

6<sup>th</sup> May 2015

Submissions  
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**Response to Public Consultation paper dated 24<sup>th</sup> March 2015 for the  
Development of a Table of Standard costs for Conducting Clinical Trials in  
Australia**

Cancer Trials Australia (CTA) welcomes the opportunity to comment on the IHPA consultation paper for the development of a table of standard costs for conducting clinical trials in Australia.

CTA is a Melbourne based not-for-profit service organisation that has been contracting and administering cancer clinical trials on behalf of clinical research organisations since 2003.

CTA is a network of 18 clinical member sites: Alfred Health, Austin Health, Ballarat Health, Barwon Health, Bendigo Health, Border Medical Oncology, Cabrini Health, Melbourne Health, North Coast Cancer Institute – Port Macquarie, Peninsula Oncology Centre, Peninsula Health – Frankston Hospital, Peter MacCallum Cancer Centre, St Vincent's Health (Melbourne), Southern Health, Sydney Local Health District- Royal Prince Alfred, The Royal Women's Hospital, Tweed Hospital and Western Health. We undertake the administrative tasks of ethics submissions and governance coordination, budget, contract and financial management of fee collection for many of our member sites.

**GENERAL FEEDBACK**

- **Cost Recovery**

CTA continues to strongly support establishing a table of standard costs associated with conducting clinical trials based on efficient cost of service. This should reflect actual activity in accordance with cost recovery principles.

Members of Cancer Trials Australia:

Alfred Health, Austin Health, Ballarat Health Services, Barwon Health, Bendigo Health, Border Medical Oncology, Cabrini Health Limited, Frankston Hospital, Ludwig Institute for Cancer Research, Melbourne Health, Peninsula Oncology Centre, Peter MacCallum Cancer Centre, Royal Prince Alfred, Royal Women's Hospital, Southern Health, St Vincent's, The Walter and Eliza Hall Institute of Medical Research, Tweed Heads Hospital, Western Health

- **Fair Market Value**

There is an expectation that costs are consistent with accepted principles of fair market value. The prices that sponsors offer must be taken into account in any construction of standardised costs. There is little point in developing a standard list of costs if they will not be recognised and accepted by the sponsors who are the key funders of clinical research in Australia.

- **Hourly rates for labour costs**

We recommend that labour costs are not only based on the award rate but take into account on-costs, overtime, and anticipated CPI increases.

The paper only makes reference to Investigators, Study Coordinators and Research Nurses. However, a majority of sites, especially the larger research institutions also have dedicated Clinical Trials Managers and Data Managers who are an integral part of the clinical trial team. The hourly rates of these positions need to be separately costed and included against activities where appropriate.

- **Organisational fixed costs and CPI increases**

Institutions provide well equipped premises together with telecommunications, IT, lighting and power. Provision of this cost item, typically referred to as overheads needs to be considered as a separate and distinct cost. The determined costs should not include allocated institutional overheads but rather added as a separate line item in the budget for transparency. Further, CPI increases are rarely taken into consideration, if a trial lasts longer than 1 year which is the case for the majority of studies. An assumption of the CPI increases during the life of a study should be included in the determination of the institutional overhead.

- **Financial Management**

The management of invoicing and fee collection is a considerable cost to the site. The set-up of itemised accounts, invoices, debt collection and management of disbursement of funds (which includes internal reconciliation against interdepartmental charges for each procedure) needs to be accounted for as a separate and distinct cost. We note there is minor reference to invoicing in 2.7.2 – Trial Administration, monitoring and reporting but would emphasise the need to properly evaluate the true hours involved in this activity.

We welcome the opportunity to work with the IPHA and other stakeholders to assist in the further development and implementation of the revised table of standard costs.

If you have any queries regarding our submission, please do not hesitate to contact us on (03) 9342 7306.

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