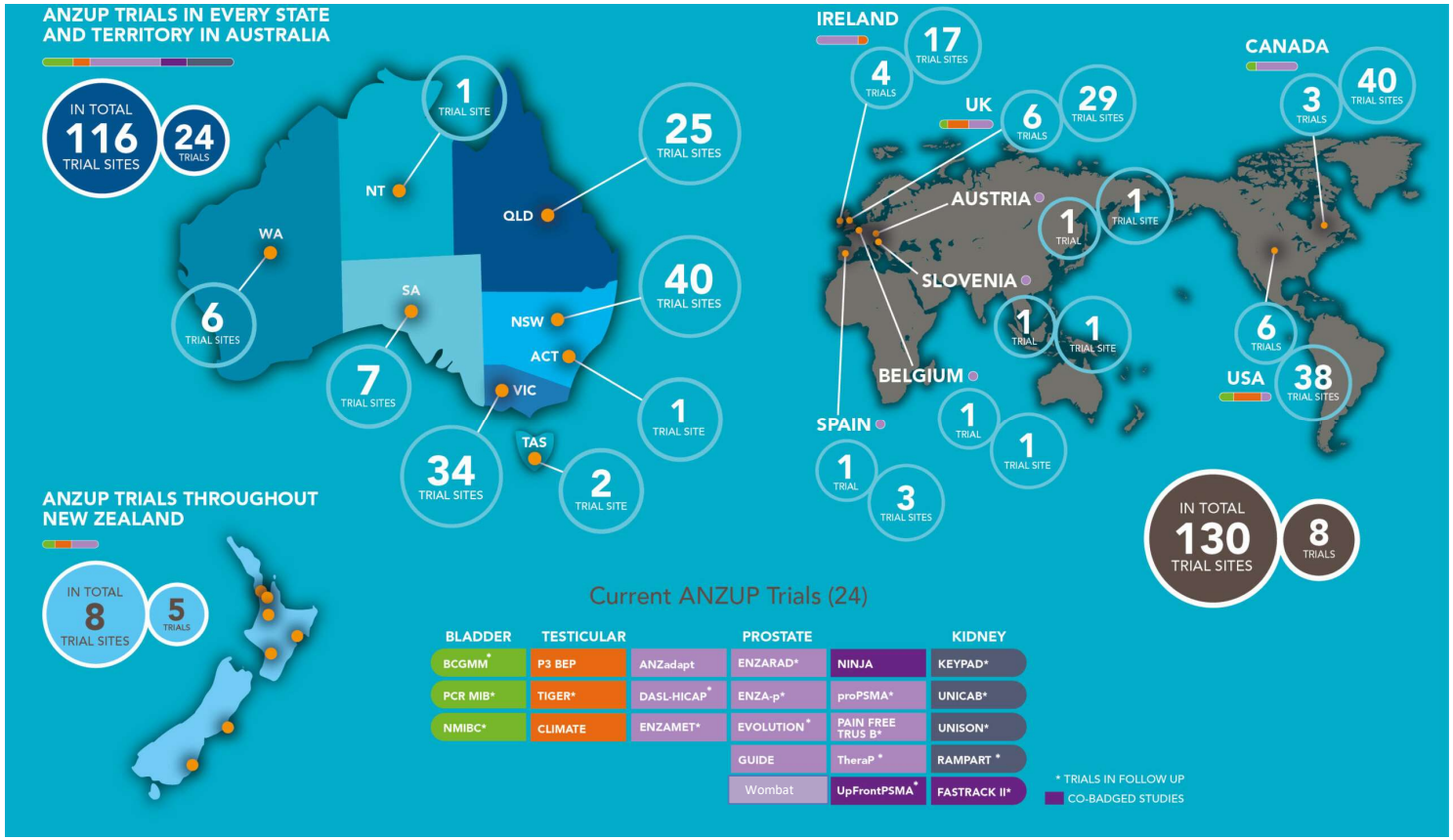
ANZUP
Cancer Trials Group Limited

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)- Update

Vinod Subhash

ANZUP Trials- Overview



ANZUP Clinical Trial- In Start Up (2024)

GenI-AIRPSACE
(Genomically Informed Active Surveillance in Intermediate Risk Prostate Cancer)

Principal Investigator: A/Prof Niall Corcoran

Hypothesis

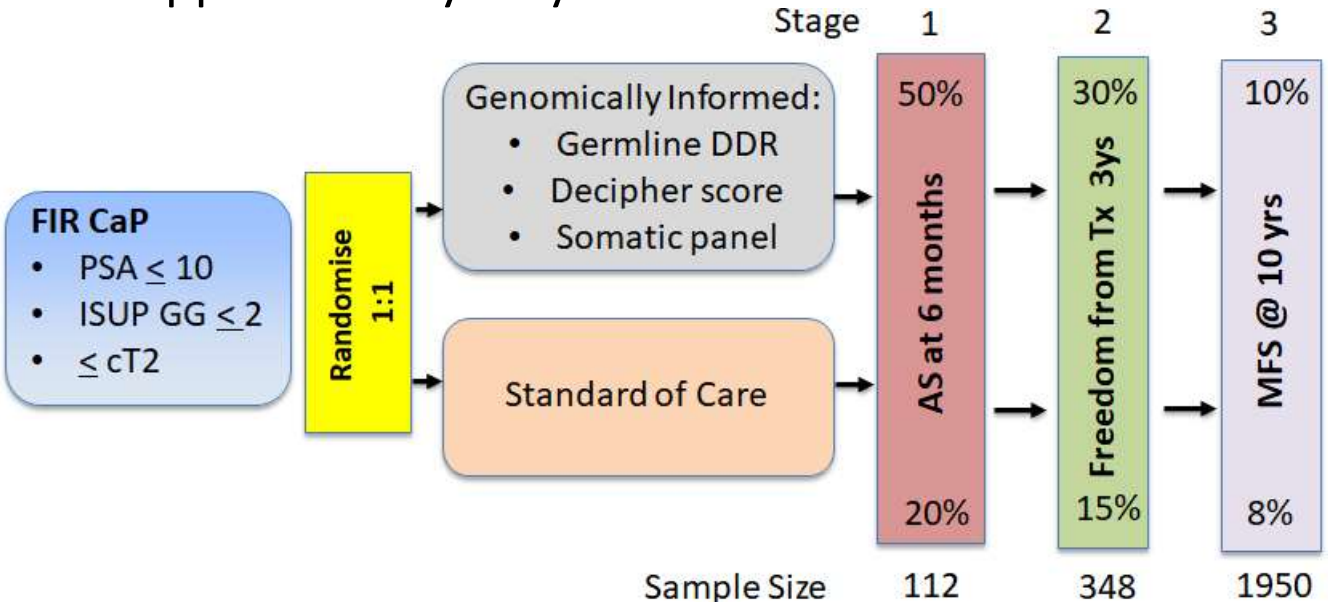
Genomic-based risk stratification at the time of diagnosis with favourable intermediate risk prostate cancer will reduce the number of people receiving radical treatment without compromising long-term oncological outcomes

Study Design & Schema

Sequential, multi-centre, open label randomised controlled trial (1:1) of risk stratification by three molecular tests to inform decision-making in localised FIR CaP

Sample Size: **Stage 1**: 112 participants, **Stage 2**: 348 participants, **Stage 3**: 1950 participants

Total Study Duration: Approximately 15 years



Stage 1, 2: Power 90% alpha=0.05, 2-sided superiority

Stage 3: Power 90% alpha=0.05, One-sided non-inferiority with non-inferiority limit of 3%

A/Prof Niall Corcoran

Study Endpoints

Primary Endpoints

Stage 1: ACCEPTANCE by participants of risk stratification by genomic information as measured by the proportion receiving active surveillance at 6 months following randomisation.

Stage 2: IMPACT of counselling informed by genomic information on treatment selection in the medium term as measured by the percentage of participants not proceeding to radical intervention within 3 years.

Stage 3: SAFETY of genomically informed treatment decision-making on long-term oncological outcomes as determined by metastasis free survival at 10 years.

Study Endpoints

Secondary Endpoints

Patient-reported outcomes between baseline, 6 and 12m after randomisation including changes in:

a. Urinary, sexual & bowel function assessed using the EORTC- QOL Questionnaires-PC-25;
b. Health-related QoL assessed using EORTC QLQ-Core 30 (C30);
c. Anxiety and depression assessed using the Hospital Anxiety and Depression Scale (HADS)
d. Fear of cancer progression assessed by Fear of Cancer Recurrence Inventory Short Form (FCRI-SF)-Severity Index.

Cost-effectiveness using existing health economic models, accompanied with data provided by the MBS and PBS, hospital admission data (for participants enrolled in Victoria and New South Wales) and data obtained from the EORTC QLU-C10D algorithm