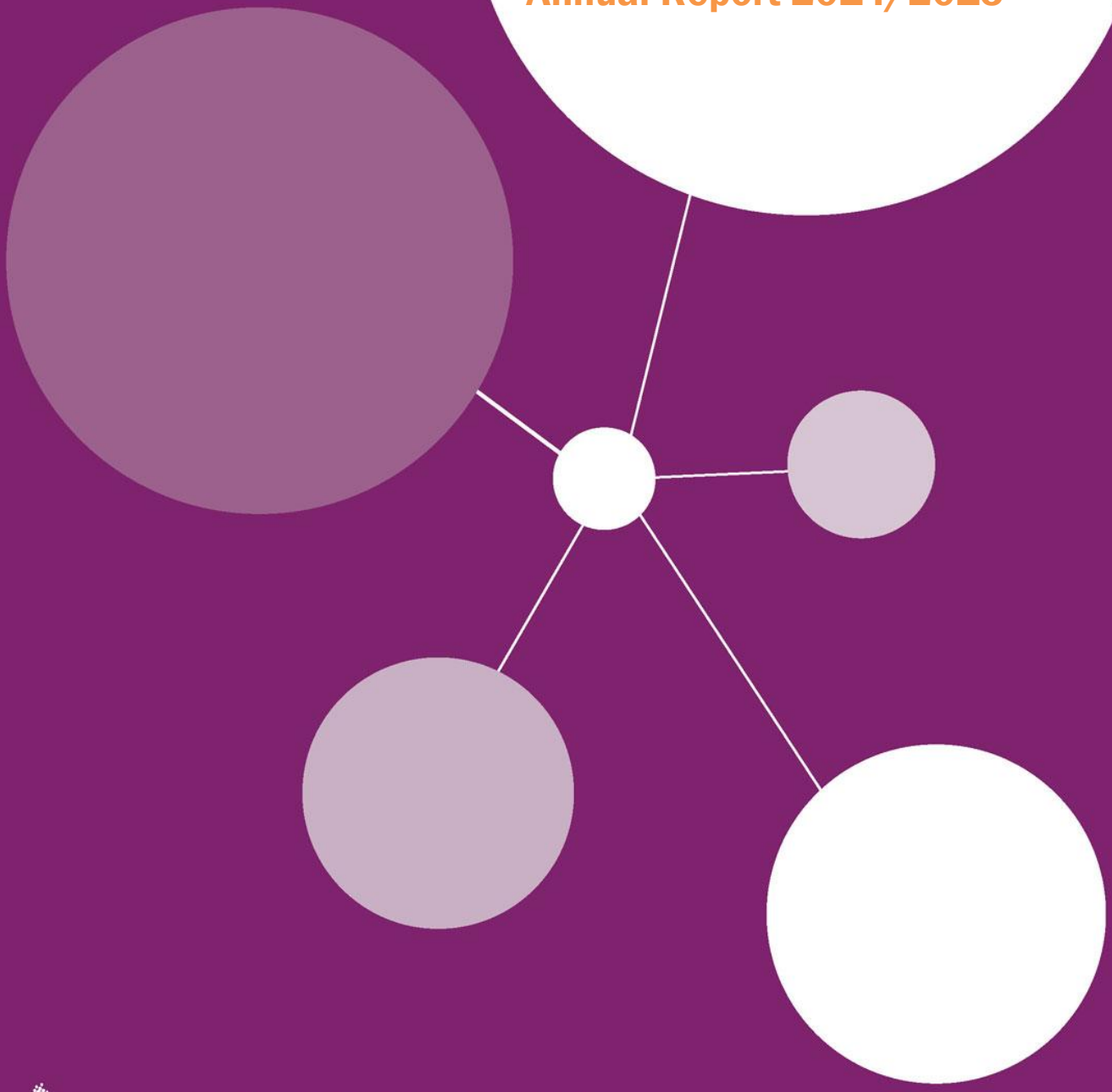
NCRI
National
Cancer
Research
Institute

NCRI Supportive & Palliative Care Clinical Studies Group

Annual Report 2014/2015



Partners in cancer research

NCRI Supportive & Palliative Care CSG Annual Report 2014/15

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

This was the first year in which the CSG carried the new name with 'Supportive Care' in front. The change has been very well received by the Group, other CSGs and patient representatives. It has enabled us to think more broadly than the previously successful but rather focused agenda of the CSG. A model of comprehensive supportive care has been discussed and adopted, which embraces palliative and end of life care but also stresses the symptom and other supportive care needs of patients (and families) at other stages (see figure below).

Thus the CSG is now addressing research opportunities at these four stages:

- at presentation
- during anti-cancer treatments
- late consequences of cancer and of anti-cancer treatments in survivors metastatic and advanced disease stage
- at end of life.

Figure 1

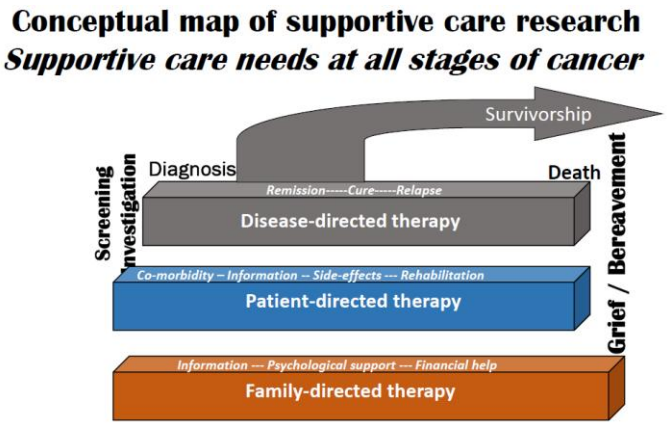
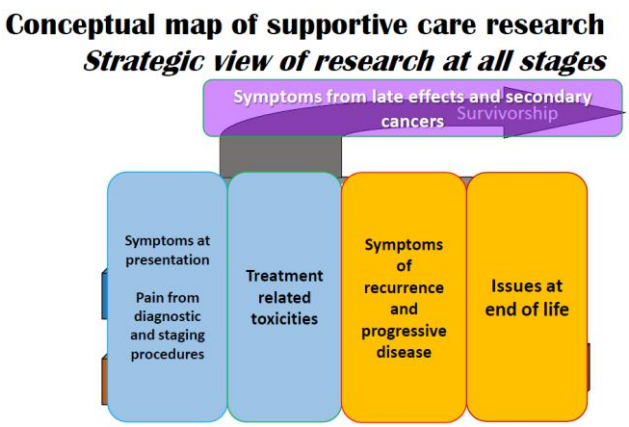


Figure 2



Within this new framework, the CSG is able to use its collective expertise and research skills to explore many new areas of cancer care research. The Chair and members have been in discussion with other CSGs, both in person by attending their meetings, strategy meetings and clinical trial days, and also by teleconferences with their chairs and subgroup chairs. The response to the new model and willingness of the CSG to broaden its scope of research has been very well received. Potential new collaborations are being discussed with disease specific CSGs

such as Brain , Colorectal andHaematological oncology, and cross-cutting CSGs such as CTRad and Teenage & Young Adults.

The potential overlap with the Psychosocial Oncology & Survivorship CSG has been addressed and we have clarified where different emphases lie. For example, with cancer survivorship studies the Supportive & Palliative Care CSG will focus on issues such as physical rehabilitation, symptom prevalence and cardiorespiratory, endocrine, metabolic and other late consequences; whereas the POS CSG could focus on psychological, lifestyle and service delivery aspects. Of course, we are both very willing to collaborate!

In summing up, the three key achievements of 2014-2015 have been:

- adoption of a comprehensive supportive care model for all stages of cancer research
- changing the name to 'Supportive & Palliative Care'
- initiating a new wave of collaboration with other CSGs in order to broaden our – and their - portfolios.

The major 'event' for the CSG was planning for the first UK supportive care in cancer research clinical trials conference, to be held in Sheffield on 4 June 2015. The details of this conference will be reported in the 2015/2016 Annual Report, but the aspects to stress here are the strong collaboration this meeting will engender across CSGs with an interest in supportive and palliative care. It will be run under the auspices of the University of Sheffield department of oncology, with support from the NCRI. The organising committee consists of research and patient representatives from the Supportive and Palliative Care CSG, and local patient and carer representatives from the Sheffield Consumer Research Panel.

2. Structure of the Group

The Group has undergone a gradual change in membership. Two of our established members – Professor George Lewith and Professor Alison Richardson have stepped down after making significant contributions over many years. Three new members have joined - Dr Vicky Coyle, Professor Jane Hopkinson and Dr Gillian Prue. Not only have they extended our breadth of specialist research skills, but we now also include Northern Ireland in our coverage. We have also taken on two trainee members - Dr Caroline Forde and Dr Xingwu Zhu, both medical oncologists with an interest in supportive care.

The subgroup structure has remained unchanged, although since Professor Ahmedzai took over the chair of the whole CSG, the position of leading the Gastrointestinal subgroup is currently under review.

3. CSG & Subgroup strategies

Main CSG

The CSG's new strategy is embodied in the new framework for comprehensive supportive care in cancer at all stages (see Figure 1, above). We have divided the whole cancer trajectory into four logical but overlapping phases:

- at presentation (including presenting symptoms, pain and other complications of diagnostics tests and early surgery)

- during anti-cancer treatments (including early treatment toxicities of chemotherapy, biological treatments and radiotherapy)
- late consequences of cancer and of anti-cancer treatments in survivors (including chronic pain, multi-organ complications, rehabilitation needs and support with transition from hospital to community care services)
- metastatic and advanced disease stage (including management of symptoms of metastatic disease, transition to palliative care services, , complications of long-term symptom management drugs, hydration and other needs at the end of life)

We have worked with NCRI and NIHR colleagues to re-configure our portfolio to comply with this new model, and this is seen in our portfolio map in Appendix 3. In this, for simplicity the 'presentation' and 'anti-cancer treatments' have been merged, an additional column is created to show 'translational' studies in the portfolio, and new rows have been added to exemplify studies that do not fit in the current subgroup structure. One of these rows is 'Health services research' and a good example of a new study of the Group which fits in that category is the HTA-funded SPECIAL study, which is exploring quality of life, survival and health economic consequences of early referral of advanced non-small cell lung cancer patients to palliative care services.

Our previous portfolio included relatively few industry-funded studies, and we are addressing this by engaging pro-actively with UK and global companies to pursue closer collaboration. One frustration is the earlier industry-supported trials and observational studies have not usually been registered with the NIHR portfolio and so they have not contributed to the national and the CSG's targets.

Our two very experienced consumer members have continued to contribute strongly to individual studies in the subgroups but also, very importantly, the main group's deliberations about our future strategy. Their endorsement of the new comprehensive framework was influential in its adoption and we will continue to rely on our consumer members to remind us of the patient's perspective of research at all stages.

The main aim for the Group in the coming year is to work towards establishing at least one new trial or study in each of the four phases.

Rehabilitation Subgroup (Chair, Mr Matthew Maddocks)

The Subgroup has enjoyed a successful year, with completion of existing studies and funding having been secured for new studies eligible for the portfolio. Our remit is to explore interventions which aim to maximise patients' ability to function, promote independence and help them adapt to their condition. Interventions can focus on impairments caused by the illness (mostly cancer) and/or its treatment. To provide some distinction from the Psychosocial Oncology & Survivorship (POS) CSG the focus is on physical impairments and management, and shorter-term consequences of its treatment, but this is by no means restrictive. Indeed, many studies are co-adopted by the other portfolio. More joint work, particularly in the development and planning of new studies, is welcomed and encouraged.

The current portfolio offers a range of studies spanning exercise and self-management interventions, symptom prevalence and aetiology, and development of functional assessment

tools. Many current studies are nearing the end of recruitment or are in follow-up phase, so a high turnover of studies is expected in the first half of the forthcoming year.

One of the challenges of rehabilitation studies, in particular trials, is the facilities and/or resource required to offer interventions; many of which require face-to-face contact or specialist equipment. This, coupled with capped funding for pilot and development work, has led to most studies being undertaken in a small number of sites. Subgroup members would like to see studies recruiting larger numbers of patients, across many sites, and crucially being open to new sties joining. This will require larger, pragmatic trials supported by funding streams such as the NIHR HTA workstream, or simpler, resource-light studies that can be opened without heavy demands staff time.

Study proposals have been submitted with formal peer review and input from the Lung CSG.

The Rehabilitation Subgroup and its members have working links with, among others, the European Association of Palliative Care, Multinational Association of Supportive Care in Care, Society on Cachexia and Wasting Disorders and Association of Chartered Physiotherapists in Oncology & Palliative Care.

Pain & Neuropathy Subgroup (Chair, Professor Marie Fallon)

The overall aim of the Pain Subgroup is to develop robust research in the area of cancer pain. The Subgroup has a strong translational programme which is informing the clinical studies. The research being undertaken encompasses both clinical trials of novel analgesic agents (DB RCTs) which have secured funding from CRUK and Marie Curie Cancer Care, and large scale trials assessing analgesic management strategies (EPAT, TVT study).

We also have strong links with pharma which has led to commercial studies (e.g. cannabinoids for cancer pain, capsaicin for neuropathic pain).

Gastrointestinal Subgroup (Chair, Professor Sam Ahmedzai)

The Gastrointestinal Subgroup is currently focusing on the following areas:

- management of chemotherapy-induced nausea and vomiting;
- impact of opioid-induced constipation on cancer patients at different stages;
- late bowel effects of pelvic radiotherapy.

Within these areas, we have undertaken the following activities:

- conducted a national survey of chemotherapy nurse specialists to evaluate the emetic experience of patients having chemotherapy and local compliance with published anti-emetic guidelines;
- conducted a national observational study of the prevalence and impact of opioid-induced constipation and patient experience of prescribed and over-the-counter laxative treatments (BOI; AstraZeneca);
- participated in a European non-interventional study of ‘standardised laxative treatment’ for the management of opioid-induced constipation (SLT-4501; Mundipharma)
- initiated a study of bowel late effects following prostate cancer radiotherapy, using a new screening tool and testing a new approach to integrated gastroenterology and oncology intervention (EAGLE: Prostate Cancer UK).

In addition, existing studies submitted with members of the Supportive & Palliative Care CSG that are now actively recruiting include the ROCS trial, which is exploring palliative radiotherapy in addition to self-expanding metal stent for improving outcomes of dysphagia and survival in advanced oesophageal cancer.

Professor Ahmedzai is currently still acting as Chair of the Subgroup since taking over as CSG Chair, however a new subgroup chair is being sought as is a priority for the coming year.

Vascular Subgroup (Chair, Dr Vaughan Keeley)

The Vascular Subgroup focuses on thromboembolic problems in malignancy and lymphoedema. Subgroup members have been involved in a number of portfolio studies. The following are some examples:

Thromboembolism

- The SELECT D trial - This is examining anticoagulation therapy in selected cancer patients at risk of recurrence of venous thromboembolism. Chief Investigator: Annie Young. This trial is currently in recruitment.
- ALICAT - A feasibility study to inform the design of a randomised control trial to identify the most clinically, and cost effective, length of anticoagulation with low molecular weight Heparin in the treatment of cancer associated thrombosis. This trial closed in December 2014. Unfortunately it showed that a full RCT was not likely to be feasible.

Lymphoedema

- Multi frequency bioimpedance in the early detection of lymphoedema - This study of 1100 patients treated for breast cancer, with axillary node clearance, has completed recruitment and is in follow up. Chief Investigator: Professor Nigel Bundred.
- PLACE - Prevention of lymphoedema after axillary clearance by external compression. Chief Investigator: Professor Nigel Bundred. This study is in recruitment. It is a randomised control trial and, to date, has recruited nearly half of the intended target.
- CCRN 2359 (FLEXDOSE) - This is an industry funded portfolio adopted trial to determine the optimum duration of intermittent pneumatic compression treatment per day for lymphoedema. This is a small study and has nearly recruited half the number of patients required.
- LiMS - This is a study of leg oedema in Multiple Sclerosis, aimed to determine the prevalence and impact of the condition and to obtain some data on the cause or mechanisms.

It should be noted that whilst the Vascular Subgroup focus is broadly on the supportive care elements of the CSG, some of the studies include patients with progressive illnesses other than cancer.

4. Task groups/Working parties

There are currently no task groups or working parties in the Supportive & Palliative Care CSG.

A conference organising committee was set up to oversee the conference to be held on 4th June, showcasing the CSG's achievements and discussing new research opportunities with other CSGs. This committee consists of four members from the CSG (consumer representative Mrs Sharon

Paradine, Dr Teresa Young, Dr Annie Young and Professor Sam Ahmedzai), and three local members of the Sheffield Consumer Research Panel (Mr Malcolm Babb, Mrs Jacqui Gath and Ms Shirley Harrison).

5. Patient recruitment summary for last 5 years

In the Supportive & Palliative Care CSG portfolio, 14 trials closed to recruitment and 15 opened. The main trend in our clinical studies portfolio has been a progressive increase in both non-interventional and interventional study recruitment. As before, non-cancer patients form part of this CSG's remit and this is shown in the non-interventional studies. In 2014/2015, however, the proportion of cancer patients in the non-interventional observational studies was sharply elevated.

Table 1 Summary of patient recruitment by RCT/Non-RCT

Year	All subjects		Cancer patients only		% of cancer patients relative to incidence	
	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT
2010/2011	2134	1022	1415	974	-	-
2011/2012	488	637	130	622	-	-

Table 2 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	570	399	303	399	-	-
2013/2014	1473	393	524	324	-	-
2014/2015	1336	498	1290	473	-	-

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

The Supportive & Palliative Care CSG has networked extensively in the past year with all of the other NCRI CSGs and cross-cutting groups. The Chair and other members have been and will be presenting the CGS's new model and opportunities for cross-fertilisation at meetings of the following groups: CTRad; Teenage & Young Adults, Upper GI; Colorectal; Lung; Prostate; Psychosocial Oncology. Further presentations at other CSGs are planned in the coming year.

The Group is also collaborating with other groups nationally and internationally: UKONS; BTOG; MASCC; IASLC; Association for Palliative Medicine; Marie Curie Cancer Care.

The Chair has attended an initial meeting with national subspecialty chairs covering supportive, palliative and psychosocial oncology research interests. Following this, he is making individual contact with the subspecialty leads to identify problems and barriers to delivering supportive care studies in hospitals and community (including hospice) settings. Good models of supportive care research facilitation will be identified and disseminated through the CSGs and at the 2016 annual clinical trials meeting. The trainee members will be engaged in this exercise.

7. Funding applications in last year

The Supportive and Palliative Care CSG has been highly successful in the past year in winning grants from sources such as NIHR HTA, MRC, Marie Curie and other UK charities.

Table 3 Funding submissions in the reporting year

Other committees			
Study	**Committee & application type**	**CI**	**Outcome**
SPECIAL: Does early referral of patients with metastatic non-small cell lung cancer to UK specialist palliative care services make a difference in their quality of life or survival trial?	NIHR HTA	Professor Sam Ahmedzai	Funded
CHAT-P: web-based Composite Holistic Adaptive needs Assessment Tool and care planning in Prostate cancer	PC UK / Movember	Professor Sam Ahmedzai	Funded
EAGLE: Improving the Wellbeing of Men by Evaluating and Addressing the Gastrointestinal Late Effects of Radical Treatment for Prostate Cancer	PC UK / Movember	Staffurth J, Nelson A, Andreyev J, Green J, O'Sullivan J, Professor Sam Ahmedzai	Funded
SarCaBon: A randomised double-blind phase II trial of saracatinib versus placebo for cancer-induced bone pain	MRC / AstraZeneca	Dr David Andrew, Dr Sarah Danson, Professor Rob Coleman, Professor Sam Ahmedzai	Funded
Is clarithromycin a potential treatment for cachexia in people with lung cancer?	Roy Castle Lung Cancer Foundation	Dr Andrew Wilcock	Funded
Feasibility and potential benefits of a combined interval and resistance exercise programme for patients with advanced gastrointestinal cancer.	NIHR Research for Patient Benefit	Professor Alison Richardson	Not funded
A randomised placebo-controlled, double-blind, feasibility trial of mirtazapine for breathlessness in life-limiting and advanced illness	Marie Curie	Professor Irene Higginson	Funded
Improving rehabilitation services in palliative care using gaol attainment scaling	The Dunhill Medical Trust	Dr Matthew Maddocks	Funded
HYDRANT: HYDration in advanced disease – Routine practice And New Technologies. A feasibility study of two forms of clinically assisted hydration and oral hydration in advanced illness.	Marie Curie Cancer Care. Full application	Professor Sam H Ahmedzai	Pending
The perspectives of family carers and the health care team about gastrostomy feeding at the end of life in patients with head and neck cancer.	Marie Curie Cancer Care. Outline application	Dr Vanessa Halliday, Professor Sam Ahmedzai	Full application not invited

Genetic and biological determinants of health related quality of life and pain in the Myeloma X relapse (intensive) trial	Leukaemia and Myeloma Research Fund	Professor Angela Cox, Professor John Snowden, Professor Sam Ahmedzai	Funded
Changing the face of chemotherapy-induced peripheral neuropathy: a translational approach to early identification.	Mason Medical Research Trust	Dr Sabrina Ramnarine, Professor Marie Fallon	Funded
Optimising translational capacity of melatonin administration for chemotherapy induced neuropathic pain	. BJA/RCoA	Dr Carole Torsney, Mr Barry Mccormick, Dr Lesley Colvin, Professor Helen Galley, Professor Marie Fallon	Funded
. Double-blind randomised parallel group trial of paracetamol versus placebo in conjunction with strong opioids for cancer related pain	Marie Curie/CR UK	Professor Marie Fallon, Dr K Harvey, Dr C Graham, Dr Joanna Bowden, Dr Kerry McWilliams	Funded
An exploratory study to develop and evaluate a simple bedside tool for community use to identify who is most likely to benefit from palliative radiotherapy for cancer induced bone pain	Marie Curie/CRUK	Professor Marie Fallon, Dr R Parsons, Dr A Clarke, Dr Lesley Colvin, Dr Barry Laird, C Brunell, Professor Peter Hoskin, Professor P Klepstad	Funded
MENOS4: A multicentre Randomised Controlled Trial (RCT) of a breast care nurse delivered cognitive behavioural therapy (CBT) intervention to reduce the impact of hot flushes in women with breast cancer.	Breast Cancer Campaign	Dr Deborah Fenlon, Professor Gareth Griffiths	Funded
The MENAC Trial. A randomised, open-label trial of a Multimodal Intervention (Exercise, Nutrition and Anti-inflammatory Medication) plus standard care versus standard care alone to prevent / attenuate Cachexia in advanced cancer patients undergoing chemotherapy.	Marie Curie/CRUK	Professor Ken Fearon, Dr Matthew Maddocks	Pending

8. Collaborative partnership studies with industry

Currently the proportion of purely industry-funded studies in the Supportive & Palliative Care CSG portfolio is small (6/48). However, there are a further 5 studies with joint academic/industry support.

With the new comprehensive supportive care model, the Group is now engaging more than before with the pharmaceutical industry to initiate new UK-led studies, or join with existing international studies. Unfortunately in the past many of these have not been registered with NIHR and thus have not featured in the NCRI and this CSG's portfolio. Examples of the new engagement include AstraZenca (new agent for opioid-induced constipation); Chugai (studies in cachexia); Grunenthal (new drug for cancer pain - CORAL); Mundipharma (non-randomised interventional study in opioid-induced constipation); Prostrakan (new patch formulation of granisetron); Discussions are also taking place with medical device manufacturers, eg Convatec, to explore new safer and more reliable ways of delivering drugs for symptom control as well as giving clinically assisted hydration at the end of life.

9. Impact of CSG activities

The work of the CSG has started to make an impact on clinical practice, e.g. more rigorous assessment and management of lymphoedema; greater use of formal holistic needs assessment tools in clinics. Results from drug studies are generally not mature enough, to have made a significant change in prescribing in oncology and palliative care settings.

The future for supportive and palliative care interventional studies is, however, more promising, in part owing to the rise of new targeted therapies that will focus more on cancer symptoms and treatment toxicities. Examples include anti-NGF antibodies for management of bone cancer and potentially other forms of neuropathic pain; pharmaceutical packaging of peripherally acting opioid antagonists for targeted treatment of opioid-induced constipation; anti-ghrelin agents for cancer cachexia. Some of these agents have been trialled in USA and other European countries but discussions are underway with industry to initiate new studies now in UK centres.

Members of the CSG have contributed to the 2014-2015 James Lind Alliance priority-setting partnership with Marie Curie Cancer Care, which launched its results in early 2015. There are over 80 topics identified, many of which could be developed by the CSG into funding applications for observational studies, clinical trials or health service delivery model research

10. Consumer involvement

The CSG has two consumer members who attend the biannual meetings of the main group and are actively involved in the subgroups. It is accepted that consumer involvement is pivotal, and the current advocates are a supportive and perceptive component of the Supportive & Palliative Care CSG. The consumers have commented on draft protocols and have helped to inform trial design throughout the year.

One of the consumers, Mrs Lesley Turner, is a co-applicant on three supportive care studies and is a founder member of the Breast CSG working group on symptom management, providing a link between the two CSGs. The group is currently working on Hot flushes and lymphoedema. Mrs Turner has also carried out research on mentoring within the CSGs and co-authored a report

which has been copied to the NCRNCC and NCRI/NCRN to help inform the strategic review of consumer involvement. She also co-produced a survey to gather information for an editorial about follow up for cancer patients which was published in Clinical Oncology. Lesley has also presented a 40 minute plenary lecture to the East Yorkshire Clinical Academic Trainees and Doctoral Clinical Fellows on the impact of good Patient and Public Involvement. She has been a member of the Patient and Public Involvement (PPI) Steering Group and a member of the NCRI Hub. She has acted as the Chair of SPADE (Strategic PPI Advice, Delivery and Evaluation Panel) delivering specific projects to a tight time scale.

Mrs Sharon Paradine has commented on a number of programme grants, and has been instrumental as part of a team planning the first UK Clinical Trials Conference for Supportive Care in Cancer Research to be held in Sheffield in June 2015.

11. Open meetings/annual trials days/strategy days

The CSG will hold its first clinical trials day, which has been organised as an open conference at the University of Sheffield, on 4th June 2015. Delegates will consist of researchers from the Supportive & Palliative Care as well as the many other CSGs, sponsors from industry and national charities. The overall aim of the conference will be 'To promote supportive care research at all stages of cancer'. Specific objectives are to include:

1. To review NCRI supportive and palliative care trials portfolio
2. To facilitate interaction with other NCRI groups
3. To bring the activities of the NCRI to a wide audience.

Further details will be given in the 2015/16 annual report.

12. Progress towards achieving the CSG's 3 year strategy

The CSG's current research strategy is aimed at populating the new framework for comprehensive supportive care research at all stages of cancer (see Figures 1&2 above). The areas which are currently strong are 'treatment-related toxicities' and 'symptoms of recurrence and progressive disease'. More work needs to be done on 'symptoms at presentation', 'issues at end of life' and 'late effects in survivors'. This will be done largely by engaging other CSGs to design studies to explore these issues in specific cancers, sometimes by making 'add-on' studies to existing trials. Increasingly we will aim to add translational elements to new studies, directing funding application as appropriate to CTAAC, charities or industry.

13. Priorities and challenges for the forthcoming year

The key priorities for the Supportive & Palliative Care CSG for the coming year are to:

- Use the CSG's own skills and work with other CSGs to design and ideally submit for funding at least one new study in each of the identified phases in the new framework
- Successfully deliver the first trials meeting in June 2015 and start organising a second in 2016 to make this an annual event
- Increase the number of studies with a translational element.

The main challenges we face this year are:

- Breaking down the old subgroup orientation of the CSG to embrace a wider skill-mix in designing new studies in other clinical areas, eg at presentation of cancer, survivorship, health services research
- Overcome difficulties in getting supportive and palliative care studies funded at national level
- Identifying barriers to implementation of existing and new studies in centres with poor history of recruitment and retention of patients, including in hospices.

14. Concluding remarks

In summary, 2014/2015 has seen a radical re-visioning of the Supportive & Palliative Care CSG. From the reworded title, to the new theoretical framework of comprehensive supportive care research across all stages of cancer, the CSG is now poised to engage more actively in the 'mainstream' of NCRI clinical trials activity. Its new intake of members and trainee members will help us break down the old subgroup oriented approach to a more integrated model of designing and implementing multidisciplinary research. This will require considerable energy and commitment to re-focus the existing members' significant research expertise and skills. The Chair is determined to encourage each CSG member to make their maximum contribution to work not only for their own discipline and organisation, but much more for the greater good of the NCRI.

15. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies
- A – Main CSG Strategy
- B – Rehabilitation Subgroup Strategy
- C – Pain & Neuropathy Subgroup Strategy
- D – Gastrointestinal Subgroup Strategy
- E – Vascular Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

Professor Sam Ahmedzai (Supportive & Palliative CSG Chair)

Appendix 1

Membership of the Supportive & Palliative Care CSG

Name	Specialism	Location
Dr Gillian Prue	Chronic Illnesses	Belfast
Dr Jacqui Stringer	Complementary Therapies	Manchester
Mrs Sharon Paradine	Consumer	Suffolk
Mrs Lesley Turner	Consumer	Southampton
Dr Teresa Young	Health Service Researcher	Middlesex
Dr Vicky Coyle	Medical Oncologist	Belfast
Dr Caroline Forde*	Medical Oncologist	Belfast
Dr Anthony Maraveyas	Medical Oncologist	Hull
Dr Dawn Storey	Medical Oncologist	Glasgow
Dr Xingwu Zhu*	Medical Oncologist	Middlesex
Professor Jane Hopkinson	Nurse	Cardiff
Professor Annie Young	Nurse	Warwick
Professor Sam H Ahmedzai (Chair)	Palliative Medicine	Sheffield
Dr Richard Berman	Palliative Medicine	Manchester
Professor Marie Fallon	Palliative Medicine	Edinburgh
Professor Miriam Johnson	Palliative Medicine	York
Dr Vaughan Keeley	Palliative Medicine	Derby
Dr Matthew Maddocks	Physiotherapist	London
Professor Gareth Griffiths	Statistician	Southampton

* denotes trainee

Membership of the Subgroups

Rehabilitation Subgroup		
Name	**Specialism**	**Location**
Mrs Sharon Paradine	Consumer	Suffolk
Mrs Lesley Turner	Consumer	Southampton
Dr Teresa Young	Health Service Researcher	Middlesex
Dr Andrew Wilcock**	Medical Oncologist	Nottingham
Professor Alison Richardson	Nurse	Southampton
Professor Annie Young	Nurse	Warwick
Dr Anthony Byrne	Palliative Medicine	Penarth
Professor Miriam Johnson	Palliative Medicine	York
Dr Matthew Maddocks (Chair)	Physiotherapist	London
Professor Ken Fearon	Surgeon	Edinburgh

Gastroinestinal Subgroup		
Name	**Specialism**	**Location**
Professor Annie Young	Nurse	Warwick
Dr Sam Ahmedzai (Chair)	Palliative Medicine	Sheffield
Dr Richard Berman	Palliative Medicine	Manchester
Dr Anthony Byrne	Palliative Medicine	Penarth

Pain & Neuropathy Subgroup		
Name	**Specialism**	**Location**
Professor George Lewith	Acupuncturist	Southampton
Dr Barry Laird	Clinician Scientist	Edinburgh
Dr Jacqui Stringer	Complementary Therapies	Manchester
Mrs Sharon Paradine	Consumer	Suffolk
Mrs Lesley Turner	Consumer	Southampton
Dr Dawn Storey	Medical Oncologist	Glasgow
Professor Sam Ahmedzai	Palliative Medicine	Sheffield
Professor Mike Bennett	Palliative Medicine	Leeds
Professor Marie Fallon (Chair)	Palliative Medicine	Edinburgh

Vascular Subgroup		
Name	**Specialism**	**Location**
Ms Teresa Young	Health Service Researcher	Middlesex
Dr Anthony Marayevas	Medical Oncologist	Hull
Professor Annie Young,	Nurse	Warwick
Dr Vaughan Keeley (Chair)	Palliative Medicine	Derby
Dr Simon Noble	Palliative Medicine	Newport

* denotes trainee

** denotes non-core member

Appendix 2

CSG & Subgroup Strategies

A – Main CSG Strategy

The CSG's new strategy is embodied in the new framework for comprehensive supportive care in cancer at all stages (see Figure 1 above). We have used the definition of 'supportive care in cancer' from MASCC – the Multinational Association for Supportive Care in Cancer:

"Supportive Care in Cancer is the prevention and management of the adverse effects of cancer and its treatment. This includes management of physical and psychological symptoms and side effects across the continuum of the cancer experience from diagnosis through anticancer treatment to post-treatment care. Enhancing rehabilitation, secondary cancer prevention, survivorship and end of life care are integral to Supportive Care.

Supportive Care:

- *alleviates symptoms and complications of cancer*
- *reduces or prevents toxicities of treatment*
- *supports communication with patients about their disease and prognosis*
- *allows patients to tolerate and benefit from active therapy more easily*
- *eases emotional burden of patients and care givers*
- *helps cancer survivors with psychological and social problems"*

Based on this definition and scope of supportive care, we have divided the whole cancer trajectory into four logical but overlapping phases:

- at presentation (including presenting symptoms, pain and other complications of diagnostics tests and early surgery)
- during anti-cancer treatments (including early treatment toxicities of chemotherapy, biological treatments and radiotherapy)
- late consequences of cancer and of anti-cancer treatments in survivors (including rehabilitation needs and support with transition from hospital to community care services)
- metastatic and advanced disease stage (including transition to palliative care services, management of symptoms of metastatic disease, complications of long-term symptom management drugs, hydration and other needs at the end of life)

Our strategy for the CSG in the coming years is to ensure that we address supportive care needs of cancer patients at all stages, by the following four actions:

1. Initiating new studies in each stage of cancer from the CSG's expertise and using funding from NIHR and other RC UK sources
2. Collaborate with pharmaceutical and medical device companies to initiate new industrially supported studies
3. Collaborate with other NCRI CSGs and cross-cutting groups such as CTRad to increase studies in those groups with supportive and palliative care endpoints
4. Ensure we are addressing the patient and carer agenda in designing studies which place quality of life and patient experience at the centre of our studies.

In addition, the CSG will address the scientific basis of symptom palliation by including, wherever possible and appropriate, translational elements to future studies.

An important objective of our new broader approach is to conduct more work on developing studies outside of the existing subgroups. Thus, the topic of hydration at the end of life has grown in importance in recent years, since the 'demise' of the Liverpool Care Pathway. The CSG will address this and other cross-cutting supportive care and end of life issues by drawing together expertise from individuals both within the CSG and also by co-opting experts from outside.

B – Rehabilitation Subgroup Strategy

The Subgroup's remit is to explore interventions which aim to maximise patients' ability to function, promote independence and help them adapt to their condition. Interventions can focus on impairments caused by the illness (mostly cancer) and/or its treatment. To provide some distinction from the Psychosocial Oncology & Survivorship CSG the focus is on physical impairments and management, and shorter-term consequences of its treatment, but this is by no means restrictive. Indeed, many studies are co-adopted by the other portfolio. More joint work, particularly in the development and planning of new studies, is welcomed and encouraged.

The current portfolio offers a range of studies spanning exercise and self-management interventions, symptom prevalence and aetiology, and development of functional assessment tools. Many current studies are nearing the end of recruitment or are in follow-up phase, so a high turnover of studies is expected in the first half of the forthcoming year.

One of the challenges of rehabilitation studies, in particular trials, is the facilities and/or resource required to offer interventions; many of which require face-to-face contact or specialist equipment. This, coupled with capped funding for pilot and development work, has led to most studies being undertaken in a small number of sites.

Subgroup members would like to see studies recruiting larger numbers of patients, across many sites, and crucially being open to new sties joining. This will require larger, pragmatic trials supported by funding streams such as the NIHR HTA work-stream, or simpler, resource-light studies that can be opened without heavy demands staff time.

C – Pain & Neuropathy Subgroup Strategy

The overall aim of the Pain & Neuropathy Subgroup is to develop robust research in the area of cancer pain. The Subgroup has a strong translational programme which is informing the clinical studies. The research being undertaken encompasses both clinical trials of novel analgesic agents (DB RCTs) which have secured funding from CRUK and Marie Curie Cancer Care, and large scale trials assessing analgesic management strategies (EPAT, TVT study).

The Pain & Neuropathy Subgroup also has strong links with pharma which has led to commercial studies (e.g. cannabinoids for cancer pain, capsaicin for neuropathic pain).

D – Gastrointestinal Subgroup Strategy

The Gastrointestinal Subgroup is currently focusing on the following areas:

- management of chemotherapy-induced nausea and vomiting
- impact of opioid-induced constipation on cancer patients at different stages
- late bowel effects of pelvic radiotherapy.

Other areas that may be addressed in future studies include: gastrointestinal mucositis with high dose chemotherapy and radiotherapy; bowel obstruction and its medical management; malignant ascites.

E – Vascular Subgroup Strategy

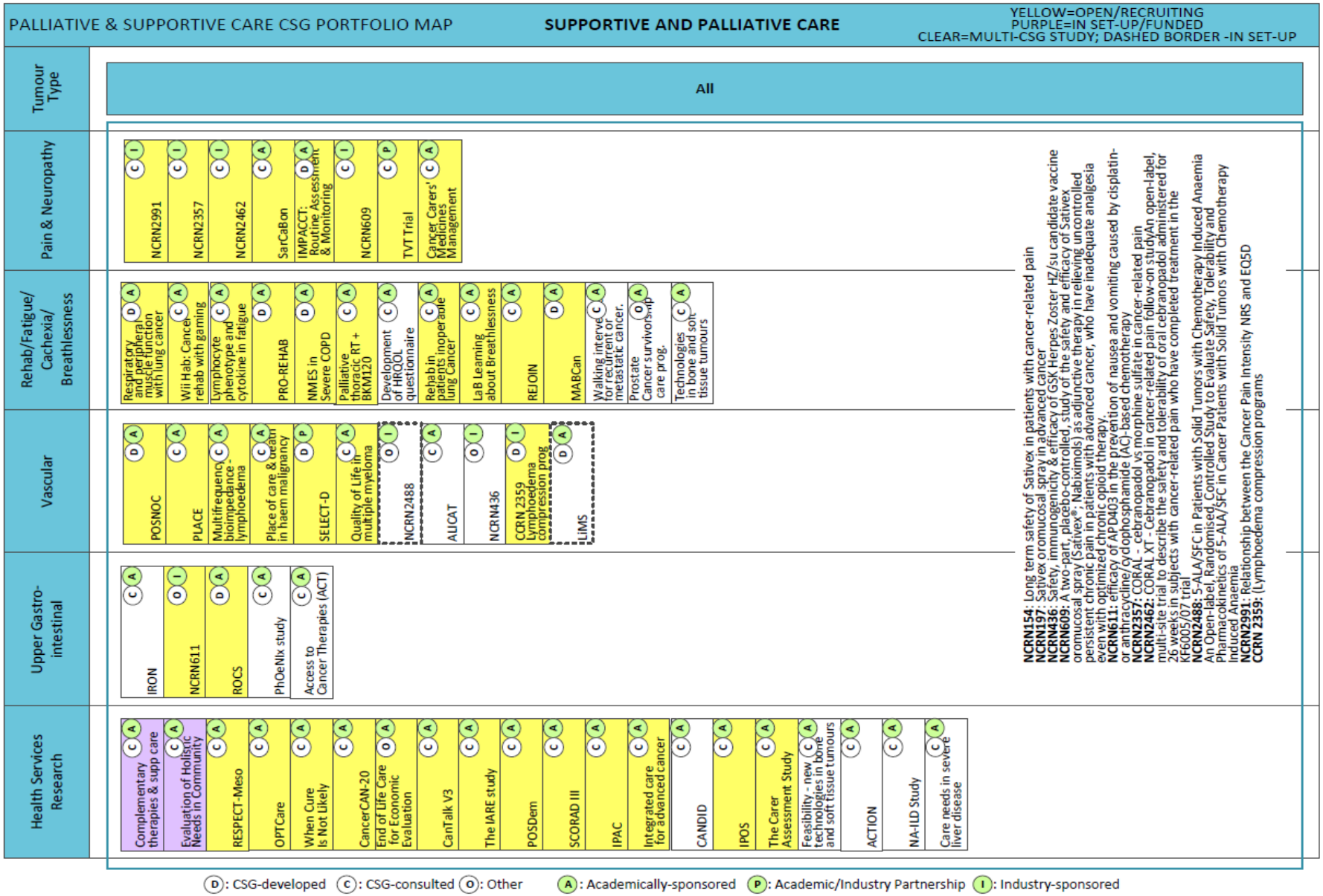
The Vascular Subgroup focuses on thromboembolic problems in malignancy and lymphoedema. Subgroup members have been involved in a number of portfolio studies, including the following areas:

- Thromboembolism
- Lymphoedema.

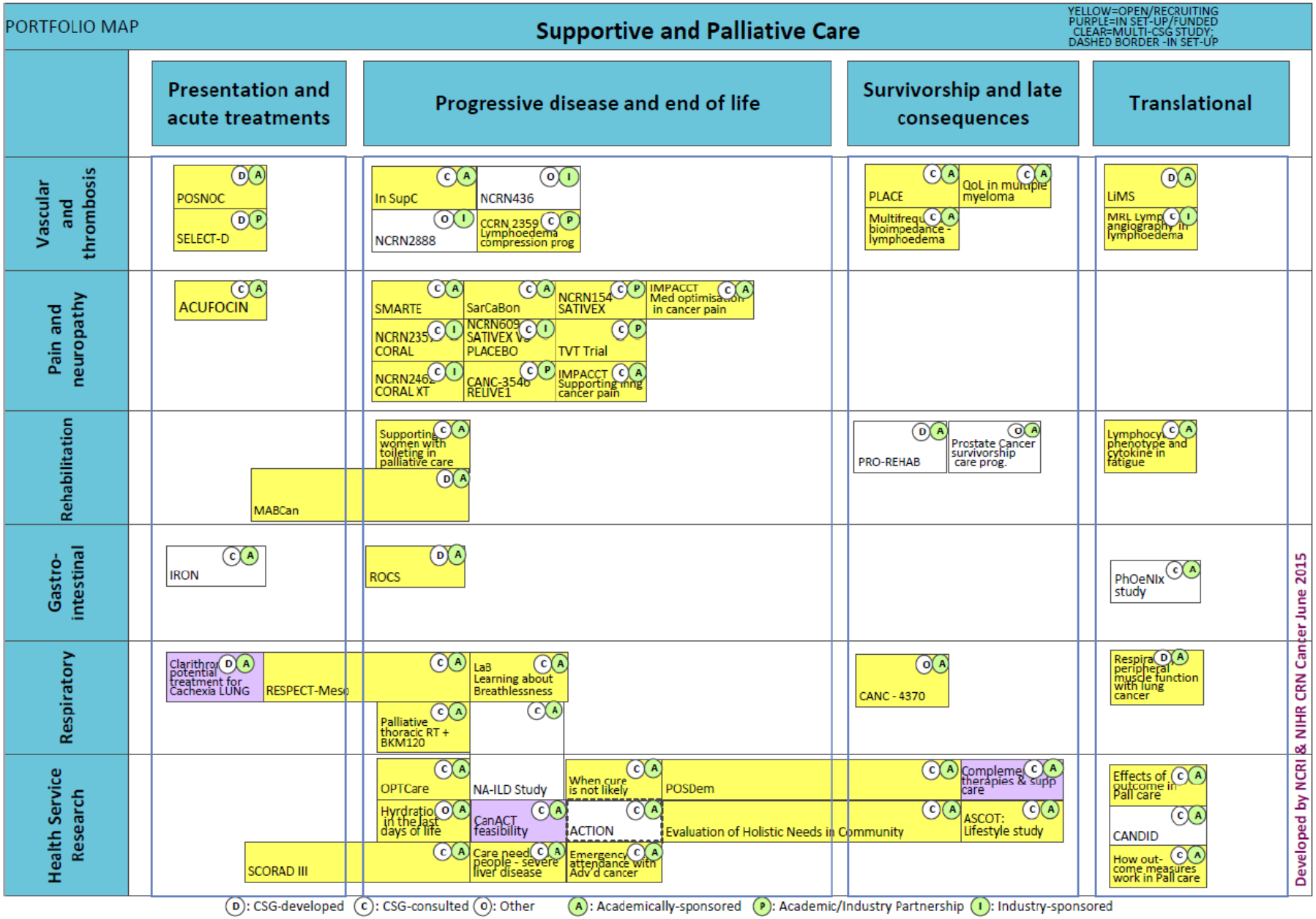
It should be noted that whilst the Vascular Subgroup focus is broadly on the supportive care elements of the CSG, some of the studies include patients with progressive illnesses other than cancer.

Appendix 3

Portfolio map (as at March 2015, close of reporting year)



Portfolio map (revised version to be taken forward, as referenced in section 3)



Appendix 4

Publications in the reporting year

NMES trial

Maddocks M, Halliday V, Chauhan A, Taylor V, Nelson A, Sampson C, Byrne A, Griffiths G, Wilcock A, Neuromuscular electrical stimulation of the quadriceps in patients with non-small cell lung cancer receiving palliative chemotherapy: A randomized phase II study (2013), *PLOS ONE*. Dec 8:e86059.

KPS

Fallon M, Storey D, Krishnan A, Weir C, Mitchell R, Fleetwood-Walker S, Scott A, Colvin L. Cancer treatment related neuropathic pain: Proof of Concept Study with menthol, a TRPM8 agonist. *Supportive Care in Cancer 2015* (published online Feb 2015) (DOI) 10.1007/s00520-015-2642-8

Seretny M, Currie G, Sena E, Ramnarine S, Grant R, MacLeod M, Colvin L and Fallon M. Incidence, prevalence and predictors of chemotherapy-induced peripheral neuropathy: a systematic review and meta-analysis. *Pain* 2014; 155(12):2461-2470

Pachman D, Watson J, Lustberg M, Wagner-Johnston N, Chan A, Broadfield L, Cheung Y, Steer C, Storey D, Chandwani K, Paice J, Jean-Pierre P, Oh J, Kamath J, Fallon M, Strik H, Koeppen S, Loprinzi C. Management Options for Established Cancer-Induced Peripheral Neuropathy. Supportive Care in Cancer 2014; 22: 2281-2295

Currie G, Sena E, Fallon M, MacLeod M, Colvin L. Using animal models to understand cancer pain in humans. *Curr Pain Headache Rep* 2014; 16(6) 423

Mulvey M, Rolke R, Klepstad P, Caraceni A, Fallon M, Colvin L, Laird B, Bennett M. Confirming neuropathic pain in cancer patients: applying the NeuSIG grading system in clinical practice and clinical research. *Pain* 2014 155(5); 859-863

MacLeod N, Price A, O'Rourke N, Fallon M, Laird B. Radiotherapy for the treatment of pain in malignant pleural mesothelioma: a systematic review. *Lung Cancer* 2014; 83: 133-138

EPAT Trial

Besley C, Kariuki H, Fallon M. A pilot study investigating the effect of a patient-held assessment tool in palliative care out-patients attending a rural Kenyan hospital. *Palliative Medicine* 2014; 28(9): 1156-1160

TVT Trial

Ripamonti C, Bossi P, Santini D, Fallon M. Pain related to cancer treatments and diagnostic procedures: a no man's land? *Annals of Oncology* 2014; 25: 1097-1106

McWilliams K, Simmons C, Laird B, Fallon M. A systematic review of opioid effects on the hypogonadal axis of cancer patients. *Supportive Care in Cancer* 2014; 22: 1699-1704

Pregabalin study

Sande TA, Scott AC, Laird BJA, Wan HI, Fleetwood-Walker SM, Kaasa S, Klepstad P, Mitchell R, Murray GD, Colvin L, Fallon M. The characteristics of physical activity and gait in patients receiving radiotherapy in cancer induced bone pain. *Radiotherapy and Oncology* 2014; 11(1): 18-24

Cancer Carers' Medicines Management

Latter S, Hopkinson JB, Lowson E, Duke S, Anstey S, Bennett M, Smith P, May C, Richardson A (2014) Study protocol for a feasibility trial of Cancer Carer Medicines Management (CCMM): an educational intervention for carer management of pain medications in cancer patients at end of life. *Working Papers in Health Sciences*. 1(8) Summer ISSN 2051-6266/20140044

Hopkinson J. (2014) Challenges to pain medicines management at home: commentary on the Schumacher et al. papers. *Journal of Pain and Symptom Management*. 48(5), 760-761.

Appendix 5

Major international presentations in the reporting year

Pregabalin study

2014 Strathcarron Conference, The character of bone pain

KPS

2014 Association of Palliative Care Congress, Harrogate. Ketamine in Pain Study

EPAT, KPS, Pregabalin, TVT

2015 AOSRA-PM 2015, Thailand. Cancer pain assessment and management

2014 Asian Australasian Federation of Pain Societies Congress, Taiwan. Challenges in the Management of Cancer Pain: Key Learnings

TVT

2014 Norwegian National Conference of Palliative Care, Trondheim. The future in palliative care – where are we going? Non-cancer patients

Pregabalin, TVT

2014 CIRSE, Glasgow. Bone pain in cancer patients – Non-IR treatment options

EORTC SWB36 Validation Phase 4 Trial

T. Young. Cross-cultural Validation of an EORTC Measure of Spiritual Wellbeing (SWB), (2014). European Association of Palliative Care (EAPC) Congress, Lleida, Spain. 5th May 2014

T. Young, Psychometric Validation of an EORTC Measure of Spiritual Wellbeing in patients with advanced cancer, (2014) International Society of Quality of Life Conference (ISOQOL), Berlin 18th Oct 2014

Cancer Carers' Medicines Management

Duke S, Anstey S, Lund S, Hopkinson JB, Richardson R, May CR, Smith PW, Bennett MI, Latter SM. (Sept 2014) Using ethno-drama to create an interactional intervention as part of modelling a complex intervention in a phase I-II research study. 12th International Conference on Communication in Healthcare (ICCH), Amsterdam, The Netherlands.

Hopkinson J, Richardson A, Lowson E, Duke S, Anstey S, Bennett M, Smith P, May C, Latter S (Jun 2014) Cancer Carers Medicines Management: a feasibility trial of an educational intervention for managing end of life pain medication. MASCC, Miami, USA.