MINUTES OF THE 46TH CLINICAL STUDIES COMMITTEE MEETING (SUMMARY)

Pharmacy Services Division, Drug Regulatory Authority of Pakistan

File No: 16-46/2023-CSC (PS)

OCTOBER 27, 2023
DRUG REGULATORY AUTHORITY OF PAKISTAN
Prime Minister Health Complex, Park Road, Chak Shahzad,
Islamabad.

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46th meeting of the Clinical Studies Committee was held on 27th October, 2023 in the Committee room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr. Obaidullah, Director Pharmacy Services. 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.	Dr. Mirza Tasawer Baig	Associate Professor in the Department of Pharmacy Practice, Faculty of Pharmacy, Ziauddin University, Karachi and Clinical Pharmacist at Dr. Ziauddin Hospital, Karachi, Sindh.	Member
iii.	Ahsan Ul Haq Athar	Deputy Director, Pharmacy Services Division.	*Ex-officio Secretary*

3. Following members attended the meeting online through team software.

i.	Prof. Dr. Fazal Subhan	Department of Pharmacy, CECOS University of IT and Emerging Sciences, Peshawar, Khyber Pakhtunkhwa.	Member
ii.	Prof. Munawar Alam Ansari.	Professor of Pharmacology, Dean Faculty of Pharmacy, Liaquat University of Medical Sciences, Jamshoro, Sindh.	
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.	Mr. Waqas Latif	Data Analyst/Biostatistician in Quality Enhancement Cell (QEC) at University of Health Sciences, Lahore, Punjab.	Member

4. Mr. Malik Muhammad Asad, Mr. Nouman Yousuf, Mr. Hafiz Muhammad Jawad Ali and Mr. Shafqat Hussain Danish assisted the Committee and Secretary in presentation of the agenda.

AGENDA ITEM I:

CONFIRMATION OF THE MINUTES OF THE 45th CLINICAL STUDIES COMMITTEE MEETING.

The minutes of the 45th CSC meeting held on 27th October, 2023. Minutes were shared with CSC members through email/ what's app group on 17th October 2023. 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. Submitted for confirmation of CSC Members.

Decision:

All the Members of the CSC confirmed the Minutes of 45th CSC meetings.

AGENDA ITEM II:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FOR PHASE II CLINICAL TRIALS FROM THE ZIAUDDIN UNIVERSITY, KARACHI F. No.15-46/2023 CTS.

The Committee decided the case as follows:

"The CSC after detailed discussion, deliberation and as per inspection panel recommendation decided to approve Clinical Trial Site (CTS) Situated at Dr. Ziauddin Hospital, Clifton Campus, Karachi to act as CTS for phase-II Clinical Trials except their PK/PD parts, which would be the responsibility of Sponsor. Moreover, CSC directed to provide requisite medical facilities for trial subject including ICU (if required) during study period without any fail.

AGENDA ITEM III:

APPLICATION FOR APPROVAL OF APPLICATION TO ACT AS CRO AT M/S KAMAL LABORATORIES, RAWALPINDI F. No.15-39/2023-CRO.

DEFERRED CASE OF NEW CRO FOR LICENSE IN 45TH MEETING OF CSC:

The Committee decided the case as follows:

"The CSC after detailed discussion and deliberation decided that any two members of the panel constituted vide letter no. 15-39/2023-CRO dated 21st August 2023, will visit the premises for verification of compliance report submitted by the applicant. After submission of the verification report of the panel members the case will be processed for issuance of license upon approval of Chairman CSC.

AGENDA ITEM-IV:

PROTOCOL AMENDMENT OF CLINICAL TRIAL TITLED AS "A PHASE II, RANDOMIZED, OBSERVER-BLINDED, PLACEBO CONTROLLED TRIAL TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF HECOLIN® IN HEALTHY PREGNANT WOMEN BETWEEN GESTATIONAL AGE 14-34 WEEKS AND NON-PREGNANT WOMEN OF 16-45 YEARS OLD". F.No. 03-35/2023-CT.

The Committee decided the case as follows:

The CSC after detailed discussion and deliberation decide to approve the protocol amendment (Protocol Version-03, Dated 10 May 2023) and related amended documents of an already approved Clinical Trial titled, "A Phase II, Randomized, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Safety and Immunogenicity of Hecolin® in Healthy Pregnant Women between Gestational age 14-34 Weeks and Non-Pregnant Women of 16-45 Years Old", under the Bio-Study Rules, 2017.

AGENDA ITEM V: (DEFERRED CASE OF 44TH MEETING OF CSC)

APPLICATION FOR APPROVAL OF CLINICAL TRIAL TITLED AS, "PREVENTION OF IRON DEFICIENCY ANEMIA POST-DELIVERY (PRIORITY TRIAL)" FROM THE AGA KHAN UNIVERSITY HOSPITAL (AKUH), DEPARTMENT OF COMMUNITY HEALTH SCIENCES STADIUM ROAD, KARACHI. F. No.03-43/2023-CT (PS)

The Committee decided the case as follows:

The CSC after detailed discussion and deliberation decide to approve the clinical trial titled, "Phase-III Clinical Trial titled, "Prevention of Iron Deficiency Anemia Post-Delivery (PRIORITY Trial)", under the Bio-Study Rules, 2017.

Further, the CSC approved following IMPs to be used in the trial, that will be purchased locally:

Ferric Carboxymaltose (Ferinject 500 mg/10 mL): Vifor (International)	*630 vials*
Ferrous Sulphate: 200 mg (65 mg elemental Iron)- Nawabsons, Lahore:	*113,400 (1134 boxes of 100 tablets each)*
Folic Acid 400µgm- Nutrifactor, Faisalabad:	*113,400 (1890 bottles of 60 tablets each)*

AGENDA ITEM VI: (DEFERRED CASE OF 45TH MEETING OF CSC)

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)

The Committee decided the case as follows:

The CSC after detailed discussion and deliberation decide to:

i. *approve the clinical trial titled, "A Phase-II, Open-Label Study to Assess the Safety and Efficacy of Bemnifosbuvir (BEM) And Ruzasvir (RZR) in Subjects with Chronic Hepatitis C Virus (HCV) Infection", under the Bio-Study Rules, 2017, to be conducted at following clinical trial site(s):*
   a. *The Aga khan university (AKUH), stadium road, Karachi (CTS-0003)*
   b. *Ziauddin University Hospital 4/B, Shahrah-e-Ghalib Rd. Block 6 Clifton, Karachi (CTS-0086)*

ii. *Approve following IMPs required for the trial:*
   Investigational Product, Dosage, and Mode of Administration:
   • BEM will be provided as 275-mg tablets (A2-275 mg tablets)
   • RZR will be provided it~ 90-mg capsules
   • Subjects will take 550 mg BEM (as 2 x 275-mg tablets) and 180 mg RZR (as 2 x 90-mg capsules) once daily for 8 weeks
   • Study drugs will be taken together orally
   • Subjects will be instructed to take the study

iii. *Directed the PI to submit clarification regarding IRB of Central Park Hospital, Lahore, as it is addressing the person other than Site PI (i.e. Dr. Syed Nayab Haider) mentioned in the application.*

iv. *Authorized the Chairman CSC to verify the required documents before issuance of registration certificate.*

AGENDA ITEM VII

DECREASING POSTOPERATIVE BLOOD LOSS BY TOPICAL VS INTRAVENOUS TRANEXAMIC ACID IN OPEN CARDIAC SURGERY (DEPOSITION) TRIAL. (F. NO.03-21/2022 DD (PS).

Decision of CSC in 46 meeting:

The CSC after detailed discussion decided to defer the clinical trial for seeking clarifications from PI for following points:

i. Provide details which are missing in the study like confounders which are related to pre-bleeding like most patients are on antiplatelet management/therapy, heparin, Clopidogrel. This study has no detail that when such medicines are stopped or how many days stopped before surgery.

ii. Tranexamic Acid is contra-indicated in the patients with epilepsy, while one outcome of this study is post seizures. Clarify exclusion criteria about this.

iii. Provide details about Surgical Bleeding in this study. Post-operative bleeding and surgical bleeding are two different categories of bleeding. Post-operative bleeding also depends on skill set of individual doctor, apart from medication.

iv. Traneximc Acid has wide therapeutic index. The seizures are linked with maximum level of dose. Clarify the dose selection for IV and Topical.

v. Inflammatory response is mentioned nowhere in the study. What are the pump related issues in bleeding? If pump time is prolonged like if 120 minutes is pump time and blood of patient is in contact with non-endothelial surface, then bleeding also occurs more in such patients. Provide details about pump time and inflammatory response.

vi. If topical use of Tranexamic Acid is to be observed, then why those patients are not excluded who go for beating heart surgery, where no such confounder will be present like pump associated bleeding coagulopathy.

vii. There is 3800 sample size globally. However, sample size in Pakistan is only 50 and also there is no detail of arms that how many arms will be and how many patients will be in one arm.

viii. The trial is to be performed during cardiac surgery so there should be no financial cost of cardiac surgery for such all patients who participate in the trial.

AGENDA ITEM VIII:

PART-A

APPLICATION FOR PROTOCOL AMENDMENT 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 of CSC in 46th meeting:

The CSC after deliberations decide to:

i. *Approve following amended documents:*
   a. *Protocol Version 4.0 (2020-05-19)*
   b. *Protocol Version 5.0 (2023-04-24)*
   c. *ICF version 4.0*

ii. *Defer the close out report as the trial was a multicentre global trial with a sample size of 2800 globally and composition of DSMB was from Shifa International Hospital only and directed the Principal Investigator and Intuitional Review Board (IRB) to provide report of international Data and Safety Monitoring Board (DSMB) regarding 01 Serious Adverse Event (SAE) and 04 Deaths of subjects who participated in the trial*

iii. *Authorized Chairman, CSC to constitute panel for verification of destruction of IMP as per previous delegations of powers for "Destruction of unused /expired IMP after Clinical Trial" to Chairman, CSC in 43rd meeting held on 2nd June 2023*

AGENDA ITEM IX

Part-A

APPLICATION FOR APPROVAL OF PROTOCOL AMENDMENT FOR CLINICAL TRIAL "PERI-OPERATIVE ISCHEMIC EVALUATION-3 (POISE-3) TRIAL. F.NO.03-07/2019-CT(PS)

Decision of CSC in 46th meeting:

The CSC after deliberations decide to:

i. *Approve following amended documents/protocols:*

   a. *Protocol Version V5.0 (27-08-2019)*
   b. *Protocol Version V6.0 (09-04-2020)*
   c. *Protocol Version V7.0 (22-07 2021)*

ii. *Defer the close out report as the trial was a multicentre global trial with a sample size of 10000 in 27 countries and composition of DSMB was from Shifa International Hospital only and directed the Principal Investigator and Intuitional Review Boards (IRBs) of Shifa International Hospital and Aga Khan University Hospital to provide report of international Data and Safety Monitoring Board (DSMB) regarding 01 Serious Adverse Event (SAE) and 06 Deaths of subjects at Shifa International Hospital and 01 Death at Aga Khan University Hospital of subject who participated in the trial.*

AGENDA ITEM X

APPLICATION FOR APPROVAL OF AMENDMENTS FOR CLINICAL TRIAL "A PHASE 3 RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED STUDY TO EVAUATE THE EFFICACY AND SAFETY OF BEMNIFOSBUVIR IN HIGH RISK OUTPATIENTS WITH COVID-19. F.NO.03-37/2023-DD-CT(PS)

Decision of CSC in 46th meeting:

The CSC after deliberations decide to approve following amended documents:

i. *Protocol Version 2.0 dated 15 June 2023.*
ii. *ICF Version 2.0 19 July 2023.*
iii. *Assent Form Version 1.0 dated 4 August 2023 for adolescents.*

iv. Patient Recruitment flyer-poster v 4.0 dated 28 June 2023.
v. Investigator's Brochure Edition 10 dated 18 July 2023.

AGENDA ITEM XI

APPLICATION FOR APPROVAL OF 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 of CSC in 46th meeting:

The CSC after deliberations decide to approve following amended documents:

i. Investigator's Brochure Addendum 1, v3.0 dated 4th April 2023.
ii. Main ICF V3.0, Pak1.0 dated 19 July 2023.
iii. Updated Infographic instructions for dosing V1.1 dated 22 Feb 2023
iv. Subject Case Report Forms V2.0 dated 7th August 2023.

AGENDA ITEM XII

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. F. No.03-51/2023-CT(PS).

Decision of CSC in 46th meeting:

The CSC after detailed discussion and deliberation decided to as follows:

i. *To approve the study titled as* 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 to be conducted at following clinical trial sites.

Site(s)	PI
Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad (0052)	Dr. Qasim Mahmood Buttar
Rehman Medical Institute, Peshawar (0060)	Dr. Abdul Wahid

ii. *To approve following IMPs with the direction to get Clearance Certificate from Import & Export department of DRAP:*

Drug Name	Total Quantity of IP to be imported
BCD-263/Opdivo 10mg/ml 4ml (double blinded period)	720 vials
BCD-263/Opdivo 10mg/ml 10ml (double blinded period)	1440 vials
BCD-263/Opdivo 10mg/ml 4ml (open label period)	2400 vials
BCD-263/Opdivo 10mg/ml 10ml (open label period)	4800 vials
Total	**9360 Vials**

Study Therapy

Group	Test Drug	Reference Drug
Intervention Name	BCD-263	Opdivo
INN	Nivolumab	Nivolumab
Dosage Form	Concentrate for infusion for solution	Concentrate for infusion for solution
Strength	10mg/ml	10mg/ml

Route & Method of Administration	IV	IV
Dosing Regimen	480mg once every 4 weeks	480mg once every 4 weeks
Name of Manufacturer	**JSC BIOCAD, Russia.** 198515, Saint Petersburg, Intracity Municipality Settlement of Strelna, ul, Svyazi, 38, bldg..1, office 89	Bristol-Myers Squibb Holdings Pharma Ltd. Liability Company, USA Road 686 km 2.3 Bo. Tierras Nuevas, Manati, Puerto Rico 00674, FEI#2650089

iii. Defer the approval of this trial for following two sites as these sites have license of trial specific only and CSC advised the PI to submit request for addition of Site once these sites are licensed for Phase-III trial.

Site(s)	**PI**
Mayo Hospital, Lahore	Dr. Muhammad Abbas Khokhar
Allied Hospital, Faisalabad	Dr. Muhammad Tahir Bashir

AGENDA ITEM XIII:

APPLICATION FOR AMENDMENT IN PROTOCOL 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" F.No.03-38/2023-CT (PS)

Decision of CSC in 46th meeting:

The CSC after deliberations decide to approve amended protocol V2.0_27 June, 2023 for already approved 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".

AGENDA ITEM XIV:

RATIFICATION/CORRIGENDUM IN 45TH CSC MEETING DECISION FOR 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)

The Committee decided the case as follows:

The CSC after deliberation and discussion ratified the updated IMPs and trial ancillary items and in continuation to 45th CSC meeting decision decided case as follows:

i. Approve the Phase-III Clinical Trial titled, "A Phase 3, Randomized, Observer-Blind, Controlled, Multicenter, Clinical Study to Evaluate Immunogenicity and Safety of a MF59-Adjuvanted Quadrivalent Subunit Cell-derived Influenza Vaccine (aQIVc) in Comparison with Quadrivalent Influenza Vaccines, in Adults Aged 50 Years and Older." under the Bio-Study Rules, 2017, to be conducted at following Clinical Trial Site(s):

a. Aga Khan University, Karachi
b. The Central Park Teaching Hospital, Lahore.

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

IMPs	***Molecule***	***Strength***	***Pack Size***	***Manufacturer***	***TOTAL***
aQIVc HD	*Adjuvanted Quadrivalent Influenza Vaccine (aQIV) influenza vaccine is a sterile preparation of four purified influenza virus antigens in an isotonic buffer solution, combined with the MF59 adjuvant, for Intramuscular administration. aQIV is provided in a pre-mixed format in syringes and contains the antigens of two type A strains and two type B strains*	*containing 45 µg HA/strain and 19.5 mg squalene (MF59 adjuvant), in a total volume of 1.0 mL, formulated in a prefilled syringe (PFS).*	*1 Syringe – 1.0 ml, formulated in a prefilled syringe / per kit.*	*Seqirus Inc., 475 Green Oaks Parkway Holly Springs, NC 27540, USA*	*214*
QIVr	***Flublok Quadrivalent/Supemtek** is a vaccine indicated for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.*	*containing 45 µg HA/strain (nonadjuvanted), in a total volume of 0.5mL, formulated in a PFS*	*1 Syringe – 0.5 ml, formulated in a prefilled syringe / per kit.*	***Flublok** -Protein Sciences US 1000 Research Parkway Meriden, Connecticut 06450, United States* ***Supemtek -** Sanofi Pasteur Parc Industriel d'Incarville, 27100 Val de Reuil, France*	*143*
aQIV	***FLUAD QUADRIVALENT** is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine.*	*containing 15 µg HA/strain and 9.75 mg squalene (MF59 adjuvant), in a total volume of 0.5 mL, formulated in a PFS*	*1 syringe - 0.5 mL, formulated in a PFS / per kit.*	*Seqirus Inc. 475 Green Oaks Parkway Holly Springs, NC 27540 USA* *Seqirus Vaccines Limited Gaskill Road, Speke, Liverpool L24 9GR, United Kingdom*	*143*
Repackaged & relabeled by: *M/s Catalent Pharma Solutions, 031 Red Lion Road, Philadelphia, PA19114, USA.* *M/s Catalent Pharma Solutions-SNG, Pte. Ltd., No. 1 Jalan Kilang #02-01, Singapore, 159402, Singapore*					

IMPs	***Site***	***Role***	***Address***
aQIVc HD	*Seqirus Inc., US*	*Manufacturer and MAH*	*Seqirus Inc., 475 Green Oaks Parkway Holly Springs, NC 27540, USA*
	Catalent Pharma US *Catalent Singapore (optional)*	*Repacker*	*Catalent Pharma Solutions, LLC, 10381 Decatur Road Philadelphia, PA 19114, USA* *Catalent Pharma Solutions-SNG Pte. Ltd., No. 1 Jalan Kilang #0201, Singapore, 159402*
	Seqirus Inc US	*Release*	*Seqirus Inc., 475 Green Oaks Parkway Holly Springs, NC 27540 USA.*
aQIV (Fluad)	*Seqirus Inc US* *Seqirus Vaccines Limited (UK)* *Seqirus Netherlands*	*Manufacturer and MAH* *Manufacturer* *MAH*	• *Seqirus Inc., 475 Green Oaks Parkway Holly Springs, NC 27540 USA.* • *Seqirus Vaccines Limited, Gaskill Road, Speke, Liverpool, L24 9GR, United Kingdom* • *Seqirus Netherlands B.V., Paasheuvelweg 28. 1105 BJ, Amsterdam. The Netherlands*
	Catalent Pharma US *Catalent Singapore (optional)*	*Repacker*	• *Catalent Pharma Solutions, LLC, 10381 Decatur Road Philadelphia, PA 19114 USA.* • *Catalent Pharma Solutions-SNG Pte. Ltd., No. 1 Jalan Kilang #02-01 Singapore, 159402*
	Seqirus Inc US	*Release*	*Seqirus Inc. 475 Green Oaks Parkway Holly Springs, NC 27540 USA*

QIVr (Flublok)	*Protein Sciences US*	*Manufacturer*	*Protein Sciences US, 1000 Research Parkway, Meriden, Connecticut 06450, United States*
	Sanofi Pasteur US	*MAH*	*Sanofi Pasteur US, 1 Discovery Drive, Swift water Pennsylvania 18370, USA*
	Catalent Pharma US	*Repacker*	*Catalent Pharma Solutions, LLC, 10381 Decatur Road Philadelphia, PA 19114, USA*
	Seqirus Inc US	*Release*	*Seqirus Inc., 475 Green Oaks Parkway Holly Springs, NC 27540, USA.*
QIVr (Supemtek)	*Sanofi Pasteur Aventis Pharma Limited trading as Sanofi Pasteur*	*Manufacturer and MAH*	*Sanofi Pasteur Parc Industriel d'Incarville, 27100 Val de Reuil, France Aventis Pharma Limited trading as Sanofi Pasteur (License Numbers: PLGB 04425/0879) 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.*
	Catalent Pharma Solutions-SNG	*Repacker*	*Catalent Pharma Solutions-SNG Pte. Ltd. No. 1 Jalan Kilang #02-01, Singapore, 159402*
	Seqirus Inc US	*Release*	*Seqirus Inc. 475 Green Oaks Parkway Holly Springs, NC 27540 USA*

Batch and Expiry:

Blinded Batch Number on kits: 20103039 / Blinded Expiry on kits: 02/2024
Active: Batch aQIVc HD # 20103039; 02/2024
Comparator QIVr (Flublok®): Batch# 20103039; 02/2024
Comparator QIVr (Supemtek UK): Batch# QFAA2303; 05/2024
Comparator aQIV (Fluad Tetra US): Batch# 20103039; 02/2024
Comparator aQIV (Fluad Tetra EU): Batch# 3029515; 04/2024

Packaging site and address:

- *Catalent Pharma Solutions, 3031 Red Lion Road, Philadelphia PA 19114, USA.*
- *Catalent Pharma Solutions-SNG, Pte. Ltd., No. 1 Jalan Kilang #02-01, Singapore, 159402, Singapore.*

Ancillary Supplies:

eCOA mobile device Moto G32 for patient diary	*650 pcs*	*1 equipment/subject * 500 estimated number of subjects for all sites = 500 + 650 (500*15%) buffer = 650*

Name of Ancillary Items	***Quantity of Ancillary Items required for one (01) subject***	***Quantity of Ancillary Items required for "500" subjects***	***Total Quantity of Ancillary Items required (including 30% overage)***
13x15 bag of 30 Tube Holder - Absorbant	*2 tube holders/visit*	*1000*	*1300*
Diagnostic Refrigerated 2-8oC Shipper	*2 per site*	*4*	*5*
Large Cryo Box with 6x6 grid insert (ASIA)	*10 boxes per site*	*20 boxes*	*30 boxes*
Specimen Shipping Bags (SSB) (Pack of 10 bags)	*2 SSB bags/visit*	*500*	*650*
Standard Bulk Supply Box	*2 per site*	*4*	*5*
Urine cups 90ml or 120ml	*1 per site*	*125 (assuming 25% of participants are female)*	*163*
Pregnancy kit - Office Use (Multiple test per box) Cassette (AL)	*2 per site*	*125 (assuming 25% of participants are female)*	*163*

Manufacturer name and address	***Q Squared Solutions (Beijing) Co. Ltd.,*** *Unit 101-102, Building 15, No. 8 Liangshuihe 2nd Street, Han's Enterprise Bay, Beijing Economic-technological Development Area(BDA), Beijing 100176, China.* *Q2 Logistics Dept* *QLSG_Logistics@q2labsolutions.com* ***Q Squared Solutions Holdings LLC,*** *1600 Terrell Mill Road, Suite 100, Marietta, GA 30067, USA* *Tel: +770-373-3648* *Q2 Logistics Dept* *QLSG_Logistics@q2labsolutions.com* ***Q Squared Solutions Limited,*** *The Alba Center Rosebank Livingston EH54 7EG, United Kingdom* *Tel: +44 (0) 1506 814077* *Q2 Logistics Dept* *QLSG_Logistics@q2labsolutions.com*

Manufacturing site name and address	***Q Squared Solutions (Beijing) Co. Ltd.,*** *Unit 101-102, Building 15, No. 8 Liangshuihe 2nd Street, Han's Enterprise Bay, Beijing Economic-technological Development Area(BDA), Beijing 100176, China* *Q2 Logistics Dept* *QLSG_Logistics@q2labsolutions.com* ***Q Squared Solutions Holdings LLC,*** *1600 Terrell Mill Road, Suite 100, Marietta, GA 30067, USA* *Tel: +770-373-3648* *Q2 Logistics Dept* *QLSG_Logistics@q2labsolutions.com* ***Q Squared Solutions Limited,*** *The Alba Center Rosebank Livingston, EH54 7EG, United Kingdom* *Tel: +44 (0) 1506 814077* *Q2 Logistics Dept* *QLSG_Logistics@q2labsolutions.com*

A. Ancillary Supplies to site/PI

Item Description	***Quantities***	***Justification***
Fridge Tag 2 L Vaccine Temperature Monitor	*8 pcs*	*2 sites x 2 =4 + 100% buffer = 8*
Fridge Tag External Sensor with Glycol	*8 pcs*	*2 sites x 2 =4 + 100% buffer = 8*
Freezer LIBERO CE data logger	*2 pcs*	*1 per site*
Freezer LIBERO CE data logger probe	*2 pcs*	*1 per site*
data loggers for home visits	*6 pcs*	*3 per site*
Sharps Container	*8 pcs*	*2 sites =2 x 2=4 + 100% buffer = 8*

Item Description	***Quantities***	***Justification***
25G x 1" needle 100x box	*8 boxes*	*2 sites x 2 =4 + 100% buffer = 8*
25G x 1 1/2" needle 100x box	*8 boxes*	*2 sites x 2 =4 + 100% buffer = 8*

A. Equipment for patient

Item Description	***Quantity***	***Justification***
Moto G32	*650 pcs*	*1 equipment/subject * 500 estimated number of subjects for all sites = 500 + 650 (500*15%) buffer = 650*
Reaction Rulers	*1000 pcs*	*500 subjects + 100% buffer = 1000*
Body Thermometer	*1000 pcs*	*500 subjects + 100% buffer = 1000*

B. Printed Materials

Item Description	***Quantities***	***Justification***
Mini Protocol	*6*	*x*
Chart Review Checklist Booklet	*6*	*x*
Participant Study Guide	*500*	*500 subjects + 30% buffer = 650*
Subject Card	500	500 subjects + 30% buffer = 650

AGENDA ITEM XV:

RATIFICATION OF TYPOGRAPHIC ERRORS IN THE DECISION OF AMENDMENT APPLICATION OF ALREADY APPROVED CLINICAL TRIAL TITLED "A PHASE-III, MULTICENTRE, RANDOMIZED, DOUBLE-BLIND, 24-WEEK STUDY OF THE CLINICAL AND ANTIVIRAL EFFECT OF S-217622 COMPARED WITH PLACEBO IN NON-HOSPITALIZED PARTICIPANTS WITH COVID-19", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-25/2023-CT (PS)

The Committee decided as follows:

The Committee acknowledged and ratified the correct letter issued as per above mentioned details.

AGENDA ITEM XVI:

APPLICATION FOR APPROVAL OF INCREASE IN ENROLLMENT and IMPORT OF ADDITIONAL IMPs IN 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", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-40/2023-CT (PS).

The Committee decided the case as follows:

The CSC after detailed deliberation and discussion decided:

i. *to approve recruitment of additional 180 subjects/patients from Pakistan. Previously 720 subjects out of 1440 were approved to be recruited from Pakistan, now after approval it will be 900 Subjects out of 1440 to be recruited in Pakistan in an 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" as per the amended (Version 3.3, Dated 28th July, 2023).*

ii. *approved the additional investigational products required for additional/increased recruitment target (180 Subjects). Details are as follows:*

Investigational Product Name	*Poliomyelitis Vaccine (Vero cells), Inactivated, Sabin Strains*
Additional Target	*180 Subjects*
Dose Formulation	*Prefilled syringes*
Each Prefilled Syringe contains	*Poliovirus antigens; 15DU(type I), 45DU(type II) and 45DU (type III) / 0.5mL*
Quantity to be imported	*180 x 3 (3 doses) = 540 + 50 (buffer) = 567*
Total boxes to be imported	*57*

iii. *It is decided that, the above CSC decision is subject to submission of IRB approval from Aga Khan University Hospital, Karachi and revised IRB approval from Central Hospital Gujranwala as submitted IRB approval is from Chairman IRB only, or for clarification, details of meeting along with minutes may be provided in which IRB approval was granted.*

iv. *The Committee authorized the Chairman CSC for verification of IRBs and then issuance of approval/decision letter.*

AGENDA ITEM XVII:

APPLICATION FOR EXTENSION IN TRIAL DURATION AND AMENDMENT IN PROTOCOL AND RELATED DOCUMENTS OF ALREADY APPROVED PHASE-IV 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).

Case-I (For Amendment & Extension of CT)

The Committee decided the case as follows:

The CSC after deliberation and discussion decided to:

i. *approve the amendments and related following documents of already approved Phase-IV Clinical Trial titled, "Randomized, Open Label, Multicenter, Non-Inferiority Clinical Trial for New Treatment Modalities for Cutaneous Leishmaniasis Caused by Leishmania Tropica".*

Details of amended documents is as follows:

S.No.	*Documents*	*Current/Amended Version*	*Dated*
1	*Trial Protocol PRO-sIPV-4001*	*3.3*	*28th July,2023*
2	*Master Information Sheet and ICF for Adult (English/Urdu)*	*3.3*	*28th July,2023*
3	*Master Information Sheet and ICF for Parent/LAR (English/Urdu)*	*3.3*	*28th July,2023*
4	*Diary Card (English/Urdu)*	*1.2*	*28th July,2023*
5	*Site Worksheet/CRF*	*2.0*	*28th July,2023*

ii. *approve the extension in trial duration till 13th September 2024 (from 14th June 2023) as per NBC approval.*

Case-II (For Amendment & Extension of CT)

APPLICATION FOR IMPORT OF ADDITIONAL QUANTITIES OF IMPs FOR ALREADY APPROVED PHASE-IV 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).**

The Committee decided the case as follows:

The CSC after deliberation and discussion decided to defer the case for Import of Additional Quantities of IMPs due to following reasons:

i. *Applicant/PI haven't provided prescribed processing fee of Rs. 25000/- for miscellaneous request.*
ii. *PI haven't provided reconciliation record for previously approved/imported IMPs and devices along with Drug Import Licence and clearance certificates.*
iii. *PI haven't provided justification and calculations for use of requested additional IMPs and thermos-devices.*

AGENDA ITEM XVIII:

APPLICATION FOR THE ADDITIONAL QUANTITY, OF IP REQUIREMENT FOR 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)", FROM AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No. 03-12/2022-CT

The Committee decided the case as follows:

The CSC after detailed deliberation and discussion decided:

i. *to approve additional IMPs required for an 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)", due to IMP expiration at the end of Dec 2023.*
ii. *that approval is subject to submission of reconciliation report for previously approved IMPs. The Committee authorized the Chairman CSC for verification of IMPs reconciliation report and then issuance of approval/decision letter.*

AGENDA ITEM XIX:

APPLICATION FOR AMENDMENT IN ALREADY APPROVED CLINICAL TRIAL TITLED "TRANSNASAL CAPSULE ENDOMICROSCOPY FOR VISUALIZATION OF THE SMALL INTESTINE IN ENVIRONMENTAL ENTERIC DYSFUNCTION (EED) POPULATION IN PAKISTAN. F. No.03-18/2020-DD (PS).

The Committee decided the case as follows:

The CSC after detailed deliberation and discussion decided:

i. *to defer the case for further deliberations and decided to refer the case to the MDMC Division for opinion regarding applicability of GMP certificate of the device as per international harmonized legislation.*
ii. *The case will be placed again in next meeting with MDMC Division remarks.*

AGENDA ITEM XX:

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 of the Committee:

The CSC after deliberation and discussion decided to defer the case for further deliberations and advised that the "National Biosafety Guidelines for Research, Development and Production of Human Stem Cells" will be shared with all CSC members for review, comments and for further deliberation in the next CSC meeting.

AGENDA ITEM XXI:

APPLICATION FOR DRAP GUIDANCE ON CLINICAL TRIAL SUPPLIES AND IMPs MANAGEMENT, FROM M/S IQVIA PAKISTAN, KARACHI. F. No.08-04/2023-Misc (PS)

The Committee decided the case as follows:

The CSC after deliberation and discussion decided:

i. *to defer the case for further deliberations and decided that the following documents will be shared with all CSC members for review, comments and for further deliberation on role of Sponsor, Principal Investigator and CROs on IMPs handling (import, storage, distribution, reconciliation, destruction and re-export) in the next CSC meeting:*

   a. *The Bio-Study Rules, 2017.*
   b. *Guidance on Clinical Trial Application (Guidelines).*
   c. *ICH-GCP Guidelines (E6, R2).*

AGENDA ITEM XXII:

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-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).

The Committee decided the case as follows:

The CSC after deliberation and discussion decided:

i. *to defer the case for further deliberations after submission of justification/ clarification on following observations;*

   a. *How could Phase-III of a trial can be started if its Phase-I still in operation and Phase-II has not been conducted. Phase-I (Active / Not Recruiting) details are available with identification number* ***NCT05974969*** *(https://classic.clinicaltrials.gov/ct2/show/NCT05974969?term=NCT05974969*
   b. *Mayo Hospital / King Edward Medical University Lahore. (CTS-0090) haven't generalized Phase-III Clinical Trials approval.*
   c. *IRB approval for Mayo Hospital/King Edward Medical University Lahore from relevant IRB/ERC is not provided.*
   d. *CoPP / Free Sale Certificate for Darzalex, issued by relevant regulatory authority is not provided.*
   e. *Evidence of registration for Darzalex® issued by relevant regulatory body is not provided.*
   f. *Instead of submission of published Phase-I and Phase-II trial data, applicant provided un-published data/Summary from the Sponsor/Manufacturer of test drugs.*

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