

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/23/000163**

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 for change in CTNOC holder from M/s Labcorp Drug Development India Pvt. Ltd. GCT/CT04/FF/2023/36625 (GCT/29/23) dated 21-03-2023 to M/s Fortrea Development India Private Limited GCT/CT04/FF/2023/40758 (GCT/163/23) dated 20/12/2023 (Protocol No.: D3254C00001 Version No. 7.0 dated 29-JUN-2022 & Addendum IND-1, dated 04/Aug/2023)– regarding.

Reference: Your online reference no. GCT/CT04/FF/2023/40814 (GCT/160/23) dated 12/12/2023 on the subject mentioned above.

Sir,

This Directorate has no objection for amendment in CTNOC 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 Multicentre, Randomised, Double-blind, Parallelgroup, Placebo-controlled, 24-week Phase 3 Study with an Open-label Extension to Evaluate the Efficacy and Safety of Benralizumab in Patients with Hypereosinophilic Syndrome (HES)**” All other conditions mentioned in the CTNOC approval letter issued to you vide F. No. CT/23/000029 dated 06.09.2023 remain same.

Yours faithfully,

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