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/ Biorespository

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	Contracts
Partners	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!