

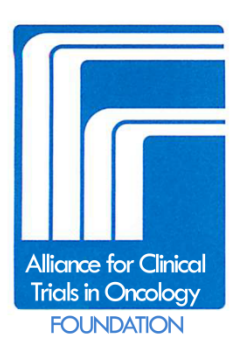
Alliance Foundation Trials

AFT

Suzanne George, MD

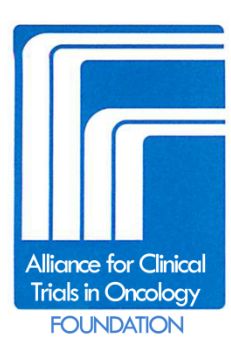
Group Vice-Chair, Alliance

Vice President, Alliance Foundation

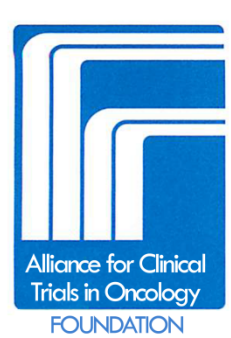


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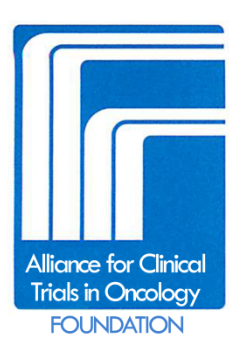
- Goal: Sponsor and execute investigator initiated trials which are developed by the Alliance disease committees, but are unable to be executed through the NCTN system



- 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



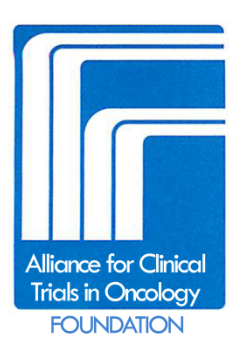
- Full operations
 - Collaborations;
 - Industry partners – may be possible registration trial, to hypothesis generating Phase I/II trials
 - Mayo – SDC
 - Washington University – Biospecimens/ Biorespository



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



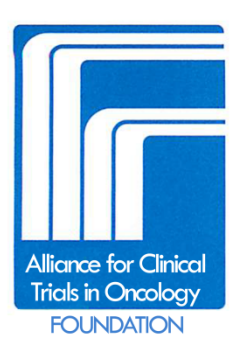
AFT Operations Assessment
led by Executive Officer, sponsored by
appropriate Program Director

Funding
Partners

Contracts
Portfolio Feasibility

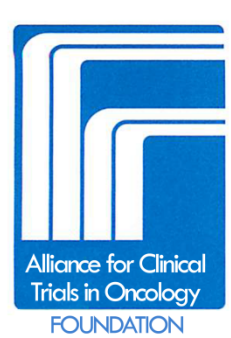


Alliance Executive Committee



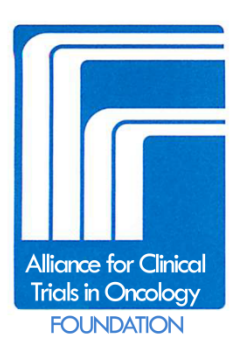
Next Steps

- 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



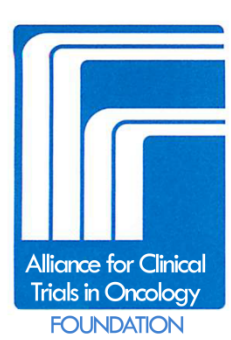
Next Steps

- 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



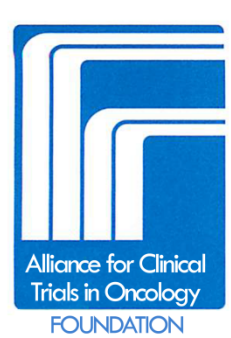
Next Steps

- 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



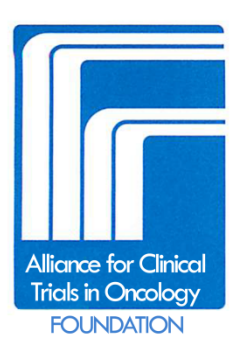
Regulatory

- 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!