Inaugural Australian

Cholangio*carcinoma* Stakeholder Meeting

Opening dialogue between dedicated individuals and organisations

Executive Summary

15 DECEMBER 2021
6pm-8pm

ORGANISED BY:

SERVIER

IN COLLABORATION WITH:

AGITG
AUSTRALASIAN GASTRO-INTESTINAL TRIALS GROUP

GI CANCER INSTITUTE
GASTRO-INTESTINAL CANCER RESEARCH

pancare FOUNDATION

CCA

Omico.
Australian Genomic Cancer Medicine

rare cancers AUSTRALIA

Specialised Therapeutics

AstraZeneca

Meeting participants

Russell Conley	CEO - GI Cancer Institute & AGITG
Jan Mumford	Chair - AGITG Consumer Advisor Panel Chair and Executive Director - Genetic Alliance Australia
Heather Leroy	Industry partnerships specialist - Pancare
Katrina Walsh	Research Manager - Pancare
Steve Holmes	CCA survivor, patient mentor, founder of Cholangiocarcinoma Australia
Guy Tancock	Medical Lead, Oncology - Servier ANZ
Dr Maung Maung Oo	Director, Medical and Patient Affairs - Servier ANZ
Dr Cécile Lou	Asia Pacific Sector Medical Director - Servier Laboratories
Fardaad Choksey	Associate Medical Director, Oncology - AstraZeneca
David Brown	Senior Medical Manager, Oncology - AstraZeneca
Dr Lakmali Atapattu	Medical Manager, Immun-oncology - AstraZeneca
Paula Fenwick	Medical Director - Specialised Therapeutics Australia
Prof Desmond Yip	Medical Oncologist - Canberra, ACT
Dr Subo Thavaneswaran	Medical Oncologist - Darlinghurst, NSW
A/Prof Sue-Anne McLachlan	Medical Oncologist - Fitzroy, VIC
A/Prof Zee Wan Wong	Medical Oncologist - Frankston, VIC
A/Prof Niall Tebbutt	Medical Oncologist - Heidelberg, VIC
Dr Katrin Sjoquist	Medical Oncologist - Kogarah, NSW
Dr Shehara Mendis	Medical Oncologist - Melbourne, VIC
A/Prof Lara Lipton	Medical Oncologist - Melbourne, VIC
Dr Jenny Shannon	Medical Oncologist - Nepean, NSW
Dr David Ransom	Medical Oncologist - Perth, WA
Prof David Goldstein	Medical Oncologist - Randwick, NSW
Prof Nick Pavlakis	Medical Oncologist - St Leonards, NSW
Dr Connie Diakos	Medical Oncologist - St Leonards, NSW
A/Prof Adnan Nagrial	Medical Oncologist - Westmead NSW
Prof Timothy Price	Medical Oncologist - Woodville, SA
Dr Lorraine Chantrill	Medical Oncologist - Woolongong, NSW
Prof David Thomas	Medical Oncologist, CEO Omico; PI MoST- Darlinghurst, NSW
Samantha McFedries	Research Development Lead - Sydney, NSW
Dr Ben Dwyer	Senior Research Fellow - Perth, WA
Prof John Olynyk	Gastroenterologist and Hepatologist - Perth, WA
A/Prof Charles Pilgrim	Upper Gastrointestinal Surgeon - Melbourne, VIC
Dr Jessica Roydhouse	Senior Research Fellow - Hobart, TAS
Prof John Mariadason	Head Gastrointestinal Cancers Program; Oncogenic Transcription Laboratory, Heidelberg, VIC

Contributors not in attendance

Beth Abbey	Specialist cancer navigator - Rare Cancers Australia
Prof Desmond Yip	Medical Oncologist - Canberra, ACT
Dr Subo Thavaneswaran	Medical Oncologist - Darlinghurst, NSW
Dr Jenny Shannon	Medical Oncologist - Nepean, NSW
Dr David Ransom	Medical Oncologist - Perth, WA
Prof Nick Pavlakis	Medical Oncologist - St Leonards, NSW
A/Prof Adnan Nagrial	Medical Oncologist - Westmead NSW
Dr Lorraine Chantrill	Medical Oncologist - Woolongong, NSW
Samantha McFedries	Research Development Lead - Sydney, NSW
A/Prof Charles Pilgrim	Upper Gastrointestinal Surgeon - Melbourne, VIC

AGITG: Australasian Gastrointestinal Trials Group.

Servier Australia facilitated an inaugural Cholangiocarcinoma Stakeholders Meeting in December 2021 to open dialogue and gather expert opinion on the condition and its management in Australia. The meeting involved 45 key stakeholders: clinicians, researchers, patients and patient advocacy groups, as well as representatives from the pharmaceutical industry. The aim of the meeting was to gather insights and identify priorities to help inform meaningful change for cholangiocarcinoma patients.

Cholangiocarcinoma: rare and difficult to treat

Cholangiocarcinoma is cancer of the gallbladder or bile ducts. It is a rare form of cancer that affects approximately 1300 Australians each year. Like many gastrointestinal cancers, cholangiocarcinoma is most effectively treated when found early, but this can be difficult as it often does not have symptoms in its early stages. The median survival among patients with advanced disease is approximately less than 12 months, with 5-year survival rates of 10% or less. Most patients with unresectable or metastatic disease undergo palliative systemic therapy. However, survival outcomes with first- and second-line chemotherapy are modest. These factors highlight the need for new treatment paradigms in this disease.

The evolving cholangiocarcinoma treatment landscape

Due to the poor understanding of advanced cholangiocarcinoma, treatment options have so far been limited to chemotherapy. The genomic characterisation of biliary tract cancers has paved the way for developing targeted therapies and opened the door to applying personalised treatment strategies to treat cholangiocarcinoma patients. Representatives from Servier Australia, Specialised Therapeutics and AstraZeneca presented a brief overview of emerging therapies and key studies underway in cholangiocarcinoma.

David Thomas (medical oncologist): *"… it seems across the three companies you have a rich range of options for our patients and I think that's very exciting for those of us who are managing these conditions."*

References: 1. AGITG. https://gicancer.org.au/news/what-is-cholangiocarcinoma/ **2.** Zhu AX et al. JAMA Oncology 2021;7:1669-1677.

Servier Australia

GUY TANCOCK from Servier Australia presented the results of 3 key studies of emerging cancer therapies for cholangiocarcinoma: trifluridine/tipiracil, liposomal irinotecan and ivosidenib

Phase II trial of trifluridine/tipiracil* in patients with advanced, refractory biliary tract carcinoma

Trifluridine/tipiracil (FTD/TPI) has activity in both fluoropyrimidine-sensitive and -resistant tumours, which led investigators to conduct a single arm phase II trial to evaluate the safety and efficacy of FTD/TPI for patients previously treated for advanced biliary tract carcinoma. Results showed 8 (32%, 95% CI 14.9-53.5%) patients were progression free at 16 weeks in the primary analysis population (n=25), which met the pre-defined efficacy criteria. Median progression-free survival and overall survival was 3.8 months (95% CI 2-5.8) and 6.1 months (95% CI 4.4-11.4), respectively. No objective responses were seen. There were no unexpected safety signals noted.

Liposomal irinotecan plus fluorouracil and leucovorin versus fluorouracil and leucovorin for metastatic biliary tract cancer after progression on gemcitabine plus cisplatin (NIFTY): a multicentre, open-label, randomised, phase 2b study

The aim of this study was to investigate the efficacy and safety of second-line liposomal irinotecan (Nal-IRI) plus fluorouracil and leucovorin (5-FU/LV) in patients with metastatic biliary tract cancer that has progressed on gemcitabine plus cisplatin. The primary endpoint was progression-free survival. A total of 193 patients were screened for eligibility, of whom 174 (88 in the Nal-IRI + 5-FU/LV group and 86 in the 5-FU/LV group) were enrolled and included in the full analysis and safety analysis sets. At a median follow-up of 11.8 months, the median BICR-assessed progression-free survival was significantly longer in the Nal-IRI + 5-FU/LV group (7.1 months) than in the 5-FU/LV group (1.4 months) (HR 0.56, 95% CI 0.39-0.81; p=0.0019). The most common grade 3-4 adverse events were neutropenia (21 [24%] of 88 in the Nal-IRI + 5-FU/LV group vs one [1%] of 86 in the 5-FU/LV group) and fatigue or asthenia (11 [13%] vs 3 [3%]). Serious adverse events occurred in 37 (42%) patients receiving Nal-IRI + 5-FU/LV and 21 (24%) patients receiving 5-FU/LV. There were no treatment-related deaths.

Guy Tancock said there were two active studies underway overseas with Nal-IRI in cholangiocarcinoma: (i) Nal-IRI with 5-FU and leucovorin or gemcitabine plus cisplatin in advanced biliary tract cancer (NIFE) [ClinicalTrials.gov Identifier: NCT03044587] [active, not recruiting]; and (ii) Nal-IRI and 5-FU compared to 5-FU in patients with cholangio- and gallbladder carcinoma previously treated with gemcitabine-based therapies (NALIRICC) [ClinicalTrials.gov Identifier: NCT03043547] [currently recruiting].

Final overall survival efficacy results of ivosidenib for patients with advanced cholangiocarcinoma with IDH1 mutation – The Phase 3 randomised clinical ClarIDHy trial

The ClarIDHy trial aimed to demonstrate the efficacy of ivosidenib (a first-in-class, oral, small-molecule inhibitor of mutant IDH1) versus placebo for patients with unresectable or metastatic cholangiocarcinoma with IDH1 mutation. The primary endpoint was progression-free survival; overall survival was a key secondary endpoint. The primary analysis of overall survival followed the intent-to-treat principle. Other secondary endpoints included objective response rate, safety and tolerability, and quality of life. Overall, 187 patients were randomly assigned to receive ivosidenib (n=126) or placebo (n=61); 43 patients crossed over from placebo to ivosidenib.

BICR: Blinded Independent Central Review; **CI:** confidence interval; **HR:** hazard ratio; **LV:** leucovorin; **Nal-IRI:** liposomal irinotecan; **PFS:** progression-free survival; **5-FU:** 5-fluorouracil.

References: 1. Chakrabarti S et al. Oncologist 2020;25:380-e763. **2.** LONSURF Approved Product Information. **3.** Yoo C et al. Lancet Oncol 2021;22:1560-1572. **4.** ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT03044587. **5.** ClinicalTrails.gov https://clinicaltrials.gov/ct2/show/NCT03043547.

Servier Australia (CONT.)

Results showed median progression-free survival was 2.7 months (95% CI 1.6-4.2 months) with ivosidenib vs 1.4 months (95% CI 1.4-1.6 months) with placebo (HR 0.37; 95% CI 0.25-0.54; 1-sided p<0.0001). Median overall survival was 10.3 months (95% CI 7.8-12.4 months) with ivosidenib versus 7.5 months (95% CI 4.8-11.1 months) with placebo (HR 0.79; 95% CI 0.56-1.12; 1-sided p=0.09). When adjusted for crossover, median overall survival with placebo was 5.1 months (95% CI 3.8-7.6) (HR 0.49; 95% CI 0.34-0.70; 1-sided p<0.001). The most common grade 3 or higher treatment-emergent adverse event (≥5%) reported in both groups was ascites (11 patients [9%] receiving ivosidenib and 4 patients [7%] receiving placebo). Serious treatment-emergent adverse events considered ivosidenib-related were reported in 3 patients (2%). There were no treatment-related deaths. Patients receiving ivosidenib reported no apparent decline in quality of life compared to placebo.

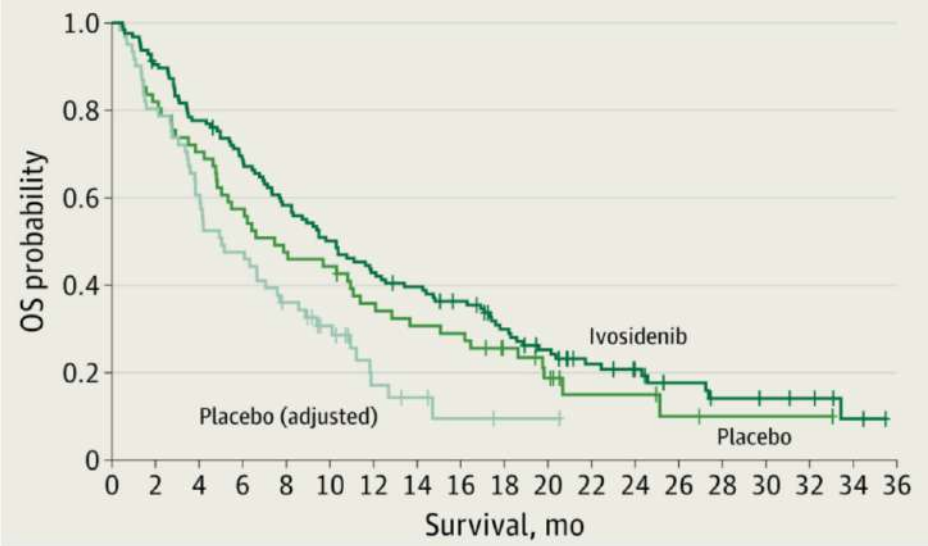


Fig 1. Kaplan meier graph of final overall survival in the Intent-to-Treat Population of the Phase III Claridhy study.

A Global Phase 3B study of ivosidenib for the treatment of cholangiocarcinoma is planned, with potential sites in Australia. The company is also preparing for TGA registration of ivosidenib in 2022.

BCI: confidence interval; HR: hazard ratio; **PBS:** Pharmaceutical Benefits Scheme; **TGA:** Therapeutic Goods Administration.
Reference: 1. Zhu AX, et al. JAMA Oncology 2021;7:1669-1677.

Specialised Therapeutics

PAULA FENWICK introduced Specialised Therapeutics, a company which collaborates with global partners to bring new specialist medicines, including pemigatinib*, to patients in Australia, New Zealand and South-East Asia. Pemigatinib is a selective, potent, oral inhibitor of fibroblast growth factor receptor (FGFR) 1, 2, and 3. FGFR2 gene alterations are involved in the pathogenesis of cholangiocarcinoma. Pemigatinib has received provisional approval from the TGA for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement.

Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study (FIGHT-202)

The FIGHT-2020 study evaluated the safety and antitumour activity of pemigatinib in patients with previously treated, locally advanced or metastatic cholangiocarcinoma with and without FGFR2 fusions or rearrangements. The primary endpoint was the proportion of patients who achieved an objective response among those with FGFR2 fusions or rearrangements. A total of 146 patients were enrolled: 107 with FGFR2 fusions or rearrangements, 20 with other FGF/FGFR alterations, and 18 with no FGF/FGFR alterations. The median follow-up was 17.8 months.

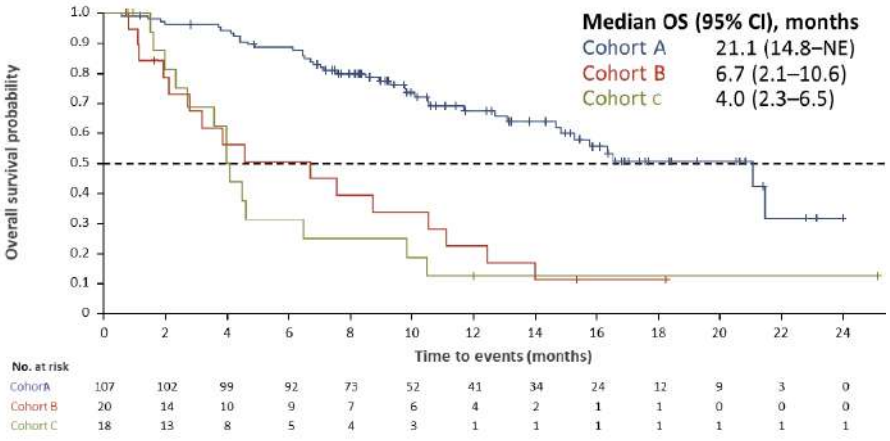


Fig 2. Kaplan Meier graph of overall survival in Cohort A (FGFR2 fusions/rearrangements), Cohort B (Other FGF/FGFR genetic alterations) and Cohort C (No FGF/FGFR genetic alterations) from the FIGHT-202 trial.

A total of 38 patients (35.5% [95% CI 26.5-45.4]) patients with FGFR2 fusions or rearrangements achieved an objective response (3 complete responses; 35 partial responses). Median time to response was 2.7 months (range 0.7-6.9 months). Median progression-free survival was 6.9 months (95% CI 6.2-9.6); the overall survival data were not mature at the data cut-off (40 [37%] of 107 patients had died; median overall survival was 21.1 months [95% CI 14.8 to not estimable]. Hyperphosphataemia was the most common all-grade adverse event irrespective of cause (88 [60%] of 146 patients); all cases were of grade 1 or 2; 3 patients required dose reduction or treatment interruption; 93 (64%) patients had a grade 3 or worse adverse event (irrespective of cause); the most frequent were hypophosphataemia (18 [12%]); none of these cases were clinically significant or serious; none led to discontinuation or dose reduction. Serous retinal detachment occurred in 4% of patients; mostly grade 1/2 (grade ≥3, 1%); and none resulted in clinical sequelae.

Paula Fenwick said continued approval of pemigatinib may be contingent upon verification and description of clinical benefit in the ongoing FIGHT-302 confirmatory study.

Specialised Therapeutics is working to establish a Special Access Scheme for patients with cholangiocarcinoma to access treatment with pemigatinib in 2022. This is dependent on supply availability.

*Pemigatinib has received provisional approval in Australia. For further details: https://www.tga.gov.au/ws-designation-notices-index?search_api_views_fulltext=pemigatinib&field_designation=All&sort_by=title&sort_order=DESC&items_per_page=10
CI: confidence interval; **FDA:** Food and Drug Administration; **FGFR:** fibroblast growth factor receptor; **TGA:** Therapeutic Goods Administration.
References: 1. Abou-Alfa GK, et al. Lancet Oncol 2020;21:671-684. **2.** Bekaii-Saab TS et al. Future Oncology 2020;16: https://doi.org/10.2217/fon-2020-0429. **3.** ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03656536.

AstraZeneca

DAVID BROWN provided an overview of the AstraZeneca pipeline in biliary tract cancer, including the TOPAZ-1 study in patients with advanced biliary tract cancer.

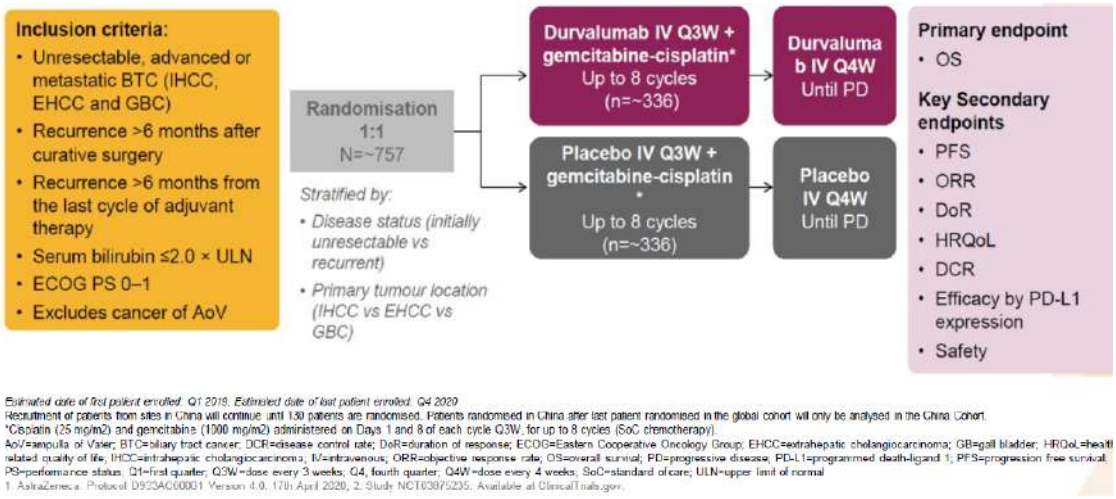


Fig 3. Study design of the TOPAZ-1 trial

TOPAZ-1 is a randomised, double-blind, placebo controlled, multicentre, global Phase III trial of durvalumab* in combination with chemotherapy (gemcitabine plus cisplatin) versus placebo in combination with chemotherapy as a first-line treatment in 685 patients with unresectable advanced or metastatic biliary tract cancer including intrahepatic and extrahepatic cholangiocarcinoma, and gallbladder cancer (ampullary carcinoma was excluded). The trial is being conducted in more than 145 centres across 17 countries including the US, Europe, South America and several countries in Asia including South Korea, Thailand, Japan and China. The primary endpoint is overall survival and key secondary endpoints include progression-free survival, objective response rate, duration of response, health-related quality of life and safety. Results of a pre-defined interim analysis have subsequently been presented at the 2022 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium set for January 20-22 in California, USA.

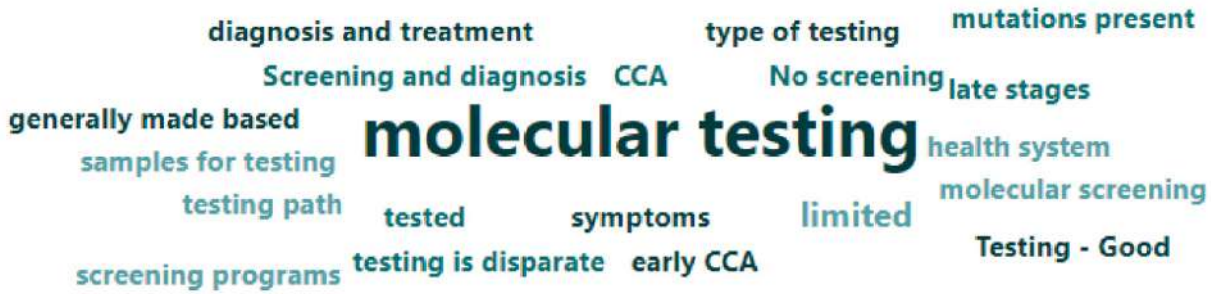
David Brown said AstraZeneca's focus on biliary tract cancer is targeting a combination approach with standard of care across different stages of disease. This includes combining a CTLA-4 inhibitor with a PD-L1 inhibitor. Our broader strategy to target solid tumours in signal finding studies, is to combine our pipeline of medicines that modulate cell cycle/DNA damage repair such as PARP inhibitors and ATR inhibitors; as well as combining with tumour drivers-signal transduction pathways that are involved driving tumour pathogenesis (MEK inhibitors).

*Durvalumab is indicated for non-small cell lung cancer and small cell lung cancer in Australia. For further details: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-PI-02382-1

References: 1. Oh DY et al. A phase 3 randomized, double-blind, placebo-controlled study of durvalumab in combination with gemcitabine plus cisplatin (GemCis) in patients (pts) with advanced biliary tract cancer (BTC): TOPAZ-1. Presented at: American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI), January 20-22, 2022; San Francisco, CA; Abstract 378. 2. AstraZeneca. https://www.astrazeneca.com/media-centre/press-releases/2022/imfinzi-plus-chemotherapy-reduced-risk-of-death-by-20-in-1st-line-advanced-biliary-tract-cancer.html. 3. ClinicalTrials.gov https://clinicaltrials. gov/ct2/show/NCT03875235. 4. IMFINZI Approved Product Information.

Screening/diagnosis and the need to do more

Participants were given the opportunity to complete a pre-meeting survey. Responses and comments are summarised below.



Current situation in regard to screening/diagnosis and molecular testing in Australia

General opinion was that there were no methods that could reliably detect bile duct cancers early enough to be useful as screening tests. Patients were often diagnosed with late-stage disease as early stages are asymptomatic. PET scans were not reimbursed for patients, and participants noted that the availability of and funding for molecular testing varied. Testing was either institution- or patient-funded, with some patients receiving referrals for testing via the MoST program (Molecular Screening and Therapeutics). It was agreed that mismatch repair testing was widely available to patients.

> **David Thomas** (medical oncologist) said: *"… the MoST program has 90 patients with cholangiocarcinoma … most frequent mutations are FGFR2 fusions and other fusions in that pathway, IDH1, sometimes IDH2 mutations, and TNB … but we have also seen a scattering of low-frequency events, including the odd NTRK and other oncogene fusions … I think with the number of drugs and the efficacy of immunotherapy in this area … a coordinated strategy that maximises how much we can learn from every patient and that brings as many opportunities as possible to those patients would be the most productive outcome …"*

Improvements needed for screening/diagnosis and molecular testing over the next 5 years

It was agreed that early molecular testing was key to improving outcomes for patients. There is a need to increase awareness of symptoms and risk factors, especially in high-risk populations. There is also a need to develop predictive testing or technologies that can be used to help identify at-risk patients. Participants agreed the additional need for discussion around funding of molecular testing, as well as standardised pathways and guidelines for molecular testing. Other improvements for patients included PET scan reimbursement and endoscopic ultrasound biopsy availability.

> **Guy Tancock** (Servier) said: *"… certainly for ivosidenib there will be the requirement for identification of IDH1 … next-generation sequencing (NGS) and molecular testing is the main mechanism by which to do that … there are a few other technologies that we can utilise, but I'd understand for the FGFR inhibitors NGS will be vital.. it's going to be really important to identify these mutations really early in the patient's journey, from initial diagnosis, rather than waiting until they're through their first-line therapies."*

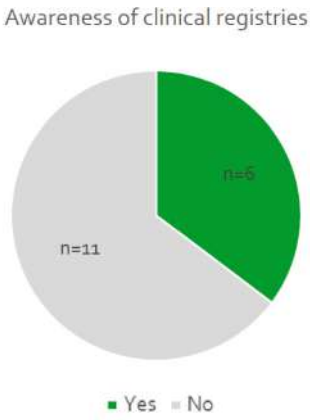
> **Lara Lipton** (medical oncologist) said: *"… in the AGITG Upper GI Working Party … we've recently given funding to Daniel Croagh for a project on Endoscopic ultrasound guided biopsy and quite comprehensive molecular profiling on cholangiocarcinoma, including hilar cholangiocarcinoma which is difficult to biopsy … and within the Upper GI Working Party we've been thinking about opportunities for a 'basket' study similar to what David Goldstein and David Thomas have done with pancreatic cancer based around the MoST study …"*

MoST is a 2-part research program with the aim of treating as many patients as possible with personalised therapies. These personalised therapies also link with clinical trials which are conducted in a series of steps which investigate the safety and efficacy of new cancer treatments and new drug combinations. The aim is to discover what the best standard treatment is, and whether a new treatment is better than existing ones. For more information, www.rarecancers.org.au
AGITG: Australasian Gastro-Intestinal Cancer Trials Group; **EUS:** endoscopic ultrasound; **FGFR:** fibroblast growth factor receptor; **IDH:** isocitrate dehydrogenase; **NTRK:** neurotrophic tyrosine receptor kinase; MoST: Molecular Screening and Therapeutics; **PET:** positron emission tomography.

Clinical registry: is it feasible?

Participants were given the opportunity to complete a pre-meeting survey. Responses and comments are summarised below.

Knowledge of clinical registries collecting information about CCA in Australia



Most participants were not aware of any clinical registries in Australia. There were some registries covering slightly different areas and a few registries noted as proposed or in planning stages including the Upper GI Cancer Registry, WEHI CCA Registry, Australian Comprehensive Molecular Evaluation of Advance Biliary Cancer, and the MoST program.

Need to capture data; potential role of the MoST program

The Upper GI Cancer Registry is soon to open. This is a quality registry rather than a treatment data registry. It is funded by the Victorian state government. The WEHI CCA Registry is a proposed registry which is currently seeking funding. It was suggested that the MoST program represents the largest cohort of cholangiocarcinoma patients within Australia.

> **David Thomas** (medical oncologist) said the MoST program had capacity and funding to screen patients for the next 3 years (until the end of 2024). He said cholangiocarcinoma screening was something he would strongly support. Over the next 3 years: *"… we would be expecting to double the number of patients screened to date … we have 90 intra- and extra-hepatic cholangiocarcinoma and 32 gall bladder cancer patients out of the first 4000 … we would be expecting to get another 120 patients making a total pool of around 240-250 patients and with affirmative action maybe a few more than that …"*

Participants agreed it was not a small undertaking to establish a robust clinical registry. Niall Tebbutt (medical oncologist) said registries were labour- and cost-intensive and would eventually be made redundant with the availability of more comprehensive medical records and the ability to link data. David Goldstein (medical oncologist) agreed but said in the short-term (in the next 5 years) registries were still needed to answer the more 'granular' questions on patient outcomes.

CCA: cholangiocarcinoma; **MoST:** Molecular Screening and Therapeutics; **WEHI:** Walter and Eliza Hall Institute of Medical Research.

Addressing patient needs with cca-specific resources

Participants were given the opportunity to complete a pre-meeting survey. Responses and comments are summarised below

Recommended patient resources

- Cancer Council (national/state)
- Pancare
- Rare Cancers Australia
- GI Cancer Institute
- CCA Intro Pack and CCA Patient Toolkit
- Healthcare navigation service
- Nurse care coordinator
- Clinical trial registry
- Clarity on treatment options
- Referral to specialist tertiary centre
- Multidisciplinary team workup
- Peer support groups (online)
- Dietary/exercise advice
- EviQ
- Australian Rare Cancers Portal (ARC)
- Stafford Fox Rare Cancer Program

Gaps in current resource availability

- CCA specific information
- Australian specific information
- Access to novel therapies
- Access to clinical trials
- Dedicated nurse consultants
- Standardised clinical pathway (+ awareness)

CCA: cholangiocarcinoma; **MoST:** Molecular Screening and Therapeutics; **WEHI:** Walter and Eliza Hall Institute of Medical Research.

Addressing patient needs with cca-specific resources (CONT.)

Cholangiocarcinoma-specific patient tool kit

Participants agreed support that is specific for cholangiocarcinoma and the Australian context was needed.

> **Steve Holmes** (Cholangiocarcinoma Australasia) said a registry of specialists in the public and private setting in each state was an immediate and necessary need. *"… the tool kit is what I use with all patients to quickly lay down the foundations to move forward and to give them the best opportunity in outcomes … I don't use any of those recommended resources … and that's probably because they're not specific to cholangiocarcinoma … so the toolkit we've developed pulls together what is internationally [recommended] and it makes it easier for me to communicate to patients who must quickly re-orientate themselves into this new challenge."*

Need for registry of surgeons and medical oncologists specialised in CCA

> **Steve Holmes** (Cholangiocarcinoma Australasia) discussed the need for and development of a patient tool kit: *"It's the most common issue I have … lining people up with the various specialties that are required ... it is the most difficult and stressful task to go through with newly-diagnosed patients."*

Need for nurse care coordinators / navigators

There is a need for dedicated nurses and coordinators and potentially a telehealth option if there are not enough patients to justify a cholangiocarcinoma-specific coordinator at an institution. Shehara Mendis (medical oncologist) said her centre's liver unit did not have an upper GI cancer coordinator despite the size of the patient catchment and unit.

> **David Goldstein** (medical oncologist) said he did have access to an upper GI coordinator: *"… I think a specific biliary coordinator is going to be challenging …" He suggested referring to the model used by Neuroendocrine Australia. "They have a limited number, maybe even just one or two, specialised resource people with a nursing background, and they then secondarily provide appropriate support for the wider group … this may be a very cost-effective model."*

Katrina Walsh said Pancare had an upper GI cancer specialist nurse available for telehealth, but they were not specific to cholangiocarcinoma. Heather Le Roy said Pancare was supporting a growing number of biliary cancer patients and carers. The charity also funds research into upper GI cancers. New resources for cholangiocarcinoma patients are in development and will be available in April 2022.

Need for standardised clinical pathway for cholangiocarcinoma in Australia

An Australian optimal clinical pathway has not been established. Implementing a pathway would be appropriate with the availability of new treatment options.

> **David Goldstein** (medical oncologist) suggested the AGITG could assist. The AGITG convened a meeting in 2015 to develop a clinical pathway for pancreatic cancer. It was subsequently published in *The Medical Journal of Australia "… the process worked very well … the model is there, and there is a way to get it circulated widely …"*

AGITG: Australasian Gastro-Intestinal Cancer Trials Group; **CCA:** cholangiocarcinoma; GI: gastrointestinal; **MoST:** Molecular Screening and Therapeutics.

NEXT STEPS

Participants agreed the group should continue discussions on identifying and prioritising projects. Participants identified three key priorities for cholangiocarcinoma in Australia:

(i) **Optimising access to molecular testing;**

(ii) **Establishing a clinical pathway for treatment; and**

(iii) **Developing cholangiocarcinoma-specific patient resources. It was agreed there was no need for a formalised group, but further meetings every 6 months would be useful to identify and provide updates on specific projects.**

Individuals or organisations who are interested in being involved in future Cholangiocarcinoma Stakeholder meetings are invited to contact guy.tancock@servier.com

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