Protocol Performance and Resource Utilization of Phase II Investigator-Initiated Trials

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Introduction

- Investigator-initiated trials (IITs) are the backbone of many cancer center clinical trial programs.
- Little is known about IIT performance metrics and associated resource use.
- We suspected many IITs are not being completed, many are taking a long time to complete enrollment, and significant resources are used to implement and manage these trials.
- We sought to verify these suspicions and to investigate possible early predictors of success.

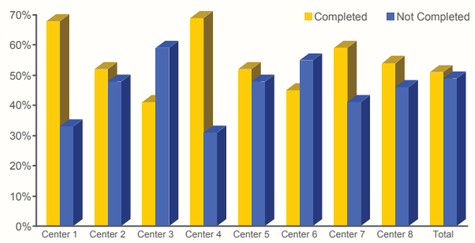
Methods

- Accrual data to phase I/II and phase II investigator-initiated therapeutic clinical trials.
- 5 cancer centers (2005-2008). Expanded to 8 centers (trials closed between 2005-2009).
- IITs were **completed** (accrual goal met, ineffective, stopped due to toxicity, etc.) or **not completed** (slow accrual, PI left, etc.)
- Other pre-specified criteria:
  - Implementation time
  - Progress at 3-month intervals
  - Resource use parameters (amendments, continuing reviews, etc.)
  - Multi-center participation

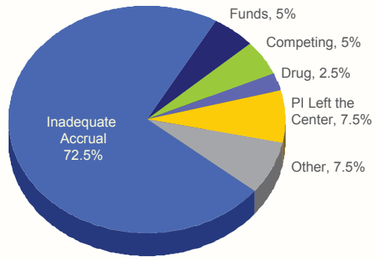
Data aggregated by PercipEnz Technologies, Inc.

Results: Protocol Performance

170 Phase II Investigator-Initiated Clinical Trials: 3320 Patients Enrolled



80 trials (47%) were not completed
58 trials were not completed due to inadequate accrual



684 (21%) patients were enrolled to studies not completed due to inadequate accrual

Resource Utilization

Total Resource Use

58 slow accruing trials, 684 patients enrolled:

68,000 hours,
8,500 hrs/center
~ $6,000/patient
$510,000/center

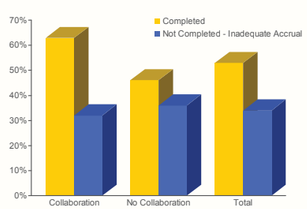
Start-up and Regulatory Resource Use

9766 hours
$586,000
$73,250/center

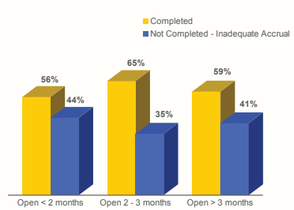
*C-Change Guidance Document for Implementing Effective Cancer Clinical Trials, www.c-changetogether.org/pubs/default.asp

Predictors of Study Completion

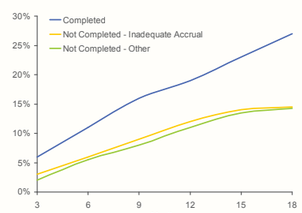
Collaboration



Activation Time



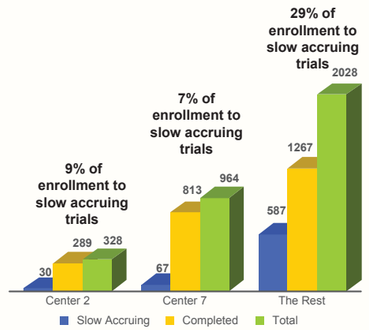
Progress at Early Time Points



46 of 78 (63%) of multi-center trials were completed

Study Closure Rules

All participating centers have enrollment criteria for continuation and closure of slow accruing investigator-initiated trials.



Conclusions

- 47% of 170 therapeutic investigator-initiated clinical trials were not completed.
- 34% of the 170 clinical trials were not completed due to inadequate accrual.
- 684 (21%) of 3320 patients participated in trials not completed due to inadequate accrual.
- Trials closed due to inadequate accrual remained open for 28 months (median)
- Significant resources are used on trials not completed.
- Multi-center trials were completed more often than trials conducted at a single institution.
- Activation time was not predictive in identifying trials unlikely to be completed.
- Progress at early time points may predict trial completion.