

From Idea to Award: Embedding Funding Strategy Into Clinical Development Workflows

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1. Background

Investigator-initiated trials (IITs) remain a cornerstone of academic oncology research, yet the pathway from scientific idea to funded study has grown increasingly complex. Historically, IITs at academic medical centers have relied on internal pilot funding, departmental resources, or institutional support to advance early-stage concepts. As financial pressures increase and research portfolios expand, diversification of external funding pathways has become essential for sustainable IIT activation. Federal funding is highly competitive, foundation and philanthropic mechanisms are targeted, and productive industry partnerships require early strategic alignment. Academic cancer centers must therefore ensure that promising investigator concepts are not only scientifically innovative but also competitively positioned within a rapidly evolving funding landscape. Structured models that integrate funding strategies early within clinical development are needed to enhance competitiveness, feasibility, and institutional stewardship.

2. Goals

The goal of this initiative was to implement a centralized funding strategy model embedded within clinical development workflows to support successful IIT activation. Specific aims were to: (1) strategically align investigator concepts with appropriate funding mechanisms early in development through structured assessment of scientific scope, maturity, feasibility, and sponsor priorities; (2) iteratively refine or reposition concepts to enhance competitiveness, including identification of necessary preclinical data, collaborators, scope adjustments, phased approaches, or alternative funding entry points while preserving scientific intent; and (3) establish an adaptable framework supporting longitudinal planning through staged or complementary funding mechanisms rather than single-point submissions.

3. Solutions and Methods

UNC Lineberger implemented Clinical Development Resources for Advancing Funding and Trials (CRAFT), a centralized model positioning concepts for funding success prior to submission. Concepts entering CRAFT may include individual IIT proposals, disease-group initiatives, platform-based priorities (e.g., CAR-T, hybrid decentralized trials), or multi-study strategies. Unlike traditional grant offices focused on submission mechanics, CRAFT operates upstream within clinical development to shape scientific scope, funding positioning, feasibility, and mechanism selection.

CRAFT is led by the Clinical Development Team, comprised of PhD-level scientists working in partnership with investigators, finance, regulatory, and industry-facing teams. Through structured, investigator-centered discussions, CRAFT develops strategic funding roadmaps that may include staged, parallel, or complementary mechanisms. This “multiple shots on goal” approach increases funding probability while supporting sustainable activation planning. Standardized tools guide feasibility review, protocol shaping, and funding-specific positioning prior to submission, ensuring advancement only when aligned with funding pathways and institutional capacity.

4. Outcomes

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Work in progress

Early outcomes demonstrate increased investigator engagement at the concept stage and more deliberate alignment between scientific aims and targeted mechanisms. Concepts are now supported by strategic funding roadmaps that diversify submissions and reduce reliance on single mechanisms. As an early signal of impact, one concept supported through CRAFT secured federal funding to advance hybrid decentralized clinical trial infrastructure. Increased funding diversification has also enabled more strategic allocation of internal institutional resources. The model has strengthened proposal positioning, cross-functional coordination, and institutional stewardship of the IIT portfolio.

5. Lessons Learned and Future Directions

Funding strategy must be treated as a longitudinal planning process rather than a single submission event. Early strategic positioning enables thoughtful concept refinement, sequencing of mechanisms, and improved alignment between scientific aims, sponsor expectations, and institutional capacity. Future efforts include formal evaluation of funding diversification, time to activation, funding success rates, and expansion of the CRAFT model across additional disease groups.