

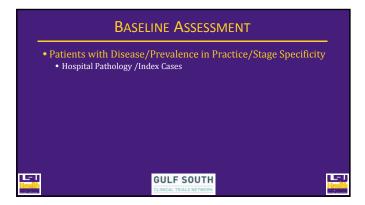
WHITE BOARDING OBJECTIVES

- 1. Basic Baseline Assessment for any Clinical Trial
- $2. \ \ Understanding \underline{Your \ Specific} \ Institutional \ process \\$
- 3. Assess Site Specific Needs for a Trial

L-L

4. SWOG 1806-Whiteboarding: Overview and Challenges from a Community NCORP site.

GULF SOUTH
CLINICAL TRIALS NETWORK







BASEL	INE ASSESSMENT
• Patients with Disease/	Prevalence in Practice/Stage Specificity
	CI Community Oxeddogy Research Program
www.ctsu.org	Connecting Investorations in ACC Cancer Research
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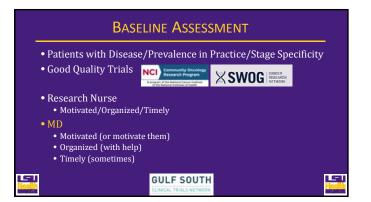
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	Newly diagnosed, Surgical Tx indicated	Advanced imaging study EAR171	FIND THE TRIALS
	Localized, Previously untreated, Intermediate rick	RT. SBRT (5 fractions) vi- NRG-GUOD IMRT (28 fractions) - NRG-GUOD	<u>.</u>
	Previously untreated, High mk, Non-metastatic	ADT + Radiation with vs NNS-00000	
Prostate	Presinally untroated, Metactatic	SST with vs. without definitive tx of primary - S1802 Narrow	Other group specific trials are not listed : eg WF1802
	Post Prostatecture, High risk	Reflation with vs	<u>.</u>
	Post Prostatectorry, High PSA	Salvage RT with Placabo	<u>.</u>
	Metastatic, Castration resistant	ADT + Abicaterone with EA0153 vs. without Calearitanel (Cristaterics	
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WHITE BOARDING OBJECTIVES

- 1. Basic Baseline Assessment for any Clinical Trial
- 2. Understanding <u>Your Specific</u> Institutional process
- 3. Assess Site Specific Needs for a Trial

L-L

4. SWOG 1806-Whiteboarding: Overview and Challenges from a Community NCORP site.

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INSTITUTIONAL PROCESS

- Process Variations--<u>Know you own process</u>
- Historical/Institutional Fiefdoms
 - "This is the way we always have done it"
 - "That can't be done"
 - "patient safety"
- Understand possible Process Improvements in activating and enrolling to CIRB approved NCTN Trials



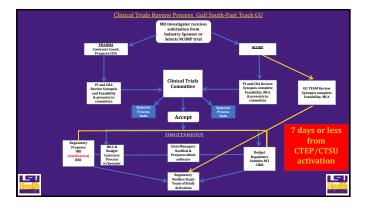
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COMPROMISE: NCTN/CIRB APPROVED STUDIES

- Responsibility falls upon the NCI-CIRB for local context considerations of participating institutions. This can be done through submitting: annual signatory institution worksheets, annual PI worksheets, study specific worksheets, and non-compliance/potential unanticipated problems worksheet reports
- Protocol Deviations and AE's are reported <u>to local IRB</u> in addition to CIRB



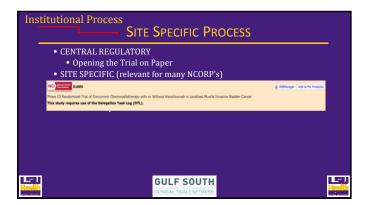




WHITE BOARDING OBJECTIVES

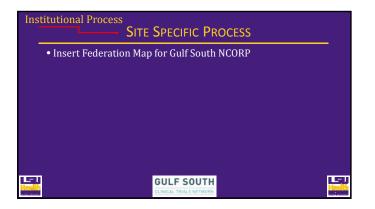
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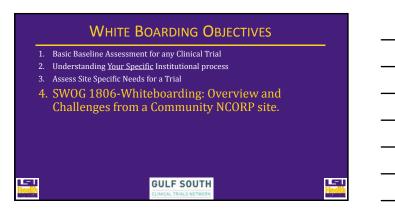
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	CLINICAL TRIALS NETWORK





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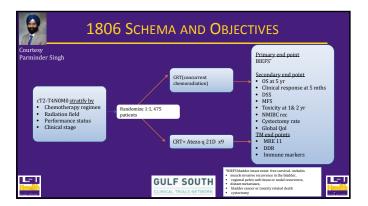
PRACTICAL REVIEW: SWOG 1806

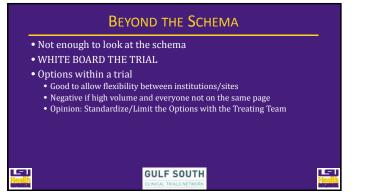
- Largest Combined Modality Therapy Trial in the US
- CMT= radical/maximal TUR followed by Chemo and Radiation
- Alternative to Cystectomy for patients with MIBC
- <u>Highly Desirable from Patient Perspective</u>

LSU

- Potential to Treat cancer and avoid removal of the bladder
- Opportunity (randomization) for Concomitant IV Immunotherapy ONA.
- Cystectomy surgeons with some reservations
 Differences in Invasive DSS and OS in non-comparative trials
 - Need for Salvage Cystectomy in non-responders/recurrences

GULF SOUTH





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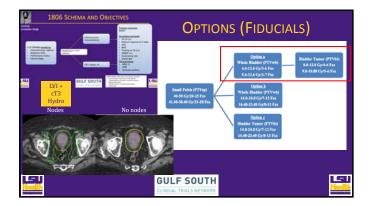
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			5-FU	500 mg/m²	IV	5-FU given on same days as doses 1-5 and 16-20 of RT
			Mitomycin-C	12 mg/m²	IV	Mitomycin-C given on same day as dose 1 of RT

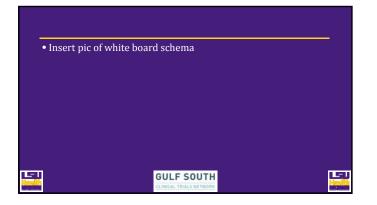
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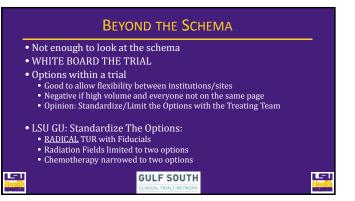
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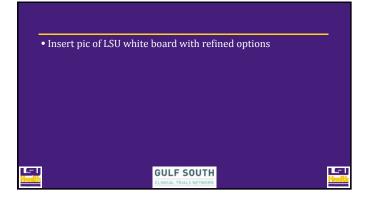
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			Mitomycin-C	12 mg/m²	IV.	Mitomycin-C given on same day as dose 1 of RT











WHITEBOARDING THE TRIAL

- Operationalizing the Trial
 - READ THE WHOLE PROTOCOL
 - Understand your institutional limitations and site specific limitations
 - Engage all Specialties (Rad Onc, Med Onc, Uro Onc)
 - MD and CRA Meeting
 - White Board Session- Timelines and Barriers and Pitfalls
 - MD/CRA lead with barriers discussed
 - Find Solutions
 - Contact PI directly / Email PI and Cooperative Group (SWOG)

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 Amendment Process Identify new barriers
 GULF SOUTH

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OCTOBER 3, 2019

- 9 accruals 1 accrual deemed ineligible due to timeline of Step 1, 2 • Amendment forthcoming to allow time line from Step 1 registration.
 - Dosimitry plans takes some time
 - Engage Dosimitrist up front at your site
 - IMRT planning was difficult on some tumor locations
 - Certification for Tomotherapy unit to aid in planning (14 days)
 - Biggest Barrier: Patient travel and intensity(financial and time) of Treatment compared to NAC and Cystectomy (6 could not enroll due to this constraint→ cystectomy)
 - Leverage case Managers, social work, philanthropy up front
 Hospital Leverage

SWOG INITIATIVE-PILOT FEASIBILITY PROJECT

Rick Bangs

LSU

- Structured Patient assistance program
- 25 patient pilot
- Collaboration between HOPE, Genetech, and SWOG
- Assessment of the financial cost of therapy/travel
- Assessment/Development of a process for patient assistance.

GULF SOUTH

• Great initiative supported by SWOG





