



F.No.08-13/2025-Misc.-GCP (PS)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division

Islamabad, 04th July 2025.

Subject: NOTIFICATION OF RISK-BASED GCP INSPECTION SCHEDULE (JUL-2025-JUN-2026) FOR ROUTINE GCP INSPECTIONS (PROTOCOL SPECIFIC). F. NO.08-13/2025-Misc.-GCP (PS)

Reference to the “Guidelines for Conduct & Reporting of GCP Inspection”, Risk-Based GCP Inspection Plan from July 2025 to June 2026 is presented herein below. The Risk-Based GCP Inspections will be conducted as per the following tentative schedule:

S.No.	Trial Reg: No.	Trial Acronym	Phase of Trial	Risk-Based Score	GCP Inspection Priority as per RB-Score	Trial Status (as of June-2025)	Approved sites	Tentative Schedule of GCP Inspection
1	CT-0074	BCD-264	Phase-III	25	Medium	Ongoing	i. Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad. (CTS-0052) ii. Rehman Medical Institute, Peshawar. CTS-0060 iii. The Aga Khan University (AKUH), Stadium Road, Karachi (CTS-0003) iv. Ziauddin University Hospital, Karachi (CTS-0086)	July-2025
2	CT-0066	PF-114	Phase-III	25	Medium	Ongoing	i. Ziauddin University Hospital, Karachi (CTS-0080) ii. Shifa Research Clinical Centre, Shifa International Hospital, Islamabad. (CTS-0026) iii. Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad (SZABMU) (CTS-0052) iv. Rehman Medical Institute, Peshawar (CTS-0060) v. Indus Hospital and Health Network, Karachi (CTS-0047)	July-2025
3	CT-0079	BCD-248-2/FLAMMINGO	Phase-II	25	Medium	Ongoing	i. Dr. Ziauddin University Hospital, Karachi (CTS-0086) ii. Mayo Hospital, Lahore. iii. Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad (CTS-0052)	Aug-2025
4	CT-0051	BCD-201	Phase-III	24	Low	Ongoing	i. Shifa International Hospital, Islamabad (CTS-0026). ii. Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad. (CTS-0052)	Aug-2025
5	CT-0059	Vivomix	Phase-II	23	Low	Ongoing	AKUH-Matiari Research & Training Center, Matiari (CTS-0035)	Sep-2025
6	CT-0073	AKUH-GCSF	Phase-II	23	Low	Ongoing	Aga Khan University Hospital, Karachi. (CTS-0003)	Sep-2025

S.No.	Trial Reg: No.	Trial Acronym	Phase of Trial	Risk-Based Score	GCP Inspection Priority as per RB-Score	Trial Status (as of June-2025)	Approved sites	Tentative Schedule of GCP Inspection
7	CT-0075	I'm Women	Phase-III	23	Low	Ongoing	i. Medicare Hospital Rawalpindi (CTS-0076). ii. Department of Gynae & Obs., Shaikh Zaid Women Hospital, Chandka Medical College, Shaheed Benazir Bhutto Medical University, Larkana. (CTS-0101) iii. (Gynae Ward) Dow University of Health Sciences / Dr. Ruth Km Pfau Civil Hospital, Karachi. (CTS-0099) iv. Gynae Ward-09, Jinnah Postgraduate Medical Centre, Karachi. (CTS-0102) v. Koochi Goth Women Hospital, Karachi (CTS-0100) vi. Bolan Medical Complex Hospital, Quetta (CTS-0104) vii. Sandeman Provincial Hospital, Quetta (CTS-0105) iii. Jinnah Hospital Lahore (CTS-0107) ix. Bahawal Victoria Hospital Bahawalpur (CTS-0108). x. Nishtar Hospital Multan (CTS-0109) xi. MCH PIMS Islamabad (CTS-0114) xii. Federal Government Poly Clinic Hospital Islamabad (CTS-0115)	Oct-2025
8	CT-0069	BCD-263	Phase-III	23	Low	Ongoing	i. Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad (CTS-0052) ii. Rehman Medical Institute Peshawar (CTS-0060)	Oct-2025
9	CT-0082	Eclipse-III	Phase-II	23	Low	Ongoing	i. Aga Khan University Hospital, Karachi. (CTS-0003) ii. Dr. Ziauddin University Hospital, Karachi (CTS-0086) iii. Central Park Teaching Hospital, Lahore. (CTS-0049) iv. National University of Medical Sciences, Rawalpindi. (CTS-0103)	Nov-2025
10	CT-0061	ESPRESSO	Phase-II	22	Low	Ongoing	Aga Khan University Hospital, Karachi. (CTS-0003)	Nov-2025
11	CT-0058	Hecolin	Phase-II	21	Low	Ongoing	Aga Khan University Hospital, Karachi. (CTS-0003)	Dec-2025
12	CT-0078	Chlorine E6 Gel	Phase-II	21	Low	Ongoing	Creek General Hospital, Karachi (CTS-0077)	Dec-2025
13	CT-0087	Low-INR	N/A	21	Low	Ongoing	i. Shifa International Hospital Ltd, Islamabad (CTS-0026) ii. Aga Khan University Hospital Karachi (CTS-0003)	Jan-2026
14	CT-0028	MSF-Leishmaniasis	Phase-IV	20	Low	Ongoing	i. Mohtarma Shaheed Bhutto General Hospital, Mariabad, Quetta. (CTS-0055). ii. Medicines Sans Frontières, Kuchlak Primary Health Center, Quetta. (CTS-0056).	Jan-2026
15	CT-0030	ACT-South Asia	Phase-IV	20	Low	Ongoing	i. Aga Khan University Hospital for Women, Karim Abad, Karachi. (CTS-0061) ii. Aga Khan University Hospital, Garden East, Karachi. (CTS-0062)	Feb-2026

							iii. National Institute of Child Health (NICH), Karachi. (CTS-0063)	
16	CT-0041	Action-III	Phase-IV	20	Low	Ongoing	i. Aga Khan University Hospital, Karachi. (CTS-0003) ii. Aga Khan Hospital for Women, Garden, Karachi (CTS-0062) iii. Aga Khan Maternal & Child Care Center (AKMCCC), Hyderabad (CTS-0083) iv. Aga Khan Hospital for Women & Children, Kharadar, Karachi. (CTS-0084)	Feb-2026
17	CT-0081	MOM-Care	Phase-III	20	Low	Ongoing	Aga Khan University Hospital, Karachi. (CTS-0003)	Mar-2026
18	CT-0085	SHIPPS	Phase-IV	20	Low	Ongoing	i. Aga Khan University Hospital, Karachi. (CTS-0003) ii. Shifa International Hospital, Islamabad. (CTS-0086)	Mar-2026
19	CT-0083	Eclipse-I	Phase-III	20	Low	Ongoing	i. Aga Khan University Hospital, Karachi. (CTS-0003) ii. Dr. Ziauddin University, Hospital, Karachi (CTS-0086) iii. Central Park Teaching Hospital, Lahore. (CTS-0049) iv. National University of Medical Sciences, Rawalpindi. (CTS-0103)	Apr-2026
20	CT-0064	HEP C-AKUH	Phase-IV	19	Low	Ongoing	i. Aga Khan University Hospital, Karachi. (CTS-0003) ii. Dow University of Health Sciences (DUHS), Ojha Campus, Karachi. (CTS-0068)	Apr-2026
21	CT-0086	CaMMS	Phase-III	19	Low	Ongoing	DHQ Hospital, Makli, Thatta. (CTS-0113)	May-2026
22	CT-0072	Priority Trial-AKUH	Phase-III	18	Low	Ongoing	Jinnah Post Graduate Medical Center (JPMC), Karachi. (CTS:0097)	May-2026
23	CT-0076	Revive-CGH	Phase-III	18	Low	Ongoing	i. Creek General Hospital, Karachi (CTS-0077) ii. Children Hospital Lahore (CTS-0087)	June-2026
24	CT-0080	RDT-HCV	Phase-IV	16	Low	Ongoing	NUMS CTU, CMH Complex, Rawalpindi (CTS-0111)	June-2026
25	CT-0084	KA6 X-Ray	Phase-IV	15	Low	Ongoing	Aga Khan University Hospital, Karachi. (CTS-0003)	June-2026

2. The inspection letter with details regarding inspection panel and finalized schedule (date and time) of inspection will be issued separately.


 04.07.2025
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Copy for information to: -

1. Deputy Director (CR-II) & (CR-III).
2. Principal Investigator and respective CRO of the subject trial(s).
3. Office file.