WHITEBOARDING A CLINICAL TRIAL
SWOG 1806

GULF SOUTH
CLINICAL TRIALS NETWORK

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Louisiana State University Health Sciences Center
New Orleans, Louisiana
@UroCancer

SWOG Fall Meeting
October 3,2019

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

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

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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.

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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

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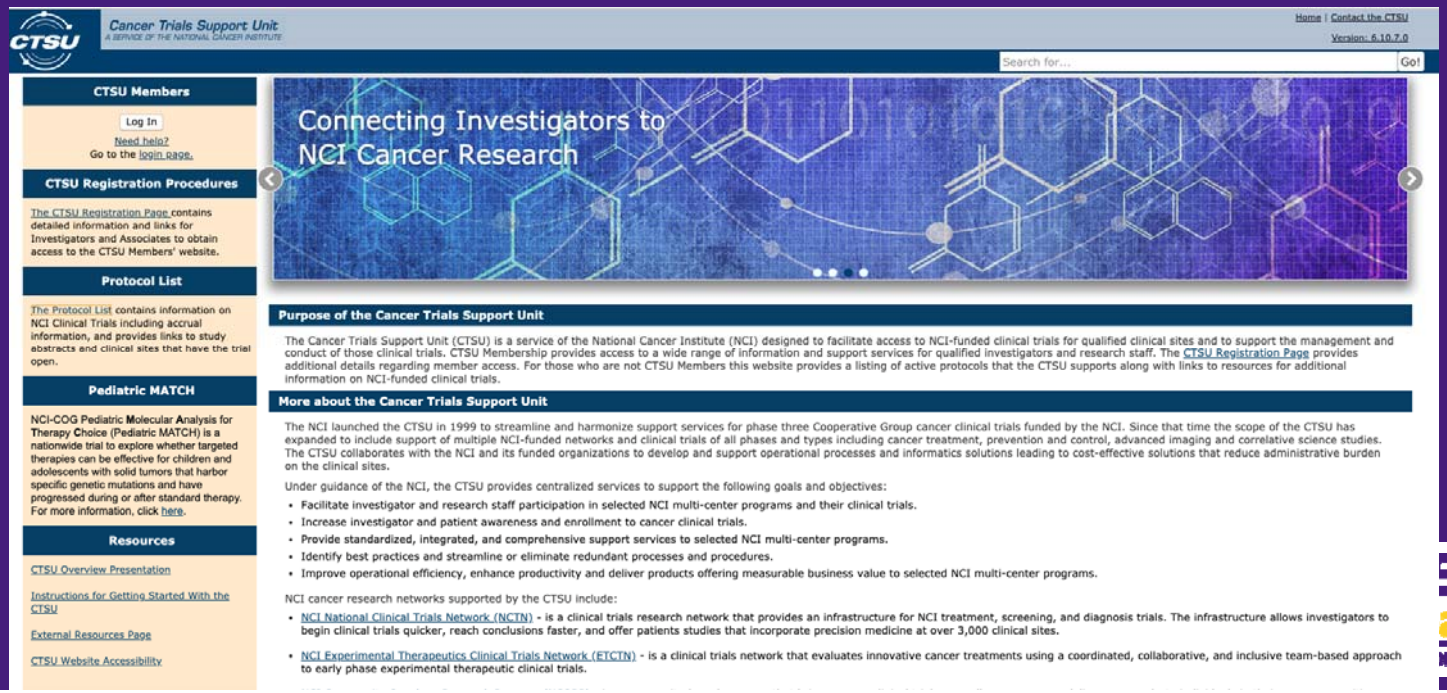
SWOG CANCER RESEARCH NETWORK

www.ctsu.org



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BASELINE ASSESSMENT

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

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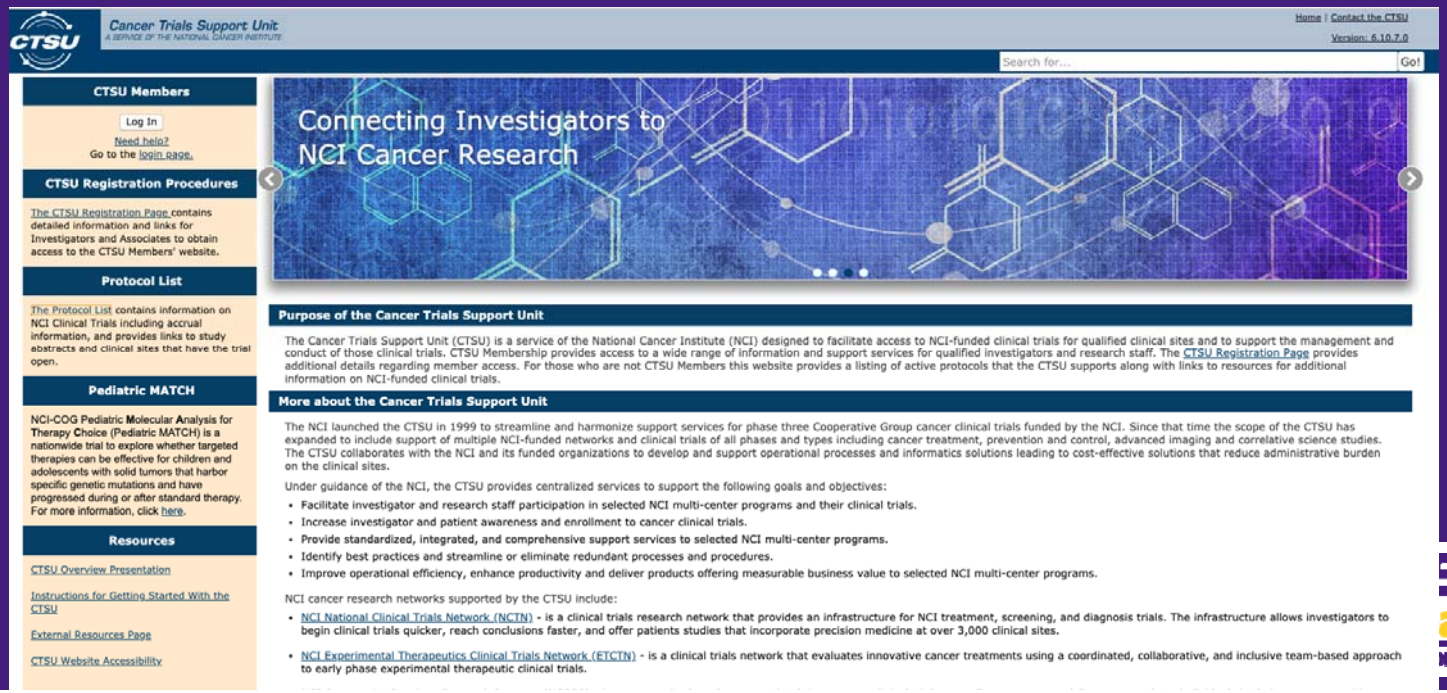

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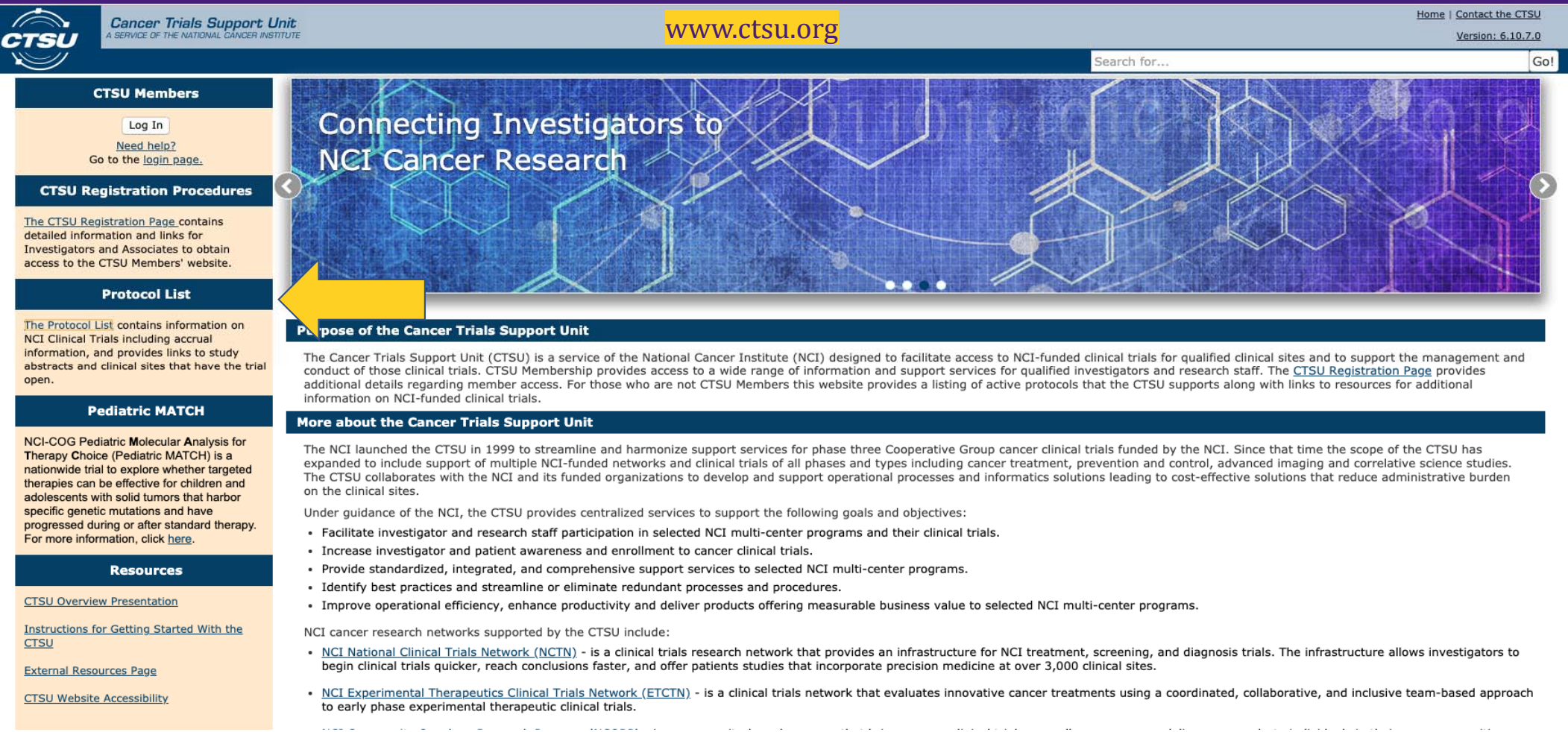
BASELINE: HOW DO I FIND THE TRIALS



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.

Phase: ALL | NIH Program: ALL | Disease: ALL | Keyword: Search

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

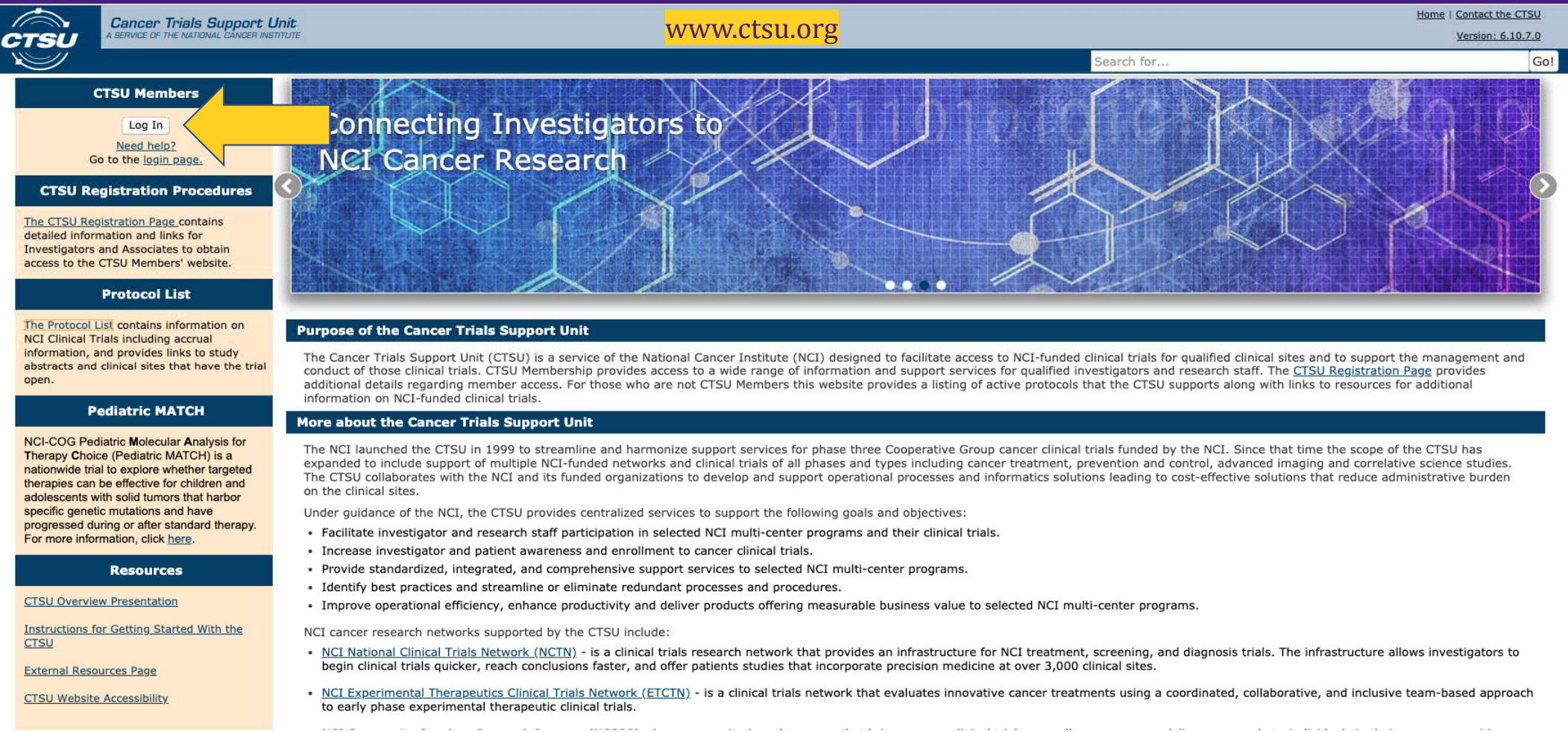
1 256

#	Protocol Number	Lead Organization	NIH Program	Disease	Status	Protocol Title	Phase	Actual/Planned Intervention Accrual	Screening Accrual	Step Type(s)
1	10013	LAO-NC010	ETCTN	Breast Cancer	Temporarily Closed to Accrual	Randomized Phase 2 Study of Neoadjuvant Chemotherapy, Carboplatin and Paclitaxel, with or Without Atezolizumab in Triple Negative Breast Cancer (TNBC)	II	67/72	N/A	INTERVENTION
2	10014	LAO-11030	ETCTN	Hematopoietic Neoplasm (excluding Leukemia, Lymphoma and Myeloma);Miscellaneous and Metastatic Cancer	Active	A Pilot Study of Atezolizumab (MPDL3280A) Following Adoptive Cell Transfer in Active Hematologic or Solid Tumor Malignancies	Pilot	17/40	N/A	INTERVENTION
3	10017	EDDO-NY158	MISCELLANEOUS	Female Reproductive System Cancer	Temporarily Closed to Accrual	A Randomized Phase 2 Trial of Atezolizumab (MPDL3280A), SGI-110 and CDX-1401 Vaccine in Recurrent Ovarian Cancer	I/II	12/75	N/A	INTERVENTION
4	10020	LAO-CT018	ETCTN	Breast Cancer	Active	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer	II	41/90	N/A	INTERVENTION
5	10066	LAO-CT018	ETCTN	Gastrointestinal Cancer	Active	A Phase 1/2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma (10017760)	I/II	22/49	N/A	INTERVENTION
6	10104	LAO-11030	ETCTN	Female Reproductive System Cancer	Active	A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer	II	82/84	N/A	INTERVENTION
7	10106	LAO-MD017	ETCTN	Lymphoma	Active	A Phase I and Randomized Phase II Study of KW-0761 (Mogamulizumab) and MK-3475 (Pembrolizumab) in Relapsed and Refractory Lymphomas	I/II	4/76	N/A	INTERVENTION
8	10150	LAO-11030	ETCTN	Female Reproductive System Cancer	Active	A Randomized Phase 2 Study of Bevacizumab and Either Weekly Anetumab Ravtansine or Weekly Paclitaxel in Platinum-Resistant or Platinum Refractory Ovarian Cancer	I/II	15/96	N/A	INTERVENTION
9	10200	LAO-MD017	ETCTN	Leukemia	Active	A Phase Ib/II Study of the Histone Methyltransferase Inhibitor Pinometostat in Combination with Azacitidine in Patients with 11q23-Rearranged Acute Myeloid Leukemia	I/II	0/48	N/A	INTERVENTION
10	10216	LAO-OH007	ETCTN	Lung, Mediastinal, and Pleural Cancer	Active	A Phase I/II Study of AZD9291(Osimertinib) and CB-839 HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer	I/II	0/18	N/A	INTERVENTION
11	10231	DCTD	NCTN	Miscellaneous and Metastatic Cancer	Temporarily Closed to Accrual	NCORP Tissue Procurement Protocol: An NCI Cancer Moonshot Study	Pilot	N/A	N/A	OTHER
12	9974	LAO-MA036	ETCTN	Lung, Mediastinal, and Pleural Cancer	Temporarily Closed to Accrual	A Phase II Study of Olaparib Plus Cediranib in Combination with Standard Therapy for Small Cell Lung Cancer	II	9/132	N/A	INTERVENTION
13	9979	LAO-MN026	ETCTN	Miscellaneous and Metastatic	Active	Phase 1 and Pharmacology Study of Oral 5-Iodo-2-Pyrimidinone-2-Deoxyribose	I	6/47	N/A	INTERVENTION

CTSU Website Accessibility

- 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.

BASELINE: HOW DO I FIND THE TRIALS-BETTER



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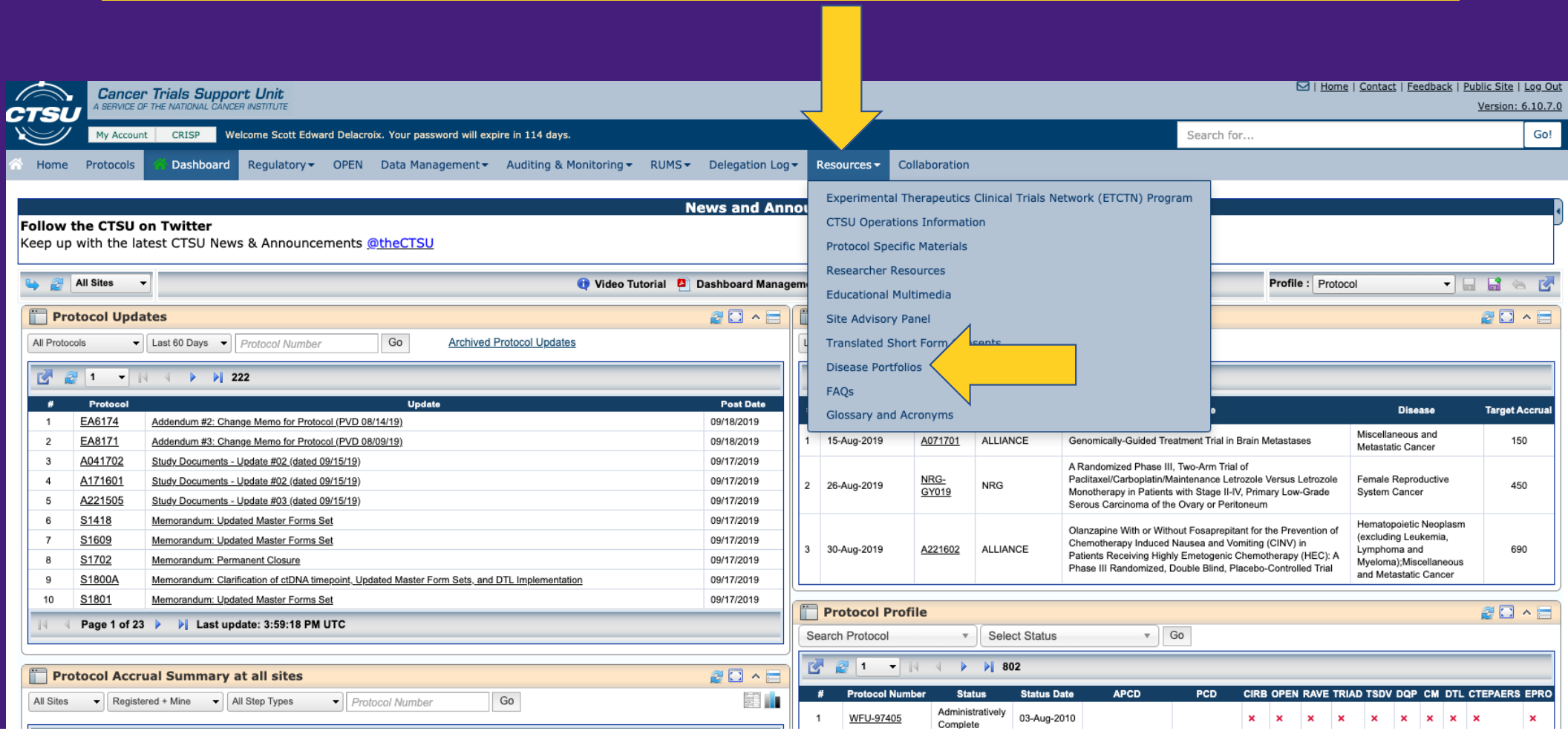
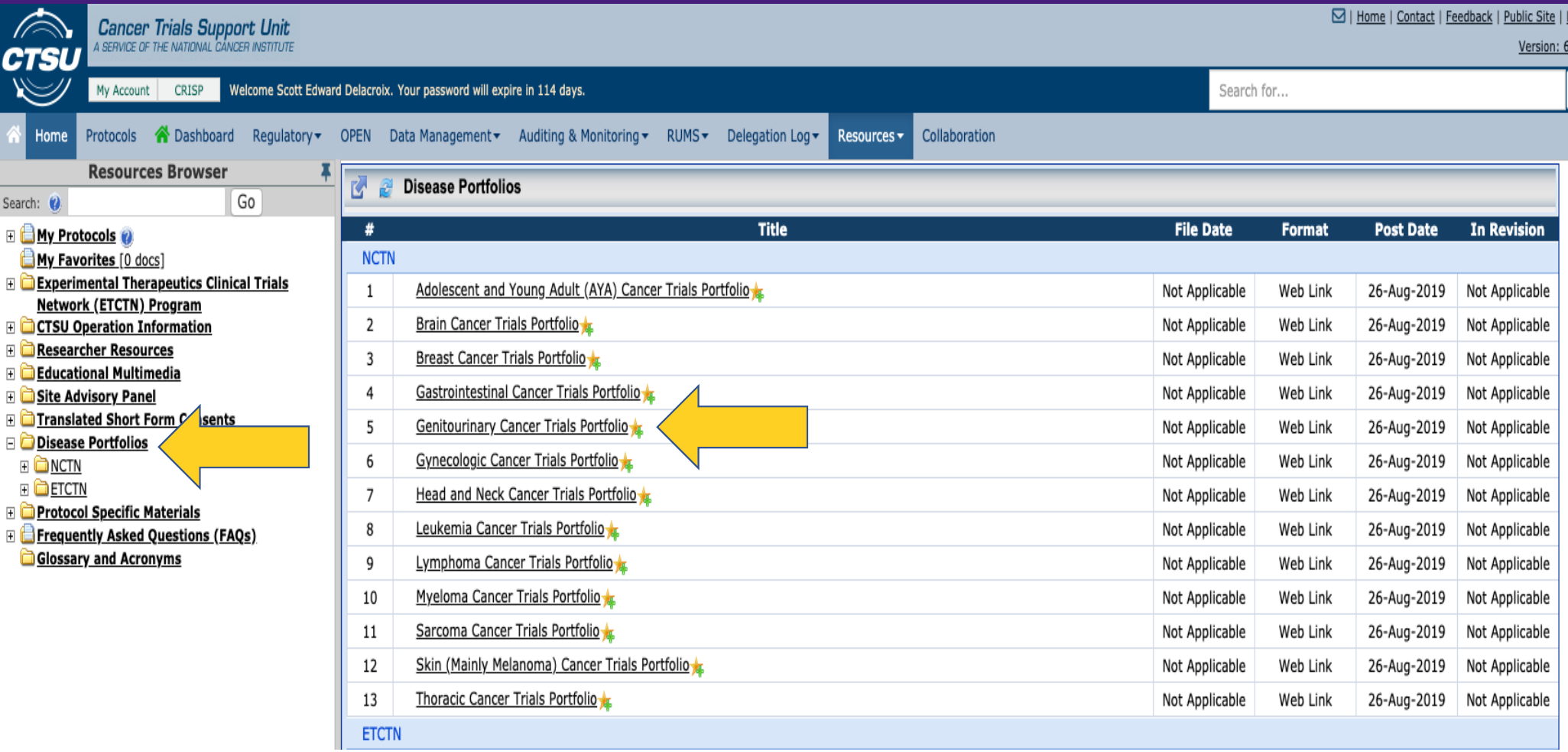


BASELINE: How do I find the Trials

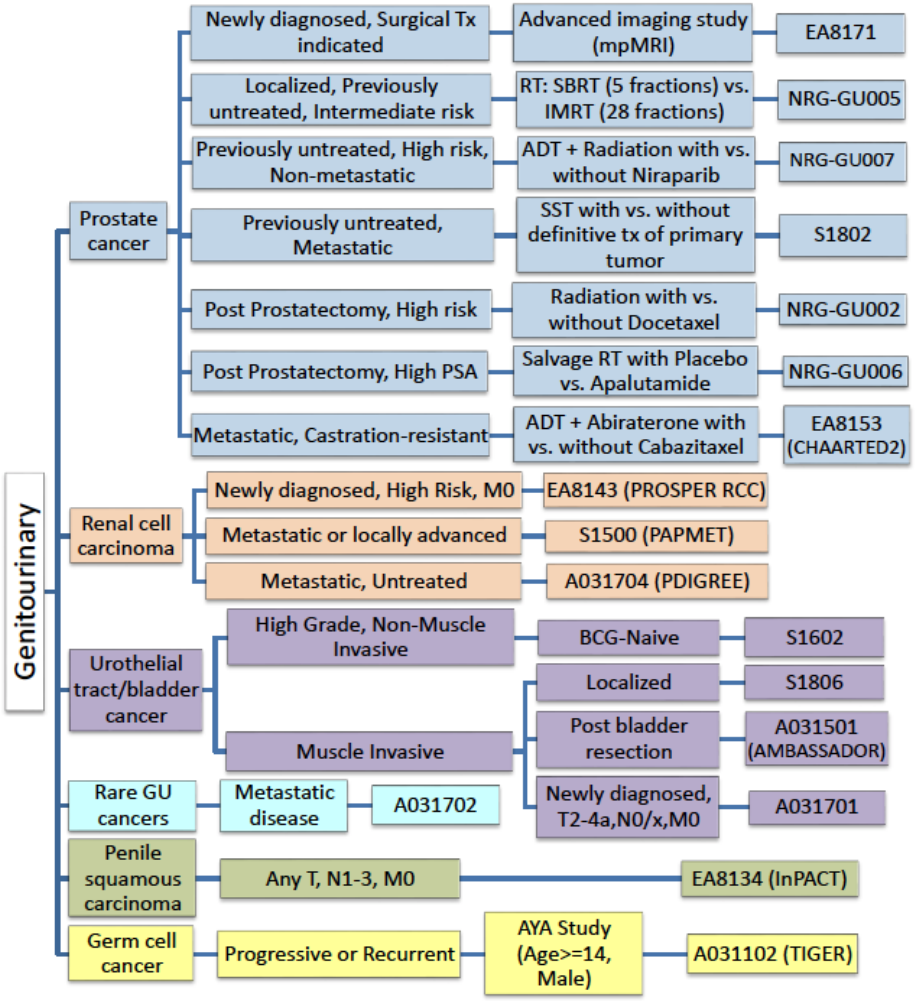


BASELINE: How do I find the Trials

Other group specific trials are not listed : eg WF1802

NCTN Genitourinary Cancer Trials Portfolio (Open as of 8/26/2019)

Each far right box includes the NCTN protocol number with a hyperlink to the associated ClinicalTrials.gov webpage. Click on it to view the protocol title and study information.



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Baseline Assessment

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

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A program of the National Cancer Institute of the National Institutes of Health

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- Research Nurse
  - Motivated/Organized/Timely

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GULF SOUTH CLINICAL TRIALS NETWORK

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Baseline Assessment

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

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SWOG CANCER RESEARCH NETWORK

- Research Nurse
  - Motivated/Organized/Timely
- MD
  - Motivated (or motivate them)
  - Organized (with help)
  - Timely (sometimes)

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GULF SOUTH CLINICAL TRIALS NETWORK

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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.

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INSTITUTIONAL PROCESS

- Process Variations--Know you 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 Beurocracy
- Politics are Local
- Local IRB hesitation due to claims that local IRBs reflect community values
- "This is how we have to do it"
- "Safety"

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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

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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 to local IRB in addition to CIRB

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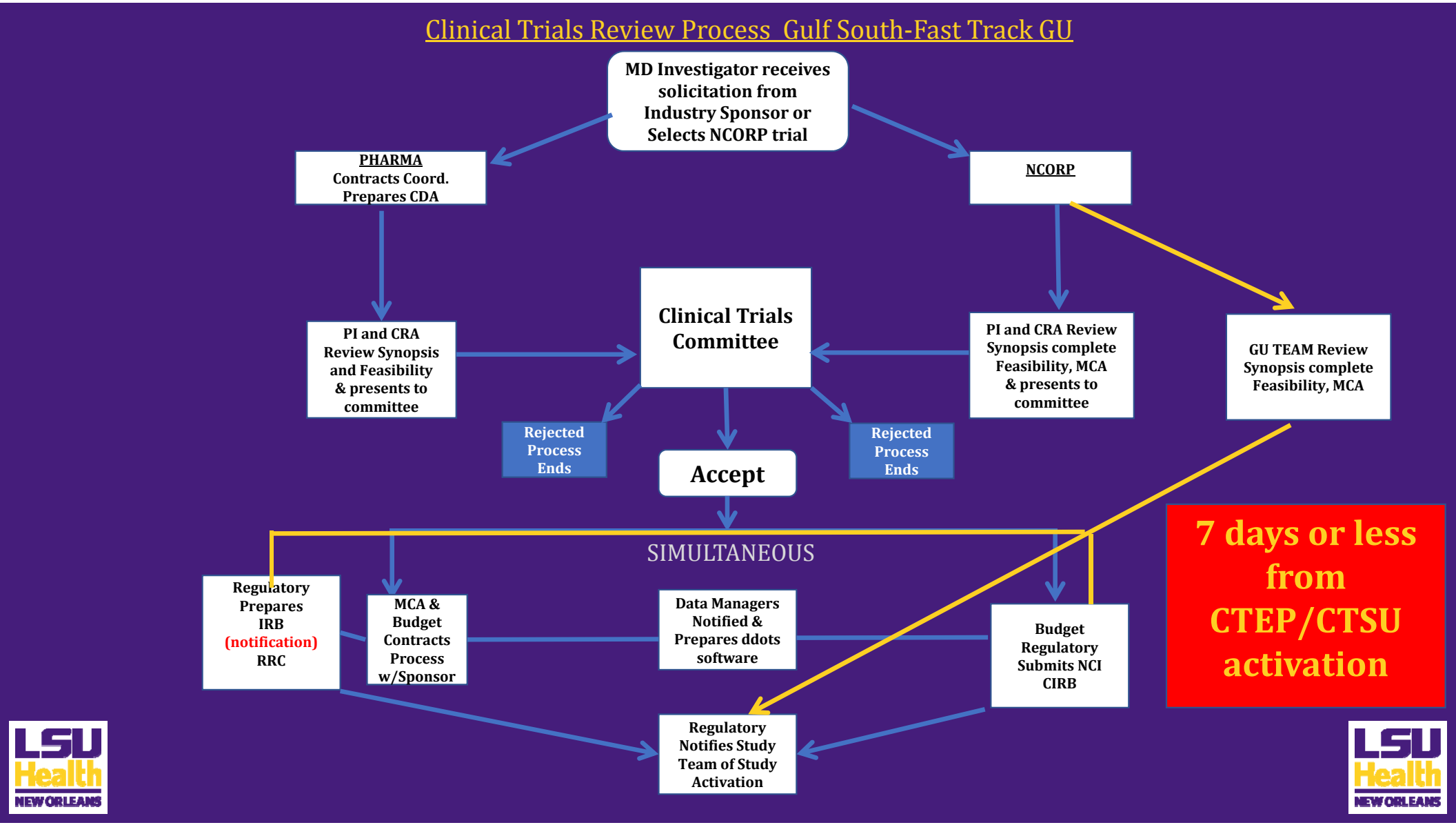
Clinical Trials Review Process Gulf South-Fast Track GU



White Boarding Objectives

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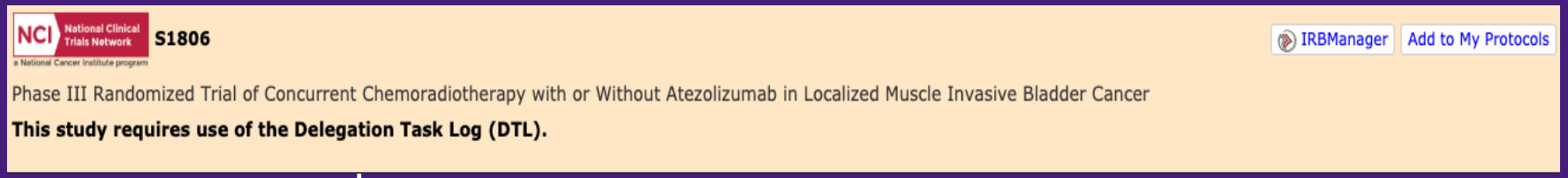
Institutional Process

Site Specific Process

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



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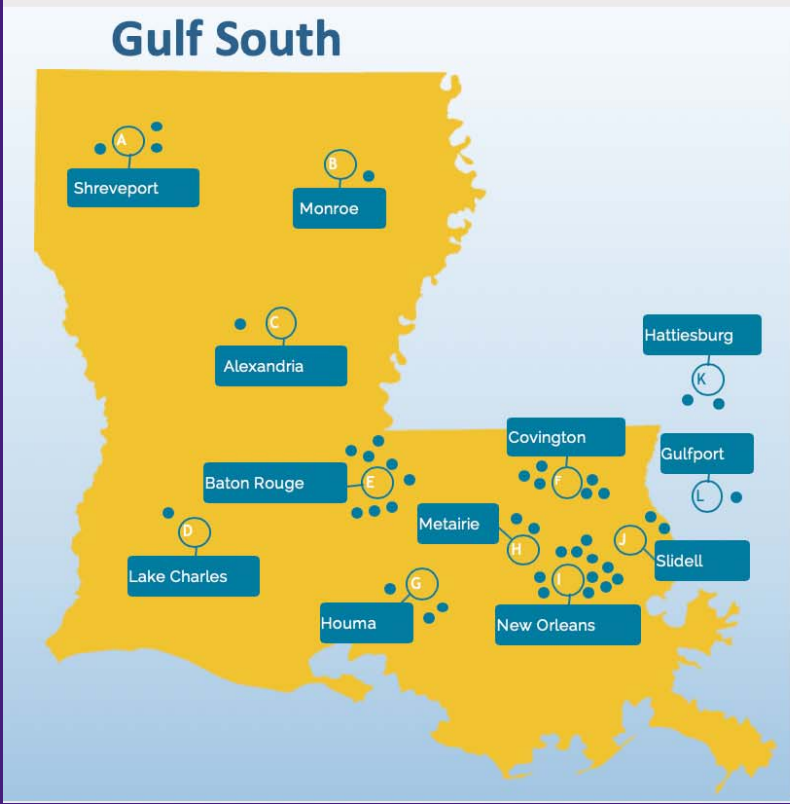
GULF SOUTH – FEDERATION (LA…)



A. Shreveport
LSU Health Sciences Center Shreveport
Willis Knighton Medical Center
CHRISTUS Highland Medical Center

B. Monroe
UH Conway Medical Center

C. Alexandria
CHRISTUS Saint Frances Cabrini Hospital

D. Lake Charles
CHRISTUS Saint Patrick Hospital

E. Baton Rouge
The NeuroMedical Cancer-Clinic
LSU Health Baton Rouge North Clinic
Mary Bird Perkins Our Lady of the Lake Cancer Center
Louisiana Hematology Oncology Associates LLC
Medical Oncology LLC
Women's Hospital
Ochsner Health Center – Summa
Medical Center of Baton Rouge

F. Covington
Mary Bird Perkins Cancer Center
Northshore Oncology Associates
Lallie Kemp Regional Medical Center – Independence
Ochsner Hematology Oncology North Shore Covington
Ochsner Health Center – Covington

G. Houma
Mary Bird Perkins Cancer Center at Terrebonne
Oncology Center of the South Inc.
Leonard J. Chabert Medical Center

H. Metairie
East Jefferson General Hospital
Robert Veith MD LLC

I. New Orleans
University Medical Center New Orleans
LSU Healthcare Network / St. Charles
Children's Hospital New Orleans
LSU Health Sciences Center New Orleans
Ochsner Medical Center – Kenner
Ochsner Medical Center – Jefferson
Ochsner Medical Center – West Bank
Ochsner Baptist Medical Center
West Jefferson Medical Center (Marrero)
Culicchia Neurological Clinic (Marrero)
Touro Infirmary

J. Slidell
St. Tammany Hospital Service District #2
Slidell Memorial Hospital
Ochsner Hematology Oncology North Shore

K. Hattiesburg (Mississippi)
Forrest General Hospital Cancer Center
Hattiesburg Clinic – Hematology/Oncology Clinic

L. Gulfport (Mississippi)
Gulfport Memorial Hospital

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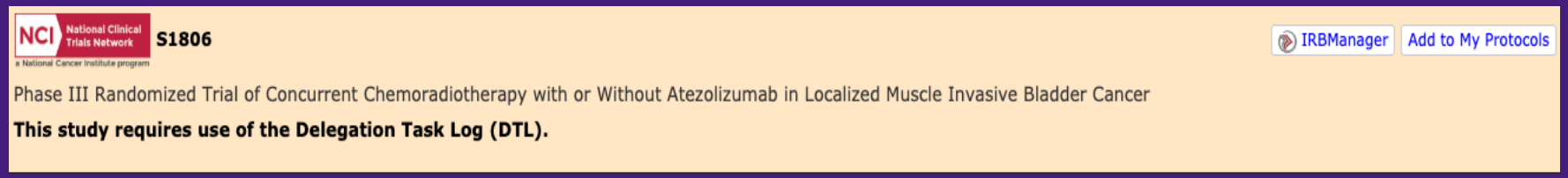

- Patients
- Med Onc
- Rad Onc
- Uro Onc
- Pathology

LEVERAGE ASSETS and BUILD PROCESSES

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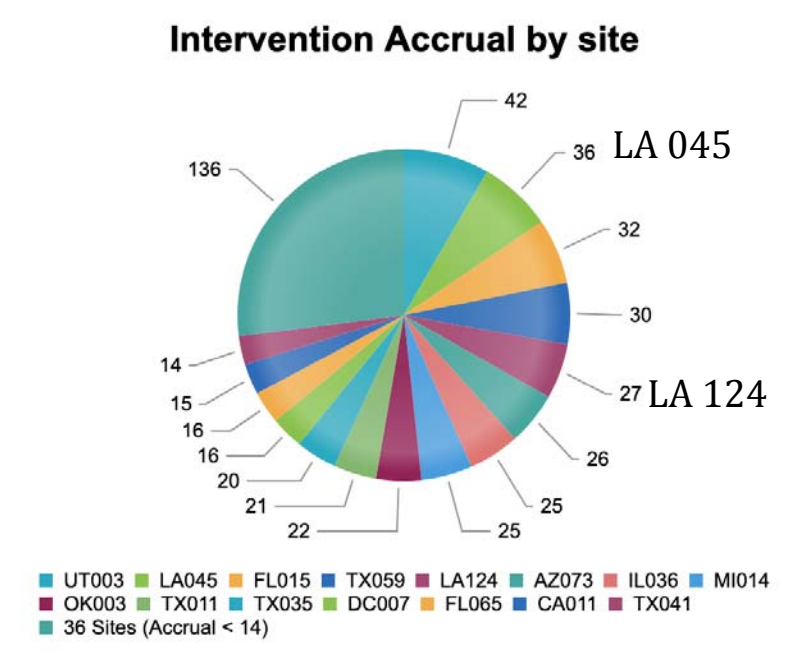
Institutional Process

Site Specific Process



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)

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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

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Parminder Singh

1806 Schema and Objectives

cT2-T4N0M0 <u>stratify by</u>
- Chemotherapy regimen
- Radiation field
- Performance status
- Clinical stage

Randomize 1:1, 475 patients

CRT(concurrent chemoradiation)

CRT+ Atezo q 21D x9

<u>Primary end point</u>
BIEFS*

<u>Secondary end point</u>
- OS at 5 yr
- Clinical response at 5 mths
- DSS
- MFS
- Toxicity at 1& 2 yr
- NMIBC rec
- Cystectomy rate
- Global Qol

<u>TM end points</u>
- 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

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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

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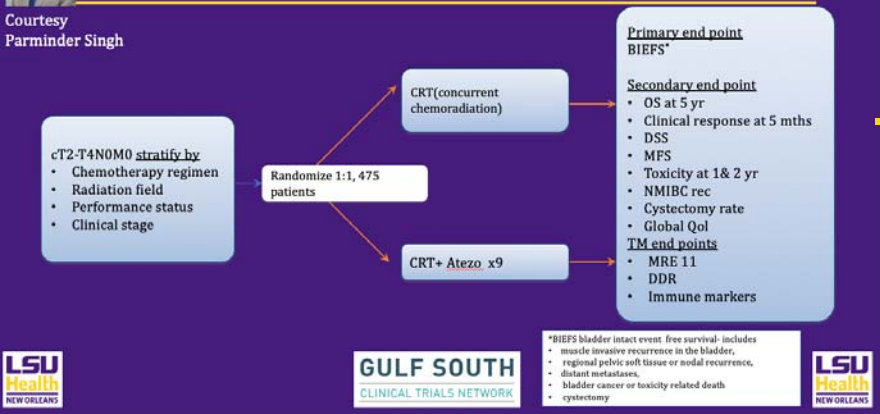
1806 Schema and Objectives



Options (Physician Choice)

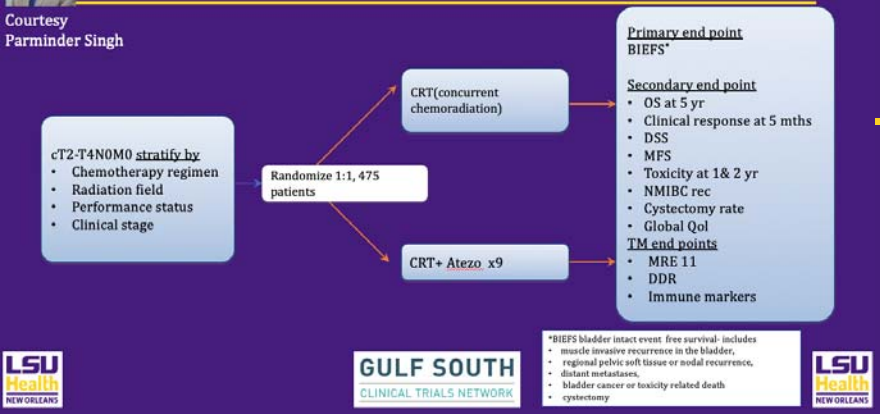
AGENT	DOSE	ROUTE	SCHEDULE
Gemcitabine	27 mg/m^2	IV	Twice weekly for six weeks

AGENT	DOSE	ROUTE	SCHEDULE
Cisplatin	35 mg/m^2	IV	Weekly for six weeks

AGENT	DOSE	ROUTE	SCHEDULE
5-FU	500 mg/m^2	IV	5-FU given on same days as doses 1-5 and 16-20 of RT
Mitomycin-C	12 mg/m^2	IV	Mitomycin-C given on same day as dose 1 of RT

Courtesy
Parminder Singh

1806 Schema and Objectives



Options (Physician Choice)

AGENT	DOSE	ROUTE	SCHEDULE
Gem GFR < 40	27 mg/m²	IV	Twice weekly for six weeks

AGENT	DOSE	ROUTE	SCHEDULE
Cisplati GFR > 40	35 mg/m²	IV	Weekly for six weeks

AGENT	DOSE	ROUTE	SCHEDULE
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

Courtesy
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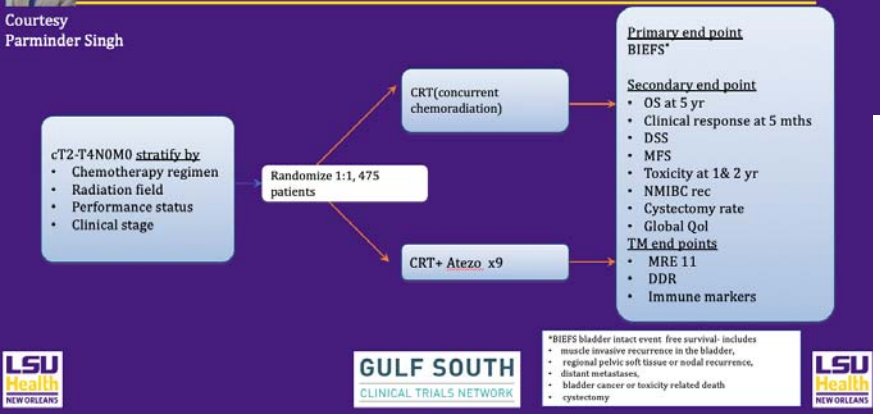
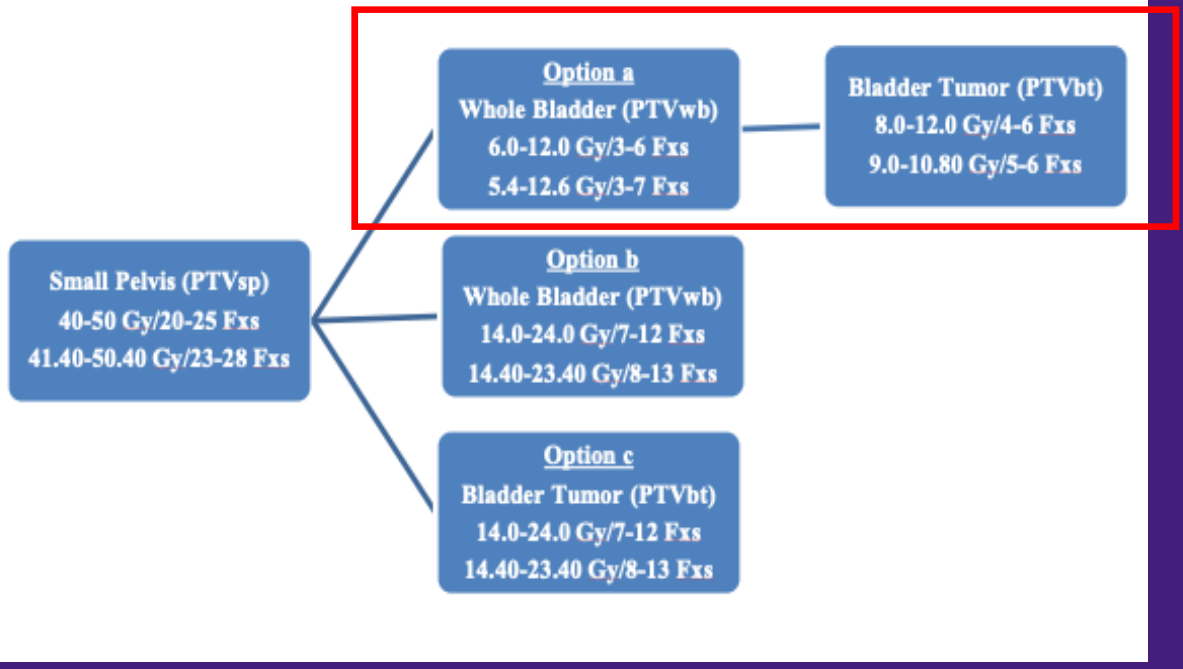
1806 Schema and Objectives



Options (Physician Choice)



Courtesy
Parminder Singh

1806 Schema and Objectives

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

Randomize 1:1, 475 patients

- CRT(concurrent chemoradiation)
- CRT+ Atezo x9

Primary end point
BIEFS*

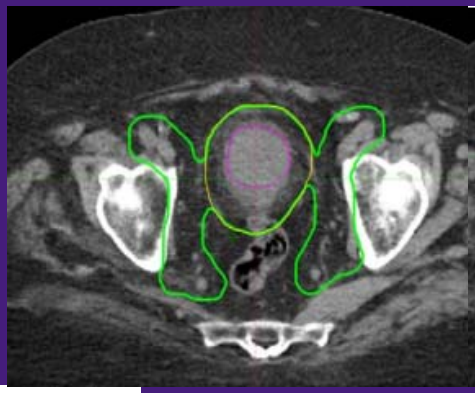
Secondary end point
- OS at 5 yr
- Clinical response at 5 mths
- DSS
- MFS
- Toxicity at 1& 2 yr
- NMIBC rec
- Cystectomy rate
- Global QoL

TM end points
- MRE 11
- DDR
- Immune markers

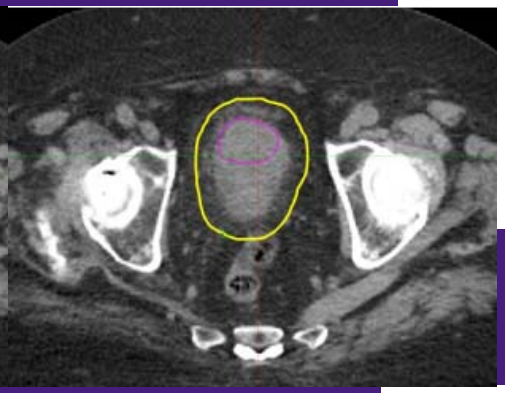
*BIEFS bladder intact event free survival- includes
- muscle invasive recurrence in the bladder,
- regional pelvic soft tissue or nodal recurrence,
- distant metastases,
- bladder cancer or toxicity related death
- cystectomy

LVI +
cT3
Hydro

Nodes



No nodes



Options (Physician Choice)

Small Pelvis (PTVsp)
40-50 Gy/20-25 Fxs
41.40-50.40 Gy/23-28 Fxs

Option a
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

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

Courtesy
Parminder Singh

1806 Schema and Objectives

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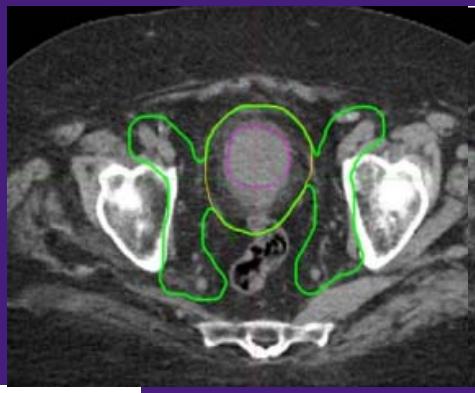

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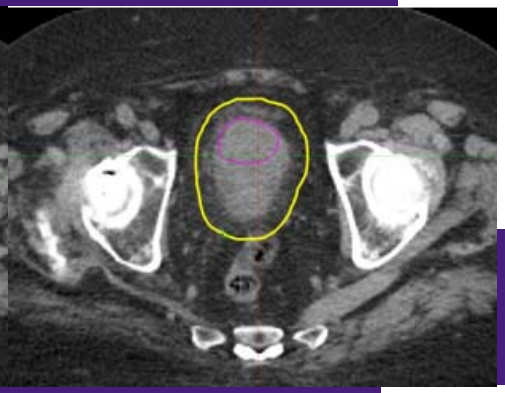

Options (Fiducials)

Small Pelvis (PTVsp)
40-50 Gy/20-25 Fxs
41.40-50.40 Gy/23-28 Fxs

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

WHITEBOARD

- 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)

AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH
-14	WK18*	14	MRI Bladder	Cytology	CT C/A/P	OR BLBX	-14	WK 30	14	MRI Bladder	Cytology	CT C/A/P	Clinic Cysto	-14	WK 42	14	MRI Bladder	Cytology	CT C/A/P	OR BLBX	-14	WK54	14	MRI Bladder	Cytology	CT C/A/P	Clinic Cysto	-14	WK 66	14	MRI Bladder	Cytology
10/1/19	10/15/19	10/29/19					12/24/19	1/7/20	1/21/20					3/17/20	3/31/20	4/14/20					6/9/20	6/23/20	7/7/20					9/1/20	9/15/20	9/29/20		
11/4/19	11/18/19	12/2/19					1/27/20	2/10/20	2/24/20					4/20/20	5/4/20	5/18/20					7/13/20	7/27/20	8/10/20					10/5/20	10/19/20	11/2/20		
11/4/19	11/18/19	12/2/19					1/27/20	2/10/20	2/24/20					4/20/20	5/4/20	5/18/20					7/13/20	7/27/20	8/10/20					10/5/20	10/19/20	11/2/20		
11/11/19	11/25/19	12/9/19					2/3/20	2/17/20	3/2/20					4/27/20	5/11/20	5/25/20					7/20/20	8/3/20	8/17/20					10/12/20	10/26/20	11/9/20		
11/25/19	12/9/19	12/23/19					2/17/20	3/2/20	3/16/20					5/11/20	5/25/20	6/8/20					8/3/20	8/17/20	8/31/20					10/26/20	11/9/20	11/23/20		
12/9/19	12/23/19	1/6/20					3/2/20	3/16/20	3/30/20					5/25/20	6/8/20	6/22/20					8/17/20	8/31/20	9/14/20					11/9/20	11/23/20	12/7/20		
1/2/20	1/16/20	1/30/20					3/26/20	4/9/20	4/23/20					6/18/20	7/2/20	7/16/20					9/10/20	9/24/20	10/8/20					12/3/20	12/17/20	12/31/20		
1/16/20	1/30/20	2/13/20					4/9/20	4/23/20	5/7/20					7/2/20	7/16/20	7/30/20					9/24/20	10/8/20	10/22/20					12/17/20	12/31/20	1/14/21		

LSU Health NEW ORLEANS

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

- LSU GU: Standardize The Options:
  - RADICAL TUR with Fiducials
  - Radiation Fields limited to two options (+/- nodes)
  - Chemotherapy narrowed to two options

LSU Health NEW ORLEANS

GULF SOUTH CLINICAL TRIALS NETWORK

LSU Health NEW ORLEANS

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

LSU Health NEW ORLEANS

GULF SOUTH CLINICAL TRIALS NETWORK

LSU Health NEW ORLEANS

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

LSU Health NEW ORLEANS

GULF SOUTH CLINICAL TRIALS NETWORK

LSU Health NEW ORLEANS

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

LSU Health New Orleans

GULF SOUTH CLINICAL TRIALS NETWORK

LSU Health New Orleans

NOMENCALTURE 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?

LSU Health NEW ORLEANS

GULF SOUTH CLINICAL TRIALS NETWORK

LSU Health NEW ORLEANS

GU Cancer Treatment and Trial Team

Eileen Mederos*
Program Coordinator

*NCORP Program Coordinator/Admin of the Year 2019

Megan Bruard
GU Research Nurse
Holly Martin
GU Research Nurse
Michelle Seeman
GU Research Nurse

Urologic Oncology

Delacroix

Gills*

#3 NCORP Treatment Trial Accruals in US 2019

Radiation Oncology

Padmanabaha

Monsour

Medical Oncology

Marquette

LSU Health New Orleans

GULF SOUTH CLINICAL TRIALS NETWORK

EJGH East Jefferson General Hospital

WHITEBOARDING A CLINICAL TRIAL
SWOG 1806

GULF SOUTH
CLINICAL TRIALS NETWORK

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 SouthNCORP
Louisiana State University Health Sciences Center
New Orleans, Louisiana
@UroCancer

SWOG Fall Meeting
October 3,2019

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

LSU Health

EJGH East Jefferson General Hospital