

NOTES FOR PRESENTATION BY DENIS STRANGMAN TO THE MANAGEMENT ADVISORY COMMITTEE MEETING OF COGNO (COOPERATIVE TRIALS GROUP FOR NEURO-ONCOLOGY), SYDNEY, 23 JULY 2009.

Here is our wish list of what we would like to see in regard to brain tumour clinical trials:

Consumer involvement in the design and planning stage ... so that the trial instigators can check at an early stage what the reaction of patients might be and seek their input.

Consultation about the content of the Patient Information Sheet (PIS) ... so that ambiguities can be removed and the concepts fully explained.

Involvement of other centres, not just the major ones ... I live in Canberra and have raised this issue of clinical trial participation by regional centres as a member of the management committee for our local oncology services. We need to develop innovative and flexible solutions.

Inclusion of health-related QOL measurements ... This is important, particularly if the proposed therapy reaches the stage of a Health Technology Assessment but, also, we want to know if the trial has deleterious effects on the patient's QOL, or perhaps improves it.

A good Registry ... A capacity should exist for patients and caregivers to undertake their own research of what trials are available, both pharma initiated and independently initiated trials, preferably by a central registry that is all-inclusive.

No cutting corners ... We know of one trial where the insurance protection of members of the group did not appear to be fully covered. The IBTA spends \$4,000 annually on adequate insurance covering directors' and officers' liability and public risk.

Management committee consumer representation ... Surely this is a commonsense objective? It occurs quite frequently in the implementation of National Health and Medical Research Council (NHMRC) education grant projects and the previous Department of Health and Ageing (now Cancer Australia) cancer support groups. I know, because I have served on the Government-appointed selection committees for both projects.

Road testing ... Once the trial design has been settled it could be run past a brain tumour focus group. We know of one large pharma company that did just this in both the USA and UK. If it's good enough for big pharma, why not non-pharma?

Practical outcomes ... We are not interested in trials whose purpose is simply to establish an academic footnote to history. We want practical results for the patients we represent.

Viable options ... There is going to be an increasing use of pre-entry genetic screening and subsequent stratification in brain tumour trials. We want to see viable and acceptable options for those who are ineligible for participation because of their particular genetic profiling and are therefore screened out. Merck Serono commenced its trial of Cilengitide with no alternative option for those screened out because of MGMT promoter status. This was the CENTRIC trial.

Later, they added the CORE trial for those who had been screened out of the CENTRIC trial. This was a good initiative and we wish to see it replicated.