Checking Eligibility: Keys To Successful Patient Enrollment

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Objectives

- Checking Eligibility: Keys To Successful New Patient Enrollment
- Identify key steps to follow.
  - Know where to go for required resources.
    - Recognize which documents provide sufficient information to confirm eligibility.
    - Identify how to avoid common pitfalls.

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Begin at the Beginning:

- Standardize the Process

An Example:

Many Small Steps
Standardization decreases errors and increases efficiency

MUST Complete Prior to Randomization on:

_____

Complete	Document needed	Request Date	Requested from:	Requested By:
	MD signature on Registration worksheet			
	MD Signature on Eligibility from protocol			
	SWOG Studies – good medical practice			
	Patient in CREDIT			
	Correct Protocol Version			
	Complete Consent/HIPPA			
	Current Consent			
	Check Credit for special notes/regs			
	Check drug section			
	Documentation of Consent review			
	Reg. Sheet/Eligibility Checklist complete			
	Check time to initiate treatment			
	Review Strat Factors with MD			
	Check consent ?'s against reg. worksheet			
	Check for credentialing requirements			

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Resources: Know Where to Go

- Use current version of the protocol
  - ALWAYS go to ALLIANCE or CTSU (printing/filing leads to errors)
    - Eligibility section 3
    - Strat Factors section 4
    - Registration section 4
    - Pre-registration assessments section 5
    - Open Enrollment Form located on ALLIANCE under the protocol page, “Case Report Forms” & CTSU under “Protocols”, type your protocol, LPO documents, Patient Enrollment Documents

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What to Print When Working Up a Patient

- Using the current version of the protocol found on ALLIANCE or CTSU

  - **Print Eligibility** from body of protocol and (highly suggested) print **stratification factors**, as these must be documented
  - **Document/Note sources** for *each* eligibility requirement
  - Print **Test schedule** and **foot notes**. Document the date each item is completed
  - Print the **Open Enrollment Form**
  - Highly recommended to use an internal **"Randomization Checklist"**

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Documentation & Sources

- Confirm Eligibility Criteria, Test Schedule & Stratification Factors found in the protocol
  - For each criteria, document sources
    - Ideally an auditor could view *just the sources you document* and conclude the patient is eligible.
    - Many eligibility points require **multiple sources**, ex: path & labs.
    - Read the entire eligibility point all the way through
    - Avoid a Pitfall: Providing this documentation allows for easy confirmation at audits and for seamless understanding in case of staff turnover

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Example of Source Documentation

3.2 Patients must have histologically or cytologically proven primary non-small cell lung cancer (adenocarcinoma, large cell carcinoma, squamous or unspecified). Disease must be Stage IV, as defined in appendix II. Disease may be either newly diagnosed or recurrent after previous surgery and/or irradiation. Patients with additional lesions in an ipsilateral non-primary lobe without M1a or M1b disease will not be considered to have Stage IV disease and are not eligible.

- 3.2 "Patients must have histologically or cytologically proven primary non-small cell lung cancer (adenocarcinoma, large cell carcinoma, squamous or unspecified)."

Source = pathology/cytology report

- "Disease must be Stage IV, as defined in Appendix II."

Review appendix II, source likely = CT CAP or bone scan, or path from biopsy of a metastatic location

- "Disease may be either newly diagnosed or recurrent after previous surgery and/or irradiation."

Source = MD note with the history of the present illness *and* if recurrent dz then also MD note from initial diagnosis noting the treatment given.

- "Patients with additional lesions in an ipsilateral non-primary lobe without M1a or M1b disease will not be considered to have Stage IV disease and are not eligible."

This likely doesn't require additional sources since you noted the sources for complete staging above.

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An Example for you!

Work in groups to note the sources you would likely use to meet each eligibility point.

- Eligible TNM Stages include:
  - **ER and PR** negative (defined as <1% staining for ER and PR by IHC):
    T2 or T3 N0, T0-3N1-3
  - **ER and/or PR** positive (defined as ≥ 1% staining for ER and/or PR on IHC):
    T0-3N1-3 or T3N0

    The eligibility of neo-adjuvant subjects is assessed on the basis of cTNM. The same eligible TNM combinations apply.
- No history of invasive breast cancer in 5 years prior to study registration other than the current diagnosis (prior DCIS at any time is acceptable).
- Patients must have had a bilateral mammogram within 12 months prior to registration, unless the initial surgery was a total mastectomy, in which case only a mammogram of the remaining breast is required. (Subjects with bilateral total mastectomies do not require imaging).
- Investigations, including chest X-ray or CT chest, bone scan (with radiographs of suspicious areas) and abdominal ultrasound or liver scan or CT abdomen have been performed between the first histologic diagnosis and the time of registration as detailed below.
  - Chest X-Ray, 2 view (or Chest CT, or PET/CT) is required only if clinically indicated or recommended by NCCN guidelines.
  - Bone scans (with x-rays of abnormal areas) are required only if clinically indicated or recommended by NCCN guidelines.
  - Abdominal imaging is required only if clinically indicated or recommended by NCCN guidelines.

3.2.2 Prior Treatment

- All adjuvant or neoadjuvant chemotherapy (at the discretion of the treating physician) and surgery completed at least 21 days prior to registration.

  Concomitant radiation, biologic therapy, hormonal therapy, and bisphosphonates are acceptable.
- Surgical margins must be clear of invasive carcinoma. If there is microscopic residual ductal in situ disease present at lumpectomy or total mastectomy margins, further excision is highly recommended. If further excision is not undertaken, the subject may still be entered on study, provided that in addition to breast or chest wall irradiation, a boost to the tumor bed is delivered. In situ lobular disease at the margin is acceptable.
- All subjects (both adjuvant and neo-adjuvant) must have sentinel lymph node biopsy and/or axillary lymph node dissection.

  Sentinel lymph node biopsy alone is allowed in the following instances:

  a) Sentinel lymph node biopsy is negative: pN0

  b) Sentinel lymph node biopsy is positive for isolated tumor cells only: pN0 (i+)

  c) Clinically node negative, T1-2 tumors with sentinel lymph node biopsy positive in < 2 lymph nodes without matted nodes and undergoing breast conserving surgery and tangential whole breast irradiation, or undergoing mastectomy and chest wall irradiation.

Where Things Get "Tricky"

- The "source document"…
  - MD noting T2N1M0 is good BUT
    - **What is the source for staging**? The information used to draw that conclusion is also needed. Ex: path, EUS, bone scan, etc..
  - Medical History doesn't match Medication List
    - Example: Patient taking synthroid but no history of thyroid abnormality

  Tip: Review PMH and Meds with indication at time of consent

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Detailed Steps

- **Is the protocol currently OPEN at your institution**
  - Studies temporarily close, updates can require IRB review
- **Are there any special requirements for training or credentialing**
  - Check when opening a protocol
- **Gather Protocol Documents:** Go to ALLIANCE website **Directly** to ensure most current version

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Detailed Steps Continued

- Protocol Documents
  - Print **OPEN Enrollment Form**
  - Print **Eligibility**
  - Print **Test Schedule w/Footnotes**
  - Print **Stratification Factors**
  - Review **Registration Procedures/Instructions** – Are there any required sub studies, QOL's, pre-reg steps, how long to initiate treatment, etc.
  - Check how quickly treatment must be **initiated** – this impacts timing for registration
  - Review Drug Section, should you order any drug in advance, how long does it take for delivery
  - Print the consent when you are ready to meet with the patient in case there are amendments that come out

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Standardize the Process!

- Develop a process and stick with it for each new patient.
  - Examples of standards used at our institution
    - **Pre-Study Checklist (see next page for our example),** we highlight all required tests, write required times on the left (ex:<14d) & write dates as they are completed
    - **Review items that can not change *EARLY* in your process**. You can not change medical history or the stage of a patient. REVIEW and CONFIRM these early. Use the staging manual to confirm stage.
    - **Randomization Checklist** – (you have a copy). Used to track when tasks are completed and to note any questions we have. This tool helps in busy environments & in case of absence or at time of audit – you can quickly refer to any questions that were explored. We use bright paper for this.

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Oncology Research Pre-study Checklist

Date:_____
Patient Name:_____
Race:_____
Medical Record #:_____

Protocol Number:_____
D.O.B.:_____/_____/_____
MD:_____
Diagnosis:_____

Allergies

Required Laboratory Tests

- ❑ CBCD_09/01/16 + 14d=09/15/16__
- ❑ CMP_____
- ❑ LDH_____
- ❑ Magnesium_____
- ❑ Uric Acid_____
- ❑ UPC Ratio_____
- ❑ Urinalysis_____
- ❑ PT/INR/PTT_____
- ❑ Fibrinogen_____
- ❑ Pregnancy_____
- ❑ Tumor Marker_____
- ❑ Flow Cytometry_____
- ❑ Immunophenotyping_____
- ❑ Triglycerides/Cholesterol_____
- ❑ Other_____
- ❑ Other_____
- ❑ Other_____

Required Physician Visits

- ❑ MD Onc_09/02/16+14d = 09/16/16_
- ❑ Gynecologist_____
- ❑ Rad Onc_____
- ❑ Surgeon_____
- ❑ Other_____

Required Scans/Exams

- ❑ MRI/CT Brain_____
- ❑ MRI/CT Neck_____
- ❑ MRI/CT Chest_____
- ❑ MRI/CT Abdomen_____
- ❑ MRI/CT Pelvis_____
- ❑ Chest X-Ray_____
- ❑ Bonescan_____
- ❑ Mammogram_____
- ❑ MUGA/Echo_____
- ❑ EKG_____
- ❑ Colonoscopy/BE_____
- ❑ Endoscopy_____
- ❑ Other_____
- ❑ Other_____

Required Study Items

- ❑ Pathology submission_____
- ❑ Study Kit before Reg/Rando_____
- ❑ Study Kit after Reg/Rando_____
- ❑ Quality of Life_____
- ❑ Chemo Scheduled_____
- ❑ Provided Drug_____
- ❑ Pharmacy Contacted_____
- ❑ Other_____

Vital Signs:
PS: 0 1 2 3 4
Ht:_____in
_____cm
Wt:_____lb
_____kg
BSA:_____m^2
BP:____/____
P/R:____/___
Temp:_____
Date_____
Sign:_____

Medications/Indication Other Notes

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Stage Your Patient

- On your own, stage your patient. Use the stage derived by others as a confirmation.

- Review all imaging for questionable areas that need follow-up. These must be addressed either by comments from the MD or by additional imaging. Be sure all areas of disease are evaluated *sounds basic but things get missed*.

- If there was only one small area of disease and it was biopsied, imaging post biopsy may be necessary to evaluate the post biopsy size for baseline tumor measurements.

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Stage Your Patient Continued

- What is needed to stage varies based on primary location of the tumor. Some examples:
  - Breast Patients, use the pre-op physical to note inflammatory or not, mobile or fixed nodes, etc..
  - Breast Patients, read carefully through the sentinel node procedure – was it successfully performed, did they find hot/blue nodes?
  - Lung, what levels of nodes were sampled? Did the operative note mention areas examined but where no nodes were present?
  - Colon/rectal, distance above the anal verge on colonoscopy, obstruction, en bloc resection, adhesions, were there multiple areas of involvement and if so did the pathologist consider these separate primaries?
  - Do all path reports show the same histology? Do you have the most recent FISH/IHC/Hormone testing results – be sure to view original reports.

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Wrapping Up

- Review things that **can not change** *early* in the process
- **Standardize** your process
- **Don't store** documents.
- **Discuss** any abnormalities with the MD and **document** what the conclusion is.
- **Document sources** for each eligibility point as you are going through the work-up.
- Review **strat factors** with the MD and document these.
- **Good practice**, have the MD sign and date eligibility from the protocol, registration worksheet and strat factors.

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Recent Discoveries:

1. **Incomplete Staging** (more tests needed to be ordered to determine T stage in EG pt, and N stage in breast pt
2. **Missing** Test Schedule Items
3. Surgical **procedure incomplete** (ex: lung nodes not sufficiently sampled or documented, Sentinel Node procedure failed so random nodes sampled (SN biopsy required), multiple areas on colonoscopy identified but only one resected, en bloc resection not performed but required for protocol)
4. Pt found to have **underlying disease** based on required tests from protocol (diabetes, bradycardia)
5. Pre-study **physical** excluded breast but pt had breast cancer
6. **Underlying condition** in conflict with treatment (ankle needing surgery but tx would had to have been delayed longer than the protocol allowed in the time to initiate treatment)
7. Self reported history **conflicted** w/underlying conditions which outside medical record documented or for which they are currently taking medication (ex: taking HTN meds but report no history of HTN and protocol excludes HTN)
8. Pts understanding of potential **time to initiate treatment**. Pt declined study when additional tests needed to be ordered
9. Pt had active infection which they were receiving treatment for by **primary care MD** so they didn't mention to Med Onc – however meds showed underlying problem & excluded from entry at that time.

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QUESTIONS?????

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