

IOM-ASCO Workshop

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Cooperative Group Chairs Report

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Therapeutic Advances

Cooperative Groups have been successfully collaborating to conduct high-quality multi-disciplinary practice-changing research in academic and community setting for decades and will continue to do so in the future.

*A National Cancer Clinical Trials System for the 21st Century:
Reinvigorating the NCI Cooperative Group Program*
Seminars in Oncology 35(5):2008 Oct

Biospecimen Repositories

Groups have developed vigorous biobanking to support translational research

- Protocol-linked
- Completely annotated
- Multiple disease entities
- Frozen and FFPE tissue, blood and derivatives, urine, saliva, circulating tumor and endothelial cells, etc.

Among largest and best annotated national repositories with patients treated according to defined guidelines

High-impact Translational Research

- *Oncotype-DX*TM predicts risk of recurrence in women with node negative breast cancer
- HPV drives outcomes in oropharyngeal cancer
- t(1p/19q) predicts superior survival in patients with low-grade oligodendrogliomas

Collaborations with Laboratory Investigators

RO1

66

P01

6

SPORES

19

Biomarker-Driven Trials

- Her-2+ breast cancer
 - Trastuzumab as adjuvant therapy (B31/N9831)
 - Lapatinib as adjuvant therapy (ALTTO)
- ER/PR+/Her-2-/Oncotype-DX™ breast cancer
 - Treatment assigned by risk (TAILOR-RX)
- *K-ras wt* stage III colon cancer
 - Cetuximab as adjuvant therapy (N0147)
- FDG-PET in non-Hodgkin's lymphoma
 - Treatment based on FDG-PET (B50303)
- 18q (-) and MSI in Stage II colon cancer
 - Risk group and randomization assigned therapy/observation (E5202)

Overall Cooperative Group Funding Structure

Funding Component	Total Costs¹
Cooperative Group Awards	\$161 M (45%)
CCOP Accrual Support	\$ 10 M (3%)
CTSU Contract	\$ 18 M (5%)
Accrual Cost Sharing	\$ 88 M (24%)
Pro-Bono Investigator Time	\$ 28 M (8%)
Industry Support	\$ 41 M (11%)
Philanthropic Support	\$ 6 M (1.5%)
Other Support	\$ 9 M (2.5%)
Total	\$361 M

^[1]Direct and indirect costs

Operational Accomplishments

- Developed detailed user needs and technical specifications for single remote data capture system
- Developed plans for complying with or exceeding OEWG timelines
- Created informatics tools for biospecimen tracking and integration with large scale multi-site clinical trials
- Developed innovative clinical trial designs, endpoint validation studies, and assessed components of RECIST and CTC

Operational Accomplishments

- NSABP and RTOG have begun plans to create a single integrated alliance
- ACOSOG, CALGB, and NCCTG have initiated formation of a single statistics and data center, and have agreed to form a new, integrated group
- ECOG and ACRIN recently announced a collaboration agreement

Issues to Address

Scientific Prioritization

- Informed and rational system for setting research priorities
 - Central control often stifles innovation
- Sufficient funding to accomplish the scientific priorities

Issues to Address

Scientific Collaboration

- Need for incentives for scientific collaboration
 - Enhanced interaction among investigators in cancer centers and other cancer research venues
- Coordinated review and support of translational science

Issues to Address

Informatics

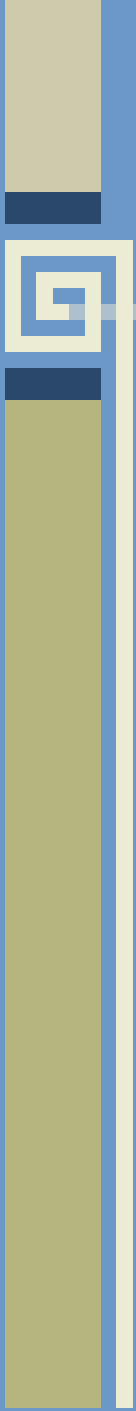
Modernization of informatics support

- Improved biospecimen annotation and informatics support
- Implementation of remote data capture system across all groups
- Overall operational management software

Summary

Accomplishments

- The Cooperative Groups have been and will continue to be vital engines to conduct multidisciplinary, practice-changing, biologically-driven clinical trials in academic and community settings
- Both scientifically and operationally, the Cooperative Groups have demonstrated willingness and capacity to respond to recommendations in the IOM Report



Summary

Issues to Address

The process of scientific prioritization, collaboration among laboratory and clinical investigators from multiple venues, and modernization of informatics support remain key issues to address in the future