A Teaching Affiliate
of Harvard Medical School

Clinical Trials 101

The Center for Breast Cancer

Henri and Belinda Termeer Center for
Targeted Therapies

Mass General Cancer Center

MGH 1811
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Topics to Discuss

- What is a Clinical Trial?
- Why is research important?
- Safety
- Phases of Clinical Trials
- Your Breast Cancer Research Team and primary team
- What to Expect with Being Involved in a Clinical Trial
- Consenting Process
- Screening Period
- On Treatment Assessments
- What is a PK/PD?
- Drug Diaries
- Storage, Handling, and Disposal
- When to Call
- Financial coverage
- Contact information

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What is a clinical trial?

- A clinical trial is research performed in humans. You may also hear clinical trials referred to as research studies or clinical studies.
- Clinical trials in cancer compare a known treatment for a specific cancer type or stage with a new approach. This can be a new drug, combination of drugs, or a different way of using known treatments.
- Oncology clinical trials may also focus on radiation therapy, surgery, devices, behavioral treatments, standard of care, and much more.

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Why is research important?

There are many reasons! Just to name a few:

- Being involved in a clinical trial gives you more treatment options
- Provides information to advance understanding and development of new therapies
- Participation helps make discoveries of new treatment options and can lead to improved survival for yourself and others
- Clinical trials advance science

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Safety is the #1 priority

- Researchers conduct extra clinical assessments during the screening process and on treatment to ensure safety.
- Examples of extra clinical assessments:
  - More frequent CT restaging scans with TIMC*
  - ECG assessments to monitor heart rhythm
  - Echocardiogram to assess cardiac output
  - Biopsies
  - Eye exams
  - Extra blood work/labs

*TIMC: outside radiology group who assesses and confirms scan results

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Phases of Clinical Trials

- Phase 1:
  - Focus is on:
    - Safety
    - How well the drug is absorbed into your body
    - Dosage (how much or how often to take the drug)
    - Identifying side effects
    - First in human
    - Information gathered during Phase 1 studies helps establish design for Phase 2 studies
    - The Termeer Center is where Phase 1 studies happen at Mass General Cancer Center.

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Phases of Clinical Trials continued

- Phase 2:
  - Evaluates if a new treatment works (efficacy)
  - Evaluates dose range
  - Further evaluates safety
  - More individuals involved than Phase 1

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Phases of Clinical Trials continued

- Phase 3:
  - Confirms effectiveness
  - Compares study drug to other standard treatment(s)
  - Collects information about how your disease is responding to treatment (through scans, blood work)
  - Can be randomized trials. This means participants are randomly assigned into separate groups that compare different treatments or other interventions.
  - Looks at long-term effectiveness

Meet the Research Team!

- Treating Physician
- Nurse Practitioner/Physician Assistant
- Research Nurse
- Clinical Research Associate/Coordinator
- Oncology Social Worker
- Sometimes the research team will differ from primary oncology team. In which case, the research team will always collaborate with primary oncology team

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What to Expect with Being Involved in a Clinical Trial

- Clinical Trial Process:
  1. Signing Consent
  2. Screening Period
  3. On Treatment Assessments
  4. Post treatment assessments

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Consent Process

- Reviewing and signing consent forms allows you to make an informed decision.
- Consent forms will provide you with the following information:
  - Description of Clinical Trial
  - Risks and Benefits
  - Alternative Procedures or Treatments
  - Review Confidentiality (keeping your identity private)
  - Voluntary Participation (you can decide whether or not to take part)
  - Contact information of the Research Team

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What is the Clinical Trial Screening Process?

- The screening process is the time between signing a consent form and starting a clinical trial
- Usually 1-2 weeks; can be longer depending on trial requirements
- The Research Team reviews your medical history and screening assessments to ensure trial requirements are met. This also confirms it is safe for you to take part in the trial

- Each trial has different screening requirements which can include:
  - Labs (sometimes fasting)
  - Imaging (CT scans, bone scan, MRI, Ultrasound)
  - Echocardiogram
  - ECG
  - Biopsy (for research purposes only)
  - Review of at-home daily medication

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On Treatment Assessments

Each trial has different requirements. The Research Team will review your schedule with you which may include:

- Frequent office visits for physical exams (can be weekly at first) to keep close monitoring and to ensure safety
- Bloodwork
- ECG
- Pharmacokinetics (PK) collection – blood work that shows the body's effect on the drug
- Vital signs, such as temperature, blood pressure, and pulse
- Monitoring side effects/adverse events
- Reviewing drug diary to ensure following of the dosing instructions
- Nursing phone calls
- Scan reviews with oncologist
    - MGH Radiologist reviews
    - Tumor Metrics/TIMC independent review for trial participants

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Drug Diary

- For clinical trials with an oral study drug, you will be given a drug diary. A drug diary helps to ensure safety and to confirm dosing instruction.
- Dosing instructions will be reviewed in the drug diary. This will include if you need to fast (not eat) before taking any drug.
- You will be instructed to:
  - document the date and time you take study drug including any missed doses
  - bring your diary with you to each clinic visit. It will be reviewed and collected by the Research Nurse at the end of a cycle

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Storage and Handling of Oral Study Medication

- Your Research Nurse will dispense oral study medication to you
- Keep all study medication in its original bottle. Do not put in a separate pill box or mix with other medications
- Some study medications need to be kept refrigerated and the research team will review this if so
- Keep in a dry location away from direct light
- Keep out of reach from children and pets
- Wash your hands before and after handling

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Disposal of Study Medication

- Bring in all study medication and empty bottles with you to each visit.
- Do not throw away empty bottles. The research team will collect them and then dispose of them.
- The research team will also collect any unused medication at the end of each cycle.

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When to call?

- You will work closely with the Research Team to review expected and unexpected side effects of your treatment
- Call with any new symptoms including but not limited to:
  - Diarrhea or constipation
  - Nausea or vomiting
  - Any skin change, rash or hives
  - New swelling in arms/legs, face
  - Dizziness, headaches or vision changes
  - Temperature of 100.4 or higher

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Financial coverage

- Clinical trial drugs are covered by the trial sponsor
- There may be co-pays for doctor's visits, blood work and CT scans
- Each trial has different billing tables with coverage plans
- Please review your insurance coverage prior to starting a clinical trial to understand coverage
- Email the financial team with specific questions prior to starting treatment on a clinical trial: Mghclinicaltrialinsurance@partners.org

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Contact information

- Please reach out to the research nursing team with questions related to clinical trials. We are here to help support you through this journey!
  - Clinical research nursing manager: 617-726-9158

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