SingHealth DukeNUS ACADEMIC MEDICAL CENTRE | Joint Office of Research

Clinical Trials
Operational Planning & Budgeting for Sites

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In a snapshot……

- Motivators of trial conduct
- Types of budgets
- Behind the scenes in IITs
- Considerations when building of budget
- Common pitfalls

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Motivators of conducting trial

Looking through eyes of sponsor…….

- Political stability of country
- Disease prevalence
- Market size – direct and indirect reach , population size
- Organized regulatory framework
- Quality of work @ site
- Experience in similar trials @ site
- PI's quest for improved outcome and thought leadership

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Motivators of conducting trial

Looking through the eyes of the site……

- Altruistic?

-Financial matters not scrutinized to same degree

-Satisfaction of developing new products and on cutting edge of research

- Financial gains?
- Both ?

-Oncology trials -supplement their menu of clinical research projects and to expand treatment options for their patients

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What's a clinical trial budget ?

Tool that tells us how much to spend and categories where the money is spent and when it occurs(cashflow)

Types of budget

Investigator Initiated Trials/ Academic Trials

Industry Sponsored clinical trials

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Investigator Initiated Trials/ Academic Trials

Grant funded trials

- ✓ Protocol from the PI's team
- ✓ Generally has a cap of total funding and classified costs
- ✓ Pays for research manpower and research based lab costs(EOM, OOE & CAPEX)
- ✓ One size does not fit all. **Customised approaches taking operational realities** into consideration are needed.
- ✓ More 'creative ' in nature

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Industry Sponsored clinical trials

Funding from commercial source

- ✓ Protocol from the company, each protocol is different
- ✓ In essence, company ‘s buying our patient data
- ✓ Purchase of services model
- ✓ **Measuring actual work (task times)** instead of the number of patients or protocols managed by a CRC

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Resources required to build a clinical trial budget?

DETAILS …… DETAILS……. DETAILS

- ✓ Final Protocol, lab manuals,etc
- ✓ Schedule of assessments
- ✓ Evaluation and Procedure Charges, including codes
- ✓ Availability and Cost of procedure
- ✓ PI's links to surrounding resources

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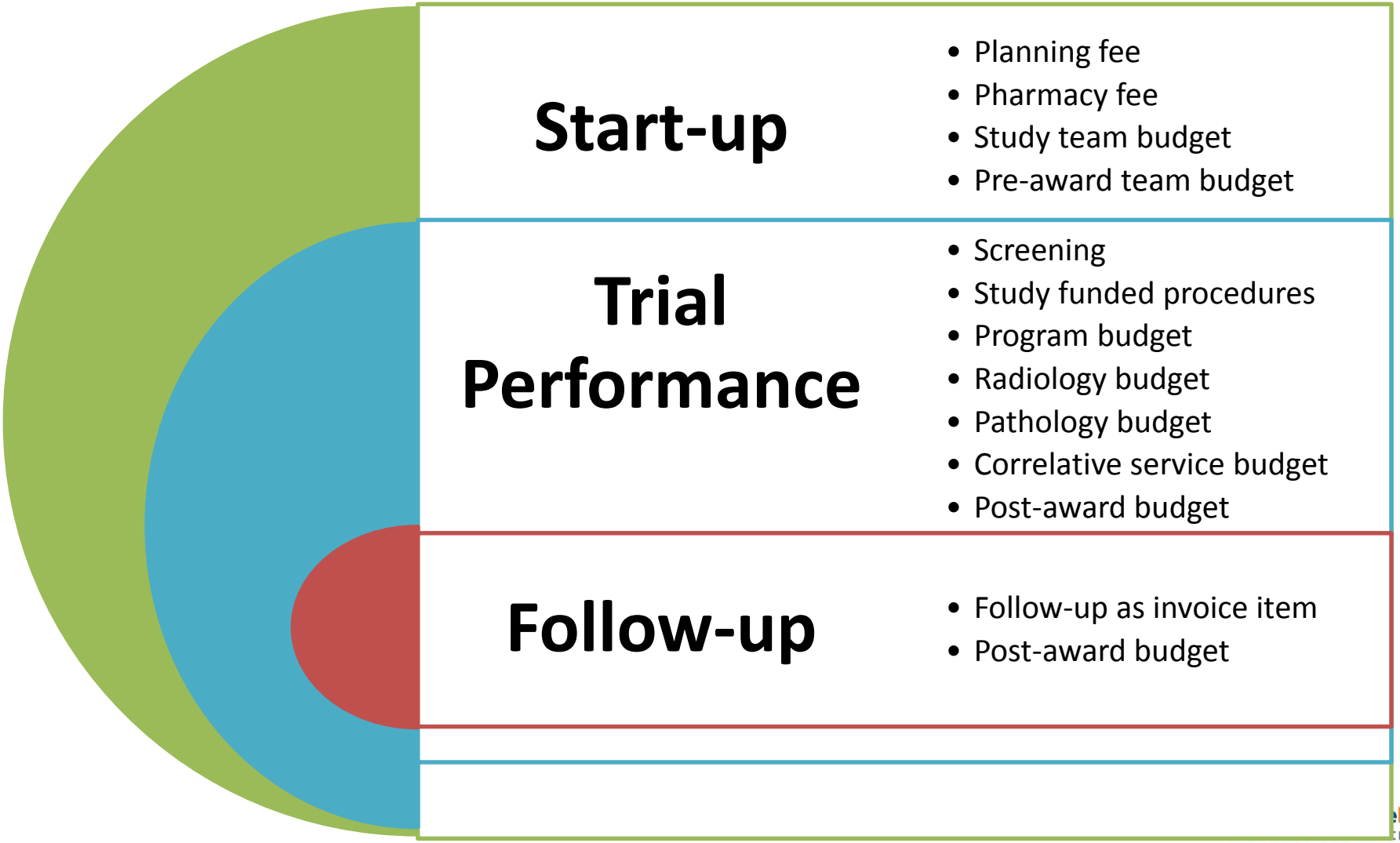
Building a clinical trial budget

Trial Budget Components ….



Factors Impacting Budgets

- **Research personnel composition**
- **The type, phase, and acuity or complexity of the protocols involved**
  - Industry sponsored trials tend to be more labour intensive
  - Cooperative group trials are more labour-driven by disease site
- **The actual time it takes to do the work**
  - Organisation of clinical trial research services within the research centre, complexity of trial
  - Long-term follow-up, if the endpoint is death
- **Associated or indirect costs**
  - Pre-award and Post-award work

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Considerations when creating a budget

- **Provide for annual increases from service line**
- If it's not the usual listed service procedures , not offered at the site, 3rd party vendors, need quotes

- **Administrative overhead**

This cost covers management resources needed to cover the pre trial work , operational clinical planning and to provide for a compliant systems at sites

- **Quality Assurance(QA) cost**

Quality plays an important role in ensuring clinical sites are conducting the trial in a compliant manner

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Considerations when creating a budget

Optional info ……

- **Site Management Organization (SMO)**

In Japan, data entry and collection tasks are outsourced to SMOs. For post approval studies, sites do not require research coordinator support. Thus sponsors are expected to hire SMOs to support the site or pay the sites to hire their preferred SMOs.

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Key Variables to Consider for Resource Budgeting & Allocation

- **Phase of trial (I, II or III)**
- **Type and stage of disease treated**
- **Anticipated complications**
  - ✓ Sample processing and/or shipping logistics
  - ✓ Patient treatment logistics and scheduling challenges
  - ✓ Data management in busy studies
  - ✓ Time limits on patient accrual reporting and data query resolution

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Key Variables to Consider for Resource Budgeting & Allocation

- **Case Report Forms (CRF)**
  - ✓The "**deliverable**" in clinical trial contracts, often **triggering payments**
  - ✓Request **a copy of the Sponsor's draft CRF** to accurately estimate labour

- **Online data entry tends to consume more study team labour**
  - ✓ doubles the amount of time spent on data entry
  - ✓ Sponsor software may operate slowly. Require to test drive it

Elements of Successful Budgeting (1)

- **Thorough analysis** of the specific protocol tasks.
- **Appropriate knowledge** of and familiarity with institutional and cluster resources
- **Delineation** of standard of care from research events & procedures
- **Estimating** a reasonable, average number of cycles or days each patient will be on study if applicable
- **Clear understanding** of the study completion timeline and requirements triggering payments as stated in the draft CTA
- **Access to updated research rates** provided by the institution

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Elements of Successful Budgeting (2)

- **Flow charting** – break down the protocol into specific paths for each patient with sections divided by service provider
- **Create a master timeline** that plots each participant's usage of critical, limited resources over time
  - Limited access to specialized care areas eg only one research MRI slot available per week
  - How patients are accrued onto a protocol will often determine the overtaxing of clinical research resources
- Create a worst-case scenario timeline and one according to plan
- Create a **billing grid** – usually derived from the study calendar
- Optional -A **break-even point and bottom line** should be analysed.

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Elements of Successful Budgeting (3)

- **Review disease registry data** to note the number of patients normally seen to accurately estimate accrual rate
- **Study team labour, ballpark recommendations**
  - Allow 4 – 12 hours per visit or 1 – 2 hours per time point for CRC labour
  - Allow 1 – 3 hours per visit for faculty labour
  - Allow 1 – 2 hours per visit for nursing, if applicable
- A **20% screen failure rate** is considered to be **fair**
- Time to chart screenings and logs that can consume enormous amounts of time
- Perform a **workload analysis** by tracking all trial activities in monthly reports to document the amount of work done within a certain time frame to create benchmarks for your institution or group

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Elements of Successful Budgeting (4)

- Factor in site costs such as **site start-up fees, IRB fees, close-out and storage fees**
- **Non-patient costs** such as core laboratory fees, and data safety monitoring board
- Factor in **3rd party vendor contractor payments**
- **Miscellaneous costs** technology solutions and regulatory filing costs
- Other factors such as, inflation, **protocol amendment and delays in enrollment**

Common Pitfalls

- **Overestimating** the ease of obtaining subjects
- **Underestimating** the time required for regulatory affairs
- **Under-budgeting** for the unexpected
- **Overestimation** of research staff efficiency

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Key take away……

Mental picture

Walk through the protocol as you would take the subject through the process to create the budget