# Lung Cancer Vaccine Trials in the UK

## The NHS Cancer Vaccine Launch Pad

An updated summary of the UK situation in March 2025

## The NHS Cancer Vaccine Launch Pad.

This new project has been specifically designed for patients with cancer to access vaccine trials at the earliest opportunity. You can read about it on the NHS England website. Oncologists/cancer specialists should be able to put patients in touch with the research nurses working on any relevant vaccine trials that are recruiting via this route. As yet there are no vaccines for ALK Positive Non-Small Cell Lung Cancer (NSCLC) in the immediate pipeline but this will be the best way to access trials as vaccines are developed.

**Childhood and adult vaccination programmes** target a number of infectious diseases caused by bacteria and viruses. They teach the immune system to recognise particular infections, fight them off and protect individuals and the whole population from the potentially serious consequences of catching these infections.

A few vaccines can reduce cancer risk. For example, HPV (Human Papilloma Virus) vaccine is offered to all children aged 11-13 to prevent HPV infection. Because HPV infection is extremely common and a strong risk factor for cervical cancer, this vaccine programme has resulted in a nearly 90% reduction in women developing cervical cancer in their 20s.

Current research in relation to **cancer vaccines** is based on using them to boost the immune system of those patients with early and late stage cancers. As they become available, the cancer vaccines will be offered to patients with a wide range of different cancers. This is completely different to the population based approach with common infectious diseases. There is no current plan that cancer vaccines will be used on a population wide basis for the prevention of cancer.

More information about cancer vaccines can be found on the Cancer Research UK website following the link: <u>CRUK</u>

### <u>"LungVax"</u>

A new lung cancer vaccine is being developed in the UK by researchers from Oxford University, University College London and the Francis Crick Institute. It is a **ChAdOx2 vaccine** using a weakened version of a common cold virus (adenovirus) that has been genetically modified so that it can't replicate in humans, and is similar to the technology used successfully in the Oxford-AstraZeneca COVID-19 vaccine. The vaccine is mid development and researchers have not yet started recruiting for the trial. Once they do, the first phase of the trial will be to determine safety and dosage.

Criteria for entry to the first trial will be patients with NSCLC diagnosed at Stage I/II within 6months post potentially curative surgical resection. Prevention of recurrence over the succeeding 5yrs will be the efficacy end point. Most trial patients are expected to be found in 55-75 year olds with a current or past smoking history who have been invited to take part in the NHS lung cancer screening roll out which is available in some parts of England and Wales. However, patients with early diagnosis of oncogene driven NSCLC followed by surgical resection aged 18yrs+ can be included in the trial.

If there's a significant reduction in recurrence in the vaccinated group, then the next trial will look at prevention in high risk individuals without lung cancer, again based on smoking history. Patients with Stage 4 Alk Positive and other oncogene driven NSCLCs who have no evidence of disease,(NED), or Stage 4 stable disease, will not be considered initially for trials of this vaccine. That may come later if results show significant prevention of recurrence post surgery and protection from lung cancer developing in high risk patients. It may take up to 8+years to get to this point. However, Prof Sarah Blagdon, who is running the trial, does think the vaccine has the potential to be effective against oncogene driven NSCLCs like ALK Positive.

https://www.lungcancercenter.com/news/lung-cancer-vaccine

## The Mobilize Trial

The Mobilize trial is run in partnership between Imperial College London and Imperial College Healthcare NHS Trust, with the first patients in the UK receiving the treatment at the National Institute for Health and Care Research (NIHR) Imperial Clinical Research Facility at Hammersmith Hospital.

UK patients have received the experimental **mRNA** therapy – a type of immunotherapy treatment called mRNA-4359 – at Imperial College Healthcare NHS Trust as part of a phase 1/2 clinical trial. The trial aims to evaluate its safety and potential for treating melanoma, lung cancer and other 'solid tumour' cancers.

The treatment is designed using messenger RNA (mRNA) and works by presenting common markers of tumours to the patient's immune system. This should help to train patients' immune systems to recognise and fight cancer cells expressing these markers, but also potentially eliminate cells that may suppress the immune response. The primary aim of the study is to assess if this new mRNA therapy is safe and tolerated by patients, either when it's administered alone or in combination with an existing cancer drug called pembrolizumab – which is a type of immune checkpoint inhibitor. Researchers are also investigating whether the combination of treatments can actively shrink tumours in patients with certain types of lung and skin cancer.

The Trial will include NSCLC patients with known epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), proto-oncogen tyrosine-protein kinase reactive oxygen species (ROS1), or other actionable mutations for which there are approved targeted therapies. They must have received prior approved targeted therapy, (or have been offered and declined approved targeted therapy) and then progressed. Participants must have a tumour lesion amenable to biopsy and must have another lesion that can be followed for response.

https://trials.modernatx.com/study/?id=mRNA-4359-P101

#### LuCa-MERIT-1

#### News report from UCLH 23 August 2024

A lung cancer patient at UCLH is the first to receive a novel cancer vaccine designed to prime the immune system to recognise and fight cancer cells. It is the first time this immunotherapy made by BioNTech, the German biotechnology company, will be studied in a clinical trial for lung cancer in the UK, where the NIHR UCLH Clinical Research Facility is the lead research site.

The investigational mRNA cancer immunotherapy for non-small cell lung cancer (NSCLC) – known as BNT116 – utilises a messenger RNA (mRNA) to present common tumour markers from NSCLC to the patient's immune system, with the aim of helping the immune system recognise and fight cancer cells expressing these markers. The investigational vaccine is designed to specifically enhance immune responses against targets primarily expressed by cancer cells, reducing the risk of toxicity to healthy, non-cancerous cells – unlike chemotherapy, which often affects both cancerous and healthy cells.

UCLH consultant medical oncologist Siow Ming Lee, who leads the national study said: "Lung cancer remains the leading cause of cancer deaths worldwide, with an estimated 1.8 million deaths in 2020. "We are now entering this very exciting new era of mRNA-based immunotherapy clinical trials to investigate the treatment of lung cancer, thanks to the foundation laid by the Office for Life Sciences, within the Department for Science, Innovation and Technology and the Department for Health and Social Care. We hope this will provide an opportunity to further improve outcomes for our NSCLC patients, whether in the early or advanced stages," said Prof Lee, who is also Professor of Medical Oncology at UCL. Prof Lee's research is supported by the National Institute for Health and Care Research (NIHR) Biomedical Research Centre at UCLH. Approximately 130 participants will be enrolled in the study across 34 research sites in seven countries, with six UK sites selected.

The primary objective of this study is to determine if BNT116 is safe and well tolerated. The trial will be enrolling patients at different stages of NSCLC, from early-stage NSCLC before surgery or radiotherapy (Stage 2 and 3) to late-stage disease (Stage 4) or recurrent cancer. The presence of a driver mutation for lung cancer such as ALK-positive, for which approved targeted therapies are available, leads to exclusion from the trial currently. However, an individual ALK-positive patient who is not a candidate for the respective targeted therapy may be considered for the trial.

The trial aims to establish the safety profile and a safe dose of BNT116 monotherapy, as well as of BNT116 in combination with established treatments for NSCLC to see if BNT116 has a synergistic anti-tumour effect when given with these established chemotherapy or immunotherapy treatments.

https://www.uclh.nhs.uk/news/first-uk-patient-receives-innovative-lung-cancer-vaccine