F.No.08-13/2024-Misc.-GCP(PS)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division
*****

Islamabad, 30th October 2024.

Subject: NOTIFICATION OF SCHEDULE FOR ROUTINE AND TRIGGERED GCP INSPECTIONS.

The Chairman, CSC is pleased to issue schedule of routine and triggered GCP Inspections under the *"Guidelines for Conduct & Reporting of GCP Inspection"*.

2. Following GCP inspectors has been nominated to conduct GCP-Inspections, mentioned against each:

S. No.	*Clinical Trial Title, Site & Type of Inspection*	*Tentative Schedule of GCP Inspection*	*GCP Inspectors*
01	• *"A PHASE 3 RANDOMIZED, DOUBLE.BLIND, PLACEBO-CONTROLLED STUDY TO EVAUATE THE EFFICACY AND SAFETY OF BEMNIFOSBTIVIR IN HIGH RISK OUTPATIENTS WITH COVID-19. (CT-0057)".* • *Al-Shifa Research Center, Al-Shifa Trust Eye Hospital, Rawalpindi.* • *Routine, Protocol Specific GCP-Inspection.*	*01st & 05th November 2024.*	*i. Brig. (R) Muzammil Hassan Najmi, Head of Department, Foundation University, School of Health Science, Rawalpindi.* *ii. Mr. Abdul Mateen, Deputy Director, Pharmacy Services Division-DRAP.* *iii. Shafqat Hussain Danish, Assistant Director (Clinical Research) Pharmacy Services Division-DRAP (Coordinator)*
02	• *"A PHASE-II RANDOMIZED, OBSERVER-BLINDED, PLACEBO-CONTROLLED TRIAL TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF HECOLIN® IN HEALTHY PREGNANT WOMEN BETWEEN GESTATIONAL AGE 14-24 WEEKS AND NON.PREGNANT WOMEN OF 16-45 YEARS OLD). (CT-0058)".* • *Aga Khan University Hospital, Karachi.* • *Triggered, Protocol Specific GCP-Inspection.*	*4th & 5th November 2024*	*i. Prof. Dr. Munawar Alam Ansari (Chairman CSC's Sub- Committee on SAEs)* *ii. Dr. Saif Ur Rehman Khattak Additional Director DRAP Karachi.* *iii. Dr. Faiza Bashir (Member Clinical Studies Committee)*

3. Furthermore, the Clinical Studies Committee in its 51st meeting held on 24th October 2024 has decided to conduct GCP Inspection of following Clinical Trials. Nomination letter of GCP inspectors shall be shared separately:

S. No.	***Clinical Trial Title & Country Site***	***Tentative Schedule of GCP Inspection***
01	*Double-Blind Randomised Placebo-Controlled Trial of High-Dose Vitamin D Supplementation in the Treatment of Complicated Severe Acute Malnutrition*	*04th Week of November 2024.*
02	*A Phase 3, Matrix Design, Partially Double-Blind, Randomized Study of the Efficacy and Safety of 50 mg Lonafarnib / 100 mg Ritonavir BID with and without 180 mcg PEG IFN-ALFA-2A for 48 weeks Compared with PEG IFN-ALFA-2A Monotherapy and Placebo Treatment in Patients Chronically Infected with Hepatitis Delta Virus being Maintained on Anti HBV Nucleos(t)ide Therapy (D-LIVR)*	*03rd week of December 2024.*

4. As per the guidelines, the following information may be requested from the inspectee (Investigator, Sponsor, CROs or Site/Center of the Clinical Trial) to be submitted to the CSC/DRAP/GCP Inspection panel;

- Research participant/enrolment status per trial site (number randomized, drop-out rate, and number of serious adverse events reported per site), at trial initiation or during the trial.
- Copies of study standard operating procedures along with amendments e.g. (monitoring procedure, informed consent procedure, serious adverse event reporting procedure, IPs / drug supply procedure).
- Trial-specific document such as Trial Master File (TMF) or Investigator Site File (ISF), a copy of the current protocol and protocol amendment and informed consent form, source data verification guidelines, IPs/product handling instructions, laboratory manual, randomization code (if it is necessary), breaking procedure (if it is necessary), monitoring plans and reports.
- Updated CV of principal investigator or investigators, and members of the IRB.
- Arrangements for direct access to any computerized systems upon which trial date or essential documents are stored.
- Any other documentation deemed necessary by the inspectors.

5. Further, it is advised to review the "Guidelines for Conduct & Reporting of GCP Inspection" and attached GCP-Checklist, for preparation, understanding and conduct of the inspection.

6. The Schedule of GCP Inspections will be uploaded on DRAP official website for information.

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