NCRI Clinical Studies Groups
Review 2011-12

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Executive Summary

The NCRI Clinical Studies Groups (CSGs) were created 10 years ago and have developed a world leading academic portfolio of trials that has enabled the NCRN to achieve a 4-fold increase in clinical trials participation within the UK. Clearly the CSGs have been highly successful, but a review of their structure, function, value for money and future strategy was requested by Professor Matt Seymour, Director of the NCRN to ensure their continued success in the next 10 years.

This review has consulted current and past CSG chairs, the NCRI funders who financially support the CSGs and the Operational Steering Group for the NCRN. The review finds that the current configuration and structure of the CSGs remains relevant and broadly effective but there are opportunities for improvement and development. The recommendations within this report seek to:

- improve the development of a more complete research portfolio, covering research areas that are relevant to multiple disease sites,
- streamline the CSG membership,
- simplify and formalise the CSG subgroup structures,
- develop a mechanism for more meaningful portfolio management,
- monitor and review budgets for CSG and subgroup meetings on a regular basis
- enhance the administrative support provided to CSGs
- simplify annual reporting

Implementation of the proposed changes is planned to take place over the next 12-18 months and will require continued investment by the NCRI partners to ensure that clinical and translational cancer research in the UK both maintains its world leading position and adapts to the increasing pace of development and changes in personalised medicine anticipated over the next 10 years.

List of appendices

Background

The NCRI Clinical Studies Groups (CSGs) were formed in 2001, coincident with the launch of the National Cancer Research Network (NCRN). They are the engine for developing and coordinating expansion of the UK's national portfolio of high quality cancer research trials and other well-designed studies, and are therefore core to the UK's national project to bring benefit to patients through increased speed and quality of cancer research. They have been key to galvanising investigators' commitment and shaping a coherent UK-wide research community and one of the factors underpinning the more than 4-fold increase in recruitment of cancer patients to research studies in the UK.

The roles of the CSGs (Appendix 1) have expanded substantially over the 10 years since their formation, but the primary purpose of each remains: to develop new research studies within a given field, addressing the most important areas of clinical and scientific need and the priorities of patients. CSGs also have a wider remit to stimulate, advise upon and co-ordinate clinical and translational research nationally, and together with NCRN to oversee the effective delivery of the whole national research portfolio.

Trial ideas are welcomed from researchers both within and outside the Groups, and include studies from international groups such as EORTC and high quality industry-sponsored trials. The national delivery of commercially sponsored trials is increasingly key to maintaining Department of Health support for the clinical trials infrastructure, and the CSGs have come to play a critical role in assuring that the best industry trials are the ones that come into the portfolio, and that once adopted they receive support from the research community and are successfully delivered.

CSGs are the primary conduit for engagement of the clinical research community and patients in research initiatives both within NCRI and with external partners, such as NCRN-ECMC-Industry Alliances and the International Rare Cancers Initiative. CSGs are also regularly called upon to provide expert advice to the Department of Health and the National Institute for Health and Clinical Excellence (NICE) to inform health service and commissioning policy. Thus, in the 12 months to April 2011, thirteen of the site-specific CSGs contributed to a total of 133 consultation rounds for NICE and produced 17 reports signalling new technologies for the National Horizon Scanning Centre.

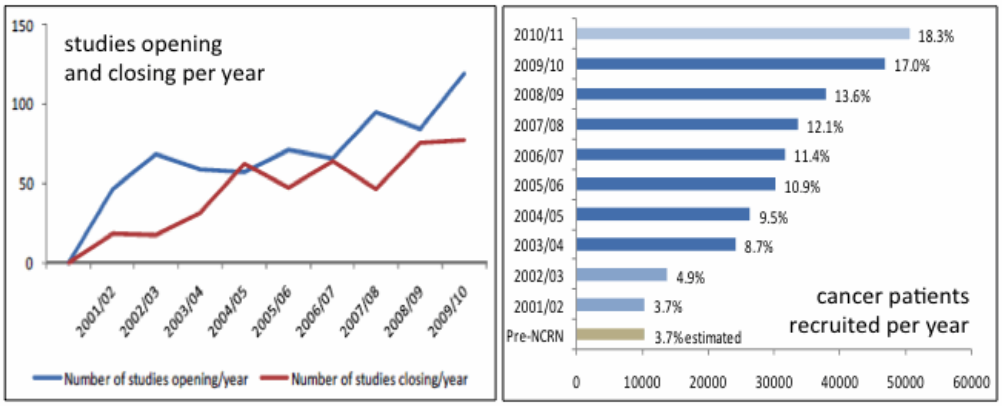
Since 2001, the portfolio of trials has grown rapidly and recruitment has increased steadily. As of February 2012, there were 1317 studies on the NCRN cancer trials portfolio, of which 488 are open, 768 closed to recruitment and 61 in set-up (Table 1). Additionally over the last 3 years, a rapidly enlarging portfolio of more than 200 industry-sponsored studies has been adopted into this portfolio. Over the 10 years since the NCRN and NCRI CSGs were formed > 250,000 cancer patients have been recruited into portfolio studies. Recruitment rates (as a percentage of

cancer incidence) continue to rise, and in 2010/11 reached 7.6% into RCTs and nearly 20% into all studies.

Table 1: CANCER TRIALS PORTFOLIO BY CSG AS OF FEBRUARY 2012.

Clinical studies group	In set-up	Open to recruitment	Closed/suspended	Total
Site-specific CSGs:				
Bladder Cancer CSG	3	10	18	31
Brain Tumour CSG	0	16	10	26
Breast Cancer CSG	8	81	142	231
Colorectal Cancer CSG	6	46	68	120
Gynaecological Cancer CSG	7	26	52	85
Haematological Oncology CSG	8	61	48	117
Head and Neck Cancer CSG	7	17	30	54
Lung Cancer CSG	5	49	63	117
Lymphoma CSG	1	37	45	83
Melanoma CSG	2	15	27	44
Prostate Cancer CSG	4	30	48	82
Renal Cancer CSG	2	12	11	25
Sarcoma CSG	2	17	10	29
Testis Cancer CSG	1	5	13	19
Upper GI Cancer CSG	4	42	51	97
Cross-Cutting CSGs:				
Biomarkers & Imaging CSG	0	3	0	3
Children's Cancer & Leukaemia CSG	3	37	64	104
Complementary Therapies CSDG	1	2	12	15
Palliative Care CSG	1	32	40	73
Primary Care CSG	0	8	22	30
Psychosocial Oncology CSG	4	24	61	89
Teenage & Young Adult CSG	0	2	2	4
Portfolio Totals	**61**	**488**	**768**	**1317**

The most readily measurable broad impacts of CSG activity are the number of studies gaining funding approval and entering the portfolio, and the numbers of patients recruited. These data, given here for all CSGs combined, show a steady increase throughout the 10-year lifetime of the CSGs and the NCRN:



It should be noted that the current rate of patient recruitment, representing over 18% of total cancer incidence, is unparalleled in the world, with USA and mainland Europe currently running at around 5%. Detailed analysis of CSG research outputs is beyond the scope of this report.

There are currently 22 CSGs: 15 disease-site specific groups, many emanating from the previous UKCCCR and MRC study groups, a recently formed Children's Cancer and Leukaemia CSG (CCL), a Teenagers and Young Adults (TYA) CSG, 5 cross-cutting CSGs (Primary Care, Psychosocial Oncology, Complementary Therapies, Palliative Care and a Translational Science Group, now known as Biomarkers and Imaging). There is also a Consumer Liaison Group (CLG). Originally there was a Radiotherapy CSG, but this was amalgamated into the CTRad group, formed 4 years ago which is currently chaired by Prof. Tim Illidge. The site-specific CSGs are:

- Breast
- Colorectal
- Gynaecology (GYN)
- Upper Gastrointestinal (UGI)
- Lung
- Lymphoma
- Haematological Oncology (H-O)
- Sarcoma
- Melanoma
- Brain
- Head and Neck (HN)
- Prostate
- Renal
- Testis
- Bladder

The inter-relationships between CSGs and the other components of the cancer research structure are summarised in Figure 1. NCRN also hosts two additional resources that interact

closely with the CSGs to optimise the quality and delivery of research studies developed by them. These are the Chemotherapy & Pharmacy Advisory Service (CPAS) and the NCRI Accredited Trials Units Heads committee.

Structure & Governance

Each CSG has around 20 (maximum 27) scientific members with expertise spanning relevant fields, plus 2-3 public/patient (PPI) members. CSG Chairs and Members are appointed competitively, after open advertisement, for fixed terms. The full CSG meets 2-3 times per year, with the option of an extended 'strategy day' every 2-3 years. CSG Subgroups are developed to develop specific aspects of the CSG's portfolio, with more flexible membership bringing in new researchers who are not yet full CSG members. In all, at any one time around 600 scientific and 50 PPI members are engaged in CSGs and CSG Subgroups, each devoting between 4 and 20 days per year to CSG tasks depending on their involvement in projects and subgroups. Several CSGs also host an annual national open meeting.

As well as reporting to the NCRI Board, the CSGs receive overall directorship from the NCRN Director and NCRN Operational Steering Group. A regular forum, chaired by the NCRN Director and attended by CSG Chairs and relevant stakeholders, is used to maintain communications and develop strategy. Each CSG produces an annual written report of activity and plans, and undergoes 3-yearly peer review entailing scrutiny by both UK and international reviewers and representatives of funders.

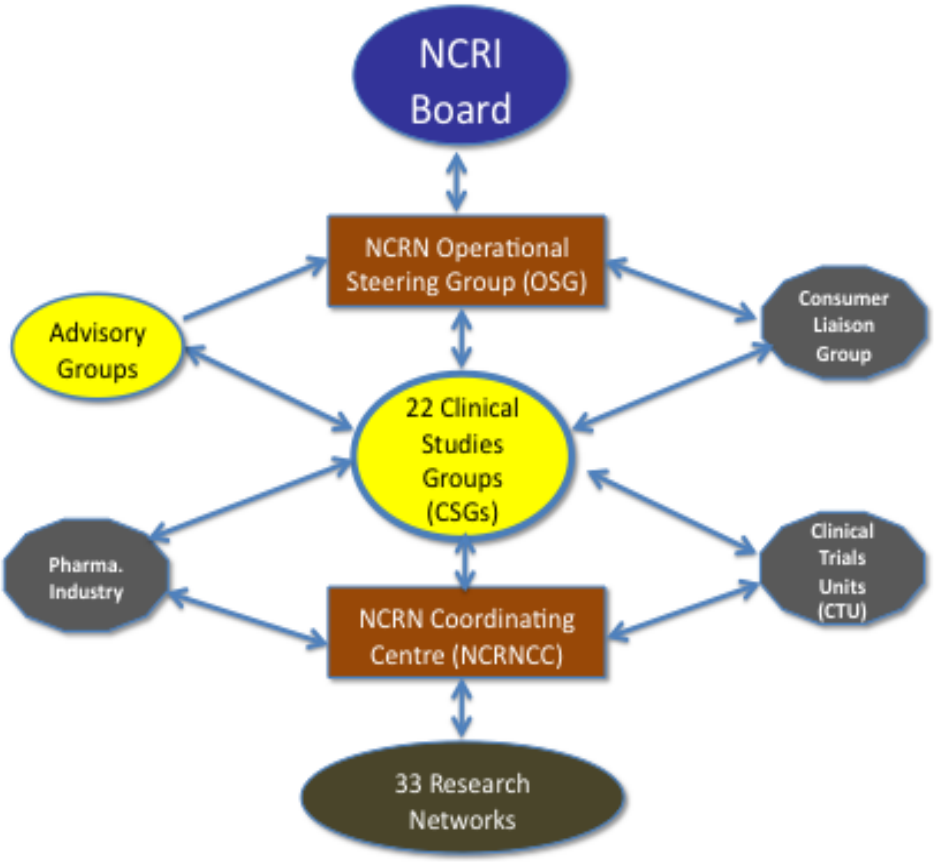


Figure 1:

CSG Chairs are appointed following advertisement and formal interview. Prospective chairs are expected to be of international standing in the disease area, with significant research experience, and display commitment, enthusiasm and the necessary skill-set to lead and chair a diverse membership. CSG Chairs are also unpaid but receive travelling expenses to attend relevant meetings. CSG Chairs are appointed for 3 years in the first instance but may apply for a second term. The CSG Chairs meet 3 times a year as a group with the NCRN Director in the above mentioned Chairs' Forum.

The CSGs have developed a number of subgroups over the years. These vary considerably in number and scope between CSGs and, despite formal existing terms of reference, are run on a much more informal basis without the same level of oversight in terms of membership, appointment of chairs or duration of tenure as exists for the main CSGs.

CSGs members are appointed following national advertisement and review of applications by one of the NCRN directors, the relevant CSG Chair and Eileen Loucaides from the NCRI CSGs Secretariat. Prospective members have to show expertise in the disease area, a demonstrable

track record in research and be at consultant level (or equivalent if non-medical). Membership, where possible, is geographically varied and includes members from the devolved nations. Representation of as many relevant specialties is encouraged e.g. surgery, medical and clinical oncology, trial statistics, pathology, radiology, and some groups also have oncology nursing representation. All CSGs include 2-3 consumer members. Membership is for three years in the first instance, renewable on application for a further two years. Continued membership beyond 5 years is allowed in exceptional circumstance where a member provides unique expertise or is chairing a successful subgroup. Members are unpaid but receive reasonable travelling expenses to attend committee meetings.

All CSGs produce an annual report. The Chair usually writes this, with considerable input from the NCRI Secretariat. The NCRN Director and the Operational Steering Group (OSG) review annual reports. Every three years, a review panel, comprised of a senior member(s) of the NCRN, 2-3 international experts in clinical research, a CSG Chair, funding representative, plus the Senior Executive to the NCRI CSGs Secretariat, assesses each CSG. The CSG Chair, usually with 2-4 other key members of the CSG attend and, on the basis of a written report and discussion at the review meeting, an evaluation on past performance and guidance on future strategy is provided.

Resources & Budget

Membership of an NCRI CSG is seen as a privilege, both by members and their NHS or academic employers. Scientific members are not paid by NCRI, but receive travelling expenses for the main CSG meetings. PPI members receive expenses and an attendance allowance from the NIHR Cancer Research Network, and NCRN also funds a Consumer Liaison Group to provide support and training. Core administrative support is provided by the NCRI CSGs Secretariat which is part of the NCRN Coordinating Centre team, hosted by CR-UK and accommodated alongside the NCRI Secretariat in the Angel Building. Services include appointment and rotation of members, organisation and minuting of meetings, booking rooms and refreshments, setting up teleconferences, organisation of annual open meetings, collation of activity data, preparation of annual reports and organisation of triennial external peer review. Project Officer posts, funded by industry partners, have allowed new cross-CSG initiatives to be developed, e.g. portfolio maps and a recent development in Screening, Prevention and Early Diagnosis.

The different size and activity levels of the 22 CSGs created variable demand for expenditure to support their meetings.

Efforts are made to limit the cost of CSG meetings. From 2012, WebEx teleconferencing will be provided by NCRN and its use is being encouraged for Subgroups. However, CSG Chairs feel that face-to-face contact is an important element of the main CSG meeting interactions. Travel expenses are limited to standard class and members are encouraged to use cheap advance purchase deals. When possible, meeting times are set to avoid the most expensive travel.

The cost of CSG meetings has been greatly limited by free use of CR-UK and MRC meetings rooms, however there is a risk that with closure of Albany House in November 2012, costs will increase. In the last year we held 36 main CSG meetings and 50 Subgroup meeting Albany House. Alternative free options are being sought, but when rooms have to be hired the typical cost is around £500 for a main CSG or £300 for a Subgroup meeting.

The Case for Review

Much has changed in the 10 years since the CSGs were established:

- The nature and complexity of clinical trials have changed, almost beyond recognition, with the requirements of the European Union Clinical Trials Directive (EU-CTD) and research governance regulations within R&D departments in NHS Trust hospitals.

- Our increasing understanding of the biology of cancer is leading to increasingly personalised (biomarker determined) treatment protocols, and as a result smaller, more specific trials than were the norm 5-10 years ago.

- The NIHR has been established, with research funding restructured through the establishment of Comprehensive Local Research Networks (CLRN), and the NCRN is now just one of several topic specific networks.

- The strategic and financial importance of working effectively and efficiently with the life science industries, especially the pharmaceutical sector is placing demands on delivery of an enlarging industry sponsored research portfolio in line with the NIHR high level objectives, and with potential impacts on the opportunities for academic research.

The **primary aim** of this review is to provide a framework for continued evolution of the CSGs to ensure they continue to provide the research leadership required to maintain the world-leading position the UK enjoys in clinical and translational cancer research. Some areas for consideration, or terms of reference to focus on in the review were defined.

1. Scope, number and balance of existing groups
    - Do we need to merge or split any existing groups to create a more evenly balanced workload?
    - Is the membership, size and balance of expertise within groups correct?
    - Are subgroups functioning?

2. New areas of activity
    - Are there areas of clinical cancer research which are currently not covered in the CSG structure but where potential research activity exists or could be stimulated?

3. Inter-CSG relationships
    - How to strengthen collaboration between cross-cutting and site specific groups?

4. Industry relationships
    - How should we strengthen/assist the CSGs in working with industry?

5. Communication with networks and Chief Investigators
    - How should CSGs be managing the portfolio?

6. International relationships
    - Working with EORTC, NCI and others

7. The CSG role beyond research
    - To what extent do we wish CSGs to advise on NHS policy outside their immediate research portfolio, through NICE, DH, etc?

8. Patient and Public Involvement
    - Is PPI input to the CSGs currently working optimally?

9. Administrative and information support
    - How to structure, fund and oversee the support for CSGs and essential subgroups.
    - Are the annual reports useful and appropriately structured?
    - Value, appropriate frequency and structure of the external peer review process

10. Examples of good models of working for wider adoption

This review has integrated views from CSG Chairs in discussion with their Group members, past CSG Chairs, representatives from the main NCRI funders (CR-UK, MRC, LLR and Macmillan) and the NCRN Executive.

First, a questionnaire addressing the structure and functions of the CSGs was sent to all CSG chairs for completion in May 2011. A 100% (23/23) return was achieved. The processes that the current CSG Chairs consider to be working well and potential areas for change were identified enabling a wide-ranging insight that has helped inform the review panel to develop a future strategy.

The main conclusions from the questionnaire were:

1. The CSGs have been highly effective in developing a broad successful research portfolio.

2. The number and range of the CSGs remains about right. Minor adjustments may be appropriate.

3. The role and nature of subgroups requires review.

4. Communications between CSGs, and also with some research funders, chief investigators and the research networks, are variable and often sub-optimal.

5. The available administrative support is no longer sufficient for many of the groups to function effectively across their broad range of responsibilities.

6. Even after a shift in resources from supporting of face-to-face meetings, additional funds would appear to be necessary to enable effective portfolio development, co-ordination and management, along with better communication between CSGs, Research Networks, CTUs, Chief Investigators (CIs), funders and industry partners.

Subsequently, these findings were debated at the NCRN Operational Steering Group, the CSG Chairs' Forum and at a face-to-face meeting of the Review Working Group. The recommendations have evolved as a result of these discussions, supplemented by multiple further written and oral inputs from CSG Chairs, the funders and the NCRN Executive. The recommendations reflect the consensus arrived at by the Review Working Group.

Recommendations proposed by the review

1. Scope, number and balance of CSGs

There has been considerable discussion about whether some CSGs should be combined. For example, could the four urology CSGs be merged into one or two CSGs, or should the Palliative Care, Psychosocial Oncology and Complementary Therapy CS(D)Gs transform into a single supportive care CSG? However, other than the incorporation of the Complementary Therapy CSDG into the Palliative Care CSG, there was no support for this from either the CSG Chairs or the funders. It was felt that while merging urology CSGs might bring symmetry with some other groups e.g. Upper GI and Gynaecology, the individual groups were functioning well, the overlap in membership was small and the financial savings would be modest at best. In terms of the Palliative Care, Psychosocial Oncology CSGs, combining them would create a CSG with subgroups with little in common and it was felt more appropriate to enhance the scope of these groups to cover some of the research areas not covered well within the portfolio as described below. An updated Structure and Scope for the CSGs can be found in Appendix 2.

The Consumer Liaison Group has previously been described as one of the CSGs but has different functions, funding stream and reporting mechanisms. It is proposed that the CLG will function

according to the strategy defined by the NIHR PPI Programme (Appendix 3) and is considered to be outside this review process.

In addition it was clear that there are a number of research areas that are important components of a comprehensive cancer research portfolio but are incompletely covered by the current structures. These include screening and prevention, survivorship and supportive care. To address this a number of changes to the cross-cutting CSGs and better integration with the site specific CSGs are recommended. It is proposed that the NCRI should:

- Maintain the current number of site specific CSGs.

- Maintain the current remit, scope, duration of office and appointment processes for CGS Chairs (Appendix 4)

- Expand Palliative Care CSG into a Palliative and Supportive Care CSG incorporating the Complementary Therapy CSDG within the subgroup structure and including a new remit for developing a trials portfolio in supportive care. Subgroups would focus on:
    - Palliative and end of life care
        - Includes care delivery and patient experience
    - Supportive care
        - Treatment complications (bone marrow suppression, N&V, stomatitis etc)
    - Complementary therapies

- Expand the Psychosocial Oncology CSG to incorporate broader aspects of survivorship in partnership with the Primary Care CSG with named input from relevant CSGs notably, but not exclusively TYA, Testis, Lymphoma, Haem Onc and Breast CSGs.

- At a recent workshop on screening, prevention and early diagnosis chaired by Prof Matt Seymour, it was proposed to develop a distinct Screening and Prevention Advisory Group. This would have major input from the Primary Care CSG, and named representation from Breast, Prostate, Colorectal, Upper GI and Lung CSGs. Formal links with the Primary Care Topic Specific Network to address prevention strategies that may impact on non-malignant disease would be established. Co-opted members to cover specific areas of expertise e.g. epidemiology would be encouraged. The Advisory Group would report to the NCRN Operational Steering Group. Screening or prevention studies developing within individual CSGs should seek advice from the Advisory Group at an early stage on aspects of design, opportunities for biomarker evaluation and translational research and potential cross-over into other tumour areas or non malignant conditions.

- ❖ A similar Advisory Group structure could be considered for future co-ordination of radiotherapy research if the funding to support CTRad is not renewed.

2. CSG membership

The current membership structures work well and should be maintained. Continued membership beyond 5 years has become more common and is no longer "exceptional". The revised remit of CSG members is shown in Appendix 5.

- ❖ Membership should be limited to 3 years with an option to renew for a further 2 years.

- ❖ Membership beyond 5 years will not normally be approved unless there are truly exceptional circumstances.

- ❖ CSG chairs are encouraged to identify lead members within the CSG for different areas of activity e.g.: translational lead, portfolio management, NICE reviews, link member for involvement with other CSGs

3. CSG size and number of meetings

Meeting costs are rising steadily as a result of increased expenditure on travel, room hire and catering.

- ❖ CSG membership should be reduced in number over the next 12-24 months (excluding consumers and observers).
    - 20 for the common cancers and those with large, complex or diverse portfolios (academic and industry):
        - Breast (currently 26 members)
        - Colorectal (20)
        - Gynaecology (26)
        - Upper Gastrointestinal (UGI) (26)
        - Prostate (23)
        - Lung (25)
        - Lymphoma (23)
        - Haematological Oncology (H-O) (20)
        - Palliative and Supportive Care (19)
        - Children's Cancer and Leukaemia (CCL) (23)
    - 15 for the less common cancers, and those with small to medium sized portfolios:
        - Sarcoma (21)
        - Melanoma (20)
        - Brain (22)
        - Head and Neck (HN) (20)
        - Renal (17)

- Testis (18)
- Bladder (21)
- Psychosocial Oncology and Survivorship (15)
- Biomarkers and Imaging (20)
- Primary care (18)
- TYA (18)

If implemented this will reduce the number of CSG members by 71 plus 19 within the Complementary Therapies CSDG (17.5%).

- CSGs should normally meet twice a year. CSGs with a very large and complex portfolio (e.g. Breast, Haem Onc) may hold a third meeting following agreement with the NCRN Operational Steering Group (OSG).

Reduction in numbers will be achieved by not replacing all members who rotate off over the coming 1-2 years.

4. Subgroup number and scope

The number and scope of subgroups varies markedly between CSGs. A more consistent structure and remit for subgroups is proposed in Appendix 6 which largely formalises existing processes that have become overlooked in recent years. In many CSGs, subgroups are recognised as the source of new trial proposals and need to be encouraged to flourish. Subgroups are an excellent forum for young researchers to become involved in clinical research. Subgroup structure and outputs should be critically evaluated at the triennial review and only continued if they add real value to the activities of a CSG.

Subgroups over and above three may be necessary but CSGs should make the case for continuing existing ones and/or creating new ones by completing Appendix 7 of this report for all of the subgroups they wish to have. Subgroups with overlapping memberships should be amalgamated. The activities and number of subgroups will be influenced by the budget available to each CSG.

- Subgroups to be limited in number and broader in remit e.g.
    - Specific disease sites requiring a separate group of clinicians e.g. oesophago-gastric, hepatobiliary and pancreas in UGI or requiring specific skills or input from multiple disease sites e.g. survivorship
    - Local therapy versus systemic therapy
    - Portfolio management (see below)
    - Consideration should be given to forming subgroups between CSGs for areas of common interest

- All subgroups will need to be approved by the NCRN OSG.

- Time limited task groups (Working Parties) (Appendix 8) are more appropriate than a formal subgroup to develop a specific area of the portfolio. Limited specific resources from NCRN to support task groups over a 12-18 month period may be sought using a modified version of the existing application form (Appendix 9).

5. Subgroup membership

The terms and conditions for chairs and members of subgroups are not as well defined as those of CSGs, nor systematically implemented .

- Appointment of subgroup chairs should be by the CSG Chair following review of the applicant's CV and in agreement with the NCRN Director/Associate Director. The NCRN Director can request appointment by interview if deemed necessary.

- Chairmanship of a subgroup should rotate every three years. Re-appointment for a further two years may be considered if unanimously supported by the core membership. This will be applied retrospectively to facilitate the development of younger research leads.

- Core membership of a subgroup should be limited to 5 years with immediate effect i.e. with the period of rotation beginning at the time of publication of this report.

- Membership requires an application and submission of curriculum vitae to the Secretariat and needs to be ratified by one of the NCRN Directors.

- All subgroups should report to the main CSG and provide brief written summaries and action points resulting from meetings.

6. Subgroup size

- Subgroup membership should be limited to a core of 10 voting members. Up to 5 additional members may be co-opted onto the subgroup but do not have voting rights and will need to be self-funding.

- Open meetings with the research community are encouraged e.g. UK-Breast Intergroup but these need external resourcing.

All CSGs should review their subgroup structure and membership over the next 6 months and implement the new terms of membership and chairmanship. CSGs wishing to have more than three subgroups should complete a proforma, included as Appendix 7, for each of its subgroups and submit these via the Secretariat to the NCRN OSG.

7. Portfolio management

CSGs are variably involved in portfolio management and the current structures make meaningful management of a large portfolio within the main meetings very difficult.

- CSGs should consider setting up a portfolio management group that meets by teleconference with the NCRN Coordinating Centre 3-4 times a year. This will be piloted in the first instance with 2-3 Groups with the aim of improving communications between CSGs, the Co-ordinating Centre, Research Networks and Trials Units. The main purpose of these Groups will be to review delivery of the research portfolio and identify recruitment problems. It is hoped that problems with initiation or recruitment of studies will be identified earlier, and enable the CSG in partnership with the networks, the CI, CTU and Steering Committee for the trial in question to either identify solutions that improve recruitment of "failing" studies, or advise on revision or closure.

- These groups should have representation from at least one CTU, at least one network manager, members of the CSG and/or relevant subgroups and a consumer representative. The group should invite CIs of trials to attend as appropriate.

- Management of the NIHR industry portfolio should be included in the activities of this subgroup.

The NCRN CC will work with interested CSGs to set up these portfolio management groups and co-ordinate the teleconferences.

8. Administrative and financial support

A full financial review of the CSG funding and expenditure has been requested by the NCRI Board to help inform future funding from 2013. In the meantime to help ensure value for money and ensure greater financial accountability more detailed budgetary information will be made available to the CSG Chairs and reviewed by the OSG.

- Each CSG will be given an approximate budget for meetings that reflects the two levels of CSG size and complexity. CSGs will have the flexibility to tailor their activities within the available budget.
- CSG Chairs should be made aware of the costs associated with the activities of their CSG and subgroups, and are encouraged to discuss strategies for streamlining resource use with the CSG Secretariat.
- A financial report will become a standing item at each Chairs' Forum

Due to ever increasing workloads, the Secretariat has found it difficult to provide the necessary support required by CSGs.

- Recent new appointment to the Secretariat and strategic use of the Project Officers should enable additional support to the reduced number of subgroups.
- Meeting papers should be circulated by e-mail / web based and provision of hard copy provided only on specific request.
- Eileen Loucaides has reviewed the workload of the Secretariat and advised on how best to give specific support to CSGs (Appendix 10).
- Matt Cooper and Karen Poole (NCRN Assistant Directors) to advise on how the NCRN CC can support the CSGs better.

9. Annual reports and triennial review

- The requirements of the annual report will be reviewed with the aim of simplifying the information reported and highlighting successes and challenges. A suggested revised template is shown in Appendix 11.
- The triennial reviews should continue but with revision of the information that avoids duplication of information held elsewhere within the NCRN. A more strategically chosen pool of international reviewers should be identified that can add real value to the process.

Appendix 1: Remit of NCRI Clinical Studies Groups

Each NCRI Clinical Studies Group has a UK-wide remit to:

1. be responsible, in liaison with the NCRN Co-ordinating Centre, CTRUs and the Research Networks, for the development and delivery of a trials portfolio that encompasses both academic and industry sponsored trials,
2. propose new trials and other well-designed studies,
3. consider trials proposed by others,
4. consider international and commercial trials for inclusion in the portfolio,
5. foster translational research (TR) in the trial portfolio that enhances the potential for stratified medicine.
6. consider studies in health service research,
7. be responsible for the membership and activities of its subgroups,
8. work with other CSGs as appropriate,
9. consider views and advice provided by PPI representatives
10. receive inputs

- from ECMCs and early clinical trials groups
- from NCRN evidence reviews and economic reviews

11. submit applications for trials approval,
12. provide tumour specific or task specific advice, as required to
    - the NCRN Operational Steering Group
    - the NCRI Board,
    - CTAAC and other NIHR research funders
    - NICE
13. undergo 3-yearly peer review of the Groups activities,

Appendix 2: Structure and Scope of NCRI Clinical Studies Groups

1. Background

The role of the NCRI Clinical Studies Groups in the development of the NCRI research portfolio has been reviewed and it is agreed that these Groups will be the primary, but not sole route through which NCRI clinical trials are considered. Clear processes for the leadership and membership of these Groups have been established to promote transparency, encourage participation and ensure Groups understand and are well equipped to undertake their role.

The NCRN is responsible for the overall management of the Groups on behalf of the NCRI. The Groups are supported by the NCRN Coordinating Centre, with offices in Leeds and London. The Coordinating Centre works with Groups as required to develop processes and systems that enable them to work effectively.

Group Chairs are appointed through a process of open competition through responding to a national advert and an appointment panel.

This paper outlines the key principles underpinning the membership and composition of the NCRI Clinical Studies Groups and details the main duties and qualities required of members.

It provides a framework for working and offers individual Groups substantial flexibility in the way in which they are organised and managed. Whilst ultimately accountable to the NCRI (via the UK NCRN Operational Steering Group) the overall responsibility for the activity and performance of the Groups and any development proposals rest with the individual Groups.

The specific organisation and structure of each Group will be determined by members in collaboration with the NCRN. Groups currently meet 2-3 times a year. Sub groups and working parties may be established with work being shared between them, depending on the nature of the activity. Regular dialogue between meetings is expected.

2. Composition and Structure

The Groups should aim to bring together the expertise and enthusiasm necessary to establish them as an authoritative voice in the cancer research community.

The membership must be composed to reflect, as reasonably as possible, the various agencies involved in the development and implementation of high quality protocols in each cancer site. As a minimum, Groups should include multi-professional representation and should be drawn from as wide a geographical area as possible.

In the smaller site-specific Groups, such as renal or testis cancer, this might be achieved by inviting experts in a particular field to address specific issues/research ideas rather than to become full members.

Formal links with local NCRN networks are encouraged and, where possible, Group membership should include representation from networks accruing the most patients to Group studies. Relevant Trials Units should also be represented.

Group membership should seek to strike a balance between experienced members with a strong track record in clinical trials and less experienced, but equally committed, members showing the potential to become leaders in the research community.

It is anticipated that each Group will include scientific, funding body and ex officio representation.

Groups are encouraged to consider appropriate international representation. Any international appointments should be supported by a formal application, reviewed by the Group and ratified by the UK NCRN Operational Steering Group (see below).

Each Group should seek to involve consumers in all aspects of its work. The level of involvement may vary but each Group should include two consumer representatives in its membership. Consumer representatives may wish to alternate attendance at meetings.

Each Group should nominate a member who will take responsibility for reporting on Experimental Cancer Medicine Centres activities. This may, but need not be, the Chair.

The size of Groups should not exceed 20 members (excluding funding body and ex officio representation), and should be proportionate to the burden of disease and size and complexity of the trials portfolio for each particular site.

Maximum 20 members recommended:

- Breast
- Colorectal
- Gynaecology (GYN)
- Upper Gastrointestinal (UGI)
- Prostate
- Lung
- Lymphoma
- Haematological Oncology (H-O)
- Palliative and Supportive care
- Children's Cancer and Leukaemia

Maximum 15 members recommended:

- Sarcoma

- Melanoma
- Brain
- Head and Neck (HN)
- Renal
- Testis
- Bladder
- Psychosocial Oncology and Survivorship
- Biomarkers and Imaging
- Primary Care
- Teenagers and Young Adults

2.1 Funding Body Representatives

Named agreed representatives of major NCRI funders will be in receipt of the papers and minutes of all meetings and may attend as Observers. Funding body representatives may nominate a deputy to attend on their behalf by prior arrangement with the Secretariat.

2.2 Consumer Representatives

Consumer representatives will be appointed in liaison with the NCRI Consumer Liaison Group.

An updated list of members of each of the Clinical Studies (Development) Group Members will be maintained on the NCRN website.

2.3 Ex officio posts

The NCRN Directors/Associate Directors and NCRI or their named nominees are members of the Group in an ex officio capacity. Ex officio members will be in receipt of all papers and minutes of Group meetings and may attend meetings as full members (although they are unlikely to attend routinely).

3. Appointment of Scientific Members

Members will be appointed through an open process. Vacancies will be routinely advertised through established NCRN/NCRI communication routes (e.g. websites) professional bodies and national advertisement.

Nominations may be made through the following channels:

- The Group's chair, in liaison with other Group members if necessary,
- The UK NCRN Operational Steering Group
- Individuals wishing to self nominate

A panel consisting of the following will review applications and appoint accordingly:

- NCRN Director or nominated Associate Director or ex-Member of the NCRN OSG >3 years or ex-CS(D)G Chair of >5 years (To chair the panel)

- Chair of NCRI Clinical Studies Group
- Representative of NCRN OSG
- Senior Executive of the NCRI Clinical Studies Groups Secretariat

The Chair of a Clinical Studies Group may also request input from additional member(s) of the Clinical Studies Group after discussion with the Senior Executive CSGs Secretariat – however if their membership is up for renewal under terms of the Members Remit this may not be appropriate.

Notification of appointment will be by letter from the Senior Executive Clinical Studies Groups Secretariat.

Membership will be for three years with the possibility of an extension of two years duration. Decisions on extensions will be made by the Selection Panel, based on the needs of the Group and the contribution of the individual to the Group's activities. At the end of a 5 year term of membership a one-year period must normally elapse before members can reapply for a further term. Exceptions to this, should they arise, will be reviewed annually on a case-by-case basis by the selection panel considering other applications, and will be limited to members who perform an essential role within the Group (eg Subgroup chair).

Members whose term of office expires before the study for which they are the Chief Investigator (CI) has been completed will maintain links with the Group through the submission of written reports. Invitations/requests to attend should be made only when pressing issues demand and should be by prior agreement with the Secretariat and the Chairman of the Group. The same relationship should be established for PIs of EORTC and other international trials that are included in the portfolio. Membership may be terminated if a scientific member fails to attend three consecutive meetings. Membership is in an individual capacity and attendance of deputies for specific meetings should reflect exceptional circumstances and be by prior agreement with the Group Chairman and Secretariat.

During tenure, relevant members will be expected to participate in Industry Adoption Panels, set up as part of the Industry Trials Adoption Committee (ITAC), which take place via teleconference. Confidentiality agreements to enable this participation should be completed and returned to the Secretariat before appointment commences.

The effectiveness and composition of the Group will be considered as part a CSG's triennial review progress.

Chairmanship and membership of NCRI Clinical Studies (Development) Groups is unpaid. However, work relating to the Groups is regarded as National Work for the purposes of the consultant contract and job planning. Members who encounter difficulty securing recognition

for their work should contact the CSG Secretariat who will write to the local general manager regarding the issue.

Appendix 3: The NCRI/NIHR Cancer Research Network Consumer Liaison Group (CLG).

Patient and carer (referred to as consumer) involvement has been integral to the structure of the Clinical Studies Groups (CSG), since their inception. The CLG has previously been described as one of the NCRI's Clinical Studies Groups, however the CLG terms of reference differs from that of the CSGs, but a key part of its function is to support recruitment of PPI members to each of the CSGs-known as core CLG members. In addition the CLG is also made up of a significant number of associate CLG members, lay people engaged in supporting research activity in a range of NCRI/NCRN projects locally, regionally, nationally. Their input to the CLG informs core members and vice versa. The role of the CLG Chair, reviewed in 2011: provides strategic advice to the NCRN, NCRI and its member organisations to assist their understanding of the PPI perspective including effective involvement of patients and the public in cancer clinical research studies

The CLG acts as a focus for consumer activity, sharing learning & development, sharing best practice and for peer-support and networking. Through its meetings and electronic communication network, it maintains a core resource for researchers and health professionals to gain consumer advice at all points of the research cycle.
During the past two years, patient and public involvement (PPI) has undergone a radical review process as part of the National Institute for Health Research (NIHR) PPI Workstream. Since May 2011 all NCRN PPI activities, which includes the CLG and PPI activities as part of the CSGs, are funded by and part of the wider NIHR PPI Programme along with PPI activity across the other 7 topic clinical research networks (TCRN's). The new contract gives the opportunity to evolve the way NCRI & NCRN deliver and manage PPI working in new partnerships with the other (TCRNs). PPI is now embedded in the NIHR structure with clear performance targets and assessment frameworks.

For NCRN all PPI activity is also reviewed/ reported quarterly through the NCRN Executive following discussion through CLG and NCRI/NCRN PPI Steering Group (PPISG).

Recommendations:
Looking forward -as part of the NIHR PPI Programme 2012-2015

- The CLG remains as a hub to support PPI both across the CSGs and in wider relevant NCRI/NCRN activity taking place locally, regionally and nationally in support of the NIHR PPI Programme.
- The CLG will continue to support PPI input across the CSGs as before but with recognition that it acts as a 'cross-cutting' group in line with its broad contribution to CSG and wider NCRI/NCRN activity.
- The CLG Chair will continue with reporting and strategic advice to NCRI/NCRN groups as outlined above

- The CLG will continue to report on its activities as part of the NIHR PPI Programme to the NCRN Exec, NCRI/NCRN PPI Steering Group, NIHR CRN CC
- To reduce duplication of reporting and make best use of limited resources, the CLG will no longer take part in the 3 year CSG review process but instead conclude its part in this process in 2012 by addressing any issues raised as part of the 2009 peer review as part of its 2012 annual report, with a link then placed within this report to future work as documented in the NCRN PPI Strategy to 2015 and Annual plan for PPI 2012-13

From 2011/12 -the CLG works with the CSGs to support delivery of *focussed PPI projects as part of the NIHR PPI Programme objectives; specifically in relation to CSGs these include:

- Develop a system enabling routine PPI review/reporting of study recruitment /retention issues in relation to portfolio studies reviewed by the CSGs
- Recruit, train, support PPI members to NCRI CSGs to agreed organisational levels which takes account of any new CSG structures as part of the CSG review
- Maintain and develop learning/training opportunities which makes it easier for patients, carers to be effectively involved in the work of the CSGs
- Maintain and develop learning/training opportunities which supports CSG research staff in understanding how best to utilise PPI to optimise the acceptability and relevance of studies to patients-hence as part of this work our plan to follow up the lay survey with a survey for CSG Chairs/scientific mentors

(*from the NCRN PPI Annual Plan)

Appendix 4: NCRI CSG Chairmanship

1. DUTIES

The Chair will directly or by delegation:

- Oversee the portfolio of trials developed or adopted by the Group.
- Contribute to studies developed or adopted by the Group.
- Monitor the progress of the Group.
- Receive input from the NCRN Co-ordinating Centre
- Provide input to the Experimental Cancer Medicine Centre (ECMC) and other translational research groups.
- Liaise with other National and International trials organisations.
- Propose membership of the Group in consultation with the NCRN Operational Steering Group.
- Report to the NCRN Operational Steering Group annually and through the peer review mechanism.
- Provide advice to the NCRN Operational Steering Group or NCRI, attending meetings as needed.
- Promote good clinical research practice.

2. QUALITIES

The candidate must have highly developed leadership skills, be an excellent communicator and skilful team player. Specifically the post holder needs to be able to demonstrate the following experience and competencies:

- Clinician with academic excellence in a cancer of relevance to the Group.
- Previous experience of chairing research meetings effectively.
- Evidence of an ability to provide leadership to a research Group.
- Be prepared to take action and implement decisions.
- Previous track record of collaborative research of relevance to the Group.

3. RELATIONSHIPS

- Responsible to the NCRN Operational Steering Group, and through this to the NCRI.
- Secretariat support will be provided by the NCRI Clinical Studies Groups Secretariat.
- The term of appointment will be 3 years in the first instance.
- Renewal for a second term will be considered by the Appointments Committee but requires a formal application.

4. REMUNERATION

This post of Chairman of an NCRI Clinical Studies (Development) Group is unpaid.

Appendix 5: Remit of Members of NCRI Clinical Studies Groups

1. DUTIES

Members are expected to attend all meetings of the Group and will contribute to the maintenance and further development of its portfolio of research by:

- Actively engaging with trials within the Group's portfolio, for instance through entering patients, offering information and advice to collaborators, presenting findings as appropriate;
- Identify existing high quality studies that should be adopted by the Group;
- Generating ideas for new trials,
- Contributing to the development of high quality applications to CTAAC and other NIHR funders through the review of trial ideas and protocols submitted to the Group;
- Contributing to consultation exercises (eg NICE) undertaken by the Group as requested;
- Contributing to the Group's annual report and peer-review of the portfolio
- Providing expert advice to the Chair, NCRI funders, and the wider cancer community as required.

2. QUALITIES

Members should have a track record of participation in research in the relevant cancer sites.

Members should contribute actively to the work of their Group, and support studies within the Group portfolio.

The intention is to develop a portfolio that is well balanced and draws on local NCRN strengths to stimulate accrual. The composition of each Group should reflect this and members should, therefore, be able to demonstrate some of the following:

- Experience of collaborative clinical trials activity in a leadership capacity;
- Success in trial accrual into national studies;
- Evidence of publications and/or presentations nationally/internationally;
- Links with cancer research networks;
- An enthusiasm and commitment to developing cancer research.

3. RELATIONSHIPS

Members will be responsible to the UK NCRN Operational Steering Group through the Group Chair. Secretariat support will be provided by the Coordinating Centre.

4. REMUNERATION

Work relating to the Groups is regarded as National Work for the purposes of the consultant contract and job planning. Membership of a Clinical Studies Group is unpaid. Reasonable travel expenses will be reimbursed in accordance with Cancer Research UK finance policy.

Appendix 6: Remit of CSG Subgroups

1. Background

Subgroups form part of the permanent structure of a site specific NCRI Clinical Studies Group (CSG) and represent an efficient distribution of effort for research in some tumour sites. The permanence of Subgroups is in contrast to Working Parties then meet to develop a particular protocol and then disband or become the basis of a Trial Management Group.

2. Function

The function of a Subgroup is to keep under review a particular area of research, to develop research protocols addressing gaps in the research portfolio and to advise the parent CSG on issues generally affecting research specific to trials within their remit. Subgroups will also be expected to respond to NICE consultations when necessary.

Any trial developed by the Subgroup will be designated as being on behalf of the parent CSG.

3. Structure

The Subgroup structure should reflect nationally recognised specialist divisions within a tumour site, the recognised stages of disease progression or a combination of both.

4. Composition

Each Subgroup should be similar in form to that of a CSG. In this sense, its size should reflect the burden of disease, should be composed to include a cross section of specialist knowledge and expertise necessary to undertake its work, should seek a broad geographical spread and international input, as appropriate. It should not exceed 10 core, voting members. Additional (non voting) attendees up to a maximum of 5 are at the discretion of the Subgroup Chair and must be self or externally funded.

Inputs from ECMCs and links to the networks should be facilitated by the parent CSG.

The effectiveness and composition of the Subgroup will be considered as part of the triennial review of the parent CSG's portfolio.

5. Chairman

The Chair must be a member of the parent CSG. Subgroup chairs will be appointed by the CSG Chair following review of the CV and in agreement with an NCRN Director/Associate Director. The NCRN Director can request appointment by interview if deemed necessary

The Chairman is responsible for ensuring that effective communication is maintained with the parent CSG through reports to each meeting and through written contributions to the peer

review of the parent CSG. The duration of chairmanship will be for 3 years and will be concurrent with membership of the parent CSG.

6. Membership

It is not necessary for all Subgroup members to be members of the parent CSG.

For administrative purposes, it is necessary to distinguish between two membership categories - full members and invited members. For both categories the duties and qualities of a CSG member are applicable and appointments to the Subgroup should be made using those criteria.

6.1 Appointment

6.1.1 Full members (see Remit of Members of NCRI CSGs section on 'Appointment of Scientific Members')

Full members must be members of the parent CSG and will be appointed through the same mechanisms as for scientific members. However, the additional responsibility of contributing to the Subgroup's work will be made clear in advertisements for full members.

Membership is in an individual capacity and attendance of deputies for specific meetings should reflect exceptional circumstances and be by prior arrangement with the group Chairman or Secretariat. Membership may be terminated if a scientific member fails to attend three consecutive meetings.

Core membership of a subgroup will be limited to 5 years

6.1.2 Invited members

Invited members are members of the Subgroup only and should be recommended by the Subgroup's Chair following discussion, approval by the Chair of the parent CSG and formal invitation to join from the Senior Executive of the Clinical Studies Group Secretariat.

On all other issues the Remit of Members of NCRI CSGs section on *'Appointment of Scientific Members'* applies to invited members.

6.2 European / International trialists

Principal Investigators of EORTC trials and other international studies adopted by the group may be invited to contribute in writing to meetings of the Subgroups as appropriate. Invitations to attend in person should be made only when pressing issues demand and should be by prior agreement with the Secretariat and the Chairman of the Sub Group with agreement on who will cover any associated costs.

7. Decision Making

In relation to protocol development, consensus on the finer points of design is not necessary but broad agreement is expected on the study's priority, the aims of the research question and the methodology used to address it. Where a divergence of opinion regarding a protocol occurs, for example, regarding the control arm of a trial, the advice of the parent CSG should be sought. The parent CSG should be informed of all significant issues regarding, or changes to, a protocol. Significance, or otherwise, should be decided by the Subgroup core membership as a whole and not through Chairman's action.

During discussions regarding a protocol, in which the Chair is involved, chairmanship should be delegated to another member.

8. Reporting Procedures

Each Subgroup should provide a written report on its activities to each meeting of the parent CSG. In particular the Subgroup should address the following:

A Details of trials in development, the contact details for the individual leading on this issue, and the projected timescales for submission of the trial for funding.

The CSGs are formally integrated into the processes through which trials are funded and included in the portfolio. To maintain the parent CSG's credibility in relation to these processes, it is vital that the parent CSG is kept fully informed of the development of any trial, and that the Chairman of the parent CSG (as a minimum) has the opportunity to see any trial protocols before they are submitted for funding. Preferably all members of the Subgroup and parent CSG should see this protocol, however there may be occasions when time constraints make this difficult to achieve.

B Information on particular concerns of the Subgroup perceived to be hindering trial development.

C Subgroups may wish to establish a Working Party to address a particular aspect of its work. A recommendation to establish a Working Party should be agreed by the parent CSG.

D Each Subgroup will be expected to provide the Chairman of the parent CSG with a written report on its activities to assist with the triennial peer review process. This is the responsibility of the Subgroup Chairman.

9. Establishing a Subgroup Structure

The decision to adopt a Subgroup structure should be considered carefully. For example, consideration should be given to whether it is more appropriate to establish a Working Party.

Typically a CSG should have between one and three subgroups and a specific case for more than this number will need agreement of the NCRN Directors. The continuing need for subgroups will be reviewed at the tri-annual peer review meeting.

A business case should be made (using the template provided at Appendix 1), defining the aims and objectives of the Subgroup and its projected lifecycle. This should be submitted to the NCRN by the Chairman of the parent CSG, in liaison with the NCRI Clinical Studies Group Secretariat. The document should estimate the cost in relation to the need for the structure, its feasibility in terms of impact on the development and management of the trials portfolio, and its sustainability in terms of an adequate supply of members to support the 3 yearly rotation. In this context, consideration should be given to the various means through which Subgroups might conduct their business. These include physical meetings, teleconferences and the e-community systems currently under development.

Particular attention might be given to the consequences of *not* establishing the proposed structure, for example an overload of business in the parent CSG making the generation of research ideas and portfolio management impractical.

The document should be prepared with a view to measurable outcomes that can contribute to the process through which the parent CSG will be peer reviewed.

Proposals to establish Subgroups will be reviewed in the light of all those received from the 20 CSGs.

The core membership of a Subgroup for whom travel and subsistence costs will be paid should not exceed 10 members.

10. Secretariat Support

The NCRI CSG Secretariat will, in liaison with the Subgroup Chair:

- Maintain records of the Subgroup's current and past membership, its composition and trials developed and/or submitted for funding, assessment of protocols for CTAAC meetings, and other information necessary for the peer review report.
- Assist the Subgroup in setting up meetings, ie circulating dates and organising a venue and catering. However, resource constraints prevent us routinely preparing papers or taking minutes at Subgroup meetings. Funds for travelling expenses are limited, restricted to core members, and must be agreed in advance. We encourage members to communicate electronically to develop ideas subsequent to any initial meetings.
- Provide general advice and information on the procedures and timing of meetings of relevance to the Subgroup.

Appendix 7: Proposal for Establishing a Subgroup

NCRI Clinical Studies Group _____

Name of Subgroup _____

Proposed Chair _____

Aim(s) and objectives

_____

_____

_____

Proposed membership
(1) please list existing members of CSG

_____

_____

_____

(2) please list additional members/trials Groups to be invited

_____

_____

_____

Expected duration of Subgroup 1 year/2 years/3 years

Expected number of face-to-face meetings 1/2/3/4/5/6

Is funding required for these? Yes/No

If so, please estimate *total* cost of all meetings £_____

Reporting and Communication Lines between Subgroups and parent CSG

Submitted by: _____ Date: _____

Appendix 8: Remit of NCRI CSG Working Parties

1. Background

Working Parties have a predefined life cycle and form a *temporary* part of a Clinical Studies Group's (CSG) structure. As such they contribute to the parent Group's work on a project specific basis.

A Working Party will disband once the work for which it was convened has been completed.

2. Function

Working Parties might be convened to identify gaps in the research portfolio, to identify study options and priorities, which may address the gap, or to develop a particular research protocol.

Any trial developed by the Working Party will be designated as being on behalf of the parent CSG.

If the Working Party was convened to develop a study protocol it will disband once an application to CTAAC or other funding body to fund the full study protocol has been submitted. Should the application be unsuccessful, a decision to reconvene the Working Party should be made by the parent CSG.

3. Models

The NCRI welcomes innovation and is open to new organisational models for the CSG Working Parties.

3.1 Broad Based or Open Working Parties

Open workshops may be convened to identify potential research projects and generate collaborations to address particular projects. They are composed on an inclusive basis and seek a large membership to reflect this. The aim of this approach is to generate research ideas that have the support of a broad cross section of the clinical research community treating potentially eligible patients.

Tightly Defined or Closed Working Parties

This is the traditional working party model with a constant membership, which invites specialists to address particular issues as appropriate.

Plus point – tight focus should encourage speed of delivery of output.

4. Composition

Because of the diverse purposes for which Working Parties may be convened and the potential multiplicity of models it is difficult to make overarching recommendations regarding

composition. A number of members should be drawn from the parent CSG. However, the composition must be appropriate to the task in question and this should be agreed in advance with the parent CSG.

1. Chairmanship

It is recommended that the Chairman should be a member of the parent CSG. However there may be occasions when this is neither necessary nor appropriate.

Chairmanship is concurrent with the life of the Working Party and the Chairman is responsible for ensuring that effective communication is maintained with the parent CSG through reports to each meeting.

5.1 Appointment

Chairmanship should be considered and agreed by the parent CSG.

2. Membership

It is not necessary for all Working Party members to be members of parent CSG. Once it begins to undertake its business, changes to the membership of the Working Party are not encouraged, but should be agreed with the parent CSG where appropriate.

Those members whose term of membership of the parent CSG expires before the Working Party completes its business should remain on the Working Party until the business has been completed.

3. Decision Making

In relation to protocol development, consensus on the finer points of design is not necessary, but broad agreement is expected on the study's priority, the aims of the research question and the methodology used to address it. Where a divergence of opinion regarding protocol occurs, for example, regarding the control arm of a trial, the advice of the parent CSG should be informed of all significant issues regarding, or changes to, a protocol. Significance, or otherwise, should be decided by the Working Party as a whole and not through Chairman's action.

During discussion regarding a protocol, in which the Chair is involved, chairmanship should be delegated to another member.

4. Reporting Procedures

Working Parties are responsible to the parent CSG and should report on their activities to each full meeting of the parent CSG.

The nature of the reporting procedures should be defined on a case by case basis. However, as a minimum, the Working Party should address the following areas:

8.1 Protocol development and submission

Details of trials in development, the contact details for the individual leading on this issue, and the projected timescales for submission of the trial for funding.

The CSGs are formally integrated into the processes through which trials are funded and included in the portfolio. To maintain the parent CSG's credibility in relation to these processes, it is vital that the parent CSG is kept fully informed of the development of any trial, and that the Chairman of the parent CSG (as a minimum) has the opportunity to see any trial protocols before they are submitted for funding. Preferably all members of the Working Party and parent CSG should see this protocol; however, there may be occasions when time constraints make this difficult to achieve.

8.2 Peer review of parent CSG

As a contribution to the peer review of the parent CSG's activity, the Chairman should submit a written report on the Working Party's activities and outcomes at end of its life cycle.

If the triennial peer review of the parent CSG takes place before the Working Party has completed its business an interim report should be submitted*.*

9. Secretariat Support

The NCRI CSG Secretariat will, in liaison with the Working Party Chair:

* Maintain records of the Working Party's membership, composition and outputs.
* Assist in setting up meetings, ie circulating dates and organising a venue and catering. However, resource constraints prevent us preparing papers or taking minutes at Working Party meetings. We only have limited funds for travelling expenses, which must be agreed in advance. Therefore we would like to encourage members to communicate electronically to develop ideas subsequent to any initial meetings.
* Provide general advice and information on the procedures and timing of meetings of relevance to the Working Party.

10. Establishing A Working Party

The decision to establish a Working Party that has funding implications will be carefully considered by the NCRN, following submission of a business case using the template provided. The proposal for the Working Party, defining the aims and objectives of the Working Party and its projected lifecycle, should be submitted to the NCRN Executive Group by the Chairman of the parent CSG, or by the proposed Working Party Chair, in liaison with the NCRI Clinical Studies Group Secretariat.

The document should provide an estimate of the cost of the Working Party and its feasibility in terms of the projected composition and its impact on the development and management of the trials portfolio. In this context consideration should be given to the various means through which Working Parties might conduct their business. These include physical meetings, teleconferences and the e-community systems currently under development.

Particular information might be given as an addendum to the consequences of *not* establishing the Working Party. The document should be prepared with a view to measurable outcomes, which can contribute to the process through which the parent CSG will be peer reviewed.

Proposals to establish Working Parties will be reviewed in the light of all those received from the 22 CSGs.

Appendix 9: Proposal for Establishing a Working Party

NCRI Clinical Studies Group _____

Name of Working Party _____

Proposed Chair _____

Aim(s) and objectives

_____

_____

_____

Proposed membership
(1) please list existing members of CSG

_____

_____

_____

(2) please list additional members/trials Groups to be invited

_____

_____=

_____=

_____=

Expected duration of Working Party 1 year/18months/2 years

Expected number of face-to-face meetings 1/2/3/4/5/6

Is funding required for these? Yes/No

If so, please estimate *total* cost of all meetings £_____

Submitted by: _____ **Date:** _____

Appendix 10: NCRI Secretariat Support to CSGs

Elliann Fairbairn (elliann.fairbairn@cancer.org.uk) Progress Reviews Membership PA Managing staff	Haem Onc Lymphoma Gynae Chairs' Forum
Samantha Kates (sam.kates@cancer.org.uk) Annual Trials meetings Finance/ expenses	CT Lung Testis Primary Care Prostate Upper GI
Laura Chambers (laura.chambers@cancer.org.uk) Annual Reports	Colorectal Sarcoma TYA Melanoma Head & Neck CCL Biomarkers
Laura Johnson (laura.johnson@cancer.org.uk) Membership Office stationery	Palliative Care Brain Psychosocial Oncology Renal Breast Bladder CPAS

Appendix 11: Template for the annual report to NCRN Operational Steering Group.

- Brief introductory Summary
- List key achievements in the year
  - Up to five
- Membership, structure and links to other national and international research groups
- Subgroups
  - Membership, achievements, list key future objectives
  - New subgroup proposals
- Task groups/Working Parties
  - Membership, achievements, list key future objectives
  - New task group proposals
- Patient accrual summary
  - Cancer patients RCT, non-RCT;
  - Non cancer patients RCT, non RCT
  - Comparison over previous 5 years
- Numbers of studies, open, in set-up and closed in year April-March
  - Successful NIHR portfolio funding applications
  - Unsuccessful NIHR portfolio funding applications
- Industry sponsored trials portfolio
  - Number of studies
  - Progress against NIHR high level objectives
- Collaborative partnership studies with industry
- Progress towards achieving 3 year strategy
  - New strategic aims
- Impact of clinical trials on routine UK clinical practice
  - List specific examples
- Consumer involvement
- Open meetings / annual trials days
- List priorities and challenges for the forthcoming year.
- Concluding remarks
- Appendices
  - Portfolio Maps
  - Publications in previous calendar year directly associated with portfolio trials
    - Full manuscripts
    - Abstracts