

Recommendations of the SEC (Renal) made in its 11th meeting held on 17.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/35/22 Online Submission (35646) Sibeprenlimab	M/s George Clinical	The firm presented Protocol Amendment 4.0 dated 15Aug 2024 protocol number: 417 – 201 – 00007. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/26/24 Online Submission (35780) TIN816	M/s Novartis	The firm presented protocol amendment version 01 dated 17 Apr 2024 and Protocol Amendment version 02 dated 29 Apr 2024 protocol no. CTIN816B12202. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/06/22 Online Submission (35272) VAY736	M/s Novartis	The firm presented proposal to increase the number of patients to be enrolled from India (14 to 24) Protocol no. CVAY736K12301. After detailed deliberation, the committee recommended for approval of Increase the number of patients to be enrolled from India (14 to 24) as presented by the firm.
4.	CT/79/24 Online Submission (35601) BAY 3283142	M/s Bayer	The firm presented protocol amendment 5, Version 3.0 dated 27-Sep-2024 protocol no. 22040. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/133/24 Online Submission (46170) Atacicept	M/s Medpace	The firm presented phase 2 clinical study protocol no. VT-001-0051 version no. original dated 15-JUL- 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
6.	CT/57/23 Online Submission (36038) LNP023 (Iptacopan)	M/s Novartis Healthcare Pvt. Ltd.	The firm presented Protocol amendment version 04 dated 26 Sep 2024 protocol no. CLNP023B12302. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
7.	CT/59/24 Online Submission (36075)	M/s George Institute Services	The firm presented protocol amendment version 2.0 dated 6th August 2024 Protocol No.: 1378-0006.

SEC (Renal) meeting dated 17.12.2024

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	BI 690517	India Pvt. Ltd.	After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
8.	CT/77/22 Online Submission (36219) Crovalimab	M/s Roche	The firm presented protocol amendment version 6.0 dated 01 July 2024 protocol no. BO42354. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.