Clinical Trial Fact Sheet Template to facilitate Budgeting Process

Singapore Healthcare Management 2018

KK Women's and Children's Hospital
SingHealth

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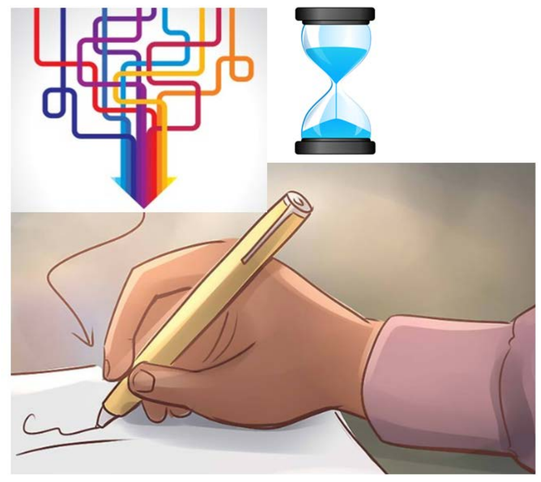
Aims

The time lag in providing budgets for Clinical Trial Sponsors is long due to various factors. The main one identified being the various exchanges of information involving multiple parties (both internal and external). We aim to look for an efficient method to gather pertinent cost parameters from numerous sources and facilitate budget preparation.



Methodology

Finance-Academic Medicine had a few meetings with key stakeholders e.g. Admin Heads from the Research Office and Clinical Research Coordinators to develop a template with basic cost parameters included for input of information by stakeholders.

After a few iterations and with feedback gathered, a Clinical Trial Fact Sheet Template (CTFaST) is built up. Key stakeholders such as Clinical Trial Sponsors, Principal Investigators and others (e.g. KK Research Centre), are involved in completing the CTFaST. The CTFaST also states the names of KKH contact parties for clarifications and submission of returns.

The CTFaST provides for a complete view of the full budget requirements and serves as a common point for reference in the process of negotiation and formalisation of Clinical Trial Agreement with Sponsors.

Results

Based on the initial implementation, the time in generating the first draft of budget improves by 50%.

Conclusion

Having a CTFaST serving as a common point of data gathering and reference has improved the efficiency of the budget preparation. The inclusion of key contacts of named parties in the CTFaST also facilitates the communication process. These have significantly reduced the turnaround time.

KKH CLINICAL TRIAL - FACT SHEET TEMPLATE

Prepared by :
Date sent to KKH :
(Please email this fact sheet to Wendy Tay <wendy.tay@kkh.com.sg>, Tracy Tay <tracy.tay.gp@kkh.com.sg>, Cecilia <cecilia.a.chandra@kkh.com.sg >, Cheryl <cheryl.gan.sy@kkh.com.sg>.

General Study Information

Please complete the section highlighted in yellow.

Sponsor :	
Contact Person (Sponsor / CRO) :	
Contact Number / Email (Sponsor / CRO) :	
Principal Investigator :	
Study Title :	
Short Study Title (if any) :	
Study/Protocol Number :	
Estimated Study Start Date (mm/yy) :	
Estimated Study End Date (mm/yy) :	
Estimated Study Duration (mths or yrs) :	
Targeted Recruitment Number :	
Main Study Site :	
Secondary Study Site (if any) :	

Notes on Completion

A) Study Team

Please indicate the number of visits according to the Study requirements.

Please input the expected number of hours to be incurred by each team member per visit for 1 subject during the Study.

If additional team member is required for the trial, please add in accordingly.

Item	Visit 1 (hrs)	Visit 2 (hrs)							Total Hours (hrs)
Study Team Member									
Investigator									-
Clinical Research Coordinator									-
Pharmacist									-
Study Nurse									-
Others: *(Please specify)*									-
									-
									-

Notes on Completion

B) Direct Patient Charge - Procedures / Tests

Please indicate the number of visits according to the Study requirements.

Blue section - Please list the procedures and/or tests required for the Study. For local lab tests, please indicate the individual test required, i.e. Biochemistry tests - Sodium, Potassium etc. For central lab tests, please indicate the number of times blood drawn for each visit for 1 subject.

Yellow section - Please input the expected number of times each procedure/test will be performed for each visit per subject.

Item	Visit 1 (no of times)	Visit 2 (no of times)							Total (no of times)
Procedures / Tests									
E.g.: Blood drawing	2.00	1.00							3.00
									-
									-
									-
									-
									3.00

C) Direct Patient Charge - Miscellaneous

Blue section - Please list the miscellaneous patient-related item required for the Study, e.g. consumables for home use (gauze, sharps bin etc.).

Yellow section - Please input the estimated cost per visit per subject.

Item	Visit 1 (S$)	Visit 2 (S$)							Total Hours (S$)
Miscellaneous (Subject transport reimbursement etc.)									
E.g. Subject transport reimbursement per subject	50.00	50.00							-
									-
									-
									-

D) Unscheduled Visit (if any)

Blue section - Please list the items that will be funded for unscheduled visit.

Yellow section - Please input the estimated cost per visit per subject.

Item	Cost (S$)
	-

E) Additional Information

Please provide details. E.g. for storage, details such as temperature, space, special handling etc.

Others (e.g. storage for Investigational Products, biological specimens/samples etc.) :	
Item that will be provided by Sponsor (kits, questionnaires, e-diary, equipment etc.) :	
Does the service of a pharmacist required?	