

Potential Change in NCI Policy Regarding the Submission of Grant Applications that Request Support for Phase III Clinical Trials

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Current NCI Policy

Phase III clinical trials can be proposed:
for investigator-initiated research
applications (R01, P01) subject to the
>\$500K direct cost approval requirement

Purpose / Rationale / Goal

- Purpose:
 - Develop and publish revised NCI policy removing Phase III clinical trials involving therapeutic interventions from the grants portfolio (R01 and P01)
- Rationale:
 - Phase III trials: multi-center, cost > \$500,000/yr more than 5 years duration in most cases
 - duplication of NCTN and CCOP infrastructure at a time of resource constraints
- Goal:
 - formalize policy change with specific exceptions

Policy Revision Process

- Met with NCI Division stakeholders
- Conducted portfolio analysis
- Drafted a revised policy
- Presented policy revision to SPL
- Solicited input from the community via RFI
- Presentation to CTAC

Portfolio Analysis

Proposed Phase III Trials in Grant Portfolio		
Mechanism	R01	P01
Submitted	102	20
Funded	28	11

QVR Search Terms: Phase III clinical trial; R01 or P01 grant mechanism, Type 1, 2 and 5; submitted and funded;

NCAB: May 2003 (2003/05) to Jan 2013 (2013/01)

Portfolio Analysis

Types of Phase III Trials in Grant Portfolio

Mechanism	R01	P01
Treatment	10	9
Prevention	8	2
Behavioral	10	0
Total Funded	28	11

NOT CA-12-013 Request for Information (RFI)

Input on a Potential Change in NCI Policy Regarding the Submission of Grant Applications that Request Support for Phase III Clinical Trials/Therapeutic Interventions

Question to extramural researchers:

Should applications proposing Phase III clinical trials be allowed for under R01 and/or P01 funding mechanisms?

- Publicized via NIH OER Listserv & CGCB distribution list
(~ 300 current and former grantees)
- Thirty day comment period

Conclusions

- Majority of extramural investigators do not propose **therapeutic** or imaging Phase III trials in the grants portfolio
- Over a 10 year period, change in policy would have affected less than 150 investigators
- Response to RFI was poor (N = 19 - very small)
- Split opinions even from same institution/organization
- Rare disease clinical trials are a concern
- Need to exclude behavioral research from policy

Proposed Policy Change

- No Phase III (efficacy) trials in the grants portfolio with exception of behavioral or public health intervention studies and cost effectiveness research provided they can be completed entirely within the 5 year grant cycle
- NCTN has incentivized trials in rare diseases via revised review criteria and the development of a common menu for the entire Network