

WHITEBOARDING A CLINICAL TRIAL SWOG 1806

GULF SOUTH
CLINICAL TRIALS NETWORK

Scott E. Delacroix, Jr. MD
Associate Professor of Urology
Director of Urologic Oncology
Program Director LSU Urology Residency
Clinical Trials Site Director Gulf South NCORP
SWOG PI for Gulf South NCORP
Louisiana State University Health Sciences Center
New Orleans, Louisiana
@UroCancer

SWOG Fall Meeting
October 3, 2019

NCI Community Oncology Research Program
LSU Health
EJGH East Jefferson General Hospital


DISCLOSURES

- I certify that I have no relevant financial disclosures
- Member NCI GU Steering Committee 10/2016-Present

LSU Health GULF SOUTH CLINICAL TRIALS NETWORK LSU Health

DISCLOSURES

- Louisiana—translation to the other 49 states questionable



LSU Health GULF SOUTH CLINICAL TRIALS NETWORK LSU Health

WHITE BOARDING OBJECTIVES

1. Basic Baseline Assessment for any Clinical Trial
2. Understanding Your Specific Institutional process
3. Assess Site Specific Needs for a Trial
4. SWOG 1806-Whiteboarding: Overview and Challenges from a Community NCORP site.



BASELINE ASSESSMENT

- Patients with Disease/Prevalence in Practice/Stage Specificity
 - Hospital Pathology /Index Cases



BASELINE ASSESSMENT

- Patients with Disease/Prevalence in Practice/Stage Specificity
- Good Quality Trials



www.ctsu.org



INSTITUTIONAL PROCESS


- CIRB **
 - Dual/parallel approval (pre 2017) vs CIRB only with notification to local (current)
 - Intra-institutional Negotiation for CIRB
 - Get ready for Intense Negotiations/Discussions



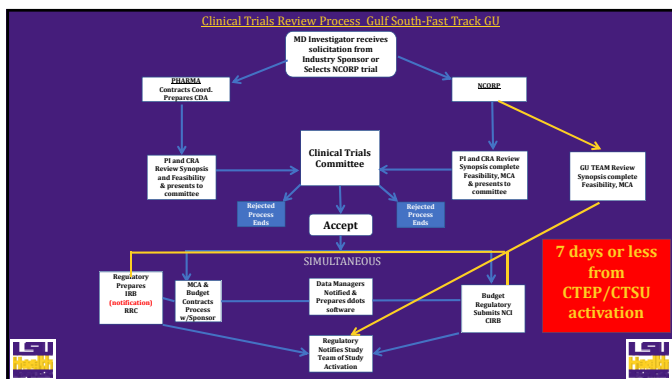


COMPROMISE: NCTN/CIRB APPROVED STUDIES

- 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 to local IRB in addition to CIRB








WHITE BOARDING OBJECTIVES



1. Basic Baseline Assessment for any Clinical Trial
2. Understanding Your Specific Institutional process
- 3. Assess Site Specific Needs for a Trial**
4. SWOG 1806-Whiteboarding: Overview and Challenges from a Community NCORP site.



Institutional Process

SITE SPECIFIC PROCESS

- CENTRAL REGULATORY
 - Opening the Trial on Paper
- SITE SPECIFIC (relevant for many NCORP's)




GULF SOUTH – FEDERATION (LA...)

- Insert map here- 30 seconds



Institutional Process → **SITE SPECIFIC PROCESS**

- CENTRAL REGULATORY
 - Opening the Trial on Paper
- SITE SPECIFIC (relevant for many NCORP's)



- Patients
- Med Onc
- Rad Onc
- Uro Onc
- Pathology

LEVERAGE ASSETS and BUILD PROCESSES

LSU Health | GULF SOUTH CLINICAL TRIALS NETWORK | LSU Health

Institutional Process → **SITE SPECIFIC PROCESS**

- Insert Federation Map for Gulf South NCORP

LSU Health | GULF SOUTH CLINICAL TRIALS NETWORK | LSU Health




WHITE BOARDING OBJECTIVES


1. Basic Baseline Assessment for any Clinical Trial
2. Understanding Your Specific Institutional process
3. Assess Site Specific Needs for a Trial
4. **SWOG 1806-Whiteboarding: Overview and Challenges from a Community NCORP site.**

LSU Health | GULF SOUTH CLINICAL TRIALS NETWORK | LSU Health

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
- **Highly Desirable from Patient Perspective**
 - 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



1806 SCHEMA AND OBJECTIVES

Courtesy Parminder Singh

cT2-T4N0M0 stratify by

- Chemotherapy regimen
- Radiation field
- Performance status
- Clinical stage

Randomize 1:1, 475 patients

GRT(concurrent chemoradiation)

GRT+ Atezo q 21D x9

Primary end point
BIEFS*

Secondary end point




- OS at 5 yr
- Clinical response at 5 mths
- DSS
- MFS
- Toxicity at 1& 2 yr
- NMIBC rec
- Cystectomy rate
- Global QoL

TM end points

- MRE 11
- DDR
- Immune markers




*BIEFS bladder intact event free survival includes

- muscle invasive recurrence in the bladder,
- regional pelvic soft tissue or nodal recurrence,
- distant recurrences,
- bladder cancer or toxicity related death
- cystectomy

BEYOND THE SCHEMA

- Not enough to look at the schema
- WHITE BOARD THE TRIAL
- Options within a trial
 - Good to allow flexibility between institutions/sites
 - Negative if high volume and everyone not on the same page
 - Opinion: Standardize/Limit the Options with the Treating Team

1806 SCHEMA AND OBJECTIVES

OPTIONS (FIDUCIALS)

Options (Fiducials):

- Small Pelvis (PTVeq): 49-99 Cy/29-33 Fx; 41-49-98-49 Cy/25-28 Fx
- Whole Bladder (PTVwb): 4-8-12.8 Cy/3-4 Fx; 5.6-12.8 Cy/3-7 Fx
- Bladder Tumor (PTVbt): 4-8-12.8 Cy/4 Fx; 9.8-18.88 Cy/5-4 Fx
- Optim A: Whole Bladder (PTVwb) 4-8-12.8 Cy/3-4 Fx; 5.6-12.8 Cy/3-7 Fx
- Optim B: Whole Bladder (PTVwb) 14.8-24.8 Cy/5-13 Fx; 14.49-21.49 Cy/8-13 Fx
- Optim C: Bladder Tumor (PTVbt) 14.8-24.8 Cy/5-13 Fx; 14.49-21.49 Cy/8-13 Fx

LSU Health | GULF SOUTH CLINICAL TRIALS NETWORK | LSU Health

- Insert pic of white board schema




LSU Health | GULF SOUTH CLINICAL TRIALS NETWORK | LSU Health

BEYOND THE SCHEMA

- Not enough to look at the schema
- WHITE BOARD THE TRIAL
- Options within a trial
 - Good to allow flexibility between institutions/sites
 - Negative if high volume and everyone not on the same page
 - Opinion: Standardize/Limit the Options with the Treating Team
- LSU GU: Standardize The Options:
 - RADICAL TUR with Fiducials
 - Radiation Fields limited to two options
 - Chemotherapy narrowed to two options

LSU Health | GULF SOUTH CLINICAL TRIALS NETWORK | LSU Health

• Insert pic of LSU white board with refined options

WHITEBOARDING THE TRIAL




- Operationalizing the Trial
 - READ THE WHOLE PROTOCOL
 - Understand your institutional limitations and site specific limitations
 - Don't push for a trial and not accrue
 - 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)
 - Amendment Process
 - Identify new barriers





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.
 - Dosimetry plans takes some time
 - Engage Dosimetrist up front at your site
 - IMRT planning was difficult on some tumor locations
 - Certification for Tomotherapy unit to aid in planning (14 days)
 - If Tomotherapy unit, certify up front
 - 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 and Team from SWOG

- 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.
- Great initiative supported by SWOG



GU CANCER TREATMENT AND TRIAL TEAM



Eileen Mederos
Program Coordinator



Megan Bruard
GU Research Nurse
Holly Martin
GU Research Nurse

Urologic Oncology

Radiation Oncology

Medical Oncology



Delacroix



Gills



Padmanabaha



Monsour



Marquette



WHITEBOARDING A CLINICAL TRIAL SWOG 1806



Scott E. Delacroix, Jr. MD

Associate Professor of Urology
Director of Urologic Oncology
Program Director LSU Urology Residency
Clinical Trials Site Director Gulf South NCORP
SWOG PI for Gulf South NCORP
Louisiana State University Health Sciences Center
New Orleans, Louisiana

@UroCancer

SWOG Fall Meeting
October 3, 2019