

Lessons from an Investigator Led Study: **TAONGA (The Thoracic Oncology Archival Tissue Study in Aotearoa New Zealand).**

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INTRODUCTION

Lung cancer remains the leading cause of cancer mortality in Aotearoa New Zealand (NZ). In the setting of advanced disease where immunotherapy is utilised, response rates remain approximately 30%, with Grade 3-4 toxicity occurring in ~20% of patients. Multiplexed immunofluorescence (mIF) and spatial transcriptomic profiling offer potential to better predict treatment response and identify novel immunotherapy targets.

The objective of TAONGA was to establish a cohort of lung cancer samples from existing archival tissue suitable for spatial molecular profiling, with the aim to recruit 80 participants. Reflections revealed critical system-level and governance barriers that challenged recruitment and data security.

METHODS

Design:
TAONGA was an investigator-led trial utilising a conventional paper-based research consent and tissue retrieval process. Patients were identified with archival surgical resection sample (pneumonectomy, lobectomy, sub lobar or wedge resection including segmentectomy n, or resected metastasis) or archival core biopsy samples with adequate tissue.

DISCUSSION AND CONCLUSION

Following recruitment challenges, processes were reviewed to better understand how to ensure robust design and improved implementation for investigator led trials in the future. The Research Fellow and CRC mapped the trial pathway using the Implementation Science framework **RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance).**

Key operational endpoints included consent completion, successful tissue retrieval, and loss to follow-up.



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<https://re-aim.org/resources-and-tools/>

RESULTS

- 100% of the archival resected lung cancer tissue retrieved had adequate tumour content for use in the planned research.
- In a 9 month period 53 tissue samples were successfully donated. This was 66% of the target.
- Of the 104 approached and given a PICF;
 - Only 3 patients declined.
 - 32 (31%) were lost to follow-up which represents the main reason for failing to consent.
 - 11 became too unwell or died before being able to provide consent.
 - The tissue for 2 patients was not able to be retrieved from the clinical laboratory.
 - 3 did not have an interpreter available to provide consent form translation.

Explicit systems mapping were critical to identify learnings for building future robust investigator led studies in the lung cancer population in Aotearoa NZ.

- Failure to anticipate the consent burden outside clinic
- Digital and IT limitations
- Tissue archival workflow complexity impacted recruitment to the study and time burden for the study team.
- Structured co-design, the use of Implementation Science frameworks
- Digital enablement.
- Paper consenting
- Lack of funding for interpreter services

Despite challenges the study was able to receive 53 tissue sample from patients and significantly contribute to the first national archival tissue bank for spatial molecular profiling in lung cancer patients.

Actionable Take Away Message and Future Direction for Research

Establishing a clear pathway for Investigator Led Studies utilising co-design methodology
Consider contributing factors limiting consent procedures
Options for e-consenting
Mapping curative intent patients discharged to primary care
Ensuring adequate staff on training log to facilitate consenting and manage sample processing