

Workshop 2.5 Overview

Good Statistical Practice - Development of Tailored Good Clinical Practice Training for Statisticians

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Statisticians are fundamental in ensuring clinical research are conducted with quality, transparency, reproducibility and integrity. All research staff should have training in Good Clinical Practice (GCP) and an awareness of GCP requirements in relation to their role. Good Statistical Practice (GCP for Statisticians) is role-specific training to equip statisticians with relevant regulatory knowledge to strengthen GCP interpretation and implementation in relation to statistician responsibilities, leading to transparent and reproducible statistical activity. Materials cover legislation and guidance across all clinical trial processes with statistical involvement, through five subject-specific modules following the logical order of the progressive stages of a clinical trial, from design through to data analysis and reporting. This training is directly relevant to all statisticians, data scientists and health economists working in clinical research, particularly the clinical trials arena.