

Benchmark in Operational Excellence

Timely Managed • Seamlessly Coordinated • Two Continents

HRIPT (irritation/sensitization) BE Studies for ANDA Submission

Cliantha research is a full service CRO with clinical and laboratory presence in India and Northern America. Cliantha reached a new milestone by successfully conducting a HRIPT study, split between India and Northern America.

Data on the two BE studies:

Molecule	Norelgestromin/Ethinyl Estradiol 150 mcg/35 mcg per day Transdermal System	Lidocaine Patch 5%
Status	Completed	Ongoing
Phase of the study	Irritation sensitization /HRIPT (Human Repeat Insult Patch Test)	
Subjects	310 female subjects (170 India 140 North America)	250 male subjects (150 India 100 North America)
Study Conduct	In two different geographical locations India and Northern America	
Key Highlights	<ul style="list-style-type: none"> • Certified trained scorers at both the locations. • All the scorers trained by US Board certified Doctor who is also the Master scorer • Minimize interscorer variability • 95% subject compliance • Study Conducted during peak covid period 	<ul style="list-style-type: none"> • Certified trained scorers at both the locations. • All the scorers trained by US Board certified Doctor who is also the Master scorer • Minimize interscorer variability

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