

## NOMADIC Trial – Lay Summary

**Background:** A diagnosis of lung cancer can be devastating. On top of this, people with lung cancer are at high risk of blood clots, usually in the legs which can spread to the lungs. Clots in the leg are known as deep vein thromboses. Clots in the lungs are known as pulmonary emboli. The risk of clots is not well appreciated by people with lung cancer, their carers and some healthcare professionals. Having a clot may delay life-saving cancer treatment and reduce a person's quality of life. Sometimes, clots are fatal. The risk of clots is higher for people with lung cancer undergoing cancer treatment when compared to those not receiving treatment. Currently, people with lung cancer are not routinely offered tablets which thin the blood to prevent blood clots happening.

**Aims:** In this study, we aim to find out if treatment with a tablet blood thinner (a direct oral anticoagulant or DOAC) as a prevention measure can reduce clots in people with lung cancer receiving cancer treatment when compared to a 'placebo' (same look of a tablet with no active ingredients). We want to know if this approach is safe for people with lung cancer and value for money for the NHS.

One side effect of blood thinners, including DOACs, is bleeding, which is sometimes serious. We have chosen the DOAC tablet called apixaban because results from many global studies suggest that apixaban may have less bleeding than other DOACs.

**Methods:** Our research will test if apixaban, at a safe and effective dose, is better at preventing blood clots than placebo. We will also explore the physical and emotional wellbeing and the quality of life of those who take part in the study.

We have designed a study called NOMADIC, involving 1134 people with lung cancer who give written agreement to take part. They will be allocated at random into two groups to receive one year of treatment with either:

1. A placebo *or*
2. Apixaban

The people taking part in the study and the healthcare professionals will not know which tablet is being taken.

**Delivery:** The study will be conducted by hospital doctors and nurses caring for people with lung cancer or people with blood clots.

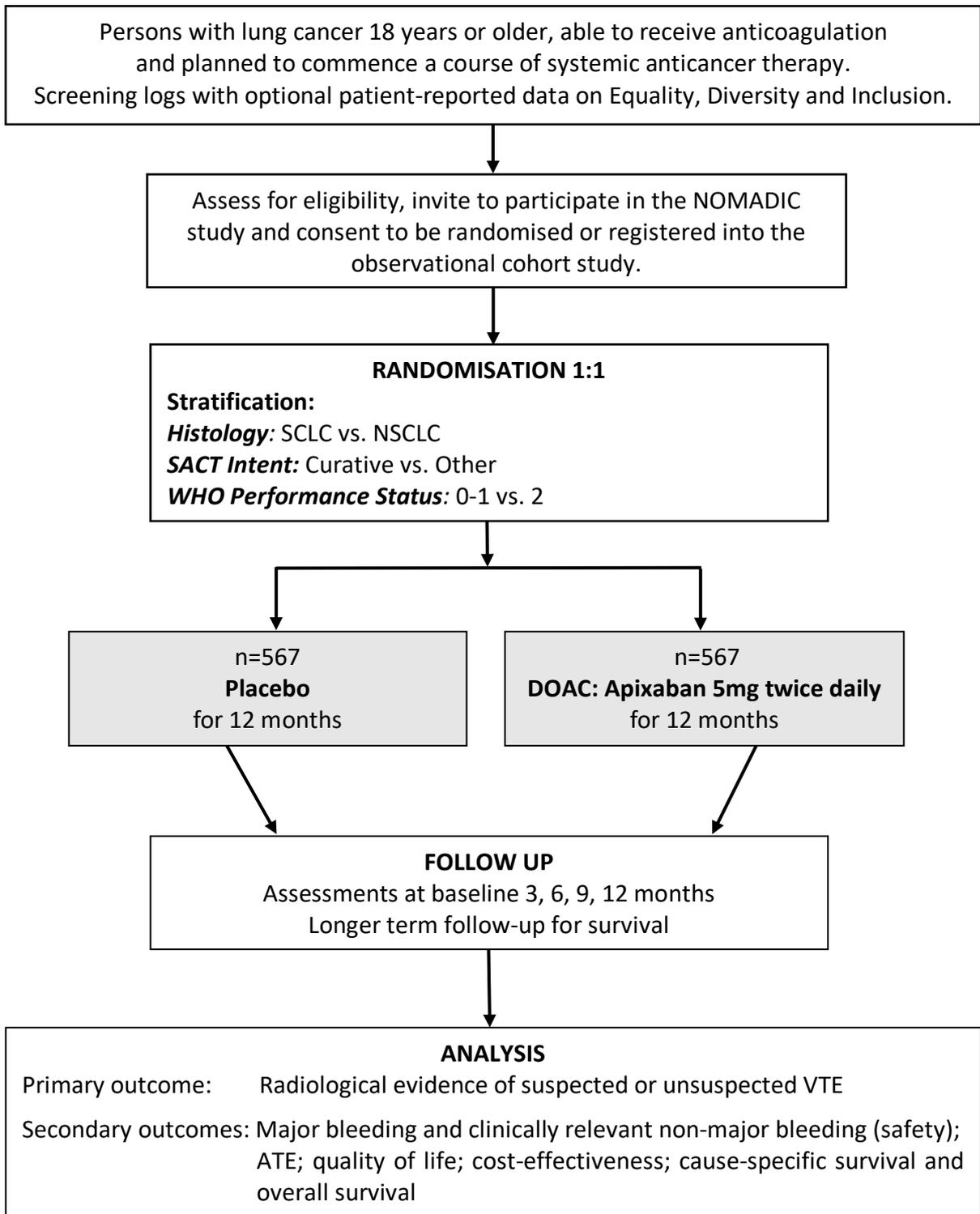
**Measurements:** All people who take part in the NOMADIC study will be asked to complete, either online or on paper, questionnaires to capture information on their quality of life and how they feel emotionally and physically, as well as any symptoms related to thrombosis or bleeding. This will be done before the study starts and at 3, 6, 9 months (for one questionnaire) and one year after the start of taking the placebo or the DOAC. We also want to identify hospital or GP visits that are likely related to this study to see what extra support may be needed in practice.

We will ask permission to interview some people taking part in the study and some healthcare professionals, to explore their experience of the NOMADIC study. We will also ask some people taking part in the study and their carers (if they have any) about the impact on their day-to-day lives from being part of the study.

Team: Our team includes people with lung cancer, carers, oncologists, haematologists, nurses, pharmacists and experts in research.

Dissemination: NOMADIC will change practice for the prevention of clots for people with lung cancer nationally and globally. To ensure results are used to inform future guidelines, we will present findings to interested people at conferences, patient outreach events, in journals and in the media.

## NOMADIC Study - Flow Diagram



### Abbreviations:

WHO – World Health Organisation; SCLC – small cell lung cancer; NSCLC – non-small cell lung cancer; VTE – venous thromboembolism; ATE – arterial thromboembolic events