Introduction
Oligometastatic NSCLC patients have better outcomes than those with the higher disease burden associated with wider spread metastatic disease. SABR/SRS have been extensively reported to result in excellent local control of individual metastatic deposits with low rates of grade 3+ toxicity. SARON is a randomised-controlled phase-III trial to investigate the impact of conventional RT and SABR/SRS in oligometastatic NSCLC patients suitable for radical treatment (maximum of 5 metastases involving a maximum of 3 organs, in-line with the recent EORTC consensus definition of synchronous oligometastatic disease).

Methods
SARON is a multi-centre, randomised-controlled trial (RCT) with an original target sample size of 340. Patients are randomised in 1:1 ratio to standard of care (SOC) alone or SOC plus radiotherapy to all disease sites. SOC in the UK in this patient population is systemic anti-cancer therapy (SACT): mono-chemotherapy, mono-immunotherapy or combination of chemo-immunotherapy, chosen according to standard guidelines.

Results
SARON opened for recruitment in 08/2016; 20 centres are open to date (06/12/2021) with 136 patients registered, 89 randomised. Following initial recruitment difficulties due to the changing landscape of SOC treatment and the subsequent impact of the pandemic, we are in the process of implementing a protocol amendment to change the design from a phase-III RCT to a practice-informing phase-II RCT. The subsequent reduction in required sample size to 134 randomised patients, whilst keeping a primary endpoint of overall survival, will ensure that the study objectives remain scientifically relevant at the expected time of reporting in early 2026. In addition to the significance level and power being relaxed, original assumptions regarding estimates for median overall survival in the control arm following the change to SACT and length of recruitment period have been re-estimated.

Conclusion
In moving to a phase-II design, SARON will remain an important clinical trial that will help guiding management of this complex patient population.