

Driving equitable cancer care - clinical trial setting

21 May 2024

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Head of Research Operations, AGITG



Acknowledgement of Country

We acknowledge the Traditional Custodians of Country throughout Australia.

Our office is based on the lands of the Gadigal people of the Eora Nation, and our membership spans across Australia and Aotearoa New Zealand.

We recognise the enduring connection between First Nations people and Country, and their Custodianship of the land, waters and sky since time immemorial.

We pay our respects to Elders across time. We extend that respect to all First Nations people we meet and engage with in our work and purpose.

Topics:

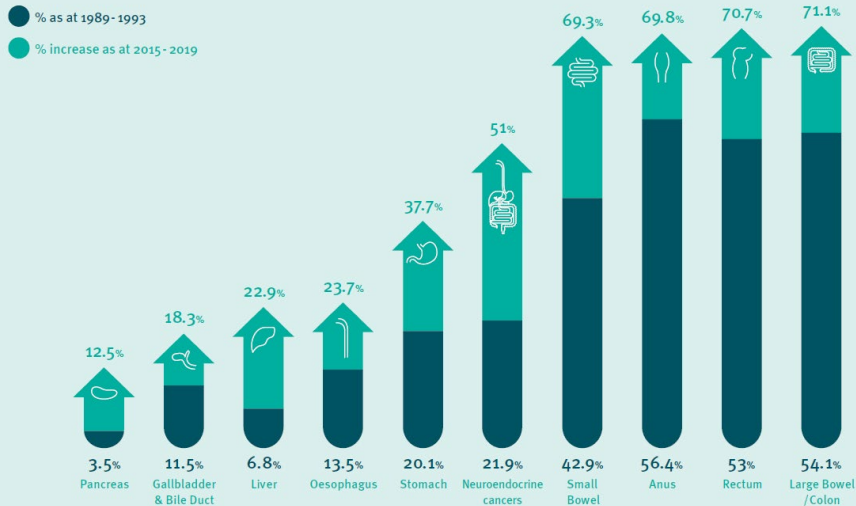
- AGITG
- Where we started this journey
- Initiatives 2021→



Working to improve patient outcomes since 1991

At the Australasian Gastro-Intestinal Trials Group (AGITG), we are working towards creating a world free from gastro-intestinal (GI) cancers.

Five-year survival rates have improved but there is still work to be done for the 36,929 Australians diagnosed with a GI cancer every year.



Source: AIHW Cancer data in Australia, Web report 2023



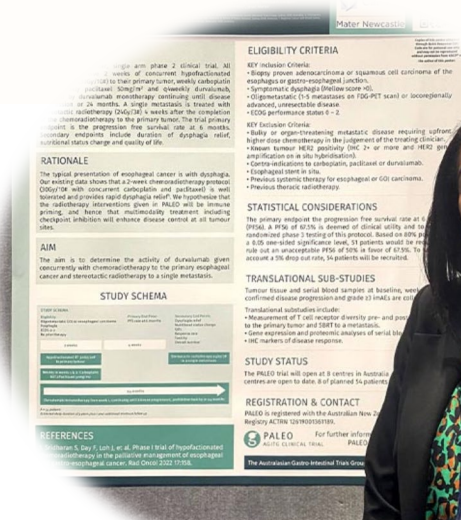
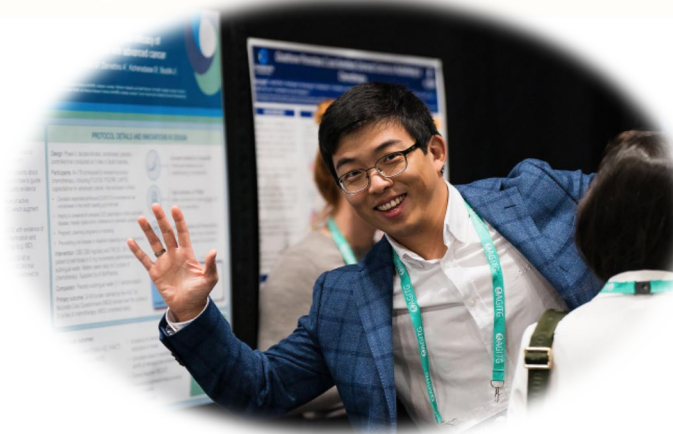
>\$12m raised
for
>28 research
projects

Our membership

- Medical Oncologist
- Trial Coordination Staff
- Surgeon
- Scientist
- Radiation Oncologist
- Gastroenterologist

- Early Career Researcher
- Consumer
- Pathologist
- Dietitian
- Statistician
- Radiologist
- Psycho-Oncologist
- Health Economist

- Endocrinologist
- Bioinformatician
- Hepatologist
- Infectious Diseases Specialist
- Indigenous Health
- Other



Mater Newcastle

ELIGIBILITY CRITERIA

KEY Inclusion Criteria:

- Stage proven adenocarcinoma or squamous cell carcinoma of the esophagus or gastro-oesophageal junction.
- Symptomatic dysphagia (NRS score > 2).
- Oligometastatic (1-5 metastases on FDG-PET scan) or biologically advanced, resectable disease.
- ECOG performance status 0 - 2.

KEY Exclusion Criteria:

- Bulky or organ-threatening metastatic disease requiring upfront high-dose chemotherapy in the judgement of the treating clinician.
- Known tumour HER2 positivity (IHC 2+ or more and HER2 gene amplification as per the stipulations).
- Contraindications to carboplatin, paclitaxel or durvalumab.
- Unplanned stem cell Graft.
- Previous systemic therapy for esophageal or GI/CA cancers.
- Previous thoracic radiotherapy.

STATISTICAL CONSIDERATIONS

The primary endpoint (the proportion free survival rate at 4 (PFS4). A PFS4 of 60% is deemed of clinical utility, and the randomised phase 3 testing of this protocol, based on 50% per a 6.0 one-sided significance level, 50 patients would be required to show an unacceptably PFS4 of 50% or lower of 60% to account a 5% drop out rate, 50 patients will be recruited.

TRANSITIONAL SUB-STUDIES

Tumour tissue and serial blood samples at baseline, week 4, week 8, week 12, week 16, week 20, week 24, week 28, week 32, week 36, week 40, week 44, week 48, week 52, week 56, week 60, week 64, week 68, week 72, week 76, week 80, week 84, week 88, week 92, week 96, week 100, week 104, week 108, week 112, week 116, week 120, week 124, week 128, week 132, week 136, week 140, week 144, week 148, week 152, week 156, week 160, week 164, week 168, week 172, week 176, week 180, week 184, week 188, week 192, week 196, week 200, week 204, week 208, week 212, week 216, week 220, week 224, week 228, week 232, week 236, week 240, week 244, week 248, week 252, week 256, week 260, week 264, week 268, week 272, week 276, week 280, week 284, week 288, week 292, week 296, week 300, week 304, week 308, week 312, week 316, week 320, week 324, week 328, week 332, week 336, week 340, week 344, week 348, week 352, week 356, week 360, week 364, week 368, week 372, week 376, week 380, week 384, week 388, week 392, week 396, week 400, week 404, week 408, week 412, week 416, week 420, week 424, week 428, week 432, week 436, week 440, week 444, week 448, week 452, week 456, week 460, week 464, week 468, week 472, week 476, week 480, week 484, week 488, week 492, week 496, week 500, week 504, week 508, week 512, week 516, week 520, week 524, week 528, week 532, week 536, week 540, week 544, week 548, week 552, week 556, week 560, week 564, week 568, week 572, week 576, week 580, week 584, week 588, week 592, week 596, week 600, week 604, week 608, week 612, week 616, week 620, week 624, week 628, week 632, week 636, week 640, week 644, week 648, week 652, week 656, week 660, week 664, week 668, week 672, week 676, week 680, week 684, week 688, week 692, week 696, week 700, week 704, week 708, week 712, week 716, week 720, week 724, week 728, week 732, week 736, week 740, week 744, week 748, week 752, week 756, week 760, week 764, week 768, week 772, week 776, week 780, week 784, week 788, week 792, week 796, week 800, week 804, week 808, week 812, week 816, week 820, week 824, week 828, week 832, week 836, week 840, week 844, week 848, week 852, week 856, week 860, week 864, week 868, week 872, week 876, week 880, week 884, week 888, week 892, week 896, week 900, week 904, week 908, week 912, week 916, week 920, week 924, week 928, week 932, week 936, week 940, week 944, week 948, week 952, week 956, week 960, week 964, week 968, week 972, week 976, week 980, week 984, week 988, week 992, week 996, week 1000.

STUDY STATUS

The PLEO trial will open at 8 centres in Australia in 2024. The trial is currently open to date. It is planned 50 patients.

REGISTRATION & CONTACT

PLEO is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR).

PALEO For further information, please contact the PLEO trial team at pleo@agtg.org.au or call 1800 000 000.

REFERENCES

Matheson A, Day F, Loh J, et al. Phase 1 trial of hypofractionated durvalumab in the postoperative treatment of oesophago-gastroesophageal cancer. *Radi Oncol*. 2022;17:176.

Our research has changed medical practice



Over 30 years
of ground-breaking
AGITG research



\$104+ million
invested in AGITG
research



83 research studies
improving outcomes for
people with GI cancer



9,446 patients
given access to new treatment
regimens on our trials

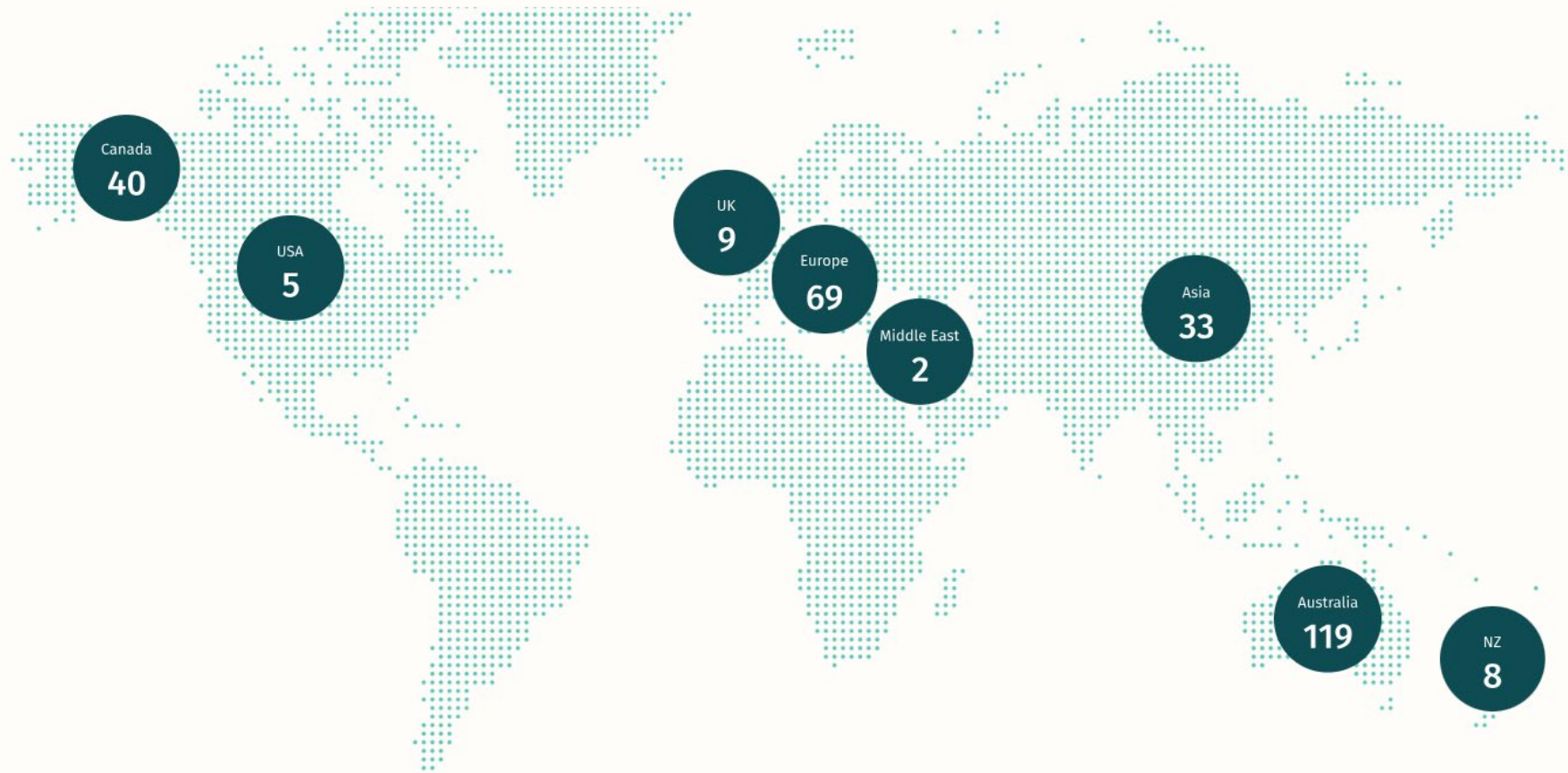


181 research articles
published in peer reviewed
journals by AGITG researchers



256 presentations
based on AGITG trials at
global research conferences

Our global footprint



Embedding equity into everything we do

Strategic pillars towards 2025:



Build a portfolio of research to improve patient outcomes



Maximise research funding by embedding fundraising alongside industry and government support



Cultivate and enhance national and international collaborations



Grow and support a diverse and multidisciplinary membership



Pursue a culture of excellence and build capacity to support innovation



Create equitable research access, conduct and participation



Our journey – 2021-2022

2021

1. Strategy review & incorporation of equity pillar
2. Launched our Research Strategy, Development & Prioritisation Framework
3. Invitations to non-member GI cancer clinicians in RRR areas

2022

1. Joined Australian Teletrial Program (ATP), Sponsor Advisory Group
2. Cultural Capability Training
3. ASM 'Decentralised trials' & EDI focused Closing Plenary, feat. Prof Gail Garvey, A/Prof Reema Harrison, Dr Abi Pal, Prof Sabe Sabeson, Prof Dorothy O'Keefe
4. Initiated turnover of Research Committees to represent a broad & diverse membership to strengthen processes and quality

2023

1. Connected with Regional Coordinating Centres (RCCCs) in NT, SA, QLD, VIC, WA
2. 1st cross-jurisdictional teletrial cluster - Queen Elizabeth Hospital, SA & Royal Darwin Hospital, NT
3. Published EDI Statement
4. ASM in Aotearoa, NZ - EDI theme, feat. Prof Lisa Jackson Pulver, A/Prof Craig Underhill, Melanie Poxton
5. Revised Study Budget Development Policy
6. Julie McCrossin AM video series: insights from experts on First Nations cultural safety, barriers to representation, need for greater diversity & inclusion in clinical trials

25th ASM

ANNUAL SCIENTIFIC MEETING

Christchurch, Aotearoa New Zealand
13-16 November 2023



Our statement on equity, diversity and inclusion

AGITG's mission is to undertake person-centred, practice-changing collaborative research into gastro-intestinal (GI) cancers. To be truly person-centred and practice changing, our research must involve and reflect the diverse needs of people with all types of GI cancer across Australia and Aotearoa New Zealand. We acknowledge the inherent inequity and imbalance in power and privilege in our health and research systems and the impact this inequity has on outcomes for certain population groups and in particular for Aboriginal, Torres Strait Islander and Māori people with cancer. We recognise the need to purposefully improve how we work to change this inequity.

2024 and beyond

1. Teletrial Ambassadors on Upper & Lower GI Working Parties
2. Teletrial clusters included during concept development
3. Funding for patient travel support (+ RRR patients) & eConsent (video animation)
4. ANZ-specific ethnicity categories for data collection
5. PICF updates to reflect gender diversity & cultural sensitivities
6. ASM 'Thinking Outside of the Box' theme, feat. Prof Gail Garvey
7. Improved storytelling consent processes for longer-term relationships, better trust-building
8. First Nations-led storytelling series: Directed by Madison Shakespeare, Gadigal Traditional Custodian & former AGITG Community Advisory Panel Member

Patient travel support

Patient allowance of up to \$40 per on-site visit to be paid upon receipt of invoice to cover the cost of parking and/or other transport related costs.

Reimbursement for RRR patients

Patients living in RRR regions may be eligible to receive remuneration for travel and accommodation costs.

Requests are submitted to AGITG for approval prior to the patient completing screening for the study.

eConsent

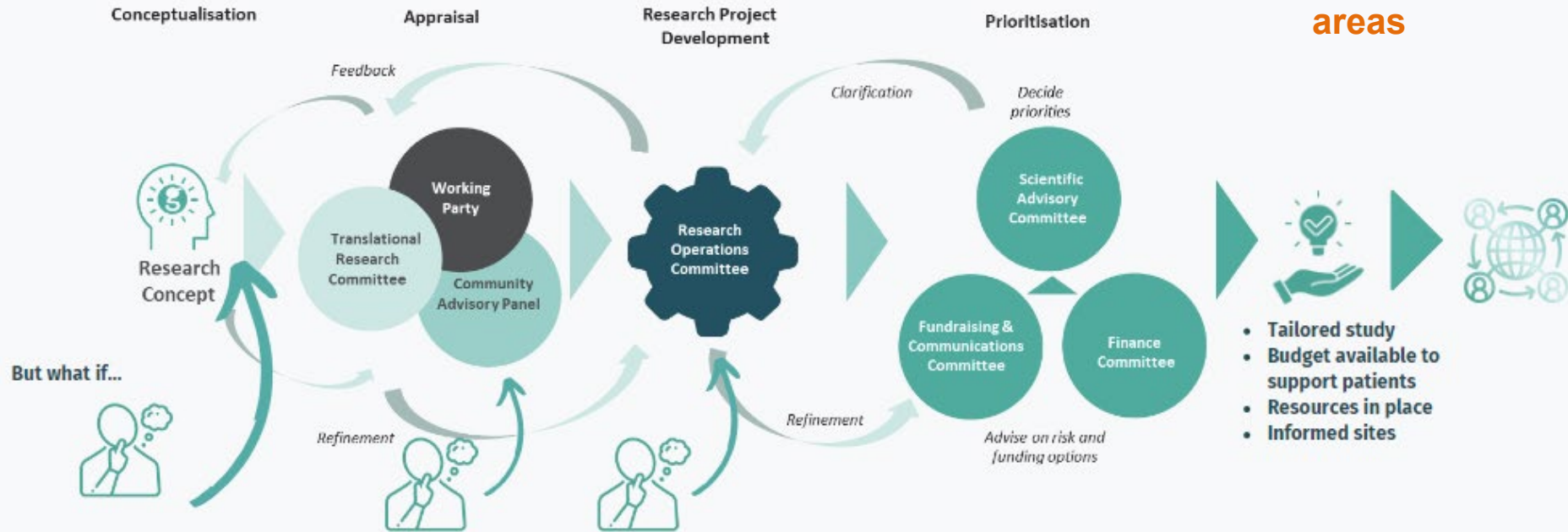
Adoption of Consentia, an online e-consent platform for patients and clinicians.

Patients can view and sign a simple pdf version of the PICF online. The platform is easy to understand and uses intuitive consent animations.

Shifting teletrials to a forethought

AGITG Research Development and Prioritisation Framework:

12% clinical trial participants live in RRR areas



ASM

26th Annual Scientific Meeting
18-21 NOV 2024
BRISBANE
Convention and Exhibition Centre

Register
now!



 **AGITG**
AUSTRALASIAN GASTRO-INTESTINAL TRIALS GROUP

Thank you

