

Annexure - II(b)
Details of clinical trial Permissions
(Form CT-06) Year 2026

S. No	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date Issued	Summary
1.	BIO/CT/25/000115	M/s Zydus Lifesciences Limited	Inactivated Chikungunya Vaccine in Single dose vial (0.5 ml).	Phase I	"A prospective, randomized, double-blind, placebo-controlled, Phase I clinical trial to evaluate the safety, tolerability and immunogenicity of Chikungunya vaccine candidate of M/s. Zydus Lifesciences Ltd. in healthy human participants" (Protocol No.: ZYCHIK 1001, Version 03 dated 30.01.2026	CT-06/2026	20.04.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 19.03.2026 CT permission was granted.
2.	BIO/CT/23/000002	M/s Serum Institute of India Pvt. Ltd.	Yellow Fever Vaccine (Live) (I.P)	Phase III	"A Phase III, Multicenter, Double blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL® in Healthy Children" vide Protocol No.: YWF:05 Version 02 dated 31.05.2023.	CT-07/2026	20.05.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 28.04.2026 CT permission was granted.

Annexure - II(b)
Details of clinical trial Permissions
(Form CT-06) Year 2026

3.	BIO/CT/25/000094	M/s Zydus Lifesciences Limited	Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried)	Phase III	“A prospective, randomized, parallel, single-blind, five-arm, active controlled, multicentre, Phase III clinical trial to evaluate the immunogenicity and safety of Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. and to evaluate lot-to-lot consistency of Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. in healthy infants aged 9-12 months [Protocol No.: ZMMR.25.001, Version no. 03 dated 26 Feb 2026].”	CT-08/2026	01.06.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.01.2026 CT permission was granted.
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(Form CT-06) Year 2026

4.	BIO/CT/25/000201	M/s Cadila Pharmaceuticals Limited	Recombinant Rabies G Protein Vaccine 50 µg /0.5 mL	Phase III	"A randomized, open-label, assessor blind, parallel, active-controlled, multicentric, bridging clinical trial to evaluate the immunogenicity and safety of three dose THRABIS vaccine (Recombinant Rabies G Protein Vaccine), administered as a simulated post-exposure immunization in healthy children." Study Code: CRSC25003, Version 02, date 22.04.2026".	CT-09/2026	25.06.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 18.02.2026 CT permission was granted.
5.	BIO/CT/25/000048	M/s Zydus Lifesciences Limited	Measles, Mumps, Rubella and Varicella vaccine (Live attenuated, Freeze dried)	Phase I	"An open label, single-treatment, single-period, single dose, clinical phase I study to assess the safety and tolerability of measles, mumps, rubella & varicella vaccine (live attenuated, freeze dried) of M/s. Zydus life sciences Ltd. in healthy, adult, human participants (Protocol No. ZYMMRV/1002, Version No. 03, dated 14/02/2026)".	CT-10/2026	25.06.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.01.2026 CT permission was granted.