA ITEM IV:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM JINNAH POSTGRADUATE MEDICAL CENTER (JPMC), KARACHI F. No.15-58/2023-CTS.

Decision:

The CSC after detailed deliberation, discussion, acceded the request for cancellation of licence number CTS-0016 issued for Women-II Clinical Trial (Phase-III) and decided to grant new licence to department of Obstetrics /Gynae, Jinnah Postgraduate Medical Centre, Rafiqui Shaheed Road Karachi, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only as per CSC decision taken in its 49th meeting held on 16th May 2024.

AGENDA ITEM V:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM SHEIKH ZAYED WOMEN HOSPITAL, LARKANA, KARACHI F. No.15-58/2023-CTS.

Decision:

The CSC after detailed deliberation, discussion, acceded the request for cancellation of licence number CTS-0011 issued for Women-II Clinical Trial (Phase-III) and decided to grant new licence to Department of Obstetrics / Gynae, Sheikh Zayed Women Hospital, Chandka Medical College, Shaheed Mohtarma Benazir Bhutto Medical University Larkana, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only as per CSC decision taken in its 49th meeting held on 16th May 2024.

AGENDA ITEM VI:

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 detailed deliberation and discussion, decided to defer the case and directed to submit revised application from expert person/employee of the M/s Dr. Ruth K. M. Pfau Civil Hospital Karachi, along-with necessary documents as required under rule 3 of the Bio-Study Rules, 2017.

AGENDA ITEM VII:

TRIAL SPECIFIC APPLICATION FOR LICENSE TO ACT AS TRIAL SPECIFIC (PHASE-II AETA, AT01B004) CLINICAL TRIAL SITE FROM CENTRAL PARK TEACHING HOSPITAL, LAHORE. F. No.15-42/2023 CTS (PS).

Decision:

The CSC after detailed deliberation and discussion, acceded to the request of the applicant to withdraw the application of Central Park Teaching Hospital, Lahore, for approval of Phase-II trial specific Clinical Trial Site.

AGENDA ITEM VIII:

APPLICATION FOR RENEWAL OF LICENCE NO. CRO-0003, TO ACT AS CONTRACT RESEARCH ORGANIZATION FROM M/S METRICS RESEARCH (PVT) LTD., KARACHI. F. No.15-21/2022-CRO.

Decision:

The CSC discussed the submitted reply and found satisfactory.

AGENDA ITEM IX:

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 detailed deliberation, discussion, decided to refer the case to the Legal Affairs Division of the DRAP for following clarifications:

i. *Whether a Public Sector University / government entity can operate as a CRO or otherwise?.*
ii. *Requirement of registration with SECP to operate as a CRO by a Public Sector University / government.*

AGENDA ITEM X:

APPLICATION FOR RENEWAL OF LICENSE TO ACT AS CRO, BY M/S CYNTAX HEALTH PROJECTS ISLAMABAD. F. No.15-52/2020 DD(PS).

Decision:

The CSC after detailed deliberation, discussion and on recommendation of inspection panel, decided

i. *to grant the renewal of licence (CRO-0008) to act as Contract Research Organization to M/s Cyntax Health Projects, Office No. 3, 4,5,6 and 13, Floor 1, Zamzama Center, Pakistan Town Phase-II, Islamabad, for the period of three years (w.e.f. 24th December 2023 to 23rd December 2026).*
ii. *directed the applicant to fulfill/ address following shortcomings/panel recommendations within period of three months and to submit compliance to the Division of Pharmacy Services, DRAP Islamabad;*
    a. *Installation of fire alarm specifically in archive room.*
    b. *Replace wooden cabinet with iron steel cabinets.*
    c. *Improvements in QMS manual and training plan.*

AGENDA ITEM XI:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE-III ONCOLOGY FROM ONCOLOGY DEPARTMENT, KING EDWARD MEDICAL UNIVERSITY/ MAYO HOSPITAL, LAHORE. F. No.15-48/2023 DD (PS).

Decision:

The CSC after detailed deliberation and discussion, decided to extend the scope of already issued licence i.e. Department of Medical Oncology, Mayo Hospital, (CTS-0090) and allowed the conduct of already approved Clinical Trials mentioned below:

i. *"A Double-Blind, Randomized Clinical Study of the Efficacy and Safety of BCD-263 and OPDIVO® as Monotherapy in Subjects with Advanced Melanoma of the skin". (CT-0069)*
ii. *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". (CT-0074)*

AGENDA ITEM XII:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE-II, III & IV FROM NATIONAL UNIVERSITY OF MEDICAL SCIENCES, RAWALPINDI. F. No.15-34/2023 DD (PS).

Decision:

The CSC after detailed deliberation, discussion, decided to

i. *Cancel the licence (CTS-0095) issued to Pak Emirates Military Hospital, Rawalpindi.*
ii. *Issue the CTS licence to M/s National University of Medical Sciences, situated at Pak Emirates Military Hospital and allied institutes (AFIC, AFIO, AFIMH, AFIRI) for Phase II, III and IV.*
iii. *For Phase-II studies, site visit may be done to confirm the relevant facilities required as per study protocol and to identify and minimize the risks to ensure subject safety.*

AGENDA ITEM XIII:

APPLICATION FOR APPROVAL OF PLACEBO PREPARATION BY PHARMACEUTICAL MANUFACTURER AND APPROVAL OF CLINICAL TRIAL TITLED "A PILOT STUDY OF AN ADAPTIVE, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFECTS OF METFORMIN IN REDUCING FATIGUE IN LONG-COVID ADOLESCENT SUBJECTS WITH PERSISTENT FEATURES" (REVIVE TRIAL) FROM TVI (CRO) KARACHI. F. NO.03-54/2024-CT (PS)

Decision:

The CSC after detailed deliberation, discussion, decided to:

i. *Approve the clinical trial titled "a pilot study of an adaptive, double-blind, randomized, placebo-controlled study to evaluate the effects of metformin in reducing fatigue in long-covid adolescent subjects with persistent features" to be conducted at following sites:*
    a. *Creek General Hospital, Karachi. (CTS-0077).*
    b. *Children Hospital Lahore (CTS-0087)*
ii. *Direct the PI to conduct base line tests (e.g. LFTs, RFTs, Blood Glucose, and CBC) before enrollment, at 14th day, 28th day and after every month during follow up period. The subjects with liver and renal impairment/ diseases shall not be enrolled in the trial.*

AGENDA ITEM XIV:

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, discussion, decided to issue reminder to the applicant in the light of CSC decision taken in its 49th CSC meeting held on 16th May 2024.

AGENDA ITEM XV:

APPLICATION FOR APPROVAL OF 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 detailed deliberation, discussion, decided as follows:

i. *to approve Clinical Trial titled, "Lay User Evaluation of The Panbio™ HCV Self-Test: A Prospective, Multicenter, Observed Untrainer User Study" (Sdrd-I-030-P)" to be conducted at Aga Khan University Hospital, Karachi (CTS-0003).*
ii. *A total of **1200** Panbio- HCV self-testing kits are to be used by 600 enrolled participants (2 per participant). Keeping a margin of 20% (240). A Total of **1440** kits will be imported to for the study.*

iii. *Proposed site "Clinic 553,554, 5th floor, Doctor's Plaza, Clifton, Karachi" will be considered after inspection by the panel and consideration of the CSC.*

AGENDA ITEM XVI:

REGISTRATION BOARD DECISION FORWARDED BY THE BIOLOGICALS DIVISION FOR CSC OPINION ON CLINICAL TRIAL AND DATA NECESSITY FOR REGISTRATION OF BIOSIMILAR (BIOLOGICAL) PRODUCT

Decision:

The CSC after detailed deliberation and discussion advised to forward following decision to the BE&R Division:

i. *The CSC notified and work under the Bio-Study Rules, 2017 for Clinical Trial Oversight in the country and instant application is not for the conduct of any clinical trial / study hence its not the mandate of CSC.*
ii. *However, the Committee is of the view that Pharmacokinetic study is one of the parts of the Phases of the Clinical Trials and can't substitute Phase-I, II and III studies, as already mentioned in the Registration Board. Moreover, Registration Board may decide the application as per merit of the case.*

AGENDA ITEM XVII:

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 detailed deliberation, discussion, decided the 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.

AGENDA ITEM XVIII:

APPLICATION FOR AMENDMNET IN DIFFERENT DOCUMENTS (PROTOCOL, IB, ICF & FOLLOW UP MEMO/TRANSCRIPT) IN ALREADY APPROVED CLINICAL TRIAL TITLED "A PHASE 3, RANDOMIZED, OBSERVER-BLIND, CONTROLLED, MULTICENTER, CLINICAL STUDY TO EVALUATE IMMUNOGENICITY AND SAFETY OF A HIGH-DOSE MF59 ADJUVANTED QUADRIVALENT SUBUNIT CELL-DERIVED INFLUENZA VACCINE (aQIVc HD) IN COMPARISON WITH A NON-ADJUVANTED QUADRIVALENT RECOMBINANT INFLUENZA VACCINE (QIVr) AND AN MF59-ADJUVANTED QUADRIVALENT SUBUNIT EGG-DERIVED INFLUENZA VACCINE (aQIV), IN ADULTS AGED 50 YEARS AND OLDER", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-46/2023-CT (PS

Decision:

The CSC after detailed deliberation, discussion, decided to approve following documents of already approved Clinical Trial titled "A Phase 3, Randomized, Observer-Blind, Controlled, Multicenter, Clinical Study to Evaluate Immunogenicity and Safety of a High-Dose MF59-Adjuvanted Quadrivalent Subunit Cell derived Influenza Vaccine (aQIVc HD) in Comparison with a Non-adjuvanted Quadrivalent Recombinant Influenza Vaccine (QIVr) and an MF59-Adjuvanted Quadrivalent Subunit Egg derived Influenza Vaccine (aQIV), in Adults Aged 50 Years and Older"

S.No.	*Document Name*	*Version*	*Date*

1	*V201_03 Protocol Version 3.0 (clean, track & Summary of Changes document)*	*3.0*	*08Dec2023*
2	*Protocol Clarification memo*	*3.0*	*19Dec2023*
3	*Final Signed Protocol Amendment V4.0 (clean, track change, Summary of changes)*	*V4.0*	*29Feb2024*
4	*aQIV Investigator's Brochure (clean, track & Summary of Changes document)*	*Ed. 5.0*	*30Aug2023*
5	*aQIVc Investigator Broucher (clean & track change)*	*Ed. 5.0*	*05Apr2024*
6	*V201-03_PAK Long Term Extension ICF (English, Urdu & TCert)*	*V1.0PAK1.0*	*06Mar2024*
7	*Safety Follow Up Day 271 and Day 365 (English, Urdu & TCert)*	*V1.0*	*01Mar2024*

AGENDA ITEM XIX:

APPLICATION FOR IP DESTRUCTION OF 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 detailed deliberation, discussion considering the case directed the applicant to be careful in future and follow the Drugs (Import & Export) Rules 1976 in true spirit, for import and expot of IMPs.

AGENDA ITEM XX:

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 detailed discussion and deliberation decided to reconsider the case after fulfillment of following recommendations of Sub-Committee on SAEs:

a. *The AEs and SAEs are required to be classified clearly with incorporation of necessary details required for the ascertainment of relatedness of the event with the use of IMP.*
b. *Complete data may be resubmitted to the IRB for their reconsideration of causality assessment.*

AGENDA ITEM XXI:

CLOSEOUT REPORT QUERY RESPONSE FROM SITE OF SHIFA INTERNATIONAL HOSPITAL DATED 10.10.2023 OF THE CLINICAL TRIAL "PERI-OPERATIVE ISCHEMIC EVALUATION-3 (POISE-3) TRIAL. F.NO.03-07/2019-CT(PS)

Decision:

The CSC after detailed discussion and deliberation decided to reconsider the case after fulfillment of following recommendations / clarification of Sub-Committee on SAEs:

a. *The AEs and SAEs are required to be classified clearly with incorporation of necessary details required for the ascertainment of relatedness of the event with the use of IMP.*
b. *Complete data may be resubmitted to the IRB for reconsideration of causality assessment.*
c. *Patient ID 520-015 was enrolled on 03.03.2020 and discharged on 08.03.2020 while referring to another hospital on account of financial constraints. This is prima facie a breach of ICF which needs to be explained.*

d. *The sub-committee was apprised that results of this study have already been published in an international journal.*

AGENDA ITEM XXII:

CLINICAL TRIAL TITLED, "A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATE THE EFFECT OF, Bi-26 (STAIN OF BIFIDOBACTERIUM LONGUM, B. INFANTIS) SUPLEMENTATION VS PLACEBO ON WEIGHT GAIN ON UNDER WEIGHT INFANTS", AL-SHIFA TRUST EYE HOSPITAL, RAWALPINDI. F. No.03-31/2023-DD (PS)

NOTIFICATION FOR DISCONTINUATION OF CLINICAL TRIAL "A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFECT OF BI-26 (STRAIN OF BIFIDOBACTERIUM LONGUM, B. INFAMY SUPPLEMENTATION VERSUS PLACEBO ON WEIGHT GAIN IN UNDERWEIGHT INFANTS".

Decision:

The CSC after detailed deliberation and discussion, decided to accede the request of the applicant to terminate the clinical trial titled "a phase 3, randomized, double-blind, placebo-controlled study to evaluate the effect of Bi-26 (strain of Bifidobacterium longum, B. infamy supplementation versus placebo on weight gain in underweight infants"

AGENDA ITEM XXIII:

A. AMENDMENTS IN PROTOCOL, INVESTIGATOR BROCHURE AND ICF OF APPROVED CLINICAL TRIAL "A PHASE III, RANDOMIZED, COMPARATOR-CONTROLLED, DOUBLE-BLIND, MULTICENTER STUDY TO EVALUATE THE IMMUNOGENICITY, SAFETY AND LOT TO LOT CONSISTENCY OF THREE LOTS OF A PIKA RABIES VACCINE (VERO CELL) FOR HUMAN USE, FREEZE DRIED IN HEALTH ADULTS USING A POST EXPOSURE PROPHYLAXIS SCHEDULE F.NO.03-36/2023-CT (PS) CT-0053

Decision:

The CSC after detailed deliberation, discussion, decided to approve following documents of already approved Clinical Trial titled "A PHASE III, RANDOMIZED, COMPARATOR-CONTROLLED, DOUBLE-BLIND, MULTICENTER STUDY TO EVALUATE THE IMMUNOGENICITY, SAFETY AND LOT TO LOT CONSISTENCY OF THREE LOTS OF A PIKA RABIES VACCINE (VERO CELL) FOR HUMAN USE, FREEZE DRIED IN HEALTH ADULTS USING A POST EXPOSURE PROPHYLAXIS SCHEDULE".

Sr.	Document	Version	Effective Date
1.	YS-002 Protocol V4.0 22Apr2024	4.0	22-Apr-2024
2.	YS-002 Main ICF v3.0 Master 22 Apr 2024	3.0	22-Apr-2024
3.	YS-002 Main ICF v3.0 PAK_English 22 April 2024	3.0	22-Apr-2024
4.	YS-002 PAK Main ICF v3.0 22 April 2024 Urdu	3.0	22-Apr-2024
5.	Investigator Brochure_YS-ON-001-v7.0_Dated_12Apr2024	7.0	12-Apr-2024

B. APPLICATION FOR RECOMMENDATION AND REGISTRATION OF PIKA RABLES VACCINE (VERO CELL) FOR HUMAN USE, FREEZE-DRIED

Decision:

The CSC after detailed deliberation, discussion, decided as follows:

i. *Applicant/PI directed to submit complete Clinical Study Report, which will be placed before the Committee for further consideration.*

AGENDA ITEM XXIV:

AMENDMENTS IN CLINICAL TRIAL "A DOUBLE-BLIND, RANDOMIZED CLINICAL STUDY OF THE EFFICACY AND SAFETY OF BCD-178 AND PERJETA® AS NEOADJUVANT THERAPY OF HER2-POSITIVE BREAST CANCER (PREFER)" F.NO.03-44/2023-CT (PS)

Decision:

The CSC after detailed deliberation, discussion, decided to approve following documents of already approved Clinical Trial titled "A Double-Blind, Randomized Clinical Study of the Efficacy and Safety of BCD-178 and PERJETA® as Neoadjuvant Therapy of HER2-Positive Breast Cancer (PREFER)", subject to provision of IRB/ERC approval from all participating sites.

Documents	Latest version and effective date
Clinical Study Protocol	Version 4, March 28, 2024
Patient Information Sheet and Informed Consent Form for female subjects of the clinical study (English)	Version 4, PAK, dated May 23, 2024
Patient Information Sheet and Informed Consent Form for female subjects of the clinical study (Urdu)	Version 4, PAK, dated May 23, 2024

AGENDA ITEM XXV:

1ST MEETING OF SUB-COMMITTEE ON SAES HELD ON 10TH JULY 2024, F.NO.16-48-1/2024-CSC (PS)

Recommendations of the Sub-Committee:

i. *The committee recommends that there may be a harmonized format for submission of SAEs, which needs to be more elaborative for better evaluation and understanding.*
ii. *Baseline lab investigations relevant to the trial (e.g. CBC, LFT, RFT, C-XR, ECG etc.) may be done before the enrolment of subjects.*
iii. *GCP audit after the commencement of recruitment, during the study can help to safeguard the subjects and avoid breach of ICH-GCP guidelines. (if required)*

4. The CSC accepted recommendation of the Sub-Committee on SAEs.

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