Feedback on: ***"Development of a Table of Standard Costs for Conducting Clinical Trials in Australia – Public Consultation Paper"***

GlaxoSmithKline Australia , 22 April 2015

Thank you for the opportunity to review the consultation paper. GSK have considered the paper and have the following feedback. We have answered each question individually as well as providing some general comments on the content. We would welcome any further discussion on this.

Consultation questions
Are the principles for developing the Table of standard costs reasonable?
Yes, the principles as described are fine
Are there any principles that should be modified or deleted? Should additional principles be adopted?
The principle of calculating costs for a particular item should be made clear that the item cost is associated to full completion of that activity. For example, item 1.2.1 (preparation of HREC application) is in principle an item conducted by sites but in practice, more is being expected of the Sponsor company to perform. It must be made clear that for all items costed, they are costed on the basis of 100% completion by the service provider and are not considered as a cost for part performance of an activity.
Please suggest wording changes and/or additional principles where necessary.

Consultation questions
Is the proposed method for deriving the standard costs for each item on the NHMRC sub-list for site authorisation reasonable?
The methods themselves are fine and again, we reiterate that there should be no cost associated with the conduct of feasibility assessments. This is akin to providing a service quotation and there is no confirmation that a study will be conducted or budget available to pay such costs. This major category should be removed.
Are there any items for which the costing approach should be modified?
Due to impending changes to the CTN process (eCTN), should the approach to item 1.3.2 be revised?
Please suggest alternative costing approaches where appropriate.
Again, there should be no item costed for feasibility assessments, this should be excluded from the list.

Consultation questions
Is the proposed method for deriving the standard costs for each item on the NHMRC sub-list for site implementation reasonable?
The methods themselves are fine.
Are there any items for which the costing approach should be modified?
For item 2.4, will the current price schedules such as SHPA be reviewed through this process?
How is item 2.5.2 proposed to be calculated? Per tube? Per cm of storage space? This item should be removed
Items 2.6.1, 2.6.2 and 2.6.3 are all listed as rates "per minute". Suggest these are changed to per hour to fall in line with standard terminology and published rates.
You have included Outpatient Time, item 2.6.7 in the list? We recommend this is removed as all clinical services and Investigator and nurse time are inclusive of overheads which should include the occupation of the facility. This should not be a standalone item.
Please suggest alternative costing approaches where appropriate.

Consultation questions
Is the proposed method for deriving the standard costs for each item on the NHMRC sub-list for site close out reasonable?
The methods themselves are fine
Are there any items for which the costing approach should be modified?
Care needs to be taken to ensure that item 3.1.1 only includes activities that are unique to close out and not activities that are considered ongoing management of a trial that should have been completed during the course of the study.
Please suggest alternative costing approaches where appropriate.

Consultation questions
Is there a need to provide for adjustments to the standard costs based on any for the identified factors? No, will be too difficult to manage all the various adjustments.
Are there other factors that should be considered for potential adjustments to the standard costs?
Please suggest methods for adjusting standard cost to account for the factors where considered necessary.