


UNIVERSITY OF ILLINOIS
CANCER CENTER

Clinical Trials

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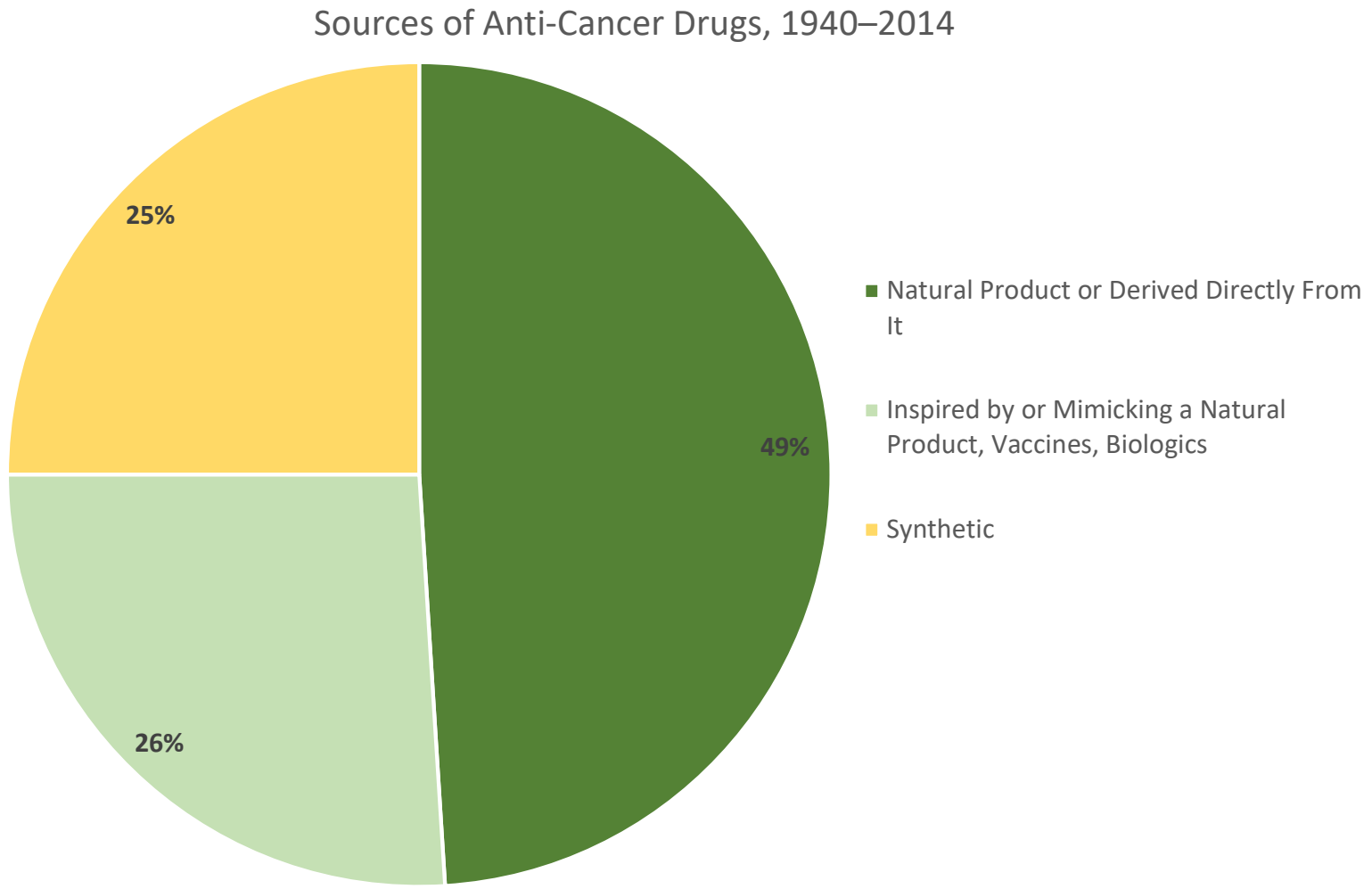
Where Anti-Cancer Drugs Come from



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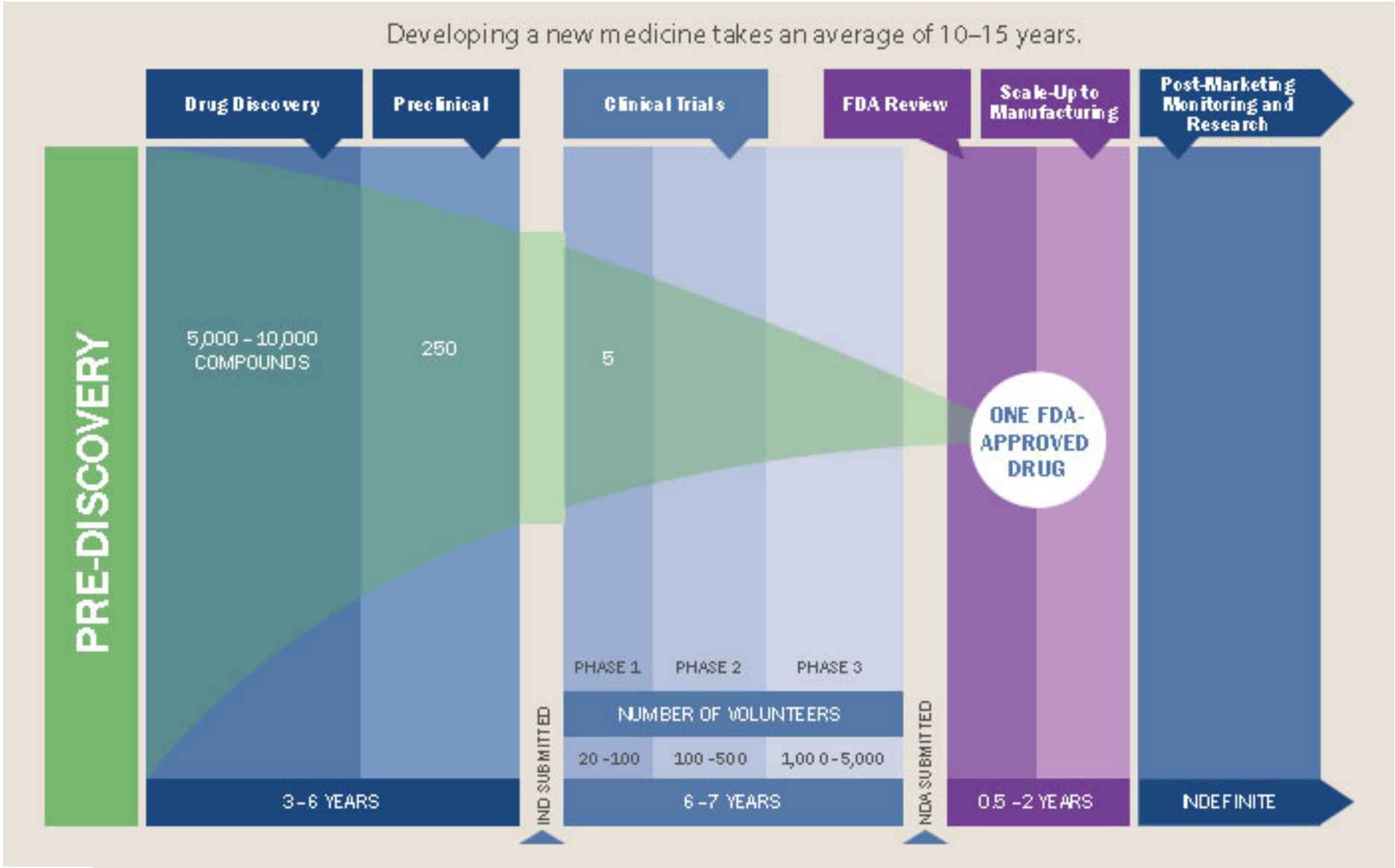
Data adapted from Newman and Cragg, *Natural Products as Sources of New Drugs from 1981-2014,* J Nat Prod 2016;79(3):629-61.

Clinical Trials Are an Important Part of Drug Development for Any Disease including Cancer…

The Drug Pipeline



IND **NDA**

Understanding the R&D Process, www.innovation.org; CBO, Research and Development in the Pharmaceutical Industry, 2006.

What Is a Clinical Trial?

- Study that aims to improve existing treatments or to replace them with new and better ones

- Before a new treatment is made widely available for patients, it must be tested in clinical trials for efficacy (how well it works) and safety

Why Do We Need Clinical Trials?

- Clinical trials are designed to help us learn more about the **benefits** and **side effects** of a new treatment

- A treatment's benefit and side effects can only be fully assessed after long-term use on patients in everyday clinical practice

What Do the Different Phases Mean?

- Phase I: Safety, finding the safest dose
  - Small group
- Phase II: Safety, finding if it works (efficacy)
  - Medium group
- Phase III: Confirming efficacy, side effects
  - Large group
  - Compare to “gold standard”
  - Usually **randomized**, may be **“Single-” or “Double-” blind**

Why would YOU want to be part of a Clinical Trial?

Everybody's reason may be different!

1. Benefits? **Access to new approaches**
2. Helping others
3. Moving science forward
4. Risks?? **New approach may not be of benefit to you:**

   Initial studies are small

   Possible drug side effects

Patient Safety on a Clinical Trial

- Informed Consent (**You/family**)
- **Physician** oversight
- **Institutional** oversight (Institutional Review Board, “IRB”)
- National (**FDA**) oversight

Multiple Safety Levels

Multiple Caring Levels

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Before You Enroll

You must **qualify**

- Inclusion criteria
- Exclusion criteria

You will go through **informed consent**

- Study purpose and details
- Risk/benefits

Know your **rights**

- You can stop participating **at any time for any reason**

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IRB normally carefully reviews the consent form in detail to make sure it explains everything in an "easy-to-get" format . . . but ask questions!!

What Will Happen on a Trial?

Protocol-driven treatment
(aka “study plan”)

Frequent monitoring

Additional support and
coordination

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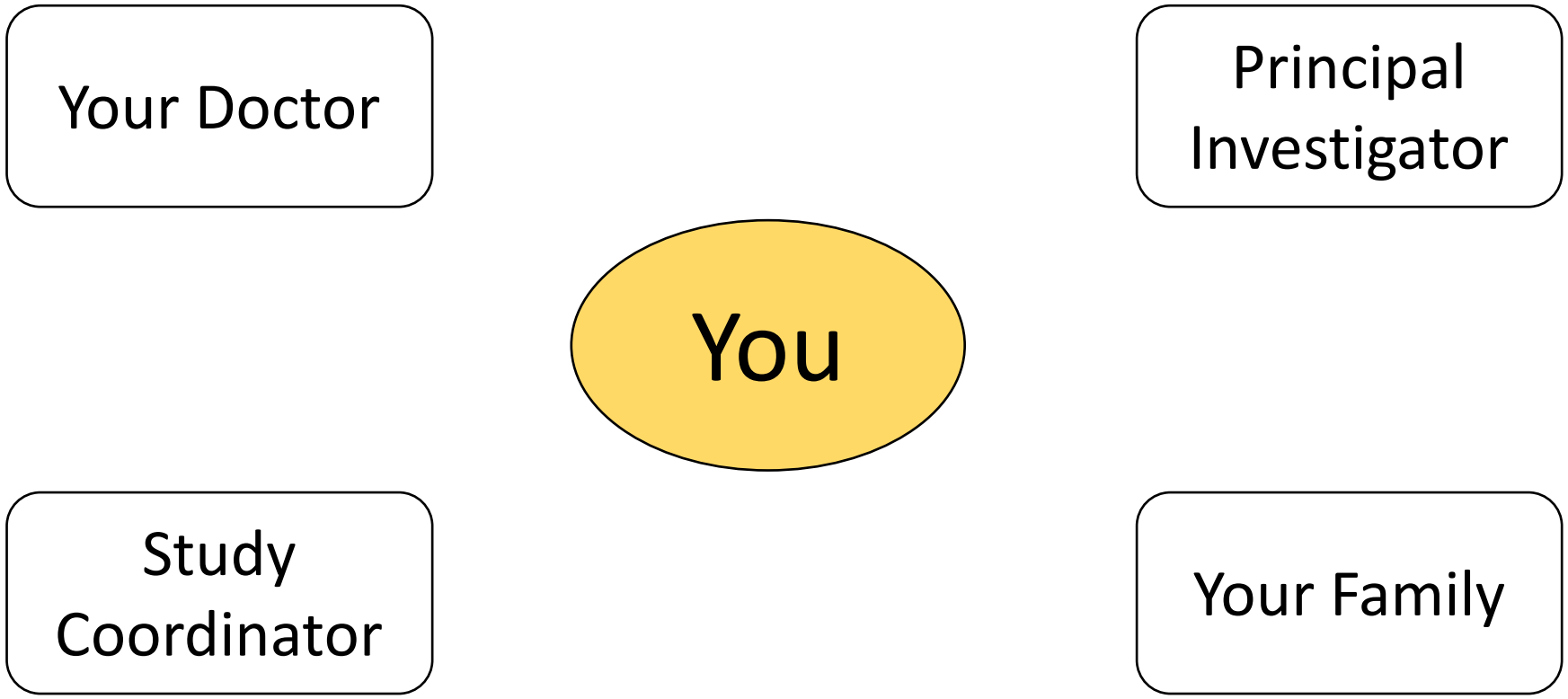
Facts about Clinical Trials

- What will happen to my data? The informed consent form will inform you how your data will be shared. **There are laws that require your data to be kept securely.**

- What are the costs to me of participating? Information about who is responsible for certain costs will be outlined in the informed consent

  - **Patient care costs**: Costs related to treating your cancer, whether you are in a trial or receiving standard treatment. The participant is usually expected to pay for these costs, which are often covered by health insurance.
  - **Research costs**: Costs associated with the trial itself, such as **research medications or extra tests which are not part of your usual medical care**. These costs are usually paid by the trial sponsor.

Who Are the Key People in a Trial?



What Happens after the Trial?

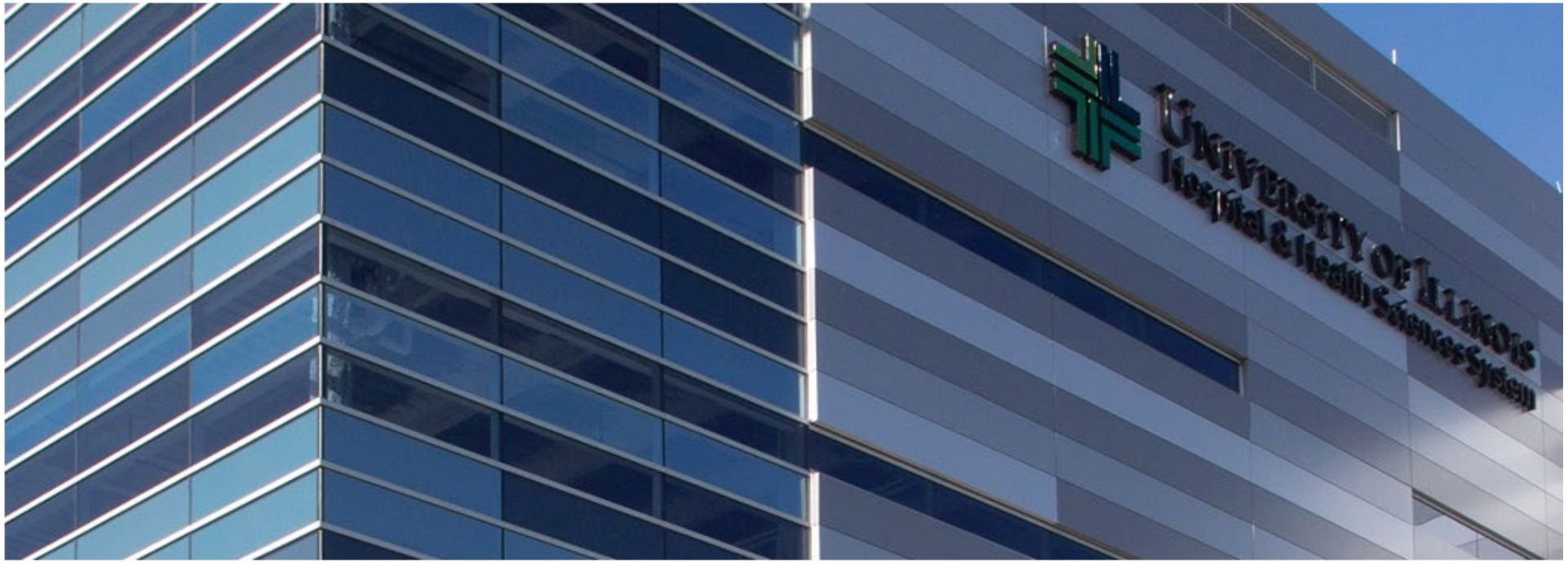
- Data is checked and audited to make sure it is correct
- Data is analyzed by a statistician
- Results are presented and/or published
- Where can I see the study results?
  - You may receive the study results from the study Principal Investigator (the study informed consent form will tell you if you will receive results)
  - Study results are required to be published on ClinicalTrials.gov

Good Questions to Ask

- Are clinical trials an option for me? If so, what types of clinical trials am I eligible for?
- What are my other options?
- What are my rights as a clinical trial participant?

Clinical Trial Resources

- University of Illinois Cancer Center: https://cancer.uillinois.edu/patients-survivors/#aboutclinicaltrials
- Food & Drug Administration (FDA): https://www.fda.gov/patients/clinical-trials-what-patients-need-know
- National Cancer Institute (NCI): https://www.cancer.gov/about-cancer/treatment/clinical-trials
- ClinicalTrials.gov



Questions?

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