MINUTES FOR THE 49TH CLINICAL STUDIES COMMITTEE MEETING, HELD ON 16TH MAY 2024

Pharmacy Services Division, Drug Regulatory Authority of Pakistan
File No: 16-49/2024-CSC (PS)

MAY 16, 2024
DRUG REGULATORY AUTHORITY OF PAKISTAN
Prime Minister Health Complex, Park Road, Chak Shahzad,
Islamabad.

	(aQIV), IN ADULTS AGED 50 YEARS AND OLDER", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. **F. No.03-46/2023-CT (PS)** **B.** NOTIFICATION OF GLOBAL SUSAR ALERT REPORT OF 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)**	
14.	**ITEM XIV:** REQUEST FOR AMENDMENTS IN ALREADY APPROVED CLINICAL TRIAL TITLED "RANDOMIZED, OPEN LABEL, MULTICENTER, NON-INFERIORITY CLINICAL TRIAL FOR NEW TREATMENT MODALITIES FOR CUTANEOUS LEISHMANIASIS CAUSED BY LEISHMANIA TROPICA". **F. No.03-60/2021 DD (PS)**	**95-96**
15.	**ITEM XV:** **A.** CLINICAL TRIAL TITLED, "A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFECT OF, Bi-26 (STRAIN OF BIFIDOBACTERIUM LONGUM, B. INFANTIS) SUPLEMENTATION VS PLACEBO ON WEIGHT GAIN ON UNDER WEIGHT INFANTS" **F. No.03-31/2023-DD (PS).** **B.** AMENDMENTS FOR CLINICAL TRIAL "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).** **C.** REQUEST FOR EXTENSION OF DRAP STUDY APPROVAL. **F. No.03-31/2023-DD (PS).**	**97-106**
16.	**ITEM XVI:** REQUEST TO EXTEND THE SAFETY OBSERVATION PERIOD FROM 12 MONTHS TO 15 MONTHS (WITHOUT A BREAK IN THE ONGOING FOLLOW UP) FOR CLINICAL TRIAL TITLED, "A MULTI-CENTER, RANDOMIZED, BLINDED, PLACEBO-CONTROLLED, PHASE-III CLINICAL STUDY TO EVALUATE THE EFFICACY, SAFETY AND IMMUNOGENICITY OF SARS-COV-2 BIVALENT mRNA VACCINE (LVRNA021) AS BOOSTER IN PARTICIPANTS AGED 18 YEARS AND OLDER WHO COMPLETED PRIMARY/1 BOOSTER DOSE(S) OF SARS-COV-2 VACCINATION"	**107-109**
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18.	**ITEM XVIII:** APPLICATION FOR AMENDMENT IN TRILA PROTOCOL & INVESTIGATOR'S BROCHURE OF ALREADY APPOVED 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 **(sIPV)** ADMINISTERED WITH OR WITHOUT ROUTINE INFANT VACCINES", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. **F. No.03-40/2023-CT (PS).**	**112-114**
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The 49th meeting of the Clinical Studies Committee was held on 16th May, 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.	Prof. Dr. Fazal Subhan	Department of Pharmacy, CECOS University of IT and Emerging Sciences, Peshawar, Khyber Pakhtunkhwa.	Member
iii.	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
iv.	Dr. Faiza Bashir	Nominee of Chairman, Pakistan Health Research Council, Islamabad.	Member
v.	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
vi.	Mr. Ahsan Ul Haq Athar	Deputy Director, Pharmacy Services Division.	*Ex-officio Secretary*

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

i.	Mr. Waqas Latif	Data Analyst/Biostatistician in Quality Enhancement Cell (QEC) at University of Health Sciences, Lahore, Punjab.	Member

4. 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 48th CLINICAL STUDIES COMMITTEE MEETING.

The minutes of the 48th CSC meeting held on 28th March, 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 48th CSC meeting were placed before the Committee.

Decision:

All the Members of the CSC confirmed the Minutes of 48th CSC meetings.

AGENDA ITEM II:

APPLICATION FOR LICENSE OF CLINICAL RESEARCH ORGANIZATION (CRO) FOR PROMEDIX (PRIVATE) LIMITED, MULTAN F. No.15-54/2022 DD (PS).

Decision:

The CSC after detailed deliberation, discussion and on recommendation of inspection panel, decided to grant the licence to M/s Promedix (Private) Limited, Building No.12, Block C, Shah Rukn-e-Alam Colony, Multan to act as Contract Research Organization, under the Bio-Study Rules, 2017.

AGENDA ITEM III:

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 detailed deliberation, discussion and on recommendation of inspection panel, decided to defer the case for following improvements:

i. *SOPs for clinical research procedures like randomization & screening, enrolment, appropriate ICF implementation, patient safety & confidentiality, administration of IMP with strict adherence to the protocol, follow-up, & safety reporting, data management, confidentiality, authorization & report writing, role of Co-PIs etc.*
ii. *Job descriptions of all clinical research team was not available.*
iii. *Team lacks the training on PV & safety reporting and data archiving, authorization & confidentiality.*
iv. *Renovation and construction procedures ongoing for Gynae & Obs. Ward.*

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 and on recommendation of inspection panel, decided to grant the 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. The site will initiate the trial after fulfilment of following improvements:

i. *Appointment of study specific pharmacists.*
ii. *The staff will be trained regarding study specific activities by the Sponsor / national study coordinator.*
iii. *To establish a system for personnel, to report any safety concern or incidents.*
iv. *For appropriate data handling and archiving, the Sponsor will provide electronic gadgets (Tablets).*

AGENDA ITEM V:

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, discussion and on recommendation of inspection panel, decided to grant the licence to Department of Obstetrics and Gynaecology at Dr Ruth KM Pfau Civil Hospital Karachi, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only. The site will initiate the trial after fulfilment of following improvements:

i. *Appointment of study specific pharmacists.*
ii. *The staff will be trained regarding study specific activities by the Sponsor / national study coordinator.*
iii. *To establish a system for personnel, to report any safety concern or incidents.*
iv. *For appropriate data handling and archiving, the Sponsor will provide electronic gadgets (Tablets).*

AGENDA ITEM VI:

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 and on recommendation of inspection panel, decided to grant the licence to Department of Obstetrics and Gynaecology at 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. The site will initiate the trial after fulfilment of following improvements:

i. *Appointment of study specific pharmacists.*
ii. *The staff will be trained regarding study specific activities by the Sponsor / national study coordinator.*
iii. *To establish a system for personnel, to report any safety concern or incidents.*
iv. *For appropriate data handling and archiving, the Sponsor will provide electronic gadgets (Tablets).*

AGENDA ITEM VII:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM FEDERAL GOVERNMENT POLYCLINIC HOSPITAL, ISLAMABAD F. No.15-64/2023-CTS.

Decision:

The CSC after detailed deliberation, discussion and on recommendation of inspection panel, decided to defer the due to following observations:

i. *Dedicated pharmacy for storage of IMPs, needs to be established*
ii. *Controlled entry and exit for record archiving facility*
iii. *Training of CTS staff as required*
iv. *To develop SOPs JDs and other documents to run the clinical trial smoothly.*
v. *Power backup incident reporting in case of AE / SAE emergency handing procedure, fire extinguisher etc.*
vi. *Dedicated space for ICF and patient consent.*

AGENDA ITEM VIII:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, PHASE III, FROM MCH CENTER, PAKISTAN INSTITUTE OF MEDICAL SCIENCES (PIMS), ISLAMABAD F. No.15-66/2023-CTS.

Decision:

The CSC after detailed deliberation, discussion and on recommendation of inspection panel, decided to defer the due to following observations:

i. *Dedicated pharmacy for storage & dispensing of IMP, having controlled entry / exit and equipped with storage facilities (cupboards, transparent bags) is required along with environmental controls (temp. humidity).*
ii. *Control access to the archival facility is required along with IT facilities and system for track and trace of record is to be established.*
iii. *The CTS team needs to be imparted with the necessary trainings for GCP, Safety reporting, PU and other trial / related areas as per requirement of the study.*
iv. *SOPs and JDs for the CTS team was not available, these documents needs to be prepared and implemented for smooth conduction of the trial.*
v. *Power backup, incident reporting in case of AE or SAE, emergency handling, procedure needs to be in place, fire extinguisher, fire ball also needs to be installed.*
vi. *Panel recommends establishment of a dedicated space alongside nursing counter in the labor room for informed consent process.*

AGENDA ITEM IX:

APPLICATION FOR APPROVAL OF A PHASE-III 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" FROM SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY, ISLAMABAD. F. No.03-49/2023-CT (PS).

Decision:

The CSC after detailed deliberation, discussion and considering the reply submitted by the applicant decided to:

i. *Approve the Phase-III 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" under the Bio-Study Rules, 2017, to be conducted at following Clinical Trial Site(s):*

Site(s)	**PI**	**Subjects enrolment**
Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad. (CTS-0052)	Dr. Qasim Mahmood Buttar (Oncologist) **National-PI**	10
Rehman Medical Institute, Peshawar. (CTS-0060)	Dr. Abdul Wahid (Oncologist) **Site-PI**	10
Aga Khan University Hospital, Karachi. (CTS-0003)	Dr. Munira Moosajee (Oncologist) **Site-PI**	10
Ziauddin Hospital, Karachi (CTS-0086)	*Dr. Adnan Abdul Jabbar* (Oncologist) **Site-PI**	10

ii. *Approve the following quantities of IMPs to be imported:*

Drug Name (IMPs)	**Total Quantity of IMP to be imported**

BCD-264/Darzalex 400 mg/20 mL (Double-blind period)	2880 vials
BCD-264 400 mg/20 mL (open-label period)	3600 vials

AGENDA ITEM X:

REQUEST FOR APPROVAL AND REGISTRATION OF BIOEQUIVALENCE STUDY OF DELANZO™DR 60MG (DEXLANSOPRAZOLE) CAPSULE OF M/S SAMI PHARMACEUTICALS (PVT) LTD WITH DEXILANT® 60MG (DEXLANSOPRAZOLE) CAPSULE. F. No. 14-02/2024-BE (PS)

Decision: -

The CSC after detailed discussion and deliberation decided as follows:

a. *to approve the BA/BE Study titled, "A single center, open label, randomized, single-dose, two-period, two-way, cross-over study to compare the rate and extent of absorption of Delanzo™ DR 60 mg (Dexlansoprazole) Capsule with Dexilant® 60mg (Dexlansoprazole) Capsule in Healthy Pakistani Subjects." to be conducted at Center for Bioequivalence Studies & Clinical Research, ICCBS, University of Karachi, Karachi.*
b. *PI will provide details of reference product regarding Import license, mode of purchase and shipment details for record.*

AGENDA ITEM XI:

REQUEST FOR APPROVAL OF PHASE-I CLINICAL TRIAL TITLED "RANDOMIZED, DOUBLE BLINDED, PARALLEL PLACEBO CONTROLLED CLINICAL TRIAL", TO EVALUATE THE SAFETY OF DIETRY HERBAL HEALTH SUPPLEMENT-I (DHS-I), DEVELOPED FOR THE TREATMENT AND/OR MANAGEMENT OF PARKINSON'S DISEASE". F. No.03-63/2021-DD (PS)

Decision: -

The CSC after detailed discussion and deliberation decided to defer the case for submission of reply from PI for following observation of the Committee:

i. *Standardization method for crude drugs/ingredients utilized in manufacture of DHS-I, with relevant reference.*
ii. *Active chemical constituents per gram dose of DHS-I.*
iii. *Methods/parameters for safety and toxicity monitoring in trial subjects.*
iv. *As trial pertains to the Parkinson Disease, so, the CSC suggested to include a Neuro-physician in the trial team as a Co-PI.*

AGENDA ITEM XII:

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 discussion and deliberation decided to defer the case for submission of reply from PI for following observation of the Committee:

i. *Whether, LFTs, RFTs, Blood Glucose and CBC are part of screening procedure of study participants.*
ii. *Safety parameters for Metformin 1000mg in paediatric population of 10-18 years of age.*
iii. *Rationale / mechanism of action of Metformin, for the treatment of fatigue? As fatigue is not a disease it's a symptom due to any reason or physical activity.*
iv. *The CSC decided to Co-Opt a Child Specialist/Pediatrician for expert review of the trial.*

AGENDA ITEM XIII:

A.
APPLICATION FOR IMPs ACCOUNTABILITY / UTILIZATION REPORT AND APPROVAL OF RE-EXPORT OF UNUSED IMPS TO THE SPONSOR OF 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 delegated the power to the Chairman CSC for constitution of the inspection panel to visit the site for IMPs accountability / reconciliation. The nominated panel after reconciliation will generate a report which will be forwarded to the Chairman CSC for further approval for re-export of the IMPs.

B.
NOTIFICATION OF GLOBAL SUSAR ALERT REPORT OF 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 delegated the power to the Chairman CSC for constitution of the panel for GCP Inspection and SUSAR verification (especially of Subject ID: 58501- 013). The nominated panel will generate a report which will be forwarded to the Chairman CSC for further consideration and decision.

AGENDA ITEM XIV:

REQUEST FOR AMENDMENTS IN ALREADY APPROVED CLINICAL TRIAL TITLED "RANDOMIZED, OPEN LABEL, MULTICENTER, NON-INFERIORITY CLINICAL TRIAL FOR NEW TREATMENT MODALITIES FOR CUTANEOUS LEISHMANIASIS CAUSED BY LEISHMANIA TROPICA". F. No.03-60/2021 DD (PS)

Decision: -

The CSC after detailed discussion and deliberation decided to defer the case for submission of following documents:

i. *Urdu Translation of "Revised Informed Consent Form".*
ii. *Urdu Translation of "Assent Form".*
iii. *IRB approvals of all active sites of the trial.*

AGENDA ITEM XV:

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

Decision in 49th CSC Meeting:

The CSC after detailed discussion and deliberation decided that trial will remain suspended and will be further deliberated in light of recommendation of GCP inspection report and decision of NBC.

B. **AMENDMENTS FOR CLINICAL TRIAL "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)**.

Decision in 49th CSC Meeting:

The CSC after deliberations decided to defer the following amendments because the trial is still suspended and NBC approval is still pending.

C. **REQUEST FOR EXTENSION OF DRAP STUDY APPROVAL. F. No.03-31/2023-DD (PS)**

Decision in 49th CSC Meeting:

The CSC after deliberations decided to defer the request for extension of DRAP approval because the trial is still suspended and NBC approval is still pending.

AGENDA ITEM XVI:

REQUEST TO EXTEND THE SAFETY OBSERVATION PERIOD FROM 12 MONTHS TO 15 MONTHS (WITHOUT A BREAK IN THE ONGOING FOLLOW UP) FOR CLINICAL TRIAL TITLED, "A MULTI-CENTER, RANDOMIZED, BLINDED, PLACEBO-CONTROLLED, PHASE-III CLINICAL STUDY TO EVALUATE THE EFFICACY, SAFETY AND IMMUNOGENICITY OF SARS-COV-2 BIVALENT mRNA VACCINE (LVRNA021) AS BOOSTER IN PARTICIPANTS AGED 18 YEARS AND OLDER WHO COMPLETED PRIMARY/1 BOOSTER DOSE(S) OF SARS-COV-2 VACCINATION"

Decision in 49th CSC Meeting:

The CSC after deliberations decided to conditionally approve the extension of the safety observation period from 12 months to 15 months and also approved following documents. However, approval letter will be issued after submission of NBC approval and remaining three IRBs approval.

Document Name	***Version***	***Version Date***
Addendum to Protocol V2.0 dated 27 June, 2023	*1.0*	*April 24, 2024*
Participant re-consent notification	*1.0*	*April 24, 2024*

AGENDA ITEM XVII:

APPLICATION FOR AMENDMENT AND INCREASE IN SUBJECTS ENROLLMENT / INCREASE IN IMP IMPORT IN ALREADY APPROVED CLINICAL TRIAL TITLED, "A PHASE 2, OPEN-LABEL STUDY TO ASSESS THE SAFETY AND EFFICACY OF BEMNIFOSBUVIR (BEM) AND RUZASVIR (RZR) IN SUBJECTS WITH CHRONIC HEPATITIS C VIRUS (HCV) INFECTION" FROM THE AGA KHAN UNIVERSITY (AKUH), STADIUM ROAD, KARACHI. F.NO.03-47/2023-DD-CT-II(PS)

Decision in 49th CSC Meeting:

The CSC after deliberations decided to:

i. *approve the increase in subject's enrollment from 41 to 100 and accordingly approved following amendments:*

Sr.	***Document Name***	***Version***	***Date***
1.	*Protocol clarification memo*	*-*	*12-Dec-2023*
2.	*List of competent authorities*	*12.0*	*21-Nov-2023*
3.	*AT-01B-004_Participant Study Medication Card_ V02 (English, Urdu & TCert)*	*V02*	*22-Sep-2023*
4.	*AT-01B-004_Physician Referral Brochure_V02 (English, Urdu & TCert)*	*V02*	*19-Sep-2023*
5.	*Atea AT-01B-004_Chart Review Checklist*	*V02*	*19-Sep-2023*
6.	*Atea AT-01B-004_Eligibility Criteria Booklet*	*V02*	*19-Sep-2023*
7.	*Atea AT-01B-004_Study information slides*	*V02*	*19-Sep-2023*
8.	*Atea AT-01B-004_Talking Points Guide*	*V02*	*19-Sep-2023*
9.	*AKU IRB Approval letter*	*-*	*18-Mar-2024*
10.	*ZU IRB approval letter*	*-*	*17-Apr-2024*
11.	*NBC approval letter*	*-*	*11-Mar-2024*

ii. *allowed further increase in import of IMPs as per following details with the direction to get Drug Import License and Clearance Certificate from Import & Export section of DRAP.*

Name of IP	***Quantity of IP for 01 patient***	***Quantity of IP for 59 patients***	***Total quantity of IP for 9 patients with 30% overage***
Bemnifosbuvir *Manufacturer:* *M/s Patheon Pharmaceuticals Inc. USA*	*06 Bottles (with 20 tablets each)*	*354 Bottles (with 20 tablets each)*	*461 Bottles (with 20 tablets each)* *9220 tablets total.*
Ruzasvir *Manufacturer:*	*06 Bottles (with 20 capsules each)*	*354 Bottles (with 20 capsules each*	*461 Bottles (with 20 capsules each.*

M/s Seran Bioscience, LLC. USA			*9220 capsules total*

iii. *However, approval letter will be issued after submission of details of medical treatment / insurance in case of any adverse event (whether related or not related to IP) and details of compensation / insurance in case of any fatal SAE, for the increased number of subjects.*

AGENDA ITEM XVIII:

APPLICATION FOR AMENDMENT IN TRILA PROTOCOL & INVESTIGATOR'S BROCHURE OF ALREADY APPOVED 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 decided to approve amendments in already approved 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", *and approved the following amended documents:*

S.No.	*Documents*	*Latest Version*
1	*Trial Protocol_PRO-sIPV-4001*	*3.4, 27th March,2024*
2	*Investigator's Brochure*	*3.0, 27th March,2024*

AGENDA ITEM XIX:

APPLICATION / NOTIFICATION FOR CHANGE OF PRINCIPAL INVESTIGATOR AT ZIAUDDIN UNIVERSITY HOSPITAL KARACHI AND SUBMISSION OF PRINCIPAL INVESTIGATOR'S QUALIFICATION DOCUMENTS FOR 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" FROM SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY, ISLAMABAD. F. No.03-49/2023-CT (PS).

Decision: -

The CSC after deliberation decided to defer the case for submission of following documents:

i. *Letter/Consent from Sponsor regarding change of Site PI of Ziauddin University Hospital Karachi.*
ii. *NBC approval letter for change of Site PI of Ziauddin University Hospital Karachi.*

AGENDA ITEM XX:

APPLICATION FOR APPROVAL OF DESTRUCTION OF EXPIRED/ UNUSED INVESTISATIONAL PRODUCT 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-PS (CT)

Decision: -

The CSC delegated the power to the Chairman CSC for constitution of the inspection panel to visit the site for IMPs accountability / reconciliation and destruction afterwards, subject to submission of prescribed processing fee of Rs.25000/-.

AGENDA ITEM XXI:

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 detailed deliberation, discussion decided to defer the case for fulfilment of following observations:

i. *NBC approval is not provided.*
ii. *Trial protocol is attached but its format is not as per ICH-GCP Guidelines.*
iii. *Summary of Investigator Brochure is not provided.*
iv. *Applicant mentioned that, they will purchase insurance for trial participants but evidence regarding insurance details/proposal is not provided.*
v. *Applicant provided details about IP but details regarding PDT equipment/device or required chemicals and about Standard of Care (SOC) IP/Products, equipment/device and their procurement process is not provided.*
vi. *Prof. Dr. Raza Shah is nominated as Co-PI in the study application and in the protocol. It is pertinent to mention here that, nominated Co-PI is General manager of nominated CRO, and he can't participate in the trial as a Co-PI due to conflict of interest.*
vii. *Protocol need to be revised as per point number vi.*

AGENDA ITEM XXII:

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

Application was received from Prof. Rizwana Chaudhry wherein she has enclosed application of Prof. Dr. Shahida Shaikh Magsi of M/s Sheikh Zayed Women Hospital, Larkana has applied for grant of licence to act as Clinical Trial Site for phase III situated at Department of Obstetrics / Gynae, Sheikh Zayed Women Hospital, Chandka Medical College, Shaheed Mohtarma Benazir Bhutto Medical University Larkana. The application is on Form-I of Bio-study Rules 2017 along with fee deposit slip of Rs. 100,000/- deposited vide slip No. 40379339698 dated 08.11.2023. Dr. Rizwana Chaudhry has also stated that this CTS was registered for Woman 2 Trial (CTS-0011). She has requested to cancel previous licence and issue the licence to conduct all phase III trials.

2. The application has been evaluated below in tabulated form according to pre- requisites as mentioned in Form-III of the Bio-Study Rules 2017.

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Application on Form I for Phase III attached.
2	Prescribed processing fee	Fee Slip number slip No. 40379339698 dated 08.11.2023of Rs.100,000/- attached.
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).	M/s Sheikh Zayed Women Hospital is a tertiary care hospital established in 1974. It deals with Obstetrics and Gynaecology with total 3 units consisted of 200 beds. It is affiliated with Chandka Medical College, Shaheed Mohtrma Benazir Bhutto Medical University Larkana. **FBR Taxpayer Profile Inquiry of Shaheed Mohtarma Benazir Bhutto Medical University Larkana attached.** Registration of Chandka Medical College Hospital issued by Sind Healthcare Comission attached. **As per Form-I, it's Sheikh Zayed Women Hospital (200 bed) while as per SHC Registration Certificate it's Chandka Medical college (400 bed).** Applicant has also attached NOC from Medical Superintendent wherein she has allowed to act as **CTS for IM Women and other Obstetrics and Gynaecology related trials.**
4	Details of premises including layout plan of the site.	Applicant has attached Master Plan of Shaikh Zaid Bin Sultan Hospital for Women Larkano. **The layout plan of Clinical Trial Site (CTS) along with its details required.**
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Applicant has provided the details of Obs and Gynae related services provided by the hospital. **Details of machinery and equipment present at clinical trial site are required.**
6	Names and qualifications of the management.	List of doctors of Gynaecology and Obstetrics Unit-I, Unit-II and Unit-III attached. Also CVs of Dr. Shahida Begum Shaikh, Prof. Dr. Fouzia Kashif, Dr. Shaista Tabassum Abro, Dr. Sumera Brohi, Dr. Shabana Bano, Dr. Basma Zia Isran, Dr. Anum Nissa Channa, Dr. Saeed Un Nisa, Dr. Bina Irshad, Miss. Javeria Abro, Dr. Nabeela Baloch, Dr. Reema Rizwan, Dr. Shazia Ahmed, alongwith

		their GCP training certificate issued by London School of Hyiegene and Tropical medicine attached. **List of PI, Co-PI, Pharmacist, Study Coordinator, Nurses and other staff related to study along with their CVs required.**
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Following allied facilities available; ICU, High Dependency Unit, Operation Theater, Anesthesia Department, Radiology Department, Pathology, Blood Bank and Ambulance Services 24/7,
8	Undertaking on stamp paper	Attached.

3. In the light of above evaluation following shortcomings/ queries have been noticed.

i. The applicant name as per Form-I is Prof. Dr. Shahida Shaikh Magsi, as per Official Stamp its Prof. Dr. Shahida Inayat Magsi, as per NOC its Prof. Dr. Shahida Magsi while as per CV its Prof. Dr. Shahida Begum Shaikh. Please provide documents with correct name along with copy of CNIC.
ii. Institution name according to Form-I is Shaikh Zayed Women Hospital (200 bed) while as per Sindh Healthcare Commission is Chandka Medical College Hospital (400 bed). Please clarify with documentary evidence.
iii. FBR Taxpayer Profile Inquiry of Shaheed Mohtarma Benazir Bhutto Medical University Larkana attached instead of Shaikh Zayed Women Hospital.
iv. NOC from Medical Superintendent, applicant has been allowed to act as CTS for IM Women and other Obstetrics and Gynaecology related trials while application is for generalized Phase III trials.
v. The layout plan of Clinical Trial Site (CTS) along with its details required.
vi. Details of machinery and equipment present at clinical trial site are required.
vii. List of PI, Co-PI, Pharmacist, Study Coordinator, Nurses and other staff related to study along with their CVs required.

4. It is proposed that shortcomings may be communicated to the applicant. Accordingly, DFA has been prepared and submitted for approval, please.

5. Reply was received from Prof. Dr. Rizwana Chaudhry in response to this office letter F.No.15-61/2023 dated 29th December, 2023. The details of reply are as followings.

Shortcoming/ query	Reply/ Response
The applicant's name as per Form-I is Prof. Dr. Shahida Shaikh Magsi, as per Official Stamp its Prof. Dr. Shahida Inayat Magsi, as per NOC its Prof. Dr. Shahida Magsi while as per CV its Prof. Dr. Shahida Begum Shaikh. Please provide documents with correct name along with copy of CNIC.	As per CNIC, the applicant's name is "Prof Shahida Magsi". The stamp included Prof Shahida maiden name and she is using it for official purposes. The copy of CNIC attached according to which name is Shahida Magsi.
Institution name according to Form-I is Shaikh Zayed Women Hospital (200 bed) while as per Sindh Healthcare Commission is Chandka Medical College Hospital (400 bed). Please clarify with documentary evidence.	Shaikh Zayed Women Hospital is a 200 bedded facility of Obstetrics and Gynecology, which is affiliated to the Chandka Medical College. However, Chandka medical College comprises, in addition to Sheikh Zayed Woman Hospital, other clinical departments, with indoor facilities and hence has total capacity of 400 beds. The copy of Sindh Healthcare Commission certificate attached according to which Shaikh Zayed Women's hospital alone is 200 bedded hospital.

FBR Taxpayer Profile Inquiry of Shaheed Mohtarma Benazir Bhutto Medical University Larkana attached instead of Shaikh Zayed Women Hospital.	Shaikh Zayed Women Hospital is affiliated to the Chandka Medical College, which is responsible for the handling of all tax related matters and hence the tax submission on behalf of its constituent departments and hospitals.
NOC from Medical Superintendent, applicant has been allowed to act as CTS for IM Women and other Obstetrics and Gynaecology related trials while application is for generalized Phase III trials.	Dr. Rizwana Chaudhry has submitted that we are applying for the grant of License for Department of Obstetrics/ Gynaecology of Sheikh Zayed Women Hospital, to act as a CTS, for all Obstetrics and Gynaecology related phase III clinical trials (including IM Woman trial).
The layout plan of Clinical Trial Site (CTS) along with its details required.	The trial participants can be recruited form any part of the obstetrics and gynecology department, which is the clinical trial site. Also, layout plan of ground floor showing archiving room and IMP storage room is attached.
Details of machinery and equipment present at clinical trial site are required.	Following is the list of machinery and equipment present at the Obstetrics and Gynaecology department of Sheikh Zayed Women Hospital, Chandka Medical College, Shaheed Mohtarma Benazir Bhutto Medical University, Larkana: 1. Stethoscope 2. Sphygmomanometer (B.P Apparatus) 3. Height & Weight Machine 4. ECG Machine 5. Suction Machine 6. Centrifuges 7. Refrigerator (for Medicines) 8. Ultra-Low Freezer -70 (For Samples) 8. Temperature Monitor 9. Digital Thermometer 10. Refrigerated Centrifuge Machine & Tubes 11. Resuscitator 12. Clinical Thermometer 13. Blood / Samples Transfer Boxes & WHO Bag 14. Alcohol Meter 15. Nebulizing System 16. Electric Suction Apparatus 17. Laryngo-Scope 18. Defibrillator 19. Oxygen Cylinder 20. Otto Scope
List of PI, Co-PI, Pharmacist, Study Coordinator, Nurses and other staff related to study along with their CVs required	Following is the list of PI, sub-PIs, Pharmacist, Study Coordinator and Nurses related to study: 1. Prof: Dr. Shahida Magsi (PI) 2. Prof Dr. Fouzia Kashif (Sub-PI) 3. Prof Dr. Shaista Abro (Sub-PI) 4. Dr. Basma Zia (Study Coordinator) 5. Mr. Asghar Ali Channa (Pharmacist) 6. Tahira Chandio (Staff Nurse) Please note the trial team can be increased as per trial requirements. Please find attached the CVs and GCP certificates of the trial team are also attached with reply.

6. In the light of above it is submitted that all queries, communicated to the applicant, has been addressed. It is proposed that panel may be constituted for inspection/ verification of the facility/ CTS. The following panel was constituted vide this office letter No.F.15-61/2023-CTS dated 04th April 2024.

a. Dr. Ahson Qavi Siddiqi, CEO, Sindh Healthcare Commission, Karachi.
b. Dr. Mirza Tasawer Baig, Member CSC, Dr. Zia Ud Din Hospital, Clifton Campus, Karachi.
c. Mr. Shafqat Hussain Danish, Assistant Director (CT), DRAP, Islamabad.

7. The panel visited the premises on 26.04.2024 and submitted the following report on check list;

CLINICAL TRIAL SITE (CTS) INSPECTION CHECKLIST

Name of facility: **Dept. of Gyna/Obs. Sheikh Zayed Women Hospital, Larkana.**
Address: **Chandka Medical College, Shaheed Mohtarma Benazir Bhutto Medical University, Larkana.**
Organization Type: - **Public** ■ Not for Profit ☐ Private ☐ Other- _____
Name of Owner / Proprietor: **Prof. Dr. Shahida Magsi.**
Date of inspection: **26.04.2024**

i. General Information	**Yes**	**No**	**NA**	**Observations / Recommendations**
Is this CTS a primary care, secondary care or tertiary care facility? (Record one in observations section)	✓			Tertiary
Is this the Composite CTS (Where Principal investigator is located)?	✓			
Is the facility registered with the Healthcare Commission?	✓			
If yes, is the certificate, available for review and is valid?	✓			
Is there enough space available for proper functioning 'for clinical trials?	✓			
Is there an outpatient facility?	✓			
If yes, On an average how many patients visit per day?	✓			Average 500 Patients
Is there an inpatient facility?	✓			
If yes, how many beds?				200 Beds
Have any clinical trials been conducted at this CTS in the past?	✓			
If yes, how many clinical trials were conducted? Give details of the Pl as well as nature and duration of the clinical trials.	✓			One. WOMEN – II Clinical Trial PI: Prof. Dr. Shahida Magsi
How many other studies currently ongoing at the site? If yes, how many clinical trials were conducted? Give details of the Pl as well as nature and duration of the clinical trials.			✓	
Is there a pharmacy / dedicated investigational Medicine dispensing area?	✓			
If yes, does the CTS have required storage facility for routine operations?	✓			
If yes, does the CTS have required trial related Investigational Product storing facility? (Investigational Product Provided by the sponsor as per requirements of the protocol).	✓			
Does the CTS have Laboratory services?	✓			
If yes, is in house or central?	✓			Both In-house & Central
Is there an X-Ray facility?	✓			
If yes, is it on-house or central?	✓			Central

Does the facility have an incinerator? If yes, document the average weight of Hospital waste disposed of per month.	✓			40 – 50 Kg / Day or 500 Kg/Month
If No, does the facility', have a contract with a Hospital waste management Company?			N/A	
ii. Study Related Staff	**Yes**	**No**	**NA**	**Observations / Recommendations**
Does the CTS have, any of the study related personnel on staff? -Principal Investigator (PI) -Sub-Investigator (Sub-PI) -Coordinator -Nurses -Pharmacists. *Give details in remarks Section	✓			
Are CVs available for Key staff members (Pl, Sub-PI, Coordinator)	✓			
iii Education and Training	**Yes**	**No**	**NA**	**Observation / Recommendations**
Have CTS personnel received or are scheduled to receive any of following trainings? o GCP o Trial related o Safety reporting o Pharmacovigilance Training o Other	✓			
Are training records available for study related staff?	✓			
Security and confidentiality is adequate to prevent unauthorized access to records?	✓			Access controlled through password & lock / key.
Is there sufficient space to store materials, archive records, equipment to function properly?	✓			
Are generators and/or UPS available utilized at the facility?	✓			
iv. Safety	**Yes**	**No**	**NA**	**Observation / Recommendations**
Is there a system in place for personnel to report any safety concern or incidents?	✓			
v. Data Handling procedures and Computer Validation	**Yes**	**No**	**NA**	**Observation / Recommendations**
Does the CTS have adequate IT facilities e.g. Computers, internet available?	✓			
Is access to computers limited by an individual username and password system (Clinical Research team members cannot share a user name)?	✓			
vi. Records and Reports	**Yes**	**No**	**NA**	**Observation / Recommendations**
Is there space available for document storage?	✓			
If yes, do access control systems to the area exist and are functional?	✓			
Is there a SOP or a system for the retention, storage, and destruction of records?	✓			
How does the site ensure the sponsor's proprietary information is not disclosed to unauthorized personnel or external organizations?	✓			Through access control, through Lock & Key and delegation of powers.
vii. Records Retention and Archival	**Yes**	**No**	**NA**	**Observation / Recommendations**
Is there a dedicated facility/area for the archival of records?	✓			

Is there control access to the archival facility?	✓			Lock & Key
Is the environment of the facility monitored and controlled?	✓			
Is the retention time for records agreed with the sponsors?	✓			As per Sponsor's SOPs
Is there a method of electronic data archive (if required)?	✓			Through sponsor's provided tablets.

Remarks of inspection team:

Panel of inspection team comprising of Prof. Dr. Mirza Tasawer Baig, Dr. Ahson Qavi and Shafqat Hussain Danish, visited Department of Obstetrics / Gynae, Sheikh Zayed Women Hospital, Chandka Medical College, Shaheed Mohtarma Benazir Bhutto Medical University Larkana, as per letter reference No. 15-61/2023-CTS dated 04.04.2024. The facility was found to be fit for "IM WOMEN" Trial only.

Concluding status of inspection / application :(Circle One)

Recommended for approval ■
Deferred for improvements ☐
Recommended for rejection ☐

7. The case was placed before the CSC for the consideration, discussion and decision..

Decision:

The CSC after detailed deliberation, discussion and on recommendation of inspection panel, decided to grant the licence to Department of Obstetrics and Gynaecology at Sheikh Zayed Women Hospital, Larkana, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only. The site will initiate the trial after the fulfilment of following:

i. Appointment of study specific pharmacists.
ii. The staff will be trained regarding study specific activities by the Sponsor / national study coordinator.
iii. To place a system in place for personnel to report any safety concern or incidents.
iv. After receipt of tablets from the Sponsor.

6. The case was placed before the CSC for the consideration, discussion and decision.

Decision:

The CSC after detailed deliberation, discussion and on recommendation of inspection panel, decided to grant the licence to Department of Obstetrics and Gynaecology at Dr Ruth KM Pfau Civil Hospital Karachi, to act as Clinical Trial Site for Phase-III IM-Women Clinical Trial only. The site will initiate the trial after fulfilment of following improvements:

i. Appointment of study specific pharmacists.
ii. The staff will be trained regarding study specific activities by the Sponsor / national study coordinator.
iii. To establish a system for personnel, to report any safety concern or incidents.
iv. For appropriate data handling and archiving, the Sponsor will provide electronic gadgets (Tablets).

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