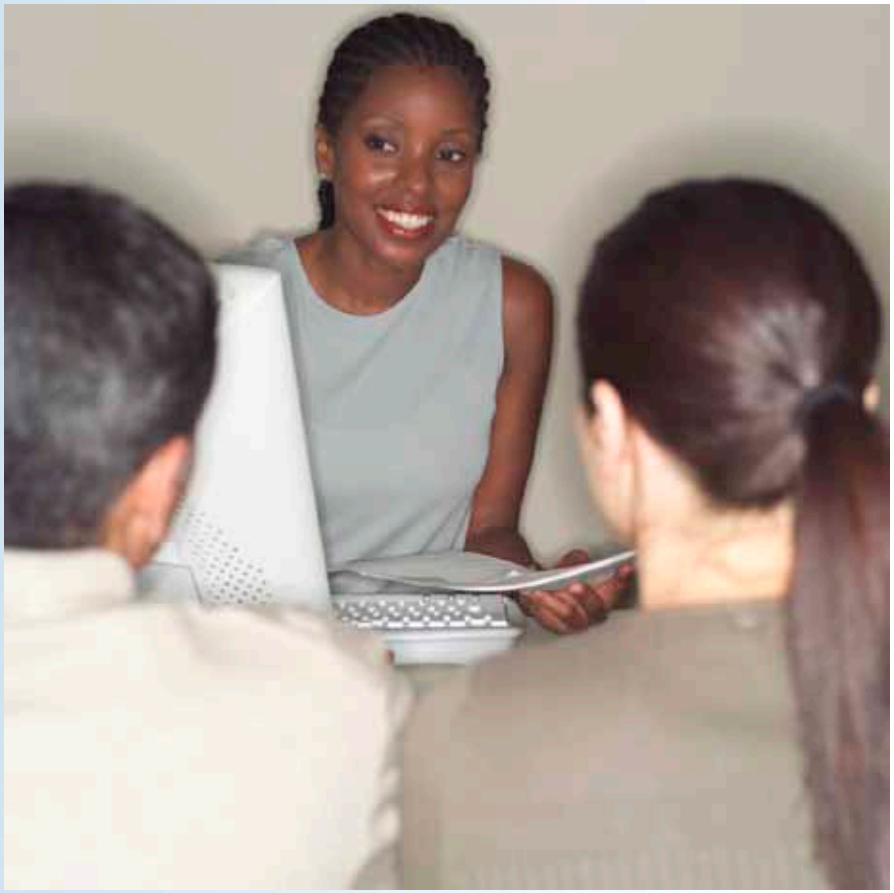
Clinical Trials: What you need to know

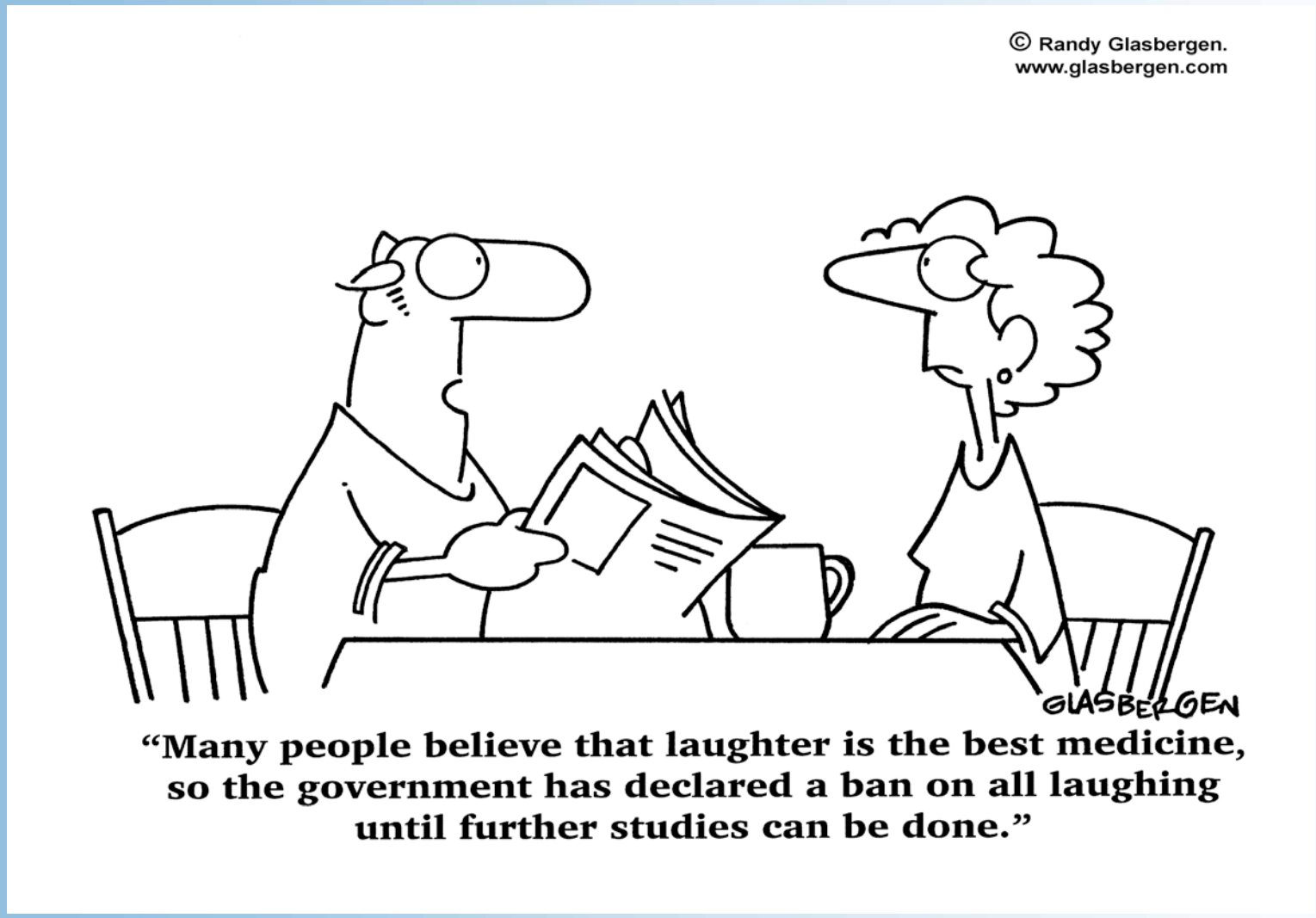
Alison Kastl, BS, CCRC | Clinical Trials
University of Cincinnati Academic Health Center

What are Cancer Clinical Trials?

- Research Studies involving people
- Try to answer scientific questions or find better ways to prevent, diagnose, or treat cancer



Why do we do clinical trials?

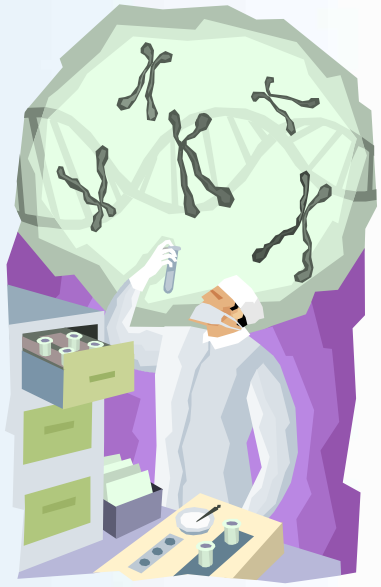


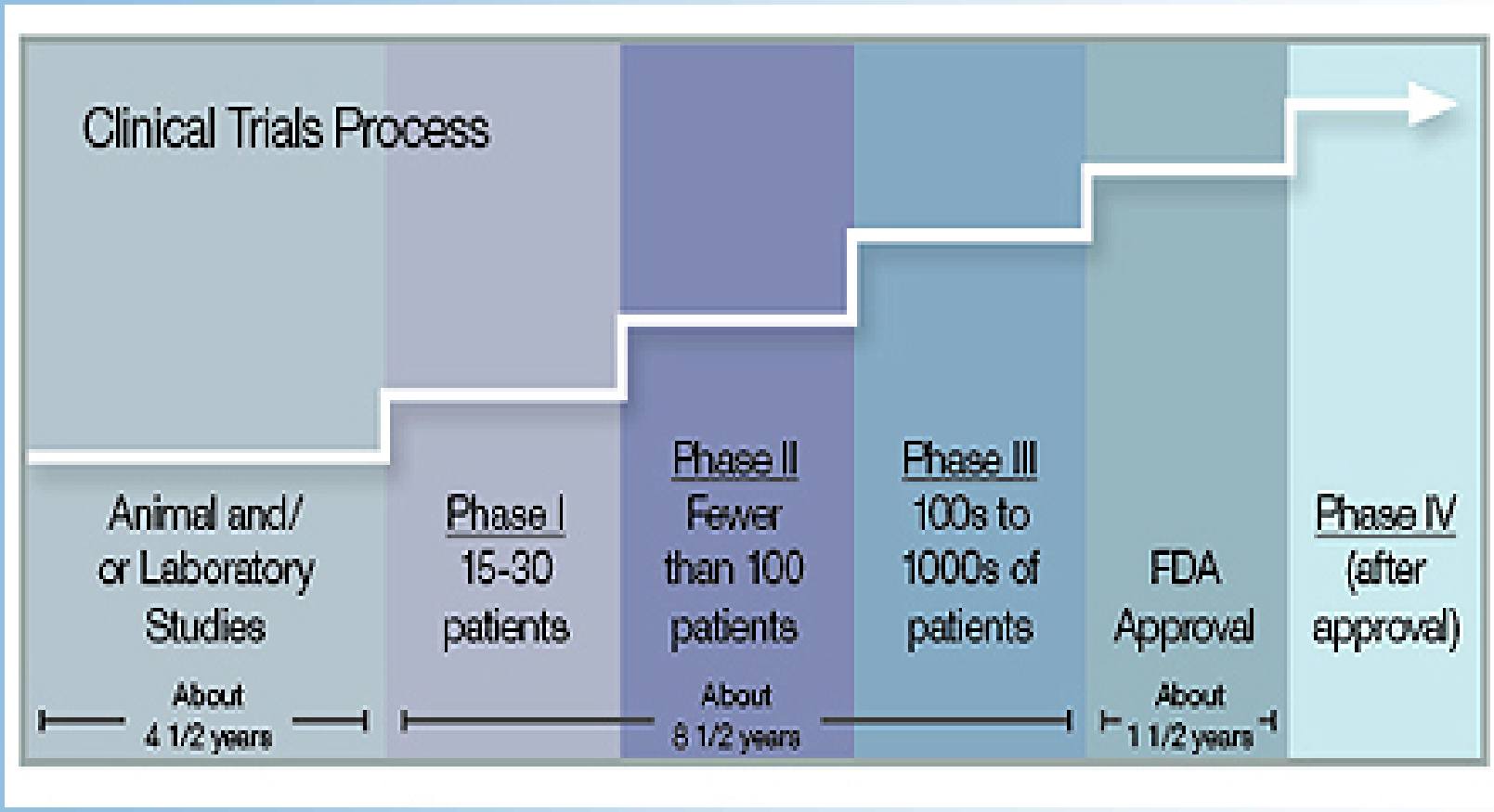
Why are Clinical Trials Important?

- Translate results of basic scientific research into potential clinical benefits.
- Contribute to knowledge and progress against cancer.
- The more people that participate in clinical trials, the faster we can answer the critical research questions that will lead us to better treatment and prevention options for all cancers.

Types of Clinical Trials

- Prevention trials
- Early-detection trials/screening trials
- Diagnostic trials
- Treatment trials
- Quality-of-life studies/ supportive care studies
- Specimen banking





Drug Development Process

- **2003 cost to bring drug to marker $802 million**
- **Current estimated cost $1.3 to $1.7 billion**

Clinical Trial Phases

- **Phase I**

  How does the agent affect the human body? What dose is safe?

- **Phase II**

  Does the agent or intervention have an effect on the cancer?

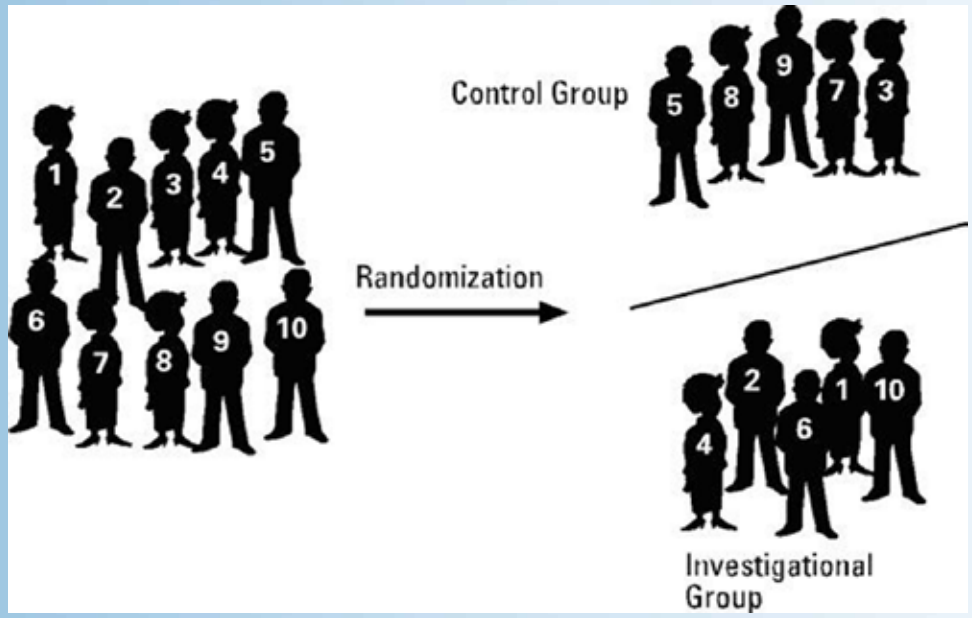
- **Phase III**

  Is the new agent or intervention (or new use of a treatment) better than the standard? Participants are randomly assigned into one of two or more groups.

Randomization

Participants have an equal chance to be assigned to one of two or more groups:

- One gets the most widely accepted treatment (standard treatment)
- The other gets the new treatment being tested, which researchers hope and have reason to believe will be better than standard treatment

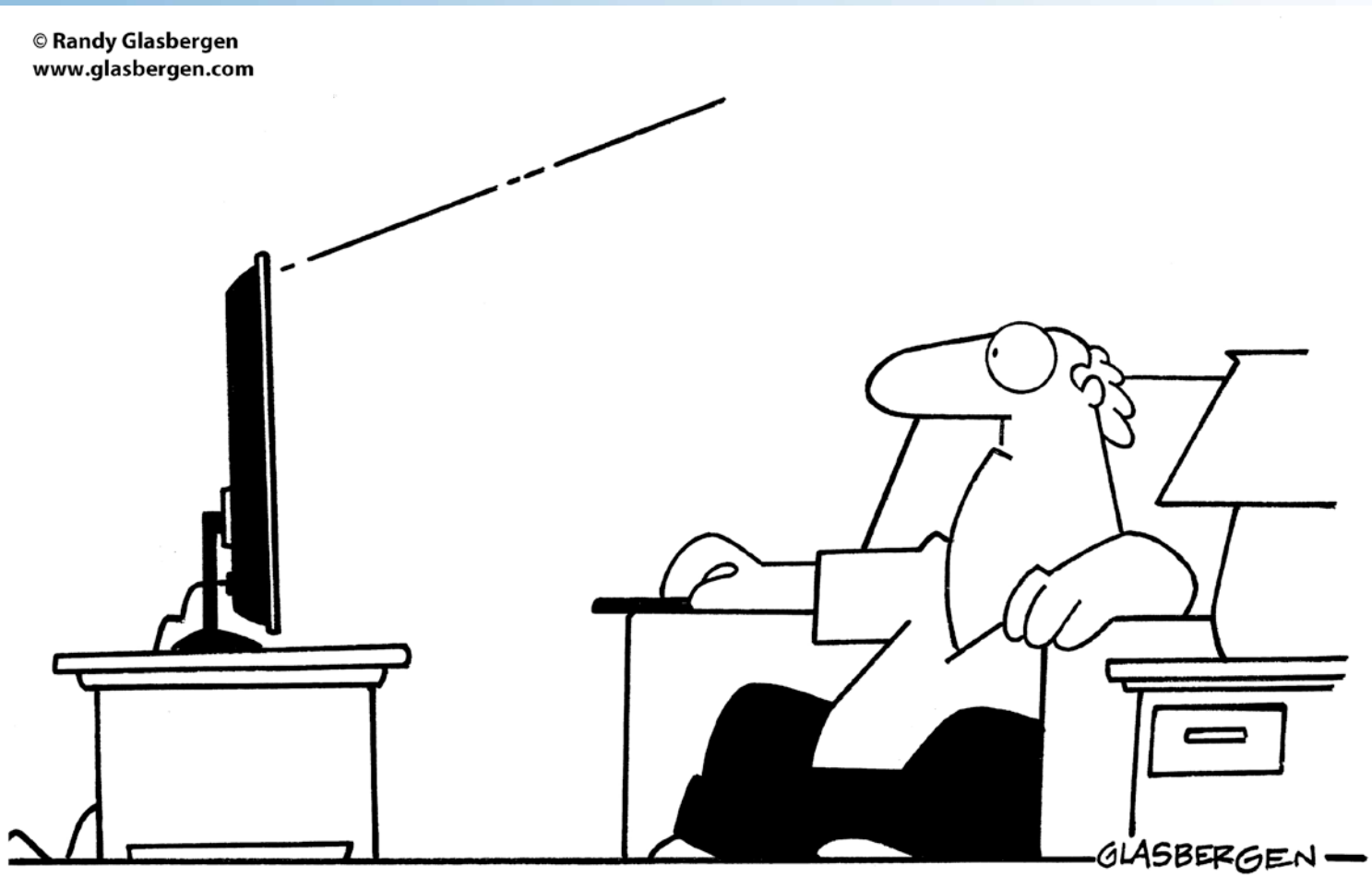


Dr. Paul Meier, Medical Statistician

- 1950s first and most vocal about use of randomization in clinical trials
- Reason: researchers try to avoid unintentionally skewing results
- Randomized trials are considered the most rigorous way to conduct a study and the best way to gather convincing evidence of treatment's effects.
- Before randomization, clinical trials were imprecise. Comparisons used could introduce bias.
- FDA requires randomized trials before approving new drugs.

What is a placebo?

- A placebo is an inactive agent.
- A placebo is only used when there is no standard treatment.
- Participants that are enrolled in a trial that includes a placebo are receiving the standard of care treatment.
- Participants are informed if the trial includes a placebo.



"Ask your doctor if Placebos are right for you!"

Clinical Trial Protocol

A written, detailed action plan that:

- **Provides background about the trial**
- **Specifies trial objectives**
- **Describes trial's design and organization**
- **Details eligibility criteria**
- **Ensures that trial procedures are consistently carried out**

Benefits of Participation

Possible benefits:

- Patients will receive, at a minimum, the best standard treatment
- If the new treatment or intervention is proven to work, patients may be among the first to benefit
- Patients have a chance to help others and improve cancer care

Risks of Participation

Possible risks:

- New treatments are not always better than standard care and they may result in increased side effects
- If a new treatment has benefits, it may not work for every patient
- Occurrence of unknown side effects
- Study may require more time and attention from the participant than the standard of care treatment

Clinical Trial Sponsors

- **Investigator Initiated**

  Local physicians develop trials that are conducted locally.

- **National Cooperative Groups**

  Funded through National Cancer Institute. Written by top investigators around the country and conducted at multiple centers.

  Examples: RTOG and NCCTG

- **Pharmaceutical Industry**

  Drug company research to test new agent and work towards obtaining FDA approval.

Patient Protection

- Federal regulations ensure that people are told about the benefits, risks, and purpose of research before they agree to participate
- Methods:
  - Scientific review
  - Institutional review boards (IRBs)
  - Informed consent
  - Data safety and monitoring boards (DSMB)

Improving Cancer Care

- Once proven safe and effective in a clinical trial, a treatment may become the new standard of care
- Most of the best cancer treatments we have today are based on what we learned from clinical trials
- People with cancer are living longer because of clinical trials

What clinical trials are available?

- Ask your doctor
- clinicaltrials.gov
- ucbraintumorcenter.com

Currently Available

- **Specimen banking studies**
  - Head and Spine Tissue Bank and Registry
  - Ohio Brain Tumor Study
  - NIH 1308 Cancer Genome Atlas for Gliomas
- **Low Grade Glioma**
  - CTSU E3F05 Radiation +/- Temodar
- **Glioblastoma**
  - 3T versus 1.5T MRI radiation planning
  - RTOG 0837 Chemoradiation + Cediranib/placebo
  - Axitinib+Radiation for elderly patients
  - RTOG 0929 ABT-888 + Temodar (temp closed)
- **Brain/Spine Mets**
  - Trental + Vitamin E for prophylaxis radiation necrosis
  - RTOG 0631 Radiosurgery for localized spine mets
- **Acoustic Neuromas**
  - Subtotal resection with backup stereotactic radiation

Pipeline

- **Glioblastoma**
  - **Celldex CDX-110 vaccine**
  - **Northwest Biotherapeutics DCVax® vaccine**
  - **NCCTG N0877 Dasatinib/Placebo + chemoradiotherapy**
  - **NCCTG N0872 Dasatinib/Placebo + Bevacizumab for recurrence**
  - **BEZ235 + Everolimus**

Questions?