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A Randomized Phase III Study of Sublobar Resection (SR) versus Stereotactic Ablative Radiotherapy (SAbR) in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

"The STABLEMATES Trial"

Sponsored by:

Joint Lung Cancer Trialist's Coalition (JoLT-Ca)

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CRO Contact List

Name	Role	Phone	Email
Rossana Berrios	Regulatory Specialist	214-648-1890	rossana.berrios@utsouthwestern.edu
Irma Smith	Quality Assurance Coordinator	214-648-2047	irma.smith@utsouthwestern.edu
Jean Wu	Clinical Research Manager	214-648-1892	Jean.wu@utsouthwestern.edu

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BACKGROUND

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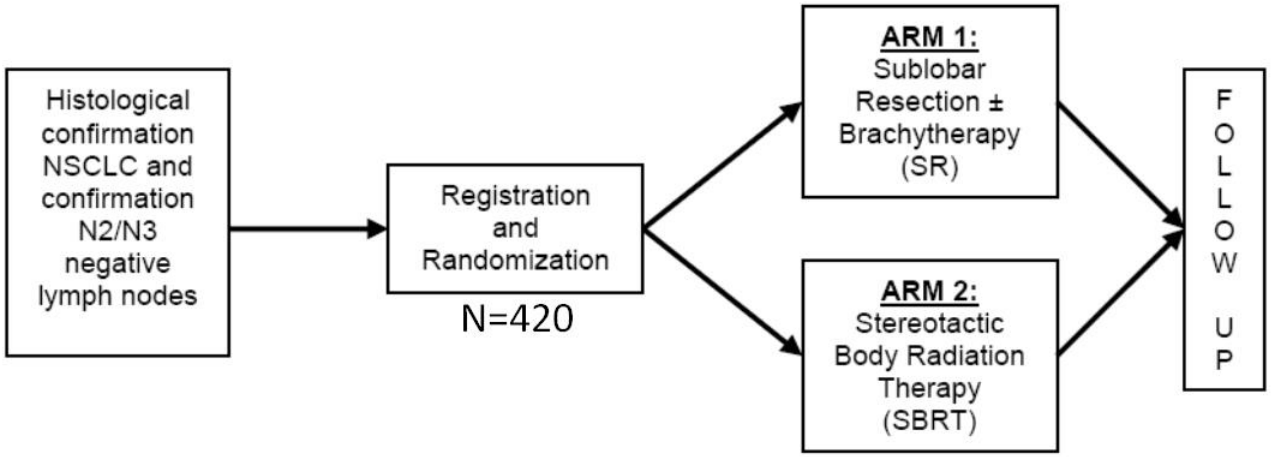
ACOSOG Z4099 / RTOG 1021

PIs: Hiran C. Fernando, MD (ACOSOG); Robert Timmerman, MD (RTOG)



- Traditional Phase III Randomized Trial
  - Patients randomized to either surgery or SAbR after consent
  - Primary endpoint = 3 year overall survival

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ACOSOG Z4099/RTOG 1021

- Comparing sublobar resection vs. SAbR in specifically high risk operable patients
  - 60 sites opened the trial in the US, Canada, and Europe
- Poor accrual
  - Extensive investigation regarding barriers to accrual
    - Equipoise of surgeons?
    - Eligibility criteria?
    - Complicated accreditation?
- Trial was modified to clarify high risk and expand eligibility
- Finally closed due to poor accrual

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High Level Trials of Disparate Therapies

- Often, the MOST IMPORTANT clinical questions in oncology
  - Surgery vs. radiation
  - Observation vs. treatment

- Patients struggle to allow an *indifferent coin flip* to solely determine an important decision in their life
  - Patients lack equipoise

- With failure of traditional phase III trials, oncologists must resort to lower level evidence
  - Retrospective series
  - matched case cohort
  - etc

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Pre-randomization

- The NSABP B-06 trial comparing mastectomy to lumpectomy/XRT had very poor accrual when originally opened for enrollment
  - Threatened closure due to patient refusal to accept the randomization

- NSABP, with great insight, re-designed the trial to utilize a randomization that occurred prior to asking the patient to participate
  - Screened eligible patients were identified prior to initial visit, randomized, and given the option to accept the randomized assignment
  - Patients refusing the randomized assignment were tracked for primary outcome on standard therapy
  - In the end, patients signed the consent AFTER the randomization

- The re-design led to successful accrual that allowed the trial to answer the question
  - 80% of screened eligible patients accepted the randomization
  - Well accepted result in the oncology community despite alternate phase III design

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New Concept

- Given the progress in site accreditation and buy-in already existing, we are going to re-open the ACOSOG/RTOG trial under the newly formed Joint Lung Cancer Trialist's Coalition (JoLT-Ca)

- The trial will be supported by industry (Varian, Elekta, and Accuray)

- Most importantly, the re-designed trial will utilize a pre-randomization to avoid the condemning problem where patients lack equipoise for trials comparing disparate therapies

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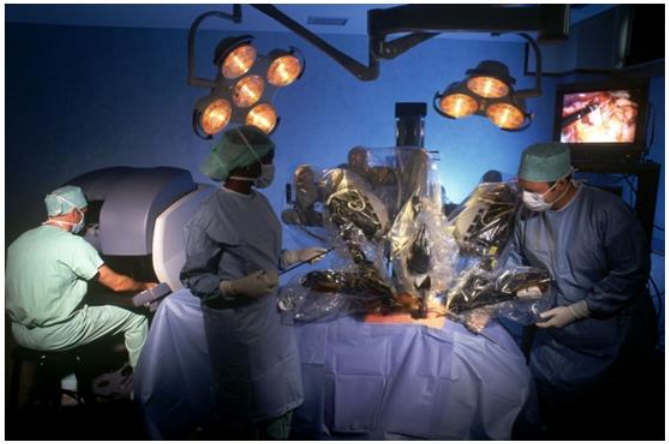
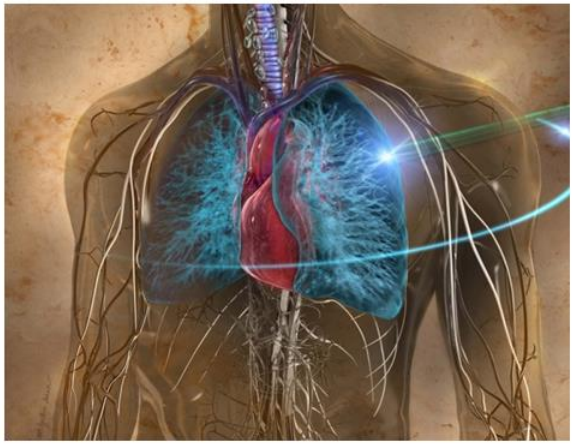


versus



Cold Blade?

Hot Ray?

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SCHEMA

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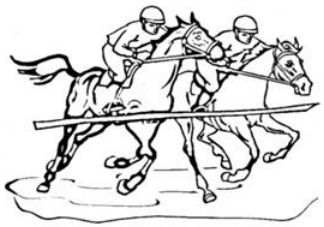

Defined High Risk Stage I NSCLC

Screen Eligible Patients/ Pre-Randomize

N = 272

Consent to Accept Randomization Assignment

Accept

N = 218

Arm 1: Sublobar Resection

N = 109

Arm 2: SAbR

N = 109

Follow for OS, Toxicity, and Patterns of Failure

Reject

N = 54*

Consent to Be Observed After Standard of Care Therapy

Accept

N = 48

Follow for OS, and Patterns of Failure

Reject

N = 6*

Failure to Consent (Off Study)

*Anticipated (actual assignment rate will be monitored)

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STUDY OBJECTIVES

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Study Objective

- To test the hypothesis that overall survival rate in high risk operable patients with Stage I NSCLC is greater in patients who undergo SAbR as compared to standard sublobar resection (SR)

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Study Endpoints

Primary Endpoint

- Overall survival rate for Stage I NSCLC who undergo SR or SAbR. Overall survival will be measured from date of treatment initiation until death.

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Study Endpoints

Secondary Endpoints

- Progression free survival for Stage I NSCLC who undergo SR or SAbR. Progression-free survival (PFS) is the time elapsed between treatment initiation and (1) any recurrence (local, regional or distant) or (2) death due to any cause.

- Local and regional recurrence rates for Stage I NSCLC who undergo SR or SAbR. Time to local and regional recurrence is defined per section 10.0 and includes patients with failures of either the primary tumor and/or regional lymph nodes.

- Distant recurrence rates for Stage I NSCLC who undergo SR or SAbR. Time to distant recurrence is defined per section 10.0 for patients with distant failure.

- Assess toxicity using the Common Toxicity Criteria for Stage I NSCLC who undergo SR or SAbR.

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SUBJECT ELIGIBILITY

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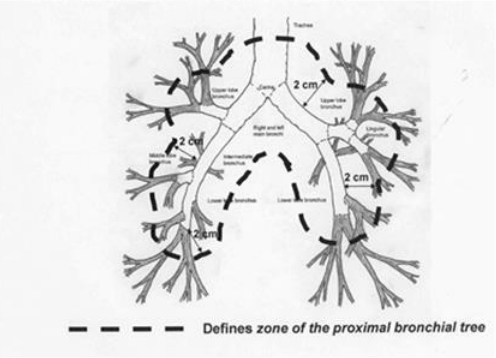
Key Inclusion Criteria

- Age **> 18** years.
- ECOG = **0**, **1**, or **2**.
- **Biopsy** and **Radiographic** findings consistent with NSCLC, including lesions with ground glass opacities with a solid component of 50% or greater.
- Tumor **≤ 4 cm** max diameter (including IA and selected IB by PET/CT scan within 90 days prior to randomization)
- All **clinically suspicious mediastinal N1, N2, or N3 lymph nodes** (> 1cm short-axis dimension on CT scan and/or positive on PET scan) confirmed **negative** for involvement with NSCLC.
- **Thoracic surgeon confirmation** location will permit sublobar resection.
- Tumor located **peripherally within the lung**.



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Key Inclusion Criteria

- **No** evidence of **distant metastases**.
- **Pulmonary function tests** (PFTs – spirometry, DLCO, +/- arterial blood gases) within 90 days prior to registration.
- Patient at high-risk for surgery by meeting a **minimum of one major criteria or two minor criteria** as described below:
  - Major Criteria
    - FEV1 ≤ 50% predicted
    - DLCO ≤ 50% predicted
  - Minor Criteria
    - Age ≥75
    - FEV1 51-60% predicted
    - DLCO 51-60% predicted
    - Pulmonary hypertension (defined as a pulmonary artery systolic pressure greater than 40mm Hg) as estimated by echocardiography or right heart catheterization
    - Poor left ventricular function (defined as an ejection fraction of 40% or less)
    - Resting or Exercise Arterial $pO_2 \leq 55$ mm Hg or $SpO_2 \leq 88\%$
    - $pCO_2 > 45$ mm Hg
    - Study credentialed thoracic surgeon believes the patient is potentially operable but that a lobectomy or pneumonectomy would be poorly tolerated by the patient for tangible or intangible reasons.
    - Modified Medical Research Council (MMRC) Dyspnea Scale ≥ 3.

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Key Inclusion Criteria

- **No prior intra-thoracic radiation therapy**. Non-thoracic radiation therapy is permitted so long as possible radiation fields do not overlap.
- **Previous chemotherapy or surgical resection** specifically for the lung cancer being treated on this protocol is **NOT permitted.**
- **No prior lung resection** on the ipsilateral side.
- **No prior invasive malignancy**, unless disease-free for ≥ 3 years prior to registration (exceptions: non-melanoma skin cancer, in-situ cancers).

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PATIENT REGISTRATION & RANDOMIZATION

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Patient Randomization

- Once the patient is **pre-screened** and **confirmed eligible**, randomization will be performed without patient involvement.
- Randomization will be done using **RedCap** (Web-based Data Management System)
- The Research Team will assign a **unique identifier** for the patient and enter only the **patient's age and sex** (additional patient information will NOT be entered at this time).
  - Unique identifier consists of Site #, followed by subsequent double digit numbers
    - For example Site #20 will use the following unique identifiers – Patient #2001, 2002, 2003, etc.
- The patient will be randomized to either **Surgical Resection (SR) or Radiation (SAbR)**.

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Patient Registration

- **Patients will be informed** of which treatment arm they have been assigned from the pre-randomization.
- If the **patient wishes consent to accept the pre-randomization** assignment, they will then go on to receive either SR or SAbR with follow-up per the study calendar.
- If the patient **rejects (refuses) to consent to the pre-randomization** assignment, they will then be offered the opportunity to be followed on the trial after standard of care treatment per the study calendar for progression free and overall survival (intent to treat analysis).
  - Standard of care will be decided by the local team according to their perceptions in conjunction with the patient's condition and wishes. Patients not accepting the pre-randomization assignment will ideally be followed and analyzed to ensure consistency between those accepting and not accepting the assignment. Typically the standard of care treatment will be surgery for most patients. However, if a patient refuses surgery and the local team considers alternate treatments standard in that context, including SBRT, the patient may be enrolled to the observation portion of the study.
- **Patients rejecting (refusing) consent for any study activities** will not be followed (lost to follow-up).

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Patient Registration

- **All eligible subjects** must be **registered with the UTSW Rad Oncology CRO through RedCap** before initiating protocol activities.
- Source Documentation to confirm eligibility criteria must be uploaded to **RedCap within 24 hrs of patient enrollment**.

- Any questions regarding patient registration and/or eligibility should be directed to:

Jean Wu, Clinical Research Manager

jean.wu@utsouthwestern.edu

214-645-8913

Monday through Friday, 8:00AM-4:00PM CST.

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STUDY CALENDAR

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Study Calendar

Tests and Observations	Within 60 days prior to ran. (except where noted)	After reg. and before SAbR or surgery	ARM 1 (SR)		ARM 2 (SAbR)		Both arms (From date of surgery/end of SAbR)[5]								Every 6 mo. thereafter until 60 mo.[6]	At time of disease relapse / PD
			At time of surgery	4 weeks post-op	Before final SAbR (same day)	4 weeks after SAbR	3 mo.	6 mo.	9 mo.	12 mo.	15 mo.	18 mo.	21 mo.	24 mo.		
History & Physical, ECOG/Zubrod PS	X			X		X	X	X	X	X	X	X	X	X	X[7]	X
Pregnancy test	X[1]															
Tumor biopsy (required) and LN biopsy (if needed)	X[9]															X
Pulmonary Function Tests	X[8]						X	X		X				X		
PET/CT scan chest/upper abdomen	X[10]							X[3]		X[3]				X[3]		X[3]
CT scan chest/upper abdomen				X			X		X		X	X	X		X	X
Adverse event assessment		X		X		X	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]		
Charlson Comorbidity Index		X														
LCSS		X		X		X	X	X		X				X	X	
QA submission to JoLT-CA Radiotherapy QA Headquarters		X[2]		X		X										

Superscript Notes – Please refer to Section 9.5 of the Protocol.

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QUALITY ASSURANCE (QA) DOCUMENTATION

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Surgery QA Documentation

- Surgical quality assurance will be performed by the surgical study chair or designee and recorded in a study specific surgical QA form (available in RedCap).
- All operative and pathology reports will be reviewed by the surgical study chair or designee for success of the resection.
- Problems or concerns about investigator performance will be communicated directly to the investigator by the study chair.

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SaBR QA Documentation

- Recorded in the study specific QA form (available at www.joltca.org) and DICOM RT datasets; which should be submitted to UTSW Radiation Oncology for review.

- For First Patient:
  - **Rapid review of the first patient's treatment plan** prior to treatment is required for each institution. **Waived if the institution already performed such first case review on the following RTOG trials: 0236, 0813, 0618, 0915, and 1021.**
  - Prior to the start of SAbR, submit the following materials for the first patient treated at your site:
    - Planning CT images (DICOM)
    - Structure contours (DICOM RT Structure Set) for critical normal structures, all GTV, CTV, and PTV contours (C1, C3)
    - Treatment plan (DICOM RT Plan) for initial and boost beam sets
    - 3-D CALCULATED dose distributions (DICOM RT Dose) for initial and boost sets of concurrently treated beams
    - Color isodose images in axial, sagittal, and coronal planes (JPEG or PNG screen captures)
    - DVH data for all required critical normal structures, GTV, CTV, and PTVs for total dose plan (DV)
    - Digital Data Submission Information Form (DDSI)

  Note: Prior to data submission, all DICOM objects have to be **de-identified** with a provided DICOM de-identification tool.

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SaBR QA Documentation

- For All Subsequent Patients:
  - Within four weeks after completion of SAbR, submit the required materials identified in Section 6.6.3 of the Protocol for all patients. Submitted digitally as **DICOM RT objects**.
  - Final Dosimetry Data Submission for All Patients - Within four weeks after completion of SAbR, submit **hard copies** of **Radiotherapy Summary Form**.

- The study co-chair or designee will perform retrospective treatment plan review after complete data for the first 50 cases enrolled have been received.

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QA Submission Instructions

- All CT planning and treatment information (e.g., planning CT files, dose files, plan files, and structure files) must be submitted digitally in DICOM RT format. Plan report including isodose distributions, DVHs and dose statistics in PDF format shall also be submitted along with digital DICOM RT datasets.

- A Secure FTP (SFTP) account with username and password can be obtained by contacting UT Southwestern Medical Center-Department of Radiation Oncology, **Yulong.yan@utsouthwestern.edu**.

- Sites must notify via e-mail when digital data are submitted. The e-mail must include the study and patient identification numbers and a description of the datasets being submitted (e.g. QA, SAbR treatment plan, etc.).

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ADVERSE EVENT REPORTING

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Adverse Events

- Definition: Any untoward or unfavorable medical occurrence in a human research study participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, clinical event, or disease, temporarily associated with the subject's participation in the research, whether or not it is considered related to the subject's participation in the research.

- AE data collection and reporting are done to ensure the safety of subjects enrolled in the studies as well as those who will enroll in future studies using similar agents.
  - AEs are reported in a routine manner at scheduled times during a trial.
  - Additionally, certain adverse events must be reported in an expedited manner to allow for optimal monitoring of subject safety and care.

- All subjects experiencing an adverse event, regardless of its relationship to study procedure, will be monitored until:
  - the adverse event resolves or the symptoms or signs that constitute the adverse event return to baseline;
  - there is a satisfactory explanation other than the study interventions for the changes observed death.

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Adverse Event Severity (NCI CTCAE v4)

- Grade 1: Mild
- Grade 2: Moderate
- Grade 3: Severe or medically significant but not immediately life threatening
- Grade 4: Life threatening consequences
- Grade 5: Death related to the adverse event

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RTOG Pulmonary Function Test Toxicity Scale

	Grade				
Adverse Event	1	2	3	4	5
FEV-1 Decline	0.90-0.75 times the patient's baseline value	<0.75-0.50 times the patient's baseline value	<0.50-0.25 times the patient's baseline value	<0.25 times the patient's baseline value	Death
Forced Vital Capacity Decline	0.90-0.75 times the patient's baseline value	<0.75-0.50 times the patient's baseline value	<0.50-0.25 times the patient's baseline value	<0.25 times the patient's baseline value	Death
DLCO Decline	0.90-0.75 times the patient's baseline value	<0.75-0.50 times the patient's baseline value	<0.50-0.25 times the patient's baseline value	<0.25 times the patient's baseline value	Death

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Serious Adverse Events (SAE)

Those events meet any of the following criteria:

- Results in death
- Immediately life-threatening
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

May be anticipated or unanticipated

May or may not be related to the research project

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Reporting

- **SAEs**: whether anticipated or an unanticipated problem as defined above, require expedited central reporting, and are submitted to the trial's central research administration (Department of Radiation Oncology Clinical Research Office, UTSW)

- **Non SAEs**: Record in REDCap CRFs

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Timing Requirements

- **Serious Adverse Events** (anticipated as reflected by warnings of the informed consent) must be submitted **within 2 working days** of the participating site PI's awareness.

- **Unanticipated Problems** (unanticipated SAEs as defined above) must be submitted **within 1 working day** of the participating site PI's awareness.

- Reporting Contact:

Jean Wu, Clinical Research Manager
jean.wu@utsouthwestern.edu
214-645-8913
Monday through Friday, 8:00AM-4:00PM CST.

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REGULATORY

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Prior to Site Activation

- Copies of all the following documents must be filed at UTSW Radiation Oncology Clinical Research Office:
  - Site contact list
  - Federalwide Assurance (FWA) or IRB Roster
  - Credentialing and Training documentation for Investigators and Study Team
  - IRB Initial Approval Letter and Approved Documents
  - Signature/Delegation log
  - Signed Protocol/Amendments Signature Page
  - Signed FDA 1572
  - Credentialing Documents for Pathology Lab listed in FDA 1572

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Ongoing Requirements

- Copies of the following documented approval of the IRB must be sent to UTSW Radiation Oncology Clinical Research Office as soon as possible after approval:
  - Protocol Amendments
  - Informed consent forms
  - Continuing review of trial
  - Any other written information to be provided to subject
  - Advertisement for subject recruitment (if any)
  - Any other documentation given approval

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Ongoing Requirements

- The following documents must be updated in an ongoing basis:
  - Curriculum Vitae (every 2 years)
  - Licenses (by expiration date)
  - FDA 1572 (per changes in Investigators)
  - Signature/Delegation Log (per changes in study team)

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Protocol Amendments

- Protocol Amendments will be distributed through email broadcast.
- Sites should submit the IRB Approval of the Amendment **within 90 days of the broadcast date.**

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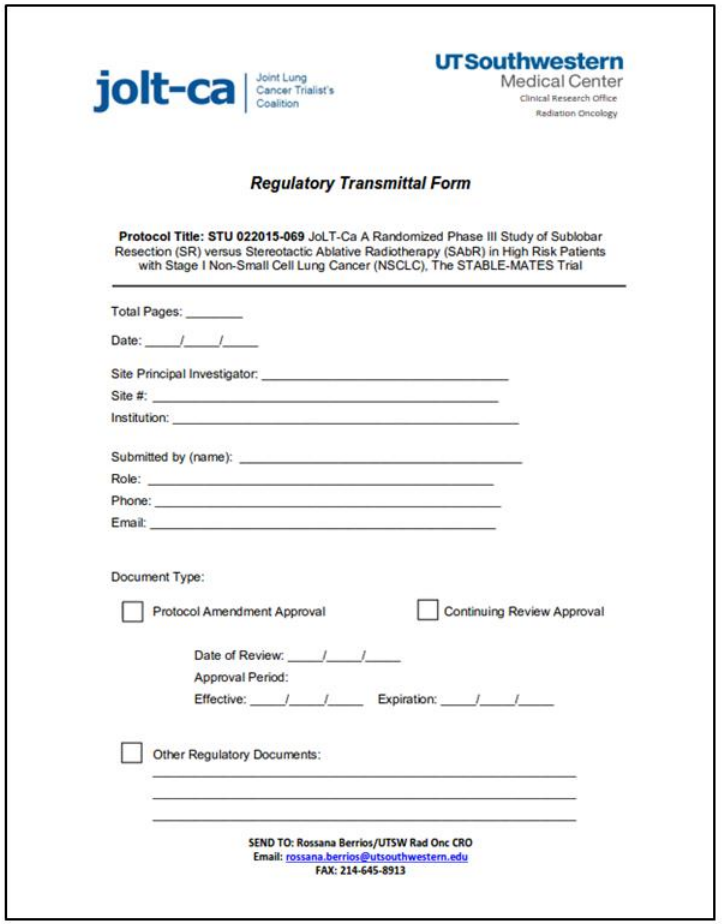
Submitting Documentation

- Submit all regulatory documentation using the form provided.
- A copy is available for download in the study website: www.joltca.org



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UT Southwestern Medical Center
Clinical Research Office
Radiation Oncology

Regulatory Transmittal Form

Protocol Title: STU 022015-069 JoLT-Ca A Randomized Phase III Study of Sublobar Resection (SR) versus Stereotactic Ablative Radiotherapy (SAbR) in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC), The STABLE-MATES Trial

Total Pages: _____

Date: ____/____/____

Site Principal Investigator: _____
Site #: _____
Institution: _____

Submitted by (name): _____
Role: _____
Phone: _____
Email: _____

Document Type:

☐ Protocol Amendment Approval ☐ Continuing Review Approval

Date of Review: ____/____/____
Approval Period:
Effective: ____/____/____ Expiration: ____/____/____

☐ Other Regulatory Documents:
_____
_____
_____

SEND TO: Rossana Berrios/UTSW Rad Onc CRO
Email: rossana.berrios@utsouthwestern.edu
FAX: 214-645-8913

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DATA SUBMISSION

REDCap

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REDCap

- **R**esearch **E**lectronic **D**ata **Cap**ture: support traditional case report form data capture for research studies
- Secure web application for building and managing online surveys and data entry forms
- Multi-site access
- Calculated fields, branching/skip logic, file uploading
- Export data to common data analysis packages (SPSS, SAS, Ror STATA)

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Requirements for Data and Source Documentation Submission

- Enrolling Patients
  - Data will be submitted in real time when patient is enrolled.
  - Source Documentation to confirm eligibility criteria must be uploaded **within 24 hrs of patient enrollment**.

- Study Visits
  - Data Submission must be completed **within 2 weeks of study visit completion.**
  - It is highly recommended to upload Source Documentation **within 2 weeks of study visit completion**.

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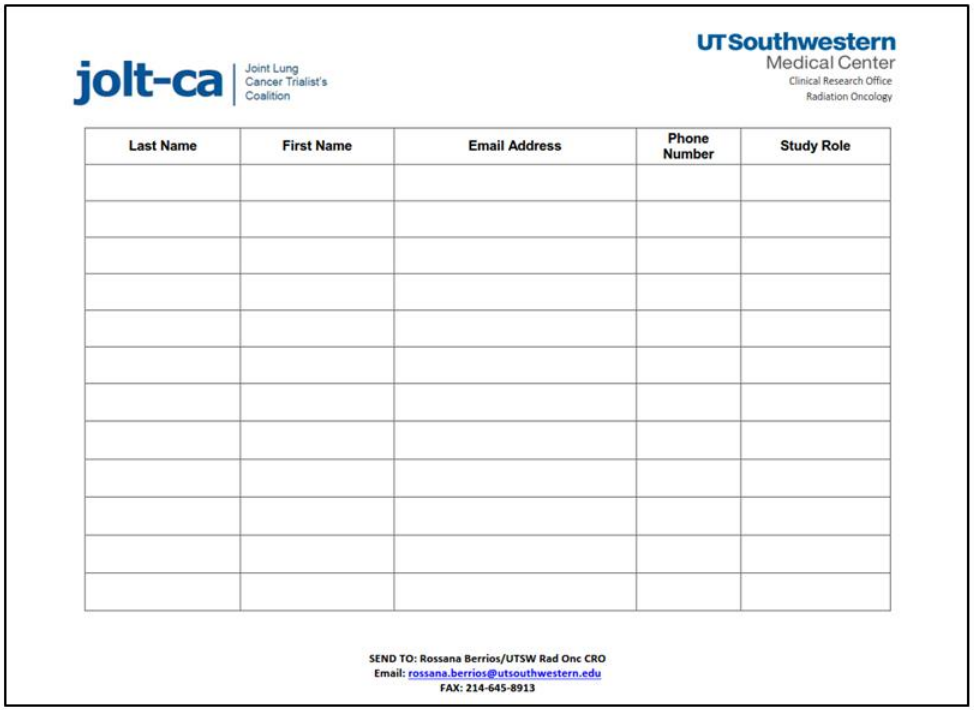
Requesting Access

- Submit the REDCap Access Form to request additional accounts.
- A copy is available for download in the study website: www.joltca.org



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UT Southwestern Medical Center
Clinical Research Office
Radiation Oncology

Last Name	First Name	Email Address	Phone Number	Study Role

SEND TO: Rossana Berrios/UTSW Rad Onc CRO
Email: rossana.berrios@utsouthwestern.edu
FAX: 214-645-8913

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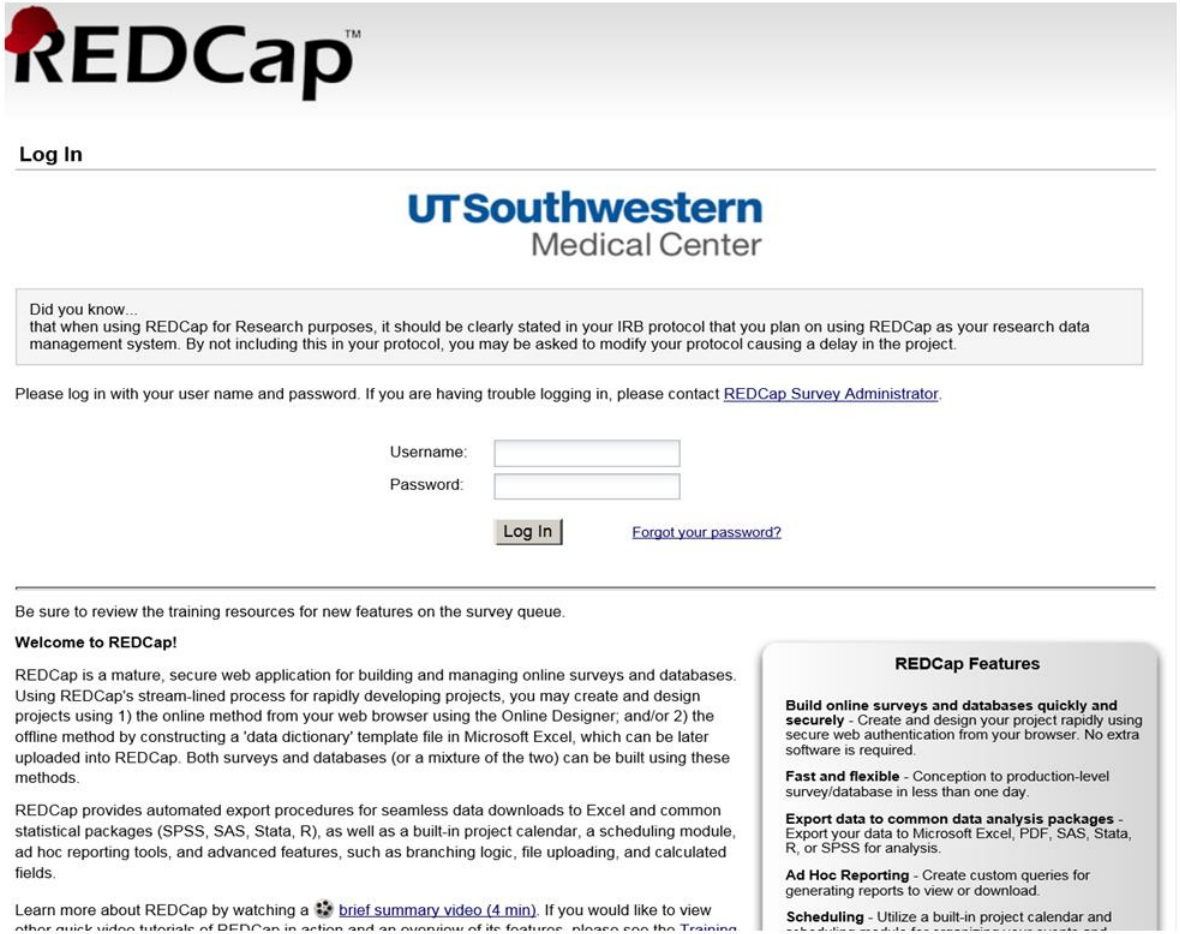
Logging into REDCap

- Open a browser and enter the following URL in the address line: https://ais.swmed.edu/redcap/.
- Enter your username and password provided to you when you were given access to REDCap.



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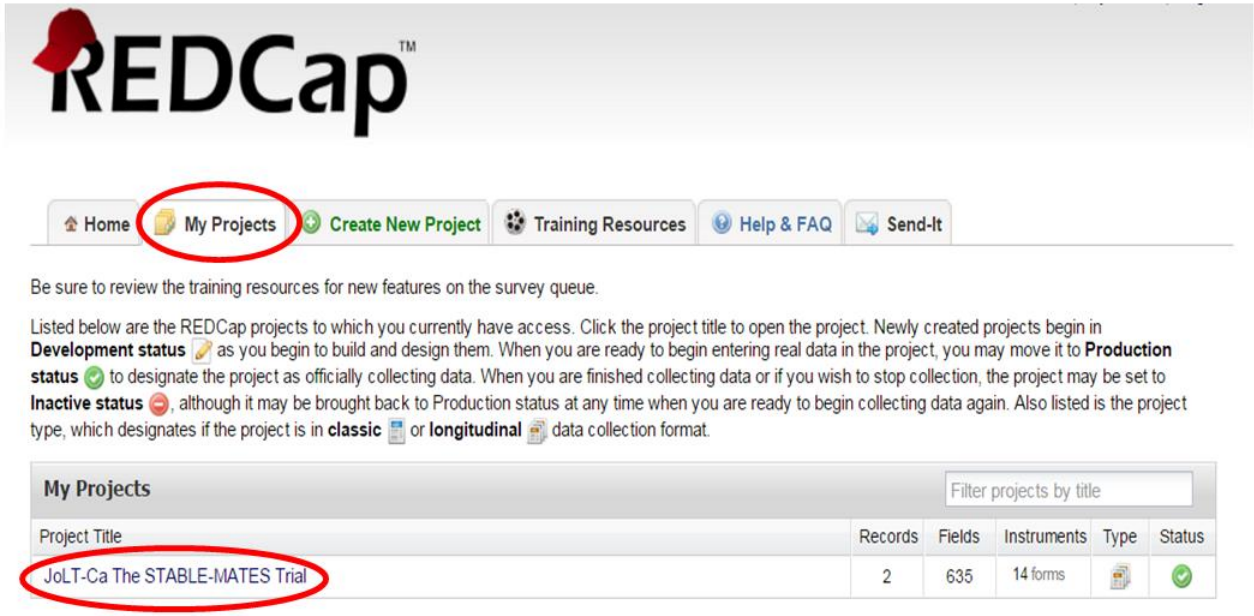
Accessing JoLT-Ca Project

- From the REDCap Home Screen select the **[My Projects]** tab to see a list of projects you are authorized to access. Click on the link to the **[JoLT-Ca The Stablemates Trial]** database.



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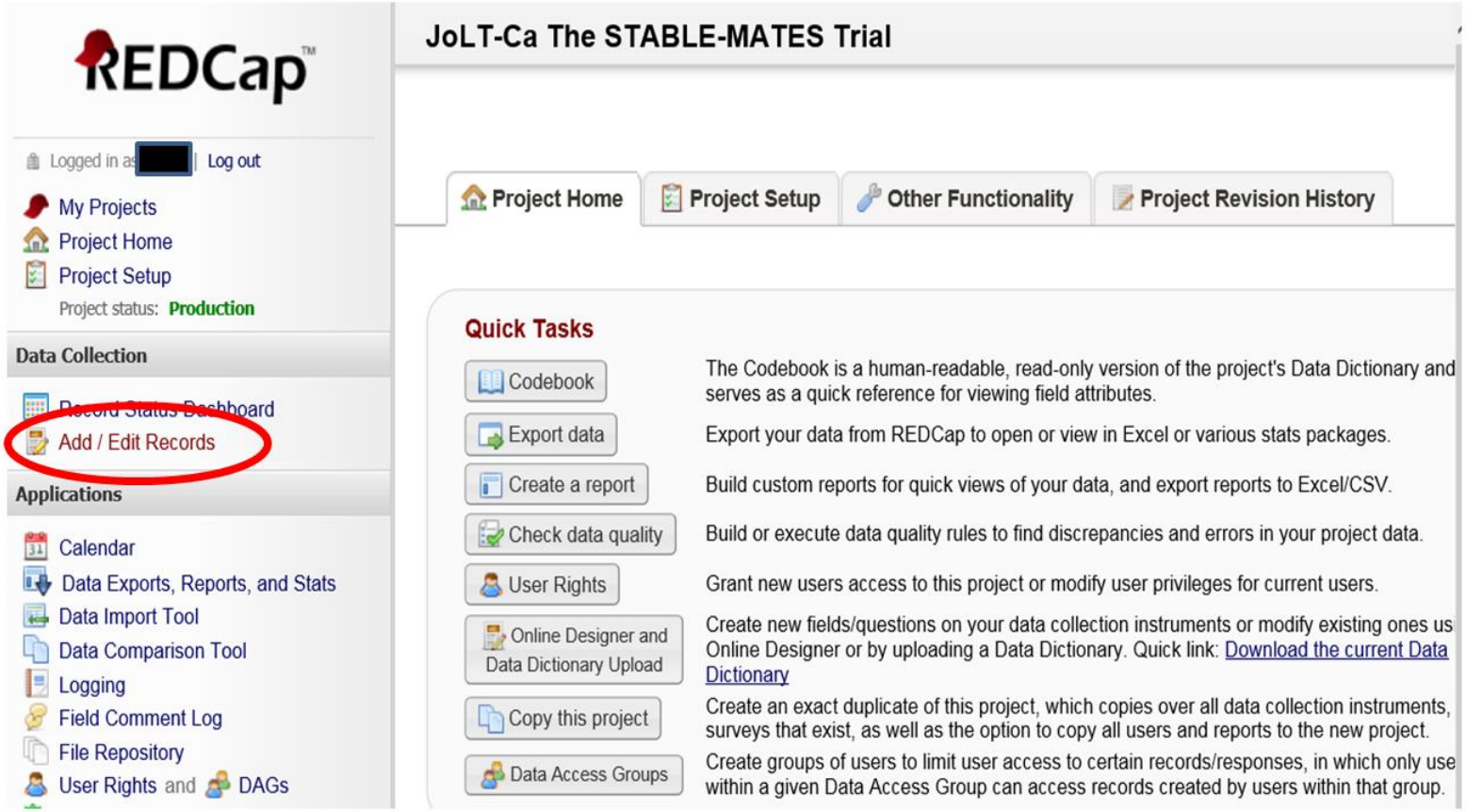
Accessing Patient Database

- Select **[Add/Edit Records],** to be able to enroll a new patient or access an existing patient database.



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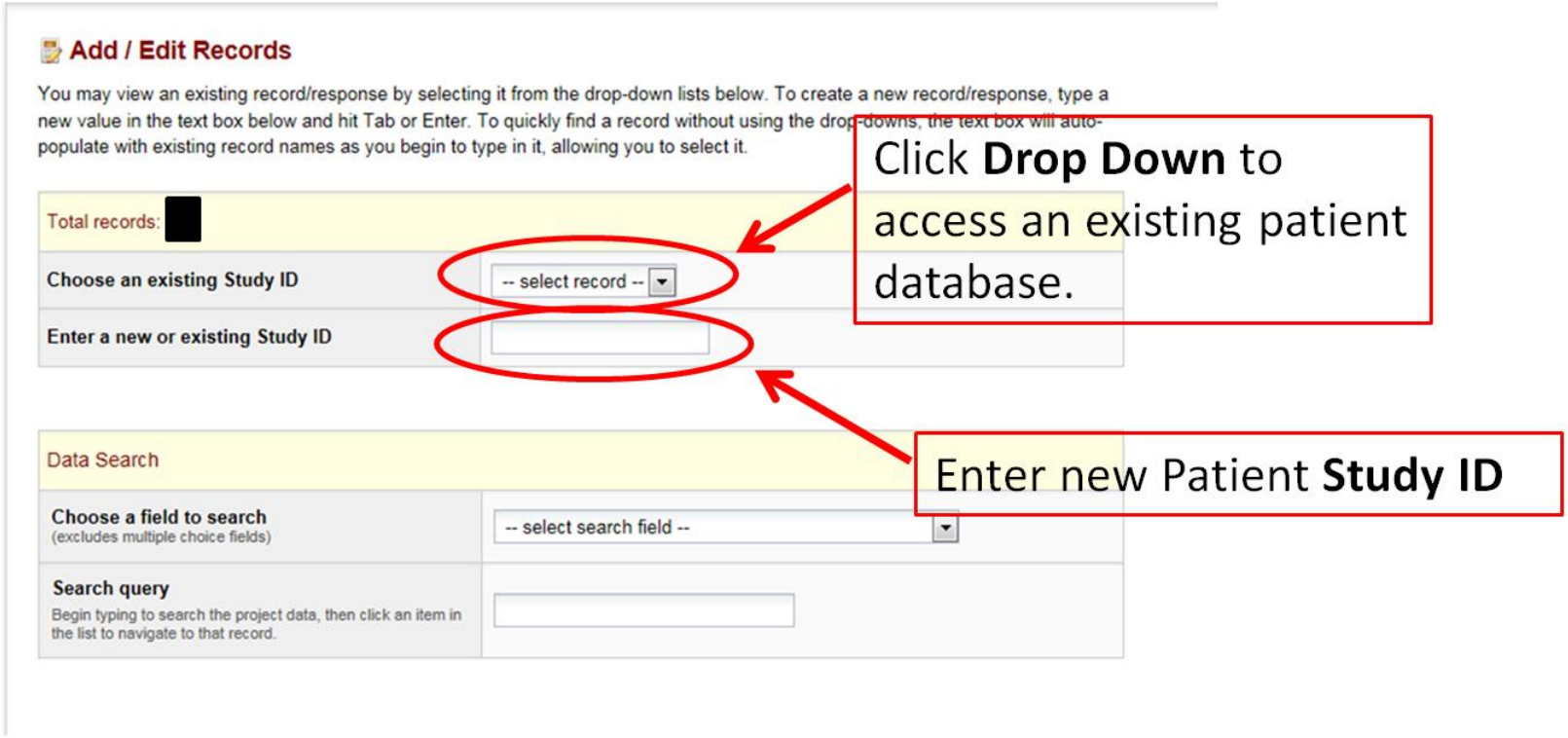
Accessing Patient Database



Unique identifier consists of Site #, followed by subsequent double digit numbers

For example Site #20 will use the following unique identifiers – Patient #2001, 2002, 2003, etc.

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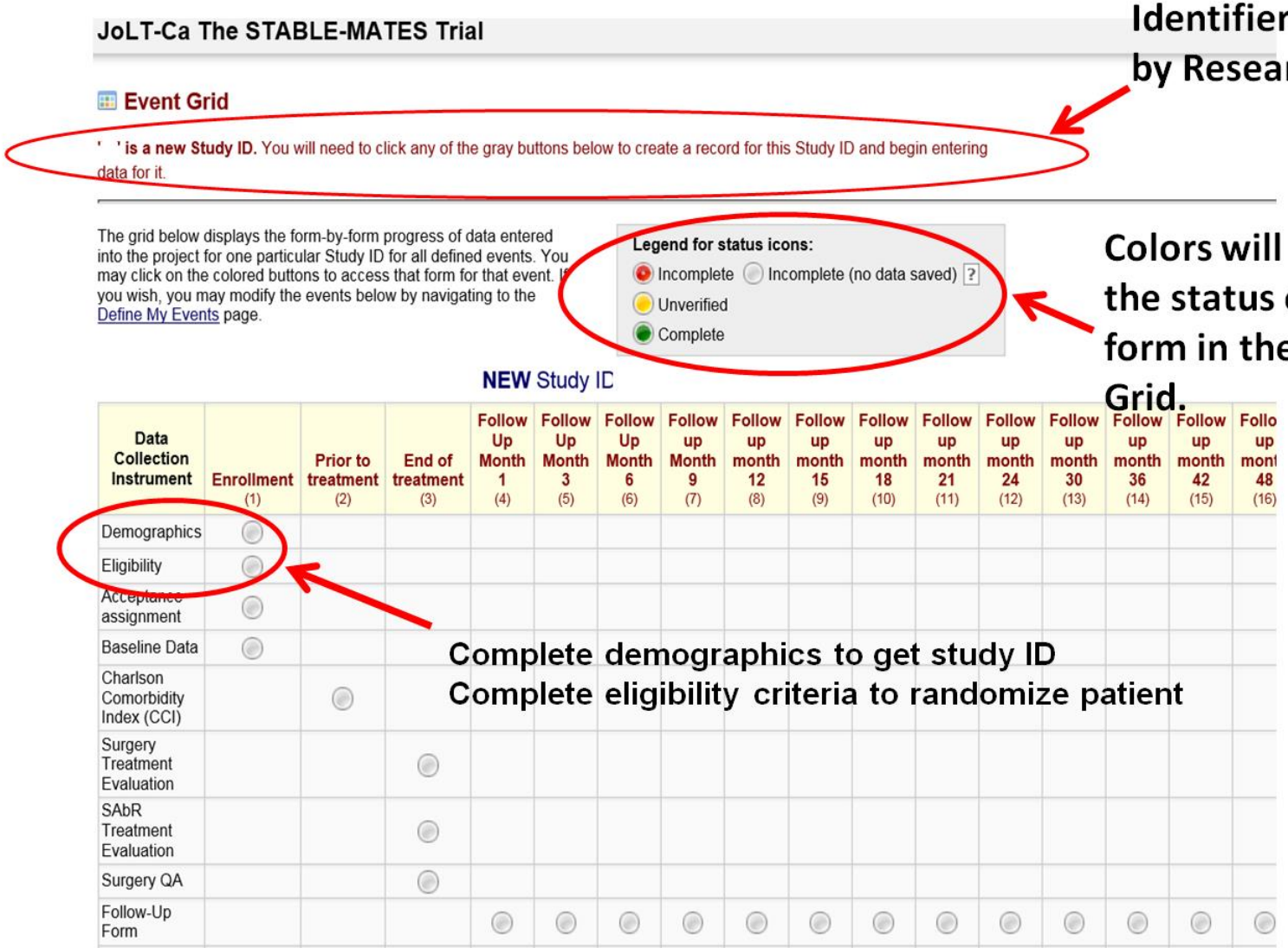
Event Grid

- Provides a summary of the patient's forms.



Study ID – Unique Identifier assigned by Research Team

Colors will indicate the status of each form in the Event Grid.

Complete demographics to get study ID
Complete eligibility criteria to randomize patient

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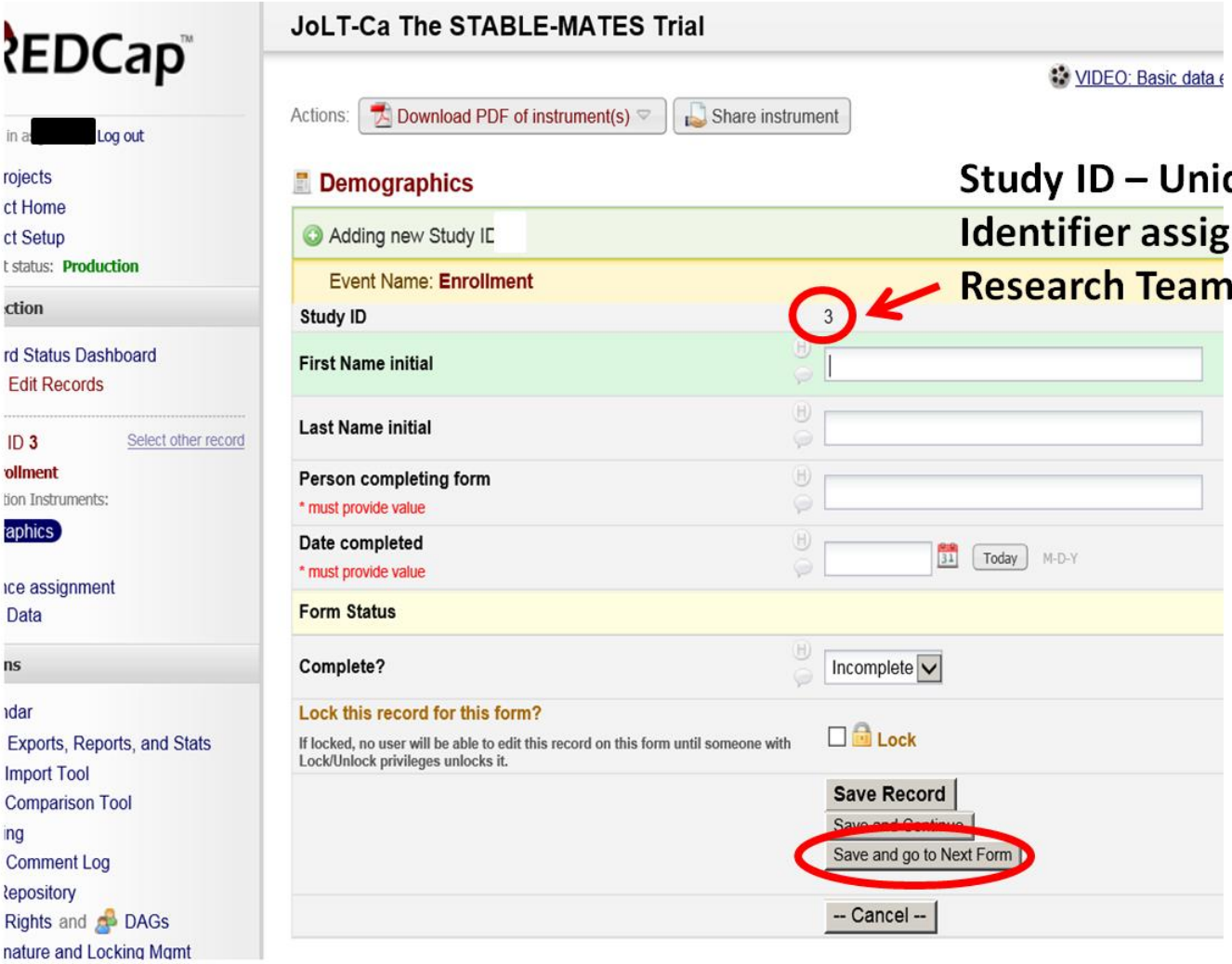
Demographics Form



Study ID – Unique Identifier assigned by Research Team

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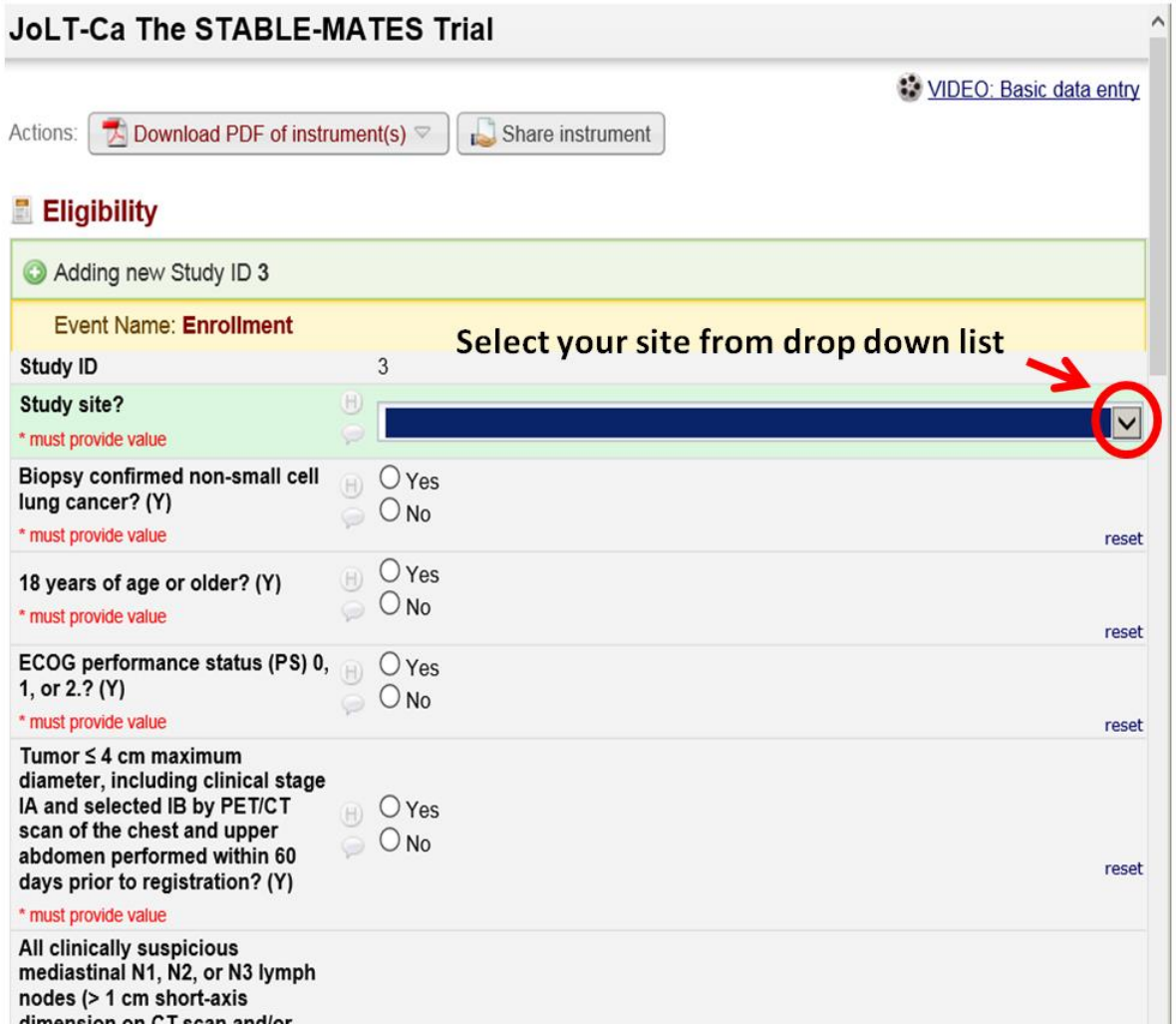
Eligibility Form

- Click **Drop down** to select your site and complete all eligibility information.
- **Gender** and **Date of Birth** are necessary to be able to randomize the patient.



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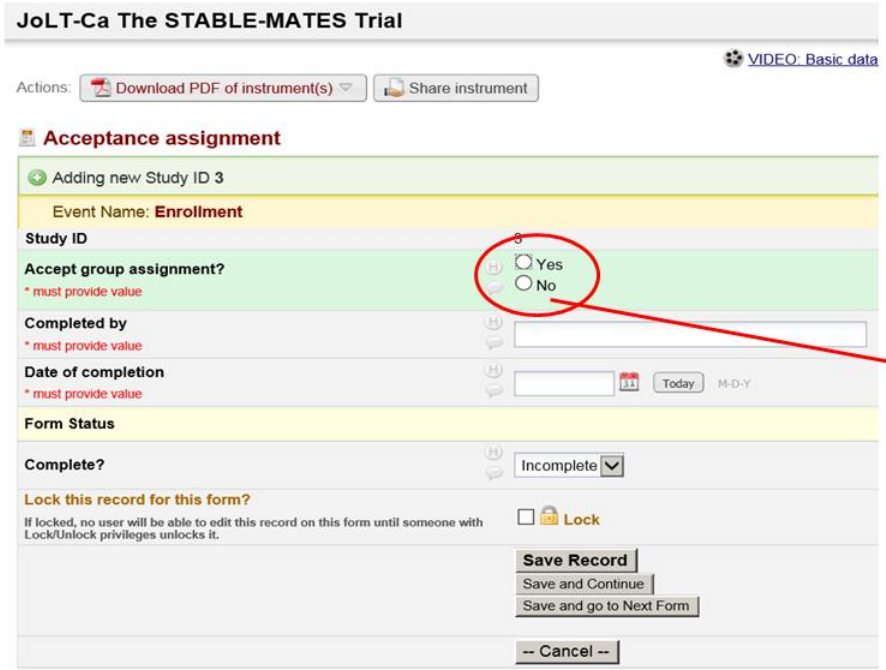
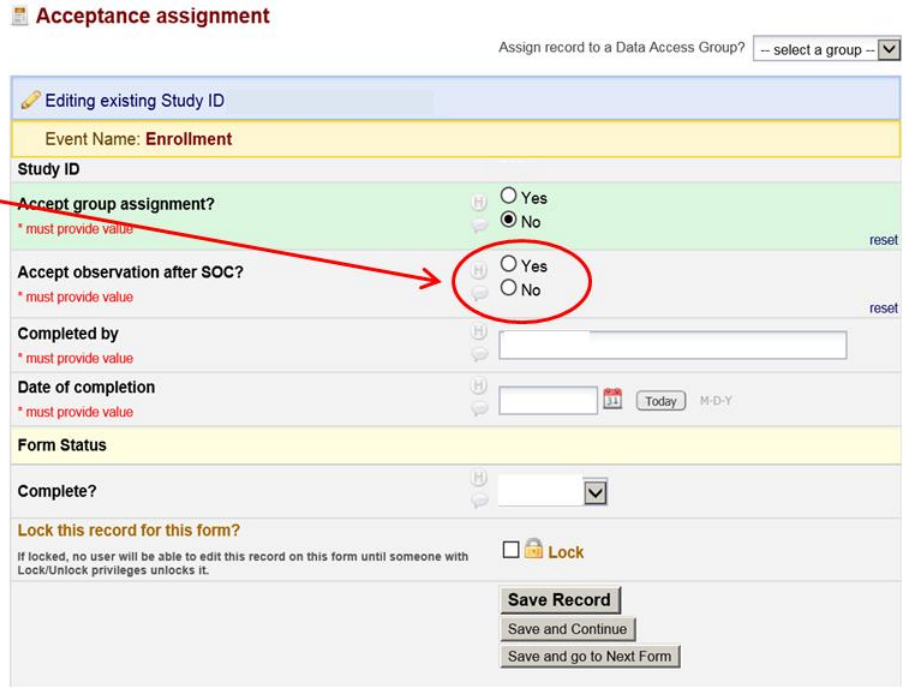
Acceptance Assignment Form

In the **Accept Assignment Form** you will be able to document if the patient accepted or rejected the pre-randomization assignment.



If the patient rejects the assignment you will be able to select if the patient agrees or rejects follow up after standard of care treatment.



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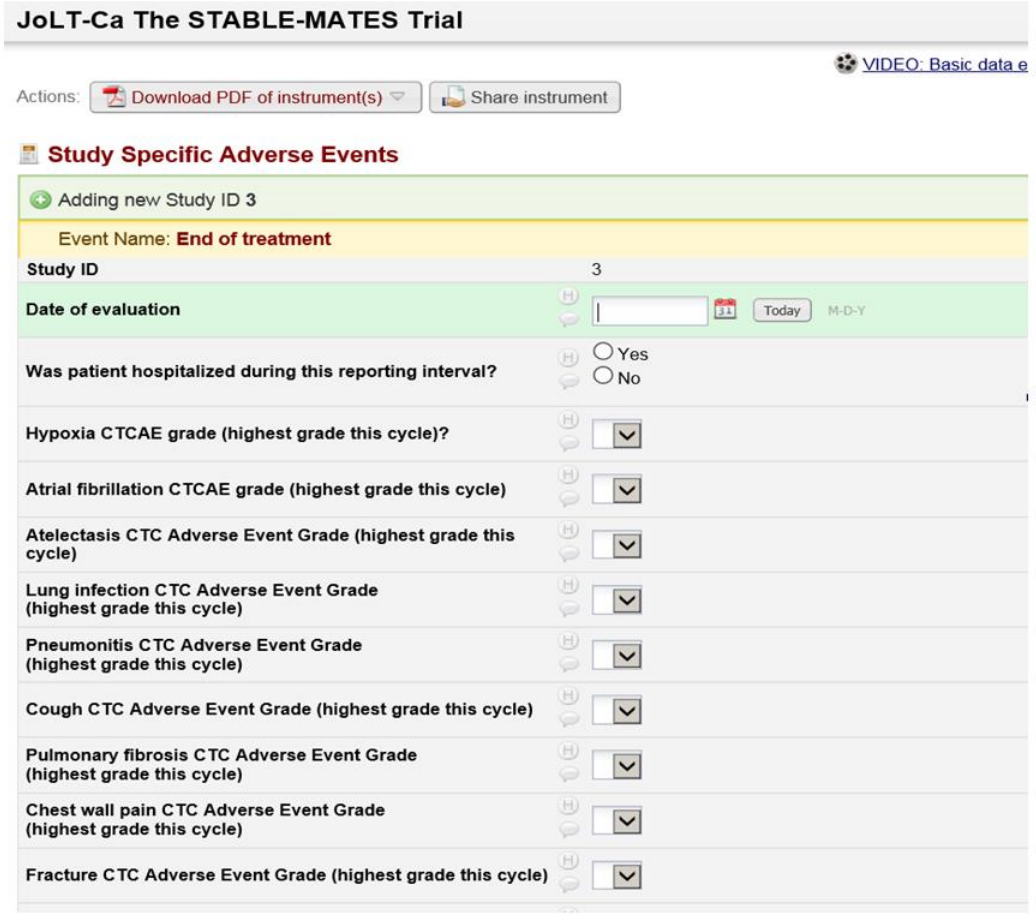
Study Specific Adverse Events Form

- Report **all Adverse Events** using the Study Specific Adverse Events Form **within 2 weeks of visit completion**.
- **Serious Adverse Events** data must be submitted **within 48 hours.**



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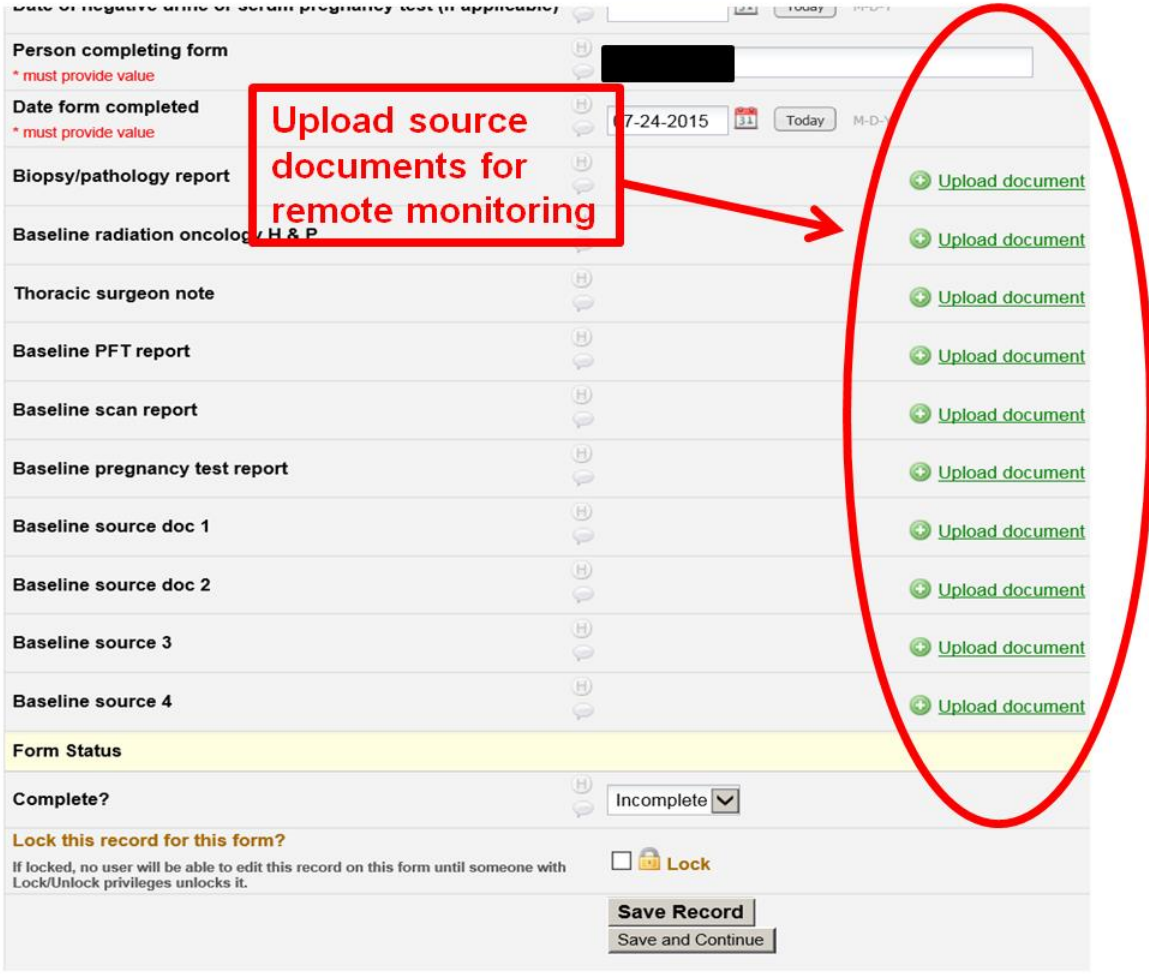
Uploading Source Documentation

- Source documentation will need to be uploaded under each study visit.
- **Data submission is required within 2 weeks of study visit completion**.
- It is **highly recommended** to also upload **Source Documentation within 2 weeks of visit completion**.



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CRO MONITORING

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Monitoring

- Data and source documentation will be reviewed **at least annually** via REDCap
- **At least 5 charts** will be reviewed for each monitoring visit
- **Notification** of the monitoring visit will be given **at least 2 weeks** prior to scheduled visit.
- A follow up report will be provided to the site within 2 weeks of the visit. **Responses are due within 2 weeks** of receipt of the monitoring report.
- For-cause on-site audit visits will be scheduled as necessary based on the following:
  - High or low data entry rate through REDCap
  - Study non-compliance
  - Number of outstanding findings from previous monitoring visits

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DATA SAFETY MONITORING PLAN

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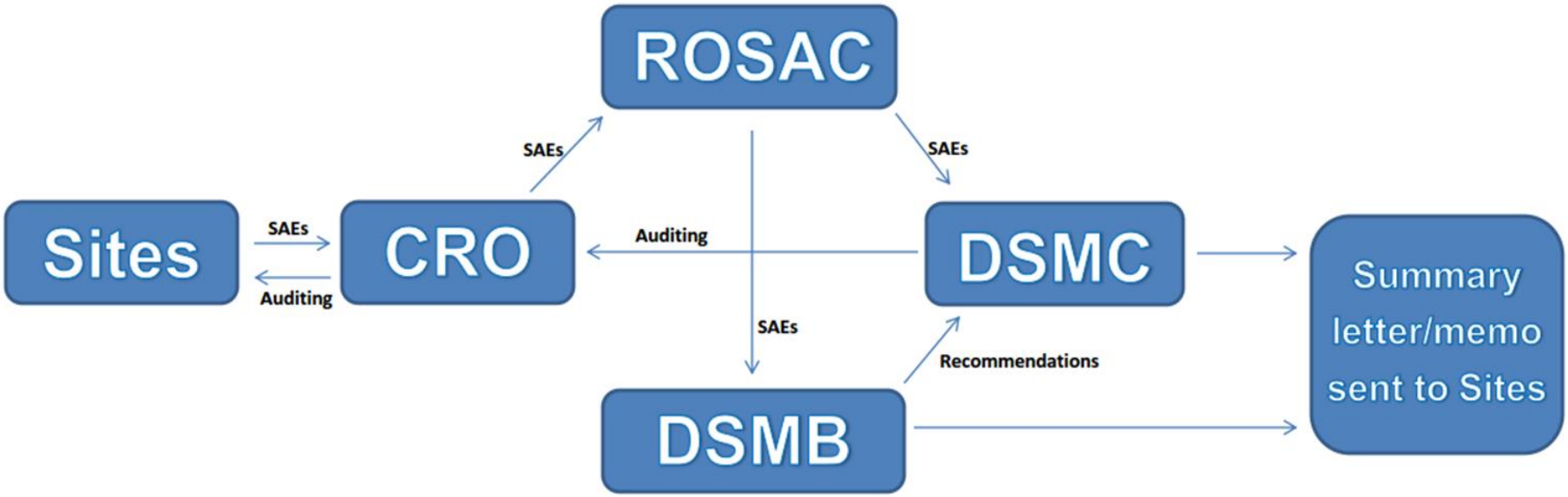
Summary



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Radiation Oncology Safety Assurance Committee (ROSAC)

- Internal UTSW Radiation Oncology Department Committee.
- Meets monthly.
- Reviews all SAEs to assign attributions and enrollment.
- All SAEs reviewed are reported to DSMC and DSMB.
- No summary (letter/memo) is produced.

Radiation Oncology Clinical Research Office (Rad Onc CRO)

- The principal investigator and the study coordinator will review SAEs on a real time basis.
- All SAEs are reported to ROSAC.
- CRO will perform audits on enrolling subsites; frequency will be based on enrollment and previous audit scores, with a minimum of once a year.
- Audits will be performed electronically.

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External Data Safety Monitoring Board (DSMB)

- Independent multidisciplinary group consisting of three clinicians and one biostatistician, who, collectively, have experience in the management of patients with lung cancer and in the conduct and monitoring of randomized clinical trials.
- Meets when needed to review summaries of adverse events and attributions, QA and compliance reports, etc. (no report is produced)
- Determines any safety issues or toxicity trends, which may suggest risk to the subjects currently enrolled in the study or to future subjects.
- Provides recommendations to modify or terminate the trial if, following review of the data, there are safety concerns.
- Will review accrual, randomization, and consenting data to compare to the trial's design to make recommendations about the trial's performance;
- Will review interim-analysis reports of trial endpoints.
- Has authority to suspend enrollment for futility; however they will not be able to reverse decisions from the DSMC of record.
- A summary (letter/memo) of the outcome of the DSMB meeting will be provided by JOLT-CA. A copy may be requested from the CRO.

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Internal Data Safety Monitoring Committee (DSMC)

- DSMC of record. Has authority to suspend enrollment.
- Established Data Safety Monitoring Committee of the Simmons Cancer Center at University of Texas Southwestern (UTSW) in Dallas, Texas.
- Meets monthly to review SAEs and AEs for incidence, expectedness, attribution to therapy, and in relation to stopping criteria. No summary (letter/memo) is produced.
- Audits trial at the UTSW Radiation Oncology Clinical Research Office (CRO) once a year, review will include CRO audit reports from subsites and interim-analysis reports of trial endpoints.
- DSMC will perform an annual comprehensive review of the study. A summary (letter/memo) will be produced by the DSMC. A copy may be requested from the CRO.

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STUDY PAYMENT

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Study Payment

- An **Invoice** is always **required**
- Always include:
  - Study ID
  - Patient Initials
  - Registration Date

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QUESTIONS?

If necessary, follow up Q&A sessions will be scheduled to address any questions that may arise.

Please forward any questions to the CRO Team.

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CRO Contact List

Name	Role	Phone	Email
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