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Streamling pathology inputs for optimisation of cost, time and quality in the conduct of breast cancer clinical trials

Abstract

Clinical trials are vital for the betterment of cancer care. With the advent of targeted therapy, present day clinical trials are mostly based on development and evaluation of biomarkers.

As considerable cost is involved in a clinical trial, it is imperative to design a trial efficiently by employing effective quality assurance measures for reliable outcomes. High-quality histopathology is crucial for a successful clinical trial. Since histopathologists have a detailed understanding of tumour biology and practical knowledge of tissue handling, their participation ensures correct patient selection for clinical trials by histological subtyping of tumour and the assessment of biomarkers using immunohistochemistry and molecular techniques.

Therefore, the role of pathologist is fundamental in every stage of a clinical trial from concept development to trial design, quality control, analysis and interpretation of results. In order to prepare pathologists to effectively contribute to the clinical trial process they need to be introduced to the generic governance of clinical trials, good clinical practice guidelines, concepts of bio-banking and biomarker validation, management of costs and manpower, quality assurance and control and biomarker validation.

However, there is lack of standardised training targeted at the needs of pathologists worldwide. It is important that pathologists from populous countries like India learn and acquire skills from institutes that already have formalised protocols to incorporate histopathology expertise into clinical trials and usher in a culture of multicentric and multidisciplinary clinical trials which has been slow to catch on due to paucity of focused formalised training in integration of skills and roles of various components needed for the successful implementation of clinical trials.