Alliance Foundation Trials
AFT

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AFT

• Goal: Sponsor and execute investigator initiated trials which are developed by the Alliance disease committees, but are unable to be executed through the NCTN system
Two primary models:

- Limited operations
  - Non-AFT sponsor
  - CRO partner hired and managed by PP
  - AFT limited scope, typically with site identification, feasibility, escalation, data-sharing, scientific input into study design along with appropriate academic credit
• Full operations:
  • AFT is the regulatory sponsor
  • IND
  • All study development, site activities, data collection and analysis
  • Samples, banking
  • Data-sharing
  • Scientific development by Alliance study chair
  • Open at a subset of Alliance trials
  • Model of an Investigator Initiated Trial – but larger scale than most studies done from an individual institution
• Full operations
  • Collaborations;
    • Industry partners – may be possible registration trial, to hypothesis generating Phase I/II trials
    • Mayo – SDC
    • Washington University – Biospecimens/ Biorepository
Alliance Foundation Trials: Study Selection

**Minimum Requirements**

- Study leadership (PI, Steering Committee Chair) is an Alliance scientific leader
- Study is open to selected Alliance Member Institutions, under AFT management
- Study data provided to Alliance for unrestricted use after completion of the trial
- Adequate support for scientific leadership and data use
Alliance Foundation Trials: Study Selection

Alliance Disease Committee

- AFT Operations Assessment
  led by Executive Officer, sponsored by appropriate Program Director
- Funding
- Partners
- Contracts
- Portfolio Feasibility

Alliance Executive Committee
Next Steps

• Assignment of AFT Project Manager

• Development of budget – requires significant input from study chair and statistical team to clarify assumptions early in the process

• Develop a protocol that is needed to answer a specific scientific question

• Thoughtful regarding data field collection, visit schedule and assessments – collect what is needed to answer the question

• What can be learned from prior studies
Next Steps

• AFT budgets will negotiate with the funding partner
• Budgets need to cover the cost of trial development, AND trial execution, management, analysis and samples
• AFT relies on a completely separate clinical trials infrastructure
• AFT is not supported by NCI grant dollars or NCI grant infrastructure
Next Steps

• Generation of site lists – subset of Alliance sites based on goals of project, prior accruals to similar studies and funding sources

• Site management will begin site engagement, including study specific feasibility, COI, and general study start-up

• In parallel, development of monitoring plans, safety monitoring plans, drug distribution approaches, etc
Next Steps

• Study Chair together with EO – develop protocol on AFT template, develop model ICF on template and with assistance of AFT staff

• Review and input re: site list, possible outreach to sites to support study start up procedures

• Develop correlative plans with TRP early on in the process
Regulatory

- IND – AFT is the regulatory sponsor of all full operations AFT trials

- Central IRB – Quorum – all AFT trials are reviewed/approved by Quorum, some sites will also use Quorum, many will use institutional IRB
Ongoing

• Excellent communication with PM and Site Management at AFT
• Close collaboration with EO around study development and execution
• Escalation point for scientific challenges
• Supportive of the team working together to execute the trial in a feasible and high quality manner
AFT – a summary

• Who – PM, SM, Budgets, Contracts, EOs
• Why – To support the key scientific concepts which arise from the Alliance Scientific Committees but are not able to be executed through the NCTN mechanism
• Where - Offices in both Boston and Chicago
• What – A group of really enthusiastic and eager team members committed to clinical trials in oncology
• When – When you need us!