You have a Study Ready to open, Now What?

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CRP Committee Education Session

Alliance Group Meeting, May 13, 2016

Presentation Objectives

- Understand the Process of Preparing a Study for Accrual
- Develop Logistic Checklists for Your Individual Institution
- Documentation Examples to make your life easier

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Background and Education

- BSN Nursing 1974 University of Pittsburgh
- 16 years in Clinical Research (Thoracic Surgery)
- 12 years combined with ACOSOG and Alliance
- Member of the Clinical Research Professionals Committee
- Surgical Liaison, Oncology Nursing Committee

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Where do I Start?

- The IRB Approval has been Received
- Staff Implementation Meetings are Completed
- But if you have not planned ahead and put a process in place, this may be in your future…

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Warning!

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The time to start planning is before the study is opened.

- Review the protocol for study specifics
- Prepare a logistics checklist
- Review protocol required documentation
- Check CTSU website for any CRF's required by the study.

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But Why?

- “First Patient-itis” is bad enough…why make it more difficult
- Makes the next patient process easier
- Another coordinator can step in with easy to follow instructions.
- No need to “re-invent the wheel” each time

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Logistics Checklist

14-166 ALCHEMIST Screening Study
Logistics Checklist for Preoperatively Consented Patients

Patient Name _____ **Initials** _____ **ID#** _____

Pre-registration eligibility criteria:

_____ Biopsy proven non-squamous NSCLC, including adenosquamous and poorly differentiated carcinoma, favor adeno **OR** suspected non-squamous NSCLC, including adenosquamous and poorly differentiated carcinoma, favor adenocarcinoma.
_____ Clinical IB (≥ 4 cm), II, or IIIA NSCLC
_____ ECOG Performance Status 0-1
_____ ≥18 years of age
_____ No neoadjuvant chemo or RT for this lung cancer
_____ No prior or concurrent malignancies within 5 years, except non-melanoma skin cancer or in situ carcinomas. A secondary primary lung cancer is considered a concurrent malignancy and would make the patient ineligible.
_____ No prior treatment w/agents targeting EGFR mutation or ALK rearrangement
_____ Females of childbearing potential must not be pregnant or nursing
_____ Patients who have had local genotyping are eligible, regardless of the local result.

When presenting the study to the patient:

The purpose of the study is to identify patients with EGFR and ALK mutations. The patient can be told that there are treatment studies available if they test positive for mutations, but they are not required to take part in those studies. There is no need to go into detail about the treatment studies. If patients are eligible, the medical oncologist will present the appropriate study to the patient.

_____ **Consented pt w/ histologically confirmed adenocarcinoma and tumor ≥ 2 cm**

_____ Enter patient as screening in CTMA
_____ Pre-register patient in OPEN on CTSU website. Print the confirmation of pre-registration for the chart; enter ID number into CTMA
_____ Enter the patient into Rave – complete/enter page 3 of CRF packet
_____ Refer to Blood Specimen worksheet for further instructions

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Logististics Checklist

_____ **Consented patients w/ suspected adenocarcinoma**

- _____ Enter patient as screening in CTMA. If patients meets the eligibility requirements on final path, the blood can be obtained at the postoperative visit

For Pre-registered patients, after surgical resection, when pathology report has returned:

_____ Patient meets the registration eligibility criteria:

- _____ Completely resected non-squamous NSCLC (including adenosquamous and poorly differentiated NSCLC, as long as squamous is not favored)
- _____ Pathologic Stage IIIA, II, or IB≥ 4 cm
- _____ Adequate FFPE tissue available for central EGFR and ALK genotyping. (Tumor must be ≥ 2 cm in diameter)

_____ If the above are met, order slides from pathology. (See pathology request instructions).

- _____ Register patient in OPEN. Print the confirmation of registration for the chart. Update patient's status in CTMA.
- _____ Update patient in RAVE – complete/enter page 4 of CRF packet
- _____ Submit slides (per Tissue submission Checklist) as soon as they are ready.

For consented patients w/ suspected adenocarcinoma. When final pathology has returned:

_____ Patient meets the registration eligibility criteria:

- _____ Completely resected non-squamous NSCLC (including adenosquamous and poorly differentiated NSCLC, as long as squamous is not favored)
- _____ Pathologic Stage IIIA, II, or IB≥ 4 cm
- _____ Adequate FFPE tissue available for central EGFR and ALK genotyping. (Tumor must be ≥ 2 cm in diameter)

_____ If the above are met, order slides from pathology. (See pathology request instructions).

- _____ Pre-register patient in OPEN. Print the confirmation for the chart; enter ID number into CTMA
- _____ Enter patient into RAVE – complete/enter page 3 in CRF packet
- ____ Register patient in OPEN
- _____ Update patient in RAVE – complete/enter page 4 in CRF packet
- _____ Submit slides (per Tissue submission Checklist) as soon as they are ready.
- _____ Obtain blood at patient's post-op visit. Enter order into EPIC prior to clinic visit. (See blood submission instructions)

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Add checklists as needed

- Pre vs Post operative consent
- Tissue Sample/Blood Draw checklists
- Radiology

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Study Required Documentation

- Study Specific Documents for Eligibility Criteria, Adverse Events, Study Visits
- Forms can be completed by hand or on the computer
- Signatures of Coordinator and Physician

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Supporting Documentation

Patient Name: **Study ID#** **Treating Physician:**
Study Number: 07-150 CALGB 140503 **Principal Investigator:** Matthew Schuchert, MD

Visit: ☐ 6 month ☐ 12 month ☐ 18 month ☐ 24 month ☐ 3 year ☐ 4 year ☐ 5 year ☐ 6 year

☐ 7 year ☐ Interim_____

Visit Date: ☐ Out of protocol window (see note)

Radiologic Studies: Date: ☐ Chest CT through adrenals ☐ PET/CT ☐ Out of window (see note)

Results: ☐ No Evidence of Disease ☐ Possible Recurrence

Site of Recurrence: ☐ Local ☐ Regional ☐ Distant ☐ See note

Pulmonary Function Testing (Due at 6 month only) Date: ☐ Out of window (see note)

Physical Exam ☐ ECOG Performance Status: ☐ See note

Vital Sign: Temp: Pulse: Blood Pressure: Weight:

Surgery indicated for recurrent disease: ☐ N/A ☐ Yes ☐ See note

Chemotherapy since last visit for this lung cancer? ☐ Yes ☐ No ☐ See Note

Where was treatment received? _____ Start of treatment date _____

Chemotherapy agents _____

Radiation Therapy since last visit for this lung cancer? ☐ Yes ☐ No ☐ See Note

Where was treatment received? _____ Start of Treatment date _____

New Primary Cancer diagnosed since last visit? ☐ Yes ☐ No ☐ See Note

Site of new primary _____ Where was diagnosis made? _____

RN/CRA Signature _____ Date _____

Physician Signature_____ Date _____

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Supporting Documentation

Patient Name: **Study ID#**

Notes:

RN/CRA Signature _____Date_____

Physician Signature_____Date_____

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Consent Packets

- Consent
- Logistics Checklist/s
- CRF Packet
- Eligibility Supporting Documentation

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Summation

- Although it may seem to add extra work, pre-study preparation can be a time saver
- Having checklists for studies you may not be familiar with can prevent eligibility mistakes and future Audit nightmares

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Conclusion

- Questions
- Further questions?

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