# Improving access to clinical trials when biopsies are required

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The requirement for tumor tissue specimens and associated analyses in order to participate in clinical trials appears to be a significant barrier to clinical trial enrollment and may delay treatment. Potential solutions to reducing or eliminating these barriers include routine tissue banking at diagnosis, easing use of available diagnostic samples, development of less invasive tests, faster turnaround time at central laboratories or allowing for local testing and more resources for timely tissue collection.

These are the conclusions drawn by investigators at Princess Margaret Cancer Center, Toronto, Canada from a study published today in the *Journal of Thoracic Oncology*, the official journal of the International Association for the Study of Lung Cancer (IASLC).

In the age of personalized and precision medicine more clinical trials are requiring mandatory submission of archival tumor tissue or repeat biopsies for analysis before patients can be enrolled in the trial. The reason for this requirement is that many of the clinical trials are evaluating targeted therapies, therapies designed for a specific alteration within the tumor. Patients are enrolled on the trial based on the presence or absence of the specific alteration or biomarker.

The authors, from January 2007 to March 2015, reviewed and prospectively tracked non-small cell lung cancer (NSCLC) patients with metastatic disease being assessed for systemic therapy clinical trials. The goals of the study were to, 1) determine the impact of the mandatory tissue requirement on the number of advanced NSCLC patients that

were able to enroll and receive therapy, 2) determine the time from initial consent to obtaining a repeat biopsy and ultimately to study therapy, and 3) determine the reasons why patients were ineligible for enrollment.

In total, 55 clinical trials were analyzed in the study, with 54 linked to therapy and 1 for biomarker analysis only. Thirty-two allowed the use of archival samples but 6 mandated repeat biopsies. Presence and/or confirmation of a specific biomarker was required in 24 trials. Trial participation was offered to 636 patients at 940 unique study encounters, with some patients enrolling in multiple trials. In the 54 trials linked to therapy, 549 potential study candidates were screened and 60% went on to receive study treatment. More patients received study treatment in trials without vs. with mandatory tissue requirement (83% vs. 55%, p