

Title	Integration of Liquid Biopsy into Lung Cancer Diagnostic Pathway
Organisations Involved	Amgen Limited and All Wales Medical Genomics Service (Cardiff & Vale University Health Board)
Collaborative Working Project Description	<p>This collaborative working project seeks to bring together stakeholders from industry and NHS Wales to transform current approaches to lung cancer care in Wales by expediting the clinical implementation of diagnostic ctDNA testing early in the diagnostic pathway. The overall aim of the Project is to reduce the Time to Treatment (TTT) of targeted therapies, resulting in improved outcomes for cancer patients.</p> <p>The intended aims of the Project are to:</p> <ol style="list-style-type: none"> i. Establish RWE comparing the ctDNA vs tissue biopsies ii. Change the pathway to using ctDNA in its practice at one pilot center <p>Scale to additional centres within lung cancer (~740 patients) to provide evidence for routine commissioning across Wales. This experiment can lay the foundation for expansion to other tumor types.</p>
Outcomes	<p>It is anticipated that the following benefits will be achieved throughout the lifecycle of the project:</p> <ol style="list-style-type: none"> i. Patients: Rapid, less invasive diagnostics that result in more appropriate treatment options, improve outcomes and avoid potentially risky repeat biopsy procedures ii. NHS: More comprehensive and timely information at Multi-Disciplinary Team (MDT) that lead to more informed, rapid treatment decisions, fewer healthcare resources utilized and improved capacity and efficiency. The ability to scale nationally and best practice sharing across health boards can reduce care variation and inequalities. <p>Amgen: Patients will have access to more rapid testing for appropriate biomarker-directed therapies. Collaborative working with the consortium will demonstrate value as partner of choice with national organisation creating reputational benefits and invaluable insights into national cancer pathological and genomics pathways</p>
Actual Outcomes	<p>Report findings from the initial cohort of 113 patients included in the Research for Patient and Public Benefit (RfPPB) pilot study:</p> <ul style="list-style-type: none"> • A total of 113 participants with suspected stage III/IV lung cancer were recruited and analysed, with 96 (85%) confirmed lung cancer cases. • ctDNA testing demonstrated high reliability, achieving 98% concordance with tissue biopsy results where both were available. • Turnaround time for ctDNA testing was significantly shorter than tissue testing — ctDNA reports were delivered ~2 weeks faster

	<p>from sample collection and ~3 weeks faster from suspicion-of-cancer to report.</p> <ul style="list-style-type: none">• The ctDNA test identified actionable variants in 24 participants, including 8 cases where variants were detected only via ctDNA (tissue unavailable or test failed), enabling potential treatment options that would otherwise have been missed.• ctDNA testing increased the overall detection of actionable variants by 31% compared with tissue testing alone in participants with NSCLC or radiological lung cancer.• 11 participants received targeted treatment based on actionable variants detected by ctDNA (10 confirmed by tissue, 1 ctDNA-only), demonstrating real-world clinical impact.• The study confirmed that early ctDNA testing can shorten time to treatment allocation, with a median of 45 days compared with 98 days for tissue-guided treatment.• The pilot learning and technical workflows developed through this project supported national scale-up across all six Health Boards in Wales, enabling broader adoption of ctDNA testing within the lung cancer diagnostic pathway. <p><i>NOTE: Full data analysis for the definitive study is still underway and is expected to be published in 2027.</i></p>
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