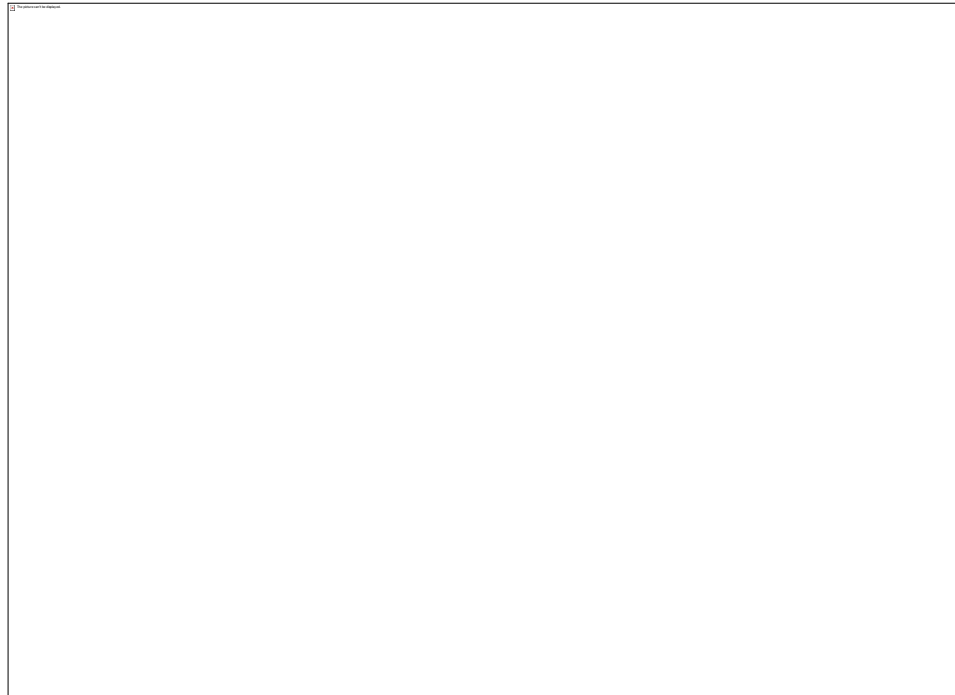# Research in Oncology

No Financial Disclosures

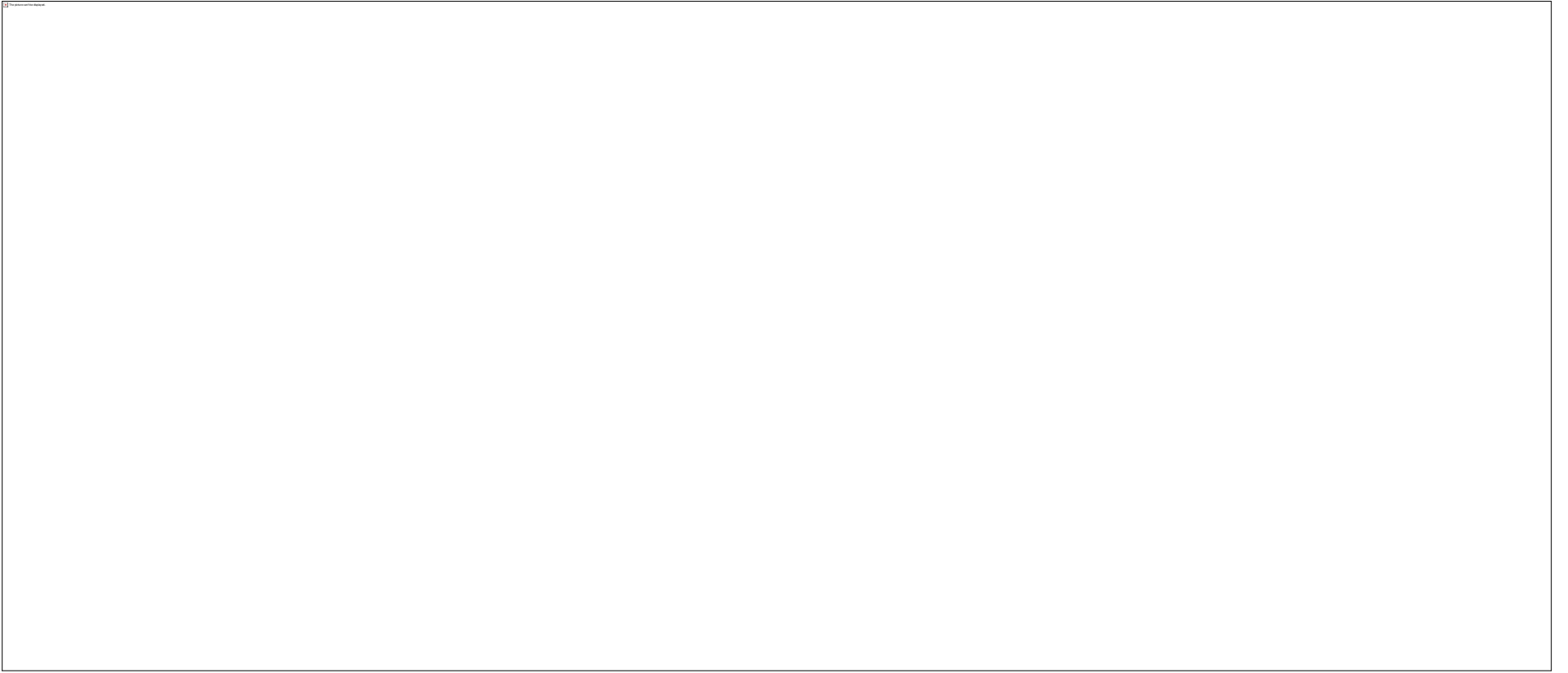# Employed by Nebraska Cancer Specialists

What is "Research"

<u>Research</u> is a systematic and organized investigation conducted to expand knowledge, gain a deeper understanding, and generate new insights in a specific field.

<u>Types of Research in Cancer World:</u>

- Observational Research
  - Public Health
  - Basic Science
- Translational Research
  - Clinical Research

But before we get there…

Basic Science Research

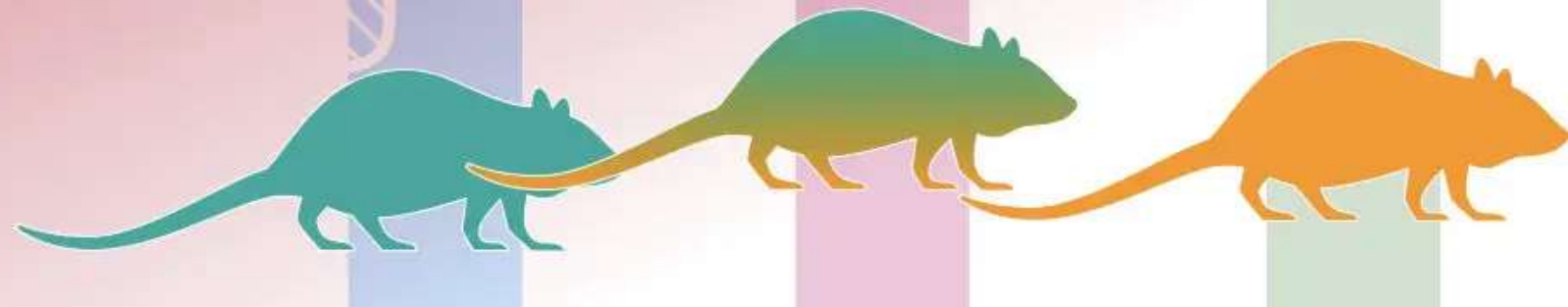# Pre-clinical studies

Pre-Clinical Studies

Translational Research

How to construct
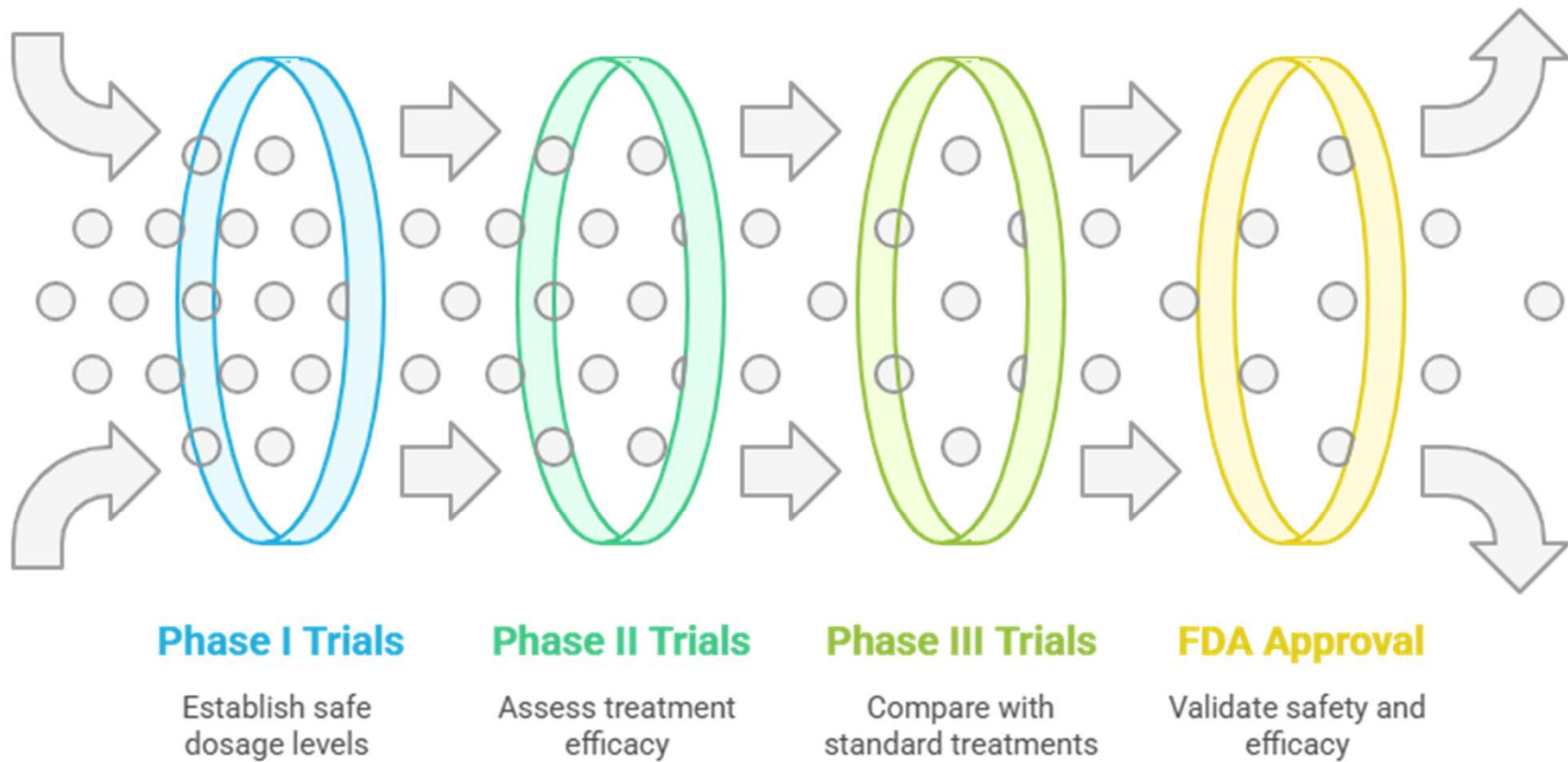
Knockout mice

Animal Models

- Design animals to have the genetic makeup of disease you're studying

- Assess how the compound/drug of interest affects these animals

- Important stage prior to human subjects research

Clinical Trials

Drug Development Process Funnel

Phase I Trials

Establish safe dosage levels

Phase II Trials

Assess treatment efficacy

Phase III Trials

Compare with standard treatments

FDA Approval

Validate safety and efficacy

Screening & Eligibility

Inclusion Criteria:

- \> 18 years of age
- Diagnosed with XYZ disease
- Has measurable disease per RECIST v1.1
- Has previously been treated with Keytruda
- Willing and able to participate

Exclusion Criteria:

- On another active treatment
- Unwilling to complete study requirements

Participation in research is always voluntary! Anyone can withdraw consent at any time for any reason
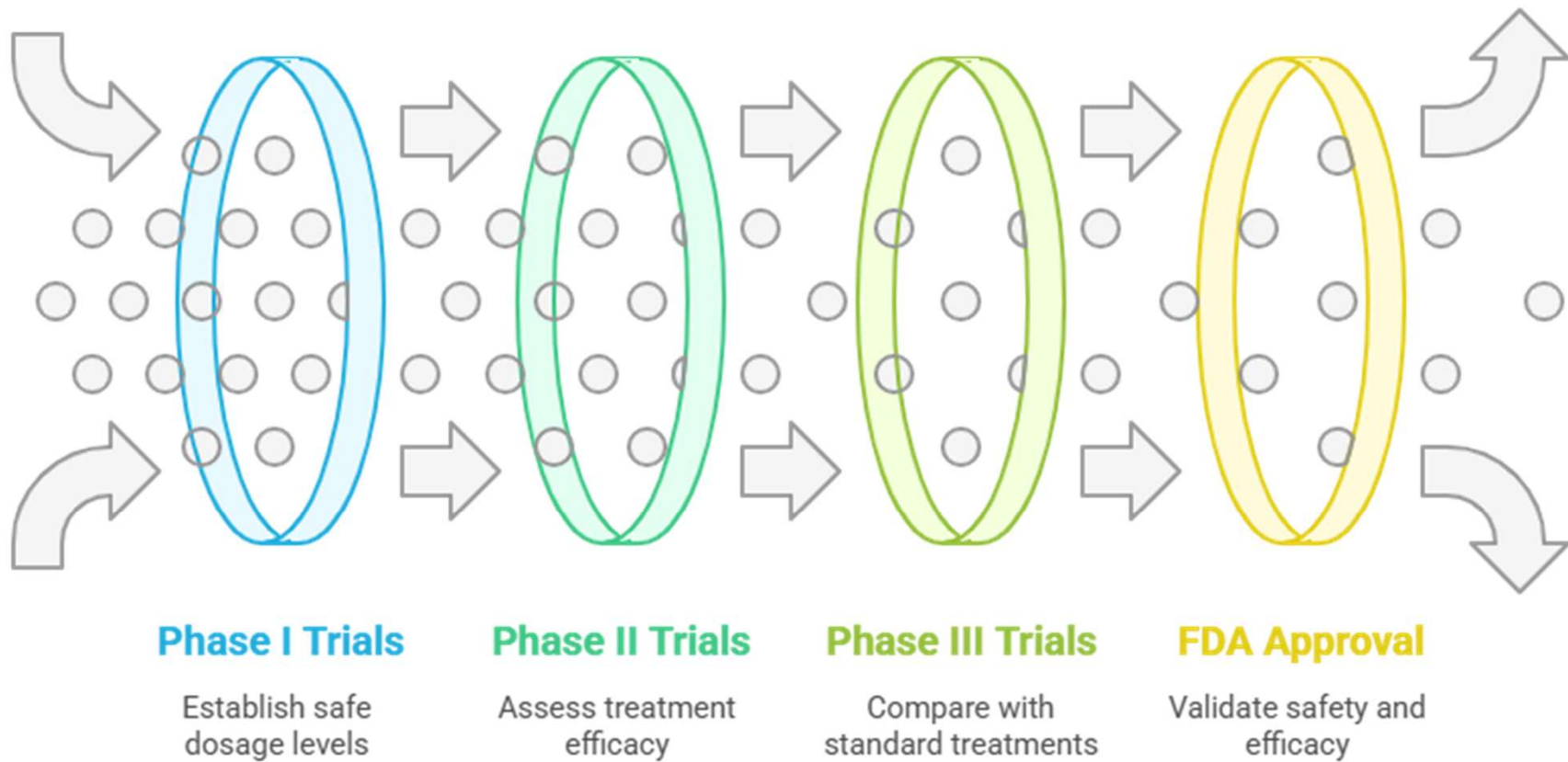
Phase 1 Clinical Trials

o Focus on safety – dose escalation

o First in human studies

o 15-50 patients enrolled

FIH/Phase 1 Clinical Trials

Screening and eligibility
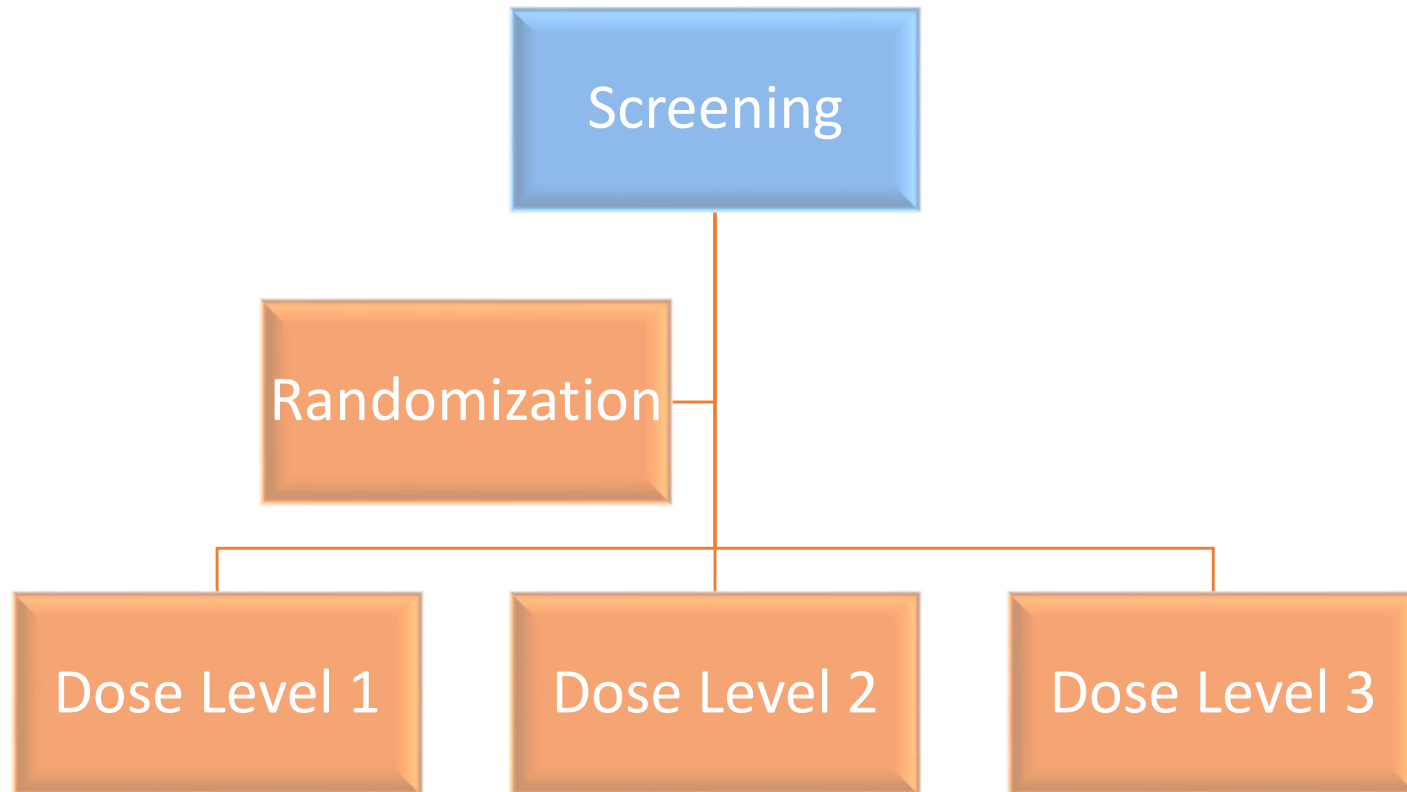
Drug Development Process Funnel

Phase I Trials

Establish safe dosage levels

Phase II Trials

Assess treatment efficacy

Phase III Trials

Compare with standard treatments

FDA Approval
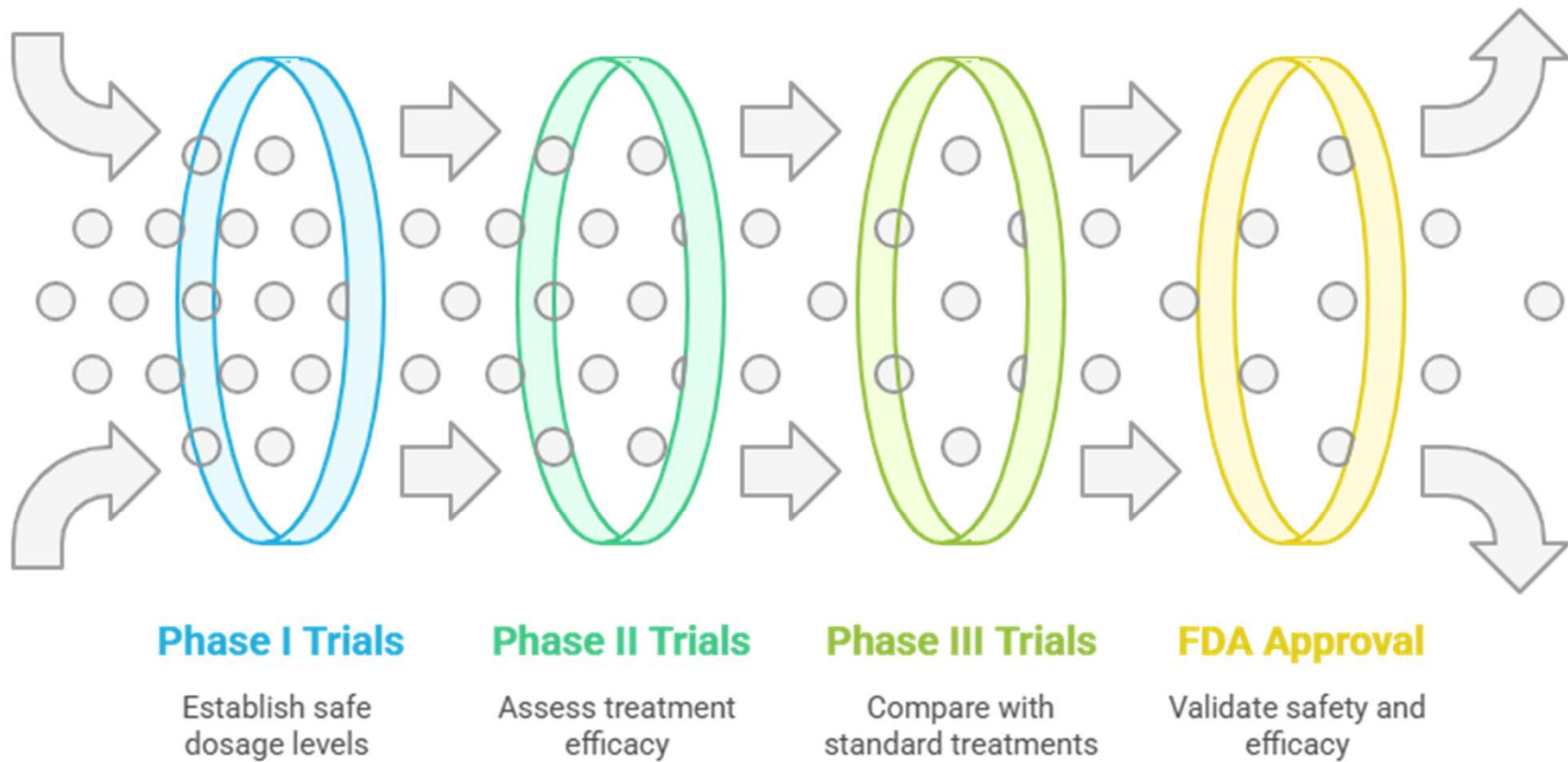
Validate safety and efficacy

Phase 2 Clinical Trials

o   Focus on effectiveness and side effects

o   Which dose / schedule / therapy combo works best?

o   ~100 patients

Phase 2 Clinical Trials

Screening

Randomization

Dose Level 1

Dose Level 2

Dose Level 3

Drug Development Process Funnel

Phase I Trials

Establish safe dosage levels

Phase II Trials

Assess treatment efficacy

Phase III Trials

Compare with standard treatments

FDA Approval

Validate safety and efficacy

Phase 3 Clinical Trials

o Comparing new drug to existing treatment options

o Hundreds to thousands of patients enrolled

Arm A

Randomization

Screening

Arm B

Arm C/SOC

Phase 4 Clinical Trials

o Treatment has been approved

o Assessing long term effects and effectiveness

o Thousands of people enrolled

What does this look like in Cancer?

1. Immunotherapy: Developing treatments that use the body's immune system to fight cancer.
   - CAR-T therapy, Bi-specifics/Tri-specifics, TIL therapy

2. Chemotherapy: Improving traditional cancer treatments to reduce side effects and increase effectiveness.

4. Radiation Therapy: Enhancing precision and reducing damage to healthy tissues.

5. Radio-ligand Therapy: "Theranostics"

Theranostics Research

- **Therapeutics + Diagnostics= Theranostics**
  - "Radio-ligand therapy (RLT)"

- Uses radiotracers to identify and treat cancer

- Diagnostics tracer – binds to the cancer cells, which can then be identified through imaging

- Treatment tracer - almost identical, but the radioactive component is a different, more powerful kind of radiation that kills cancer.

What does it take?

- 10-15 years from drug discovery to full FDA approval
- $200,000,000 - $1,000,000,000

Where can I find Clinical Trials?

- Clinicaltrials.gov
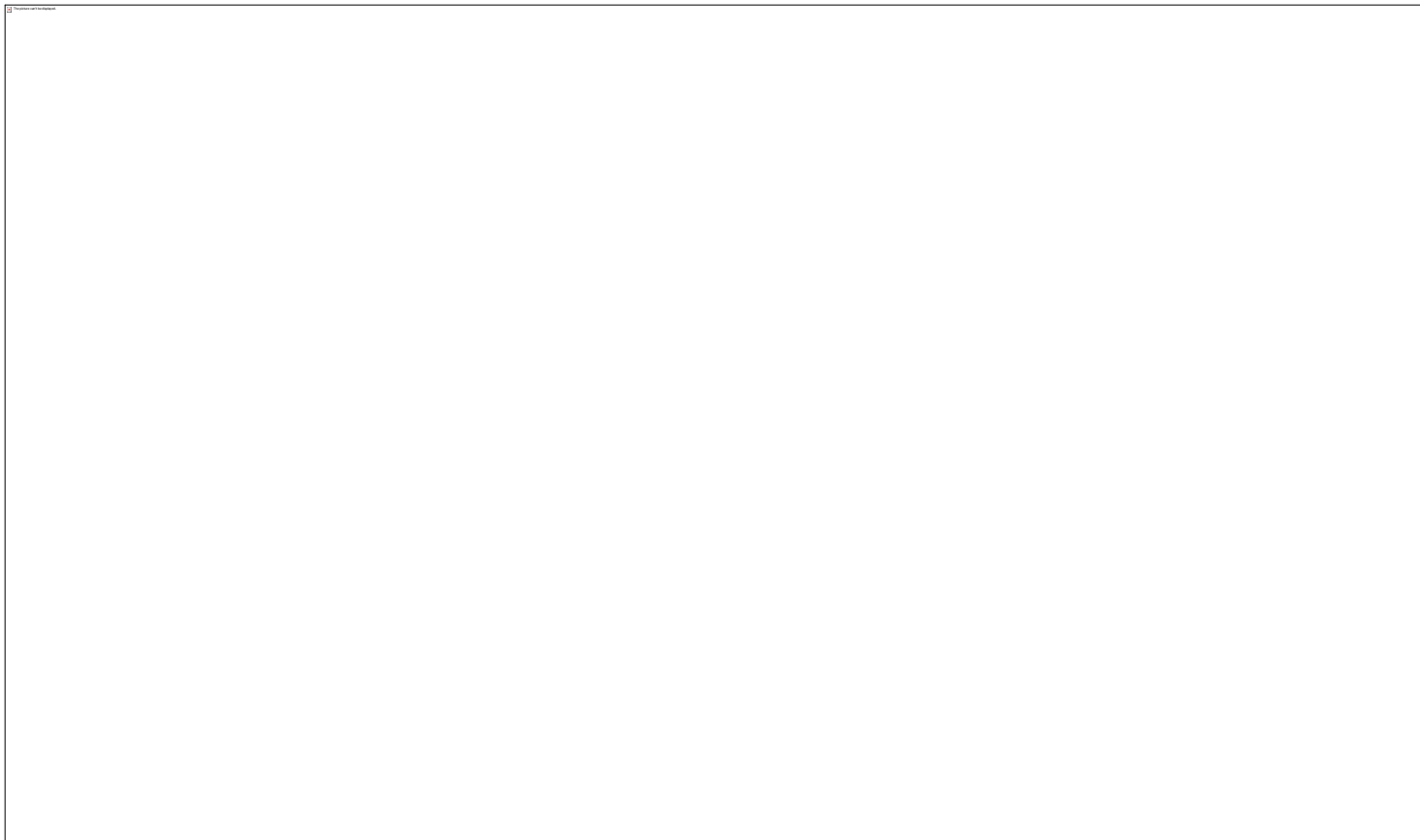
Where can I find Clinical Trials?

Diversity in Clinical Trials

New treatment options are best understood in those they were studied in.

Other Research in Cancer Space

- Observational Studies: Biomarkers, Disease Behavior, QOL

- Public Health: Disease Surveillance
  - What are the incidence rates? What are commonalities in those with Cancer? How can we prevent it?

Thank you!