MTAA comment on the Independent Hospital Pricing Authority (IHPA) paper:

Development of a table of standard costs for conducting clinical trials in Australia

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Medical Technology
ASSOCIATION OF AUSTRALIA

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1. Executive Summary

MTAA welcomes the opportunity to comment on IHPA's paper on the 'Development of a table of standard costs for conducting clinical trials in Australia'. As the global competition for attracting clinical trials is increasing there is a need for Australia to continue to attract the level of clinical trial activity that it has achieved over the past two decades[1].

Australia continues to be internationally recognised for conducting high quality clinical trials. The costs of clinical trials conducted in Australia are among the highest in world and do not compete with those in emerging markets such as in India and China. The high costs of running trials are compounded by the significant variability in Australian research site charges for performing virtually identical tasks[2].

MTAA supports strategies to enhance the clinical trial environment in Australia and ensure that Australia improves its attractiveness as a destination for global research investment.

MTAA shares the concerns of the Clinical Trials Action Group (CTAG) and Medicines Australia, noting a decline in clinical trial activity since 2007[2]. Clinical trials have many benefits particularly in the medical technology sector where the access to new technologies through clinical trials ensures that Australian clinicians can keep up to date with cutting edge technologies and encouraging the uptake of new technology in to clinical practice. Decreasing trial activity will reduce the opportunity for patients and clinicians to access new and innovative medical technologies.

Although IHPA's paper provides a good base for consultation, MTAA notes that the cost structure proposed is better suited to pharmaceutical and IVD trials that are conducted in the hospital setting. Further consultation is required to develop activity definitions for a standardized cost structure for medical device trials as the activities conducted for medical device trials differ greatly from those in pharmaceutical and IVD trials.

MTAA is of the opinion that there should be no differential costing between commercially-sponsored and non-commercially sponsored clinical trials and the standard cost list developed should be applicable to both contexts.

[1] Clinical Trials NSW Paper, 'Value of industry sponsored clinical trials in Australia', C. Bourgeois
[2] Medicines Australia Paper, 'Activity based funding for Australian public hospitals: Towards and Pricing Framework'.

2. About the Medical Technology Association of Australia

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. MTAA represents companies which account for the majority of products listed on the Australian Register of Therapeutic Goods (ARTG) and approximately 75% of the higher risk implantable medical devices products listed on the Prostheses List and used in the Australian marketplace. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small to medium sized Australian innovator companies.

3. General comments

MTAA supports strategies to enhance the clinical trial environment in Australia and ensure that Australia improves its attractiveness as a destination for global research investment.

MTAA welcomes the benefits to trial sponsors of standardizing costs which will promote a clearer and fairer cost structure across research sites. The greater transparency to costs of services provided will allow sponsors to more accurately budget for clinical trials. Sponsors will be able to have set expectations of the services provided by a research center based on the descriptions of the activities in the tables, where in the current situation responsibility for some activities can sometimes be a gray area.

Although IHPA's paper provides a good base for consultation, MTAA notes that the cost structure proposed is better suited to pharmaceutical and IVD trials that are conducted in the hospital setting. Further consultation is required to develop activity definitions for a standardized cost structure for medical device trials as the activities conducted for medical device trials differ greatly from those in pharmaceutical and IVD trials.

The cost structure for medical device trials needs to be flexible to allow for the variation in device types and disease states. For example a standardized hourly rate for staff training may inflate the cost of a trial if the medical device trials is highly complex.

MTAA is concerned that the level of granularity provided using the NHMRC list could potentially make trials more expensive.

MTAA suggests that the lists be presented by the stages of a trial and follow the format of a clinical trial agreement. This presentation removes the repetition in clinical and non-clinical services.

4. Specific comments

4.1 Developing the definitions for the list of standard items for clinical trials

MTAA suggests that the lists be presented by the stages of a trial and follow the format of a clinical trial agreement for ease of use.

Suggested groups of activities are:

1. Start-up
2. Study maintenance/Ongoing administration costs
3. Per patient costs
4. Miscellaneous patient costs/Participant reimbursements
5. Close up costs/Archiving
6. Data analysis

Please see appendix 1 for an example of how these groups could be applied to the categories in the IHPA paper.

4.1.1 Development of the NHMRC standard list (section 2.1)

MTAA is of the opinion that there should be no differential costing between commercially-sponsored and non-commercially sponsored clinical trials and the standard cost list developed should be applicable to both contexts.

4.1.2 Clinical tests and procedure items (section 2.2)

The initial definitions for the scope of clinical services are appropriate. The definitions of the major categories should remain broad to cover the wide range of clinical services which may vary depending on the trial.

4.1.3 The clinical trial support services (section 2.3)

The definitions in table 2.2 do translate to the clinical trial support services required for a medical device trial.

Reference 2.6.2 in table 2.2 cites “overheads” in the proposed scope of services. Overhead charges vary immensely from site to site and add considerable cost to conducting a clinical trial. Overheads should be removed from the table for standard costs as these tables should only reflect the costs of services provided for a trial.

Greater clarification is required for the scope of services cited for reference 2.6.2 investigator allocation as it is unclear how costing will be applied for each investigator.

4.1.4 The non-clinical services (section 2.4)

The initial definitions for the scope of services included under each item of the "non-clinical services sub-list (table 2.3) are appropriate.

If the items are grouped by clinical trial activities as suggested above (see Appendix A), there is no repetition of activities in the non-clinical services.

It should be noted that the majority of the work required to prepare applications to HREC and institutions is usually undertaken by the trial sponsor. Hence the costs associated with the preparation and submissions of applications to HREC need to consider the level of activity actually undertaken by the research center.

4.2 Costing the list of standard items for clinical trials

4.2.1 Principles to be used in costing the NHMRC list of standard items for clinical trials (section 3.1)

The principles for developing standard cost seem reasonable. The process maps developed need to be agreed and truly applicable across sites to ensure that activity based costing is reflective of actual common activities.

It is noted that the study will examine current practices in designing and implementing trials in Australian hospital. It is important that the study examines trials of varying complexity in the pharmaceutical, IVD and medical device sectors and compares them to current cost derivation processes.

The process maps used to derive activity based costing should be transparent and subject to consultation.

4.2.3 Costing the clinical test and procedure sub-list (section 3.2)

The use of the MBS as a basis of deriving standard cost is appropriate where MBS costing can be applied.

4.2.4 Costing the clinical trials support services sub-list (section 3.3) and non-clinical services sub-list (section 3.4)

Using process maps to identify resource units is robust however it is expected that there will be much variability depending on the complexity of the trial.

Items 3.1.10 and 3.1.11 should be removed from the cost of hiring or purchasing trial equipment will vary considerable depending on the type and complexity of the equipment and the vendor.

4.2.6 Potential need for adjustment to standard costs

There is a need to provide for adjustments to standard costs based on the identified factors:

Type of trial: As mentioned throughout this response the NHMRC list is relevant for pharmaceutical trials and further consultation is needed to develop definitions for trials in other sectors

Phase of trial: is another important factor where adjustment to standard costs needs to be considered. It is important to note that comparable cost to other countries is essential in attracting early phase medical device trials to Australia, as the sponsors of these trials may never see a return on their investment.

Trial Sponsor: There should be no adjustments based on trial sponsor. There should be no differential costing between commercially-sponsored and non-commercially sponsored clinical trials.

Standard care versus trial specific care: MTAA agrees that some guidance is required with the table of standard costs to indicate which items on the NHMRC list are most likely to represent standard care. Trial sponsors should only be charged for activities that are over and above standard care.

Appendix 1 – Suggested Groupings

Groupings	Major categories	Reference number	Item
1 Start up	Departmental protocol review	2.1.1	Departmental protocol review
	Departmental establishment/set up fees	2.2.1	Departmental establishment/set up fees
	Pharmacy/Investigational drug-related	2.4.1	Staff training (drug specific)
	Project development	3.1.1	Preparation of research proposal
		3.1.2	Site selection including site feasibility assessment process
		3.1.3	Preparation and submission of applications to HREC and institutions
		3.1.4	Radiation safety and /or biosafety reports
		3.1.5	HREC (ethical) review fee
		3.1.6	Institutional (site assessment) review fee
		3.1.7	Lead HREC/Lead site fee
		3.1.8	Investigator meeting
		3.1.9	Staff training
		3.1.12	Trial centre set-up and development
	Project implementation	3.2.1	Start-up meeting
		3.2.4	Medical records set-up, access and storage
2 Study maintenance/ Ongoing administration costs	Departmental ongoing administration fees	2.3.1	Departmental ongoing administration fees
	Pharmacy/Investigational drug-related	2.4.2	On call and call in/call back fees
		2.4.3	Drug stockings
		2.4.4	Drug preparation, labelling and relabelling
		2.4.5	Drug dispensing and accountability
		2.4.6	Drug transfer
		2.4.7	Drug storage and temperature monitoring
		2.4.8	Drug destruction
	Biospecimen-related	2.5.1	Biospecimen collection and processing (central and local)
		2.5.2	Biospecimen analysis (central and local)
		2.5.3	Biospecimen storage (central and local)
		2.5.4	Biospecimen destruction (central and local)Biospecimen
		2.5.5	Tissue repository set-up and management
	Clinical staff/Resource Allocation	2.6.1	Coordinating principal investigator surcharge
		2.6.2	Investigator allocation
		2.6.3	Research nurse allocation
		2.6.4	Clinical research coordinator (non-research nurse) allocation
		2.6.5	Clinic/Theatre usage
	Project Implementation	3.2.2	Pre-screening activity
		3.2.3	Recruitment activity
		3.2.5	Interpreter services
		3.2.6	Ongoing administration, monitoring and reporting
		3.2.9	Amendment preparation and submission
		3.2.10	Amendment review

Groupings	Major categories	Reference number	Item
3 Per patient costs	Screening Visit and Health Assessment	1.1.1	Clinical services provided specifically for the purposes of screening and health assessment
	Laboratory Tests/Procedures	1.2.1	Laboratory tests and procedures itemised under the MBS
	Medical Imaging	1.3.1	Imaging examinations and procedures itemised under the MBS
		1.3.2	PET-FDG/FLT scans not itemised under the MBS
	Radiation Therapy	1.4.1	Radiation therapy planning and treatment itemised under the MBS
	Other Clinical Tests or Procedures	1.5.1	Other clinical tests or procedures itemised under the MBS
	Specialist Medical Consultations	1.6.1	Specialist medical consultations itemised under the MBS
	Nursing/Allied Health Consultations	1.7.1	Nursing/Allied Health consultations not itemised under the MBS
4 Miscellaneous patient costs/Participant reimbursements	Participant -related	3.3.1	Participant payment
		3.3.2	Participant/carer time and inconvenience reimbursement
		3.3.3	Participant/carer travel
		3.3.4	Participant/carer parking
		3.3.5	Participant/carer meals
		3.3.6	Participant/carer accommodation
		3.3.7	Participant inpatient/overnight stay
		3.3.8	Participant outpatient/day stay
5 Close up costs/Archiving	Project implementation	3.2.11	Study close-out activity including preparation for audit
		3.2.12	Archiving of trial records
6 Data analysis	Project implementation	3.2.7	Data analysis (+/- study report)
		3.2.8	Trial centre data management, data analysis and ongoing administration, monitoring and reporting