Cancer Clinical Trials

BY NATALIE PERRY
Objectives:

- Provide overview of clinical trials, including types and phases of trials.
- Explain MSTI specific processes, such as how clinical trials are opened and how patients are screened and enrolled.
About Me:

- B.A. in Spanish and Anthropology from Hofstra University
- Taught for 4 years
- Worked in the MSTI Boise clinic for 3 years
- Research Project Coordinator at MSTI Research for 3 years:
  - Serve as primary contact for clinical trials sponsors and external entities
  - Coordinate research trials through study review and feasibility processes
  - Compile, maintain, analyze, and report data measurements
  - Assist with various projects including quality improvement processes, teambuilding activities, and oversight of CWI internship program
Part 1:

PROVIDE OVERVIEW OF CLINICAL TRIALS
What is a Clinical Trial?

- Clinical trials, also called cancer treatment or research studies, test new treatments in people with cancer. The goal of this research is to find better ways to treat and help cancer patients. A clinical trial is one of the final stages of a long and careful research process that begins with computer models and proceeds through many rounds of laboratory tests. Treatments and procedures that prove safe and effective in the lab move into clinical trials, where they’re studied in humans.
Why are Clinical Trials Important?

- Clinical trials are an important step in discovering new ways to diagnose, evaluate, treat, and prevent cancer, and are vital to keeping pace with the rapidly advancing field of oncology. These studies show healthcare professionals what is and is not effective, helping them decide if the side effects of a new treatment or procedure are acceptable when compared to the benefits.

- Medical research is vital to saving lives and improving quality of life, and is the foundation of every advancement that has been made in field of oncology. More than 10 million cancer survivors are living in the U.S. today, and most owe their survival to the knowledge we’ve gained through years of research, to the insight and vision of scientists and physicians, and to the courage of patients who have taken part in clinical trials.
Types of Clinical Trials

- **Treatment Trials**: Test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

- **Prevention Trials**: Look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.

- **Diagnostic Trials**: Conducted to find better tests or procedures for diagnosing a particular disease or condition.
Types of Clinical Trials (cont.)

- **Screening Trials**: Test the best way to detect certain diseases or health conditions.

- **Quality of Life Trials (or Supportive Care trials)**: Explore ways to improve comfort and the quality of life for individuals with a chronic illness.

- **Cancer Care Delivery Research (CCDR)**: studies to examine how social factors, financing systems, organizational structures and processes, health technologies, and healthcare provider and individual behaviors affect cancer outcomes, access to and quality of care, cancer care costs, and the health and well-being of cancer patients and survivors.
Phases of Clinical Trials

- There are 4 phases of clinical trials:
  - https://www.youtube.com/watch?v=dsfPOpE-GEs
Why Participate in a Clinical Trial

- Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.
  - Participation in a clinical trial is voluntary.
  - Patients enrolled in a study are closely, frequently, and carefully monitored throughout the trial.
  - The patient always has the option to withdraw from the study at any time.
  - There are multiple treatment options; patients and their doctors can decide together if a clinical trial is the right choice.
Part 2:

HOW DO WE BRING CLINICAL TRIAL OPPORTUNITIES TO OUR PATIENTS?

• MSTI SPECIFIC PROCESSES
• HOW ARE CLINICAL TRIALS OPENED?
• HOW ARE PATIENTS SCREENING AND ENROLLED?
Surgical Oncology
Medical Oncology
Radiation Oncology
Hematologic Malignancies
BMT
Hemophilia
Pediatric Oncology
<table>
<thead>
<tr>
<th>Disease Types in which MSTI offers Research Trials</th>
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<tbody>
<tr>
<td>Breast</td>
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<tr>
<td>Colon</td>
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<td>Head and Neck</td>
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<td>Hepatocellular</td>
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<td>Myelodysplastic Syndrome</td>
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<td>Pancreatic</td>
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<td>Renal</td>
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<td>Sickle Cell Disease</td>
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How Are Clinical Trials Opened at MSTI?

Cooperative Studies (federally funded)

1. PCRC Protocol Selection Committee meeting (2nd Tuesday)
2. PCRC Regulatory Coordinator Submits Study Worksheet to CIRB
3. MSTI Study Selection meeting (3rd Tuesday)
4. MSTI Feasibility Review meeting (4th Tuesday)
5. MSTI Regulatory Coordinator to submit for SL Admin/Business Review
6. PCRC New Study Review
7. Open Study at MSTI once approved by System Research

Non-CIRB studies, Regulatory starts Essential Document process

4a. Principal Investigator
   Clinical
   Pharmacy
   Finance
How Are Clinical Trials Opened at MSTI?

Industry Studies (including Pharmaceutical)

1. Identification / Receipt of New Study
2. Assessment of Study Interest / Study Start-up / Site Selection
3. Feasibility Review (one per month)
4. Regulatory Preparation and submission to Administrative Review
5. Submission to IRB Review / IRB Meeting
6. Open Study

3a. Principal Investigator
   Clinical
   Pharmacy
   Finance (MCA/BP/Budget)

3b. Contract (Contract, Budget Negotiations)
To Bring Clinical Trial Opportunities to Patients there must be:

- A group of professionals with working knowledge of all aspects of research who are willing to jump in wherever needed to do whatever needs to be done.

“The Research Staff”
Who Are the People Working in Clinical Research?

- Medical Directors:
  - Dr. Bridges – MSTI Clinical Research
  - Dr. Chang – Pediatric/Bleeding and Blood Disorders
  - Dr. Kreisle – BMT/Hematologic Malignancies and Apheresis Facility Director

- Research Managers:
  - Deborah Jones – Adult Solid Tumor and NCORP
  - Tammie Eslinger – Adult Heme/Peds/BMT
Who Are the People Working in Clinical Research?

- **Principal Investigators**: Oversee research trial management across all 5 MSTI sites
- **Project Coordinators**: Coordinate research trials through study review and feasibility processes
- **Feasibility Coordinator**: Review study protocols and study related materials to evaluate capability to comply with requirements
- **Financial Analyst**: Review and develop study budgets and financial requirements and enter billing plans into electronic CTMS
Who Are the People Working in Clinical Research?

- **Regulatory Coordinators:** Ensure documentation is in place for safety and validity of study and monitor progress of trials

- **Research Coordinators:** Screen new patients, educate patients on trial participation and provide continual teaching throughout protocol treatment

- **Research Pharmacist:** Provide oversight of investigational/study drugs (inventory management, preparation, dispensing, transport & destruction)

- **IT Programmer Analyst 2:** Serve as IT specialist for MSTI’s NCORP Grant work with CCDR
## Resource Utilization Form

### Study Coordination Considerations
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### Principal Investigator Considerations
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### Date Completed

### Special Consideration Explanation

### Special Consideration Resolution

### Financial Analyst Considerations
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### Additional Considerations
- Study Review Team Recommendations to PI to proceed to open.
- Principal Investigator Sign-Off
- Date:
- [Anticipate Site RRS Submission]
Research Feasibility Process: Considerations

- Does the study compete with any opened studies?
  - If yes, which study?
- Do we have adequate patient volumes for this study? How many subjects are expected to enroll?
- Are the inclusion and exclusion criteria too restrictive?
- Do we have experience in the therapeutic area under investigation?
- Are the procedures consistent with Standards of Care?
- Are Pathology/Lab/Imaging requirements by Sponsor acceptable?
- Are there any sub-studies?
- Do we have adequate time and scheduling availability to devote to the overall supervision of the trial?
- **Study Review Team Recommendation to PI to proceed to open this clinical trial?**
Screening/Enrolling Patients

- Types of screening:
  - Initial screening: screen all new patients for potential trials
  - If patient potentially eligible, conduct trial specific, in-depth screening
  - Providers can also ask for patients to be re-screened in the event of disease progression, which may affect their eligibility

- Provider is notified if patient is potentially eligible. The Provider decides whether the trial should be offered before in-depth screening begins

- If patient meets eligibility criteria after in-depth screening, they can be enrolled to the trial

*It is possible for a patient to sign the Informed Consent Form and not enroll on a trial.*
Informed Consent Process

- **Environment**: Private and confidential and ‘safe’ space
- **Assessment of Capacity to Consent**: Subjects must have the cognitive ability to legally consent
- **Presentation of the Elements of Informed Consent**: Use approved ICF (Informed Consent Form) as a guide to go through required elements of informed consent
- **Use of a Delayed Consent Procedure**: Provide time for participants to discuss research with family, friends, counselors or other confidants before signing the ICF
Informed Consent Process (cont.)

- **Assessment of the Subject’s Comprehension:** Ensure the participant has sufficient knowledge and comprehension of all the elements to make an ‘informed’ decision whether or not to participate in the research.

- **Documentation of Informed Consent:** Research personnel will sign the ICF attesting to the fact that the participant provided legally effective informed consent.

- **Ongoing Consent:** Participants must be informed of new findings that may influence their continued participation in research.
Resources

- ACRP: The Process of Informed Consent White Paper


- Phases of Clinical Trials: https://www.nccn.org/patients/resources/clinical_trials/phases.aspx

- MSTI Research Program PowerPoint

- The Role of Clinical Research in Cancer Care, Deb Jones