

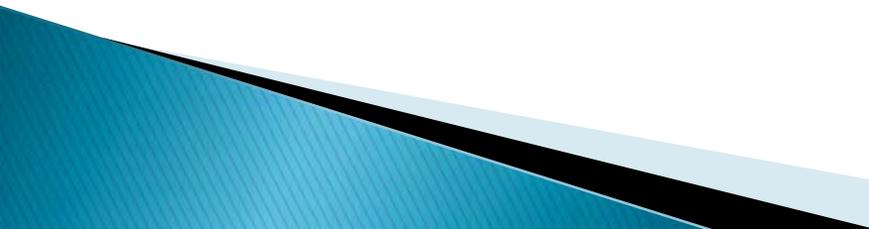


# MOCA Living Well:

## Understanding Clinical Trials

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# How do we get more effective treatments for ovarian cancer?

- All of the current treatments for ovarian cancer were approved after years of testing and large clinical trials
    - Carbo, taxol, avastin, PARP inhibitors
  - Now...new agents and new combinations are being developed and tested
  - “Old” drugs are being repurposed
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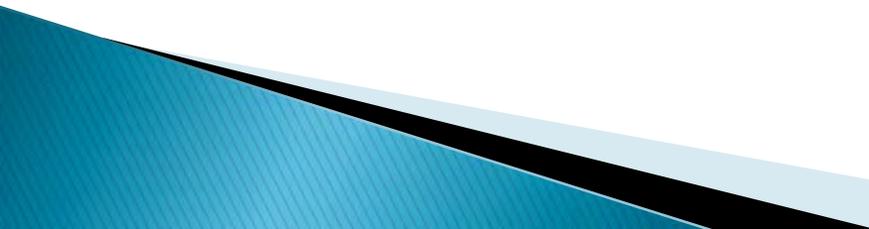
# The Scientific Process

## Stages of Research

- Basic
- Translational
- Clinical

# Basic: At the “Bench”

During this stage, researchers:

- Learn how cancer cells work by studying tissue in the laboratory
  - Identify targets for treatment (places on or in the cell that a drug will work)
  - Identify a chemical that will kill cancer cells or stop the cell's growth
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# Translational: Getting Closer

During this stage:

- Researchers do extensive studies using tissue from tumors and animals models

Questions they ask are:

- What effects does the agent have on the tissue or animal model?
  - What other factors are at work?
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# Clinical Research: The Home Stretch

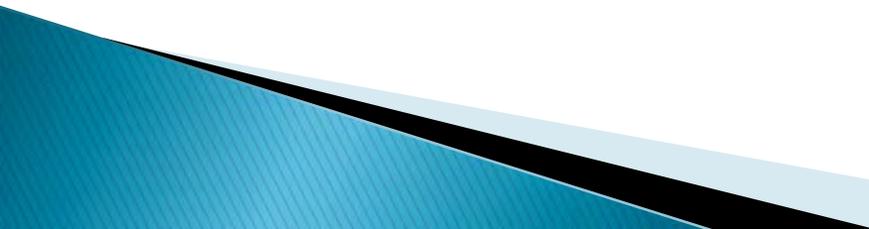
Enough has been learned about the agent/drug to begin testing in humans

Clinical trials are research studies in which people help doctors and researchers test ways to improve cancer care.

Studies are done in three phases or stages that build on one another



# What are the types of clinical trials

- Treatment trials
    - Test new treatments like drugs, surgery, new combinations or new methods.
  - Prevention trials
    - Test new approaches that may prevent or lower the risk of cancer developing.
  - Screening trials
    - Test the best way to detect cancer early.
  - Quality of Life trials
    - Explore ways to improve comfort, manage symptoms and side effects
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# What are the phases of clinical trials?

## ➤ Phase I trials:

- Evaluates how a new drug should be given, how often and what dose is safe
- Only a small number of participants enrolled

## ➤ Phase II trials:

- Continues to test the safety of the drug and how well it seems to work

## ➤ Phase III trials:

- Tests a new drug, a new combination of drugs, or a new surgical procedure in comparison to the current standard
- The participant is randomly assigned to a group
- Often enrolls large numbers of people and may be conducted at many places nationwide or even internationally

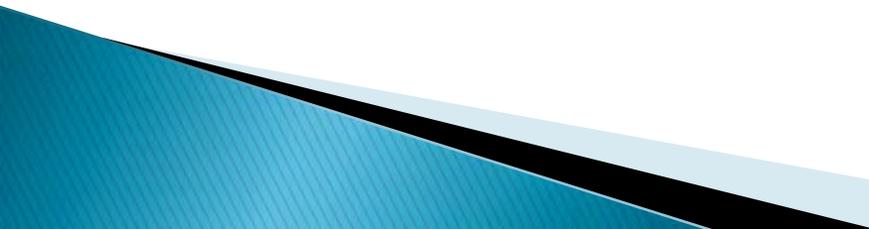
# Phase I trials – Safety

- Only a small number of people enrolled (generally up to a few dozen)
- It is often, but not always, a dose escalation trial
- The goal is to determine the Maximum Tolerated Dose (MTD)
  - Treat 3 patients at a time starting at a very low dose, then wait a given amount of time to watch for toxicities (side effects). If everyone is okay, then enroll and treat the next group of people at the next dose level, observe for side effects, and so on until unacceptable levels of side effects are seen.

# Phase II– safety and efficacy

- The experimental study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety

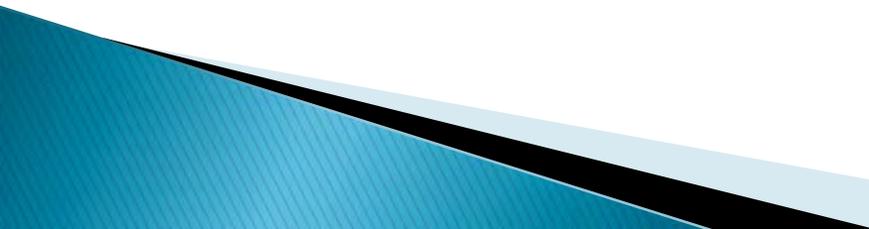
# Phase III trials –Better ?

- Large number of patients
  - Done in multiple locations, including community hospitals, international
  - Takes longer than phase 1 and 11 trials
  - Usually compares standard treatment to something thought to be better
  - Practice changing!
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# What are the benefits of participating in a clinical trial?

- Receive treatment that is on the cutting edge
  - Very close observation of disease status
  - Often times, the expense of the medication and certain tests are covered by the study protocol
  - Altruism: helping to advance the science of treating ovarian cancer
  - Never receiving less than the standard of care
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# What are the risks of participating in a clinical trial?

- We don't really know who will respond to the drugs used and who will not
  - The side effects of the drug may not be apparent at the onset of the trial
  - Participating in a clinical trial may necessitate an increase in tests, treatments and doctor's appointments
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# Why Does it Take So Long?

- There are hundreds of new cancer agents and pathways under study
  - It takes 5–10+ years for a new drug to be approved
  - Costs run into the hundreds of millions
  - Less than 5% of adult patient population participates in clinical trials
  - Scientific and regulatory processes provide rigor and safeguards for patients
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# Some considerations....

- Inclusion and Exclusion Criteria
  - Endpoints PFS OS QOL
  - Setting: Frontline, Maintenance, Recurrent
  - Learn all of your treatment options
  - Costs and effect on daily life
  - Get all your questions answered
  - Informed Consent
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# What kind of research is MOCA involved in?

- Basic, translational and clinical
- Prevention, early detection and better treatments
- MOCA has awarded nearly \$9 million for research
- MOCA advocates provide the patient perspective to MOCA, the Mayo Ovarian SPORE, NRG, DoD and pharma