



NCRI Complementary Therapies Clinical Studies Development Group

Frequently asked questions

- Involving the CT CSDG in study development**
- Registration of new study proposal**

This document sets out frequently asked questions about involving the NCRI Complementary Therapy Clinical Studies Development Group (CT CSDG) in the development of studies which consider complementary therapies. An appendix of abbreviations is also included at the base of the page.

1. What is the NCRI Complementary Therapies Clinical Studies Development Group (CT CSDG)?

The NCRI CT CSDG is one of 22 NCRI Clinical Studies (Development) Groups which represent a central component of the new framework for cancer research in the UK, providing the primary route through which new ideas for clinical trials and studies are developed. All Groups have a remit to oversee existing studies in their NIHR Cancer Research Network Portfolio.

The NCRI CT CSDG is made up of some of the UK's most experienced academic and clinical researchers and complementary therapy practitioners, whose expertise focus on the investigation of complementary therapy use along side cancer treatment. More information about group membership can be found on the NCRN website:

http://ncrndev.org.uk/index.php?option=com_content&task=view&id=117&Itemid=255

The Group was created to build and oversee a portfolio of high-quality research into complementary therapy use in cancer. The Group does not consider protocols investigating therapies used as alternatives to mainstream cancer care. The Group has 4 subgroups and is supported by a full time Research Development Coordinator.

2. What can the NCRI CT CSDG do for me?

The Group offers general or specific advice and its guidance on the necessity, feasibility, and methodology of a study or trial idea during the development period prior to the submission of a funding application. The Group can also help you seek relevant funding opportunities.

The Group can also be approached for a letter of support irrespective of whether the Group has been involved in a study's development. This is sometimes requested in advance of a submission to some funding bodies. Previous submissions to some funding bodies have had a significantly higher chance of success when developed or supported by the appropriate NCRI Clinical Studies (Development) Group.

3. Are there other advantages of involving the NCRI CT CSDG in the development of a proposal?

If the study is funded, or endorsed by a funding body e.g. CTAAC, it will be placed into the NIHR CRN Portfolio. The study will also go into the relevant NCRN CS(D)G site specific portfolios. Studies will then have access to infrastructure support via the National Cancer Research Network, other networks where applicable e.g. Primary Care Research Network, and the NIHR Comprehensive Clinical Research Network (through the Comprehensive Local Research Networks, CLRNs). This infrastructure support covers study promotion, set up, recruitment and follow up by Network staff. More information can be found on the UKCRN website:

http://www.ukcrn.org.uk/index/clinical/portfolio_new/P_benefits.html

The NCRI CT CSDG portfolio is monitored by the Group on a quarterly basis.

4. If I have a study/trial idea how would I approach the Group?

If you have an idea which you would like to develop or a study which you would like the group to support, please submit a trial proposal form. The intention of this process is to:

- ensure that the proposer(s) of new study ideas retains ownership,
- avoid unwanted 'overlap' in trials being developed
- ensure a comprehensive portfolio of complementary therapy studies can be established and maintained,
- ensure that the study has the best possible chance of being developed effectively and funded
- track study ideas and map the current complementary therapy research capacity

Please complete the [Trial Proposal Form](#) which can be and email to the CT CSDG Chair (Mr Andrew Ritchie) at andrew.ritchie@btuh.nhs.uk and to the Research Development Coordinator (RDC), Miss Julie Flynn, at Julie.flynn@cancer.org.uk.

5. If I approach the Group for support or endorsement of my study how is this gained?

Trial proposers are initially required to submit a trial proposal form as in FAQ x above. The process of registration and development is explained within the form.

Once a study proposal form has been submitted, studies ideas are considered by the relevant sub group Chair and their sub group members. Should the study idea be support, it will only be supported IN PRINCIPLE at this stage.

Once studies have been fully developed by the PDG/TMG, the final version of the outline/final grant application should be sent to the Chair of the CT CSDG for a letter of support. In writing the letter, the Chair will consider the support and advice given

by the relevant CT CSDG subgroup/member and indicate whether the study is fully supported or whether full support is subject to relevant suggested changes in the proposal.

6. How long will it take for the initial study idea to be considered?

The initial process could take between 4-6 weeks. An example timeline can be seen in figure 1 below. The length of time taken to fully develop and submit a proposal depends on a multitude of factors e.g. PDG group discussion and input from other CS(D)G's.

Week No.	e.g. Week Beginning	Schedule	e.g. Specific dates	Time (wks)
1	2 Mar 09	Submission of study proposal form RDC logs study, allocates study ID number RDC/Chair sends proposal to subgroup Chair(s)	Mon- Fri 2 Mar 09	1
2	9 March 09	Subgroup discusses proposal		1
3	16 Mar 09	Deadline for subgroup Chair response to proposer (cc RDC and Chair)	Fri 20 Mar 09	2
4	23 Mar 09	Final deadline for subgroup Chair response to proposers (extra time if further discussion required to enable support, modify or reject decision)	Fri 27 Mar 09	3
5	30 Mar 09	RDC forwards supported proposals to CT Stats group and other relevant CS(D)G groups	Mon 30 Mar 09	1
6	6 Apr 09	Study development period begins <ul style="list-style-type: none"> • Feedback and buy in from other CS(D)G • Formation of PDG • Construction of proposal • Feedback to subgroups on a quarterly basis 	Mon 6 Apr 09 onwards	X

Figure 1. Example timeline for processing new study ideas

7. Can I approach other NCRI CT CS(D)G's?

Yes you can approach other NCRI CS(D)G's for involvement in your study, but we would recommend that this is done in a coordinated manner or that you let us know if you are approaching other CS(D)G's at the same time. If you approach the CT CSDG we will automatically identify whether other CS(D)G's may warrant involvement in study development or whether you could seek group support for your study from an additional CS(D)G.

8. Who do I contact if I have anymore questions?

Please contact Miss Julie Flynn - Research Development Coordinator (RDC), at Julie.flynn@cancer.org.uk or on 0207 061 8584.

Appendix 1 – Glossary

CTAAC – Clinical Trial Advisory and Awards Committee (CRUK). A CRUK funding committee which considers applications for funding, or approval of investigator-led, except first in man studies for Phase I/II/feasibility studies and Phase II trials or Phase III trials.

CTU - Clinical Trials Unit

NCRI - National Cancer Research Network

A UK-wide partnership between the government, charity and industry which promotes co-operation in cancer research among the 21 member organisations for the benefit of patients, the public and the scientific community.

NCRI CT CSDG – National Cancer Research Institute’s Complementary Therapies Clinical Studies Development Group

One of 22 NCRI Clinical Studies Groups represent a central component of the new framework for cancer research in the UK, providing the primary route through which new ideas for clinical trials are developed

NCRN – National Cancer Research Network

Organisation which aims to provide the NHS with the infrastructure to conduct high quality cancer clinical studie and to improve the speed, quality and integration of research resulting in improved patient care.

PBSC – Previously Population and Behavioural Science Committee (CRUK), now CRUK’s Population Research Committee which considered applications which focus on screening, early presentation and diagnosis.

PDG - Protocol Development Group

Expertise who develop protocol idea and can include relevant CS(D)G member(s). Can also be the TMG as above.

RDC - Research Development Co-ordinator

TMG - Trial Management Group

Includes the Principal Investigator, clinicians, the Trial Manager, statistician and sometimes others e.g. relevant CS(D)G member(s). TMG is responsible for day to day running of trial.

NIHR CRN Portfolio – National Institute for Health Research Clinical Research Network Portfolio

Studies (clinical trials and other well designed studies which involve the NHS) that are funded by NIHR, other areas of Government, and NIHR non-commercial Partners are automatically eligible to be included in this Portfolio.