

F.No.16-53/2024-CSC Government of Pakistan Drug Regulatory Authority of Pakistan Pharmacy Services Division Ministry of National Health Services, Regulation & Coordination PM's National Heath Complex, Park Road, Chak Shahzad, Islamabad.

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Islamabad,09th January 2025.

Subject:

## TENTATIVE ANNUAL MEETINGS PLAN OF THE CLINICAL STUDIES COMMITTEE TO BE PUBLISHED ON DRAP'S OFFICIAL WEBSITE. F. No. 03-49/2023-CT (PS).

The Drug Regulatory Authority of Pakistan (DRAP) has the aim, among other, to ensure timely access to new treatment options for the people. Pakistan's diverse population and established clinical research infrastructure make it a potential hub for clinical studies in the region. To this end, the Bio-Study Rules, 2017 were notified to regulate clinical trials/studies related to therapeutic goods conducted within Pakistan, including oversight of institutions like Clinical Trial Sites (CTS), Contract Research Organizations (CROs), Bio-Availability or Bio-Equivalence Centers (BA/BE), and Bio-Analytical Laboratories. An expert committee i.e. Clinical Studies Committee (CSC) is responsible for regulation of aforementioned activities related to Clinical Research.

2. The Clinical Studies Committee in its 53<sup>rd</sup> meeting held on December 31, 2024 deliberated the necessity of having a tentative schedule for its meeting in order to align with the timely approval/disposal of applications related to therapeutic good's clinical research, adherence to international best practices, and inform stakeholders for better planning of their projects.

3. Accordingly, the CSC in the aforementioned meeting decided the case as follows:

## Decision:

The CSC after deliberation decided to approve the following tentative meeting schedule to be uploaded on DRAP official website for the information of stake holders and general public:

S. No.	CSC Meeting	Proposed Date
01	54 <sup>th</sup> CSC Meeting	28 <sup>th</sup> – 31 <sup>st</sup> January 2025
02	55 <sup>th</sup> CSC Meeting	03 <sup>rd</sup> - 08 <sup>th</sup> March 2025
03	56 <sup>th</sup> CSC Meeting	21 <sup>st</sup> – 25 <sup>th</sup> April 2025
04	57 <sup>th</sup> CSC Meeting	26 <sup>th</sup> – 31 <sup>st</sup> May 2025
05	58 <sup>th</sup> CSC Meeting	07 <sup>th</sup> – 11 <sup>th</sup> July 2025
6	59 <sup>th</sup> CSC Meeting	25 <sup>th</sup> – 29 <sup>th</sup> August 2025
07	60 <sup>th</sup> CSC Meeting	01 <sup>st</sup> – 03 <sup>rd</sup> October 2025
08	61 <sup>st</sup> CSC Meeting	$08^{th} - 12^{th}$ December 2025

4. It is further decided that, even after approval of above tentative annual schedule, the CSC meeting can be called by the Chairman CSC whenever required.

(MALIK MUHAMMAD ASAD) Secretary CSC / Deputy Director (CT-Lic.) Pharmacy Services Division-DRAP.

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- i. F. No.03-35/2023-CT (PS)
- ii. F. No.16-53/2024-CSC.