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People with cancer who are treated in clinical trials are more satisfied and do better than people who receive the same treatment outside of a clinical trial. Despite this, less than 3% of NSW adults with cancer are currently enrolled in trials. Recognising the need to build capacity and infrastructure for clinical trials research, The Cancer Council NSW worked with key stakeholders to reach agreement on the steps necessary to achieve the mutual aim of improving participation and access to cancer clinical trials. This resulted in the establishment of Cancer Trials NSW (CTN), a collaborative initiative to support and promote a wide range of cancer clinical trials research throughout NSW.

Some of the most innovative aspects of the CTN program are:

- The extensive consultation and collaboration conducted in the development and establishment of CTN.
- A unique trial selection process, developed to ensure the best trials that need the most support get this crucial boost. This means more support for trials of radiation therapy, surgery, palliative care and supportive care, not just for trials of anticancer drugs.
- A unique centre selection process to direct funds for study nurse/data management support.

Consultation and collaboration

Comprehensive consultation was done to help develop the most appropriate model for this collaborative initiative. Consultative committees were convened to provide advice and reach agreement on all aspects of CTN – including issues of policy, procedure, selection of trials and participating centres, finance, governance and management. All committees included consumers, health professionals and researchers. CTN is now well established with consensus from all the key stakeholders on suitable policies and procedures for a fair, rigorous and inclusive selection.

Trial selection

CTN trial selection occurs twice a year, with calls for applications in March and September. Continuing review and addition to the portfolio of CTN trials is designed to ensure that the mix of cancers and treatments in supported trials reflects the experience of cancer in NSW.

The CTN portfolio now includes 47 supported trials.

Trial Selection Committee

Our inclusive Trial Selection Committee comprises 26 individuals from all relevant disciplines, including three consumers, clinicians, researchers and staff of The Cancer Council NSW. Three assessment forms are used by the committee.

At least 10 committee members review and rate each trial application using:

1 the “CTN trial and concept rating form”, an electronic form that allows raters to score each trial application against specific selection criteria developed for CTN.

A content expert and a methodologic expert do more detailed assessments using two other forms:

- 2 the “Protocol critical appraisal form” developed by Davina Ghersi of the NHMRC Clinical Trials Centre; and
- 3 a modified version of the “National cancer grants ranking form”.

The results of these ratings and assessments are then summarised and form the basis of the committee’s discussions and decisions.

Trial selection criteria

To help meet the aims of CTN, selection criteria were developed and integrated into a CTN trial and concept rating form. The form includes 24 aspects grouped in six domains:

- Importance, priority and impact
- Scientific excellence
- Collaboration and involvement
- Need and efficiency
- NSW perspective
- Overall rating

Centre selection

Part two of the CTN support process is to select the NSW centres that can best increase participation and access to the selected trials. Each successful centre receives a grant of \$30,000 per annum, with annual renewal conditional on performance and evaluation. Each grant is to fund half a full-time equivalent (0.5 FTE) study nurse/data manager at the centre. Applicants are encouraged to collaborate with other departments within an institution, and for metropolitan centres to submit applications with associated regional and rural centres.

CTN now funds 14 half-time study nurse/data managers throughout NSW.

Centre Selection Committee

An inclusive Centre Selection Committee was convened with 19 individuals from all relevant disciplines, including two consumers, clinicians, researchers, cooperative trials groups, NSW Health, and staff of The Cancer Council NSW. Every committee member reviews and rates every centre application using the “CTN centre rating form”, an electronic form that allows each centre application to be rated against specific selection criteria developed for CTN.

Centre selection criteria

To help meet the aims of CTN, selection criteria were developed and integrated into a CTN centre rating form that includes 21 aspects grouped into seven domains:

- Participation
- Access and equity
- Quality
- Economy and efficiency
- Multidisciplinary care

- Contribution to Cancer Council activities
- Overall rating

Ideal applications include substantial, realistic participation in a rational subset of CTN supported trials involving collaboration, networking and links between disciplines, centres, areas and institutions. In their application each centre outlines which trials they intend to do and their proposed recruitment figures. CTN sponsored centres are encouraged to take up new supported trials as they are approved, and patients recruited are included in the evaluation of that centre.

Vision – “research in practice”

We hope that by 2010, throughout NSW:

- Participation in cancer trials is an integral part of clinical practice.
- Everyone suitable is able to participate in cancer clinical trials, both patients and clinicians.
- World-class participation delivers world’s best cancer care and outcomes.
- 90% of eligible patients are offered participation in CTN supported trials and 25% choose to take part. The targets are that everyone is given the choice, and that people are fully informed and free to choose.

What’s in the future?

Increase funding

We plan to increase the number of CTN supported study nurse/data manager positions to 20 FTE over the next five years, contingent on the success of our fundraising efforts with The Cancer Council NSW. We anticipate future applications to support centres will be invited annually as funds become available.

Trials initiation

Our initial focus has been to improve participation and access in NSW by selecting and supporting greater participation in

ongoing, high-quality trials. The next step is to identify important gaps in our cancer trials research program, and help establish high quality trials to address them. Through this initiative, CTN will provide a genuine vehicle to support locally initiated trials and build on the intellectual contribution from NSW to the global trials effort.

A national register of cancer trials

Information about each supported trial and centre is currently available on the Cancer Trials NSW website, which is part of The Cancer Council NSW website at www.cancercouncil.com.au. We aim to work with our key stakeholders and other state cancer councils to further develop this information as a basis for the establishment of a national register of cancer clinical trials.

Education and training

Educating advocates, consumers, clinicians and researchers about ongoing trials and the importance of participation is another important strategy for increasing participation and access throughout NSW. CTN has already contributed to training programs for consumers, and plans are in progress for educational programs for study nurses, data managers, clinicians and other researchers.

Conclusion

CTN provides a successful, effective model for building infrastructure to improve participation in and access to cancer clinical trials, and for developing a close collaboration between consumers, clinicians, researchers and funders. Effective involvement means inclusion at all levels including trial development, management and fund-raising, things that CTN will continue to champion in the future. CTN has only just begun and there is a long way to go, but with the continued support of our many stakeholders, the future looks bright.