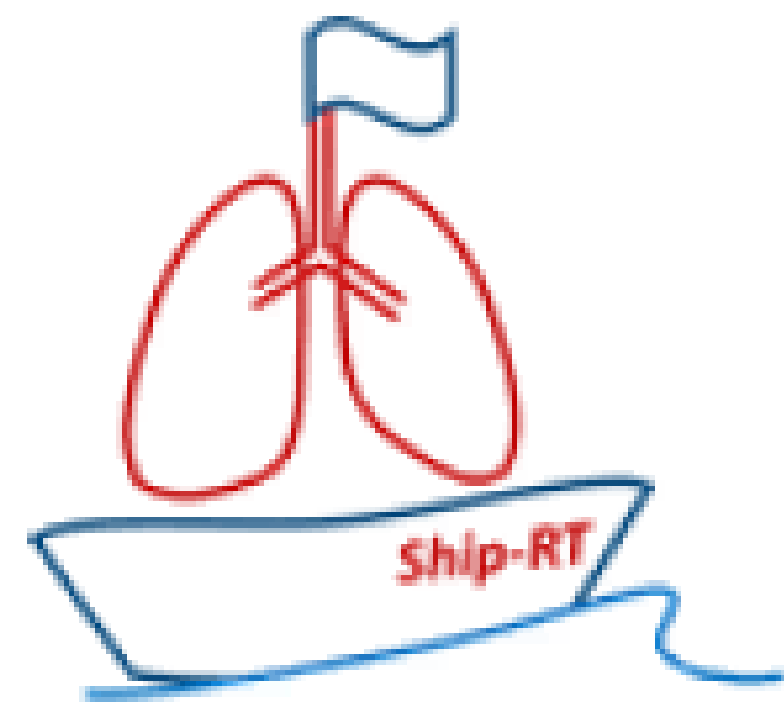




Shortened High-dose Palliative Radiotherapy (SHiP-Rt) for Lung Cancer – a Single-arm, Multi-centre, Phase-II UK Study (NCT06483308)

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01. Introduction

Significant advances with systemic therapy have improved survival for patients with advanced-stage non-small cell lung cancer (NSCLC). However, the present treatment strategies and dose-fractionation for high-dose palliative radiotherapy (RT) are based on trials from the 1990s, when RT planning was simple, typically parallel-pair or 3-dimensional conformal, with less precise delivery (1).

Contemporary lung RT uses 4D-CT, volumetric modulated arc radiotherapy (VMAT), aided by online verification using cone beam CT, which enable **greater accuracy, better target volume coverage**, whilst **reducing doses to normal organs at risk**.

Before beginning SHiP-RT, a **retrospective planning study** was conducted (2), which showed that it is potentially safe and feasible to deliver high-dose palliative radiotherapy for advanced NSCLC using a **6-fraction regimen (30Gy in 6 fractions)**. In this study it was possible to **meet clinically appropriate dose constraints** to organs at risk which indicates that toxicity from such treatments should be comparable to the standard treatments of 36Gy in 12 fractions.

02. Objective

This study aims to see if we can we safely deliver hypofractionated, high dose palliative radiotherapy, in advanced NSCLC.

03. Methods

The SHiP-Rt study aims to evaluate the **safety** and **feasibility** of reducing the number of RT fractions and RT duration, using contemporary lung RT techniques, using 4D-CT, volumetric modulated arc radiotherapy (VMAT), aided by online verification using cone beam CT. This single-arm, multi-centre, phase-II study will test the shortened, hypofractionated, accelerated, palliative RT regimen of **30Gy in 6 alternate-day fractions**, with strict normal tissue dose constraints. We aim to recruit **37 patients**, across **4 sites** within the West Midlands, UK.

Patients with **locally-advanced or metastatic NSCLC**, who are candidates for high-dose palliative RT, **before or after first line systemic therapy** are eligible for recruitment.

Developed in collaboration with the Warwick CTU, this study was reviewed by NCRI CTRad, NCRI lung CSG, and the RTTQA, with feedback included into the study design. Funding was awarded by the UHCW Charity and Coventry Hospitals Charity. Quality assurance for RT is being supported by the **RTTQA**.

Trial Design

Standard of Care Regime



Proposed Fractionation in Single Arm Study



Figure 1: A diagram to depict the differences in the timepoint and numbers of treatments between current standard of care and the protocol treatment

05. Recruitment and Results

The primary objective of this study is to assess the **safety** of the proposed dose-fractionation. Secondary objectives include evaluating **wider toxicity profiles, patient reported outcome measures (PROMS), Time to Progression (TTP), feasibility**, and the **NHS cost-saving**.

The study started recruitment in November 2024 and **completed as planned, in March 2026**, as shown by Figure 3.

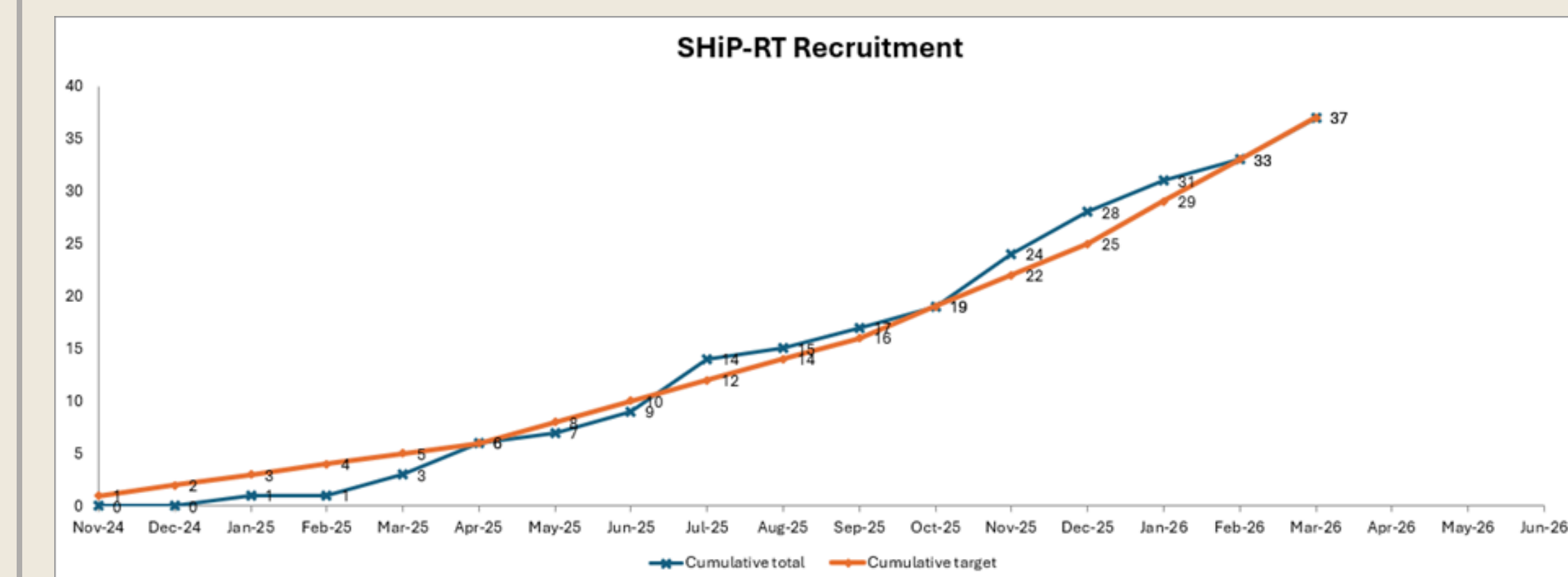
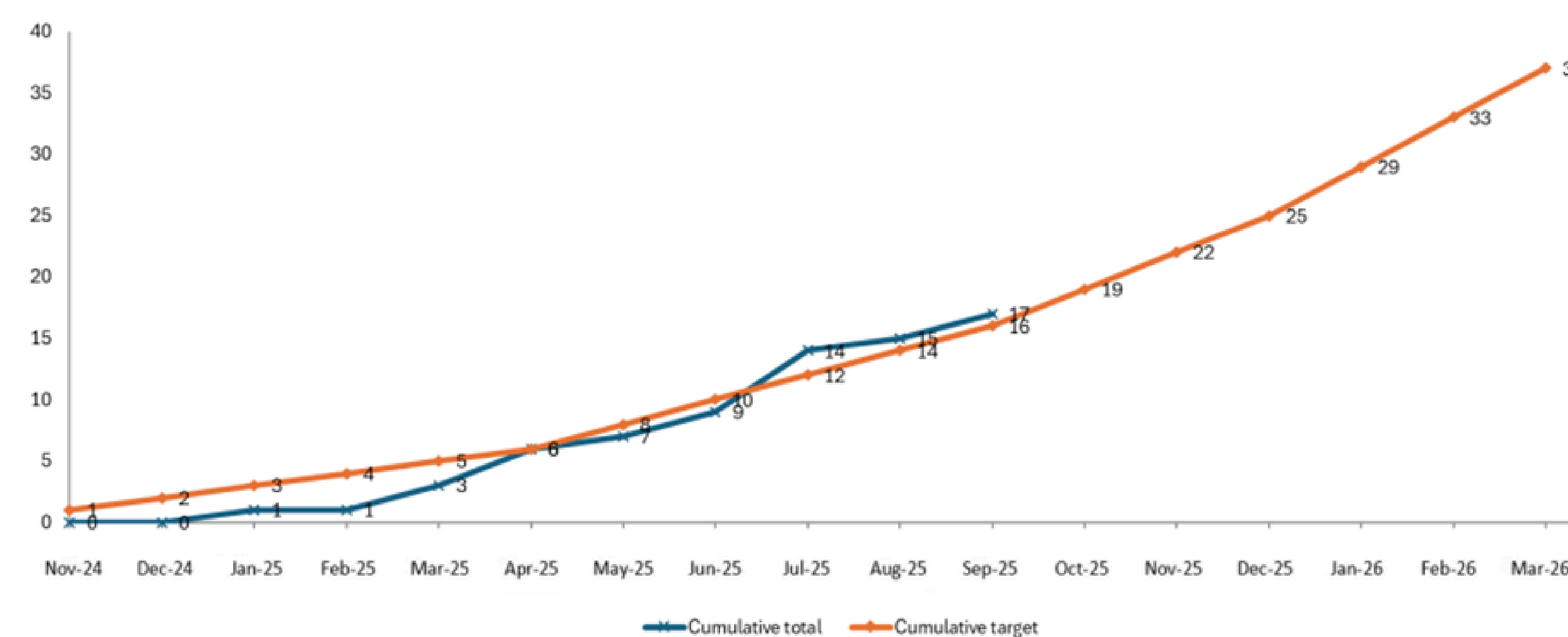


Figure 3: SHiP-Rt Recruitment Tracker

Interim Analysis: Stage 1 results (Data freeze: 24th Sep 2025)



17 patients had been recruited, and primary endpoint data available on 11 recruited patients. Of those, in **total 11/11 (100%)** have successfully completed treatment and **none reported oesophagitis at grade 3-4**. The study was allowed to continue and complete recruitment.

Patients recruited to date	N (%)
- Failed to start treatment [*]	1
- Started treatment but withdrew prior to providing primary endpoint data [*]	1
- Started treatment recently and currently remain on treatment	4
- Started treatment and have provided primary endpoint data	11
• Failed to complete treatment	0/11 (0%)
• Successfully completed treatment BUT reported a grade 3-4 oesophagitis within 4 weeks of completing RT	0/11 (0%)
• Successfully completed treatment AND did not report a grade 3-4 oesophagitis within 4 weeks of completing RT	11/11 (100%)

^{*} Patient #1
^{*} Patient #10

Figure 2: Stage 1 patients recruited to date

06. Conclusion

The potential advantages from this regimen include RT given in **fewer fractions in fewer hospital visits**, resulting in **better patient experience, cost-savings for the NHS, opportunity benefits** for other patients and **more efficient healthcare delivery**.

This study will inform a **phase III trial** to assess **efficacy** when this regime is incorporated into the **current standard of care**.

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