WHITEBOARDING A CLINICAL TRIAL
SWOG 1806

GULF SOUTH
CLINICAL TRIALS NETWORK

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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

LSU Health

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

EJGH East Jefferson General Hospital
DISCLOSURES

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

• Louisiana—translation to the other 49 states questionable
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
BASELINE ASSESSMENT

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

www.ctsu.org
BASELINE: HOW DO I FIND THE TRIALS

Connecting Investigators to NCI Cancer Research

Purpose of the Cancer Trials Support Unit

The Cancer Trials Support Unit (CTSU) is a service of the National Cancer Institute (NCI) designed to facilitate access to NCI-funded clinical trials for qualified clinical sites and to support the management and conduct of those clinical trials. CTSU Membership provides access to a wide range of information and support services for qualified investigators and research staff. The CTSU Registration Page provides additional details regarding member access. For those who are not CTSU Members this website provides a listing of active protocols that the CTSU supports along with links to resources for additional information on NCI-funded clinical trials.

More about the Cancer Trials Support Unit

The CTSU launched the CTSU in 1999 to streamline and harmonize support services for phase three Cooperative Group cancer clinical trials funded by the NCI. Since that time the scope of the CTSU has expanded to include support of multiple NCI-funded networks and clinical trials of all phases and types including cancer treatment, prevention and control, advanced imaging and correlative science studies. The CTSU collaborates with the NCI and its funded organizations to develop and support operational processes and informatics solutions leading to cost-effective solutions that reduce administrative burden on the clinical sites.

Under guidance of the NCI, the CTSU provides centralized services to support the following goals and objectives:

- Facilitate investigator and research staff participation in selected NCI multi-center programs and their clinical trials.
- Increase investigator and patient awareness and enrollment to cancer clinical trials.
- Provide standardized, integrated, and comprehensive support services to selected NCI multi-center programs.
- Identify best practices and streamline or eliminate redundant processes and procedures.
- Improve operational efficiency, enhance productivity and deliver products offering measurable business value to selected NCI multi-center programs.

NCI cancer research networks supported by the CTSU include:

- NCI National Clinical Trials Network (NCTN) - is a clinical trials research network that provides an infrastructure for NCI treatment, screening, and diagnosis trials. The infrastructure allows investigators to begin clinical trials quicker, reach conclusions faster, and offer patients studies that incorporate precision medicine at over 3,000 clinical sites.
- NCI Experimental Therapeutics Clinical Trials Network (ETCTN) - is a clinical trials network that evaluates innovative cancer treatments using a coordinated, collaborative, and inclusive team-based approach to early phase experimental therapeutic clinical trials.
### Protocol List

The Protocol List provides a listing of NCI clinical trials that are supported by the CTSU for which protocol documents are maintained on the CTSU members' website. The trials on the list are either active, near activation, or temporarily closed. The list may be sorted by any topic in the header row (e.g., Protocol Number, Lead Organization, NIH Program, Status, or Phase) by clicking on a column header; click a second time to reverse the sort. The protocol list can be exported to an Excel or CSV file, or printed by selecting the arrow icon located above the header row.

*Some accruals have occurred outside of the CTSU systems and are collected manually, thus the total accrual number may not be accurate.*

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Lead Organization</th>
<th>NIH Program</th>
<th>Disease</th>
<th>Status</th>
<th>Protocol Title</th>
<th>Phase</th>
<th>Actual/Planned Intervention Accrual</th>
<th>Screening Accrual</th>
<th>Step Type(s)</th>
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<tbody>
<tr>
<td>1 10013</td>
<td>LAO-NC010</td>
<td>ETCTN</td>
<td>Breast Cancer</td>
<td>Temporarily Closed to Accrual</td>
<td>Randomized Phase 2 Study of Neoadjuvant Chemotherapy, Carboplatin and Paclitaxel, with or Without Abciximab in Triple Negative Breast Cancer (TNBC)</td>
<td>II</td>
<td>67/72</td>
<td>N/A</td>
<td>INTERVENTION</td>
</tr>
<tr>
<td>2 10014</td>
<td>LAO-11030</td>
<td>ETCTN</td>
<td>Hematopoietic Neoplasms (excluding Leukemia, Lymphoma and Myeloma), Miscellaneous and Metastatic Cancer</td>
<td>Active</td>
<td>A Pilot Study of Atezolizumab (MDL1280A) Following Adoptive Cell Transfer in Active Hematologic or Solid Tumor Malignancies</td>
<td>Pilot</td>
<td>17/40</td>
<td>N/A</td>
<td>INTERVENTION</td>
</tr>
<tr>
<td>3 10017</td>
<td>EDDO-NY158</td>
<td>MISCELLANEOUS</td>
<td>Female Reproductive System Cancer</td>
<td>Temporarily Closed to Accrual</td>
<td>A Randomized Phase 2 Trial of Atezolizumab (MDL1280A), SGI-110 and CDX-1401 Vaccine in Recurrent Ovarian Cancer</td>
<td>I/II</td>
<td>12/75</td>
<td>N/A</td>
<td>INTERVENTION</td>
</tr>
<tr>
<td>4 10020</td>
<td>LAO-CT018</td>
<td>ETCTN</td>
<td>Breast Cancer</td>
<td>Active</td>
<td>A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (Atezolizumab; MDL1280A) in Homologous DNA Repair Deficient, Locally Advanced or Metastatic Non-HR2-Positive Breast Cancer</td>
<td>II</td>
<td>41/90</td>
<td>N/A</td>
<td>INTERVENTION</td>
</tr>
<tr>
<td>5 10066</td>
<td>LAO-CT018</td>
<td>ETCTN</td>
<td>Gastrointestinal Cancer</td>
<td>Active</td>
<td>A Phase 1/2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma (10017760)</td>
<td>I/II</td>
<td>22/49</td>
<td>N/A</td>
<td>INTERVENTION</td>
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<tr>
<td>6 10104</td>
<td>LAO-11030</td>
<td>ETCTN</td>
<td>Female Reproductive System Cancer</td>
<td>Active</td>
<td>A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer</td>
<td>II</td>
<td>82/84</td>
<td>N/A</td>
<td>INTERVENTION</td>
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<tr>
<td>7 10106</td>
<td>LAO-MD017</td>
<td>ETCTN</td>
<td>Lymphoma</td>
<td>Active</td>
<td>A Phase I and Randomized Phase II Study of KW-0761 (Mogamulizumab) and MK-3475 (Pembrolizumab) in Relapsed and Refractory Lymphomas</td>
<td>I/II</td>
<td>4/76</td>
<td>N/A</td>
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<td>8 10150</td>
<td>LAO-11030</td>
<td>ETCTN</td>
<td>Female Reproductive System Cancer</td>
<td>Active</td>
<td>A Randomized Phase 2 Study of Bevacizumab and Either Weekly Atezolizumab or Ruxpansine or Weekly Paclitaxel in Platinum-Resistant or Platinum Refractory Ovarian Cancer</td>
<td>I/II</td>
<td>15/96</td>
<td>N/A</td>
<td>INTERVENTION</td>
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<tr>
<td>9 10200</td>
<td>LAO-MD017</td>
<td>ETCTN</td>
<td>Leukemia</td>
<td>Active</td>
<td>A Phase II/II Study of the Histone Methyltransferase Inhibitor Penetrexstat in Combination with Azacitidine in Patients with 11q23-Rearranged Acute Myeloid Leukemia</td>
<td>I/II</td>
<td>0/48</td>
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<tr>
<td>10 10216</td>
<td>LAO-OH007</td>
<td>ETCTN</td>
<td>Lung, Mediastinal, and Pleural Cancer</td>
<td>Active</td>
<td>A Phase I/II Study of AZD9291 (Osimertinib) and CB-839 HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer</td>
<td>I/II</td>
<td>0/18</td>
<td>N/A</td>
<td>INTERVENTION</td>
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<tr>
<td>11 10231</td>
<td>DCTD</td>
<td>NCTN</td>
<td>Miscellaneous and Metastatic Cancer</td>
<td>Temporarily Closed to Accrual</td>
<td>NCORP Tissue Procurement Protocol: An NCI Cancer Moonshot Study</td>
<td>Pilot</td>
<td>N/A</td>
<td>N/A</td>
<td>OTHER</td>
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<td>12 9974</td>
<td>LAO-MA036</td>
<td>ETCTN</td>
<td>Lung, Mediastinal, and Pleural Cancer</td>
<td>Temporarily Closed to Accrual</td>
<td>A Phase II Study of Olaparib Plus Cediranib in Combination with Standard Therapy for Small Cell Lung Cancer</td>
<td>II</td>
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<td>INTERVENTION</td>
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<tr>
<td>13 9979</td>
<td>LAO-MN026</td>
<td>ETCTN</td>
<td>Miscellaneous and Metastatic Cancer</td>
<td>Active</td>
<td>Phase I and Pharmacology Study of Oral S-5-Iodo-2-Pyrimidine-2-Dexoxyribose Monophosphate (AZD9291) in Patients with HER2- or PD-L1-Expressing Cancer</td>
<td>I</td>
<td>6/47</td>
<td>N/A</td>
<td>INTERVENTION</td>
</tr>
</tbody>
</table>

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### BASELINE: How Do I Find the Trials

Welcome to the Cancer Trials Support Unit, a service of the National Cancer Institute.

**Follow the CTSU on Twitter**
Keep up with the latest CTSU News & Announcements @theCTSU

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**Experimental Therapeutics Clinical Trials Network (ETCTN) Program**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Target Accrual</th>
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<tbody>
<tr>
<td>Miscellaneous and Metastatic Cancer</td>
<td>150</td>
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<tr>
<td>Female Reproductive System Cancer</td>
<td>450</td>
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<tr>
<td>Hematopoietic Neoplasm (excluding Leukemia, Lymphoma and Myeloma), Miscellaneous and Metastatic Cancer</td>
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**Protocol Updates**

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<tr>
<td>1</td>
<td>LA5674</td>
<td>Addendum #2, Change Memo for Protocol FPOG 06/10/19</td>
<td>09/16/2019</td>
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<td>2</td>
<td>LA6171</td>
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<td>3</td>
<td>A5621308</td>
<td>Study Documents - Update #2, dated 09/13/19</td>
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<td>4</td>
<td>A211601</td>
<td>Study Documents - Update #9, dated 09/13/19</td>
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<td>5</td>
<td>A211605</td>
<td>Study Documents - Update #13, dated 09/13/19</td>
<td>09/17/2019</td>
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<td>6</td>
<td>A1098</td>
<td>Memorandum: Updated Master Forms Set</td>
<td>09/17/2019</td>
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<tr>
<td>7</td>
<td>A1099</td>
<td>Memorandum: Updated Master Forms Set</td>
<td>09/17/2019</td>
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<tr>
<td>8</td>
<td>A1702</td>
<td>Memorandum: Permanent Closure</td>
<td>09/17/2019</td>
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<tr>
<td>9</td>
<td>A1825</td>
<td>Memorandum: Clarification of eDNA insignificant, Updated Master Form Sets, and DTI Implementation</td>
<td>09/17/2019</td>
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<tr>
<td>10</td>
<td>A1831</td>
<td>Memorandum: Updated Master Forms Set</td>
<td>09/17/2019</td>
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**Protocol Profile**

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<th>Protocol Number</th>
<th>Status</th>
<th>Status Date</th>
<th>APCD</th>
<th>PCD</th>
<th>CRBS</th>
<th>OPEN</th>
<th>RAVE</th>
<th>TRIAD</th>
<th>TSSV</th>
<th>DOP</th>
<th>CMN</th>
<th>DTL</th>
<th>CTSAPAERS</th>
<th>EPIRO</th>
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<tr>
<td>1</td>
<td>WFYA4205</td>
<td>Administered Completion</td>
<td>03-Aug-19</td>
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</table>
# Disease Portfolios

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<th>#</th>
<th>Title</th>
<th>File Date</th>
<th>Format</th>
<th>Post Date</th>
<th>In Revision</th>
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<td>1</td>
<td>Adolescent and Young Adult (AYA) Cancer Trials Portfolio</td>
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<td>Web Link</td>
<td>26-Aug-2019</td>
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<td>2</td>
<td>Brain Cancer Trials Portfolio</td>
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<td>Web Link</td>
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<td>Not Applicable</td>
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<tr>
<td>3</td>
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<td>Web Link</td>
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<tr>
<td>4</td>
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<td>Not Applicable</td>
<td>Web Link</td>
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<td>Not Applicable</td>
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<tr>
<td>5</td>
<td>Genitourinary Cancer Trials Portfolio</td>
<td>Not Applicable</td>
<td>Web Link</td>
<td>26-Aug-2019</td>
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<tr>
<td>6</td>
<td>Gynecologic Cancer Trials Portfolio</td>
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<td>Web Link</td>
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<tr>
<td>7</td>
<td>Head and Neck Cancer Trials Portfolio</td>
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<td>Web Link</td>
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<tr>
<td>8</td>
<td>Leukemia Cancer Trials Portfolio</td>
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<td>Web Link</td>
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<td>Lymphoma Cancer Trials Portfolio</td>
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<td>Web Link</td>
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<td>10</td>
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<td>11</td>
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<td>Web Link</td>
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<td>13</td>
<td>Thoracic Cancer Trials Portfolio</td>
<td>Not Applicable</td>
<td>Web Link</td>
<td>26-Aug-2019</td>
<td>Not Applicable</td>
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</table>
BASELINE: HOW DO I FIND THE TRIALS

Other group specific trials are not listed: eg WF1802
BASELINE ASSESSMENT

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

Research Nurse
  - Motivated/Organized/Timely
BASELINE ASSESSMENT

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

• Research Nurse
  • Motivated/Organized/Timely

• MD
  • Motivated (or motivate them)
  • Organized (with help)
  • Timely (sometimes)
**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

• Process Variations--**Know your own process**
• 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
INSTITUTIONAL PROCESS: CHALLENGES OF CONVERTING TO CIRB

- Institutional Bureaucracy
- Politics are Local
- Local IRB hesitation due to claims that local IRBs reflect community values
- “This is how we have to do it”
- “Safety”

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
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.
MD Investigator receives solicitation from Industry Sponsor or Selects NCORP trial

PHARMA
Contracts Coord.
Prepares CDA

PI and CRA
Review Synopsis
and Feasibility
& presents to committee

PI and CRA Review
Synopsis complete Feasibility, MCA & presents to committee

NCORP

Clinical Trials
Committee

Accept

SIMULTANEOUS

Regulatory
Prepares IRB
(notification)
RRC

MCA & Budget
Contracts w/Sponsor

Data Managers
Notified & Prepares ddots software

Budget
Regulatory
Submits NCI
CIRB

GU TEAM Review
Synopsis complete Feasibility, MCA

7 days or less from CTEP/CTSU activation

Regulatory Notifies Study Team of Study Activation

Regulatory Prepares IRB (notification) RRC

Budget
Prepares ddots software

PI and CRA
Review Synopsis and Feasibility & presents to committee

PI and CRA Review Synopsis complete Feasibility, MCA & presents to committee

Accept

Rejected Process Ends

Rejected Process Ends
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)

Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer

This study requires use of the Delegation Task Log (DTL).
Institutional Process  

SITE SPECIFIC PROCESS  

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

Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer

This study requires use of the Delegation Task Log (DTL).

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

LEVERAGE ASSETS and BUILD PROCESSES
Institutional Process ➔ SITE SPECIFIC PROCESS

**Intervention Accrual by site**

- **LA 045**
- **LA 124**

**LA 045** - East Jefferson Hospital Based Site
- Rad Onc
- Med Onc
- Infusion

**LA-124 LSU Health Care Network Urologic Oncology Clinic**
- Uro Onc (site code start 03/2019)
WHITE BOARDING OBJECTIVES

1. Basic Baseline Assessment for any Clinical Trial
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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
- **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

SCHEMA AND OBJECTIVES

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 metastases,
• bladder cancer or toxicity related death
• cystectomy

cT2-T4N0M0 stratify by
• Chemotherapy regimen
• Radiation field
• Performance status
• Clinical stage

Randomize 1:1, 475 patients

CRT(concurrent chemoradiation)

CRT+ Atezo q 21D x9

*Courtesy Parminder Singh

Gulf South Clinical Trials Network

LSU Health New Orleans
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**

- **Primary endpoint:**
  - BDFS

- **Secondary endpoints:**
  - OS at 1 y
  - Clinical response at 5 mths
  - DFS
  - NPS
  - Toxicity at 1 & 3 yr
  - NMREC rec
  - Cystectomy rate
  - Global QoL
  - TNM and survival
  - MRI L.1
  - DNR
  - Immune markers

---

**Options (Physician Choice)**

<table>
<thead>
<tr>
<th>AGENT</th>
<th>DOSE</th>
<th>ROUTE</th>
<th>SCHEDULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>27 mg/m²</td>
<td>IV</td>
<td>Twice weekly for six weeks</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>35 mg/m²</td>
<td>IV</td>
<td>Weekly for six weeks</td>
</tr>
<tr>
<td>5-FU</td>
<td>500 mg/m²</td>
<td>IV</td>
<td>5-FU given on same days as doses 1-5 and 16-20 of RT</td>
</tr>
<tr>
<td>Mitomycin-C</td>
<td>12 mg/m²</td>
<td>IV</td>
<td>Mitomycin-C given on same day as dose 1 of RT</td>
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</tbody>
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## Options (Physician Choice)

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<td><strong>Gem</strong>&lt;br&gt;GFR &lt; 40</td>
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<td>IV</td>
<td>Twice weekly for six weeks</td>
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<tr>
<td><strong>Cisplatin</strong>&lt;br&gt;GFR &gt; 40</td>
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**Options (Physician Choice)**

- **Option a**
  - Whole Bladder (PTVwb)
  - 6.0-12.0 Gy/3-6 Fxs
  - 5.4-12.6 Gy/3-7 Fxs

- **Option b**
  - Whole Bladder (PTVwb)
  - 14.0-24.0 Gy/7-12 Fxs
  - 14.40-23.40 Gy/8-13 Fxs

- **Option c**
  - Bladder Tumor (PTVbt)
  - 14.0-24.0 Gy/7-12 Fxs
  - 14.40-23.40 Gy/8-13 Fxs
**Options (Physician Choice)**

- **Option a**
  - Whole Bladder (PTVwb)
  - 6.0-12.0 Gy/3-6 Fxs
  - 5.4-12.6 Gy/3-7 Fxs
  - 9.0-10.80 Gy/5-6 Fxs

- **Option b**
  - Whole Bladder (PTVwb)
  - 14.0-24.0 Gy/7-12 Fxs
  - 14.40-23.40 Gy/8-13 Fxs

- **Option c**
  - Bladder Tumor (PTVbt)
  - 14.0-24.0 Gy/7-12 Fxs
  - 14.40-23.40 Gy/8-13 Fxs

**Nodes**
- Yes
  - cT3
  - LVI
  - Hydro

**No nodes**
**Options (Fiducials)**

**Primary endpoint**
- BRTS

**Secondary endpoint**
- OS at 5 yr
- Clinical response at 5 mths
- DFS
- NPFS
- Toxicity at 1 & 3 yr
- NMRC onc
- Cystectomy rate
- Global QoL
- TM and survival
- MSU 11
- IDR
- immune markers

**LVI + cT3 Hydro**

- **Nodes**
  - No nodes
  - Small Pelvis (PTVsp)
    - 40-50 Gy/20-25 Fxs
    - 41.40-50.40 Gy/33-28 Fxs
  - Whole Bladder (PTVwb)
    - 6.0-12.0 Gy/3-6 Fxs
    - 5.4-12.6 Gy/3-7 Fxs
  - Bladder Tumor (PTVbt)
    - 8.0-12.0 Gy/4-6 Fxs
    - 9.0-10.80 Gy/5-6 Fxs

- **No nodes**
  - CRT+ Atenu x9
  - Randomize 1:1:475 patients

**Gulf South Clinical Trials Network**

**1806 Schema and Objectives**

- cT2-T4NO3MO
- Chemotherapy regimen
- Radiation field
- Performance status
- Clinical stage
- CRT (concurrent chemoradiation)
- Randomize 1:1:475 patients
- CRT+ Atenu x9

**Options**

**Node +**

- No nodes
- Small Pelvis (PTVsp)
  - 40-50 Gy/20-25 Fxs
  - 41.40-50.40 Gy/33-28 Fxs
- Whole Bladder (PTVwb)
  - 6.0-12.0 Gy/3-6 Fxs
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- Bladder Tumor (PTVbt)
  - 8.0-12.0 Gy/4-6 Fxs
  - 9.0-10.80 Gy/5-6 Fxs

**Node -**

- Nodes
- Whole Bladder (PTVwb)
  - 14.0-24.0 Gy/7-12 Fxs
  - 14.40-23.40 Gy/8-13 Fxs
- Bladder Tumor (PTVbt)
  - 14.0-24.0 Gy/7-12 Fxs
  - 14.40-23.40 Gy/8-13 Fxs
## Dissect the trial

## Pre-treatment Timeline

## Dates Dates Dates

## Consents versus Enrollment

## Treatment Timeline

## Follow up Timeline with adjustments (Rave could be better on this)
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 (+/- nodes)
  • Chemotherapy narrowed to two 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

- 8 accruals 1 accrual deemed ineligible due to timeline of Step 1, 2
  - Amendment forthcoming to allow time line from Step 1 or 2 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

- 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
NOMENCULTURE FAUX PAS

HOW DO WE GET THIS DONE?

WHY do we do it this way?

Eliminate:

• Can we do this?
• That’s not how we do it here...
• It’s a policy....
• We can’t do this?

Patient Safety
Patient Convenience
Clinic Workflow – How?
Hospital Workflow - How?
Bureaucratic Policies-Why?
Institutional Fiefdoms-Why?
GU CANCER TREATMENT AND TRIAL TEAM

Eileen Mederos*  
Program Coordinator

*MNCORP Program Coordinator/Admin of the Year 2019

Megan Bruard  
GU Research Nurse

Holly Martin  
GU Research Nurse

Michelle Seeman  
GU Research Nurse

Urologic Oncology  
Radiation Oncology  
Medical Oncology

Delacroix  
Gills*  
Padmanabaha  
Monsour  
Marquette

#3 NCORP Treatment Trial Accruals in US 2019

GULF SOUTH  
CLINICAL TRIALS NETWORK

LSU Health NEW ORLEANS  
EJGH  
East Jefferson General Hospital
WHITEBOARDING A CLINICAL TRIAL
SWOG 1806

Scott E. Delacroix, Jr. MD
Associate Professor of Urology
Vice Chairman of Academics
Co-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