Adding Value and Impact:

A Toolkit for Consumer Members of Clinical Studies Groups

Acknowledgement
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Contents

Foreword

For 25 years I have been involved in designing and running cancer clinical trials, and for the first 10 years of that time it didn't occur to me or anyone else in the field to ask patients and their carers to contribute as equal partners in that endeavour. In fact, when the concept was first introduced many people were sceptical – would patients be too emotionally involved? unable to understand the scientific issues? too narrow in their personal interests?

Thank goodness the NCRI and NIHR CRN: Cancer has changed all that. From the initial tentative steps on CSGs, we have time and again seen consumer members making the crucial point, asking the killer question, suggesting the design or modification to make research succeed. More and more, clinical researchers in the UK now turn first to their consumer colleagues for thoughts about the questions we need to ask, the design of trials, the acceptability of new treatments, the size of benefits we need to demonstrate.

Like any coming-of-age it has been slow and has had its ups and downs, but it has ultimately been hugely worthwhile. Consumer members are now an absolutely integral part of how the clinical cancer research world functions in the UK, and our model and attitudes are being noticed and followed around the world.

This Toolkit marks another step in the process, and I am sure will be helpful to new consumer members joining the NCRI family. On behalf of NCRI I would like to thank Mat Baker and everyone who has contributed to its production.

Professor Matt Seymour
NCRI Director of Clinical Research, August 2014

Foreword

When I first sat on an NCRI Clinical Studies Group, I found I had a supportive and experienced consumer colleague and an excellent scientific mentor, and all three of us were members of a group whose Chair and other members were very encouraging to consumer involvement too.

Even so, for the first couple of meetings, I wondered why I was there. Then it dawned on me that I knew the answer to that. I was there to make a difference, to add value to the discussions, to help inform the decisions, to make an impact on research that would benefit my fellow cancer patients. And it dawned on me too that the question that I was trying to ask was actually, “How do I do it?”

Talking through things with my colleagues on the Consumer Liaison Group, I found that we have all struggled with that one. So a couple of years ago, Mat Baker started to write down some of our answers. Whenever we came up with a website we liked enough to share, whenever we used a tip that worked, whenever we found guidance that we used over and over again, we gave it all to Mat and he created our Toolkit.

This is that Toolkit. Now in its third edition it has been put together entirely by cancer consumers and it contains only advice and hints and suggestions that have worked on more than one occasion for more than one person. And like any good Toolkit, it may well be useful for far more than sitting on an NCRI Clinical Studies Group. Certainly we hope so, because most of us now sit on more than one research committee or group, and still we keep our Toolkit handy.

I hope you will keep it handy too. More importantly, I hope you find it useful. And if you come up with a tool we can add to it, please let us know!

Richard Stephens
Chair, Consumer Liaison Group, August 2014

Introduction

This toolkit has been developed by current PPI (consumer) members to assist incoming members of Clinical Studies Groups (CSGs) to take up the role of PPI representative in an effective manner.

The Role Profile for PPI members of the NCRI Clinical Studies Groups is another useful document[1].

Who is the toolkit for?

Whilst the toolkit is aimed primarily at PPI members of CSGs and CSG sub-groups, it may also be of interest to all CSG members to enhance their understanding of the role undertaken by patients and carers attending as members alongside them.

[1] Click on the link to access these documents and resources.

Setting the context for active involvement in CSGs

It might be helpful to consider the following 3 thoughts or areas regarding active involvement.

1) Collaborative Working

Researchers face many problems in the design and delivery of clinical trials. These include the complex matters of trial development, presentation and recruitment, through to dissemination and the application of trial findings. The NCRI Consumer Forum seeks to position consumers as part of the solution to the problems being faced by researchers; as collaborators whose unique experience and expertise can improve the effectiveness of trials in the production of patient and public benefits.

The title ‘consumer’ should not limit your thinking about this role. In the realm of public services, service user involvement has forced a reconsideration of the traditional role set of ‘client’ and ‘professional’. The involvement of individuals and groups in successful efforts to enhance the quality and quantity of services they use has challenged the passive connotations associated with the terms ‘client’ and ‘consumer’ and prompted new and dynamic models based upon the concept of ‘co-production’. It is important therefore that in seeking to establish a collaborative relationship with researchers we emphasise that our particular experience and expertise, as patient and lay advisors, has an important role in the production of effective and successful cancer research.

The NCRI Consumer Forum pursues an agenda-setting role within the cancer research community. Consumer involvement over the last decade has been associated with an increase in research in cross cutting areas such as screening and early diagnosis. Members of the NCRI Consumer Forum are currently active in the development and analysis of the National Cancer Patient Experience Survey (NCPES) and in formulating proposals for widening participation in clinical trials.

See “Action on Access: Widening patient participation in clinical trials”[1] on the NCRI website.

Setting the context for active involvement in CSGs

2) Style and Tone

The second thought relates to what may be described as ‘style and tone’. When you are in a CSG or CSG sub-group meeting there will be an interest in what you have to say about such things as the way in which the design of a trial affects the motivation of patients and carers to be involved. You may also have questions about the relevance of a trial and how it will deliver benefits for patients.

What you should try and do:

✓Listen and learn from others

✓Draw on your own direct experience and knowledge appropriately in order to inform discussion and debate

✓Raise matters beyond your own direct experience

✓Take pains to develop collaborative relationships with colleagues and other research professionals

✓Communicate effectively and economically on points that are relevant to the discussion

✓Value your experience and developing expertise and do not allow any perceptions that you may have concerning your lack of medical or research knowledge to diminish this.

Remember:

✓Good points can be missed because an apologetic sounding comment can detract from its importance,

✓Be clear and confident. Try and make your points clearly by saying, for example, that ‘a design could be improved by……’ or ‘that patients would be interested in participating because of ……’.

✓Express yourself positively. Don’t apologise for lack of knowledge. Instead say, ‘From a lay point of view……’ or ‘As someone with a related condition I would question…… or I would strongly support……’

Setting the context for active involvement in CSGs

3) Support and Advice

The third thought acknowledges that this is a demanding role and seeks to emphasise the importance of drawing upon the support and guidance that is available to you from within the NCRI environment.

3.1 The NCRI Clinical Research Groups Team
Keep in touch with the NCRI Consumer Forum administration based at the Angel Building. Nicola Keat is the NCRI Head of Clinical Research Groups and she has executive responsibility for the operation of CSGs. The current Consumer Lead is Richard Stephens. The role of Consumer Lead is undertaken by a consumer and this role is combined with the Chair of the NCRI Consumer Forum. The administration of NCRI consumer matters is undertaken by Natalie Salhov. Natalie can be contacted by email: natalie.salhov@ncri.org.uk

3.2 Scientific mentorship
You will be assigned a scientific mentor. This person will be a clinician from the same CSG as you. Their role is to support you in understanding the clinical dimensions of the trials for which your CSG is responsible. They should also be able to assist you with general questions that you may have regarding trial methodologies. Try and establish a good relationship with your scientific mentor; she or he will know from experience that the benefits for clinicians of consumer involvement are much greater when the consumer is feeling comfortable with the clinical and scientific aspects of discussion.

3.3 Peer mentorship and support: the Consumer Forum
Never underestimate the wealth of experience and wisdom that exists within the NCRI Consumer Forum! The Forum is a unique resource: a well-informed group of people with a wide range of professional skills and cancer experiences and perspectives. Forum meetings are always informative and often inspiring. Take the opportunity to not only participate fully in the discussions but to network and to build up contacts to provide advice and support in the future. The Forum is a very welcoming place and highly supportive of new members. The current Consumer Lead and Chair is Richard Stephens. Richard can be contacted by email via Natalie: natalie.salhov@ncri.org.uk

Setting the context for active involvement in CSGs

All CLG members have access to a group email service:NCRI-CONSUMER-FORUM@JISCMAIL.AC.UK. The email service provides regular updates on key issues relevant to research and PPI and is also an excellent way for members to keep in touch, share relevant news and best practice. Further details from Natalie: natalie.salhov@ncri.org.uk

3.4 CSG co-membership
It is usual to have 2 consumer members sitting on each CSG. It is likely that your co-members, at the time of your appointment, will have useful experience to share with you. This will include an appreciation of the particular culture and dynamics of the group, its expectations of consumer members, and the challenges, or otherwise, associated with achieving an effective consumer voice. You should consider drawing on this experience and working closely with your co-member as you establish your presence within the CSG.

3.5 Working with your CSG Chair
Shortly after your appointment the CSG Chair will request a meeting with you. You should use the opportunity that a meeting provides to clearly identify how and where the CSG discharges its responsibilities. Whilst it is usual that the discussion of new lines of research enquiry occurs within the main CSG meeting, the assessment of trial applications for funding and the process of portfolio management is likely to occur within its sub-groups. As a consequence it should be possible, in collaboration with your CSG Chair, scientific mentor and your consumer co-member, to identify how you will be able to maximise your contribution and the impact you have. This is likely to occur, in part, through sub-group membership.

Setting the context for active involvement in CSGs

3.6 Assistance with Reporting
As a CSG consumer member you are expected to:
(i) provide a report to each CSG meeting
(ii) contribute to the drafting of the CSG's Annual Report

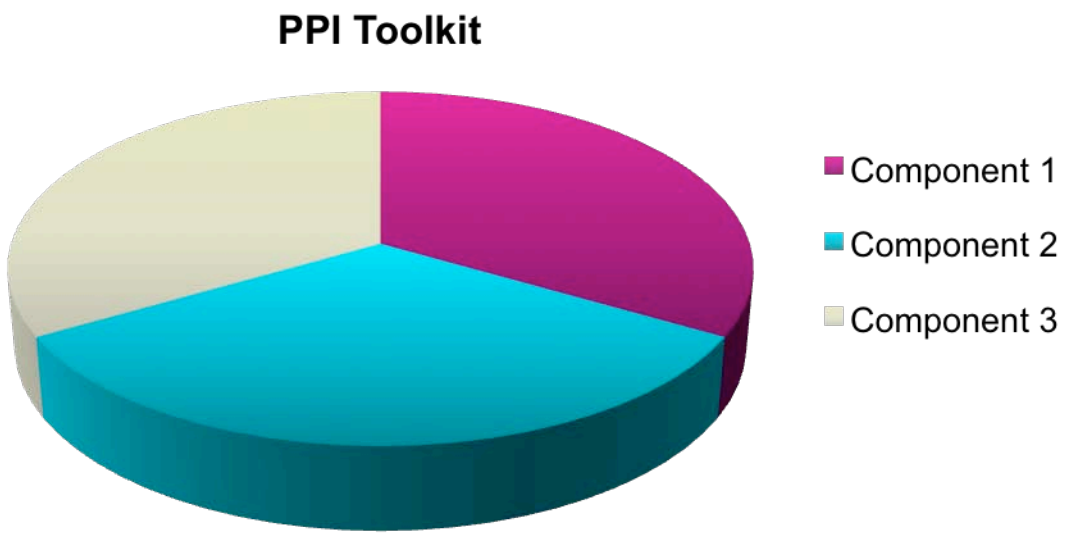
With regard to the first requirement a pro-forma has been provided by the NCRI Consumer Forum Steering Group to assist you in the completion of your report. In the verbal presentation of your report, however, you should resist getting bogged down by the written detail and simply focus on one or two matters that you believe are of particular relevance to the group and concentrate your efforts and the limited time available (probably about 5 minutes) upon achieving some impact in this respect. See The CSG Consumer Report Pro-forma[1].

With regard to the second requirement, the Chair should collaborate with consumer members when drafting the section of the annual CSG report concerned with consumer involvement. This should cover consumer involvement in the main group, in the sub-groups, in associated trial development and trial management groups and how the mentoring of consumer members is working. It is intended that the regular use of the CSG Consumer Report Pro-forma will assist you and the Chair in capturing and pulling together much of this information.

3.7 Learning opportunities to support you in your role
All new members have access to a range of learning experiences as part of an induction programme. Its content and delivery are shaped by patients and carers themselves and this training is always highly rated. In addition the NCRI supports your development through the sponsorship of a large number of bursaries provided to enable consumers to attend the annual NCRI Conference. This is the UK's flagship cancer research conference and usually takes place in November each year and you are strongly advised to apply for this opportunity when you are invited. Other great learning opportunities are provided by the conferences staged by Cancer Research UK (CRUK) and the National Cancer Registration and Analysis Service (NCRAS) and both provide a limited number of consumer bursaries to attend.

The 3 Components of this Toolkit

Now that we have worked through the introductory observations and advice we shall move onto the 3 substantive components of the toolkit.



1. Themes and questions to assist you in contributing to the appraisal of trial applications for funding

2. Themes and questions to assist you in contributing to the process of ongoing portfolio management

3. Signposts to essential resources that will support you in the role of 'consumer representative'

The toolkit presupposes the active involvement of patients, carers, and the public in cancer research. It is intended to help you to take up an active role as a 'consumer' in the work of the CSG to which you have been appointed, especially with regard to the development and appraisal of new research proposals and in the ongoing management of the portfolio of research studies associated with the CSG.

The 3 Components of this Toolkit

Component 1: Themes and Questions to assist you in contributing to the appraisal of trial applications for funding

An important function of the CSG is to review applications for funding prior to those applications being submitted to committee. The Cancer Research UK Clinical Trials Awards and Advisory Committee (CTAAC) is an notable example here.. Many of these applications will have been discussed at a formative stage within the CSG and will have the support of members of the group. Consequently, you may have the opportunity to both discuss prospective trial proposals within the CSG and to provide comment upon the same proposals more formally as a member of the CSG when they subsequently go forward to CTAAC, or elsewhere, as applications for funding.

A number of recent studies have identified that many research trials fail or underperform because they fail to recruit patients to the trial protocol in the numbers required and in the funded timescale. Issues associated with poor recruitment are identified and discussed in a recent paper by Ian Jamieson, former Consumer Representative on the Prostate CSG, 'Recruiting Patients to Clinical Trials'[1]. The capacity of a trial to recruit satisfactorily is often indicated by its accessibility. The extent to which its purposes are clear and straightforward, the terms of participation transparent and the ultimate benefits for patients articulated well will suggest something about its viability. This is the context within which the consumer representative can contribute significantly.

The themes and questions to assist you in contributing to the appraisal of trial applications are identified below.

Theme 1.1	**Patient and Public Involvement** Ian Jamieson summarises evidence indicating that where there has been patient and public involvement in the design of a trial there are likely to be fewer barriers to recruitment and that information to support patient understanding will be clear and appropriate. It is therefore necessary to assess a research proposal in terms of the way the research team has involved, and plans to involve, patients, carers and others representing the public interest.

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Questions:
- How has the research proposal benefitted from the involvement of patients and carers?
- Does the research proposal identify a consumer as co-applicant?
- Are there robust plans and is there budgetary provision to support the ongoing involvement of consumers in the management of the trial?

Theme 1.2 **Research Relevance**

It is important that the trial proposal incorporates a clear statement of purpose. This should identify how the trial will contribute significantly to the development of cancer science and to improvements in the treatment of cancer. The proposal should also clearly articulate how trial outcomes could lead to patient and public benefit. It should demonstrate the use of systematic review in the identification and appraisal of existing evidence relevant to the trial and its objectives. Potential participants should be able to see how taking part will meet their needs and that the trial has the potential to improve the treatment options available for future patients.

Questions:
- What is the question being asked?
- Is the question clear?
- Can this trial be justified by a systematic review of relevant existing evidence?
- What is the trial outcome designed to change in practice?
- Does it have the potential to improve the lives of patients?
- Is it something that patients would be interested in?

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Theme 1.3 Feasibility and Safety of the Trial Design

The design of the proposed trial will incorporate a great deal of methodological detail and information on such things as the statistical power of the study and its methods of analysis. Don't be daunted! Underlying all this clever stuff there are fundamental issues that may require clarification. For example, has the trial taken account of the nature of patients' lives: will the approach to patient recruitment work?

Questions:

- Have patient and public representatives been consulted on relevant aspects of the trial design?
- Have patient and public representatives been consulted on how participation in the trial should be presented to potential patient participants, e.g. in relation to patient information, lay summaries, etc?
- Is it likely that recruitment to the trial will be successful?
- Is participation being needlessly denied to some patients? Are the exclusion criteria clinically necessary or based upon unquestioned assumptions, for example, about age, mental health status or language/cultural competence? Are there populations being inadvertently, yet systematically, excluded?
- The Consumer Forum challenges exclusion criteria based on arbitrary age limits. With younger patients, these have been based on the traditional boundaries between childhood and adulthood, i.e. 18 years. Consumer Forum members and the Teenage and Young Adult CSG have successfully argued that there is no scientific or ethical basis for this particular boundary in clinical trials. NCRI and CTAAC guidelines are now for adult trials to have 16 as the default lower age of entry. Trials initiated by industry and/or in other countries may still use 18 as the default age, often because of legal obligations in participating countries. In such a situation, consumer representatives might enquire whether 16-17 year olds could still be recruited within the UK but perhaps have their data stored separately.

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There are legitimate reasons for research to focus on a particular age group; children's cancer research is based on this premise. There may also be reasons to exclude younger patients if therapies are less safe than with adults. The administrative and/or insurance implications may also act as disincentives to recruit younger patients, especially if the cancer being studied is unlikely to occur in many 16-17 year olds.

So an exclusion age of 18 may be justifiable, but you may wish to cite the CTAAC funding application requirements and ask for an explicit justification to be shown as to why the default age of 16 has not been chosen.

- Is there a possibility that a prospective trial may be competing with other trials for participants? This is likely to be particularly problematic where participants with uncommon genetic mutations are being sought. In such circumstances, irrespective of whether there are sufficient patients to render the trial or trials viable, is it the case that of the trials competing for participants, one or more may be significantly less attractive to patients and hence less viable?

- Has the patient pathway, as defined by the design of the trial, taken account of the lives of patients and carers? Is it likely that it will be perceived as unduly onerous and deter participation and contribute to participants dropping out?

- Is the experience of being a participant on the control arm as well supported as that of being on an experimental arm of the trial?

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- Is it the case that the treatment associated with the control arm is the best available current treatment and not 'worse' than that which the participant would receive were they not to participate?
- If poor outcomes worsened the lives of the people taking part in the trial what steps would be taken to address this?
- If positive outcomes improved the lives of the people taking part in the trial, at what point would the principle of equipoise determine that all participants become eligible for the 'experimental' treatment?

Theme 1.4

Impact

While patients participate in trials to gain some possible benefits for themselves, the major contribution that they make is to the development of cancer science and treatment for the benefit of future patients. It is therefore important that trial proposals should include a clear commitment to the full and speedy dissemination and publication of results.

Questions:

- Does the trial proposal incorporate a clear statement of its purpose with regard to scientific and treatment development and the way in which trial outcomes may have the potential to support future applications?
- Are there mechanisms to inform the patients who have been involved in the trial, and/or their carers, of the trial outcomes and how these are contributing to scientific and treatment developments?
- Are there provisions within the trial proposal specifying how and where trial outcomes will be disseminated and for which purposes?
- Have patient and public representatives been involved in dissemination planning? Are there plans to disseminate to lay audiences, commissioners and policy makers? (At this point you may want to look at 'The Dissemination Checklist'[1]).

The 3 Components of this Toolkit

Theme 1.5

Value for Money

Many of the trial proposals that you consider will be competing for public funds. All of the trial proposals will incorporate expectations about the willingness of patients and their carers to commit a portion of their lives to supporting the research venture.

Questions:

- Although you may not be able to comment in detail you may wish to ask whether the outcomes in terms of patient benefit are commensurate with the commitment of public and voluntarily donated funds.
- Similarly, it should be asked whether the potential outcomes are commensurate with the commitment that is anticipated that patients and carers will make in participating in the support of the trial.

- It is also appropriate to ask whether the proposed work is being undertaken in whole or in part elsewhere and whether the proposed work contributes to a balance in the research portfolio for which the CSG is responsible.

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Component 2: Themes and Questions to assist you in contributing to the process of ongoing portfolio management

The other important function of the CSG is to monitor the performance of the portfolio of studies and trials for which it shares responsibility. If the portfolio is large this can be a difficult activity for the CSG Chair to co-ordinate effectively. It is important nonetheless that underperforming trials are identified and that, in reports to the CSG, the problematic issues are identified. Underperformance is typically associated with poor or slow recruitment of patients and the failure of a trial to complete within its funded period.

NCRI now produces status reports that assist with the identification of poorly performing trials. The Portfolio Maps provided on the NCRI website provide an excellent starting point. It is important to note that the input of consumer representatives can be very helpful in discussions focussed upon overcoming barriers to recruitment in trials where this has become an issue.

Portfolio Maps can be found at http://csg.ncri.org.uk/portfolio-maps[1]

The themes and questions to assist you in contributing to the process of portfolio management are identified below.

Theme 2.1	**Portfolio Balance** The CSG has the task of ensuring that the portfolio of trials for which it is responsible is balanced in supporting research that addresses all the relevant challenges in the field whilst also pursuing research in areas that demonstrate the potential for rapid or significant development. This aspect of the CSG's work will be seen in the consideration of prospective trials that are seeking support and funding. The CSG will seek to achieve a portfolio of trials that is coherent, balanced and which will deliver returns in relation to scientific development and patient and public benefit.

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Questions:
- What is the impact of this CSG in securing research for patient and public benefit? To what extent is there evidence of consumers having been involved in this?
- Is the portfolio coherent; does it adequately cover all relevant themes and challenges including those directly related to patient and public benefit?
- Does the CSG take an overview and seek to establish a balance in the range of trials it supports and manages?
- Do the CSG sub-groups follow suit? In promoting research in specific areas do they have regard for ensuring that resources are fairly distributed and for supporting a CSG portfolio that addresses the full range of relevant clinical challenges?
- How does the size of this CSG's portfolio vary from that of comparable others and what may this reflect in terms of research capability and/or research funding priorities?

Theme 2.2 **Portfolio Delivery**

The CSG has the task of overseeing the trials in its portfolio and of trying to ensure that these trials deliver the outcomes within the timescale for which they are being funded. The attention given to the consideration of a trial when it appeared at 'proposal stage' will have a bearing here. The key issues here are of recruiting patients to time and target. Your task, in representing the patient and public interest is to ensure that the CSG, and its sub-groups, are operating proactively in monitoring the performance of trials for which they are responsible, taking appropriate actions with regard to liaising with Trial Management Groups and Data Management and Safety Committees as necessary, and in sharing good practice. A further important aspect of delivery is the dissemination of research outcomes and findings. Whilst it is incumbent upon the CSG Chair to provide a list of publication outcomes in their annual report it is important that the CSG maintains clear expectations concerning the responsibility of trials to undertake the rapid dissemination of findings, including the production of publications.

The 3 Components of this Toolkit

Questions:
- Does the CSG oversee the close monitoring of trial performance in terms of patient recruitment in relation to the funded duration of the study?
- Do the CSG sub-groups closely monitor trial performance in terms of patient recruitment in relation to the funded duration of the study?
- Does the CSG take action, including the provision of support, for underperforming trials?
- Does the CSG communicate exacting expectations regarding the importance of the rapid and appropriate dissemination and publication of trial outcomes and findings?

Theme 2.3 **Patient and Public Involvement (PPI)**

PPI, also known as Consumer involvement, is relevant to Portfolio Delivery because it can:
• improve trial effectiveness, especially in recruiting
• support the dissemination of research findings
• help maintain the focus on patient and public benefit

Questions:
- Are consumers involved at the trial management level in the trials on the CSG portfolio?
- Where trials are running into difficulty in relation to timely recruitment have consumers been involved at a local level in attempts to resolve these difficulties? If this is not the case, what is the potential for this to be a feature of future problem solving?
- Where trials are running into difficulty in relation to timely recruitment of patients are there ways in which consumer representatives on the CSG can make an input to the problem solving advice offered by the CSG?

The 3 Components of this Toolkit

- Where a trial has completed successfully, do the dissemination arrangements include mechanisms whereby patients who have been involved in the trial, and/or their carers, can be informed of the trial outcomes and how these are contributing to cancer science and treatment developments?
- Does the CSG engage with consumers to develop innovative means of making trial findings widely available to lay public stakeholders and constituencies?

Theme 2.4 **Value for Money**

The research portfolio associated with your CSG will represent a significant investment in public funds. The commitment of time, energy and expense on the part of patients and carers will not be inconsiderable either. The CSG must fulfill the task of overseeing the process whereby these commitments of social resources yield the outcomes for cancer science and patient and public benefit for which these commitments were made.

'Billions of pounds are wasted each year in the steps from research question to publication: much research is unnecessarily duplicated, poorly designed, unpublished or unusable'. (From written evidence submitted by Sir Iain Chalmers, James Lind Initiative PR 47, 9 March 2011. http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/856/856vw_16.htm)

Questions:

- What is the overall financial commitment of this portfolio?
- Does the CSG work to ensure value for money by addressing the potential for overlap and duplication in the development of trial proposals?
- Does the CSG and its sub-groups offer adequate monitoring, scrutiny and proactive leadership in the review of trial performance and portfolio delivery?
- Does the CSG contribute to the effective stewardship of public and voluntary funds?

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Theme 2.5

Impact & Priorities for the Future

Each CSG Chair produces an annual report in the late summer. CSG annual reports are published on the NCRI website. These documents offer both a summative review of the work of the CSG and the performance of its trial portfolio, and a statement of intent in the form of a 3-year strategy. This includes a set of priorities for the forthcoming twelve months. Forthcoming actions should seek to address recruitment issues in trials, portfolio gaps and trial development, and other significant matters such as translational research and consumer involvement. As a consumer representative of the CSG you will be asked to contribute your views during the drafting of this report. It is important that you familiarise yourself fully with your CSG's annual report so that you are able to raise questions as to the extent to which portfolio actions taken during the subsequent year are consistent with the stated priorities and strategy. Annual Reports can be found at http://csg.ncri.org.uk/reports-and-publicatons-2/annualreports/[1]

Questions:

- New Trials - the development of stratified medicine will have the effect of reducing the requirement for large trials in the future, except in the cases of rare cancers. CSGs will, nonetheless, be keen to support larger trials that have the potential to recruit highly in order to raise overall levels of participation in clinical trials. Pressure to raise overall levels of participation has the potential to introduce perverse incentives. For example, larger undemanding trials may come to be favoured. Do those trials being considered for support address questions that fall within the CSGs' stated priorities and strategy?

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- Are the issues affecting recruitment identified within the annual report being addressed and considered in discussions of new trial proposals?
- Do prospective trials coming under the consideration of the CSG contribute to portfolio balance in addressing the portfolio gaps that are identified in the annual report's stated priorities and strategy?
- Do the stated priorities and strategy clearly articulate with patient and public benefits? In which ways can the involvement of consumer representatives on this CSG help with the group's greater effectiveness in fulfilling its portfolio management responsibilities into the future?

The 3 Components of this Toolkit

Component 3: Signposts to resources that will support you in the role of consumer representative.

There are 2 types of resources being signposted in this section. The first group can be referred to as ‘handy tools’. The second group of resources can be referred to as ‘useful resources’

Resource Handy Tools

3.1 NCRI now produces status reports that assist with the review of trial performance. The Portfolio Maps provided on the NCRI website are updated monthly and provide an excellent starting point.

3.1.1 The Portfolio Maps are a new facility and are still in the process of development. Portfolio maps are provided for all CSGs, comprising the 16 cancer site-specific CSGs and the 5 generic/cross-cutting CSGs. They provide an excellent source of information both about a CSG’s portfolio and the individual trials that comprise it. This includes those trials that have been funded and are in the process of being set up and those that are open and recruiting.

The CSG portfolio is typically segmented into cancer type with a portfolio map for each and will typically also include a separate portfolio map for industry trials that have been adopted onto the CSG portfolio. Each portfolio is helpfully stratified in terms of intervention focus and disease sub-type where appropriate. This assists with questions regarding priorities and balance within the portfolio.

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Clicking onto a specific trial on a Portfolio Map takes you through to summary information regarding the trial including closure date, sample size and, in the majority of instances, recruitment to date. Although the recruitment start date is not usually identified on this page, this information can usually sbe gained by clicking through to the Plain English trial description on the Cancer Help UK website. If this link is available it will be found in the Additional Information section.

By knowing when the trial started recruiting, how much longer the trial has to run, and the recruitment to date, you are in a position to ask questions concerning trial and portfolio delivery.

You are strongly advised, when you have a bit of spare time, to visit Portfolio Maps which can be found at http://csg.cri.org.uk/portfoliomaps. No amount of guidance is as good as getting involved and finding your own way around the maps that are of particular interest to you!

3.1.2 The National Cancer Intelligence Network (NCIN) website is an important resource. The NCIN, an NCRI initiative currently part of Public Health England, is a UK wide initiative working to drive improvements in standards of cancer care and clinical outcomes by improving and using the information collected about cancer patients for analysis, publication and research. The NCIN website offers a great deal of data and analysis on cancer incidence and survival rates and their variation in terms of geography, ethnicity, social deprivation, gender, etc. The NCIN website can be found at http://www.ncin.org.uk/home[1]

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3.1.3	A number of experienced CSG consumer representatives have found it helpful to write fairly detailed plans of how they hope to contribute effectively at CSG and CSG sub-group meetings. These same consumer representatives describe also the benefits of reviewing one's own performance in this respect after a meeting. An example of a Meeting Planning and Review Form[1] that you may wish to use or adapt for these purposes, is available from the PPI Toolkit link.
3.1.4	The NCRI Clinical Studies Group Secretariat has produced the CSG Consumer Report Pro-forma[1]. It is designed to assist consumer members of CSGs in the production of their written reports to CSG meetings.
3.1.5	A CSG Consumer Report Pro-forma (worked example)[1], is also available.
Resources	**Useful References**
3.2	Useful references provide additional guidance and information that is likely to be useful to you. It is not a definitive 'reading list' but does include selected materials that are relevant to CSG membership.
3.2.1	'Impact of Patient, Carer and Public Involvement in Cancer Research'[1]. NCRN 2012.
3.2.2	'Overview of Patient and Public Involvement at NCRI and NCRN'. http://www.crn.nihr.ac.uk/cancer/pcpie/
3.2.3	'Action on Access: Widening patient participation in clinical trials'. http://ncri.org.uk/wp-content/uploads/2013/07/2012 NCRI-Action-on-access-report.pdf[1]
3.2.4	'Role Profile for PPI members of NCRI Clinical Studies Groups'[1].

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3.2.5	'Patient and Public Involvement in Cancer Research. Information for Clinical Studies Groups'[1].
3.2.6	'Patient and Public Involvement in Research Groups: Guidance for Chairs'[1].
3.2.7	'Patient and Public Involvement: Getting going as a researcher'[1].
3.2.8	'How to Appraise a Research Proposal'. Trans–Humber Consumer Research Panel. 2006. Please contact the group via http://www.manton.karoo.net/[1]
3.2.9	'Recruiting Patients to Cancer Trials'[1]. A paper prepared for the Prostate Cancer Clinical Studies Group. Ian Jamieson, 2012.
3.2.10	'Predicting Success or Failure of Recruitment to Clinical Trials'[1]. A paper prepared for the NCRN Portfolio Balance and Delivery Group. Philip Johnson, 2012.
3.2.11	'How to Write a Good Lay Summary'[1]. Helen Bulbeck for *Clinical and Translational Radiotherapy, 2012.*
3.2.12	'Overview of Recruitment to Trials in England, citing the findings of the National Cancer Patient Experience Survey 2012'[1]. Professor Matt Seymour, 2013.
3.2.13	'Opportunities for patient and public involvement (PPI) in trial design'[1]. Helen Bulbeck for *Clinical and Translational Radiotherapy, 2013.*
3.2.14	The Dissemination Checklist[1]. CLG 2014. (This is displayed on the following pages).

The Dissemination Checklist

Essential Principles	
1.	Trial results, whether successful or unsuccessful and irrespective of outcome, should be disseminated as widely as possible to maximise their value to commissioners, to clinicians and to patients and to ensure the effective future use of research resources.
2.	Trial results should be disseminated in a variety of ways so that they are easily accessible to all stakeholders and relevant constituencies, for example on a central public register.
3.	An important priority in any dissemination plan is that of updating trial participants or their representatives on developments as the trial proceeds and to inform them of trial results promptly, or to inform them how and when they may access the results themselves.
4.	Patient and public interests are best served by ensuring that results are available in an accessible Plain English form. Particular attention should be paid to disseminating the information to, or enabling access to it, for those patients and members of the public affected by the aims and circumstances of the research and by its outcomes.
5.	Trial participants and those with experience of trial participation are uniquely qualified to assist with the planning and dissemination of trial findings and provision should be made for their involvement in this task.

Checklist
Researchers are subject to an ethical imperative to ensure that all trial findings are disseminated widely to research participants and the relevant constituencies and institutions within the communities in which they work. Dissemination is the crucial step in the effective application of trial outcomes and should therefore be planned in detail, drawing on the necessary expertise, at the outset of any research undertaking.

The Dissemination Checklist

1.	Is there a plan for the dissemination of trial findings built into the research proposal including outline costings?	Yes/No
2.	Have people with the experience of research participation contributed to the dissemination plan and is there provision within the research proposal to support the involvement of people with experience of research participation in the management of dissemination activities?	Yes/No
3.	Does the dissemination plan incorporate arrangements that ensure that trial participants or their representatives are updated on developments as the trial proceeds and promptly informed of the trial's results?	Yes/No
4.	Does the dissemination plan provide for communication in a differentiated form with a range of relevant audiences: *Scientific?* *Clinical Practice?* *Commissioners?* *Trial participants?* *Those affected by the circumstances/aims of the research??* *The wider public?*	 Yes/No Yes/No Yes/No Yes/No Yes/No
5.	Does the dissemination plan provide for the widespread communication of results irrespective of outcome?	Yes/No

This checklist emerged from discussions that took place at the Dragons' Den Workshop at the National Cancer Research Institute (NCRI) Conference in Liverpool in 2013. The discussions included contributions from researchers and from members of the Consumer Liaison Group (CLG).

The Dragons' Den Workshop at the NCRI Conference brings together researchers and NCRI Consumers. The Workshop provides the opportunity for cancer researchers to present prospective studies to an informed lay audience and to benefit from the collaborative discussion of issues raised.

Notes

Glossary/List of Acronyms

Consumers	Patients, carers and members of the public whose lives have been affected by cancer
CLG	Consumer Liaison Group
CSG	Clinical Studies Group
PPI	Patient and Public Involvement
NCPES	National Cancer Patient Experience Survey
NIHR	National Institute for Health Research
NIHR CRN: Cancer	National Institute for Health Research Clinical Research Network: Cancer
NCRI	National Cancer Research Institute
CTAAC	Cancer Research UK Clinical Trials Awards and Advisory Committee
NCIN	The National Cancer Intelligence Network
SPADE	Strategic PPI Advice, Delivery and Evaluation Group
TSG	Trial Steering Group (responsible for providing strategic oversight and advice)
TMG	Trial Management Group (responsible for the operational management of the trial)

Hard copies of this Toolkit may be obtained by contacting patient.crncancer@nihr.ac.uk

To find out more about getting involved contact patient.crncancer@nihr.ac.uk