

Southwest Oncology Group View of Barriers to Cooperative Group Accrual

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Barriers to Accrual

- Patient Barriers
- Physician Barriers
- Us
 - Harmonization of Groups, Centers, SPORES
 - Lack of discourse
 - “Audrey” phenomenon



SWOG 2007

TYPE	ACCRUAL	SITES	AVERAGE
U-10 Holder	938	13	72
Medical Center	355	21	17
CCOP	1059	27	39
Affiliate	801	107	8
TOTAL	3153	168	

NCI Cancer Centers in SWOG

HOLDING U-10

- Arizona
- City of Hope
- Cleveland Clinic
- Colorado
- UC-Davis
- Michigan
- Moffitt
- MD Anderson
- Puget Sound (Seattle Alliance)
- USC
- Wayne (Karmanos)

SWOG Rules:
Minimum 50 pts/yr
Leadership includes accrual

NOT HOLDING U-10

- Baylor
- Columbia
- Hawaii*
- UC-Irvine
- New Mexico*
- Oregon
- UT San Antonio
- Utah
- ~~UCLA~~

* Minority based cancer center
hold CCOP award

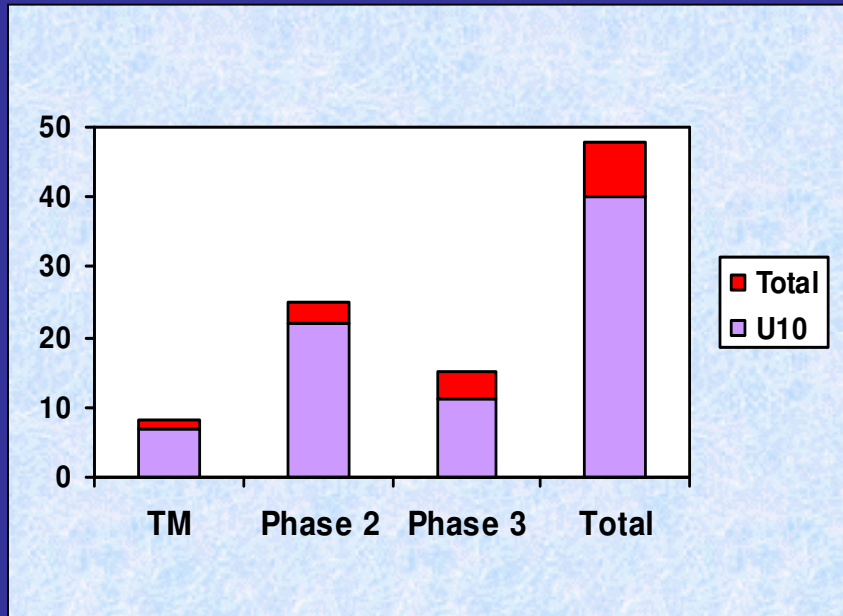
SPORES at SWOG Sites

18 SPORES Represented at SWOG Institutions

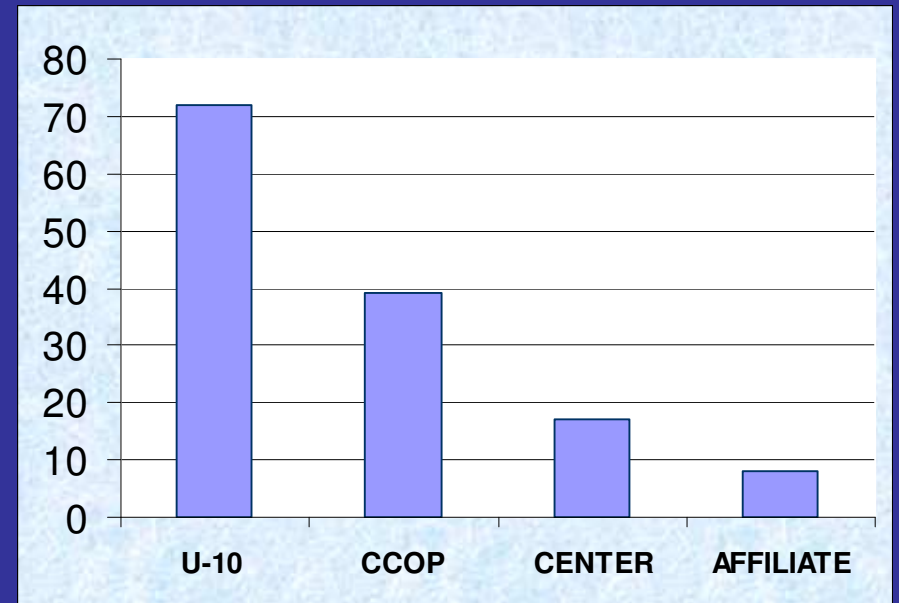
Breast	2
GU / Prostate	5
Gyn / Ovarian	4
Lung	1
Lymphoma	3
Leukemia	1
Skin	1
GI	1

Contribution of U-10 Sites 2007

Protocols



Accrual



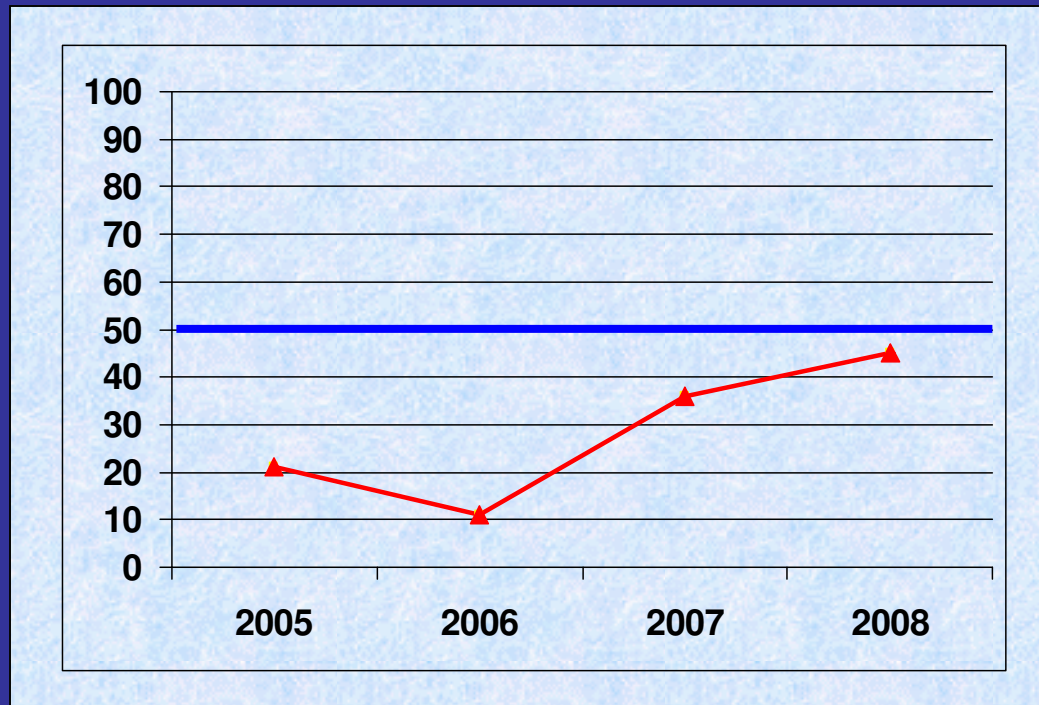
Manuscripts:

-87% of all manuscripts authored by U10 faculty

Cancer Center A

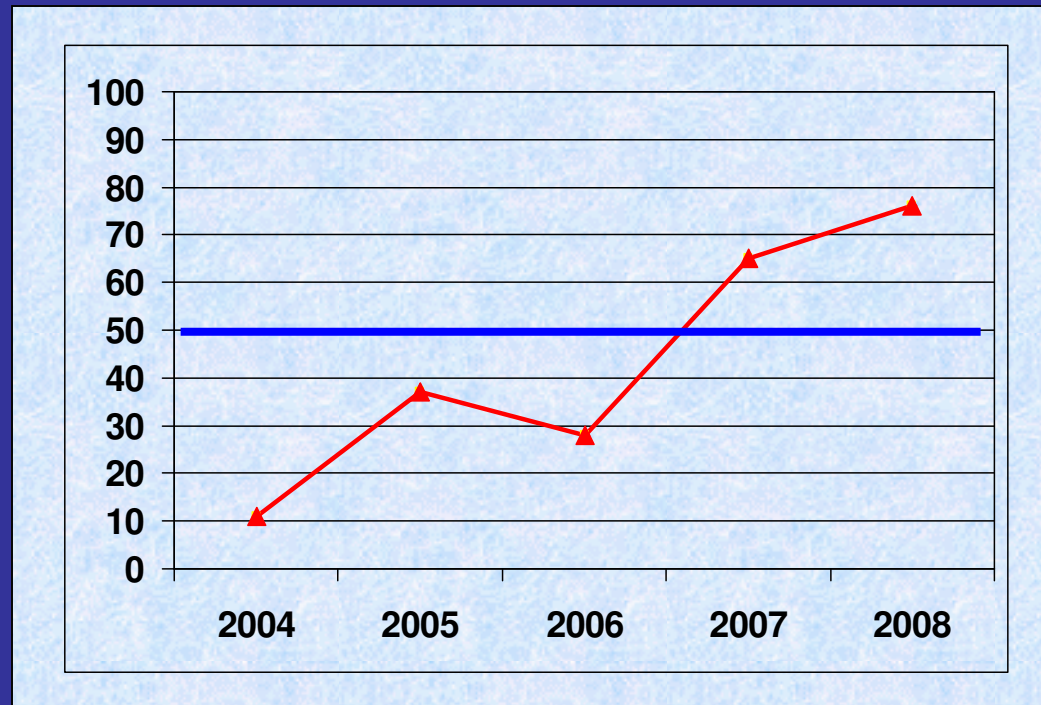
- Joined SWOG 1990
- Accrual 2002= 42 treatment entries
- Resigned SWOG 2003
- Cannot/will not do studies for \$2K
- Popularized financial analysis of clinical trials to determine threshold of interest

Cancer Center B



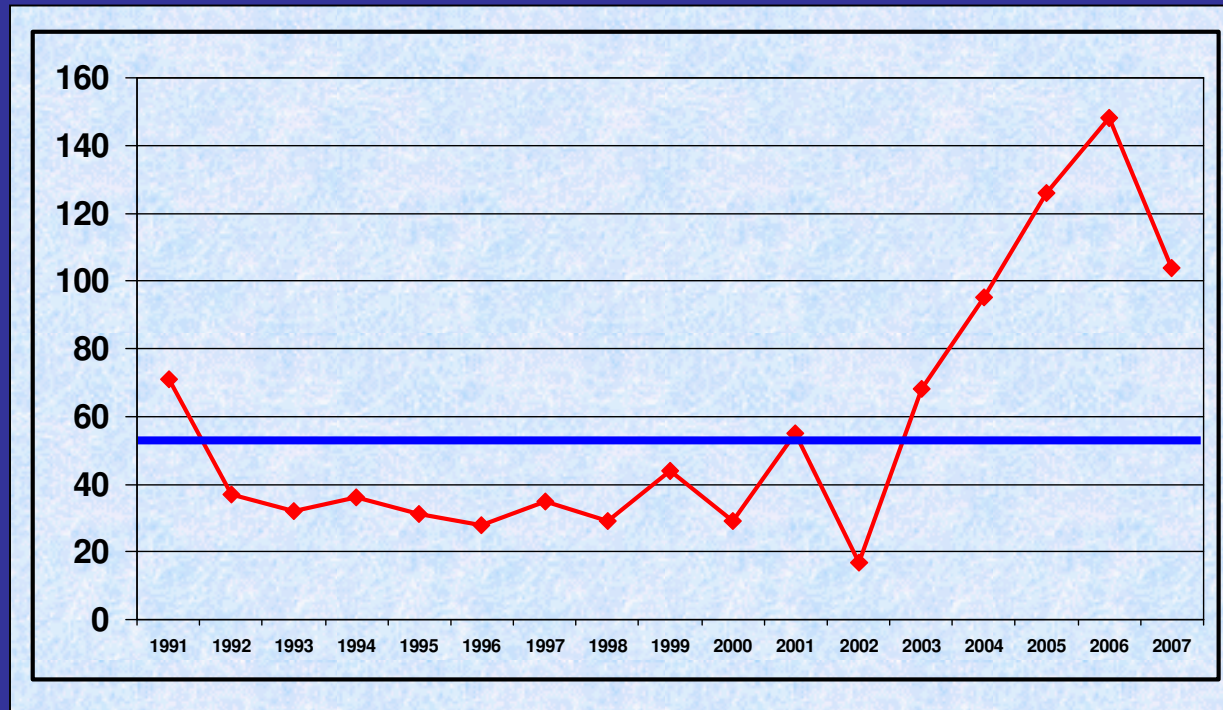
- 4 PI's in 4 years
- 3 resigned - lack of support from cancer center director
- Cancer center director former leader of SWOG
- Unlikely this U-10 will be competitive

Cancer Center C



- SWOG group chair consulted at institution in 2006
- Recognition of problem and commitment to change
- Center likely to become the premier institution within SWOG

Cancer Center D



- U10 supported data managers - reassigned to higher priority studies
- Action plan: move data managers to dept of medicine approved by CTEP
- Data managers moved out of cancer center

Priority Criteria for Cancer Center Resources-Center D

1. Investigator initiated trial funded by grant or foundation
2. Investigator initiated trial
3. Pharmaceutical funded contract trials
4. Investigator initiated trials through DOD/Phase II Consortium
5. Investigator initiated Cooperative Group trials
6. Multi-center trials initiated outside Center

Conclusions From Examples

- Money is necessary
 - But not sufficient
- Center Leadership Essential
- Guidelines for Centers, Groups, SPORES are not aligned
 - A Work Still in Progress

U10 Site Grants

- U10 sites equal our:
 - Major intellect
 - Major accrual
 - Most often cancer centers
- Meeting with CTEP
 - “U10’s capped”
 - “Unfair-funded at higher”
 - Where’s the memo?

Patient Barriers

- Consider cardiology/hypertension studies
- Change old criteria
 - Number of regimens
 - Other malignancy
- Placebo controlled studies
 - My ethics or yours
 - Lowest bar-clinical efficacy
 - Sham iv's and pk studies

Trials should primarily serve patients needs, not future societal considerations

Physician Barriers

- Provide salary support for PI's
- Coltman Career Development Awards and Mid-career Development Awards
- Cancer Center/Department leadership
 - Not promotion committees
 - Remind major medical centers (cancer centers, universities) of downstream revenue

Steps to Consider

- Align goals of groups, centers, SPORE's regarding therapeutic clinical trials
- Recognize strength of U-10 mechanism
- Review phase 2 contract
 - Often a mini cooperative groups with insufficient infrastructure support
 - Competing with cooperative groups at what groups do best (multi-institutional studies)

A SIGN IN AN OLD BARN IN OHIO

Steps for success:

- working together
- finding new ways to look at old problems
- taking calculated risks



Orville and Wilbur Wright, 1906