Clinical Trial Coordinator Presentation

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CLINICAL TRIALS ENROLLMENT:
Practical Tips to help you meet or exceed the standard!

STANDARD 1.9 Clinical Trial Accrual

“As appropriate to the cancer program category, the required percentage of patients is accrued to cancer-related clinical trials each year. The clinical trial coordinator or representative reports clinical trial participation to the cancer committee each year.”
<table>
<thead>
<tr>
<th>Category</th>
<th>Minimum Required Percentage* Accrual to Clinical Trials</th>
<th>Commendation Percentage* Accrual to Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated Network Cancer Program</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>NCI-designated Comprehensive Cancer Center Program</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td>Academic Comprehensive Cancer Program</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Veterans Affairs Cancer Program</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Comprehensive Community Cancer Program</td>
<td>4</td>
<td>6</td>
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<td>Community Cancer Program</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Hospital Associate Cancer Program</td>
<td>Exempt</td>
<td>2</td>
</tr>
<tr>
<td>Pediatric Cancer Program</td>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>Freestanding Cancer Program</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

**IT’S A BALANCING ACT!**

- Know your enrollment goals!
- Calculate your projected numbers EARLY!
- Review your open studies/timelines
- Know your top cancer sites
- Know your physician needs/preferences
BALANCING

**EXPENSES**
- Federally funded
- Limited resources
- Hefty time commitments

**REVENUE**
- Pharmaceutical
- Nominal resources
- Minimal time requirements

STANDARD 1.9

Programs with research involving human subjects must be:
- Approved by an IRB
- Written informed consent is obtained
- Program accrues patients to cancer related clinical research at least the minimum percentage based on the category and number of analytic accessions.

Patients eligible to meet the standard are seen at the program for:
- Diagnosis and/or treatment and placed in a trial through program
- Diagnosis and/or treatment and placed in a trial through staff physician office
- Diagnosis and/or treatment and placed in a trial through another program (referral)
- Any reason and placed in a cancer prevention or cancer control clinical trial

These include:

Quality of Life related to cancer (supportive care trials)

Economics of care related to cancer
**PLANNING**

**TOP CANCER SITES**
- Lung (185)
- Breast (150)
- Colon (80)

**850 ANALYTICAL CASES/YR**
- Minimum 4% (*34pts/year)
- Commendation 6% (*51pts/year)

**CURRENT OPEN TRIALS**
- Treatment patients
- Lung: 63325 patients
- EMR: 34 pts
- Colon: 16034 patients
- MM: 3 patients

- Observational patients
- PROMIS: 8 patients
- S1007: 5 patients

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**UTILIZE AVAILABLE RESOURCES**
- CTSU (Treatment/Prevention/Non-Therapeutic)
- Clinicaltrials.gov
- Industry (Pharmaceuticals)
- National Organizational Meetings
- Cancer Support Community
  - [http://www.cancersupportcommunity.org](http://www.cancersupportcommunity.org)

**PATIENT ENROLLMENT**
- Screening patients from the start- (EMR challenges, staff education, physician communication)
- Current Trials Spreadsheet
- Utilize study resources for recruitment
- Community or Program specific support groups
- Cancer awareness (Komen, YMCA, American Cancer Society)
- Tumor Board attendance
**NCCN GUIDELINES**

**Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.**

<table>
<thead>
<tr>
<th>Trial Category</th>
<th>Protocol / PI</th>
<th>Eligibility</th>
<th>Schema</th>
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</thead>
<tbody>
<tr>
<td><strong>BREAST</strong></td>
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<tr>
<td>Registry</td>
<td>PROMIS/Jacquin</td>
<td>Breast cancer stages I-III or inoperable</td>
<td>Women with Oncotype DX Intermediate RS (18-31) Symphony' breast cancer genomic profile (includes mammaprint, blueprint, targetprint, theraprint) Physician survey to determine if treatment recommendation changes with Mammprint</td>
</tr>
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<td>Registry</td>
<td>PROMIS/Jacquin</td>
<td>Breast cancer stages I-III or inoperable</td>
<td>Women enrolled in PACCT-1/TAILORX study after 5 years North American Breast Cancer Groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer</td>
</tr>
<tr>
<td>Treatment/ Adjacent</td>
<td>S1007/Jacquin</td>
<td>Hormone receptor-positive and Her2-negative. 1-3 positive lymph nodes. Oncotype DX done on trial or already known - RS ≤ 25 to be eligible</td>
<td>Patients are randomized to hormonal therapy + or - chemotherapy</td>
</tr>
<tr>
<td>Treatment/ Adjacent</td>
<td>S1207/Kotla</td>
<td>Completion of adjuvant chemotherapy and pathologically negative lymph nodes, and a tumor measuring 2 cm in greatest diameter, and an Oncotype DX® Recurrence Score &gt; 25 (completed as standard of care)</td>
<td>Completion of adjuvant chemotherapy, and pathologically 1-3 positive lymph nodes, and an Oncotype DX® Recurrence Score &gt; 25 (screened via S1007 or otherwise). Phase III - randomized, placebo-controlled, adjuvant endocrine therapy +/- one year of everolimus in high-risk, hormone receptor-positive and HER2/neu negative patients</td>
</tr>
<tr>
<td>Other</td>
<td>ACRIN A011104/J. Sidrys</td>
<td>Female only, pathologically confirmed dx of breast cancer-needle biopsy only no surgical excisions, clinical Stage I-II, Triple negative or Hormone Receptor negative with HER2 positive. No previous invasive or DCIS, no bilateral BC, no known BRCA positive pts</td>
<td>Effects of pre-operative breast MRI on surgical outcomes, costs, and QOL of women with breast cancer. Stage I-II breast cancer eligible for Breast Conserving Therapy</td>
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<tr>
<td><strong>LUNG</strong></td>
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<tr>
<td>Treatment/ Adjacent</td>
<td>EMR 63325-Jacquin</td>
<td>Stage III, unresectable NSCLC, with prior CRT, minimum 2 cycles platinum based chemo, RT ≥ 60Gy total tumor dose. Documented stable disease or objective RECIST response after primary CRT within 4 weeks prior to randomization</td>
<td>Phase III - randomized, double-blind, placebo-controlled, trial of tecemotide versus placebo. No chronic steroid use or prior immunotherapy within 4 wks, no HIV, no splenectomy - 1:1 randomization</td>
</tr>
<tr>
<td><strong>MULTIPLE MYELOMA</strong> ( Newly Diagnosed)</td>
<td>Millennium C16014/Kotla</td>
<td>Newly diagnosed, ineligible for stem cell transplant, <em>pre screening consent prior to bone marrow bx</em> measureable disease, ECOG PS 0-2, able to take prophylactic aspirin</td>
<td>Double blind, randomized, placebo controlled, lenalidomide/dexamethasone +/- MLN9078</td>
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</table>

**TRACKING ENROLLMENT**

- Staff meetings
- EMR reports
- Meetings with study investigators
- Clinical trial searches for patients (utilize a tickler file for follow-up)
SUMMARY

- PLANNING!
- ENROLLMENT GOALS
- BALANCE STUDY TYPES
- COMMUNICATION
- CREATE TOOLS
- KNOW/UTILIZE YOUR RESOURCES
KEEP YOUR NOSE IN IT! THE END 😊