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1. Background

There is impetus to identify biomarkers in testicular germ cell tumours (TGCT) to help select those at high-risk of relapse following orchidectomy and target interventions to prevent over-treatment.

miR-371 has been shown to reliably predict presence of active malignancy over and above currently available biomarkers.

More clinical evidence is required to ascertain its clinical utility as a marker of residual disease to guide treatment recommendations in stage 1 TGCT and other settings.

In this ongoing trial, we aim to demonstrate the **clinical utility** of miR-371 in detecting minimal residual disease in individuals with clinical stage 1 TCGT following orchidectomy.

3. Methods

Clinical data: Administered by Australia's testicular cancer registry, iTestis.

Biospecimen tracking: REDCap.

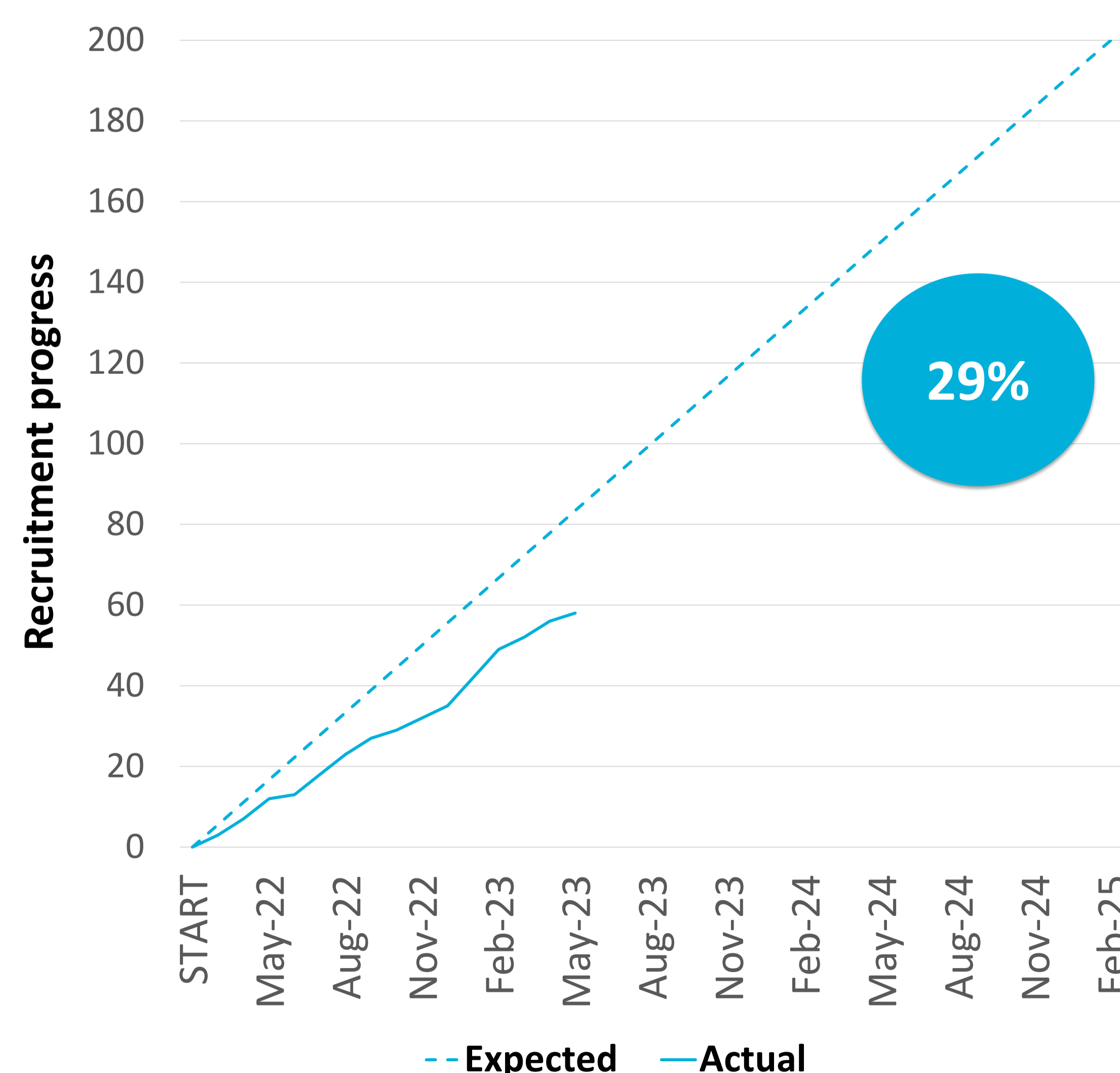
Sample type: At defined timepoints during follow-up, serum, plasma and buffy coat will be collected to perform miR-371 analysis using quantitative PCR technology. Archival tissue from diagnosis ± relapse is identified for future translational research.



4. Study Progress



- Recruitment commenced February 2022.
- 11/12 sites actively recruiting in Australian and New Zealand.



This ANZUP investigator-initiated study is being led by ANZUP in collaboration with the Walter and Eliza Hall Institute of Medical Research (WEHI).

ANZUP receives valuable infrastructure support from the Australian Government through Cancer Australia.

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Website: www.anzup.org.au

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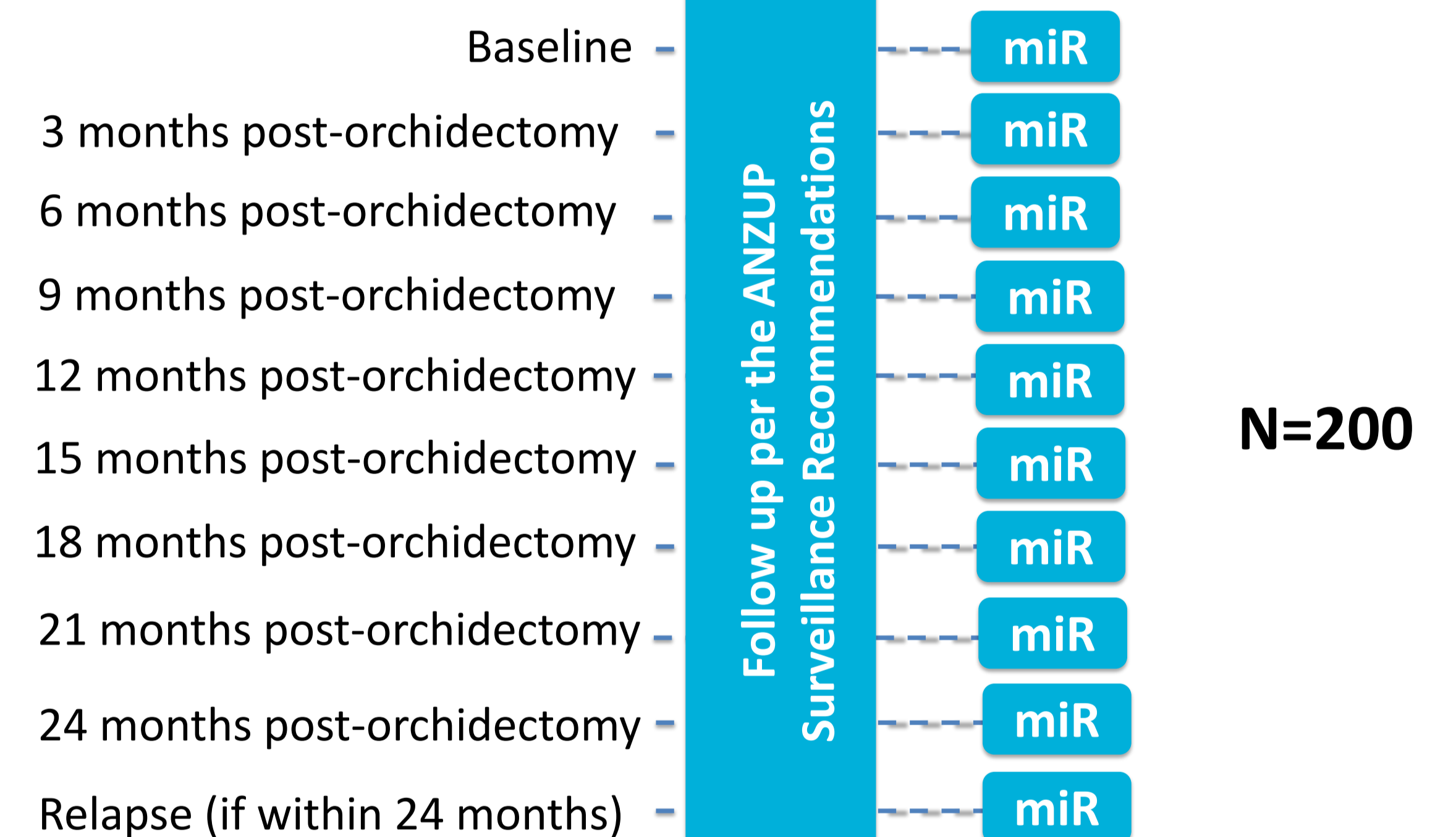
2. Study Design

Orchidectomy + perioperative staging

Population

- Adults with clinical stage 1 testicular germ cell tumour (seminoma OR non-seminoma).
- Consent within 6 weeks of Orchidectomy.
- Planned for active surveillance without adjuvant treatment.

Consent and completion of screening activities



Primary Outcome

12-month relapse free-survival in post-orchidectomy miR-371-positive and -negative populations.

Secondary Outcomes

- miR-371 elevation at time of clinically-confirmed relapse.
- Change in miR-371 during active surveillance and at time of relapse.
- Interaction between cost and clinically-confirmed relapse.
- Contribution of patient-level data to joint analysis of COG AGCT1531 and SWOG 1823.

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