

1.2 Statement of Statistician, Medical writer and Reviewer

The Neo-Registry has been conducted as per Declaration of Helsinki (Ethical principles for Medical Research Involving Human Subjects, revised by the WMA General Assembly, Fortaleza, Brazil, October 2013) and is consistent with ICH-GCP (E6-R1, Step 5) & ISO14155 guidelines along with the local regulatory requirements of GCP for Clinical Research and all relevant SOPs of Hospital. I have done the data analysis of this project and accept the responsibility for correctness of the data produced in this report.

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