



# Alliance Budgets

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# Overview of Alliance Budgets

- Alliance federal grants and BIQSPF (biomarker) supplements or contracts – Boston/Chicago offices prepare and submit to NCI
- Foundation budgets to gain support from industry in support of NCTN – Denise and Vance
- AFT, LLC budgets for industry-only - Bobby

# Basics of a Budget

- Categories – part of direct cost
  - Salary/personnel
  - Consultant costs
  - Equipment
  - Supplies
  - Travel
  - In/outpatient care (non-Alliance)
  - Alterations and renovations (non-Alliance)
  - Other Expenses

# Basics of a Budget

- Consortium/Contractual cost
  - Sub awards to other sites of performance inclusive of their indirect costs (IDC)
  - Prime site gets % IDC of the first \$25K
- Combined budget is “total cost”

# Funding Types

- Federal = R01, T32, K, U10, etc
  - Alliance receives 3 main U10's for operations, SDC and NCORP
  - Many sub award sites
  - Additional BIQSPF supplements or contracts
- Foundation = funding agreement with industry to supplement federal grants, meeting support and scholar awards
- AFT = contracts with industry partner

# BIQSPF Requirements

- Biomarker, Imaging and Quality of Life Studies Funding Program
- Concept, proposal for integrated or integral biomarker, budget and justification
  - Payment of internal or external lab to analyze samples
  - Site funding for biopsy, scans
- Review coincides w/CTEP review of concept
- Awarded to BWH

# Foundation Budgets

- “Investigator-initiated study”
- During concept development study chair makes contact with company to determine interest in providing drug or funding
- Executive officer, CFO and project manager are main contacts throughout negotiations
- Call to review SCRC comments w/study chair
- Build budget and submit via portal for company review
- Initiate calls w/company and Alliance team
- Initiate agreement process w/ goal to sign by activation

# Typical Foundation Budget

- Central office
- Stats and Data Center
- Per case payments to sites
- Non-standard of care visits or procedures
- Drug cost or distribution services
- Pathology or correlative science



# Investigator-Initiated Budgets

- Understanding financial components of study budget is key to activate, conduct and complete a trial
- Study budget is road map to advance the mission of the science
- AFT's budget preparation centered on evaluation of concept or protocol and resources at the site and organizational levels

# How AFT is Funded

- Concepts vetted by disease committee and undergo intake process with AFT stakeholders
- Research grants are sought from industry or private research partner (“funder”) via portal submission
- Funder may provide financial support and/or study drug

# Creating Master Study Budget

- After approval of concept by the intake review team, initial budget drafted
- Important elements
  - Protocol evaluation
  - Resource assessment at site and within AFT
- After internal approval of budget, it is submitted with concept via portal
- Site budgets develop upon signing of an agreement with funder

# Master Budget Includes

- AFT salaries and expenses
- Vendors
  - Drug supply, storage and shipment
  - CRO
  - Safety monitoring
  - Stats and Data Center
- Site payments
- Central IRB

# Development of Site Budget

- Budget built on per visit/cycle basis
- Payments cover start-up fees, non-SOC visits or procedures, PI, Study Coordinator/Research Nurse and other site costs
- Internal database used for pricing based on previously negotiated budgets
- Payments made follow laws and regulations by US and ex-US for sites and vendors

# Reminders

- Study chairs cannot negotiate on our behalf or agree to dollar figures
- Budgets developed centrally by Alliance staff and study team
- Often have short turnaround times
- Need to anticipate everything that needs funding in the study
- Finalizing budget or contract may delay study activation – start early!

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