NCRI
National
Cancer
Research
Institute

NCRI Upper Gastro-intestinal Cancer Clinical Studies Group

Annual Report 2016-17

Partners in cancer research

NCRI Upper Gastro-intestinal Cancer CSG Annual Report 2016-17

1. Executive Summary (including top 3 achievements in the year)

The Upper GI CSG is highly successful and to date retains a large portfolio of ongoing trials with a track record in delivering successfully completed studies. It has continued to produce high impact, practice changing research including ESPAC 4, PET-PANC and TACE-2 during this reporting year. The main challenge is to retain a suitable portfolio in a different funding environment. Although there have been some successes, most notably the £33m Precision Panc and ORANGE 2 Segments, most applications to CRUK have not been successful. Although the direction of travel appears to be to fund only biomarker driven studies (e.g. PRECISION-Panc), upper GI cancer does not at present lend itself to such studies as suitable biomarkers are not mature. Strategically, therefore, the Group will focus on other funding sources such as NIHR and Industry. The utility of the GeL Upper GI CIP is yet to be determined and the contribution of cancer in GeL has so far been less than satisfactory. However, the oesophagogastric Stratified Medicine bid to CRUK has some promise.

The CSG continues to enjoy high quality applications from senior clinicians for membership, plus the quality of the applications for the two trainee positions on the Group have been quite exceptional. In September 2016, we held a successful Annual Trials meeting in a less expensive conference venue and a small registration charge which may be a model for the future.

2. Structure of the Group

The Group has wide representation from surgery, medical and clinical oncology, statisticians, consumer members and pathology. The membership has almost completely changed in the last five years but the balance between the specialties has been maintained. Attendance at CSG meetings is extremely good.

Whilst the range of expertise on the Group is satisfactory, we note it is difficult to recruit imaging specialists and although there is a pathologist on the CSG, very few apply. Members also vary in respect of their contribution but at present most function well and contribute to the CSG.

It is variable how consumer members contribute. In the past, the Group has had excellent PPI representation but recently this has worked less well and attendance has often been poor. At present, due to the resignation of Yvonne Carse who was on the Group for three years, there is

only one consumer member on the Group. Our newest member, Dr Philip Bell, has only been to two meetings but so far has participated well and the NCRI are advertising for Yvonne's replacement in the summer.

Since 2015, the Group has had two trainee representatives complete a full 18 month term and recruited two new trainees at the end of 2016. The competition for the two trainee positions was extremely high. On both rounds, the highest scoring surgeon and oncologist were appointed and to date, all have contributed to the working of the CSG and been active in all four Subgroups.

3. CSG & Subgroup strategies

Main CSG

The CSG has a history of undertaking practice changing research. By contrast, many big, high cost, long duration trials have been negative. There is good engagement in the research community which involves a large number of clinically able clinical scientists and there is a good pipeline of new investigators. However, in recent years, there has been a relatively poor recent grant funding record from CTAAC (now CRC), including trials that are high priority and potentially practice changing. This applies to studies in CRLMs which have high priority for both the Upper GI and Colorectal CSGs.

There has also been mixed success with other funding bodies. HTA funded LAVA and ROMIO but generally is unreceptive to upper GI cancer trials. Strategically, it is appropriate to devise biomarker driven trials to fit with the CRC objectives, e.g. PRECISION-Panc. However, biomarkers are less will developed in, for example, oesophagogastric cancer, although PLATFORM is one attempt but has had modest recruitment to date. A major initiative is a Stratified Medicine bid in OG cancer facilitated by CRUK. In biliary tract cancer, one of the Group's particular strengths, biomarkers do not currently exist and only discovery is feasible. Increased use of non-CRUK funding sources (e.g. EME) seems appropriate as commercial opportunities outside neuroendocrine remain limited.

Neuroendocrine Subgroup (Chair, Professor Tim Meyer)

The Subgroup has had a successful year ending with Professor Tim Meyer taking over as Chair of the Subgroup from Professor Juan Valle in March 2017.

The studies are principally commercial, the investigator-led studies having been declined for funding by CTAAC/CRC. Despite this, the UK is increasingly seen as an important contributor to national and international NET studies, including an enhanced profile with Industry. This is not least in part due to the accreditation by the European Neuroendocrine Tumour Society (ENETS) of 10 UK centres as Centres of Excellence (the single most number of centres per country across Europe). The establishment of the Centres of Excellence (Birmingham, Coventry, Liverpool, Southampton, Sheffield, Royal Free/UCL, Imperial, Kings, The Christie and Oxford) has galvanised both clinical and translational research. In addition, translational research in NETs is being developed alongside the clinical portfolio with the UKINETS Research Committee (previously TransNET) chaired by Dr Chrissie Thirlwell.

Oesophagogastric Subgroup (Chair, Dr Tom Crosby)

It has been a challenging time for OG cancer research with a succession of negative trials (ST03, OE05, SCOPE 1, REAL 3) and relatively poor recruitment to current national studies despite studies that span the patient pathway (BEST, NeoAEGIS, SCOPE 2 and PLATFORM).

As highlighted in the OG Subgroup strategy (see Appendix 2), the priorities for the Subgroup in the coming year is to:

1. Detect cancer and treating it an earlier stage through appropriate surveillance techniques and endoscopic therapies where appropriate.
2. Develop more effective treatments (that are effective in the majority of patients in terms of response or survival) and to be able to select the right patients for the right treatments at the right time. Therefore, being able to select those patients who will/will not benefit from surgery, radiotherapy and systemic therapy (SACT) in potentially curative patients and the type of SACT, in particular, the role of immunotherapy in advanced disease.

The Subgroup is facilitating two aligned bids to support a stratified medicine agenda in OG cancer. The first is a bid by an exciting scientific collaboration of Oxford, Cambridge, the Marsden and Southampton to the MRC to discover and validate biomarkers and actionable targets and ultimately test these in an adaptive stratified study in 'early' oesophagogastric adenocarcinoma. The second will be to CRUK to develop a Virtual Centre and Network of Excellence to support both trial recruitment and submission of bio-informatic material for scientific discovery, translational research and the ability to be able to process such material in a timely manner to recommend a personalised therapeutic approach.

Hepatobiliary Subgroup (Chair, Mr Hassan Malik)

Mr Hassan Malik took over as Chair of the Subgroup from Professor John Bridgewater in 2016. The Subgroup meets biannually and has a total membership of 14. The Subgroup has had a strong record of collaborative working, study generation and high impact publication, especially in colorectal liver metastases and biliary tract cancer. As well as involving user groups, the Subgroup has incorporated the CUP programme but this aspect has not been straightforward and needs reviewing.

There is an international extension of the biliary tract group (International Biliary Tract Cancer Collaborative) which meets twice a year and is increasing in profile and collaborative activity resulting in significant publications. A task group has been established to produce an adaptive application with the Colorectal CSG on colorectal liver metastases and this proposal will be submitted shortly.

Pancreatic Subgroup (Chair, Dr Stephen Falk)

Dr Stephen Falk was appointed as Subgroup Chair in succession to Professor Neoptolemos in 2012 and is due to rotate in the next year. Meetings have been held face-to-face or by teleconference and all members are or will be Chief Investigators in planned studies. All current national academic trials have been developed by members of the Subgroup and/or have had significant input into commercial studies.

The Subgroup has had great success with the recently completed and internationally practice changing ESPAC 4 and PET-PANC trials. The focus now (other than the surgical trials) is a stratified approach through the overarching Precision Panc initiative, for which a total of £33 million funding has been approved. This is a synergistic and dynamic platform aligning and coordinating pre-clinical discovery and clinical development. The ultimate goal is to offer every pancreatic cancer patient molecular profiling with a viable and attractive clinical trial option to find "the trial for the patient" rather than "the patient for the trial", create opportunities for scientific research that were previously intractable and enable forward and backward translation

between the laboratory and the clinic. The Subgroup has collaborated to make this bid successful and all studies will be reviewed and supported through the Subgroup. Subgroup members have developed the clinical studies that will form part of the programme.

4. Task groups/Working parties

Colorectal liver metastases remains an area of commonality and interest between the Upper GI and Colorectal CSGs. A current Task Group is developing a trial in this area examining optimal neo-adjuvant chemotherapy and the role of surgical cytoreduction.

5. Patient recruitment summary for last 5 years

In the Upper Gastro-intestinal Cancer CSG portfolio, 15 trials closed to recruitment and 21 opened. There has been no real change in recruitment or the number of trials on the portfolio since 2013/14.

Table 1 Summary of patient recruitment by Interventional/Non-interventional

Year	All participants		Cancer patients only		% of cancer patients relative to incidence	
	Non-interventional	Interventional	Non-interventional	Interventional	Non-interventional	Interventional
2012/2013	1006	3237	964	2777	4.0	11.4
2013/2014	904	1866	882	1652	3.6	6.8
2014/2015	1178	1863	1092	1543	4.5	6.3
2015/2016	1303	1504	969	1236	3.98	5.07
2016/2017	1241	1806	1077	1470	4.42	6.03

6. Links to other CSGs, international groups and network subspecialty leads

As detailed above, there is a Working Group in place with the Colorectal CSG to develop trials in colorectal liver metastases. The International Biliary Cancer Trials Collaboration, led by John Bridgewater, meets at ASCO and ESMO and is growing in strength, with more attendees year on year and collaborative trials already running (e.g. ACTICCA 1). Several publications have resulted from the collaboration.

7. Funding applications in last year

As in 2015/16 the funding environment remains difficult in cancer and few proposals have been funded. However, at the end of the 2016/17 period the £33M Precision Panc was approved. Other successes have be ORANGE 2 Segments proposal (Primrose, CRUK) and Rapid Evaporative Ionisation Mass Spectrometry for Examination of Circumferential Surgical Excision Margins (Zoltan, CRUK) with which the CSG has had no involvement.

Table 2 Funding submissions in the reporting year

Cancer Research UK Clinical Research Committee (CRUK CRC)			
Study	**Application type**	**CI**	**Outcome**
May 2016			
Earlier diagnosis and prevention of oesophageal adenocarcinoma-the role of image cytometry in	Full application	Professor Anthony Watson	Not funded

detecting relevant DNA abnormalities in Barrett's oesophagus patients			
Sample collection for the randomised Phase II/III trial to study radiotherapy dose escalation in patients with oesophageal cancer treated with definitive chemo-radiation with an embedded Phase II trial for patients with a poor early response using positron emission tomography (PET)	Sample collection	Dr Richard Adams & Dr Thomas Crosby	Not funded
Stratification of chemotherapeutic response in pancreatic cancer patients to allow personalised choice of treatment based on levels of cellular defence enzymes	Full application	Dr Eithne Costello	Not funded
Validation of a Prognostic Index containing both Clinical and Molecular features to predict outcome in Oesophageal Adenocarcinoma	Full application	Mr Christopher Peters	Not funded
Neo-adjuvant chemotherapy followed by surgery versus surgery alone in high-risk patients with resectable colorectal liver metastases	Outline application	Professor Daniel Palmer & Mr Hassan Malik	Full application not invited
Precision Panc UK: Personalising treatment for pancreatic cancer	Outline application	Professor Andrew Biankin	Full application invited
Rapid Evaporative Ionisation Mass Spectrometry for Examination of Circumferential Surgical Excision Margins	Full application	Professor Zoltan Takats & Mr Daniel Leff	Funded
November 2016			
IRE-PAC: Two arm, prospective, multicentre, randomised trial of induction chemotherapy followed by chemotherapy with or without irreversible electroporation for patients with locally advanced, unresectable pancreatic ductal adenocarcinoma.	Outline application	Professor Jorg Kleeff	Not invited to full
ESPAC-6: Multi-centre, international open label, randomised controlled trial of neoadjuvant chemotherapy versus immediate surgery in patients with resectable pancreatic cancer.	Outline application	Professor Paula Ghaneh	Not invited to full
A Programme of Stratified Approaches to the Management of Pancreatic Ductal Adenocarcinoma	EMPA Outline	Professor Daniel Palmer	Not invited to full
ORANGE II PLUS AMENDMENT	Full (Amendment)	Professor John Primrose	Supported
The development and validation of an ultrasensitive multimarker pancreatic cancer screen	Full (Biomarker Project Award)	Professor Jason Davis	Not Supported
Other committees			
Study	**Committee & application type**	**CI**	**Outcome**
DIPLOMA: Distal pancreatectomy, laparoscopic or open for malignancy	HTA	Mr Mohammed Abu Hilal	Not Successful

8. Collaborative partnership studies with industry

There is limited interest from Industry in Upper GI cancer trials at present outside of NET and in

association with Precision Panc as discussed elsewhere. For the EPOC 4 proposal, we are in negotiation with Amgen for the provision of a bevacizumab bio-similar.

9. Impact of CSG activities

The Upper GI CSG trials portfolio has had a major impact on routine clinical practice in the UK and worldwide in the last five years. The ABC studies have changed practice in biliary cancer and are now the published standard of care in both Europe and the USA. New EPOC and SCOPE gave evidence of the potential harmful effects of EGFR blockade in certain circumstances. Neo Scope and SCALLOP gave evidence for the use of chemoradiotherapy in OG and locally advanced pancreatic cancer. Although OEO-5 and STO-3 were negative, they added knowledge on chemotherapy in oesophageal adenocarcinoma and stomach cancer respectively. As part of international trials, the NET Subgroup has played a key role in advances in treatment in these tumours. The BILCAP trial reported just at the end of the 2016/17 period and is practice changing world-wide.

Members of the committee regularly serve as experts on NICE technology appraisals, although most applications. The Group Chair chairs the Pancreas Cancer Guidelines Committee and another CSG member also contributes to this.

The Group regularly inputs into the Horizon Scanning exercise.

10. Consumer involvement

Dr Philip Bell (non-medical doctorate) joined the group in July 2016 and has played an active role both at CSG Meetings and involving himself as Co-Applicant in various Upper GI funding applications such as IRE-PAC and European Study Group for Pancreatic Cancer (ESPAC) trial 6. Philip also sits on several cancer oversight committees for Non Upper GI research projects such as PATHOS, RE-AKT and CreSt 2. He is also Vice Chair of the Cancer UK Clinical Trials Unit Patient and Public Involvement Group at Liverpool University from where he reflects the thoughts to the CSG.

At present, we have only one consumer representative on the Group as Yvonne Carse decided to step down due to difficulties managing other commitments. The second consumer position is currently being advertised by the NCRI and it is hoped that this will be filled by the next CSG meeting.

11. Open meetings/annual trials days/strategy days

Upper GI CSG Annual Trials meetings has in the past been very well attended as a “no cost” meeting. Traditionally, the meeting was funded by industrial sponsorship but in recent years this has proved increasingly difficult as industry funding is stretched more thinly. In 2016, a registration charge was made at the meeting for the first time, the costs being mitigated by an unrestricted grant from Celgene. We were pleased to see that attendance remained high. For the future, consideration may be given to a pan-gastrointestinal meeting and also integration with the NCRI Conference may be considered.

The Neuroendocrine Subgroup also participates in the annual UKINETS meeting at which the NETs Subgroup Chair is invited to give a portfolio review to raise the profile of clinical research opportunities.

12. Priorities and challenges for the forthcoming year

Priorities

1. The Group will assimilate the recommendations of the QQR and, under a newly appointed Chair, develop a strategy which is fit for purpose for the next five years.
2. To target other funding sources other than CRUK to get high priority, CSG developed trials funded. Targets include HTA and EME.
3. To bring to fruition the current oesophagogastric stratified medicine project.

Challenges

1. The funding position of CRUK, which mandates biomarker driven trials, is difficult in an area like upper GI where biomarkers are poorly developed. The Group will also struggle with hypothesis driven only tissue collection when often the value of such collections is known only after the trial result.
2. The priorities in the current NHS where the overwhelming clinical workload militates against prioritising research.
3. Capacity of the NHS to deliver what is required in terms of tissue to permit personalised medicine and in NHS Digital to meet the needs of investigators.

13. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies

A – Main CSG Strategy
B – Neuroendocrine Subgroup Strategy
C – Oesophagogastric Subgroup Strategy
D – Hepatobiliary Subgroup Strategy
E – Pancreatic Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

Professor John Primrose (Upper Gastro-intestinal Cancer CSG Chair)

Appendix 1

Membership of the Upper Gastro-intestinal Cancer CSG

Name	Specialism	Location
Dr Saoirse Dolly*	Clinical fellow	London
Dr Yuk Ting Ma	Clinical Lecturer	Birmingham
Dr Tom Crosby	Clinical Oncologist	Cardiff
Dr Stephen Falk	Clinical Oncologist	Bristol
Dr Maria Hawkins	Clinical Oncologist	Oxford
Dr Somnath Mukherjee	Clinical Oncologist	Oxford
Professor Tim Underwood	Clinical Scientist	Southampton
Dr Philip Bell	Consumer	Amlwch
Dr Bristi Basu	Medical Oncologist	Cambridge
Professor Ruth Langley	Medical Oncologist	London
Professor Tim Meyer	Medical Oncologist	London
Professor Daniel Palmer	Medical Oncologist	Liverpool
Professor Russell Petty	Medical Oncologist	Aberdeen
Dr Paul Ross	Medical Oncologist	London
Dr Richard Turkington	Medical Oncologist	Belfast
Dr Gordon Hutchins	Pathologist	Leeds
Mr Richard Fox	Statistician	Birmingham
Professor Hugh Barr	Surgeon	Gloucester
Professor Andrew Biankin	Surgeon	Glasgow
Professor Paula Ghaneh	Surgeon	Liverpool
Mr Nigel Jamieson*	Surgeon	Glasgow
Mr Hassan Malik	Surgeon	Liverpool
Professor John Primrose (Chair)	Surgeon	Southampton

* denotes trainee member

Membership of the Subgroups

Pancreatic Subgroup		
Name	**Specialism**	**Location**
Dr Stephen Falk (Chair)	Clinical Oncologist	Bristol
Dr Somnath Mukherjee	Clinical Oncologist	Oxford
Mrs Yvonne Carse	Consumer	Launceston
Professor John Bridgewater	Medical Oncologist	London
Dr Pippa Corrie	Medical Oncologist	Cambridge
Professor Jeff Evans	Medical Oncologist	Glasgow
Professor Daniel Palmer	Medical Oncologist	Liverpool
Professor Will Steward	Medical Oncologist	Leicester
Professor Juan Valle	Medical Oncologist	Manchester
Dr Karin Oien	Pathologist	Glasgow
Trevor Cox	Statistician	Liverpool
Professor Paula Ghaneh	Surgeon	Liverpool
Professor John Primrose	Surgeon	Southampton
Professor Andrew Biankin	Surgeon	Glasgow

Hepatobiliary Subgroup		
Name	**Specialism**	**Location**
Mrs Helen Morement	AMMF Chair of Trustees	London
Dr Maria Hawkins	Clinical Oncologist	Oxford
Mr John Symons	Consumer	Newbury
Dr John Bridgewater	Medical Oncologist	London
Dr Tim Meyer	Medical Oncologist	London
Professor Daniel Palmer	Medical Oncologist	Liverpool
Mr Paul Ross	Medical Oncologist	London
Professor Juan Valle	Medical Oncologist	Manchester
Dr Harpreet Wasan	Medical Oncologist	London
Ms Pam O'Donoghue	Nurse	London
Dr Andre Lopes	Statistician	London
Dr John Primrose	Surgeon	Southampton
Mr Hassan Malik (Chair)	Surgeon	Liverpool

Neuroendocrine Subgroup		
Name	**Specialism**	**Location**
Dr Nick Reed	Clinical Oncologist	Glasgow
Dr Jonathan Wadsley	Clinical Oncologist	Sheffield
Ms Carole Beckett	Consumer	Manchester
Professor Mark Pritchard	Gastroenterologist	Liverpool
Dr John Ramage	Gastroenterologist	Hampshire
Dr Alan Anthoney	Medical Oncologist	Leeds
Dr Wasat Mansoor**	Medical Oncologist	Manchester
Professor Tim Meyer (Chair)	Medical Oncologist	London
Professor Juan Valle	Medical Oncologist	Manchester
Professor Ashley Grossman	Neuroendocrinologist	London
Dr Prakash Manoharan	Radiologist	Manchester
Mrs Louise Stanton	Statistician	Southampton
Mr Neil Pearce	Surgeon	Southampton

Oesophagogastric Subgroup		
Name	**Specialism**	**Location**
Dr Tom Crosby (Chair)	Clinical Oncologist	Cardiff
Mr David Chuter**	Consumer	Bognor Regis
Professor Heike Grabsch**	Histopathologist	Leeds
Professor David Cunningham	Medical Oncologist	London
Professor Jeff Evans	Medical Oncologist	Glasgow
Dr Hugo Ford	Medical Oncologist	Cambridge
Professor Janusz Jankowski	Medical Oncologist	Warwick
Dr Ruth Langley	Medical Oncologist	London
Dr Naureen Starling	Medical Oncologist	London
Professor Anne Thomas	Medical Oncologist	Leicester
Dr Somnath Mukherjee	Clinical Oncologist	Oxford
Professor Jane Blazeby	Surgeon	Bristol
Mr William Allum	Surgeon	London
Professor Robert Mason	Surgeon	London
Mr Shaun Preston**	Surgeon	Surrey
Professor Tim Underwood	Surgeon	Southampton

* denotes trainee member
**denotes non-core member

Appendix 2

CSG & Subgroup Strategies

A – Main CSG Strategy

The Group strategy as outlined in October 2011 and supported by the Group's progress review in 2013. It will be revised based on the Upper GI Quinquennial Review (QQR) on 24 April 2017 which will be available for the new Chair to implement following the overdue departure of the present Chair:

1. The subgroup structure was re-examined. It was widely agreed that with the advent of CTRad that radiotherapy should be embedded in the other subgroups and a relationship established with CTRad.
2. It was agreed that the Screening and Prevention Subgroup, which dealt only with Barrett's Oesophagus, was not appropriate and the suggestion was a group be formed which included prevention, screening, early diagnosis and imaging. Subsequently, however, the NCRI review of CSGs and Subgroups set an absolute maximum of four Subgroups and it was subsequently agreed that these areas would be embedded in the four remaining subgroups and a relationship established with the cross cutting Prevention, Screening and Early Diagnosis Advisory Group which has been set up across all CSGs.
3. The four Subgroups (oesophagogastric, pancreatic, hepatobiliary and neuroendocrine tumours) should remain in their present form but the membership and chair arrangements should conform to the new NCRI review proposals with a strict tenure of membership.
4. The membership of the subgroups would be reviewed and it was agreed that a statistician should sit on each subgroup.
5. CUP should be included within the Hepatobiliary Subgroup.
6. The Group felt that GIST, which sat with the Sarcoma CSG, should move to the Upper GI CSG on the basis that 1) GIST was not a sarcoma and 2) in terms of the clinical management it involved principally the Upper GI MDT. The Chair agreed to take this to the NCRI Directors.
7. New trial methodologies were discussed. It was accepted that very large phase III trials using a single chemotherapy schedule in unselected patients was probably in the past and that the future would be dominated by adaptive and biomarker driven trial designs.
8. Surgical trials were discussed. Accepting the problems with recruitment, it was agreed that it was appropriate to try to develop more high quality trials in surgical methodologies.
9. Arrangements for the development of radiotherapy trials were discussed and it was agreed that the Group should work closely with CTRad to develop high quality radiotherapy proposals.
10. A major national strategy was to encourage and develop industry studies and the advantages of an AZ collaboration was discussed. It was agreed the Group would work to increase collaboration with industry trials.
11. The Group also considered various novel trial ideas which would be developed through the subgroups subsequently.

B – Neuroendocrine Subgroup Strategy

Aim

To improve outcomes for patients with NETs through clinical and translational research, built on a coordinated infrastructure for these rare tumours.

Strategy

To ensure that the NET portfolio has a multi-disciplinary broad base of studies (clinical and translational) covering all aspects of NETs. This includes:

1. Establishing the UK (through the NCRI) as a competitive place for industry to run clinical trials.
2. Broadening the scope of the clinical trials portfolio in patients with NETs; these include:
    - Increasing the number of studies where gastroenterologists are best placed (e.g. gastric or rectal carcinoids).
    - Ensuring the portfolio includes studies focusing on symptoms and quality of life.
    - Increasing the number of studies incorporating radiotherapy-based questions.
    - Providing the opportunity for translational questions to be addressed within the scope.
    - Developing studies addressing surgical questions and the use of adjuvant therapy.
3. Development of clinical studies in NETs other than GEP (e.g. lung NETs, phaeochromocytomas and paragaglionomas) with a similar multi-disciplinary approach.
4. To develop innovative therapeutic strategies.

C – Oesophagogastric Subgroup Strategy

Aim

The Oesophagogastric Subgroup aims to improve outcomes for patients with OG cancer through progressive clinical trials and cutting edge translational research.

Strategy

The strategy of the Subgroup is to ensure that the OG trial portfolio provides comprehensive coverage of all aspects of OG cancer and achieves a balance between translational and clinical research. In particular, we will:

- Continue to support and encourage translational research to increase understanding of the factors that cause and drive OG cancer.
- Continue to develop strategies to prevent OG cancer and new diagnostic techniques to facilitate an early diagnosis.
- Continue to develop innovative new therapeutic strategies. This includes:
    - Investigating the role of immunotherapy in OG cancer and how it may be integrated into the paradigm for early and advanced disease, including possible combinations with radiotherapy, chemotherapy or targeted agents and biomarker selection.
    - Investigating novel therapies, new surgical techniques and advanced radiotherapy techniques such as intensity-modulated radiotherapy (IMRT).
    - Developing and refining therapeutic strategies for all stages of disease, including neoadjuvant therapy, surgery/local therapies and adjuvant therapy for localised disease and multiple lines of treatment for advanced disease.

- Developing trials that focus on common challenges in the management of OG cancer, including elderly patients, with an emphasis on research that can be translated into meaningful outcomes for patients.
- Developing an evidence base for OG cancer to inform decision-making and health policy.

To deliver these priorities we will:

- Encourage collaborative approaches, seeking to increase both national and international partnerships to facilitate rapid study recruitment and cutting edge translational research. This includes supporting the establishment of national and international multi-centre trials, including trials with adaptive designs.
- Encourage industry partnerships, seeking to facilitate the rapid development of trials investigating new therapeutic agents.
- Continue to support and develop the best researchers, at all stages of their careers, by encouraging submission of trial proposals for discussion and feedback from the OG Subgroup.
- Assist with grant funding applications by providing a forum for peer-review and discussion of trial proposals, and letters outlining support for important new studies.
- Discuss areas of unmet need in cancer research, to enable trials to be developed to address major therapeutic challenges and any gaps in the portfolio.

D – Hepatobiliary Subgroup Strategy

The Hepatobiliary Subgroup is a recognised international leader in the management of HB cancers. The aim of the Subgroup is to improve outcomes for patients with primary hepatobiliary malignancies and metastatic liver disease through practice changing clinical and translational research.

The TACE 2 study, initiated by this Subgroup, was presented at ASCO in 2016 and has demonstrated the Subgroup's ability to recruit a large cohort of patients, with this challenging condition, into a clinical trial that was delivered on time. For ASCO 2017, the BILCAP study, as well as the final overall survival analysis from the new-EPOC trial, is likely to make a significant impact on patient management.

Aim

In order to achieve its aim of having a balanced portfolio, the Subgroup's portfolio currently incorporates studies in surgery, adjuvant as well as advanced first and second line studies, including trials of loco-regional therapies and radiotherapy. Our challenge moving forwards is to exploit novel trial designs that are biomarker driven and which are meaningful to both patients and the oncology community.

Strategy

- Liver metastases:
  - Continue to collaborate with the Advanced Disease Subgroup (Colorectal CSG) to develop studies in mCRC.
  - Non colorectal/non-NET - Following on from NCRI Future of Surgery workshops and feedback from the QQR report, the Subgroup will set up a time limited working party with other CSG stakeholders to investigate the possibility of developing an umbrella study in this area.

- HCC: Following feedback from QQR, we will formally contact the UK HCC consortium to look at developing closer links with hepatologists and the CSG. This may enable us to support further epidemiological, surveillance and preventative studies in high risk population for HCC.
- Cholangiocarcinoma: Following on from the success of ABC studies, the Subgroup is keen to build a platform through which a biomarker driven approach to advanced disease could be investigated. If successful, such an approach could be applied to the adjuvant setting following completion of the ACTICCA1 study.

E – Pancreatic Subgroup Strategy

Aim

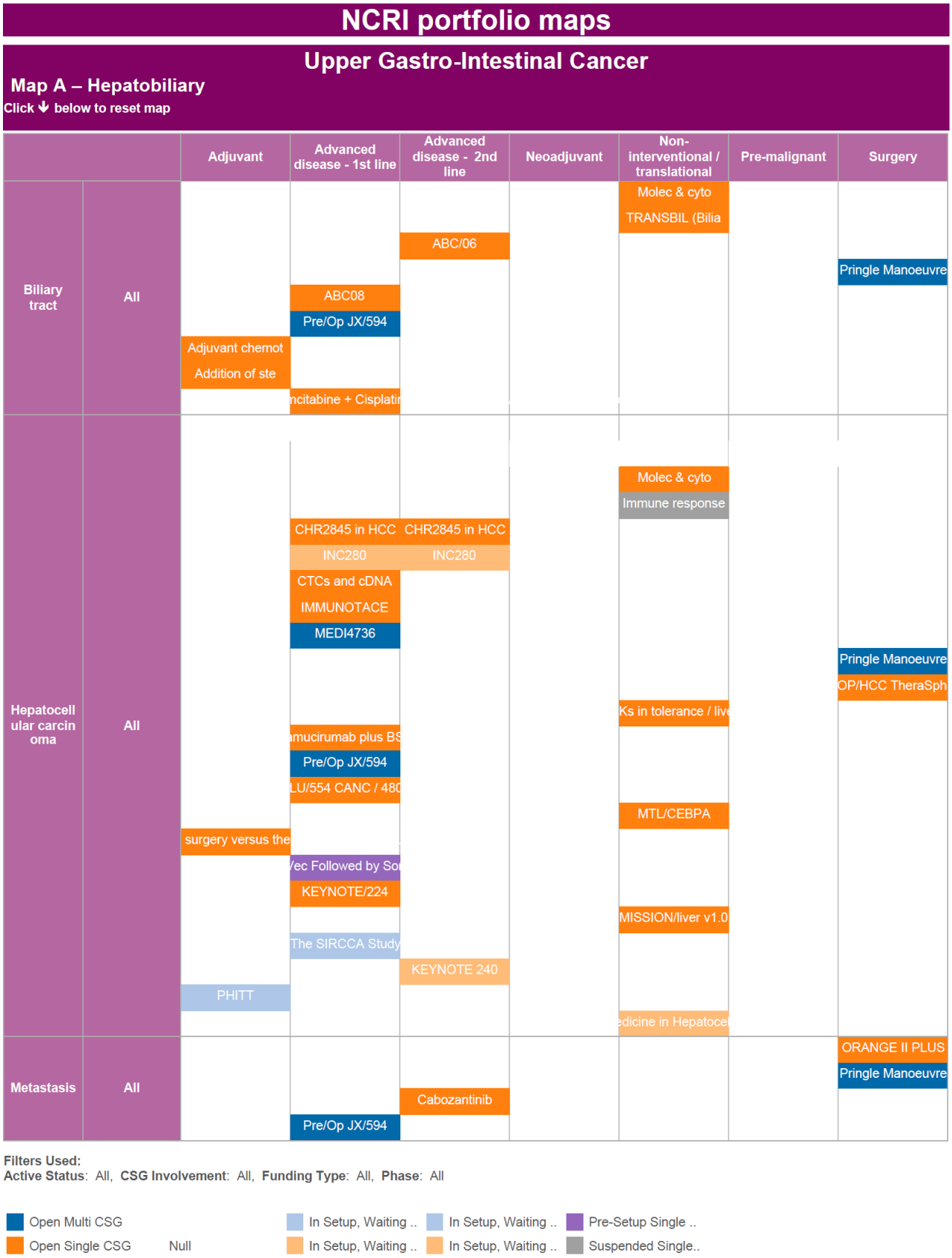
The Pancreatic Subgroup aims to improve outcomes for patients through a broad range of clinical trials encompassing all relevant clinical scenarios with cutting edge translational research.

Strategy

- To have a portfolio actively recruiting and in development within early diagnosis, staging, therapy and supportive care.
- Continue to support and encourage translational research to increase understanding of the factors that cause and drive pancreas cancer.
- Continue to develop innovative new therapeutic strategies. This includes:
    - Investigating novel targeted therapies, immunotherapy, new surgical techniques and advanced radiotherapy techniques such as intensity-modulated radiotherapy (IMRT).
    - Developing and refining therapeutic strategies for all stages of disease, including neoadjuvant therapy, surgery/local therapies and adjuvant therapy for localised disease and multiple lines of treatment for advanced disease.
    - Developing trials that focus on common challenges in the management of pancreas cancer, including symptoms such as cachexia.
    - Developing an evidence base for the molecular biology of pancreas cancer to inform decision-making and health policy.

Appendix 3

Portfolio maps



NCRI portfolio maps

Upper Gastro-Intestinal Cancer

Map B – Neuroendocrine

Click ↓ below to reset map

		Advanced disease - 1st line	Neoadjuvant	Surgery	Symptom control / non-interventional / translational
Intestines	Low grade (g1/g2)				DIB/NET Study Clarinet/FORTE
Lung & other	High grade (g3)				
	Low grade (g1/g2)				[18F]/FET/ßAG/TOCA IMMUNET
Pancreas	High grade (g3)	PDR001 in Neuroendocrine Tumours			
			Development of an EORTC QoL Module for Pancreatic NET: Phases 1/3 v1.0		
	Low grade (g1/g2)				[18F]/FET/ßAG/TOCA
		SEQTOR REMINET			
		PDR001 in Neuroendocrine Tumours			
					Clarinet/FORTE

Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

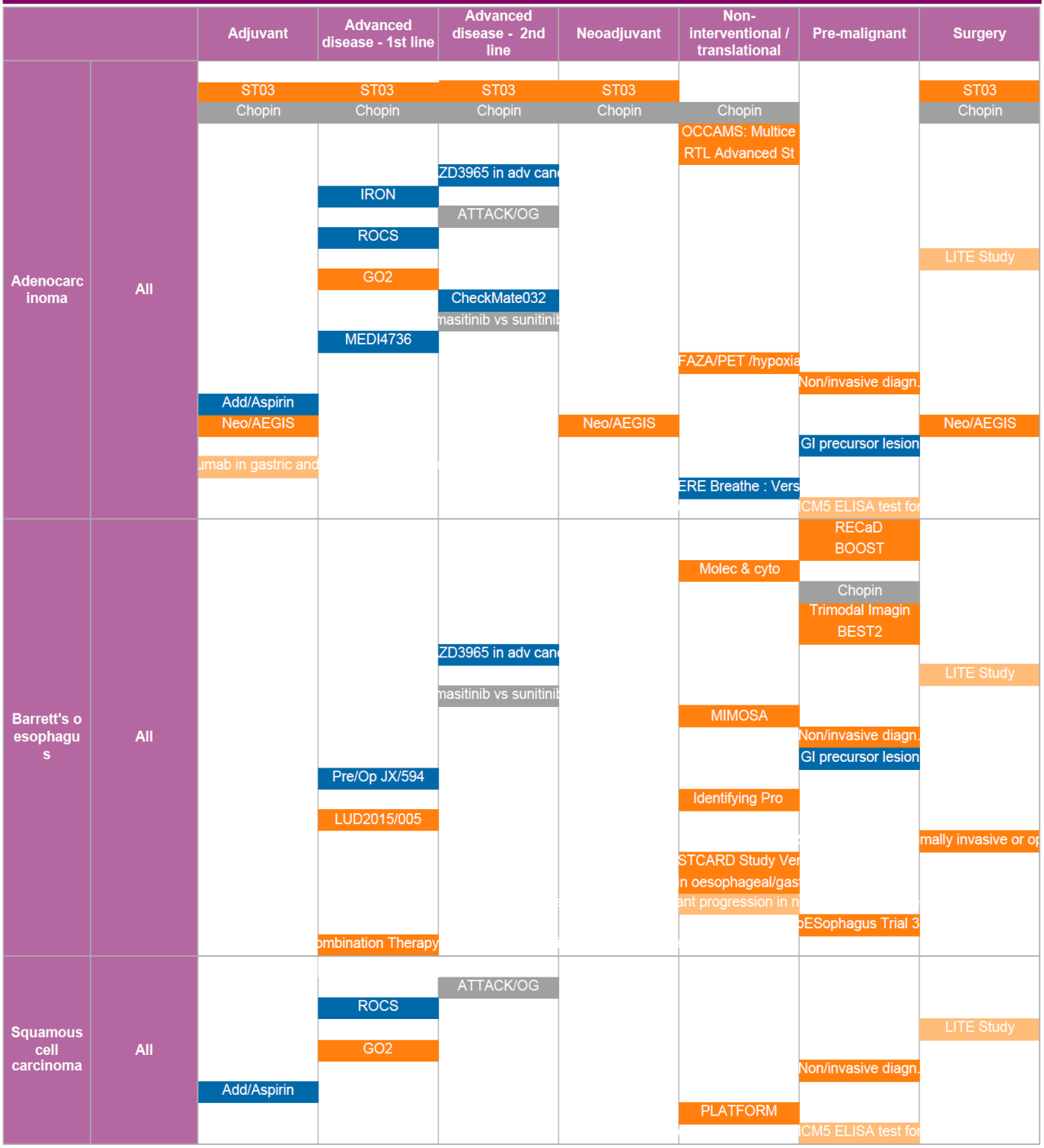
Open Single CSG In Setup, Waiting ..

NCRI portfolio maps

Upper Gastro-Intestinal Cancer

Map C – Oesophageal, junctional tumours (type I/II)

Click ↓ below to reset map



Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

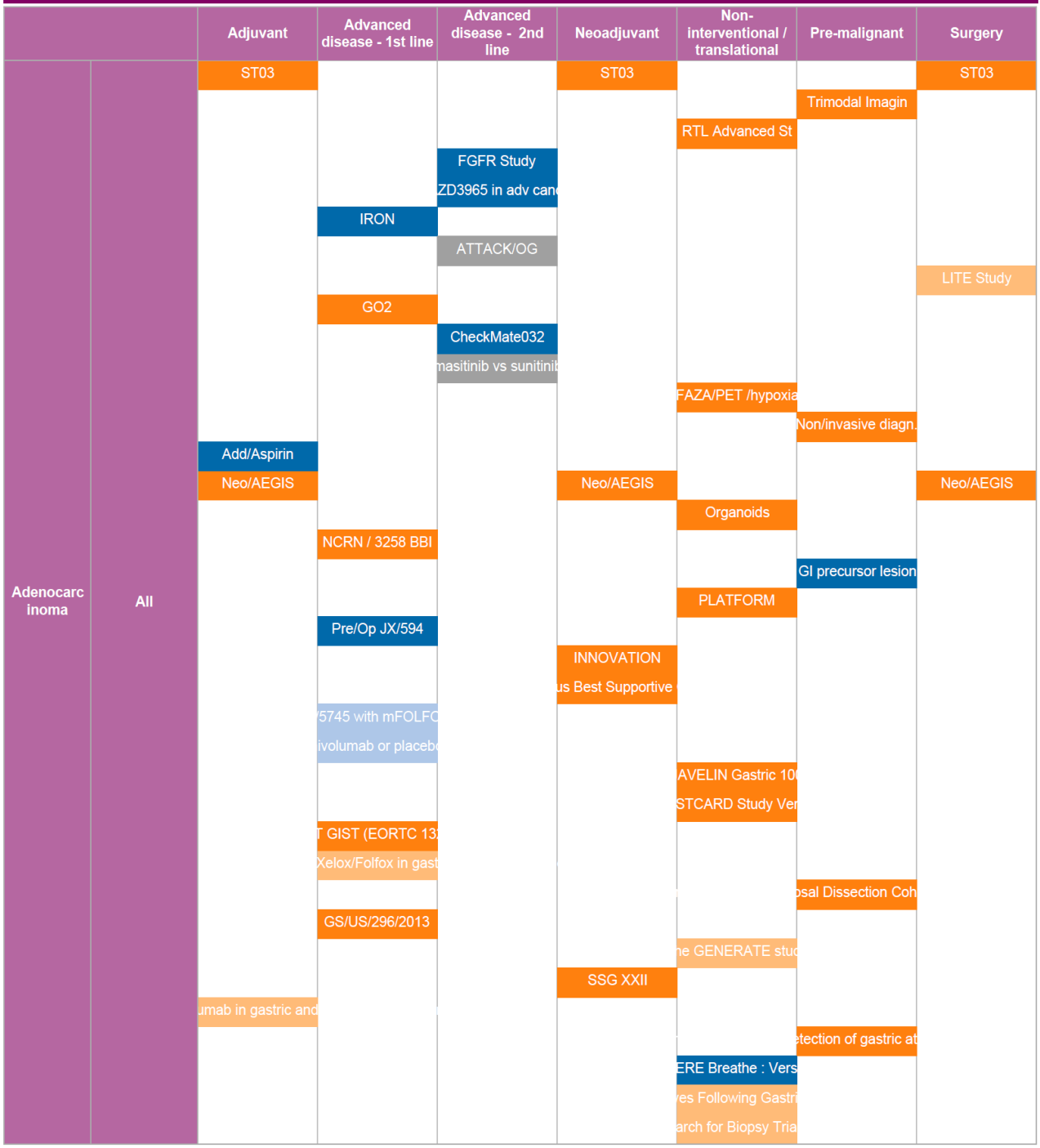
Open Multi CSG | Null | In Setup, Waiting .. | Suspended Single..
Open Single CSG | In Setup, HRA Ap.. | In Setup, Waiting ..

NCRI portfolio maps

Upper Gastro-Intestinal Cancer

Map D – Stomach, junctional tumours (type II/III)

Click ↓ below to reset map



Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

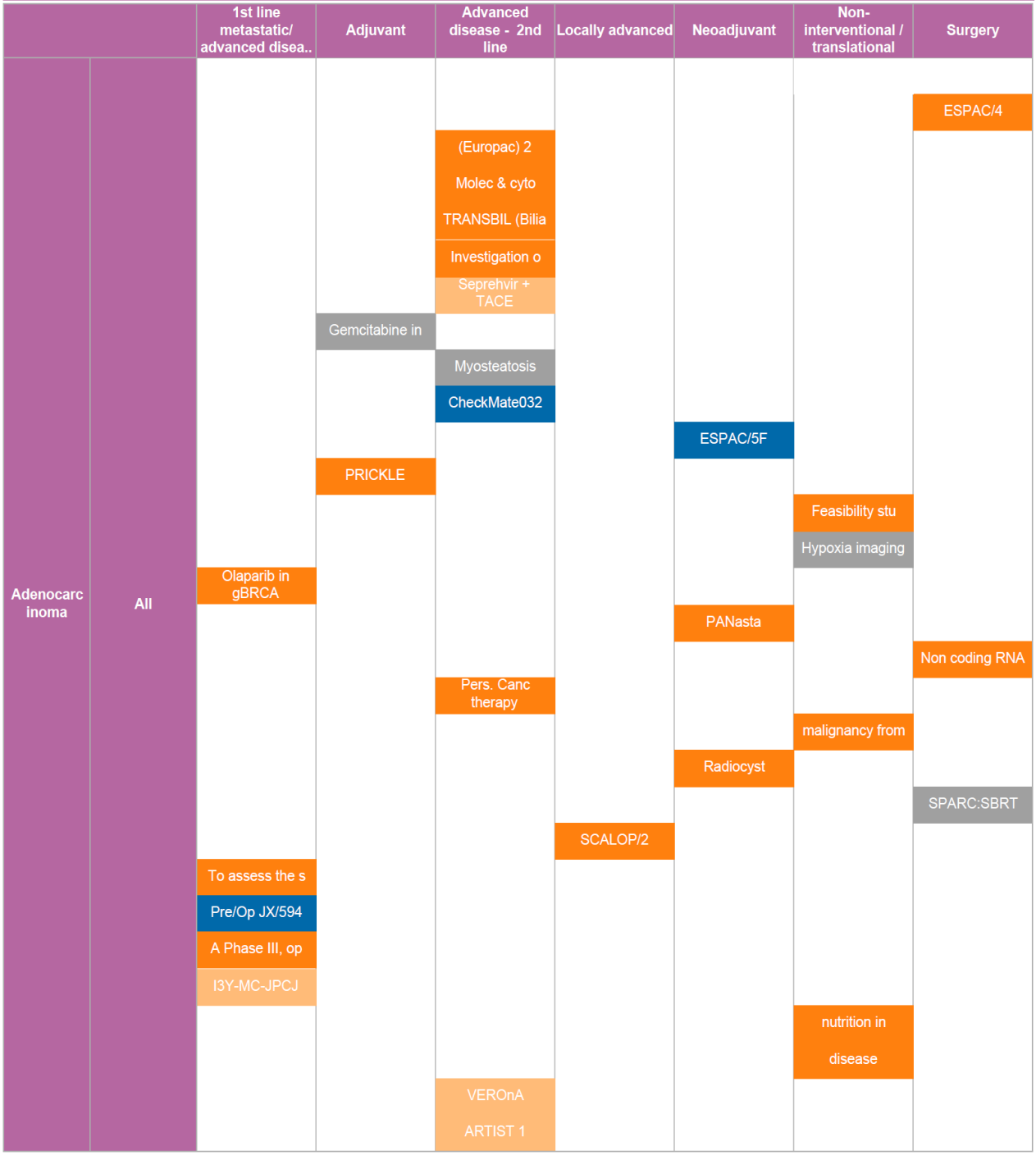
Open Multi CSG | In Setup, HRA Ap.. | In Setup, Waiting .. | Suspended Single..
Open Single CSG | In Setup, Waiting .. | In Setup, Waiting ..

NCRI portfolio maps

Upper Gastro-Intestinal Cancer

Map E – Pancreas

Click ↓ below to reset map



Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Multi CSG
Open Single CSG
In Setup, HRA Ap..
In Setup, Waiting ..
In Setup, Waiting ..
Suspended Multi ..
Suspended Single..

Appendix 4

Publications in the reporting year

Study	Reference
ST03	Cunningham D, Stenning SP, Smyth EC, Okines AF, Allum WH, Rowley S, Stevenson L, Grabsch HI, Alderson D, Crosby T, Griffin SM, Mansoor W, Coxon FY, Falk SJ, Darby S, Sumpter KA, Blazeby JM, Langley RE. Peri-operative chemotherapy with or without bevacizumab in operable oesophagogastric adenocarcinoma (UK Medical Research Council ST03): primary analysis results of a multicentre, open-label, randomised phase 2-3 trial. Lancet Oncol. 2017 Feb 2. pii: S1470-2045(17)30043-8. doi: 10.1016/S1470-2045(17)30043-8. [Epub ahead of print]
	Cunningham, D., S. P. Stenning, E. C. Smyth, A. F. Okines, W. H. Allum, S. Rowley, L. Stevenson, H. I. Grabsch, D. Alderson, T. Crosby, S. M. Griffin, W. Mansoor, F. Y. Coxon, S. J. Falk, S. Darby, K. A. Sumpter, J. M. Blazeby and R. E. Langley (2017). "Peri-operative chemotherapy with or without bevacizumab in operable oesophagogastric adenocarcinoma (UK Medical Research Council ST03): primary analysis results of a multicentre, open-label, randomised phase 2-3 trial." Lancet Oncology 18(3): 357-370
SYMNET	Ruszniewski P, Valle JW, Lombard-Bohas C, Cuthbertson DJ, Perros P, Holubec L, Delle Fave G, Smith D, Niccoli P, Maisonobe P, Atlan P, Caplin ME; SYMNET study group. Patient-reported outcomes with lanreotide Autogel/Depot for carcinoid syndrome: An international observational study. Dig Liver Dis. 2016 May;48(5):552-8. doi: 10.1016/j.dld.2015.12.013
RADIANT-4	Yao JC, Fazio N, Singh S, Buzzoni R, Carnaghi C, Wolin E, Tomasek J, Radere M, Lahner H, Voi M, Pacaud LB, Rouyrre N, Sachs C, Valle JW, Delle Fave G, Van Cutsem E, Tesselaar M, Shimada Y, Oh DY, Strosberg J, Kulke MH, Pavel ME. (2016). "Everolimus for the treatment of advanced, non-functional neuroendocrine tumours of the lung or gastrointestinal tract (RADIANT-4): a randomised, placebo-controlled, phase 3 study. Lancet. 387(10022):968-77.
NETTER-1	Strosberg J, El-Haddad G, Wolin E, Hendifar A, Yao J, Chasen B, Mittra E, Kunz PL, Kulke MH, Jacene H, Bushnell D, O'Dorisio TM, Baum RP, Kulkarni HR, Caplin M, et al ; NETTER-1 Trial Investigators. Phase 3 Trial of 177Lu-Dotatate for Midgut Neuroendocrine Tumors. N Engl J Med. 2017 Jan 12;376(2):125-135. doi: 10.1056/NEJMoa1607427.
	Kulke MH, Ruszniewski P, Van Cutsem E, Lombard-Bohas C, Valle JW, De Herder WW, et al. A randomized, open-label,

COOPERATE-2 trial	phase 2 study of everolimus in combination with pasireotide LAR or everolimus alone in advanced, well-differentiated, progressive pancreatic neuroendocrine tumors: COOPERATE-2 trial. Ann Oncol 2017 doi 10.1093/annonc/mdx078
COG	Russell D Petty, Asa Dahle-Smith, David AJ Stevenson, Aileen Osborne, Doreen Massie, Caroline Clark, Graeme I Murray, Susan J Dutton , Corran Roberts, Irene Y Chong, Wasat Mansoor, Joyce Thompson, Mark Harrison, Anirban Chatterjee, Stephen Falk, Sean Elyan, Angel Garcia-Alonso, David Walter Fyfe, Jonathan Wadsley, Ian Chau, David Ferry and Zosia Miedzybrodzka*. Gefitinib and Epidermal Growth Factor Receptor Gene Copy Number Aberrations in Esophageal Cancer. Journal of Clinical Oncology. 2017. Accepted March 2017 In Press.
TRANSCOG	E. Van Cutsem, Y-J. Bang, W. Mansoor, R. Petty, Y. Chao, D. Cunningham, D.R. Ferry, N.R. Smith, P. Frewer, J. Ratnayake, P. K. Stockman, E. Kilgour, D. Landers. A Randomized, Open-label Study of the Efficacy and Safety of AZD4547 Monotherapy Versus Paclitaxel for the Treatment of Advanced Gastric Adenocarcinoma with FGFR2 Polysomy or Gene Amplification. Annals of Oncology 2017. Accepted March 2017 In Press.
SCOPE 1	Crosby T, Hurt CN...Mukherjee S (last author). Long-term results and recurrence patterns from SCOPE 1: a phase II/III randomised trial of definitive chemoradiotherapy +/− cetuximab in oesophageal cancer. (2017) British Journal of Cancer doi: 10.1038/bjc.2017.21
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SCALOP trial	Fokas, E., Spezi, E., Patel, N., Hurt, C., Nixon, L., Chu, K.-Y., Staffurth, J., Abrams, R., Mukherjee, S. Comparison of investigator-delineated gross tumour volumes and quality assurance in pancreatic cancer: Analysis of the on-trial cases for the SCALOP trial. (2016) Radiotherapy and Oncology, 120 (2), pp. 212-216.
ORANGE II	Wong-Lun-Hing EM, van Dam RM, van Breukelen GJ, Tanis PJ,Ratti F, van Hillegersberg R, Slooter GD, de Wilt JH, Liem MS, de Boer MT, Klaase JM, Neumann UP, Aldrighetti LA, Dejong CH; ORANGE II Collaborative Group. Randomized clinical trial of open versus laparoscopic left lateral hepatic sectionectomy within an enhanced recovery after surgery programme (ORANGE II study). Br J Surg. 2017 Apr;104(5):525-535. doi: 10.1002/bjs.10438. Epub 2017 Jan 31.
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Patient-Reported Outcomes and Quality of Life with Sunitinib Versus Placebo for Pancreatic Neuroendocrine Tumors: Results From an International Phase III Trial	Vinik A, Bottomley A, Korytowsky B, Bang YJ, Raoul JL, Valle JW, et al. Targeted oncology Dec 2016;11(6):815-24 doi 10.1007/s11523-016-0462-5
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Appendix 5

Major international presentations in the reporting year

Study	Conference details
SCALOP trial	O-003 Long-term outcome from the SCALOP trial: a multi-centre randomized phase II trial of gemcitabine or capecitabine-based chemoradiation (CRT) for locally advanced pancreatic cancer (LAPC). C. Hurt J. Bridgewater S. Falk S. Cummins H. Wasan T. Crosby G. Radhakrishna C. Jephcott R. Roy A. McDonald R. Ray G. Joseph J. Staffurth R. Abrams G. Griffiths T. Maughan S. Mukherjee. Ann Oncol (2016) 27 (suppl_2): ii118-ii119 - WORLD GI CONGRESS
NET01 trial	T Meyer, W Qian W, J Valle, J. W., Talbot, D., Cunningham, D., Reed, N., Corrie, P. (2016). Capecitabine and streptozocin +/- cisplatin for gastroenteropancreatic neuroendocrine tumours: predictors of long-term survival in the NET01 trial. ANNALS OF ONCOLOGY, 27. doi:10.1093/annonc/mdw369.31 – ESMO, October 2016
LUNA study	Ferolla, P., Brizzi, M. P., Meyer, T., Mansoor, W., Mazieres, J., Cao, C. D.Baudin, E. (2016). Efficacy and safety of pasireotide LAR or everolimus alone, or in combination in patients with advanced carcinoids (NET) of the lung/thymus: Results from the randomized, phase 2 LUNA study - Presented at: 41st Congress of the European-Society-for-Medical-Oncology (ESMO). doi:10.1093/annonc/mdw369.1 – ESMO, October 2016
CALM-NET	T Meyer, K Higgs, M Hickling, A Houchard. CALM-NET: A Multicentre, Exploratory Study to Assess the Clinical Value of Circulating Tumour Cells (CTCs) Enumeration in Patients (Pts) with Functioning Midgut NETs Receiving Lanreotide Autogel (LAN) – ENETS, March 2017