

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Tel. No: 01123236965, Fax: 01123236971
E-mail: dcj@nic.in

File No: **CT/24/000004**

To

M/s Fortrea Development India Private Limited,
Building No. 1, Unit No. 601, Raheja Mindspace, Plot nos.
Gen/2/1/D/E/F, MIDCTTC Industrial Area, Shiravane,
Thane (India) – 400706.

Subject: Amendment in CTNOC & TL for change in CTNOC holder from M/s Labcorp Drug Development India Pvt. Ltd. GCT/CT04/FF/2021/25705 (GCT/76/21) dated 07-07-2021 to M/s Fortrea Development India Private Limited GCT/CT04/FF/2024/41396 (GCT/04/24) dated 11/01/2024 (Protocol No.: D5086C00001, Version 1.0, dated 26-FEB-2021 and Addendum IND-1, Version: 1.0 dated 18-OCT-2021) – regarding.

Reference: Your online reference no. GCT/CT04/FF/2024/41396 (GCT/04/24) dated 11/01/2024 on the subject mentioned above.

Sir,

This Directorate has no objection for amendment in CTNOC & TL for change in CTNOC holder from M/s Labcorp Drug Development India Pvt. Ltd, to M/s Fortrea Development India Private Limited as submitted vide your above mentioned application under the Phase 3 clinical trial titled “**A Phase III, Open Label, Randomised, 3-Arm, Multi-Centre Study of Savolitinib plus Durvalumab versus Sunitinib and Durvalumab Monotherapy in Participants with MET-Driven, Unresectable and Locally Advanced or Metastatic Papillary Renal Cell Carcinoma (PRCC) (SAMETA)**” All other conditions mentioned in the CTNOC approval letter issued to you vide F.No. CT/21/000076 dated 20.04.2022 & TL/CT/22/000134 dated 20.04.2022 remain same.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing Authority