Comment from COSA and
the Cancer Cooperative Trials Groups on the
Refinement of the standard list of items associated with conducting Clinical Trials in Australia

Clinical Oncology Society of Australia

Thank you for the opportunity to comment on the revised List of standard clinical trial items that has been developed following stakeholder consultation. These comments are from the Clinical Oncology Society of Australia (COSA) and Australia's 14 national Cancer Cooperative Trial Groups. COSA is Australia's peak multidisciplinary organisation representing health professionals working in cancer. Australia's 14 national Cancer Cooperative Trial Groups have a record of world-class international research in oncology. Please see Appendix One for a list and description of these groups.

In the 2013 joint submission to the IHPA discussion paper for development of a table of standard costs for conducting Clinical Trials in Australia COSA and Australia's 14 national Cancer Cooperative Trial Groups made several important recommendations. We are pleased to note the refinement of recommendations to the standard list of items associated with conducting investigator initiated clinical trials in Australia. Rather than commenting on each revised item in the list we have limited our comments to the Key Principles underpinning revision of the List.

2.1 Scope of the activities of the List

The decision to limit the scope of the activities on the List to those activities typically conducted at or by trial sites provides clarity about who is performing the activities on the List and reduces the potential for confusion and duplication which was problematic in the original List. We previously recommended that a table of standard costs would need to have relevance to the private sector. We therefore welcome the statement that the List has been developed for both public and private hospitals.

2.2 Structure of the List

We agree that the previous three part sub-structure covering 'Clinical –Tests and Procedures'; 'Clinical – Trial Support Services' and 'Non Clinical Services' caused some overlap of activities on the List. We commend the structure of the revised List according to the clinical trial life-cycle which significantly reduces the potential for duplication and confusion.

2.3 Inclusion of items that are defined as fees on the List

We support the streamlined approach of all items being described as activities. We agree that revising the List to describe all items as activities/services and not as a mixture of items that describe activities and items that describe fees removes the potential for duplication. However this also means it will not take into account prevailing or usual practice fees. As stated in the report this will leave the question of fees to be determined between the trial sponsor and trial site with reference to the cost of the activity as published by IHPA.

2.4 Reduce emphasis on pharmacy department activities

Reducing the emphasis on pharmacy department activities by bundling them and including more specific references to activities undertaken by other supporting departments makes the List more representative of trials where there are not only specific pharmaceutical requirements but specific imaging and pathology requirements for clinical trials.

2.5 Extra clinical services items on the List

We agree with the inclusion of an item to explicitly cover ward bed-days (including same-day suite) as a clinical resource within the refined List. This reflects the typical practice in some hospitals of admitting trial patients for study drug administration or monitoring at day stay chemotherapy suites.

2.6 Activities specific to trial intervention type

We agree with the approach of a shorter List with a core set of items that are applicable to activities conducted at or by clinical trial sites for the majority of trials. However, as the List does not include any additional activities related to non-pharmaceutical intervention trials it will have limited applicability in research outside of pharmaceutical trials. There is little or no mention of other trials such as surgical, radiation, allied health or quality of life, all of which are as important as pharmaceutical trials, albeit less common.

2.7 Activities specific to trial sponsor type

An important recommendation from our previous submission was that the type of sponsor – i.e. investigator/cooperative trial group initiated research versus commercial pharmaceutical company initiated research – be factored into the discussion about costing clinical trials in Australia. The decision not to alter the List to better reflect the activities associated with clinical trials where the funder/sponsor is not a pharmaceutical company is therefore disappointing. This approach might seem reasonable from the perspective that activities performed at trial host sites associated with clinical trials with non-pharma sponsors are the same as activities associated with pharmaceutical sponsored trials. However, it does not acknowledge or seek to address the fundamental differences in the underlying rationale, funding models and available resources that exist between commercial industry sponsored trials and investigator/cooperative group trials.

2.8 Activities specific to trial setting

The majority of clinical trials are performed in hospitals, however, not including any additional activities for trials performed outside this setting will limit the widespread applicability of the List, we agree this may present an opportunity for subsequent refinement of the List.

We would also like to indicate that costing a core set of activities will still not address disparities in costs that vary according to the geographical location of institutions, particularly for regional and rural hospitals.

2.9 Activities specific to trial phase

As acknowledged in the report the Phase of the trial can influence the type of activities performed and this is particularly the case for Phase I trials. In our original submission we recommended that adjustment to standard costs need to be provided according to the Phase of the trial. The activities of the List are limited to Phase III trials with no provision for allowances of the increased complexity and therefore inherent costs associated with conduct of Phase I trials; this should be considered in the next iteration of the List.

Our original submission also suggested the importance of adjusting cost to take into account the population target, and in particular paediatric trials. The streamlining of the List with activities relevant to the majority of clinical trials but not including paediatric trials will mean sites will need to negotiate costs for extra activities not covered by the List. We also suggest that this is considered in future refinements of the List.

2.10 Defining of standard of care

We are very pleased to note in the principles published with the List that, in determining trial budgets, it is only clinical services over and above the standard of care that should be considered for costing to the clinical trial. This was an important recommendation from our original submission and we applaud the decision to make this clear in the principles to guide the use of the standard List.

Conclusion

Overall the refinement of the standard List of items associated with conducting Clinical Trials in Australia has improved the List, however the List is by no means comprehensive of all activities associated with clinical trials and this may well have the effect of limiting its applicability, and should be addressed in the future.

We remain concerned that the widespread adoption of these recommendations as industry standards will jeopardise the viability of clinical trials research in Australia if the result is a cutting of existing costs and a shift of costs to researchers and health services. There is also no question that these recommendations will severely undercut any ability that clinical trial units in hospitals currently have to support underfunded research such as investigator-initiated, grant-funded or cooperative group trials.

The true test of course will be to see how the list functions in reality for sponsors and trial sites. We would very much hope that there is a timely review planned to evaluate the actual success of the list as an authoritative reference point to reduce uncertainty around clinical trials costs and a review of what the ramifications have been for the different types of sponsors and trial sites involved in clinical trials.

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Appendix One – Cancer Cooperative Trial Groups in Australia

Australasian Sarcoma Study Group (ASSG) aims to improve outcomes for sarcoma and related tumours in the Australian community by undertaking outstanding research.

Australasian Gastro Intestinal Trials Group (AGITG) is Australia's largest independent non-profit organisation conducting clinical trials into gastrointestinal cancers.

Australasian Leukaemia & Lymphoma Group (ALLG) is the only not for profit organisation designing and delivering investigator initiated clinical trial research into blood cancers.

Australasian Lung Trials Group (ALTG) is a multi-disciplinary organisation dedicated to reducing the incidence, morbidity and mortality of lung and thoracic cancer in Australia and New Zealand.

Australian New Zealand Breast Cancer Trials Group (ANZBCTG) conducts an independent, collaborative breast cancer clinical trials research program to save lives from breast cancer.

Australian and New Zealand Children's Haematology and Oncology Group (ANZCHOG) are the leading body representing the interests of children and adolescents with blood diseases and cancer.

Australia New Zealand Gynaecology Oncology Group (ANZGOG) supports collaborative research to improve outcomes of women with gynaecological malignancies through randomised clinical trials.

Australia New Zealand Melanoma Trials Group (ANZMTG) coordinates and conducts quality research for melanoma control.

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) develops and conducts cancer research in urogenital and prostate cancers.

Cooperative Trials Group for Neuro-Oncology (COGNO) aims to conduct investigator initiated and collaborative group trials addressing important clinical questions in patients with brain tumours.

Palliative Care Clinical Studies Collaborative (PaCCSC) is a national multicentre research network to support clinical studies in palliative care.

Primary Care Collaborative Cancer Clinical Trials Group (PC4) supports the development of high quality cancer research in primary care.

Psycho-oncology Cooperative Research Group (PoCoG) aims to develop capacity and collaboration to conduct large-scale, multi-centre psycho-oncology and supportive care research.

Trans-Tasman Radiation Oncology Group (TROG) is a cooperative multidisciplinary organisation dedicated to the control of cancer through quality multicentre research into radiotherapy.