

**IMMEDIATE**

F.No.16-48/2024-CSC  
Government of Pakistan  
**Drug Regulatory Authority of Pakistan**  
Ministry of National Health Services, Regulation & Coordination  
PM's National Health Complex, Park Road, Chak Shahzad, Islamabad.  
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Islamabad, the 29<sup>th</sup> April, 2024

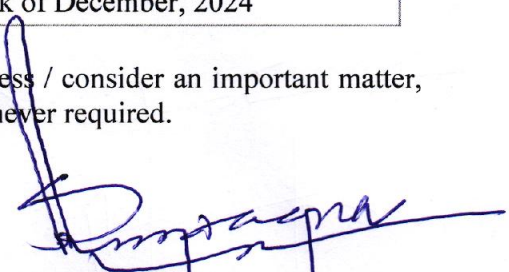
**SUBJECT: - ANNUAL TENTATIVE MEETING CLINICAL STUDIES COMMITTEE PLAN**

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 research, trials, and studies related to therapeutic goods conducted within Pakistan, including oversight of institutions like clinical trial sites, Contract Research Organizations (CROs), Bio-availability or Bioequivalence (BA/BE), and Bio-analytical Laboratory. An expert committee i.e. Clinical Studies Committee (CSC) is responsible for regulation of aforementioned activities related to clinical research.

2. Clinical Studies Committee in its 48<sup>th</sup> meeting held on March 28, 2024 deliberated the necessity of having a tentative schedule for its meeting in order to align with the timely approval of applications related to clinical research related to therapeutic goods, adhere to international best practices, and inform stakeholders for better planning of their projects. Accordingly, the CSC in the aforementioned meeting decided to approve the tentative schedule of meetings as per following details.

S. No.	CSC Meeting	Tentative Schedule
1.	49 <sup>th</sup> CSC Meeting	2 <sup>nd</sup> week of May, 2024
1.	50 <sup>th</sup> CSC Meeting	4 <sup>th</sup> week June, 2024
1.	51 <sup>st</sup> CSC Meeting	2 <sup>nd</sup> week of August, 2024
1.	52 <sup>nd</sup> CSC Meeting	4 <sup>th</sup> week of September, 2024
1.	53 <sup>rd</sup> CSC Meeting	2 <sup>nd</sup> week of November, 2024
1.	54 <sup>th</sup> CSC Meeting	2 <sup>nd</sup> week of December, 2024

3. Further it was decided that in order to address / consider an important matter, the CSC meeting can be called by the Chairman CSC whenever required.

  
**Ahsan Ul Haq Athar**  
Deputy Director / Secretary (CSC)  
Division of Pharmacy Services DRAP

**Distribution;**

All CSC members

✓ Director, MIS Division with request to upload on DRAP official website

29/04/2024