1991
• AGITG opens first clinical trial to patient participation under the auspices of the NHMRC Clinical Trials Centre, University of Sydney - two colorectal cancer studies from the USA Clinical Trials: ECOG 2000, ECOG 2002

1992
• AGITG developed first trials for colorectal cancer and oesophageal cancer
• Professor John Zalcberg OAM appointed Chair of the AGITG Clinical Trials: AG9601, AG9702

1993
• First AGITG Annual Scientific Meeting (ASM) held in Launceston, TAS
• AGITG incorporated as Company Limited by Guarantee
• First Board of Directors elected
• Recruitment opens for patient participation in colorectal cancer clinical trial Clinical Trial: CO.02

1994
• AGITG and Trans Tasman Radiation Oncology Group (TROG) collaborate to develop a trial for rectal cancer patients
• AGITG participates in trials developed by the European Organisation for Research and Treatment of Cancer (EORTC)
• AGITG participates in trials for gastro-oesophageal cancer, advanced gastro-intestinal stromal tumours (GIST), advanced hepatocellular carcinoma and liver cancer Clinical Trials: PA.3, ESPAC 3, TOP GEAR, REGISTER, DECO

1995
• AGITG and the NCIC collaborate on the next colorectal cancer trial
• AGITG and NCIC develop a trial for colorectal cancer Clinical Trials: ATTAX 2, Adjuvant GIST, ABC

1996
• AGITG and Trans Tasman Radiation Oncology Group (TROG) collaborate to develop a second colorectal cancer clinical trial Clinical Trial: ATTAX 3
• AGITG Consumer Advisory Panel established
• AGITG and the NCIC collaborate to develop a colorectal cancer clinical trial Clinical Trial: CO.17

1997
• The Alan Bishop Fund for GST Research is established
• Four AGITG developed clinical trials were launched to investigate new treatments for oesophageal cancer, gastric cancer and gastrointestinal stromal tumour
• AGITG participates in a colorectal cancer clinical trial led by the EORTC Clinical Trials: AGC01, AGC02, GIST, TOP GEAR, REGISTRY, PETINE-1

1998
• Five AGITG developed clinical trials open to patient participation investigating new treatments for biliary tract cancer, pancreatic cancer, colorectal cancer and cancer of the oesophageo-gastric junction
• External Review of AGITG conducted by three world leaders in GI cancer research
• The GI Cancer Institute Engage Program launched Clinical Trials: ABC, CO-17, PMX, GAP-GEMOX, ACOGAMPE

1999
• AGITG and Trans Tasman Radiation Oncology Group (TROG) collaborate to develop a trial for rectal cancer patients
• AGITG and NCIC collaborate on the next colorectal cancer trial
• AGITG and the NCIC collaborate to develop a colorectal cancer clinical trial Clinical Trial: CD.17

2000
• AGITG and the NCIC collaborate to develop a colorectal cancer clinical trial
• Advanced GST study results published in the Lancet Clinical Trial: CD.17

2001
• AGITG and the NCIC collaborate to develop a colorectal cancer clinical trial
• AGITG and NCIC collaborate with the Scandinavian Sarcoma Group to develop a trial for gastrointestinal stromal tumour
• ASCO Best New Concept Award awarded

2002
• AGITG and NCIC collaborate on the next colorectal cancer trial
• AGITG collaborates with the Scandinavian Sarcoma Group to develop a trial for gastrointestinal stromal tumour
• Professor Tim Price appointed as Chair of the AGITG

2003
• AGITG and the NCIC collaborate to develop a colorectal cancer clinical trial
• Advanced GST study results published in Journal of Clinical Oncology Clinical Trial: CD.17

2004
• First AGITG developed oesophago-gastric cancer trial
• First AGITG developed trial in colorectal cancer to accrue patients internationally
• New Concepts Symposium is introduced at the AGITG Annual Scientific Meeting
• First Research Fellow appointed
• AGITG trials for oesophageal cancer, GIST, biliary tract, pancreatic, and colorectal cancer Clinical Trials: MAX, ATTAX 2, Advanced GST, ABC, GEMOX, GEMOX, ACOGAMPE

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• AGITG and Trans Tasman Radiation Oncology Group (TROG) collaborate to develop a trial for rectal cancer patients
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2012
• AGITG and NCIC collaborate on the next colorectal cancer trial
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2016
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• AGITG and the NCIC collaborate on the next colorectal cancer trial

The Australasian Gastro-Intestinal Trials Group (AGITG) and the GI Cancer Institute are dedicated to achieving better health outcomes for patients with gastro-intestinal cancer by addressing key unanswered questions through the conduct and promotion of clinical and related biological research in Australasia and internationally.

The 2016 Annual Report is a celebration of the Group’s 25th anniversary and recognises its many achievements over that period in gastro-intestinal cancer research innovation and excellence.
Since 1991, our key priority has been to undertake research that is centred on patient care and improves medical practice in the treatment of gastrointestinal cancer.

Our challenge: to defeat gastrointestinal (GI) cancer, making it a manageable disease and, ultimately, a disease of the past.

The AGITG is a multi-disciplinary collaborative group of medical oncologists, surgeons, radiation oncologists, statisticians, data managers, allied health care professionals and consumers with a focus on cancers of the oesophagus, stomach, liver, pancreas, gallbladder, large and small bowel, rectum and anus.

The GI Cancer Institute is the community division of the AGITG, working across Australia to raise funds and awareness of GI cancer and clinical trials.

We are committed to changing outcomes for people with GI cancer.

About Clinical Trials
Treating GI cancer is often extremely complex and, usually, requires a combination of surgery, radiotherapy and specialist drugs (chemotherapy).

To improve patient care, clinical trials are needed to evaluate which combination of treatments will work best for particular groups of tumours and people.

Clinical trials are not about laboratories and test tubes. They are about real people dealing with a disease testing the optimal combination of medications, surgical techniques and radiation treatments to deliver the best results.

Conducting clinical trials in Australia means that Australian patients can access the latest treatments three to five years earlier than if those trials were conducted overseas.

Major advances in treating GI cancers and improving patient quality of life are possible as a result of clinical trials.

Locations for GI cancers
1. Oesophagus
2. Liver
3. Stomach
4. Gallbladder
5. Pancreas
6. Large Bowel
7. Small Bowel
8. Rectum
9. Anus

Five Year Survival
GI Cancer: 49%
Breast Cancer: 90%
Prostate Cancer: 92%

Help us lift the 5 year survival rate of GI Cancer

$46 million invested in AGITG research
49 clinical trials improving outcomes for people with GI cancer
4,000+ patients given access to new drug regimens on our trials
83 research articles by AGITG in high impact, peer reviewed journals
1,132 people supported through Engage Community Forums
195 presentations based on AGITG trials at global research conferences
“The underlying spirit is one of collaboration driving agreement on key clinical questions to find ways for questions to be resolved.”

Professor John Zalcberg OAM
The AGITG plays a major role in clinical trial research on the global stage and has international collaboration links with the United Kingdom, Europe, Asia and North America.
In 1991, a handful of medical oncologists started a conversation about how to deliver improved results for their patients with gastro-intestinal (GI) cancer. The discussion focussed on their concerns around existing treatments. Connecting with each other at medical conferences, or via fax and phone, they came to the conclusion that the only way to discover meaningful solutions for their patients was to collaborate as a group.

Two questions occupied the minds of this small group of clinicians: the role of adjuvant treatment for colon cancer, and the timing of palliative care chemotherapy for people with advanced colon cancer. At the time only one drug – 5fu – was available for colon cancer, and the timing for its administration was still a matter of debate. 

Having come to the conclusion that clinical trials provided answers for patients. At the same time, we were a part of overall growth in Australia as clinical trials became recognised for their important role in delivering improved healthcare overall.

Since 1991 we have evolved into a larger, sophisticated group with more than 1,000 members. The AGITG incorporated as a Company Limited by Guarantee in 2000 and now encompasses a wide range of medical specialists, scientists, nurses, allied health professionals and consumers. As a group we have led and designed global studies and increased our linkages and collaborations with international groups such as the European Organisation of Research and Treatment of Cancer (EORTC), Scandinavian Sarcoma Group (SSG), Canadian Cancer Trials Group (CCTG), European Study Group for Pancreatic Cancer (ESPAC), and many others. As a result, the AGITG has been integral to worldwide changes in medical practice in a number of GI cancers, including gastric, pancreatic, colorectal, oesophageal and biliary tract cancers and gastro-intestinal stromal tumour (GIST). The group has led trials of combined modality therapies in stomach and rectal cancer, and established surgical guidelines in Australia for pancreatic cancer among many other significant achievements.

In 2008, recognising the need for greater involvement from GI cancer patients, survivors, caregivers and family members, we established the Consumer Advisory Panel (CAP). Most importantly, the CAP provides advice to the AGITG on general research directions and priorities from a consumer perspective.

A broader purpose to our mission has evolved over time: to share the latest knowledge with our membership as well as educate the next generation of GI cancer clinicians. Both of these objectives have been met through the development of the AGITG Annual Scientific Meeting (ASM). The ASM provides a world class forum for the exchange of ideas with invited international speakers and our educational Preceptorships (Harvard short course model for senior trainees and junior consultants).

Our evolution and growth has not been without challenges, both inside and outside the organisation. Some of these challenges include the global tightening of pharmaceutical R&D since the global financial crisis, the fact that government research support favours short-term “project” funding over large scale clinical trials, and the demand for increasing trial accrual to the level required to undertake large Phase III trials.

To meet these challenges, the group has implemented a strategic and diversified research portfolio, including developing translational research projects and pilot/feasibility studies to collect data for larger clinical trials. We have extended our membership base, cemented strong links to other successful international organisations, established efficient governance processes, delivered globally recognised scientific outputs in high impact factor medical journals and international conferences, and diversified funding through community engagement and support. 

In our 25th year it is important to acknowledge the handful of clinicians, in particular Professor Bruce Gray, Professor John Zalcberg DAM, Professor Stephen Ackland, Professor Michael Findlay, and Professor Bryan Burmeister, who were a core part of that first, nascent group, and who took the initial step by highlighting those two questions on behalf of their patients.

It is also critical we take a moment to acknowledge the fact that the advances made in improving treatments for people with GI cancer have come about through the enormous effort of many people, all working for the common good. Treatments have progressed only by the effective coming together of multidisciplinary medical professionals, nurses, allied health professionals, patients and their families from Australia and New Zealand, who have voluntarily given their time over the past 25 years to address key unanswered questions and achieve better health outcomes for patients with gastro-intestinal cancer.

Since returning from the UK, the AGITG has been a major part of my professional life. As a gastro-intestinal Medical Oncologist, the expertise and advice of colleagues with similar interests has been invaluable in the progress of my career as a GI clinician and researcher. Subsequently I was given the opportunity to join the board and SAC and be part of the group’s growth and contribute to the ongoing research program. The AGITG has led trials that have made significant contributions to the improvement in care for patients with GI cancers and I have been proud to be part of this team. My main task now, having taken on the role of Chair of the board and SAC, is to try to continue the fantastic work achieved thus far and hopefully build further - with the collaboration of our many members who give up significant time in their busy lives to be part of the group’s research program.

Professor Tim Price
MBBS DithSc (Med) FRACP
Chair
This year marks the 25th year of the AGITG conducting and promoting clinical and related biological research to improve health outcomes for patients with GI cancer. Over the past quarter century, through the tireless efforts of the AGITG membership, we have been instrumental in advancing significant changes in medical practice, not only in Australia but worldwide.

The work of the AGITG has enabled patients throughout Australia and New Zealand, in regional, rural and city-based medical centres, to access clinical trials, new personalised treatment options, unfunded cancer treatments, and new state-of-the-art cancer treatments, three to five years earlier than if the research were conducted overseas. In the Australasian medical community, the AGITG has made significant contributions through the mentoring of oncologists in clinical research, the development of international research links, and by conducting outstanding academic research.

There were a number of highlights in 2016, each reflecting the fact that over the years our mission has never wavered from that of pursuing better health outcomes for patients with gastrointestinal cancers. A major highlight of the year was the opening of the INTEGRATE II clinical trial. Based on results from the AGITG INTEGRATE trial, INTEGRATE II is an AGITG designed and led Phase III clinical trial in advanced gastro-oesophageal cancer which will be conducted in Australia, New Zealand, Korea, Japan, Taiwan, Canada and the USA. Support for the INTEGRATE II trial was received from Bayer Healthcare Pharmaceuticals in late 2015. The INTEGRATE II team has been immensely busy since then, preparing for the activation of the trial. The first patient was enrolled at Townsville Hospital, QLD, in late October.

In 2016, the AGITG Innovation Fund was awarded to a pilot study titled MONARCC, for metastatic colorectal cancer, developed by Dr Matthew Burge and collaborators. Dr Burge received the Best New Concept Award in 2014 for an early stage concept that was further developed into the MONARCC Study. The funding for the AGITG Innovation Fund is made possible by the generosity of charitable donations raised through the GI Cancer Institute’s Gutsy Challenge. The AGITG 18th Annual Scientific Meeting, “Looking back and moving forward”, held in September at the Sofitel Melbourne on Collins, brought together more than 300 delegates and seven outstanding international guests to delve into the many unanswered questions in GI cancer research. Over the three day conference there were updates on AGITG clinical trials, discussions on the future of GI cancer research, new concept presentations, interactive poster presentations and multiple keynote addresses. Not forgetting the important recognition of the 25th year anniversary, there was the ceremonial cutting of a large celebratory cake.

Also in September, we hosted the fourth annual Pancreas Cancer Research Workshop in partnership with the Australasian Pancreatic Club. The meeting was a resounding success with excellent attendance across disciplines, and robust, research-centred discussion. Six concepts were presented and assessed in terms of feasibility and clinical relevance.

For a fourth year we held a Preceptorship in Colorectal Cancer in early November. Convened by Professor Eva Segelov, and supported by an educational grant from Roche Products, this educational opportunity, based on the Harvard short course intensive learning model, is a highlight for both the preceptors, senior trainees and junior consultants in attendance. Excitingly, through support from Shire, we were proud to announce an additional Preceptorship in Upper GI Cancer to be held in May 2017.

We hosted a two-day meeting of the Commonwealth Neuroendocrine Tumour Collaboration (CommNETS), led by Professor Segelov and Dr Simron Singh of Canada. The gathering built on the success of the 2015 Meeting in bringing together leaders in the field of NETs – clinicians, researchers and consumers from Australia, New Zealand and Canada - to further identify gaps in neuroendocrine tumour research. This medical practice activity was supported by an unrestricted grant from Ipsen Australia and Ipsen Canada. Closing out the year we held a meeting of pancreatic cancer experts in Singapore. International colleagues met and discussed topics of controversy in the management of pancreatic cancer patients to produce an expert opinion consensus for publication.

Four areas of research interest were discussed and the meeting was supported through an educational grant from Shire.

The Gutsy Challenge team organised by the GI Cancer Institute cycled across Cambodia to raise funds for AGITG research. AGITG Principal Investigator, Associate Professor Chris Kanapetis, led the team of seven, through heat and torrential rain, raising more than $51,000 for the AGITG Innovation Fund.

To provide information about gastrointestinal cancer and the latest clinical trials research, our Engage Community Forums were held in Hobart (TAS) and Newcastle (NSW). The forums received funding support from the Cancer Australia Supporting People with Cancer grant initiative, Clayton Utz, the Royal Bank of Canada and Newman’s Own Foundation.

Over the years the AGITG and GI Cancer Institute activities have resulted in both excellence and innovation in GI cancer research to benefit patients throughout the world. None of this is possible without the support of our community of medical professionals, patients, families, survivors, carers, donors and supporters. With your continued involvement we will build on the past 25 years to further improve the lives of people with gastrointestinal cancer.

Russell Conley
Executive Officer

Picture (L-R): 1. Professor Alan Venook presenting at the Annual Scientific Meeting 2. Engage Community Forum held in Hobart 3. Dr Rebecca K.S. Wong presenting at the Annual Scientific Meeting 4. Associate Professor Nick Pavlakis discussing INTEGRATE II 5. Gutsy Challenge Cambodia cycling team 6. Professor Tim Price presenting Dr Matthew Burge the AGITG Innovation Fund Award
I am pleased to report the Australasian Gastro-Intestinal Trials Group continues to undertake significant clinical trials research, leading to major new findings and helping to improve clinical practice in Australia, New Zealand and worldwide. Since its inception some 25 years ago, AGITG has undertaken 49 international clinical trials in Australia, New Zealand, Asia, Europe, the UK and North America.

In 2016, we have seen the culmination of six clinical trials in gastro-intestinal cancer with the publication of final results: TACTIC evaluating targeted therapy with chemotherapy in gallbladder cancer; LAP-07 assessing chemoradiotherapy and erlotinib in pancreatic cancer; INTEGRATE evaluating regorafinib, a novel therapy in advanced gastric cancer; ICECREAM assessing targeted therapy with or without chemotherapy in a rare form of colorectal cancer with KRAS G13D mutations; ATTAX3 assessing targeted therapy and chemotherapy in gastric cancer; and QUASAR2 assessing adjuvant therapies in colorectal cancer. Many of these studies have helped shape future research, both within the group and beyond.

In particular, the INTEGRATE trial demonstrated significant improvements in the control of advanced gastric cancer from regorafinib in a Phase II trial, and these promising results have now led to the launch of INTEGRATE II. This global Phase III trial is being led by the AGITG and the NHMRC Clinical Trials Centre in collaboration with cancer groups and investigators from Korea, Japan, Taiwan, Canada and USA, and will determine if regorafinib can improve overall survival in these patients.

In addition, we are continuing to undertake the important TOPGEAR trial assessing the benefit of adding chemoradiotherapy to chemotherapy and surgery in the initial management of gastric cancer. This trial has now recruited 325 patients from Australia, New Zealand, Canada and Europe, and early results have demonstrated that this additional treatment can be delivered safely short term. Evaluation of long term impacts on survival needs several more years’ follow-up.

This year there has also been a focus on challenges in the recruitment of patients with some rarer cancers. The ALT-GIST clinical trial for gastrointestinal stromal tumour (GIST), undertaken in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC) and the Scandinavian Sarcoma Group (SSG), has recruited slower than expected. But it will continue as a phase II trial in 2017, assessing impact of this novel treatment sequence on tumour response. In contrast, the CONTROL NETS clinical trial assessing a radionuclide therapy for neuroendocrine tumour has recruited well and is close to its pilot phase allocation of 48 patients. Initial funding support for the trial has come from the Unicorn Foundation, the University of Sydney, and a Perpetual IMPACT Philanthropy Grant. However, we continue to seek support for the main trial from funding agencies.

We did receive funding from NHMRC for the NABNEC trial, a randomised Phase II study for neuroendocrine carcinomas, and this began recruitment in late 2016.

We did receive funding from NHMRC for the NABNEC trial, a randomised Phase II study for neuroendocrine carcinomas, and this began recruitment in late 2016. During 2016, much work was undertaken in preparing new concepts and grant applications thanks to the diligence of several people within the AGITG in collaboration with the NHMRC Clinical Trials Centre and through the Upper and Lower GI Working Parties. We are pleased to have been awarded funding starting in 2017 from Cancer Australia and Cancer Council NSW for two trials in colorectal cancer to further support the ASCOLT trial assessing adjuvant therapy with aspirin in colorectal cancer and the SPAR trial assessing the use of a statin therapy in combination with chemoradiotherapy for rectal cancer.

There have been 17 manuscript publications in 2016 and nine presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting, ASCO Gastrointestinal Cancers Symposium and the European Society for Medical Oncology 2016 Congress.

The collaboration of many people on a global basis continues to underpin the efforts of our clinical trials research program. The hard work of clinical investigators, research coordinators and staff at each site, AGITG, the NHMRC Clinical Trials Centre, and all the AGITG committee members, have contributed significantly to the successful outcome of this research. We are indebted to the patients and their carers for their support and the vital services they bring to these trials.
Established in 2008, the AGITG Consumer Advisory Panel (CAP) comprises GI cancer survivors, patients and carers. As a volunteer group, the CAP provides advice to the AGITG on general research directions and priorities from a consumer perspective as well as identifying unmet needs in the community.

CAP key activities include the review of new trial concepts, identification of gaps in research, assistance to ease the understanding of trial patient information and consent forms, and advice on patient recruitment strategies.

The CAP also supports the GI Cancer Institute with initiatives such as the Engage Community Forum Program and the Gutsy Challenge.

During 2016 the panel continued its progress on the 2014 project to prioritise a list of gaps in research that would warrant further investigation. In 2014, each panel member either chose a gap topic, or was assigned one, and prepared a briefing paper. Following consultation with the Chair and Group Coordinator, the Gaps briefings were referred to the relevant Working Party in 2015/16 for discussion and further investigation. In 2016 the CAP also expressed a desire to the Working Parties and Scientific Advisory Committee to consider how patient benefits from clinically recommended diet and exercise could become part of AGITG trials.

The Engage Community Forum program developed by the CAP was somewhat curtailed in 2016 as our application to Cancer Australia for ongoing funding was not successful. Since 2013, forums have been held in: Sydney; Melbourne; Perth; Wide Bay, QLD; Hawthorn, VIC; Epping, NSW; Orange, NSW; Albury-Wodonga, NSW; Gawler, SA; Hobart, TAS; Newcastle, NSW. All forums were extremely well received. Presentations about GI cancer, clinical trials and quality of life issues were tailored for each area under the guidance of CAP members (where available) who mentored the local planning committees. Along with clinicians, CAP members have also been involved in presenting at the forums during the year.

The CAP consisted of 10 members at the start of 2016. During the year, three members retired from the panel for various reasons and expressions of interest have been called to increase CAP membership.

The work of the CAP is instrumental in providing a voice for survivors, patients, carers and families impacted by GI cancer.

Dan Kent
Chair
Consumer Advisory Panel

Liza’s Story

When Hal Harvey was first diagnosed with inoperable pancreatic cancer, his wife, Liza, was Parliamentary Secretary for the Minister for Small Business in Western Australia. Her demanding job, however, did not stop the couple making the most of Hal’s remaining time.

Against the advice of medical oncologists, Hal and Liza along with their three children, Sarah, Elizabeth and Jack, went travelling around Western Australia. At Hal’s funeral, Liza told the gathering “Our favourite saying was bite off more than you can chew and then chew like hell.”

This attitude didn’t waver as Hal’s condition worsened. In 2012, Liza would go to cabinet meetings in the morning and then sit with Hal through his chemotherapy sessions in the afternoon.

Hal went to his doctor in 2011 after a rapid onset of jaundice. His doctor initially thought the problem was hepatitis, but blood tests and scans showed that there was a tumour on Hal’s pancreas. Hal was eligible for surgery to have it removed.

However, once he was on the operating table it became clear that the tumour had wrapped itself around the superior mesenteric artery and could not be fully removed. He was given six months to live. “The psychological stuff that goes on and the anxiety that we both experienced before getting the results of each CT scan, led to a very tough three and a half years” Liza said.

Liza is now a committed supporter of the GI Cancer Institute and will be speaking at the Engage Community Forum in Perth in 2017.

CONSUMER ADVISORY PANEL REPORT
Oesophageal cancer in Australia continues to grow. In 2013 there were 1,434 diagnoses. In 2012, oesophageal cancer claimed 1,203 lives decreasing in 2014 to a mortality rate of 1,198.

Trials open to recruitment INTEGRATE II
Following the promising results from the INTEGRATE study, INTEGRATE II, an AGITG led Phase III clinical trial in gastro-oesophageal cancer, opened to recruitment in Australia. The first patient on the study was enrolled in late October 2016 at Townsville Hospital, QLD. Eleven sites in Australia and New Zealand were activated in 2016 and 16 more sites in our region will be activated in 2017. Sites in Korea, Japan, Taiwan, Canada and the USA will open in 2017.

There currently exist few effective treatment options for patients with advanced gastro-oesophageal cancer that has returned after surgery, or where it is incurable (metastatic) at diagnosis. Chemotherapy can be effective at first, but the options for treatment are limited once the cancer has become resistant to it. A second course of a different chemotherapy (docetaxel or irinotecan) can prolong survival, but not all patients are fit to receive this treatment. For those who do receive a second course, their cancer will eventually become resistant (or “refractory”) to these drugs. In these situations, there are currently no accepted treatment options shown to be both effective against the cancer and tolerable for patients. Better treatment options are urgently needed.

Regorafenib (BAY 73-4506) is a therapy targeting a number of different signals in the cancer cell that cause it to grow and produce blood vessels. In other cancers, such as colon cancer and gastrointestinal stromal tumour (GIST), regorafenib has been proven to be of benefit when other drugs have ceased to work. The AGITG Phase II trial INTEGRATE demonstrated efficacy with the use of regorafenib in advanced gastro-oesophageal cancer. INTEGRATE II is being undertaken to confirm the findings of the Phase II trial in a larger population.

If the study is positive it will provide evidence for regorafenib as a new standard of care after other treatments no longer benefit patients with this type of cancer.

Trials in follow-up DOCTOR
This study broke new ground in pre-operative therapy for oesophageal cancer. It was the first to focus on changing the therapy for metabolic non-responders to preoperative therapy to try to improve response and, potentially, survival. It was also innovative in other ways, such as in assessing whether changes to therapy can salvage a response. It provided valuable data regarding the potential to individualise therapy related to the tumour characteristics – so-called “tailored therapy”. Surgery forms the mainstay of curative treatment, but survival remains poor. Pre-operative chemotherapy, with or without concurrent radiotherapy, has resulted in modest improvements in outcome. Increasing the proportion of responders to pre-operative therapy remains one of the major challenges facing patients with localised oesophageal cancer.

The primary analysis was presented at ESMO 2016. Docetaxel added to chemotherapy, and particularly with radiotherapy, can induce high rates of histological responses in non-metabolic responder patients. Therefore tailoring multimodality therapy based on individual PET response is safe and feasible in oesophageal cancer, although the impact on survival requires longer follow up.
Stomach cancer (also known as gastric cancer) affects a significant number of people. In 2011, 2,093 Australians were diagnosed with the disease and 1,143 people died in 2012. In 2013 incidence of stomach cancer increased to 2,117 however, fewer people (1,137) died in 2014 than in 2012.

Trials in recruitment

TOPGEAR

Surgery may cure those with localised stomach cancer, but most patients present with more advanced cancer which, when treated with surgery, will recur in 70% of cases. Thus, surgery alone is not an adequate treatment. There are currently two “standard” methods used worldwide to treat patients with more advanced stomach cancer: treatment with chemotherapy before and after surgery, or a combination of radiation plus chemotherapy following surgery. We believe that combining these two approaches will provide even greater benefit, especially if the combination of radiation plus chemotherapy is given prior to surgery.

This randomised controlled trial will build on previous research and compares chemotherapy given before and after surgery, with or without adding concurrent chemotherapy and radiotherapy. The trial is being led by the AGITG and includes participation from the Canadian Cancer Trials Group and the European Organisation for Research and Treatment of Cancer. TOP GEAR had 325 patients enrolled at December 31. A formal analysis is due to take place in Q2/3 2017 (after 300 patients have been followed up for a minimum of six months from completion of adjuvant chemotherapy) to evaluate progression-free survival. Preparation for this analysis has begun, including review of criteria by the International Trial Management Committee.

ALT-GIST

Gastro-Intestinal Stromal Tumours (GIST) are rare cancers that can develop in different locations throughout the gastro-intestinal tract. When they have spread to other places (metastatised) or are not able to be surgically removed, they are not curable with any current treatment. Medications have been developed that improve survival in patients with metastatic GIST. They work by blocking the signals that make these cells grow and spread. One of two drugs available on the Pharmaceutical Benefits Scheme in Australia, imatinib, is used as the initial treatment for incurable GIST. Although many people with metastatic disease respond to imatinib initially, in almost all cases the cancer becomes resistant to this drug and starts to grow. Patients are then treated with another drug known as sunitinib.

Unfortunately, this drug is no longer effective there are no other treatment options. Until recently, a search for active new medicines in this setting had failed. Since then, regorafenib has been shown to significantly delay progression in this setting. Regorafenib works in a similar way to imatinib although it targets a number of additional enzymes in tumour cells. This may allow it to work more effectively, especially if the cancer becomes resistant to imatinib.

There are 32 sites open across Australia, Asia, Europe and Scandinavia with 34 patients recruited at the end of December 2016.

CONTROL NETS

Neuroendocrine Tumours (NETs) are rare cancers that can develop in different locations throughout the body, including the gastro-intestinal tract and the pancreas. These cancers develop from neuroendocrine cells which are usually found in the nervous system and the endocrine (hormone) system, and help to control normal body functions. NETs that have spread around the body (metastatised), or can’t be removed by surgery, are incurable using currently available treatments. Survival can be long for some patients, depending on the growth rate of the cancer cells. Although NETs are rare in terms of the number of new cases each year, the total number of patients with NETs in Australia at any given time impacts on the community.

The aim of the study is to assess whether the combination of radioligand + chemotherapy is more effective than either radioligand or chemotherapy alone in mid-gut and pancreatic NETS. If the combination treatment demonstrates its superiority in this setting, it could be further investigated in a larger Phase III randomised trial, the results of which would guide best practice treatment.

In June 2016, CONTROL NETS was awarded $370,000 from the Perpetual IMPACT Philanthropy grant scheme to support an additional 25 participants beyond the pilot phase. The study has now recruited 30 out of 46 patients in the pilot phase since opening in December 2015, supported by funds from Unicorn Foundation and University of Sydney Bridging Grant. CONTROL NETS is currently under consideration for NHMRC funding.

NABNEC

The aim of the study is to assess which treatment is most promising – carboplatin and etoposide chemotherapy, or carboplatin and paclitaxel chemotherapy – in improving disease response rates in patients with advanced Neuroendocrine Carcinomas (NECs). Finding the treatment that is most promising would then allow it to be investigated further in order to guide best practice. The trial will also look at outcomes of survival, monitor the side effects of treatment, identify useful markers of prognosis and response, and increase our understanding of the biology of NECs.

NABNEC is funded by an NHMRC Project Grant from 2016-2020 and ethics approval was obtained in March 2016. Sites have been selected, and the agreement with Specialised Therapeutics Australia for provision of an additional Grant from 2016-2020 and ethics approval was obtained in March 2016. Sites have been selected, and the agreement with Specialised Therapeutics Australia for provision of an additional 25 participants beyond the pilot phase was signed in November 2016.

Trials in follow-up

EORTC 62024 – Adjuvant GIST

The Adjuvant GIST trial, also conducted with the EORTC, aims to determine if giving imatinib to people with resectable GIST as a follow-up treatment after surgery increases their survival rate.

After two years of treatment and a median follow up of 4.7 years, the interim analysis of the data confirmed that adjuvant imatinib has an overt impact on relapse-free survival. No significant difference in imatinib monotherapy versus placebo in terms of overall survival was observed, although in the high-risk subgroup there was a trend in favour of the adjuvant arms. Results of the interim analysis were printed in the Journal of Clinical Oncology in October, 2015.

Data collection and follow up of these patients was scheduled to end in December 2016 when data cleaning and the final analysis for this trial will be undertaken.

Over many years, the AGITG has enabled me to collaborate with numerous colleagues, all of whom shared a common purpose – defining new ways that we can improve the life of patients with gastrointestinal cancer. I’m extremely proud of what we’ve achieved, none of which would have been possible unless we joined forces as clinicians and consumers to draw a line in the sand – to state, unequivocally, the status quo is not good enough! I feel privileged to have shared our knowledge with so many patients and their families and personally have learnt an enormous amount from talented, hard-working and committed people who have been part of this vision.

Professor John Zalcberg OAM, Principal Investigator

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Professor John Zalcberg OAM, Principal Investigator
Pancreatic cancer is amongst the most lethal of all adult cancers – 2,865 people were diagnosed with pancreatic cancer in 2013 and an estimated 2,547 people died from it in Australia in 2014. The five-year survival rate is just 7.7%. There have been no major improvements in outcomes over the past 30 years.

GAP
Trials in follow up
This trial aims to evaluate the impact of pre-operative pancreatic surgery can identify patients with aggressive tumour biology who may be spared the effects of resection surgery, while also identifying patients most likely to benefit from radical therapy.
Analysis concluded that peri-operative gemcitabine and Abraxane (nab-paclitaxel) is feasible and well tolerated. The pre-operative regimen was associated with an RO resection rate comparable or higher than surgical series without pre-operative therapy, although the primary endpoint of 85% could not be met. The value of this regimen will also depend on longer outcomes related to recurrence and survival. The GAP study had a poster presentation at ASCO 2015 and ASCO GI 2015 with another presentation in 2016.

Cancer of the gallbladder and bile ducts is rare, accounting for 774 people diagnosed in 2013 and 239 deaths in 2014. The five year survival rate is 19.2%.

TACTIC
Patients with locally advanced or metastatic biliary tract cancer with KRAS wild-type (i.e. no mutation of the KRAS gene detected) are usually treated with two chemotherapy drugs. The TACTIC trial aims to determine whether the addition of a new antibody treatment called panitumumab is safe and will improve the chance of survival.

The final analysis commenced in 2015 and was completed in 2016. Primary results were published in the journal Cancer Chemotherapy and Pharmacology in June 2016.

Worldwide, liver cancer is the sixth most common form of cancer. In 2013, 1,778 people were diagnosed with liver cancer in Australia and 1,732 people died in 2014 as a result of it. The five year survival rate is 17.3%.

ATTACHE
The ATTACHE trial compares the effectiveness of six months’ of chemotherapy given after surgery with the same chemotherapy given three months before and three months after surgery for patients with bowel cancer that has spread to the liver. The aim is to discover which option is more beneficial in outcome and patient quality of life. The ATTACHE study will also look at how side-effects of chemotherapy can be reduced and the cancer eliminated, or managed, longer-term.

Analysis of the data combining the EPOC B study and ATTACHE, with initial data from C11, resulted in a poster presentation at ESMO 2015: “Feasibility of trials to assess safety and toxicity of peri-operative and post-operative adjuvant therapy for Hepatic Metastases from Colorectal Cancer”. The analysis concluded that post-operative chemotherapy following liver resection is not associated with any additional morbidity and is associated with an apparent improved complication rate against peri-operative therapy. There is a comparable chemotherapy completion rate in both arms. This schema was endorsed on two continents as worthy of study. Despite this, trial recruitment has been unexpectedly low. The trial groups agreed to explore the question of what degree of clinical equipoise exists in relation to liver resection and adjuvant chemotherapy. The main paper will include equipoise data. Preparation is underway and the manuscript in final review.

Charlie’s Story
On the day his fourth child, Olivia, was born, Charlie Tootell was diagnosed with bowel cancer. He was 37 years old. Charlie fought bushfires but it had never crossed his mind that one day he would be fighting cancer.
Charlie and Bianca own a crop dusting company in rural Mungindi, a small town on the border of Queensland and New South Wales.
“Blokes in general are pretty reluctant to go to a doctor,” said Charlie. “If a doctor says it’s all alright then you aren’t going to push the matter.
In November 2013, Charlie and Bianca were in Wollongong to see her gynaecologist, Dr Keith Colman. Charlie and Dr Colman got on very well. “They would talk more about farming, aircraft and motorbikes than about me having the baby,” remarked Bianca. “Dr Colman asked one simple question ‘and how have you been Charlie?’ and to my surprise Charlie started telling him what was going on.”
Only a few days later his diagnosis came through. Not only was he diagnosed with bowel cancer but the cancer had spread to his lymph nodes.
Two years since his diagnosis, and with cancer free results, Charlie is optimistic. He is determined to let people know you are never too young to be diagnosed with GI cancer. He emphasises that in rural areas everybody – especially men – need to get checked.
Charlie kindly agreed to share his story for the GI Cancer Institute 2016 tax appeal.
Colorectal cancer is cancer of the colon or rectum. It is also called bowel cancer and is the most common type of GI cancer. Australia has one of the highest rates of colorectal cancer in the world. In 2016, 17,520 people were diagnosed with colorectal cancer in Australia, up from 14,962 in 2013. The five year survival rate is now at 68.7%.

**Trials open to recruitment**

**ASCOLT**

Aspirin is known to be helpful in preventing and treating heart and blood vessel diseases and there is growing evidence that aspirin possesses some anticancer properties. Studies into large groups of patients with colorectal cancer suggest that aspirin may reduce recurrence and improve survival in patients with localised colorectal cancer. However these findings need to be confirmed by information from randomised clinical trials before treatment with aspirin can be considered standard therapy for this group of patients. Investigating the role of aspirin in colorectal cancer patients was chosen as the highest priority by Australian consumers, clinicians and researchers at a national forum convened by the AGITG and University of Sydney in August 2011. The ASCOLT study will provide proof of the role of aspirin in patients with localised colorectal cancer and will set a new standard nationally and internationally. As aspirin is inexpensive, readily available and familiar to most people, any impact on increased survival is likely to result in its wide use as a cost-effective agent. ASCOLT is being conducted in 12 countries throughout Asia and Australasia.

A successful Cancer Australia grant application was submitted in March 2016. The AGITG will be the lead for overall translational activities in collaboration with the Walter and Eliza Hall Institute. The recruitment timeline was extended until December 2017.

**InterACT**

The main purpose of this international, multicentre trial is to establish which chemotherapy regimen is more effective for inoperable advanced or metastatic anal cancer. By comparing two well-known and widely used combination chemotherapies, we aim to demonstrate which is most effective and less toxic for patients with this disease. The results of this study are likely to establish the standard of care for patients with inoperable anal cancer. This study also aims to acquire important information on the biology of anal cancer by incorporating translational research as part of its overall research aim.

The first site was open to recruitment in March 2016. Since then an additional four sites have opened and the first Australian patient randomised in January 2016.

**Trials in follow-up**

**ICECREAM**

Previous AGITG studies have demonstrated that cetuximab, an EGFR (epidermal growth factor receptor) monoclonal antibody, prolongs survival in patients refractory to all other chemotherapy, resulting in Australian Pharmaceutical Benefits Scheme funding (Sept 2011). Some doctors believe combining this treatment with irinotecan will achieve better results because one older UK trial reported modest increases in cancer shrinkage and duration of cancer control. However side-effects were greater, and survival was not increased on this study.

Soon after the initial cetuximab clinical trials were reported, the AGITG and other groups showed that cetuximab was not effective in people who have the specific abnormality (mutation) in their colon cancer cells called a KRAS Gene Mutation. Up to 40% of patients have this abnormality, which can be easily tested, and so only patients without this mutation (KRAS wild-type) are given this treatment. When restricted to this subgroup, the benefits of cetuximab are significantly enhanced.

The picture has become more complicated in the past 12 months with further research showing patients with one particular type of KRAS mutation (G13D) may actually benefit from cetuximab treatment after all. Currently, cetuximab is only US FDA and Australian TGA approved for patients without any KRAS mutation.

This study aims to evaluate whether cetuximab should be given alone or in combination with irinotecan chemotherapy in KRAS wild-type patients with progressing cancer, despite previous treatment with oxaliplatin and irinotecan chemotherapy. The data on the effect of cetuximab on patients with G13D KRAS mutation was presented and published in 2016.

Recruitment closed for the RAS wild-type patients on June 30, 2016 with a final total recruitment of 101. An abstract of this analysis is planned for submission to American Society of Clinical Oncology Annual Meeting 2017.

**AlaCART**

AlaCART is the largest Australasian trial in rectal surgery. The current major treatment for rectal cancer is surgical removal of the cancer, requiring a large cut through the abdomen. The AlaCART trial looks at whether a less invasive laparoscopic resection is as safe and effective as the current procedure.

This trial did not test whether laparoscopic resection was better, but rather whether it was no worse than the traditional treatment.

Since joining the AGITG some 20 years ago, I have gained invaluable clinical knowledge and gained a strong scientific contribution to clinical trials design, conduct and interpretation, culminating in meta analyses in oesophageal cancer, the results of which has led to a change in clinical practice worldwide. To be part of the AGITG is both satisfying and an enriching experience, especially with the extent of scientific, clinical endeavours of the group, which is reflected in its national and global reputation as a premier collaborative trial group.

Professor Val Gebski, Biostatistician

Main analysis of the study is underway with the aim of first SCOT results publication in mid-2017. Also planned is an analysis of the toxicity and quality of life data with publication planned in 2017.

**CO.23**

The AGITG collaborated with the Canadian Cancer Trials Group on a large global study called CO.23 to examine the impact of a new type of drug, cancer stem cell inhibitors, on people with advanced bowel cancer who had exhausted all other treatments.

The CO.23 interim analysis data was reviewed by the Canadian Cancer Trials Group Data Safety Monitoring Committee (CCTG DSMC) which concluded that, per protocol criteria, there was no evidence of efficacy with the experimental arm. The trial was, thus, declared “futility”. Recruitment closed May 2014. Follow-up continued for survival status, and a final analysis occurred in late 2015. Results are pending.

**PETACC-6**

An international study led by the European Organisation for the Research and Treatment of Cancer (EORTC), PETACC-6 is testing whether adding a new chemotherapy drug oxaliplatin to standard chemotherapy and radiotherapy before and after surgery improves disease-free survival for people with locally advanced rectal cancer.

The PETACC-6 database was locked on December 31, 2015 and analysis of data was undertaken early in 2016. The results were presented at ESMO 2016 as a poster presentation. Five-year follow up data will be collected until mid-June 2017 when final analysis will be undertaken.
Many of the trials in the AGITG portfolio collect tissue and blood samples from their patients. These samples are used in translational research studies to seek biomarkers – biological flags that may help to select those patients most likely to benefit from a treatment, or to spare particular patients from treatment toxicities.

Thirty-one AGITG trials collect or have collected tissue and blood from patients. More than 80% of these trials have confirmed translational research studies. Work is progressing on many of these studies. Proposals using these patient samples undergo scientific review by the trial management committees, the Upper and Lower GI Working Parties, and the Scientific Advisory Committee. The joint AGITG–Canadian Cancer Trials Group Correlative Research Committee reviews proposals relating to the Correlative Research Committee for the Canadian Cancer Trials Group, the Scientific Advisory management committees, the European Society for Medical Oncology, and the European Medical Journal. The study was included in an article on neoadjuvant treatment (an oral multi-kinase inhibitor) for GI cancers in the European Medical Journal.

**A study of hypertension and betablocker use in patients with metastatic colorectal cancer in the CD.17 trial showed these factors are neither significant prognostic factors nor predictive of benefit from treatment with cetuximab, though patients with baseline hypertension may do better on cetuximab. This was presented in a poster at ASCO GI by Canadian collaborator Dr Shelly Sud, medical oncologist.**

**Two studies on the easily obtained and inexpensive blood biomarker, the neutrophil, to lymphocyte ratio (NLR), were presented as posters at the European Society for Medical Oncology 2016 Congress (ESMO 2016) by medical oncologist Dr Connie Diakos. One study was based on the metastatic colorectal cancer trials CD.17 and CD.20. The translational research collaborations are with a broad mix of clinical and scientific researchers from Australia, New Zealand and overseas.**

**2016 highlights include**

- A blood biomarker study from the AGITG INTEGRATE trial was presented as a poster at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco by translational research fellow and manager, Dr Sonia Yip. The study showed that high plasma levels of IL8, VEGF-A and sVEGFR-1 may be adverse prognostic factors in patients with refractory advanced oesophago-gastric cancer. Video presentations of the study were made for online education sites HemOnC (2016) and priME Oncology. The study was included in an article on neoadjuvant treatment (an oral multi-kinase inhibitor) for GI cancers in the European Medical Journal.

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**TRANSLATIONAL RESEARCH**


Journal publications and conference presentations provide clinicians and patients with the most up-to-date treatment results. In 2016, the AGITG published clinical trial results in leading international medical journals. The 13 publications included trials in biliary tract cancer, advanced gastric cancer, colorectal cancer, and locally advanced pancreatic cancer.

Publications


The AGITG is an exceptional team of medical researchers, clinicians, consumers and support staff with whom I am privileged to work with. I have been inspired by every member of this team throughout my years of association. The strength of the AGITG lies in the dedication of its members from whom I have learnt so much.

Dr Jenny Shannon, Principal Investigator

American Society of Clinical Oncology Gastrointestinal Cancers Symposium, San Francisco


The AGITG presented at international cancer conferences in the US and Europe. Showcasing AGITG trial results to international colleagues is an important focus for the AGITG at these high profile international conferences. Results for DOCTOR, INTEGRATE, GAP, CO.17, CO.20, MAX, ALaCaRT, and ARCAD were featured. The ARCAD results have come from an international collaboration which uses data from colorectal cancer trials analysed together in order to identify any larger patterns in the data and treatment outcomes.

European Society for Medical Oncology 41st Congress, Copenhagen


American Society of Clinical Oncology 2016 Annual Meeting, Chicago

To successfully obtain funding for academic research and the establishment of a clinical trial takes a considerable amount of effort, time, and collaboration across multidisciplinary teams. Follow the genesis of an AGITG clinical trial—MONARCC—from identification of the problem to obtaining funding for a pilot study supported by the AGITG Innovation Fund.

**Step 1. Identification of a gap in research**
Dr Matthew Burge, a medical oncologist, increasingly saw elderly patients presenting with metastatic colorectal cancer who were unlikely to tolerate combination chemotherapy regimens. His patients were at significant risk of experiencing onerous side effects, making it difficult for them to tolerate treatment or gain any meaningful benefit from the treatment provided. Dr Burge identified a need to research more appropriate treatment options for this patient group that could ultimately be applied to younger patient groups.

**Step 2. Literature review**
A search for information to guide the treatment management of his patients confirmed a gap in knowledge.

**Step 3. Discussions with colleagues and the pharmaceutical industry**
Following the literature review, Dr Burge held a number of discussions with his medical colleagues at Royal Brisbane Hospital, members of the AGITG, and representatives from pharmaceutical company Amgen Australia. He decided the best way forward was to get formal feedback from AGITG members and international speakers attending the AGITG Annual Scientific Meeting, and he entered the study into the 2014 New Concepts Symposium.

**Step 4. Presentation to local and international peers**
Dr Burge presented a concept at the AGITG Annual Scientific Meeting in 2014 entitled “A randomised Phase 2/3 study of infusional FU/LV with panitumumab V FU/LV/capecitzumab bevacizumab as first line therapy for never resectable, RAS and RAF wild type metastatic colorectal cancer.”

The concept was popular and the audience responded positively. Dr Burge received the Award for Best of New Concepts, 2014.

**Step 5. Further development**
The AGITG’s Upper GI and Lower GI Working Parties are the working parties of the Scientific Advisory Committee (SAC). The working parties include medical oncologists, surgeons, radiation oncologists, statisticians, translational scientists, consumers and allied health practitioners.

Amgen Australia is the pharmaceutical company that manufactures and markets panitumumab. The Lower GI Working Party looks at cancer of the bowel, anus and rectum while the Upper GI Working Party focuses on cancers of the oesophagus, gallbladder, pancreas, stomach and liver.

Dr Burge discussed the randomised clinical trial with the Lower GI Working Party. Based on the verbal feedback from this multidisciplinary group of peers and Amgen, Dr Burge revised the concept to present to the AGITG Scientific Advisory Committee (SAC). The Lower GI Working Party looks at cancer of the bowel, anus and rectum while the Upper GI Working Party focuses on cancers of the oesophagus, gallbladder, pancreas, stomach and liver.

**Step 6. Presentation to the AGITG Scientific Advisory Committee (SAC)**
The SAC is the focal point for widespread discussion of research ideas. Its members, who are drawn from the AGITG and the NHMRC Clinical Trials Centre, are experts in the fields of medical oncology, surgery, radiation oncology, biological research, quality of life research, statistics, study coordination and consumer involvement. The SAC discussed Dr Burge’s research project and ratified the trial under the AGITG name.

**Step 7. How to fund the Study?**
To get the study off the ground, Dr Burge decided the way forward was to apply to the AGITG Innovation Fund for a grant of $100,000 to conduct a pilot trial. The data collected during the pilot study would be critical to securing additional funding from either the pharmaceutical company or the NHMRC.

**Step 8. Application to AGITG Innovation Fund**
Dr Burge prepared a grant application for the 2015 AGITG Innovation Fund but unfortunately it was unsuccessful.

**Step 9. A pilot study is started**
Five years after Dr Burge’s initial identification of a need for a specific patient population, the pilot phase for the MONARCC Study is planned to open in 2017 with funding from the AGITG Innovation Fund in 2016.
The AGITG was delighted to host a Scientific Meeting (ASM) held ANNUAL SCIENTIFIC MEETING continues to provide a forum for Organising Committee, the ASM edge research and evidence based and international medical professionals on the latest cutting- edge research and evidence based treatments. Under the guidance of meeting convenor Professor Eva Segelov, and the ASM Executive Organising Committee, the ASM continues to provide a forum for mutual exchange of knowledge to improve the treatment of GI cancer patients. The AGITG was delighted to host a distinguished plethora of experts in multi-disciplinary fields from across the globe:

- Professor Edgar Ben-Josef (University of Pennsylvania, USA);
- Associate Professor Jeffrey Meyerhardt (Dana-Farber Cancer Institute, USA);
- Associate Professor Magnus Nilsson (Karolinska Institute, Sweden);
- Professor Phil Quirke (University of Leeds, UK);
- Dr Simmon Singh (University of Toronto, Canada);
- Professor Alan Venook (University of California, USA);
- Dr Rebecca Wong (Canadian Cancer Trials Group and University of Toronto, Canada).

The opening day plenary session included presentations from the international faculty with a focus on ‘Colorectal cancer and optimising outcomes in quality, lifestyle and patient centred care’.

The trial session followed focussing on Colorectal & Anal Cancer Trials with highlights including: the ICECREAM trial and its success of running a trial on a population selected based on molecularly defined mutation status; the ASCOLT trial and the combination of simple aspirin therapy to improve survival, providing great opportunities on a translational research front to identify possible markers and sub populations who will benefit; the InterAACT trial and the challenges of setting up an international multi-centre trial on a relatively rare cancer; and the overview from Professor Alan Venook on where the future of colorectal cancer (CRC) trials may be heading in the age of biomarkers, and how to utilise new therapies to gain the most benefit for our patients. The keynote session – ‘New Paradigms in Molecular Pathology of CRC From Lab to Trials Practice’ was led by Professor Phil Quirke.

Radiation Oncologists gathered later in the day for an inspired workshop led by Professor Edgar Ben-Josef and Dr Rebecca Wong, who addressed current indicators and state-of-the-art radiotherapy practice for treatment of pancreatic cancer, as well as the potential for stereotactic body radiotherapy and novel systemic combinations.

On Day Two the keynote breakfast session, ‘Changing Attitudes to Changing Lifestyle’ was led by Associate Professor Jeffrey Meyer while the alternative breakfast workshop addressed the use of stereotactic body radiotherapy for treatment of primary liver cancer and liver metastases. These sessions were well attended by medical and trial staff.

The AGITG is an instrumental part of my professional life. It allows me to be involved with cutting edge trials, to interact nationally and internationally with peers, to mentor junior staff, and to provide my patients with the best possible care.

Professor Eva Segelov, Principal Investigator

On the final day of the meeting, the focus moved to oesophago-gastric cancer trials and began with a breakfast keynote by Associate Professor Nilsson on the multi-disciplinary management of oesophago-gastric cancer. This session was followed by a close look at a number of clinical trials in this area, including the newly established INTEGRATE II, TOP GEAR, and DOCTOR Translational Project. Associate Professor Nilsson and Dr Wong discussed the surgical perspective and integration of RT in Upper GI Cancer Trials. Following the morning session the trial session dealing with hepatopancreatobiliary, GIST and NET was held with a focus on AGITG clinical trials in these cancers.

Rounding out the three days of ideas and information exchange was the final session – a light hearted debate with Hot Topics including ‘That Canada “trumps” the US in cancer care’, ‘That SBRT stands for Surgical Brothers Retirement Taskforce’ - that surgeons are on the dinosaur path to extinction and, finally, ‘That quirks cannot be tolerated’.

While light hearted, this session touched on very serious and confronting issues facing modern oncology practice, such as sustainability of health care, and the strengths and weaknesses of different funding options for cancer care internationally. The international faculty and audience debated the role of novel technologies and the controls around introduction of new treatments into health care settings, particularly where some of these new technologies have intuitive appeal but limited evidence. The final debate addressed the tensions that exist between individual clinical freedoms, personalised medicine, and quality control and outcome measures. In many ways this final session captures the very soul of the AGITG meetings: collaborative, thought provoking, forward looking, innovative, and fun.

Our ongoing gratitude goes to everyone who participates and makes this meeting a success. Special thanks go to our sponsors. The meeting would not be possible without their support. 

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Treatment of advanced bowel cancer has improved significantly during the past few years. The number of different chemotherapy and targeted, or “biologic”, therapy options has also increased. Therefore the complexities of treatment decisions faced by the treating oncologist have also increased. For many patients, oncologists remain uncertain as to what is the best treatment regimen to use at diagnosis. In addition, the best sequence in which to prescribe all the available drugs is not known. While there is a lot of emerging clinical trial data, many patients seen in daily practice do not fit the patient population enrolled on to these trails.

This trial seeks to determine the best initial treatment for a patient population that cannot withstand the expected side effects of the commonly used combination chemotherapy regimens. This is a common patient population diagnosed with advanced bowel cancer in Australia.

The study will compare low intensity targeted therapy (panitumumab), without chemotherapy, which is generally well tolerated. The hypothesis is that panitumumab will be a safe, acceptable and convenient regimen for elderly and/or frail patients with newly diagnosed advanced colorectal cancer.

“Winning this award means a huge amount to me. The recognition of the importance of this research question from the AGITG is particularly gratifying,” said Dr Burge. “I now plan to lead a national study which, I hope, will improve the treatment options and outcome for elderly patients with advanced colorectal cancer.”

Specialised Therapeutics Australia Chief Executive Officer, Mr Carlo Montagner, said “every great achievement begins with a single idea. “We look forward to seeing this great concept evolve over time so that it, too, may ultimately improve the lives of cancer patients around the world.”

The AGITG thanks Specialised Therapeutics Australia for their continued support of the New Concepts Symposium and Best of New Concepts Award.

New Concepts Symposium

The New Concepts Symposium, held at the AGITG Annual Scientific Meeting (ASM) and sponsored by Specialised Therapeutics Australia, is designed as a novel way to reach out to a wider spectrum of the group. This session provides an opportunity for delegates to present embryonic new concepts for feedback and discussion with the audience as well as comments from international guests in terms of perspective, international interest and relevance.

In 2016, the New Concepts Symposium featured four excellent presentations of embryonic research concepts. This year the Best of New Concepts Award was presented to Professor Eva Segelov of St Vincent’s Hospital (Sydney) for her concept “Inducing immunogenicity in rectal cancer: A Phase II trial of aspirin +/- PD-1 inhibitor in combination with neoadjuvant chemoradiation therapy for locally advanced rectal cancer: The INTIMACCI study (Inducing Tumour Immunogenicity with Aspirin, chemoradiation and Checkpoint Inhibition).”

“It is an honour to receive the Best of New Concepts Award, supported by Ipsen, said Dr Sharon Pattison of University of Otago for ‘Mismatch repair deficiency, inflammatory score and prognosis in gastric cancer’. The abstract described how recent studies have identified different molecular subtypes of gastric cancer, as yet not utilised in clinical decision-making for patients. One of the described molecular subtypes is microsatellite instability or mismatch repair deficiency. The abstract reported on the clinical and pathological variables associated with mismatch repair deficient gastric cancer using a multi-centre cohort of patients undergoing curative resection. Of 155 tumours, 12 were mismatch repair deficient, and compared with mismatch repair proficient tumours these were associated with a more pronounced inflammatory infiltrate and a lower rate of recurrence and death from gastric cancer. Mismatch repair deficiency and a higher inflammatory score were both associated with improved survival, and on multivariate analysis that included stage of disease and Lauren classification histological subtype inflammatory score remained significant. This small retrospective study concluded that both mismatch repair status and degree of inflammation need to be investigated further in gastric cancer as variables with prognostic significance.”

“Without our patients and their families support in giving their time and information, we wouldn’t be able to do our studies in gastric cancer,” said Dr Sharon Pattison, Southern DHB, Dunedin, New Zealand. “This award is recognition of the contributions that they make.”

The runner up was Dr Melanie McCoy, St John of God Hospital, Subiaco, for ‘Immune biomarkers of response to chemoradiation in locally advanced rectal cancer’. “Ipsen, we are proud that this small contribution for Best of Posts is able to advance research and positive outcomes for patients.”

The AGITG is grateful for sponsorship from Ipsen for the Best of Posts.
S-fluorouracil in the treatment of resectable rectal cancer – a systematic review and meta-analysis. The abstract summarised the efficacy and toxicity of adding oxaliplatin to fluoropyrimidine chemotherapy in treating patients with resectable rectal cancer. Seven randomised trials evaluating the combination versus single-agent fluoropyrimidine were identified, five in the preoperative setting, concurrent with radiation, one perioperatively and one postoperatively, involving a total of 4,444 patients. The conclusion reached was that despite significant improvements in the pathological complete response rate, local and distant recurrence rates, there was no significant improvement in overall survival with the addition of oxaliplatin. The less than optimal dose intensity and/or compliance with oxaliplatin can mostly be explained by its addition concurrent with radiation in the majority of included trials. This, along with an absence of studies evaluating the addition of oxaliplatin to a fluoropyrimidine in the induction setting probably explains this lack of improved survival.

“Recognition from members of the AGITG is a great honour,” said Dr Thavaneswaran. “I have received amazing support and feedback during my fellowship with the AGITG and to be recognised for a project in GI cancer research that I initiated myself is fantastic.”

Professor Eva Segelov at the Preceptorship in Colorectal Cancer

The 2016 AGITG Preceptorship in Colorectal Cancer was held in November 2016 in Melbourne. Senior trainees and junior consultants attended this two-day intensive learning course based on a complete review of literature to understand the evolution of treatment for colorectal cancer in the adjuvant and metastatic setting in the context of current treatment paradigms. Learning takes place in small group interactive sessions along the Harvard short course model.

The preceptorship was convened by Professor Eva Segelov and Preceptors included Professor Eva Segelov, Associate Professor Peter Gibbs, Dr Chris Jackson, and Associate Professor Chris Karapetis.

“I was delighted to be invited to be a preceptor at the 2016 AGITG Preceptorship in Colorectal Cancer. This was a fantastic experience, and I would seize the opportunity to be involved again. The group led discussion was excellent; the registrars were well prepared, thoughtful, and highly engaged. It was also an excellent stimulus to re-read many of the papers and trials that I hadn’t looked at for years, so a real refresher for me also. In addition to this, I greatly valued hearing the insights and thoughts of other preceptors about their interpretation of the evidence as well as their personal involvement in the development of the studies. It is a rare opportunity to learn so much from knowledgeable colleagues. Overall the event was one of the highlights of my year and I hope I get invited back again!” Dr Chris Jackson, Preceptor, 2016.

The AGITG Preceptorship in Colorectal Cancer is supported by an educational grant from Roche Products Pty Limited.

Participants of the Pancreas Cancer Research Workshop

4th Annual Pancreas Cancer Research Workshop

The AGITG and the Australasian Pancreas Club (APC) hosted the 4th Annual Pancreas Cancer Research Workshop in September, immediately preceding the AGITG 18th Annual Scientific Meeting. Co-chaired by Dr Lorraine Chantrill of the AGITG and Dr Chris Scarlett of APC, this free and open workshop aimed to develop new collaborations and relationships between researchers, healthcare providers, consumers and pharmaceutical companies. The meeting was a resounding success with very good attendance across disciplines and robust, research-centred discussion.

There were two outstanding invited speakers: Professor Edgar Ben-Josef, a distinguished radiation oncologist and researcher from the University of Pennsylvania who was able to elaborate on possible biomarkers for radiotherapy in pancreatic cancer, and Dr Paul Timpson from The Garvan Institute, who impressed the audience with his real-time studies of intravital imaging of pancreatic cancer.

We were very pleased to have concepts presented from researchers based in Melbourne, Adelaide and Sydney. Concepts included further analysis of the APGI dataset in terms of long-term survivors, as well as text mining to elucidate clinical syndromes associated with genomic aberrations. We also heard from the Biogrid team who had a proposal for a translational registry. A second-line clinical trial using panitumumab in KRASWT pancreas cancer was presented and also research into a diagnostic test for IPMN was workshoped. Feedback from the presenters was that they were helped enormously by the input from the experts in the room.

This open forum allows Australian investigators and researchers to share their ideas so we can all appreciate the depth and breadth of research in this disease. Our expert panel emphasised the need for collaboration now more than ever as funding sources become scarce.

“It is evident from the concepts presented, and the level of participation in the workshop, that we have reached a critical mass in pancreatic cancer research. As funding becomes more difficult to obtain, we are fortunate in Australia to be in an excellent position to work together and leverage available opportunities. Now is the time to collaborate to improve treatment for patients with pancreatic cancer,” said Dr Lorraine Chantrill.
INVESTING IN RESEARCH

CommNETS Research Collaboration

The second meeting of the Commonwealth Neuroendocrine Tumour Collaboration (CommNETS) was held in December to review gaps in NET research. The mission of the CommNETS research collaboration is to improve the outcomes of NET patients through accelerated collaboration between patients, clinicians and researchers in member nations. The two-day meeting brought together NET clinicians, researchers and consumers from Australia, New Zealand and Canada.

The meeting started with a summary of 2016 achievements, among them:

• Formalised CommNETS relationship with AGITG and Canadian Cancer Trials Group;
• Working groups/projects;
• Research projects one major, several minor;
• Engagement with other societies: North American Neuroendocrine Tumour Society (NANETS) and industry;
• Publications and presentations;
• Oral presentation American Society of Clinical Oncology Annual Meeting (2017);
• Poster presentations at several international scientific meetings and the AGITG ASM;

As a group, it was decided that all members should be actively involved in at least one project and that attendance at CommNETS 2017 will be reliant on project involvement. We had an excellent session with Dr Danny Heng, our invited speaker, regarding his experience in establishing a renal database that has been very successful and now has an extensive international buy-in. Lessons learned were particularly informative, as was his overall message that much can be achieved with relatively little if there is a will. This led to the discussion about the CommNETS major project of establishing a registry for NETs, which is underway.

Both Dr Thavaneswaran and Dr Chan were very busy throughout their Fellowship year.

Dr Thavaneswaran assisted with an NHMRC grant application and a Canada Cancer grant application. The Cancer Australia application was for follow up funding for the AGITG ASCOLT study and the NHMRC grant application was for the UK-developed CREATE study. She assisted with the drafting of the manuscript for the pooled analysis of the AGITG ATTACHE study, the UK EPICO-B study and the NSABP C-11 study, incorporating the clinical equipoise survey data to better characterise the reasons for poor patient accrual to these studies.

“During my fellowship at the AGITG I was fortunate to receive mentorship from many renowned researchers,” said Dr Thavaneswaran. “This gave me the confidence to undertake a systematic review and meta-analysis as a unit in my Masters of Medicine with the review topic and oversight provided by Professor Tim Price, AGITG Chair.”

Dr Thavaneswaran wrote an abstract based on this review, and presented it at the AGITG Annual Scientific Meeting in the Fast Forward Presentation section, and received the first place award for this category.

Subsequent to the Fellowship program, Dr Thavaneswaran continues to be involved with the AGITG as a member of the team working on the ‘quad WT’ arm of the AGITG ICCREAM study, providing clinical input to trials staff, central adjudication of the primary outcome, and contributing to the ASCO abstract and results manuscript.

During his Fellowship at the AGITG, Dr Chan was given two opportunities to present clinical trial results at international conferences. He was instrumental in preparing results from the GAP Study, which was presented as a poster at the GI cancer (non-colorectal) session at the American Society of Clinical Oncology (ASCO) 2016 Annual Meeting in Chicago. This AGITG study examining the role of neoadjuvant chemotherapy prior to surgery in pancreas cancer showed an association between response to pre-operative chemotherapy on CT and a complete resection (R0) at surgery. Responding patients also had a longer period without the cancer returning. In addition to presenting the poster, Dr Chan has been actively involved in preparing the manuscript of the main study results.

Dr Chan was also actively involved in preparing data and presentation materials for the DOCTOR trial, which were delivered by Dr Andrew Barbour as an oral presentation at the European Society for Medical Oncology (ESMO) 2016 Congress, in Copenhagen. The AGITG DOCTOR study is a randomised phase II study of pre-operative cisplatin, fluorouracil and daceisol (±/-radiotherapy based on poor early response to cisplatin and fluorouracil for resectable oesophageal adenocarcinoma. For both the ALT-GIST and INTEGRATE II clinical trials, Dr Chan assisted in development and central oversight activities throughout the year. These included site initiations, protocol development and amendments and updates to Participant Information and Consent Forms (PICF) with particular regard to the updated side effect profile of regorafenib. He also undertook research on regional differences in clinical practice for treatment of advanced gastric cancers in the INTEGRATE II participating countries. This provided valuable information on the variation in practice important to the successful development and conduct of the AGITG led international INTEGRATE II trial.

Dr Chan is currently involved with the AGITG ASCOLT study (2017) and the ASCOLT II study to continue the follow up of patients who have completed treatment. The ASCOLT II study is a global, multi-institutional study which aims to evaluate the role of SIRT for high-risk patients with advanced pancreatic cancer who have not had a complete resection (RO) at surgery and may benefit from additional therapy to improve their outcomes. The study is coordinated by AGITG and has multiple recruitment sites in Australia and overseas, with the aim of enrolling 100 patients by the end of 2018.

My involvement with AGITG has led to both friendship and collaboration with a wide variety of people ranging from relatives of patients to other investigators. The collaboration across the organisation underpins its strength as a group that can undertake practice changing trials for patients with GI cancer.”

Associate Professor Niall Tebbutt, Principal Investigator

Dr Lorraine Chantrell at the expert meeting: Expert Meeting on Pancreatic Cancer

“Controversies in the management of patients with pancreatic cancer” in December, a group of AGITG and international experts met in Singapore to discuss this issue. The meeting was chaired by Professor Eva Segelov and attendees included, from the international faculty: Professor Dirk Arnold, Professor Florian Lordick, Professor Ian Chau, and Dr Radka Obermannova. The AGITG faculty included Professor Tim Price, Conjoint Professor David Goldstein, Dr Howard Chan, AGITG Fellow

AGITG Fellowship Program

During 2016, Dr Subotheni Thavaneswaran and Dr Howard Chan continued their involvement in gastro-intestinal cancer research through their Fellowship with the AGITG. Research Fellows provide academic and clinical expertise for particular areas of research or specific projects.

Participants at the CommNETS Annual Meeting

“...”

“...”
Infrastructure Grants
Funds provided by Cancer Australia to support AGITG infrastructure are managed by the University of Sydney NHMRC Clinical Trials Centre. These funds are not reported in the financial accounts of the AGITG, unless transferred to support specific AGITG expenses.

Funding
Cancer Australia Infrastructure Grants: 1 July 2013 to 30 June 2016 - $1,400,093. During 2016 $230,865 was transferred to the AGITG and was reported in the 2016 financial accounts.

Research Grants
Funds provided by Cancer Australia, Cancer Council and the National Health and Medical Research Council in support of trial coordination are also managed by the University of Sydney NHMRC Clinical Trials Centre. These funds are not reported in the financial accounts of the AGITG. However, funds to support site payments and insurance costs relating to these studies are transferred to the AGITG and are reflected in these financial accounts. Grants contributing to AGITG trials conducted during the 2016 financial year are outlined as follows.

AlaCaRT: A phase III prospective randomised trial comparing laparoscopic assisted resection versus open resection for rectal cancer.

Funding
- NHMRC Grant: $932,586 (2011)
- NHMRC Grant: $573,259 (2015)

Funds were received by AGITG in 2016 ($52,000) for site payments and insurance costs. This income and associated expenditure are included in the 2016 Income Statement.

ASCOLT Translational Study: A translational study of samples collected on the international ASCOLT adjuvant colorectal cancer aspirin trial.

Funding
Perpetual Trustee Company Limited (2015)
- The Jessica & Wallace Hore Foundation: $25,000
- Elaine Haworth Charitable Endowment: $41,522
- The Merrett Endowment: $35,922

No funds were received in 2016. Expenditure on this trial is included in the 2016 Income Statement.

CO.20 and CO.17 Translational Research: Low-Frequency KRAS Mutations as a Predictive Biomarker for Cetuximab Resistance (the “KRAS Project”).

Funding
Perpetual Trustee Company Limited (2015)
- Ronald Geoffrey Arnott Foundation: $108,000

No funds were received in 2016. Expenditure on this trial is included in the 2016 Income Statement.

KRAS Project:

- Cancer Australia and Bowel Cancer Australia Grant: $328,000 (2014)
- NHMRC Grant: $756,136 (2013)
- NHMRC Grant: $387,000 (2011)
- NHMRC Grant: $197,000 (2011)
- NHMRC Grant: $55,127 (2011)

Funds were received by AGITG in 2016 ($52,000) for site payments and insurance costs. This income and associated expenditure are included in the 2016 Income Statement.

TOPGEAR: A randomised phase II/III trial of pre-operative chemoradiotherapy versus pre-operative chemotherapy for resectable gastric cancer.

Funding
- NHMRC Grant: $756,136 (2013)

Funds were received in 2016 ($52,000). Expenditure on this trial is included in the 2016 Income Statement.

CONTROL NETS: Capecitabine ON Temozolomide Radionuclide therapy Octreotate Lutetium-177 NeuroEndocrine Tumours Study.

Funding
- Unicom Foundation: $200,000 (2015)
- University of Sydney Bridging Grant: $30,000 (2015)

No funds were received in 2016. Expenditure on this trial is included in the 2016 Income Statement.

Community Grants
Funds provided by the Cancer Australia’s Supporting people with cancer Grant initiative for the Engage Community Forums program.

Additional support was received from commercial institutions.

Funding
- Cancer Australia: $80,000 (2014)
- Royal Bank of Canada $5,000 (2015)
- Clayton Utz Foundation: $2,000 (2015)
- Newman’s Own Foundation $19,935 (2015)

No funds were received in 2016. Expenditure on this program is included in the 2016 Income Statement.
BOARD OF DIRECTORS

Professor Michael Findlay
Resigned May 2016
Deputy Chair
MBChB FRACP MD
Professor Findlay is the Professor/Head of the Discipline of Oncology faculty of The University of Auckland. He is Founding Director, Cancer Trials New Zealand — a new national cancer clinical trials organisation. He is a Consultant Medical Oncologist, Auckland City Hospital. He has held his current position of Deputy Chairman of the Board since 2004 and has been actively involved with the AGITG since 1994.

AGITG Committee Positions:
Member, Scientific Advisory Committee
Member, Lower GI Working Party
Member, Public Affairs, Marketing and Fundraising Committee

Associate Professor Niall Tebbutt
Deputy Chair & Treasurer
PhD MRCP FRACP
Associate Professor Niall Tebbutt trained at Oxford University in the UK and has extensive experience in the management of patients with gastro-intestinal cancer. He has a strong involvement in clinical research and has published more than 120 manuscripts. He is responsible for leading GI cancer research at both the Austin and Northern hospitals and holds appointments at Austin Health, Northern Health and the Olivia Newton John Cancer Research Institute.

AGITG Committee Positions:
Deputy-Chair — Appointed May 2016
Treasurer and Chair, Finance & Risk Management Committee
Chair, Lower GI Working Party
Member, Scientific Advisory Committee

Conjoint Professor David Goldstein
Resigned May 2016
MBBS FRCP (UK) FRACP
Professor Goldstein is the Conjoint Clinical Professor in the Department of Medicine at the University of New South Wales, a senior Staff Specialist in Medical Oncology, Prince of Wales Hospital, Sydney, and Past President of the Clinical Oncology Society of Australia (COSA). He was Chairperson of the Gastrointestinal Malignancies Group, Clinical Oncology Society of Australia (COSA), was on the COSA executive team for six years and has just completed his term as President of the organisation.

AGITG Committee Positions:
Member, Scientific Advisory Committee

Professor Tim Price
Chair
MBBS DHthSc (Med) FRACP
Professor Price is Senior Consultant Medical Oncologist and Director of Medical Oncology and Clinical Cancer Research at The Queen Elizabeth Hospital in Adelaide. His major clinical interest is in the treatment of patients with gastro-intestinal cancer and he is currently involved in an extensive GI clinical trial program. He is Professor at the University of Adelaide, Colorectal Cancer Stream leader for SAHMRI, and has GI translational and laboratory research collaborations with the Bazil Hetzel Institute.

AGITG Committee Positions:
Chair, Board of Directors
Chair, Scientific Advisory Committee
Member, Corporate Governance Committee
Member, International Development Committee
Member, Upper GI Working Party
Member, Operations Executive Committee

"It’s a great honour to chair a Board of Directors so rich with experience, expertise and commitment.”
Professor Tim Price

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Professor Tim Price

Professor John Simes
Group Coordinator
BSc MBBS SM FRACP MD
Professor Simes is the Senior Principal Research Fellow and Director, NHMRC Clinical Trials Centre, University of Sydney, and Director, AGITG Coordinating Centre, NHMRC Clinical Trials Centre. He is Professor of Clinical Epidemiology, School of Public Health, University of Sydney, and a Medical Oncologist, Royal Prince Alfred Hospital, Sydney. John has been a founding member of AGITG since 1991 and member of the board since 2000.

AGITG Committee Positions:
Group Coordinator
Member, Scientific Advisory Committee
Member, International Development Committee
Chair, Operations Executive Committee
Ms Christine Liddy AO  

FAICD BA  

Christine is a Board Member and Past President of the Royal Flying Doctor Service of Australia and former National Vice President of the RFDS. She is also a member of the Board of The University of NSW Foundation and the Dame Patrice Menzies Foundation, a Council Member of the Friends of the Sydney International Piano Competition, Advisory Board Member of the Mosman Art Gallery and Cultural Centre, and member of the Capital Campaign Committee of the State Library of NSW and the RFDS Capital Campaign Committee.  

AGITG Committee Positions:  

- Chair, Annual Scientific Meeting (ASM) Organising Committee  
- Chair, Education Committee  
- Member, Scientific Advisory Committee  
- Member, International Development Committee  
- Member, Lower GI Working Party.

Professor Trevorrow Leong  

MBBS, MD, FRANZCR  

Professor Leong is Acting Director of the Division of Radiation Oncology and Cancer Imaging at Peter MacCallum Cancer Centre. He is an academic radiation oncologist, actively involved with clinical research programs, and has been a principal investigator in numerous phase I/II/III studies relating to gastrointestinal malignancies. He has been involved with AGITG activities for more than 10 years as a trial investigator and member of the SAC.  

AGITG Committee Positions:  

- Company Secretary  
- Member, Corporate Governance Committee  
- Member, Upper GI Working Party  
- Member, Scientific Advisory Committee  
- Member, International Development Committee  

Ms Mary Padbury  

BA LLB (Hons)  

Mary was Chairman of Ashurst Australia from 2005 to 2015. She was elected Vice Chairman of the global firm on the financial merger of Ashurst LLP and Ashurst Australia from November 2013. Mary is a board member of the Commonwealth Bank of Australia, The Macfarlane Burnet Institute for Medical Research and Public Health Limited, Melbourne University Law School Foundation, Victorian Legal Admissions Board, and a member of Chief Executive Women. She was appointed Chair of the Trans-Tasman IP Attorneys Board by the Commonwealth Minister for Industry, Innovation and Science in October 2016.  

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MBBS FRACS MD  

Professor Watson is Head of Department of Surgery at Flinders University and Head of Oesophago-gastric Surgery Unit at Flinders Medical Centre. His research interests include clinical and biological aspects of benign and malignant oesophageal disease, including molecular biology of Barrett’s oesophagus and oesophageal carcinoma. David is a Past President of the Australia and New Zealand Gastric and Oesophageal Surgery Association.  

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- Member, Scientific Advisory Committee  
- Member, International Development Committee  
- Co-Chair, AGITG-APC Pancreas Cancer Research Workshop.
Scientific Advisory Committee

The Scientific Advisory Committee (SAC) is the focal point for widespread discussion of research ideas. Its members, who are drawn from the AGITG and the NHMRC Clinical Trials Centre (CTC), are experts in the fields of medical oncology, surgery, radiation oncology, biological research, quality of life research, statistics, study coordination and consumers. The SAC’s key role is to determine the research priorities of the AGITG. The committee’s open dialogue leads to the development of a common language, interaction and commitment to trials by a broad range of medical specialists, allied health professionals and consumers.

The working parties meet bi-monthly to:

- Identify gaps in research activities;
- Develop and/or facilitate new clinical research concepts;
- Review the scientific merit of research proposals;
- Explore funding and feasibility opportunities in liaison with the Operations Executive Committee;
- Nominate Principal Investigators;
- Nominate Trial Management Committee members.

SAC meetings foster a spirit of collaboration and cohesion between a diverse group of people who share a common goal: to improve patient care through GI cancer clinical trials.

Upper GI and Lower GI Working Parties

The AGITG’s Upper GI and Lower GI Working Parties represent the disciplines of medical oncology, surgery, radiation oncology, statistics, translational science and study coordination. The Upper GI Working Party focuses on cancers of the oesophagus, gallbladder and pancreas, stomach and liver, while the Lower GI Working Party looks at cancer of the bowel, rectum and anus.

Upper GI Working Party

- Dr Lorraine Chantrill
  Chair
  Medical Oncologist
- Dr Andrew Barbour
  Surgeon
- Dr Alexander Boussioutas
  Gastroenterologist
- Ms Katie Benton
  Dietician
- Dr Yu Jo Chua
  Medical Oncologist
- Professor Jonathan Fawcett
  Surgeon
- Professor Mike Findlay
  Medical Oncologist
- Professor Val Gебски
  Statistician
- Dr Karush Haighighi
  Surgeon
- Professor Trevor Leong
  Radiation Oncologist
- Dr Lara Lipton
  Medical Oncologist
- Mrs Jan Mumford
  Consumer
- Associate Professor Nick Pavlakis
  Medical Oncologist
- Professor Tim Price
  Medical Oncologist
- Dr Amy Shorthouse
  Medical Oncologist
- Professor John Simes
  Medical Oncologist
- Dr Katrin Sjoquist
  Medical Oncologist
- Dr Koroush Haghighi
  Medical Oncologist
- Dr Andrew Barbour
  Surgeon
- Professor John Simes
  Medical Oncologist
- Dr Jennifer Shannon
  Medical Oncologist
- Dr Andrew Stevenson
  Surgeon
- Associate Professor Nick Pavlakis
  Medical Oncologist
- Dr Matt Price
  Medical Oncologist
- Dr Amy Shorthouse
  Radiation Oncologist
- Professor John Simes
  Medical Oncologist
- Dr Katrin Sjoquist
  Medical Oncologist
- Dr Belinda Steer
  Dietician
- Clinical Professor Nigel Spry
  Radiation Oncologist
- Ms Kate Wilson
  Associate Oncology Program Manager
- Dr Sonia Yip
  Oncology Translational Researcher

Lower GI Working Party

- Associate Professor Niall Tebbutt
  Chair
  Medical Oncologist
- Dr Andrew Barbour
  Deputy Chair
  Surgeon
- Dr Matthew Burge
  Medical Oncologist
- Dr Jayesh Desai
  Medical Oncologist
- Professor Michael Findlay
  Medical Oncologist
- Mr Alexander Heriot
  Surgeon
- Mr Peter Hewett
  Surgeon
- Professor David Joseph
  Radiation Oncologist
- Mr Dan Kent
  Consumer
- Dr Lara Lipton
  Medical Oncologist
- Dr Ben Markman
  Medical Oncologist
- Dr Paul McMurrick
  Surgeon
- Dr Sam Ngan
  Radiation Oncologist
- Professor Bridget Robinson
  Medical Oncologist
- Professor Eva Segelov
  Medical Oncologist
- Associate Professor Jeremy Shapiro
  Medical Oncologist
- Professor John Simes
  Medical Oncologist
- Dr Karush Haighighi
  Medical Oncologist
- Dr Andrew Barbour
  Surgeon
- Professor John Simes
  Medical Oncologist
- Dr Andrew Stevenson
  Surgeon
- Ms Kate Wilson
  Associate Oncology Program Manager
- Dr Sonia Yip
  Oncology Translational Researcher
- Dr Nik Zeps
  Biological Scientist
To manage the operations of the AGITG to achieve this purpose, the company must ensure business fundamentals are met and that resources are available and managed.

Despite the ongoing limitation of opportunities for new research, 2016 has seen the structures and processes developed over the past 20 years brought to the fore to achieve a positive result on several fronts.

The ongoing search for new research through the network of the AGITG has seen the opportunity to initiate the INTEGRATE II trial, including international collaboration. This is a significant opportunity for the AGITG and the outcomes from the trial are much anticipated.

The Innovation Fund has provided members with opportunities to initiate research concepts developed from within the AGITG network. Research has commenced on three concepts that we hope will enable further, future development of these and new concepts. This use of the success of the fundraising program provides a positive engagement between our donors and our membership.

The funding from Cancer Australia that supports the infrastructure costs associated with conducting research has been important in providing core funding to the AGITG. The support from Cancer Australia recognises the need for infrastructure as a crucial component in the operation and management of the processes surrounding the conduct of research in addition to funding required for the conduct of the trials and sub-studies themselves.

The fundraising program of the AGITG under the name the GI Cancer Institute continues to develop. From this resource, the Innovation Fund and other support has been provided while the donor reserves and donor engagement has been built further. Other initiatives, including the Annual Scientific Meeting, the Engage Program, the Preceptorship Program and the Pancreatic Cancer Expert Meeting, provide opportunities to support various sectors of the community. These activities enable the work of the AGITG to be promoted, the outcomes from the research to be communicated, and the talent from within the network to be engaged with the scientific and the general communities.

The relationships within the industry sector continue to be a significant component of the AGITG network. Pharmaceutical industry supported research and collaborations with the NHMRC Clinical Trials Centre of the University of NSW remain crucial to the conduct of AGITG research, both locally and internationally.

For the AGITG, the contributions from government, industry, participating institutions, investments, donors and members provides the resource framework and the scope through which the company can pursue its objectives and central purpose. Each of these resources, both individually and collectively, is important to the AGITG, and we appreciate and respect the support to date. In response to that support we will continue to manage those resources to the best of our endeavours, and will maintain our focus on our central purpose, today and into the future.

The result for the 2016 financial year was an increase in the net assets of the AGITG of $793,946. This was achieved through increases in the reserves of $564,085 and a surplus for operations of $206,861.

To continue to achieve such positive results will require the range of contributors to the AGITG to continue and grow their support, and for governance and management of the AGITG to direct those resources to the benefit of the company and its central purpose for the future benefit of the community.

The achievement of the AGITG will continue with ongoing support and the focused management that has been provided to the company since its incorporation. While challenges remain, those challenges also provide opportunities for example the increasing international collaboration on scientific research projects. With the right support, opportunities can lead to greater community support and benefit.

During this, my first year in the role as Treasurer, I am grateful for the support provided to me and the systems and processes developed under those who have previously occupied this role.

In particular, I thank Professor David Goldstein for his guidance and direction in the transition of the role. During the year I have appreciated the dedicated and professional support from the Finance and Risk Management Committee, headed by our Executive Officer, and the support team within the AGITG.

I look forward to leading the financial aspects of the challenges and opportunities for 2017 with the team and structure within the AGITG to support both me and the board.
### Statement of Profit or Loss and Other Comprehensive Income

**For the Year Ended 31 December 2016**

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td>$4,457,817</td>
<td>$3,088,090</td>
</tr>
<tr>
<td><strong>Other income</strong></td>
<td>$1,382,835</td>
<td>$1,387,104</td>
</tr>
<tr>
<td><strong>Administration/Infrastructure expense</strong></td>
<td>$(448,629)</td>
<td>$(469,321)</td>
</tr>
<tr>
<td><strong>Depreciation and amortisation expense</strong></td>
<td>$(9,590)</td>
<td>$(9,960)</td>
</tr>
<tr>
<td><strong>Trial and Site Costs</strong></td>
<td>$(3,691,570)</td>
<td>$(2,870,788)</td>
</tr>
<tr>
<td><strong>Scientific Events</strong></td>
<td>$(790,392)</td>
<td>$(728,713)</td>
</tr>
<tr>
<td><strong>Marketing/Fund Raising costs</strong></td>
<td>$(445,334)</td>
<td>$(502,746)</td>
</tr>
<tr>
<td><strong>(Deficit) / Surplus before income tax</strong></td>
<td>$455,137</td>
<td>$(106,334)</td>
</tr>
<tr>
<td><strong>Income tax expense</strong></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>(Deficit) / Surplus for the year</strong></td>
<td>$455,137</td>
<td>$(106,334)</td>
</tr>
</tbody>
</table>

**Other comprehensive income after income tax**

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Deficit) / Surplus for the year</strong></td>
<td>$455,137</td>
<td>$(106,334)</td>
</tr>
</tbody>
</table>

**Total comprehensive income for the year**

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total comprehensive income attributable to members of the entity</strong></td>
<td>$455,137</td>
<td>$(106,334)</td>
</tr>
</tbody>
</table>

### Statement of Financial Position

**As at 31 December 2016**

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$5,146,370</td>
<td>$2,500,645</td>
</tr>
<tr>
<td>Financial Assets</td>
<td>$7,785,863</td>
<td>$6,432,727</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>$678,404</td>
<td>$280,413</td>
</tr>
<tr>
<td>Other assets</td>
<td>$74,379</td>
<td>$93,649</td>
</tr>
<tr>
<td><strong>Total Current Assets</strong></td>
<td>$13,685,016</td>
<td>$9,307,444</td>
</tr>
<tr>
<td><strong>Non-Current Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>$64,521</td>
<td>$60,911</td>
</tr>
<tr>
<td><strong>Total Non-Current Assets</strong></td>
<td>$64,521</td>
<td>$60,911</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td>$13,749,537</td>
<td>$9,368,355</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current Liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>$404,712</td>
<td>$195,970</td>
</tr>
<tr>
<td>Other short term liabilities</td>
<td>$5,383,671</td>
<td>$1,886,456</td>
</tr>
<tr>
<td><strong>Total Current Liabilities</strong></td>
<td>$5,788,383</td>
<td>$2,082,426</td>
</tr>
<tr>
<td><strong>Non-Current Liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term provisions</td>
<td>$56,812</td>
<td>$51,990</td>
</tr>
<tr>
<td>Other long term liabilities</td>
<td>$1,969,258</td>
<td>$2,305,178</td>
</tr>
<tr>
<td><strong>Total Non-Current Liabilities</strong></td>
<td>$2,026,070</td>
<td>$2,357,168</td>
</tr>
<tr>
<td><strong>Total Liabilities</strong></td>
<td>$5,844,453</td>
<td>$4,439,594</td>
</tr>
<tr>
<td><strong>Net Assets</strong></td>
<td>$5,935,084</td>
<td>$4,928,761</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reserves</td>
<td>$2,557,154</td>
<td>$1,886,182</td>
</tr>
<tr>
<td>Retained Earnings</td>
<td>$3,377,930</td>
<td>$2,042,579</td>
</tr>
<tr>
<td><strong>Total Equity</strong></td>
<td>$5,935,084</td>
<td>$4,928,761</td>
</tr>
</tbody>
</table>

|                              |            |            |
| **Contingent Liability**     | -          | -          |
YOUR SUPPORT MAKES THE DIFFERENCE

With thanks to you, breakthroughs and improvements in medical practice for people with GI cancer are possible. Your support provides the answers to the many unanswered questions and together, one day, we can make GI cancer a disease of the past. There are many ways you can make a difference to the lives of people who have been diagnosed with GI cancer.

Make a donation
Any donation, no matter what size, will help us conduct our clinical trials and lead to better health outcomes for patients. Or you can pledge your support as a regular giving partner, providing the financial stability that allows us to plan for the future. Donate online at gican.org.au or post a cheque to the GI Cancer Institute, Locked Bag M250, Camperdown, NSW 2050.

Take a Gutsy Challenge
Get gutsy for GI cancer and take a Gutsy Challenge. Have some fun and raise much-needed funds for vital research to find a cure for GI cancer. Participate in a fun run, a cycle challenge or other sporting event, host a healthy lunch or morning tea, hold an auction or give up a vice for a week: whatever is gutsy and suits you. You can take the Gutsy Challenge by yourself or, better still, engage with your friends, family, or work colleagues to help the GI Cancer Institute raise funds. Find out more about the Gutsy Challenge by calling 1300 666 769, or visit gican.org.au

Leave a Gift in your Will
Leaving a gift to the GI Cancer Institute in your Will, whether large or small, makes a difference and enables cutting edge research into new treatments for patients beyond your lifetime. For a confidential conversation, please contact Russell Conley, Executive Officer, on 1300 666 769.

Honour a loved one
Losing a loved one to GI cancer is very difficult but sometimes our last moments can make an enduring difference to others. In lieu of flowers, please consider in Memory donations to support innovative research for improved outcomes for future generations. For more information, please contact Angie Fox, Donor Relations Coordinator on 1300 666 769.

Volunteer
Our volunteers are highly valued and make a real difference to our ability to fund our clinical trials. If you have expertise, a business skill, a survivorship story to share, or even some time to spare, we are always looking for volunteers to help us promote our initiatives at the GI Cancer Institute.

Community support is vital in funding AGITG research now and into the future. For more information on how to get involved, please contact us on 1300 666 769 or visit gican.org.au

Tiffany’s Story
Olympic host and sports broadcaster Tiffany Cherry took on a new sporting challenge and it was a long way from Rio. The keen cyclist, who recently hosted Channel 10’s health and fitness show, Everyday Health, was back on her bike after two years off following the birth of her daughter, Vivienne.

In October 2016, Tiffany and a group of other gutsy cyclists undertook the GI Cancer Institute’s Cambodia Gutsy Challenge to raise money for the GI Cancer Institute’s research into gastrointestinal cancer, particularly pancreatic cancer.

Tiffany joined the team, which included leading oncologist Associate Professor Chris Karapetis, and rode across Cambodia for a cause which is close to her heart.

“One of my dearest friends lost her brother recently to this awful disease. While thousands of Australians are diagnosed every year, the five-year survival rate is still only 7%. There is a desperate need for more research and I was thrilled to be doing my bit to find a cure.”

While the seven-day, 360 km event was demanding, Tiffany is the first to admit she relishes a challenge – and nothing like what so many cancer patients have to endure. Health and fitness are so important and I was thrilled to be involved and help raise funds for GI cancer research.”

Tiffany participated in the Cambodia Gutsy Challenge thanks to the generous sponsorship of Specialised Therapeutics Australia.
Thank you to our members who give their time, expertise and commitment freely, to our sponsors who support our activities financially, and to our donors who give generously to continue to change medical practice in Australasia and throughout the world. We could not continue our important work without your support.

GI Cancer Institute Sponsors

Platinum Sponsors

Gold Sponsor

Silver Sponsor

Silver Sponsor