



# Phase II trial of neoadjuvant PD-1 vaccine PD1-Vaxx in operable MSI-high colorectal cancer



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## Introduction

- **Colorectal cancer** is the third most common cancer
- Approximately 80% of patients have **resectable disease** at diagnosis, though recurrence remains high for later stages of disease, even with adjuvant therapy
- Anti-tumour **immune response** plays an important role in determining outcomes
- **MSI-high** colorectal tumours have been observed to respond well to immunotherapy, where such tumours up-regulate immune checkpoints such as PD-1 and PD-L1
- Imugene Limited have developed PD-1 Vaxx an **anti-PD-1 vaccine**, to produce a polyclonal B-cell antibody response

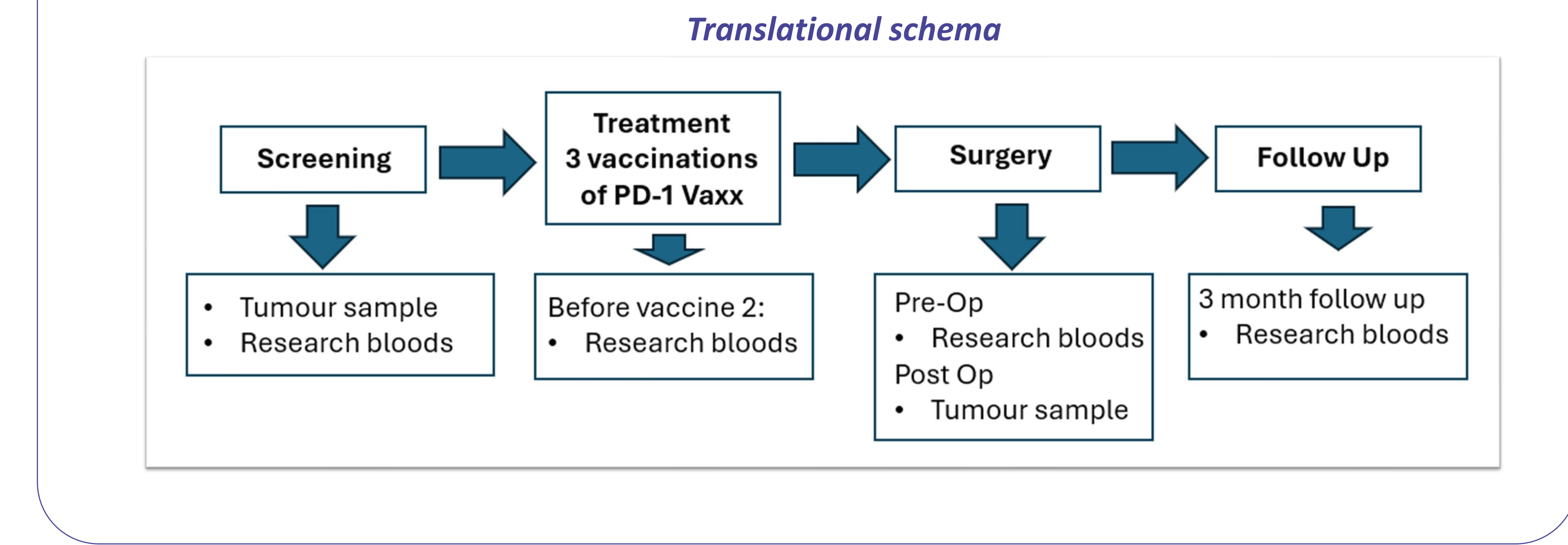
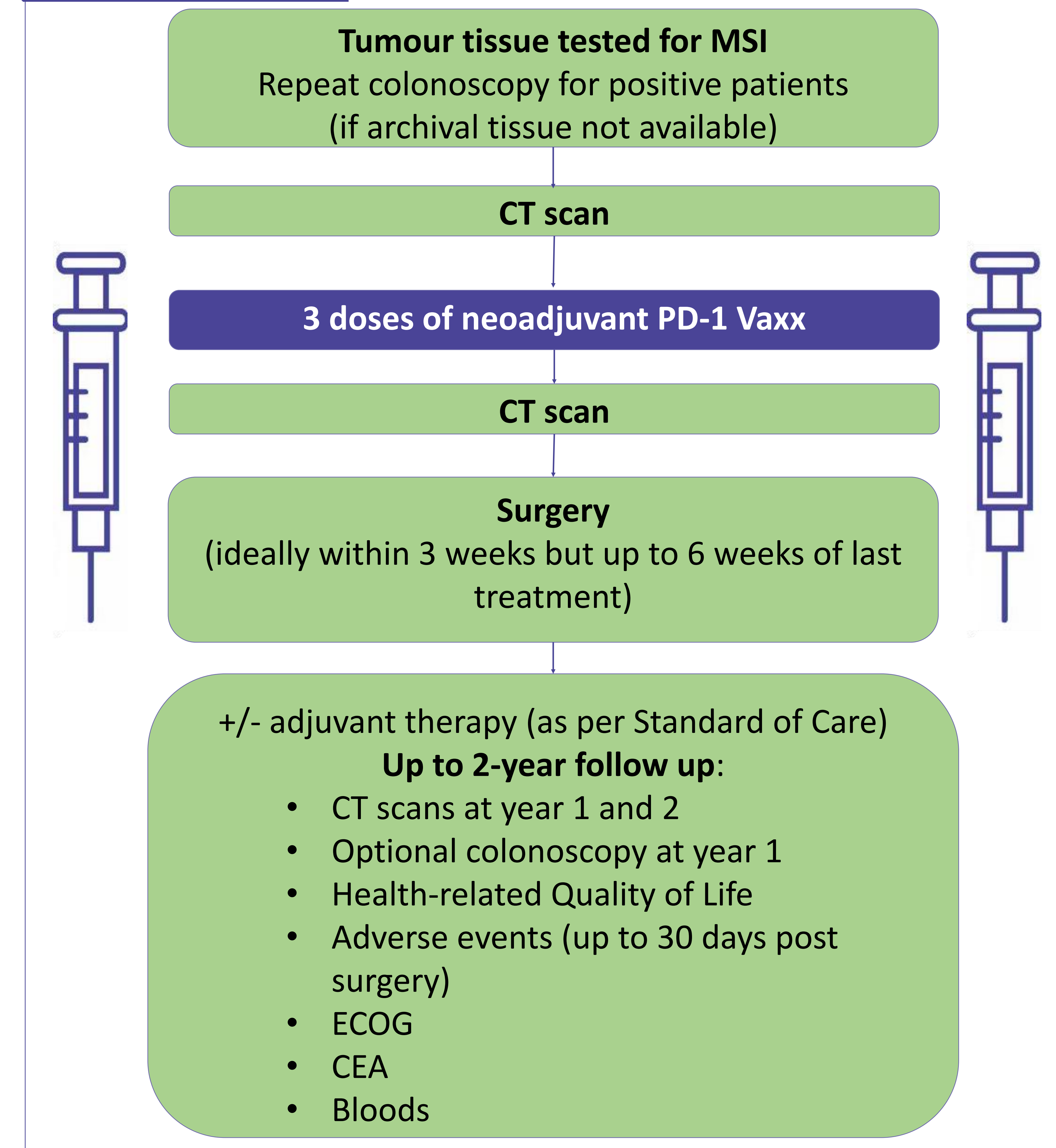
## Objectives

- Primary**
- To determine **major pathological response** following administration of PD-1 Vaxx
- Secondary**
- To assess **safety** of PD-1 Vaxx
  - To determine disease response (**complete response** and **objective response rate**)
  - To assess **disease-free survival** (post-surgery) and **overall survival**
  - To assess health-related **quality of life**
  - To assess complications of surgery (Clavien-Dindo)
- Translational**
- Profile circulating and tumour infiltrating immune cell populations
  - Tumour phenotyping
  - TIL gene expression analysis
  - Tumour sequencing and prediction of neo-epitopes

## Status

- **Australia** - Ethics approval obtained Nov2024. Study opened to recruitment 30May2025. PPFV 16Jun2025. 2 sites open. 2 participants enrolled.
- **UK** - Sites in set up.

## Trial schema



## Contacts

- **Australia** – [agitg\\_neo-polem\\_mailbox@gicancer.org.au](mailto:agitg_neo-polem_mailbox@gicancer.org.au)
- **UK** – [neopolem@soton.ac.uk](mailto:neopolem@soton.ac.uk)

## Design

- **Bayesian Optimal Phase II (BOP-2) Design**, single arm, open label, sample size **n=44**
- Interim **futility analyses** after n=10 and n=20
- Formal **continuous toxicity review** for the first n=15 participants, with stopping rules
- 6-10 sites across **UK** and **Australia**

## Key eligibility

- Operable MSI-high histologically-confirmed adenocarcinoma of the colon or high rectum
- ECOG performance status 0 or 1
- Radiological evidence of operable disease and measurable disease (per RECIST 1.1)
- Classified as MSI-high or MMR deficient
- Stage II (T3-4, N0) or III (any T, N1-2, M0) CRC
- Treatment naïve

## Outcomes

- **Primary**
- Major pathological response rate (≤10% viable tumour cells)
- **Secondary**
- Adverse events (NCI-CTAE ) and surgical complications
- Complete response (no viable tumour cells)
- Objective response rate prior to surgery (RECIST v1.1)
- Disease-free (DFS) and overall survival (OS)
- EORTC QLQ-C30 and EQ-5D-5L

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