

Information about the NCRI Cancer CTU Group

This is a new group, and we hope that member CTUs themselves will shape the working practices over time. In the first instance, below are some questions and answers that set out NCRI's initial expectations about how this will work.

Why is NCRI moving from CTU accreditation to a CTU working group?

CTUs are an essential partner in the development and delivery of cancer trials, and NCRI recognises the value of having been able to work with cancer CTUs over the past 10 years through its accreditation scheme introduced in 2003. The UKCRC subsequently introduced a registration process for CTUs across all diseases, which includes peer review of systems and processes, and many CTUs with core funding also report separately to funders on their work.

To ensure that NCRI supplements rather than duplicates these processes, the decision has been taken to stop conducting separate peer review and accreditation in cancer, but to retain the invaluable connections between those CTUs at the forefront of developing cancer clinical trials. As a result, we are now taking applications from CTUs to become members of an NCRI Cancer CTU Group.

What does NCRI see as the group's purpose?

The NCRI Cancer CTU Group will bring together leading cancer CTUs to contribute at a national level to the advancement of cancer clinical trials. The group's role includes:

- facilitating connections and collaboration between CTUs
- acting as a collective voice for issues affecting cancer CTUs and cancer trials
- sharing skills and best practice on cancer trials with other CTUs
- engaging with funding bodies, the NCRI Clinical Studies Groups and the UK Clinical Research Networks
- providing an easy point of contact for cancer CTUs to interface with other parts of the national/international research infrastructure
- contributing to national strategic initiatives/priorities in cancer research.

We expect the member CTUs to take a role in building the group's remit under these overarching aims, to ensure that it best meets their needs.

Are individuals or CTUs the 'members' of the Group?

The CTU itself is the member of the group, and each trials unit would put forward just one application. As part of the application, we ask all CTUs to provide the name of the person who will act as the primary contact and meeting representative. This would be expected to be the CTU Director or Head – or for cross-disease CTUs, this might be the senior cancer lead. The person putting forward the application is encouraged to seek whatever internal permissions might be needed.

What benefits will there be to CTUs if they join the group?

Member CTUs will be able to badge themselves as being members of the NCRI Cancer CTU Group, and a short profile of member CTUs' interests and capabilities will be hosted on the NCRI website, with redirects to CTU websites. CTU Directors/cancer leads will be able to meet with each other to discuss areas of common interest, and the group will allow them to be part of a collective voice to research funders, policy makers, legislators and others.

In the first instance, meeting frequency is expected to mirror the format used at present, which is two half-day meetings a year for CTU leads, with two further half-day meetings for Operations Leads. We also expect some of the Directors/cancer leads to be able to connect with the NCRI Clinical Studies Groups Chairs at their twice-yearly meetings, though practicalities around group size may require a subset of representatives to be nominated, or attendance to be rotated.

And what will be expected of member CTUs?

The representatives of member CTUs will be expected to share their own expertise to support coordination between cancer CTUs and guide the national delivery of cancer trials. This includes contributing to meeting/workshop agendas and presenting topics for information/discussion.

Where there are challenges identified that affect all cancer CTUs, or projects that would benefit national cancer trial delivery, it is expected that member CTUs would work together to address them, for the shared benefit of CTUs working on cancer trials. This could mean providing advice to, and working in partnership with, NCRI Clinical Studies Groups, research funders and others.

It is expected that the CTU representative will be the CTU Director or lead for cancer, and that every reasonable effort be made to attend meetings. Serial non-attendance for 3 meetings in a row will result in the CTU's removal from the group.

Who will lead the group?

In the early setup of the group, we will draw on the expertise of the current Heads of NCRI-accredited CTUs, who have been working together for a number of years. We will ask the current Chair to be the interim Chair for the first few meetings. Thereafter, we expect that once member CTUs and their representatives are established, the group will nominate a Chair from amongst these.

Why are entry criteria applied – shouldn't this be open to all CTUs?

After many years of running working groups at NCRI, it is clear that both overall group size and the degree of common agenda of group members are very important in being able to create a functioning group. Our aim is to create a way for CTUs with a major focus on cancer to work on driving national innovation and quality, but without making the group so large or diffuse that it is unable to function effectively.

What are the entry criteria?

CTUs are able to join the group if they meet the following criteria, as set out in section 2 of the application form.

Criterion	Demonstrated by
Appropriate procedures and infrastructure in place for trial delivery	Possession of full UKCRC registration status
Substantial volume of work on cancer trials	As listed on the NIHR UKCRN portfolio: At least 10 interventional, multicentre cancer trials of any size OR 3–10 interventional, multicentre cancer trials with total target recruitment of >2000 UK patients
Ongoing commitment to cancer trials	At least 1/3 of the trial activity (by whichever of the two trial volume measures used above) being in trials that are open/in setup.

Section 3 of the application form also asks for some further information on CTUs' connections and collaborations. No fixed entry requirements have been set for this, but we would expect CTUs to demonstrate some involvement in national groups or initiatives that contribute to the advancement of trials work beyond their own locality. This is in keeping with the group's overarching purpose of cancer CTUs working together to contribute to the advancement of cancer trials at a national level.

Why have these entry criteria been selected?

We are asking for members to have full UKCRC registration, as this demonstrates that CTUs have the necessary processes and infrastructure to function well.

We are asking for members to demonstrate a certain volume of trial activity in the national portfolio, to ensure that member CTUs are working on trials that have won peer-reviewed funding and are contributing at a national level. The criteria are focused on interventional, multicentre trials, as this is the area where the greatest coordination need and greatest commonality of challenges and opportunities amongst CTUs is expected to be seen. Multicentre trials also indicate involvement that extends beyond a CTU's own locality, and it is expected that some trials will have Chief Investigators outside the host institution. To recognise that CTUs will have differing profiles of trial activity, both number of trials and target number of patients to be recruited are accepted as alternative measures of volume.

We are asking for a proportion of the cancer trial activity to be on trials that are open or are funded and in setup, to ensure that CTUs in the group are those for whom cancer work is an active and ongoing commitment.

How does the application process work?

If your CTU wishes to join the group and meets the criteria set out, the Director or cancer lead needs to complete the application form and return it to NCRI by the date specified. The information supplied in the application will be cross-checked against the UKCRC records of registered units, and the information in the NIHR Cancer Research Network portfolio database. The contribution to national groups will be cross-checked where possible against online

membership lists. The applications will be assessed by a member of the NCRI secretariat and decisions confirmed by the NCRI Clinical Research Director and the Chair of the NCRI Clinical and Translational Strategy Group.

How often will new applications be taken?

We will invite new applications every two years. We will ask member CTUs to renew their membership every two years as well, to ensure that they continue to meet the criteria and that our information on expertise and collaborations of the CTUs remains up to date.

What happens if my CTU meets criteria now, but does not at the next round?

The criteria are designed to promote a commonality of agenda and a functional group size, not to penalise units for fluctuations in activity. If a CTU that is currently a member drops below the threshold on one occasion, they will be able to remain on the group. If they fail to meet criteria twice, they will leave the group; this is to ensure that if a CTU's priorities move away from cancer we do not retain members indefinitely. They will be welcome to reapply at the next round if their cancer focus increases again.

Serial non-attendance of CTU representatives at 3 consecutive meetings may also result in removal from the group.

If my CTU doesn't meet the criteria to be a member, how else can I be involved?

We hope to continue the 1-day annual CTU meeting that has been run so successfully for the past 9 years; subject to budget and space, this would be open to CTUs outside the group who work in cancer, as well as member CTUs. You can also request to receive feedback from meetings, and it may be possible to attend certain meetings as an invited member, with the Chair's invitation.